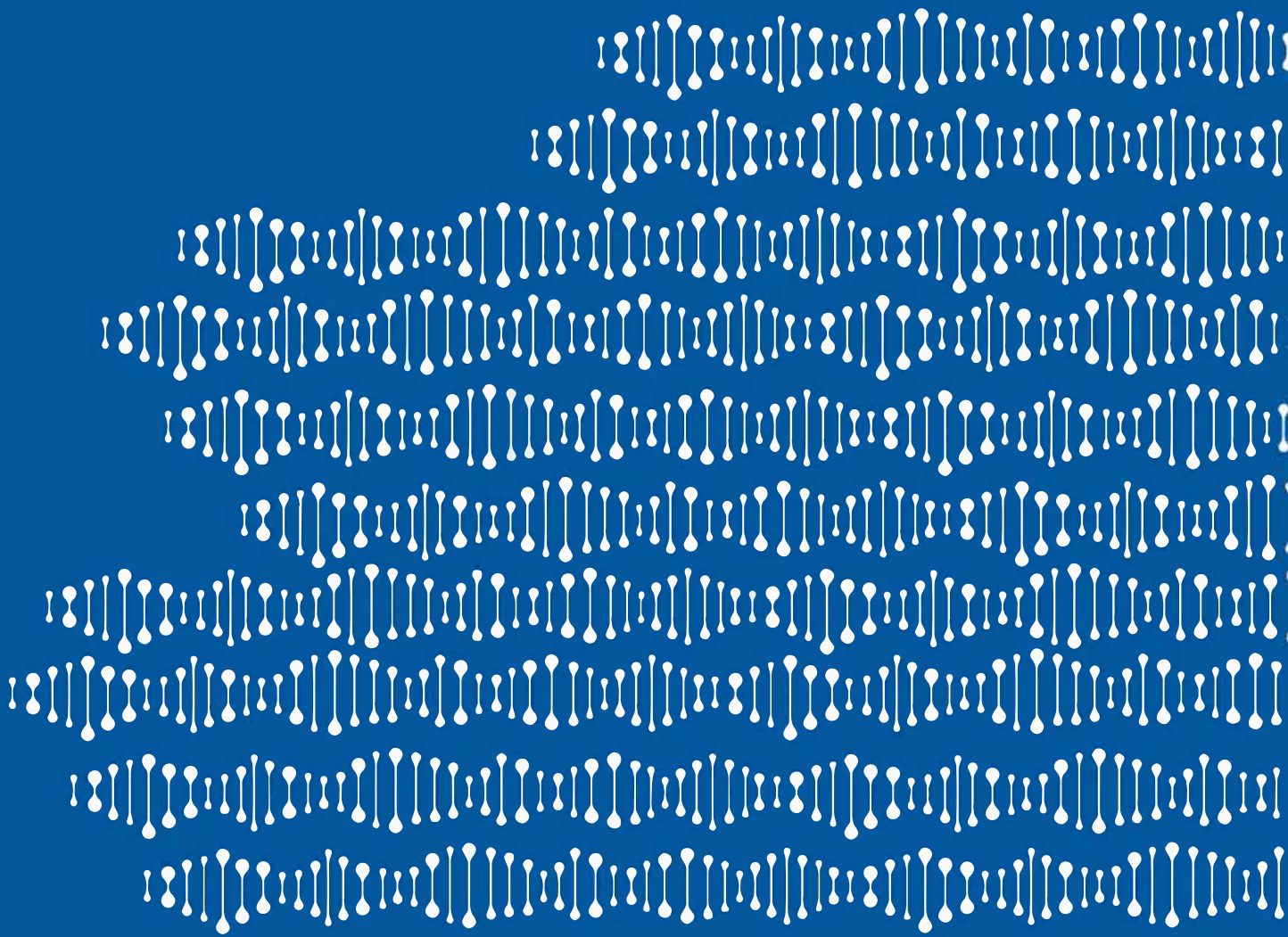
Cancer Prevention & Research Institute of Texas

Proposed Grant Awards

August 17, 2022



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: MICHELLE LE BEAU, PH.D., CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH FY2022 RECRUITMENT AWARD RECOMMENDATIONS FY2022, CYCLE 22.9.AND 22.10

DATE: AUGUST 3, 2022

The Scientific Review Council (SRC) and Program Integration Committee (PIC) recommendations for FY2022 recruitment cycles 22.9 and 22.10, includes **three awards** from two grant mechanisms totaling **$10,000,000** as displayed in Table 1. The recommendations include a previously deferred Established Investigator application from cycle 22.9. At the May 3, 2022, meeting, the Program Integration Committee (PIC) deferred two recruitment applications from cycle 22.9: RR220067 that is included in Table 1, and RR220070, that was withdrawn by the nominating Institution.

Table 1:

Grant Mechanism	**SRC Recommendations**	
	Awards	**Funding**
Recruitment of Established Investigators	1	$6,000,000
Recruitment of First-Time, Tenure Track Faculty Members	2	$4,000,000
Total	**3**	**$10,000,000**

Program Priorities Addressed:
The applications proposed to the Program Integration Committee for funding address the following Academic Research Program Priorities: recruitment of outstanding cancer researchers to Texas and childhood and adolescent cancers, as shown in Table 2 and Attachment 1.

Table 2

Program Priorities Addressed by Grant Recommendations		
# Awards*	**Program Priorities**	**Funding***
3	Recruitment of outstanding cancer researchers to Texas	$10,000,000
1	Childhood and Adolescent Cancers	$2,000,000
*Some grant awards address more than one program priority and are double counted.		

1. RECRUITMENT OF ESTABLISHED INVESTIGATORS SLATE FY22.9

Peer Review Recommendations
The applications were evaluated and scored by the Scientific Review Council (SRC) to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of Recruitment of Established Investigators Awards: The aim is to recruit outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.

Funding levels for Recruitment of Established Investigators Awards:
Up to $6 million over a period of 5 years.

Below is a listing of the candidates with their associated expertise:

RR220067
Candidate: Zhiguo Zhang, Ph.D.
Funding Mechanism: Recruitment of Established Investigator
Applicant Organization: The University of Texas M. D. Anderson Cancer Center
Original Organization of Nominee: Columbia University Irving Medical Center
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 2.0
Recommended Total Budget Award and Duration: $6,000,000
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas; Childhood and Adolescent Cancers

Description:

The University of Texas MD Anderson Cancer Center has nominated Zhiguo Zhang, PhD for a CPRIT Recruitment of Established Investigators Award, and appointment as a Professor in the Department of Epigenetics and Molecular Carcinogenesis. Dr. Zhang is currently a Professor at Columbia University, and is world-renowned for his discoveries related to the molecular mechanisms of inheritance of epigenetic patterns and how these mechanisms impact the functions of oncohistones in driving the development of pediatric gliomas. Epigenetic alterations to chromatin (DNA, RNA, and structural proteins) play a causal role in tumorigenesis, tumor evolution, and drug resistance. A major unresolved question in modern biology is how epigenetic information is propagated into daughter cells during mitotic cell divisions, ensuring genome integrity and cell identity. The overall goals of Dr. Zhang's research are to elucidate the molecular mechanisms of epigenetic inheritance in both normal and cancer cells, to discover epigenetic mechanisms underlying gliomagenesis, and to identify novel drug targets and therapeutics for the treatment of pediatric gliomas.

3. RECRUITMENT OF FIRST-TIME TENURE TRACK FACULTY MEMBERS SLATE FY22.10

Peer Review Recommendations
The applications were evaluated and scored by the Scientific Review Council to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Purpose of First-Time Tenure Track Faculty Recruitment
The aim is to recruit and support very promising emerging investigators, pursuing their first faculty appointment in Texas, who can make outstanding contributions to the field of cancer research.

Funding levels for First-Time Tenure Track Faculty Members Recruitment
Up to $2 million over a period of up to 5 years.

Below is a listing of the candidates with their associated expertise:

RR220094
Candidate: Steven Boeynaems, Ph.D.
Funding Mechanism: Recruitment of First-Time Tenure Track Faculty Member
Applicant Organization: Baylor College of Medicine
Original Organization of Nominee: Stanford University
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.0
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Description:

Baylor College of Medicine is nominating Steven Boeynaems, PhD for a Recruitment of First-Time, Tenure-Track Faculty Award, and appointment as an Assistant Professor in the Department of Molecular and Human Genetics and a member of the Dan L. Duncan Comprehensive Cancer Center. Dr. Boeynaems is a talented scientist with a stellar publication record. He has unique expertise in characterizing biomolecular condensates - membraneless assemblies of proteins and nucleic acids. Dr. Boeynaems' prior work demonstrated how such condensates allow cells to sense and respond to diverse intrinsic and extrinsic stresses. The goal of Dr. Boeynaems' research will be to untangle the role of biomolecular condensates in stress signaling and resilience in the tumor microenvironment in brain tumors, using innovative synthetic biology tools and proteomics methods. A long-term goal is to exploit vulnerabilities within this stress response pathway to develop novel therapies.

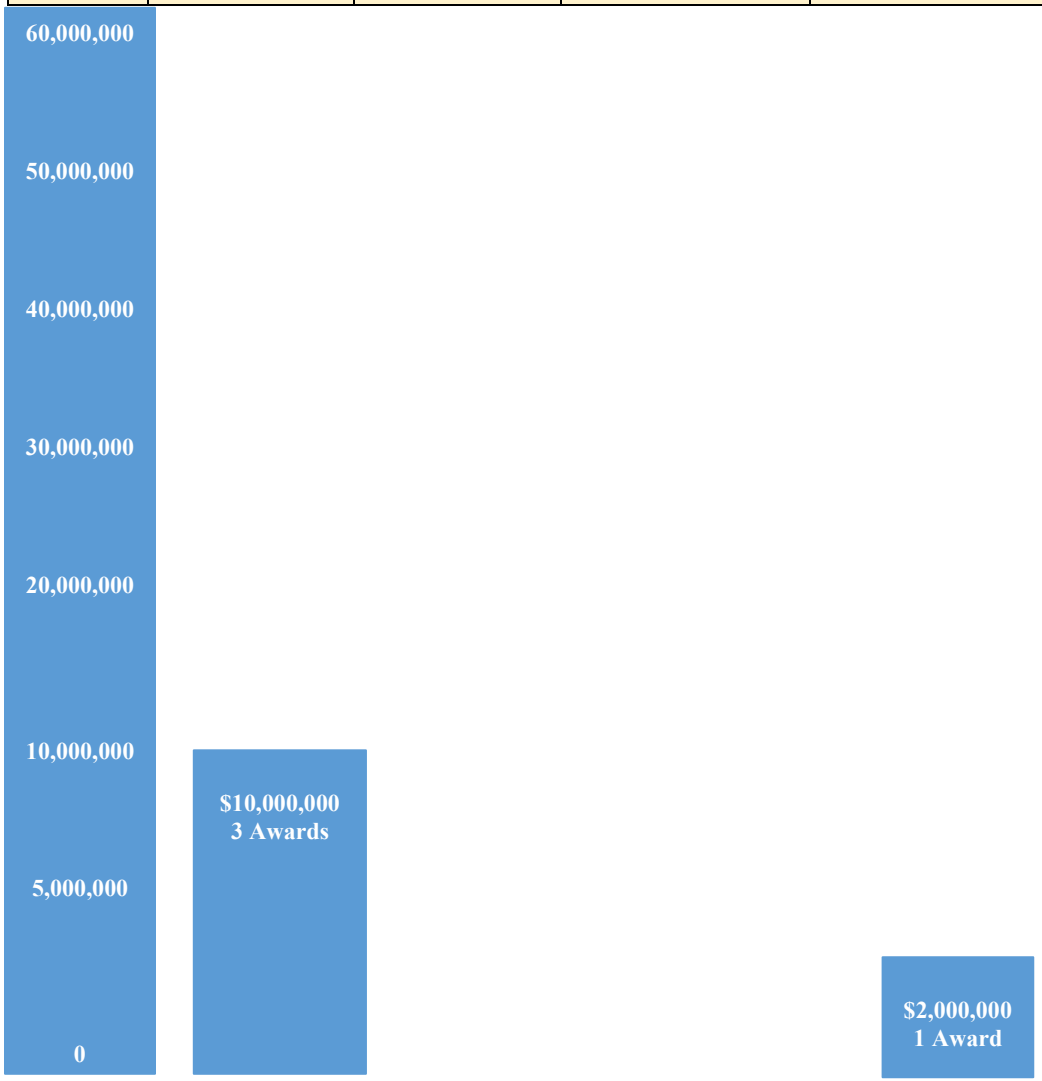
RR220101
Candidate: Siqi Liu, Ph.D.
Funding Mechanism: Recruitment of First-Time, Tenure-Track Faculty Member
Applicant Organization: University of Texas Southwestern University
Original Organization of Nominee: Rockefeller University
Overall Evaluation Score [Rating Scale 1.0 (highest merit) to 9.0 (lowest merit)]: 1.0
Recommended Total Budget Award and Duration: $2,000,000.
CPRIT Priorities Addressed: Recruitment of outstanding cancer researchers to Texas

Descriptions:

Siqi Liu, PhD is nominated by UT Southwestern University for a CPRIT First-Time, Tenure-Track Faculty Award, and appointment as an Assistant Professor in the Department of Pharmacology. Dr. Liu has an exceptional background in studying skin wound repair, and signaling via the innate immune system – the body's first defense against infections or pathogens. She is the recipient of a prestigious K99/R00 early investigator award from the NIH. Cutaneous squamous cell carcinoma (cSCC) is the second most common cancer, causing ~10,000 deaths in the US annually. The prevalence of cSCC is increasing, due to our aging population; however, relatively little is known about high-risk cSCC, and current therapies are limited by low therapeutic efficacy. Chronic wounds and burns are major risk factors for cSCC. Dr. Liu has discovered a novel innate immune pathway that senses and coordinates wound repair and is significantly upregulated in nearly all human cancers. In her research laboratory, Dr. Liu will investigate how skin cancers hijack and evade a normal repair process to fuel their growth via innate immune activation, to provide insights into these mechanisms, and to inform novel, targeted therapeutic strategies.

Attachment #1

*Academic Research Program Priorities Addressed by Recommended Awards (*Some grant awards address more than one program priority and are double counted.)							
Scale	Recruitment of outstanding cancer researchers to Texas	Drug Discovery	Access to innovative clinical trials	Childhood and Adolescent Cancers	Population Disparities	Computational biology and analytic methods	Hepatocellular Cancer



- **Recruitment of Established Investigators (RFA R-22-1 REI):**
  Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.
  Award: Up to $6 million over a period of five years.

- **Recruitment of Rising Stars (RFA R-22-1 RRS):**
  Recruits outstanding mid-level investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.
  Award: Up to $4 million over a period of five years.

- **Recruitment of First-Time Tenure Track Faculty Members (RFA R-22-1. RFT**):
  Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research. Award: Up to $2 million over a period up to five years.

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

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San Diego Branch

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August 2, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Dr. Patel and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on on May 12, 2022 (REC Cycle 22.10), July 14, 2022 (REC Cycle 22.10) and August 1, 2022 (REC Cycle 22.10) to review the applications submitted to CPRIT under the Recruitment of Established Investigators, and Recruitment of First-Time, Tenure Track Faculty Members.

The SRC recommends two applications, which are inlcuded on the attached list. The recommended funding amounts and the overall evaluation scores are stated for the grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is $4,000,000

The recommendation meets the SRC's standards for funding. These include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

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San Diego

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Rank	App. ID	Mechanism	Candidate	Organization	Budget	Overall Scores
1	RR220094	RFTFM	Steven Boeynaems, Ph.D.	Baylor College of Medicine	$2,000,000	1.0
2	RR220101	RFTFM	Siqi Liu, Ph.D.	The University of Texas Southwestern Medical Center	$2,000,000	1.0

RFTFM = Recruitmen of First-Time, Tenure Track Faculty Members

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

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April 25, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

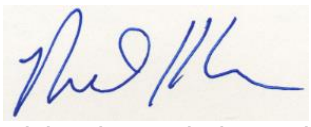
Dear Dr. Patel and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on February 10, 2022 (REC Cycle 22.7); on March 10, 2022 (REC Cycle 22.8) and on April 14, 2022 (REC Cycle 22.9) to review the applications submitted to CPRIT under the Recruitment of Established Investigators, of Rising Stars and of First-Time, Tenure Track Faculty Members.

The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation scores are stated for each grant application. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is $57,998,029. Please note that applications RR220073 and RR220059 recommended by the SRC were withdrwan prior to the Program Integration Committee meeting; therefore, the applications are not included in the rank order list on page two of this letter.

These recommendations meet the SRC's standards for funding. These include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,



Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

LUDWIG CANCER RESEARCH

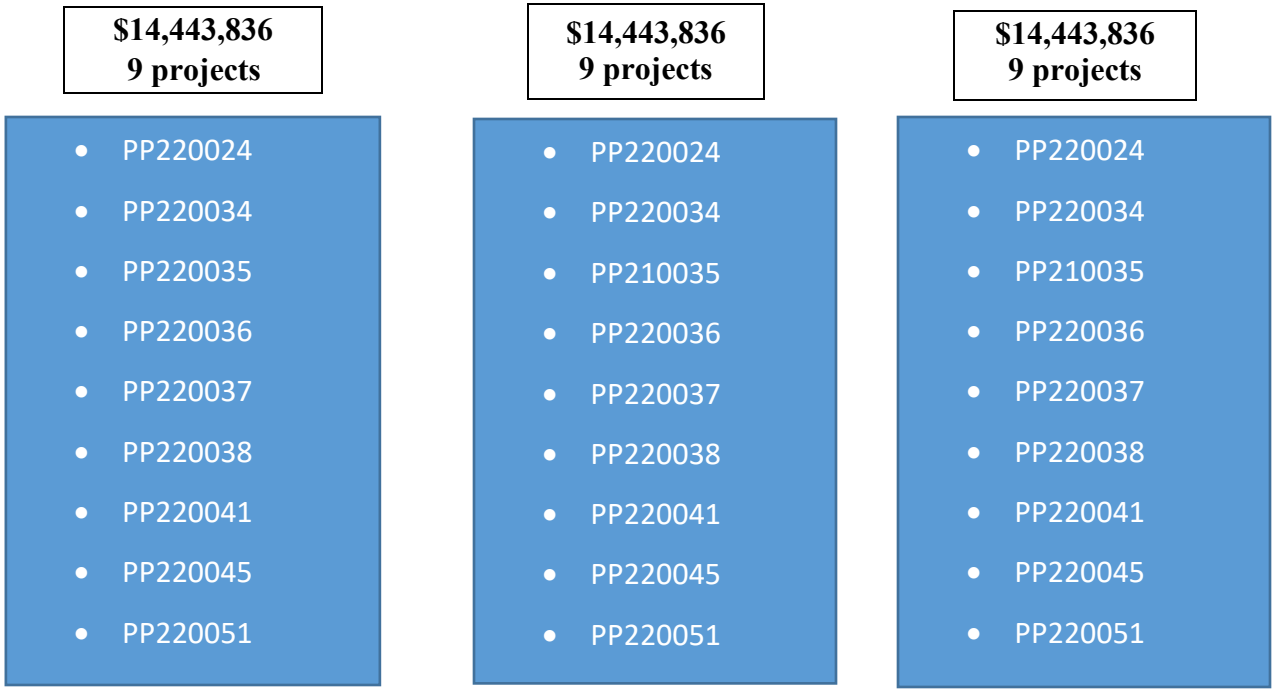
San Diego

ludwigcancerresearch.org

Rank	App. ID	Mechanism	Candidate	Organization	Budget	Overall Scores
1	RR220084	RFTFM	Linde Miles	The University of Texas Southwestern Medical Center	$2,000,000	**1.0**
2	RR220087	RRS	Hans Renata	Rice University	$4,000,000	**1.0**
3	RR220068	RFTFM	Elizabeth Wasmuth	The University of Texas Health Science Center at San Antonio	$2,000,000	**1.0**
4	RR220069	RFTFM	William Hudson	Baylor College of Medicine	$2,000,000	**1.0**
5	RR220075	RFTFM	Nicholas Riley	The University of Texas at Austin	$2,000,000	**1.0**
6	RR220033	REI	Pavan Reddy	Baylor College of Medicine	$6,000,000	**1.0**
7	RR220062	RFTFM	Aria Vaishnavi	The University of Texas M. D. Anderson Cancer Center	$2,000,000	**1.0**
8	RR220065	RFTFM	Mingjie Dai	Rice University	$2,000,000	**1.4**
9	RR220072	RRS	Christine Lovly	The University of Texas M. D. Anderson Cancer Center	$4,000,000	**1.4**
10	RR220063	RRS	Ku-Lung Hsu	The University of Texas at Austin	$4,000,000	**1.7**
11	RR220051	REI	Michael Taylor	Baylor College of Medicine	$6,000,000	**1.8**
12	RR220081	RFTFM	Jonathan Clinger	Baylor University	$1,998,029	**2.0**
13	RR220086	RFTFM	Jason Schenkel	The University of Texas M. D. Anderson Cancer Center	$2,000,000	**2.0**
14	RR220088	RRS	Abdel Kareem Azab	The University of Texas Southwestern Medical Center	$2,000,000	**2.0**
15	RR220067	REI	Zhiguo Zhang	The University of Texas M. D. Anderson Cancer Center	$6,000,000	**2.0**
16	RR220070	RRS	Marios Giannakis	The University of Texas Southwestern Medical Center	$4,000,000	**2.0**
17	RR220055	RFTFM	Samantha Yruegas	Rice University	$2,000,000	**2.0**
18	RR220066	RFTFM	Deepshika Ramanan	The University of Texas M. D. Anderson Cancer Center	$2,000,000	**2.2**
19	RR220035	RFTFM	Qian Zhu	Baylor College of Medicine	$2,000,000	**2.5**

REI = Recruitment of Established Investigator
RRS = Recruitment of Rising Stars
RFTFM = Recruitmen of First-Time, Tenure Track Faculty Members

Prevention Program Priorities Addressed by Recommended Awards August 17, 2022			
Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence	**Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence**	**Prioritize underserved populations**	**Prevention Program Assessment**



Note: Some grant awards address more than one program priority and will be double counted.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE
FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER
SUBJECT: PREVENTION GRANT AWARD RECOMMENDATIONS – FY 2022 CYCLE 2
DATE: AUGUST 3, 2022

Summary and Recommendation:
The Program Integration Committee (PIC) has completed its review of the recommendations forwarded by the Prevention Review Council (PRC) and recommends awarding 9 projects for FY 2022 Cycle 2 totaling $14,443,836. The grant recommendations are presented in two slates.

Grant Mechanism	Number	Amount
Evidence-Based Cancer Prevention Services	5	$ 4,964,235
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	4	$ 9,479,601
TOTAL	**9**	**$14,443,836**

Background:

FY 2022 Cycle 2 (22.2)
CPRIT released three RFAs in October 2021 for the second review cycle of FY 2022. Sixteen applications requesting $21,458,195 were submitted; twelve applications requesting $16,383,803 underwent peer review discussion by teleconference on April 25, 2022. The PRC met June 3 to finalize recommendations to the Program Integration Committee. The PRC recommendations include 8 awards totaling $13,467,985 and one award for $975,851 from Cycle 22.1 for a total of $14,443,836.

Program Priorities Addressed
All the recommended applications address more than one of the Prevention Program priorities. See the attached chart for additional detail.

Number of Applications Addressing Priorities		
9	Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence	$14,443,836
9	Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence	$14,443,836
9	Prioritize underserved populations	$14,443,836

Cycle 22.2 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP220036	EBP	Increasing the use of HPV vaccination services among medically underserved young adults	Roncancio, Angelica M	University of Houston	1.6	1	$991,308
PP220034	EPS	Screening to Optimize Prevention of CRC in East Texas (STOP CRC ET)	McGaha, Paul	The University of Texas Health Center at Tyler	1.8	2	$2,482,127
PP220038	EPS	Advancing Implementation of Evidence-Based Strategies for Tobacco Prevention and HPV Vaccination in Pediatric Safety Net Settings	Montealegre, Jane R	Baylor College of Medicine	2.3	3	$2,499,180
PP220045	EBP	Inpatient Screening and Treatment for Unhealthy Alcohol Use and Tobacco Use as a means of cancer prevention	Ramesh, Jananie	The University of Texas at Austin	2.6	4	$999,957
PP220037	EPS	Project ACCESS: Increasing Access to Cervical Cancer Screening & Treatment Services in Texas	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	2.9	5	$2,498,445
PP220024	EBP	Promoting Prevention in Survivorship Care in Rural Texas	Kvale, Elizabeth	The University of Texas at Austin	3.3	6	$975,851
PP220041	EBP	Fecal Immunochemical Testing for Screening and Treatment of Occult Neoplasia (FIT-STOP)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	4.0	7	$999,999
PP220051	EPS	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations- Program title: GetFIT	Mika, Virginia	University Health System	4.5	8	$1,999,849
PP220035	EBP	DEFEAT breast cancer: Delivering Education, Focused navigation, and Equitable Access throughout East Texas.	McGaha, Paul	The University of Texas Health Center at Tyler	5.0	9	$997,120

EBP: Evidence-Based Cancer Prevention Services
EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

Prevention Program Slates

Evidence-Based Cancer Prevention Services

Mechanism:
This award mechanism seeks to fund projects that will deliver evidence-based cancer prevention and control clinical services. Priority will be given to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.

Award: Maximum of $1M; Maximum duration of 36 months.

Recommended projects (5): $4,964,235

Nine applications were submitted in this mechanism. Five Evidence-Based Cancer Prevention Services projects are recommended.

Project Descriptions

PP220036	Increasing the use of HPV vaccination services among medically underserved young adults	Roncancio, Angelica M	University of Houston	1.6	$991,308
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize underserved populations					

The goal of this project is to increase HPV vaccination (initiation and completion) among underserved, predominantly low-income, young adult patients served by five clinics in Brazoria and Galveston Counties and seven clinics in Bastrop, Caldwell, Gonzales, Guadalupe, and Victoria Counties. The program will implement a provider-directed intervention (PDI), practice-level intervention (PLI) and community education and outreach. Organizational capacity and readiness assessments will identify the factors that influence the HPV vaccination practices of health care providers and identify barriers to be addressed. The results will inform the development of the PDI and PLI to increase HPV vaccination among patients. Community level education and outreach for residents and training for health care professionals will be included. This comprehensive approach promotes best practices by training providers and clinic staff to disseminate information on HPV and the HPV vaccine, improves patient-provider communication, and enhances health care systems' capacity to improve the delivery of HPV vaccines to clinic patients.

PP220045	Inpatient Screening and Treatment for Unhealthy Alcohol Use and Tobacco Use as a means of cancer prevention	Ramesh, Jananie	The University of Texas at Austin	2.6	$999,957
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize underserved populations					

This project aims to utilize an evidence-based strategy in an inpatient setting to identify patients with unhealthy alcohol use and/or tobacco use, provide behavioral intervention, offer medication-assisted treatment if appropriate, and develop an outpatient plan to continue treatment. The proposal builds on the extensive experience of team members to develop this type of program in a novel setting, as well as the resources established through the existing CPRIT-supported outpatient programs for alcohol and tobacco screening and treatment. Implementing the proposed interventions in this inpatient setting takes advantage of an episode where patients may be particularly motivated to make behavioral change and provides an opportunity to reach patients who may not be engaged in outpatient care. Additionally, the screening, treatment, and referral services would be integrated into a hospital that does not currently have an addiction consult service. This project plans to tackle alcohol and tobacco use disorders by utilizing multiple modalities to reduce the morbidity and mortality of alcohol- and tobacco-related diseases, particularly cancers linked to these risky behaviors.

PP220024 (from Cycle 22.1)	Promoting Prevention in Survivorship Care in Rural Texas	Kvale, Elizabeth	The University of Texas at Austin	3.3	$975,851
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize underserved populations					

LiveStrong Cancer Institutes and Texas Oncology have partnered to propose the implementation and evaluation of an evidence-based systematic clinical approach to survivorship care. The POSTCare Survivorship Care Process is focused on the under-addressed preventive and psychosocial health needs of cancer survivors. The process is a patient-informed, theory driven, and highly innovative nurse-delivered survivorship care process. This proposal seeks to serve cancer patients who are completing active treatment in rural clinics based in three rural counties (Hunt, Lamar, and Titus) and deliver guideline concordant prevention-focused survivorship care and promote healthy lifestyle discussions via telehealth. The proposal takes advantage of the "teachable moment" at the completion of active cancer treatment to engage rural cancer survivors in healthy lifestyle behaviors that reduce the risk of cancer recurrence, reduce the risk of second primary cancers, and improve quality of life.

PP220041	Fecal Immunochemical Testing for Screening and Treatment of Occult Neoplasia (FIT-STOP)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	4.0	$999,999
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize underserved populations					

This application proposes to develop the Fecal Immunochemical Testing for Screening and Treatment of Occult Preneoplasia (FIT-STOP) in the South Plains (COG-2) led by TTUHSC-UMC Cancer Center. FIT-STOP's strategic approach of public-private-community partnerships will utilize the established network from CPRIT-funded breast and cervical cancer screening projects to target the uninsured/underinsured population of the South Plains for education, awareness, screening, and prevention through FIT-STOP. The strategy of public-private-community partnership has been extremely successful in the past and will be utilized for outreach to target CRC screening as a new focus to enhance screening/prevention in COG-2. This model utilizes the evidence-based approaches of "Train the Trainer", culturally sensitive educational materials, community activists, the "precede-proceed" model, and use of "multiple intervention" approach for completion of screening. FIT-STOP will target the population of COG-2 via an educational and awareness campaign utilizing traditional and social media. All positive tests will be offered colonoscopy and work up. Outreach and resource identification will be available to all income levels, but ethnic minorities and rural communities will be primary targets.

PP220035	DEFEAT breast cancer: Delivering Education, Focused navigation, and Equitable Access throughout East Texas.	McGaha, Paul	The University of Texas Health Center at Tyler	5.0	$997,120
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize underserved populations					

This application will focus on recruiting, educating, and screening underserved and uninsured women between 40 to 75 years of age in a seven-county area of East Texas, based on the current American Cancer Society breast cancer screening guidelines. The project will use a unique integrated public health and clinical model which accounts for rurality and optimizes success and will focus on professional education regarding bias and racism in the healthcare system. The focus will be on the African American population in rural East Texas that are faced with unique challenges related to access, delivery of education, and provision of screening services. The access to care model incorporates strong partnerships with regional collaborators, incorporating numerous community health facilities to create awareness of screening options and recruit screening participants. This project leverages the availability of robust primary care programs at

The Health Science Center at UT Tyler (HSC) to assist with recruitment for breast cancer screening.

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

Mechanism:
This award mechanism seeks to support the coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.

Award: Maximum of $2M for initial expansions and $2.5M for maintenance expansions; Maximum duration of 60 months.

Recommended projects (4): $9,479,601

Four applications were submitted in this mechanism. Four Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations projects are recommended.

Project Descriptions

PP220034	Screening to Optimize Prevention of CRC in East Texas (STOP CRC ET)	McGaha, Paul	The University of Texas Health Center at Tyler	1.8	$2,482,127
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize underserved populations					

This expansion proposal intends to add four additional counties to the 32-county service area of the previous colorectal cancer screening project in East Texas, providing services to an area with some of the highest colorectal cancer (CRC) incidence and mortality rates in Texas. The project plans to increase CRC screening (FIT and colonoscopies) rates by partnering with existing and four new health centers. The project plans to implement a professional continuing education component to optimize all efforts. The project will expand and provide screening tools to medically underserved areas in the region. Being in a rural area poses many challenges such as long distances to the closest medical facilities and difficulty reaching people in such a wide geographical distribution. Partnering with both Federally Qualified Health Centers (FQHCs) and local health departments will optimize the project's preventive goals. By following an improved access to care model, the project will continue to build strong partnerships with collaborators, engaging numerous community health facilities to raise awareness for and provide CRC screenings for the un-/under-insured.

PP220038	Advancing Implementation of Evidence-Based Strategies for Tobacco Prevention and HPV Vaccination in Pediatric Safety Net Settings	Montealegre, Jane R	Baylor College of Medicine	2.3	$2,499,180
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize underserved populations					

This project will expand on the implementation and evaluation of an HPV vaccination program and a comprehensive e-cigarette and other tobacco products screening, counseling, and referral program within Harris Health System, the third largest safety net health system in the U.S. The program is targeted to healthcare providers, parents, and pediatric patients ages 11-18 years. The program utilizes multi-level evidence-based strategies including provider education and training, practice facilitation, systems improvement, patient (parent) education, and patient reminder, recall, and navigation. Over the past five years, the program has led to markedly higher vaccine initiation and up to date rates within the health system, which respectively increased between 2015 and 2021 from 72% to 87% and from 28% to 80%. The program plans to leverage the infrastructure and strategies of the program to expand the role of pediatric providers in cancer prevention, specifically by expanding the work to additional safety net clinics and health systems. These include Legacy Community Health, a federally qualified health center (FQHC) system that provides outpatient care for over 17,100 adolescent patients and operates 15 community and 35 school-based clinics serving pediatric patients; as well as Community Health Network, an FQHC that serves the southeastern counties around Harris County. The project will also continue to implement the program within the Harris Health system.

PP220037	Project ACCESS: Increasing Access to Cervical Cancer Screening & Treatment Services in Texas	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	2.9	$2,498,445
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize underserved populations					

This expansion of the current CPRIT-funded project (PP190014) will continue to offer cervical cancer prevention services to women at the 10 existing collaborating sites in the Rio Grande Valley (RGV), Laredo, Northeast Texas, Bastrop, and Alvin, and include new sites in Corpus Christi, Waxahachie, and Pasadena. The program uses a comprehensive approach which includes public education about screening and HPV vaccination through community outreach and clinic in-reach, coupled with patient navigation to services. The program will also provide education and training to local providers to build capacity to deliver quality cervical cancer prevention

services through hands-on colposcopy and LEEP training courses and telementoring using Project ECHO.

PP220051	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations-Program title: GetFIT	Mika, Virginia	University Health System	4.5	$1,999,849
CPRIT Priorities addressed: Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; prioritize underserved populations					

This proposal focuses on establishing Get FIT as a comprehensive evidenced-based outreach, education, navigation, and FIT colorectal screening program in Bexar and Maverick Counties, specifically low-income Hispanic individuals who make up most of these communities. The focus will be on the medically underserved areas of these counties. This comprehensive program will consist of 1) culturally tailored outreach strategies incorporating components from the A Su Salud model reaching uninsured patients; 2) navigation to screening services using bicultural navigators to help mitigate barriers to care, providing follow-up care, and increased patient satisfaction; and 3) patient education on current guidelines and options for CRC screenings. This program will enhance successful existing program models surrounding prevention and early disease detection as well as provide information on the FIT test as an option for those reluctant to undergo colonoscopy screening.

June 13, 2022

Dr. Mahendra Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Roberts and Dr. Patel,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for the FY2022 Cycle 2 Evidence-Based Cancer Prevention Services (EBP) and Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations and (EPS) grant awards.

The PRC met on June 3, 2022, to consider the applications recommended by the peer review panel following their April 25, 2022, meeting. The PRC recommends 9 projects totaling $14,443,836. One of the recommended projects, PP220024, was submitted and reviewed in FY2022 Cycle 1 but the PRC took no action on the application at that time.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PRC made no changes to the goals, project objectives, or timelines of the applications.

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary, or tertiary prevention. In making these recommendations the PRC continued to consider the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All the recommended grants address one or more of the Prevention Program priorities.

Sincerely,
Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

Attachment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Cycle 22.2 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP220036	EBP	Increasing the use of HPV vaccination services among medically underserved young adults	Roncancio, Angelica M	University of Houston	1.6	1	$991,308
PP220034	EPS	Screening to Optimize Prevention of CRC in East Texas (STOP CRC ET)	McGaha, Paul	The University of Texas Health Center at Tyler	1.8	2	$2,482,127
PP220038	EPS	Advancing Implementation of Evidence-Based Strategies for Tobacco Prevention and HPV Vaccination in Pediatric Safety Net Settings	Montealegre, Jane R	Baylor College of Medicine	2.3	3	$2,499,180
PP220045	EBP	Inpatient Screening and Treatment for Unhealthy Alcohol Use and Tobacco Use as a means of cancer prevention	Ramesh, Jananie	The University of Texas at Austin	2.6	4	$999,957
PP220037	EPS	Project ACCESS: Increasing Access to Cervical Cancer Screening & Treatment Services in Texas	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	2.9	5	$2,498,445
PP220024	EBP	Promoting Prevention in Survivorship Care in Rural Texas	Kvale, Elizabeth	The University of Texas at Austin	3.3	6	$975,851
PP220041	EBP	Fecal Immunochemical Testing for Screening and Treatment of Occult Neoplasia (FIT-STOP)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	4.0	7	$999,999
PP220051	EPS	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations- Program title: GetFIT	Mika, Virginia	University Health System	4.5	8	$1,999,849
PP220035	EBP	DEFEAT breast cancer: Delivering Education, Focused navigation, and Equitable Access throughout East Texas.	McGaha, Paul	The University of Texas Health Center at Tyler	5.0	9	$997,120

EBP: Evidence-Based Cancer Prevention Services
EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	T.A.C. § 702.19 STANDING WAIVER FOR FY 2022
DATE:	SEPTEMBER 10, 2021

Summary

This is to notify the Oversight Committee that pursuant to the authority provided to the Chief Executive Officer in T.A.C. § 702.19(e), I grant CPRIT's Chief Prevention Officer Ramona Magid a waiver from the general prohibition against communicating with grant applicants. The waiver is applicable for FY 2022 and will be effective for all prevention review cycles planned during the fiscal year. No Oversight Committee action related to this waiver is necessary.

Background and Discussion

The Chief Prevention Officer is a statutorily mandated member of the Program Integration Committee (PIC). Texas Administrative Code § 702.19 prohibits substantive communication between a grant applicant and a member of a peer review panel, the PIC, or the Oversight Committee while the application is pending a final decision. The restriction on communication prevents even the appearance of unequal treatment during the grant review process.

Traditionally, a chief program officer leads each CPRIT program with the assistance of a program manager who fields inquiries from and provides technical help to applicants completing their CPRIT grant applications. I promoted Ms. Magid to the Chief Prevention Officer position upon Dr. Becky Garcia's retirement in June 2019. However, the prevention program manager position has remained vacant since Ms. Magid's promotion. Until CPRIT fills the program manager position, she is the sole point of contact for the prevention program. The communication waiver is necessary so that Ms. Magid can assist grant applicants who have questions during the application process.

Like the FY 2021 waiver, I am granting a standing waiver for Ms. Magid for FY 2022 as long as she remains the sole point of contact for the prevention program. Approving this standing waiver does not favor any grant applicant over another. Ms. Magid will provide technical assistance only and will not comment on the substance of a grant application. CPRIT will include this waiver in the grant record for the FY 2022 prevention grant applications.

Product Development Research Priorities Addressed by the 22.2 Cycle Proposed Awards

The chart below reflects that all recommended applications address one or more of the Product Development Research priorities.

Applications Addressing Priorities*	Product Development Research Priorities	Award Amount per Priority*
5	Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies	**$39,433,920**
9	Funding projects addressing large or challenging unmet medical needs	**$64,868,655**
9	Investing in early-stage projects where private capital is least available	**$64,868,655**
5	Stimulating commercialization of technologies developed at Texas institutions	**$26,986,736**
1	Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations	**$14,268,315**
9	Providing appropriate return on taxpayer investment	**$64,868,655**

*Some proposed awards address more than one priority.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS
From: KEN SMITH, PHD, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject: FY 22.2 PRODUCT DEVELOPMENT RESEARCH AWARD RECOMMENDATIONS
Date: AUGUST 1, 2022

Summary of Recommendation:

The Product Development Review Council (PDRC) recommends that the Program Integration Committee (PIC) and the Oversight Committee approve product development research awards to the following applicants: Atom Mines, InformAI Inc., Xerient Pharma Inc., PLUS Therapeutics, Inc., Stellanova Therapeutics, Asylia Therapeutics, Rapamycin Holdings Inc., NUCORE Medical and PanTher Therapeutics. The table below reflects the ranked award recommendations, including the maximum recommended funding amounts and the evaluation scores for the nine applications recommended for awards.

The PDRC did not make any changes to timelines or budgets for the nine projects recommended for funding. However, two recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP220053 and DP220054 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP220066 related to clinical data, timelines and development plans. I will address the proposed contingencies at the meetings with the PIC and the Oversight Committee

FY 2022 Cycle 2 Award Recommendations

Rank	ID	RFA	Company	Project	Score*	Budget
1	DP220039	TXCO	PLUS Therapeutics Inc.	Single-Dose 186RNL for Leptomeningeal Metastases: Multicenter Phase 1/2a Study to Determine MTD/MFD, Safety and Efficacy, Leading to Pivotal Registrational Trial	2.2	$17,613,605
2	DP220028	SEED	Stellanova Therapeutics Inc.	Development of DKK3-Targeted Therapeutic Antibodies for Cancer	2.3	$3,000,000
3	DP220038	SEED	Asylia Therapeutics	Humanization, Validation, and Clinical Translation of Cell Surface Heat Shock Protein 70-Targeted Antibody-Drug Conjugates for T-Cell Non-Hodgkin Lymphomas	2.3	$3,000,000
4	DP220055	TXCO	Atom Mines	Commercial-Scale Enrichment of Stable Ytterbium-176 for Production	2.0	$2,500,000

Rank	ID	RFA	Company	Project	Score*	Budget
				of No-Carrier-Added Lutetium-177 for Use in Prostate Cancer Therapy		
5	DP220053	TXCO	Rapamycin Holdings Inc.	Development of eRapa for the Treatment of Familial Adenomatous Polyposis, a Rare Genetic Disease Associated with a High Risk of Colorectal Cancer	2.7	$16,999,999
6	DP220043	SEED	Xerient Pharma Inc.	Oral Amifostine as an Upper GI Tract Radioprotectant for Effective Radiotherapy Treatment of Pancreatic Cancer	2.2	$2,934,737
7	DP220063	SEED	InformAI Inc.	RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology	2.2	$1,552,000
8	DP220066	RELCO	PanTher Therapeutics Inc.	Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer	3.6	$14,268,315
9	DP220054	SEED	Nucore Medical	Clinical Validation of the MiTR Core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention	3.4	$2,999,999
					TOTAL	**$ 64,868,655**

* - Average of reviewers' scores following company presentation peer review meeting

Background - FY 2022 Review Cycle 2

CPRIT released three product development RFAs in October 2021 for the second review cycle of FY 2022. CPRIT opened the application portal on December 1, 2021, and received 34 proposals by the January 26 deadline. Peer review panels met March 21 – 22 and selected 15 companies to present proposed projects live via Zoom April 11 - 14. Following company presentations, the review panels selected 11 companies to move into due diligence review by the PDRC. The PDRC met July 13, 14, and 19 to review the due diligence reports and make final award recommendations for FY 2022 awards.

PDRC Chair Dr. Jack Geltosky noted in his letter to the PIC and the Oversight Committee that the PDRC's recommendation to fund these nine awards reflected 50+ hours of individual review and panel discussion of each application as well as the PDRC's review of the diligence materials for each company. Dr. Geltosky also indicated that the PDRC did not make a final decision on one grant recommendation due to CPRIT budgetary constraints. The PDRC will consider whether to recommend the pending application for an award at a future meeting, perhaps as early as September.

Product Development Research Priorities Addressed by the 22.2 Cycle Proposed Awards

The chart below reflects that all recommended applications address one or more of the Product Development Research priorities.

Applications Addressing Priorities*	Product Development Research Priorities	Award Amount per Priority*
5	Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies	**$39,433,920**
9	Funding projects addressing large or challenging unmet medical needs	**$64,868,655**
9	Investing in early-stage projects where private capital is least available	**$64,868,655**
5	Stimulating commercialization of technologies developed at Texas institutions	**$26,986,736**
1	Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations	**$14,268,315**
9	Providing appropriate return on taxpayer investment	**$64,868,655**

*Some proposed awards address more than one priority.

Mechanism of Support and Product Development Research Objectives

Applications submitted in the 22.2 review cycle responded to one of three product development research RFAs.

- *Texas Company Product Development Research Award* (TXCO)

  This award mechanism seeks to support early stage "startup" and established companies in the development of innovative products and services with significant potential impact on cancer patient care. The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Companies must be headquartered in Texas.

  Strong candidates for the TXCO award have developed a sufficiently robust data package, value proposition, regulatory strategy, manufacturing plan, and experienced business/management team to warrant the amount of funding requested.

  Award: Maximum amount $20 million over 36 months

- *Relocation Company Product Development Research Award* (RELCO)

  This award mechanism seeks to support early stage "startup" and established companies in the development of innovative products and services with significant potential impact on cancer patient care. The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Companies must relocate to Texas upon receipt of award.

  Strong candidates for the RELCO award have developed a sufficiently robust data package, value proposition, regulatory strategy, manufacturing plan, and experienced business/management team to warrant the amount of funding requested.

  Award: Maximum amount $20 million over 36 months

- *Seed Award for Product Development Research* (SEED)

  This award mechanism seeks to support early stage "startup" companies in the development of innovative products and services with significant potential impact on cancer patient care.

  The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Company applicants must be headquartered in Texas or be willing to relocate to Texas upon receipt of award

  Strong candidates for the SEED award have developed compelling discovery stage data and/or developed a working prototype (if applicable) around a novel compound, diagnostic, device, computational tool, etc. that warrants further development efforts to establish proof of concept (POC) on the early pathway to commercial product. In addition, strong candidates have at a minimum developed a strong value proposition, preliminary regulatory strategy, preliminary manufacturing plan, and early business/management team to warrant the amount of funding requested.

  Award: Maximum amount of $3 million over 36 months.

CPRIT Award Contract and Risk Mitigation

Investing in early-stage translational cancer research is inherently risky. Products in development at CPRIT Product Development Research awardees that show promise in the laboratory and in animal studies may not make a measurable difference in humans or the treatment's side effects may be so severe as to not justify the benefits. Along with the increased risk of technical failure, human studies are more complex and expensive than laboratory and animal studies.

CPRIT addresses the risk associated with product development research awards by tying disbursement of funds to the grantee achieving specific project goals and objectives. The award

contract requires the company to report at least annually on its progress. To receive the next tranche of project funding, the grantee must show that it has accomplished all the goals and objectives for the previous project year. The company will only receive the entire approved award amount if it successfully achieves all project goals and objectives. Because contractual goals are usually associated with project milestones, such as receiving FDA approval for an Investigational New Drug filing or completing a clinical trial, achieving all agreed-upon goals also means that the project is making meaningful progress to becoming a treatment option.

Product Development Research Awards
Recommended by the PDRC for FY 2022 Review Cycle 2

PLUS Therapeutics, Inc.
Proposed TXCO Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a TXCO Award for Product Development Research to PLUS Therapeutics, Inc. for $17,613,605.

Plus Therapeutics is a publicly listed company based in Austin. Plus is developing a Rhenium-186 NanoLiposome (186RNL), which is a novel radiotherapeutic to combat several cancers including recurrent glioblastoma, 186RNL is safe and well-tolerated while delivering a radiation dose to the tumor that is up to 15 times higher than typically achievable with standard radiation therapy. Plus is developing 186RNL to treat leptomeningeal metastases. Leptomeningeal Metastases (LM) are a rare but typically fatal complication of advanced cancer that affects the fluid-lined structures of the central nervous system. LM are diagnosed in 5% of cancer patients.

CPRIT Product Development Research Priorities Addressed

Plus Therapeutics' proposed project addresses four of the six Product Development Research Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early-stage projects where private capital is least available; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

The investigational product is BMEDA-chelated Rhenium-186 NanoLiposome (186RNL). Rhenium-186 is an ideal radionuclide for CNS cancers such as LM because of its long 90-hour half-life, beta particles' short ~2mm path length, low dose rate, and high radiation density that overwhelms proliferating cellular innate DNA repair mechanisms. For 186RNL treatment of LM in humans, PLUS has obtained FDA Fast Track designation and IND clearance and will pursue FDA Orphan Drug and Breakthrough Therapy designations in the future.

The purpose of the two-part, Texas-based multicenter (The University of Texas Health Science Center San Antonio, The University of Texas Southwestern Medical Center, and The University of Texas MD Anderson Cancer Center) Phase clinical trial is to characterize the safety, tolerability, PK, dosimetry, and antitumor activity of 186RNL administered intrathecally, via an intraventricular catheter system (Ommaya reservoir), as a single agent in 61 LM subjects. If successful, PLUS intends to seek FDA investigational new drug (IND) clearance to initiate and complete a Phase 2 pivotal trial in 120 subjects (final N subject to data and statistical analysis plan) with leptomeningeal metastases to support a new drug application (NDA) submission with the FDA.

The company expects 186RNL to deliver a much higher and more targeted dose of radiation during a single administration compared to traditional RTs; have a high safety margin with minimal risk of bone marrow suppression; may be able to treat all LM patients, unlike some other therapies that rely on tumor targeting technology for a subset of patients; ease of administration with well-accepted and currently utilized access technology.

Plus intends to complete parts 1 and 2 of a Multicenter Phase 1 Clinical Trial of IT-Delivered 186RNL to treat LM, which will include compiling safety data, identifying a maximum tolerated dose, assess the safety, tolerability, efficacy of 186RNL in subjects with LM for Phase 2 pivotal clinical trial. Plus intends to complete Multicenter Phase 2 Clinical Trial of IT-Delivered 186RNL to treat LM, which will lead to preparations for filing an NDA submission to the FDA.

Select Reviewer Comments

"*This tackles the issue of leptomeningeal metastasis with no therapy at the moment. IND has been filed and cleared by the FDA. In spite of some weaknesses about lack of preclinical data particularly in combination therapy for some models, the application remains solid and promising."*

"*The strengths are high unmet need albeit a very small population. Data in GBM are encouraging. There is FDA green light for the next clinical trial. The competition is limited, and the biomarker strategy if executed should improve targeting the most likely to respond..."*

"The intended product is currently already in clinical trials in glioblastoma and overall de-risks the intended product, clinical strategy, and the company."

StellaNova Therapeutics, Inc.
Proposed Seed Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Seed Award for Product Development Research to StellaNova Therapeutics, Inc. for $3,000,000.

StellaNova Therapeutics Inc. is a Houston-based company based around research conducted at MD Anderson Cancer Center demonstrating that cells in the tumor microenvironment of pancreatic cancer (PDAC) and triple negative breast cancer (TNBC) produce Dickkopf-3 (DKK3) that acts on neighboring cancer cells to stimulate their growth, metastasis and resistance to standard therapy.

CPRIT Product Development Research Priorities Addressed

StellaNova Therapeutics, Inc.'s proposed project addresses five of the six Product Development Research Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early-stage projects where private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

Novel therapies are urgently needed for pancreatic cancer and triple negative breast cancer, two of the most aggressive cancers with no effective cure. For pancreatic cancer, 4,420 Texans and 60,000 Americans are diagnosed each year and only 7% are expected to survive 5 years. Triple negative breast cancer is also aggressive, affecting 3,000 women in Texas and 42,000 in the US annually, with a disproportionate impact on African American and Hispanic women. Given the lack of effective therapies for these diseases, the successful development of DKK3-targeted therapy has the potential to be practice-changing for the field.

StellaNova is developing novel antibodies to block DKK3 (anti-DKK3 mAb). Anti-DKK3 mAb inhibited tumor growth in mice and produced long-term survival with no toxicity. For TNBC, treatment also reduced lung and brain metastases. Anti-DKK3 mAb is effective either alone or in combination with immunotherapy. Preclinical models validated the importance of DKK3 on the genetic and pharmacological levels, revealing that (1) DKK3 knockout inhibited PDAC tumor growth and metastasis, and increased survival in the KPC model, and (2) anti-DKK3 mAb (JM6-6-1) inhibited PDAC progression and metastasis, increased survival, and promoted an influx of CD8+ T cells into the "immunologically cold" tumor microenvironment. StellaNova will generate a high-quality producer cell line and generate cGMP qualified Master Cell Bank (MCB)

for the large-scale production of the Development Candidate Humanized anti-DKK3 antibody which can be used for IND enabling GLP toxicity studies. These studies will be used for a cGMP 2000-L scale batch production that will be used in Phase 1/1B clinical trials.

Select Reviewer Comments

"The preclinical data establishing DKK3 as a possible therapeutic target in pancreatic cancer from Dr Hwang's lab are excellent. JM6-6- 1, a murine DKK3 neutralizing antibody, has been evaluated in a wide range of mouse models (granted preliminary data presented in very small tumors initially). These data seem promising."

"This is a very solid application arising from work done by top-notch, world-class cancer biology researchers at MD Anderson."

"The company appears to have excellent team with requisite skills and knowledge to move this project forward, including experienced CRO and mAb expertise. Stellanova is part of SPOROS Bioventures portfolio, who is well known to CPRIT for other parallel initiatives, and appears well organized in supporting this type of development."

Asylia Therapeutics, Inc.
Proposed Seed Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Seed Award for Product Development Research to Asylia Therapeutics, Inc. for $3,000,000.

Asylia Therapeutics, Inc. is a Houston-based, privately held development stage biopharmaceutical company which received a CPRIT award in 2020. Asylia is developing antibody therapies for cancer based on the discovery of the central role of heat shock protein-70 (HSP70) in tumor antigen presentation, immune activation and cellular stress responses.

CPRIT Product Development Research Priorities Addressed

Asylia's proposed project addresses four of the six Product Development Research Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early-stage projects where private capital is least available; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

Asylia discovered two entirely novel monoclonal antibodies with distinct mechanisms of action. ASY-77A targets the extracellular, soluble form of HSP70 released from cancer cells in complex with tumor-derived antigenic peptides (currently funded CPRIT SEED grant) and 239-87, targeting the cell surface form of HSP70, which is the focus of this proposal.

Asylia is developing an antibody drug conjugate (ADC) based on antibody 239-87, that recognizes the cell surface form of HSP70. Treatment with 239-87 resulted in prolonged eradication (cures) of several cancer types in mice transplanted with human cancer cells. Asylia plans to humanize and optimize mouse mAb, 239-87 to be able to manufacture cell line to produce the antibody, as well as to optimize a linker to connect the antibody to the drug. Asylia will also improve process development for ASY-87 to perform IND-enabling toxicology studies. The company will produce an ADC conjugate that can be tested for safety and efficacy in cancer patients who are failing current therapies in cancers, in particular those with T-cell lymphoma. Encouraging initial trial results will support the broader testing in other tumor types with high cell surface HSP70 expression such as Myeloma and Breast Cancer.

Select Reviewer Comments

"*Targeting HSP70 could have a wide range of cancer applications. Based on preclinical data that it shows highest expression in T-cell lymphoma, they wish to start there. T-cell lymphoma has a very high unmet need."*

"In summary, this is a very professionally prepared application by a highly competent management team. CsHSP-70 is a promising new cancer therapeutic target with considerable preclinical validation as well as supporting clinical outcomes correlations."

"Additional in vivo preclinical studies in combination with an HDAC inhibitor and in combination with BV are planned. Not only do these approaches provide a potential backup strategy in PTCL, but they may set the stage for a post (accelerated) approval confirmatory study, and moreover, may pave the way for integration of the agent with SOC agents for earlier lines of therapy."

Atom Mines
Proposed TXCO Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a TXCO Award for Product Development Research to Atom Mines for $2,500,000.

Atom Mines is a small Austin-based company which utilized a Magnetically Activated and Guided Isotope Separation ("MAGIS") technology developed at The University of Texas at Austin, which will enable the production of the stable isotope Ytterbium-176 (176Yb) needed to make the radio-isotope Lutetium-177 (177Lu). 177Lu is an effective beta-therapy agent approved for certain neuroendocrine cancers and soon to be approved for prostate cancer, the second leading cause of cancer death in men, with clinical trials underway for a range of cancers. 177Lu can be used to target small tumors and dispersed, inoperable metastatic cancer using precise delivery molecules. 176Yb is currently only available in small quantities from Russia and that supply is uncertain due to geopolitics and competition for limited production capacity.

CPRIT Product Development Research Priorities Addressed

Atom Mine's proposed project addresses four of the six Product Development Research Priorities:

- Funding projects addressing large or challenging unmet medical needs;
- Investing in early-stage projects where private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

Ytterbium-176 (176Yb) is the stable precursor required to make carrier-free 177Lu, and 176Yb is currently only available in very limited quantities from Russia. Russian supplies have remained limited due to competition for production capacity for other isotopes, while global demand has more than doubled. This supply is in jeopardy due to deteriorating geopolitics, corruption, and competition for limited calutron separation capacity.

A reliable, domestic source of pure 176Yb is required to produce sufficient carrier-free 177Lu to support FDA-approved drugs and ongoing cancer research, trials, and therapies in Texas and globally. Novartis has two products Pluvicta and Lutathera which utilize 177Lu. Atom Mines utilizes an isotope separation developed by Prof. Mark G. Raizen at The University of Texas at Austin. Magnetically Activated and Guided Isotope Separation ("MAGIS") uses lasers to temporarily magnetize atoms that is then followed by separation with arrays of magnets.

Atom Mines LLC has fully demonstrated 176Yb enrichment to medical-grade purity of 99.5%. MAGIS will enable domestic commercial production of 176Yb, as well as other rare isotopes for widespread medical use. Atom Mines intends to scaleup 176Yb production initially to 200 grams; validate purity of routine batches and of 177Lu produced by industry partner and irradiators. Atom plans to scale up to 500 grams within three years and ultimately to kilogram quantities, which will support tens of thousands of doses for prostate cancer therapy per year.

Select Reviewer Comments

"*Indeed, the Department of Energy openly recognizes the lack of separation capabilities in the United States and the need for new domestic capabilities. The company has demonstrated that Novartis has a need for this material to develop and test novel prostate cancer therapy and has a production site in Texas, as well as a global distribution partnership with a German company, Eckert and Ziegler, which has invested in the company."*

"Atom Mines will use the efficiency of MAGIS technology to greatly reduce the cost of separating stable isotopes and make important medical isotopes for therapeutics already approved or in the process of approval."

"There is no risk in this proposal short of not being able to meet the demand at commercial scale since several possible therapeutics may use this radiotherapeutic approach."

Rapamycin Holdings Inc.
Proposed TXCO Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a TXCO Award for Product Development Research to Rapamycin Holdings Inc. for $16,999,999.

Emtora Biosciences (formerly Rapamycin Holdings Inc.) is a San Antonio company that has developed eRapa, a novel form of the FDA-approved active ingredient rapamycin. Rapamycin has previously shown promise in treating gastrointestinal diseases and in cancer prevention, but is limited by toxicity. eRapa is targeted to the colon and is delivered at lower doses, resulting in lower toxicity. The company is developing eRapa to prevent colorectal cancer in patients with Familial Adenomatous Polyposis (FAP). In 2019, Emtora received a CPRIT Product Development (SEED) award for a Phase IIa study of eRapa in FAP, which is currently underway.

CPRIT Product Development Research Priorities Addressed

Rapamycin's proposed project addresses four of the six Product Development Research Priorities:

- Funding projects addressing large or challenging unmet medical needs;
- Investing in early-stage projects where private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

Data supports that rapamycin augments the immune system, prevents cancer in cancer-prone animal models, and prolongs health and life span. It has been demonstrated that rapamycin reduces the percentage of CD4 and CD8 T lymphocytes that express PD-1 (exhaustion marker), which inhibits T cell signaling and is more highly expressed with age and exposure to cancer. The results of Emtora's Phase I clinical trials in prostate cancer indicate that e-Rapa is safe and well-tolerated at all doses and schedules tested; more tolerable at intermittent dosing schedules; has no adverse effect on quality of life; has a consistent and predictable absorption profile (unlike rapamycin); produces measurable and favorable changes in the immune system; and no patients on eRapa experienced disease progression during the study.

Emtora proposes to manufacture drug product to support the addition of a fourth cohort in the current Phase IIa study of eRapa in FAP. The proposal would expand and complete the CPRIT-funded Phase IIa study of eRapa in Familial Adenomatous Polyposis (FAP) and prepare for and execute Randomized Placebo-Controlled Trial of eRapa in FAP.

Select Reviewer Comments

"*This new encapsulated rapamycin formulation, eRapa, is targeted specifically to the colon and is delivered at a consistent and lower dosage, not only reducing toxicities but also capitalizing on the potential of partial inhibition of the mechanistic target of rapamycin (mTOR) to act as a chemopreventive agent.*"

"*The applicant has a good standing with CPRIT through a previous Seed Award, has received ODD, has an open IND, and is currently in phase 2a clinical trials in FAP. As such, the proposal is highly de-risked."*

Xerient Pharma Inc.
Proposed Seed Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Seed Award for Product Development Research to Xerient Pharma Inc. for $2,934,737.

Xerient is a Houston-based startup dedicated to the development of an orally administered tablet that releases very efficient radioprotectant molecule in the duodenum. Xerient demonstrated that it is possible to repurpose an FDA-approved radioprotectant, and reformulate it in a tablet with a targeted-delivery and in-body-monitoring functionalities to allow very efficacious radiation therapy.

CPRIT Product Development Research Priorities Addressed

Xerient's proposed project addresses four of the six Product Development Research Priorities:

- Funding projects addressing large or challenging unmet medical needs;
- Investing in early-stage projects where private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

Pancreatic cancer cannot be cured without surgery. Nearly 90% of patients present with unresectable disease (locally advanced + metastatic), leaving patients and clinicians with very few treatment options once chemotherapy is completed. Radiation therapy cannot substitute for surgery because of morbid radiotoxicity to the nearby intestines that occurs before the tumor is controlled. Thus, treatment-related gastrointestinal (GI) radiation toxicity may be the single greatest barrier to improving treatment responses for unresectable pancreatic cancer. There are no known medications that can selectively protect the intestines from the side effects of treatment-related GI radiation toxicity.

Amifostine is a well-known therapeutic and is the only FDA-approved radioprotector, but it has significant toxicity when given intravenously (the only approved route of administration). Orally delivered amifostine is a pro-drug that is activated in the small intestine by endogenous intestinal alkaline phosphatases. If administered just prior to radiation, the active metabolite, WR-1065, is then produced locally in the gut and protects the intestinal tissue during radiation, then is rapidly degraded. Orally administered amifostine is highly efficacious and enables ablative radiation therapy to pancreatic tumors, which triples survival in a murine model. Oral amifostine coupled with ablative radiotherapy can be a curative treatment in selected patients with unresectable pancreatic cancer.

Xerient intends to develop and test an enteric-coated version of amifostine (EC-amifostine) that maximizes payload delivery in the duodenum in a timeframe relevant to radiotherapy that will be clinically efficacious with targeted delivery and monitoring functionalities. Xerient will complete GLP toxicology studies, allowing the company to proceed with a clinical Phase I safety trial in humans. Xerient will evaluate the activity and tolerability of EC-amifostine in a canine model and confirm that amifostine can protect intestinal tissue from radiation in a porcine model.

Select Reviewer Comments

"The molecule is well known and studied and FDA approved as a radioprotectant when given IV."

"Many patients with pancreatic cancer would definitely benefit from radiotherapy, but because of the toxicity to the duodenum, it is not used. The ability to deliver safe and effective doses of targeted radiotherapy would be of great potential benefit to these patients who have few therapeutic options."

"If successful, this product could have fast uptake as SOC in radiation centers with new possibility of benefit to pancreatic cancer radiotherapy."

InformAI Inc.
Proposed Seed Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Seed Award for Product Development Research to InformAI Inc. for $1,552,000.

InformAI Inc. is a Houston-based company focusing on AI solutions that speed up medical diagnosis at the point-of-case and improve radiologist productivity. With 360 degrees of radiation access and delivering a wide range of beam intensities, a nearly infinite number of avenues exist to target a malignant lesion while minimizing off-target effects. Deep learning methods are well-positioned to optimize this process, identifying radiation plans that deliver a therapeutic radiation dose to cancer while optimally minimizing unwanted radiation exposure to healthy tissue and neighboring organs.

CPRIT Product Development Research Priorities Addressed

InformAI's proposed project addresses five of the six Product Development Research Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;

- Investing in early-stage projects where private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

InformAI proposes to create RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for planning Radiation Oncology in the head and neck region. To date, a minimally viable business prototype has been created, led by work out of The University of Texas Southwestern Medical Center's Medical Artificial Intelligence and Automation Laboratory in collaboration with the Department of Radiation Oncology.

Preliminary testing and validation efforts of the model are promising. InformAI has entered into a Sponsored Research Agreement with UT Southwestern to lead the product scaling, validating, technological hardening, regulatory approval, and commercialization efforts necessary to transform this prototype technology into a finished business offering.

Deep learning methods are well-positioned to optimize the creation of radiation plans that deliver a therapeutic radiation dose to cancer while optimally minimizing unwanted radiation exposure to healthy tissue and neighboring organs. A deep learning radiation planning tool could solve current pain points in the radiation oncology workflow, improving the safety, efficiency, quality, and usability of multiple product modalities. According to the company, no products available on the market leverage deep learning methods to create the 'first pass' radiation treatment plan.

InformAI intends to expand its dataset including acquiring access to additional 400 head and neck segmented and annotated head and neck de-identified patient scans. Inform AI will validate its label claims through clinical research with the purpose of preparing for the FDA regulatory approval process. InformAI will also ensure that its product is widely, if not universally, integrable with all TPS used in the routine practice of radiation oncology.

Select Reviewer Comments

"There is a clear unmet need in radiation oncology addressed in this proposal with the use of AI to help create more efficient and automated dose plans and associated organ segmentation. There is a clear value proposition to patients and oncologist in improving the efficiency and the accuracy of the dose plans for the clinicians."

"This approach has the potential to make radiation planning faster and more accurate than current standards of care. This is rendered possible by recent and current informatics advances, and it is likely that AI will affect the medical practice also in areas other than radiation therapy, thus the submission is well positioned in the future stream of innovative approaches."

PanTher Therapeutics, Inc
Proposed RELCO Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a RELCO Award for Product Development Research to PanTher Therapeutics, Inc. for $14,268,315.

PanTher Therapeutics is a clinical stage oncology company working on treatments for solid tumors. The company is currently based in Cambridge, Massachusetts, and will relocate to Texas if it receives a CPRIT award.

PanTher's novel approach looks to significantly increase drug accumulation at the tumor site, while dramatically reducing systemic side effects to improve antitumor activity, preserve quality of life and lower overall healthcare costs. PanTher's PTM-101 product is a laparoscopically delivered, fully degradable film. This product has the potential to improve tumor response and reduce pancreatic tumors to allow for curative resection.

CPRIT Product Development Research Priorities Addressed

PanTher's proposed project addresses five of the six Product Development Research Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e. disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early-stage projects where private capital is least available;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations; and
- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

PanTher's first product, PTM-101, is a drug eluting delivery implant intended to provide paclitaxel directly onto the tumor. PTM-101 is composed of paclitaxel and a bioresorbable polymer poly (lacticco-glycolic acid) (PLGA). The PTM-101 implant is minimally invasively inserted via a trocar during diagnostic laparoscopy and surgically placed directly onto the peritumoral area. PanTher's platform has demonstrated pre-clinical validation – enabling chemotherapy to penetrate 40 times deeper and reach 5-fold higher concentration inside the tumor mass when compared to systemic delivery.

The PLGA ingredients biodegrade over time, resulting in the sustained release of paclitaxel directly towards the tumor, thereby providing localized treatment. The PLGA polymer biodegrades into lactic and glycolic acids, which are metabolized naturally. For controlled and sustained release of paclitaxel, PTM-101 will be comprised of two different layers of PLGA. The non-tumor facing side of PTM-101 consists of 75:25 PLGA and the tumor facing side of PTM-101 contains paclitaxel incorporated into 50:50 PLGA polymer. The PLGA 50:50 will fully degrade in approximately 1 month (35 days), resulting in Paclitaxel release directly onto the tumor mass.

PanTher's proposal is for the initiation and completion of a Phase Ib/II trial in the US and Australia to build upon the current first-in-man trial to assess efficacy. Over the course of discussions with the FDA, PTM-101 has been deemed a combination product with drug primary mode of action and cleared to use the 505(b)(2) accelerated path to the clinic with a well-defined understanding of the IND package requirements.

PanTher has addressed and completed the majority of testing to be included in the IND submission as part of the ethics approval to start the phase 1 in Australia. The first-year development plan will focus on expansion of the already validated CMC and GMP manufacturing processes for the dose-escalated PTM-101, as well as completing GLP tox studies. Upon IND clearance from the FDA, PanTher will focus on the enrollment and completion of the Phase Ib/2 trial in the US and Australia, in partnership with MD Anderson and other clinical sites.

Select Reviewer Comments

"*The approach significantly increases drug accumulation at the site, while dramatically reducing systemic side effects to improve antitumor activity and preserve quality of life, provide pretreatment before surgery or improvement for tumors that are nonresectable."*

"The application has a number of strengths including the following: (1) prior phase 1 results, (2) sound management and development teams, (3) significant financial backing, (4) straightforward CMC development pathway due to the experience with paclitaxel and PLGA, and (5) lack of competition of locally administered therapies in pancreatic cancer."

Nucore Medical
Proposed Seed Award for Product Development Research

Summary of Recommendation

The PDRC recommends that the PIC and Oversight Committee approve a Seed Award for Product Development Research to Nucore Medical for $2,999,999.

Nucore Inc. is a Houston-based medical device company resulting from a multi-year collaboration between J&J's Center for Medical Device Innovation @ The Texas Medical Center and California-based Precision Thoracic to innovate novel technologies focused on the early interception, diagnosis, and treatment of lung cancer.

CPRIT Product Development Research Priorities Addressed

Nucore's proposed project addresses three of the six Product Development Research Priorities:

- Funding projects addressing large or challenging unmet medical needs;
- Investing in early-stage projects where private capital is least available; and

- Providing appropriate return on taxpayer investment.

Project Summary and Scientific Rationale

Early interception of suspicious lung nodules, by nature, means dealing with small, amorphic, and heterogeneous nodules that are extremely challenging to diagnose with current needle biopsy techniques. Surgical wedge resection (i.e. open or VATS) is an option, but these complex procedures unnecessarily sacrifice large quantities of functional lung tissue and can often expose fragile patients to unjustified surgical risks. Clinicians need a tool that can provide a minimally invasive, tissue sparing, targeted resection of suspicious small and intermediate-sized lung nodules, facilitating definitive diagnosis.

Nucore has developed Minimally-invasive Targeted Resection (MiTR-core™), the first medical device designed to safely remove lung nodules in a simple, quick, and minimally invasive procedure. The MiTR-core procedure will enable clinicians to remove suspicious nodules upon initial detection, will provide a definitive diagnosis of the nodule, spare healthy lung tissue, and in the event of cancer, provide direct access to the site of the nodule for further targeted therapy.

MiTR-core™ is a tissue-sparing transthoracic nodulectomy tool for CT-guided targeting of a suspicious nodule followed by minimally invasive access, coring, resection, and RF-based sealing of the lung to prevent blood and air leaks. The amount of diagnostically viable tissue extracted using MiTR-core is more than 2,000 times greater than the tissue extracted using existing needle techniques. In addition to facilitating greater specificity and sensitivity, the specimen size will allow for rapid characterization of the cancer and, potentially, real-time sequencing.

The Nucore team has advanced MiTR-core from a concept to functional prototypes and rigorously tested it on the bench and in a series of nine acute porcine studies. MiTR-core has successfully demonstrated proof-of-concept in 2 chronic porcine studies. The company will strengthen its clinical and commercial case for MiTR-core through clinical data analytics (e.g. clinical outcome and cost databases, retrospective chart review, prospective multi-center registry trial), prepare for a First-in-Human study through regulatory submission, and manufacture clinical build devices and advance the device through a First-in-Human study.

Select Reviewer Comments

"*With financial support of $4.5 million from JNJ's Center for Medical Device Innovation, Nucore Inc, a Houston-based company, has developed a biopsy device that is much less invasive than wedge resection, essentially eliminates the false-negative/indeterminate issue associated with fine-needle biopsy, and by virtue of a tissue sealing feature, does so with minimal to no complications of hemothorax and pneumothorax, in effect, addressing the follow-up definitive diagnostic barriers to LDCT lung cancer screening uptake noted above."*

"This device could be really useful in terms of yielding actionable results in a far less invasive procedure than currently available."

July 27, 2022

Dr. Mahendra Patel
CPRIT Oversight Committee Chair
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
CPRIT Program Integration Committee Chair
Via email to wroberts@cprit.texas.gov

Dr. Patel and Mr. Roberts,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 22.2 grant award cycle. The PDRC convened on July 19, 2022, and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Atom Mines, InformAI Inc., Xerient Pharma Inc., PLUS Therapeutics, Inc., Stellanova Therapeutics, Asylia Therapeutics, Rapamycin Holdings Inc., NUCORE Medical and PanTher Therapeutics. The attached table reflects the ranked award recommendation for the nine (9) grant applications.

The PDRC did not make any changes to timelines or budgets for the nine (9) projects recommended for funding. However, two (2) recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP220053 and DP220054 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP220066 related to clinical data, timelines and development plans. Dr. Smith will address the proposed contingencies with the PIC and the Oversight Committee.

I also note that at its July 19, 2022, 22.2 Due Diligence Meeting, the PDRC took "No Action" on one (1) application for CPRIT FY 2022 award budget reasons and to receive additional information. We anticipate that the PDRC will make an award recommendation, if any, regarding this pending application for your consideration as early as the September 2022 Oversight Committee meeting.

Each of the companies included in the PDRC's recommendation reflets 50+ hours of individual review panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,

Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

FY22.2 Product Development Review Council Recommendations

Ranking	ID	Mechanism	Type	PI Last Name	Organization	Application Title	Score from Peer Review
1	DP220039	TXCO Therapeutics	Resubmission	Sims, A.	PLUS Therapeutics, Inc.	Single-Dose 186RNL for Leptomeningeal Metastases: Multicenter Phase 1/2a Study to Determine MTD/MFD, Safety and Efficacy, Leading to Pivotal Registrational Trial	2.2
2	DP220028	SEED Therapeutics	Resubmission	Schuler, E.	Stellanova Therapeutics, Inc.	Development of DKK3-Targeted Therapeutic Antibodies for Cancer	2.3
3	DP220038	SEED Therapeutics	New	Miller, J.	Asylia Therapeutics	Humanization, Validation, and Clinical Translation of Cell Surface Heat Shock Protein 70-Targeted Antibody-Drug Conjugates for T-Cell Non-Hodgkin Lymphomas	2.3
4	DP220055	TXCO MD&D	New	Dorius, K.	Atom Mines	Commercial-Scale Enrichment of Stable Ytterbium-176 for Production of No-Carrier-Added Lutetium-177 for Use in Prostate Cancer Therapy	2.0
5	DP220053	TXCO Therapeutics	New	Kingman, S.	Rapamycin Holdings Inc.	Development of eRapa for the Treatment of Familial Adenomatous Polyposis, a Rare Genetic Disease Associated With a High Risk of Colorectal Cancer	2.7
6	DP220043	SEED Therapeutics	New	Taniguchi, C.	Xerient Pharma Inc.	Oral Amifostine as an Upper GI Tract Radioprotectant for Effective Radiotherapy Treatment of Pancreatic Cancer	2.2
7	DP220063	SEED MD&D	New	Havelka, J.	InformAI Inc.	RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology	2.2
8	DP220066	RELCO Therapeutics	New	Indolfi, L.	PanTher Therapeutics, Inc	Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer	3.6
9	DP220054	SEED MD&D	New	Nathan, J.	NUCORE MEDICAL	Clinical Validation of the MiTR Core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention	3.4

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

August 11, 2022

Oversight Committee Members,

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of grant contracts for the nine companies that the Oversight Committee will consider for product development grant awards at its August 17, 2022, meeting. The Program Integration Committee has recommended these companies for grant awards.

Although CPRIT disburses most grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.02(a). Typically, the grant amount to be paid in advance is based upon the project year budget or tranche amount. All grant recipients, including those that receive advance payment of grant funds, are required to submit quarterly financial status reports that are reviewed and approved by CPRIT's financial staff. The product development grant recipients must also certify that they have matching funds available to invest in the project prior to any disbursement of funds. Failure to submit the financial status reports on a timely basis or to certify matching funds will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

Advance payment of grant funds is necessary because the projects proposed for grant awards involve preclinical work and/or clinical trials. The cost structure for this type of work is highly front loaded and service providers require substantial upfront payments. Advancing grant funds allows these projects to begin work as quickly as possible.

Sincerely,

Wayne Roberts
CPRIT Chief Executive Officer

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

August 8, 2022

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 21 grant applications totaling $89,312,491. The PIC recommendations for three academic research, nine prevention, and nine product development research grant awards are attached.

Dr. Michelle Le Beau, CPRIT's Chief Scientific Officer, Ramona Magid, CPRIT's Chief Prevention Officer, and Dr. Ken Smith, CPRIT's Chief Product Development Officer, have prepared overviews of the academic research, prevention, and product development research slates to assist your evaluation of the recommended awards. The overviews are intended to provide a comprehensive summary with enough detail to understand the substance of the proposal and the reasons endorsing grant funding. In addition to the full overviews, all the information considered by each Review Council is available by clicking on the appropriate link in the portal. This information includes the application, peer reviewer critiques, and the CEO affidavit for each proposal.

The approval of these grant recommendations is governed by a statutory process that requires two-thirds of the members present and voting to approve each recommendation. Vince Burgess, CPRIT's Chief Compliance Officer, will certify that the review process for the recommended grants followed CPRIT's award process prior to any Oversight Committee action.

The award recommendations will not be considered final until the Oversight Committee meeting on August 17, 2022. Consistent with the non-disclosure agreement that all Oversight Committee members have signed, the recommendations should be kept confidential and not be disclosed to anyone until the award list is publicly announced at the Oversight Committee meeting. I request that Oversight Committee members not print, email, or save to your computer's hard drive any material on the portal. I appreciate your assistance in taking all necessary precautions to protect this information.

If you have any questions or would like more information on the review process or any of the projects recommended for an award, CPRIT's staff, including myself and Dr. Le Beau, Ms. Magid, and Dr. Smith are always available. Please feel free to contact us directly should you have any questions. The programs that will be supported by the CPRIT awards are an important step in our efforts to mitigate the effects of cancer in Texas.

Thank you for being part of this endeavor.

Sincerely,
Wayne R. Roberts,
Chief Executive Officer

ACADEMIC RESEARCH GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of three academic research grant proposals totaling $10,000,000. The recommended grant proposals were submitted in response to the following grant mechanisms: *Recruitment of Established Investigators;* and *Recruitment of First-Time, Tenure-Track Faculty Members.* The Scientific Review Council (SRC) provided the prioritized list of recommendations for the awards to the presiding officers on July 20, and August 2, 2022. The PIC approved the award recommendations as presented by the SRC including a previously deferred application, RR220067.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these academic research proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional;
- Address federal or other major research sponsors' priorities in emerging scientific or institutions of higher education;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;
- have a demonstrable economic development benefit to this state;
- enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources; and
- address the goals of the Texas Cancer Plan.

Academic Research Recruitment Grant Award Recommendations						
Rank	**Application ID**	**Mechanism**	**Candidate**	**Organization**	**Budget**	**Final Overall Score**
1	RR220094	RFTFM	Steven Boeynaems, Ph.D.	Baylor College of Medicine	$2,000,000	1.0
2	RR220101	RFTFM	Siqi Liu, Ph.D.	The University of Texas Southwestern Medical Center	$2,000,000	1.0

Academic Research Recruitment Grant Award Recommendations						
Rank	**Application ID**	**Mechanism**	**Candidate**	**Organization**	**Budget**	**Final Overall Score**
3	RR220067	REI	Zhiguo Zhang	The University of Texas M.D. Anderson Cancer Center	$6,000,000	2.0

REI: Recruitment of Established Investigators
RFTFM: Recruitment of First-Time, Tenure-Track Faculty Members

PREVENTION GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of nine prevention grant proposals totaling $14,443,836. The recommended grant proposals were submitted in response to the *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* and *Evidence-Based Cancer Prevention Services* grant mechanisms. The Prevention Review Council (PRC) provided the prioritized list of recommendations for the awards to the presiding officers on June 13, 2022. The recommendation includes an application from cycle 22.1 on which the PRC previously took no action.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these prevention proposals met the following CPRIT funding priorities:

- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state
- have a demonstrable economic development benefit to this state; and
- address the goals of the Texas Cancer Plan.

Prevention Grant Award Recommendations							
Rank	**Application ID**	**Mechanism**	**Application Title**	**PD**	**PD Organization**	**Budget**	**Final Overall Score**
1	PP220036	EBP	Increasing the use of HPV vaccination services among medically underserved young adults	Roncancio, Angelica M	University of Houston	$991,308	1.6

Prevention Grant Award Recommendations							
Rank	**Application ID**	**Mechanism**	**Application Title**	**PD**	**PD Organization**	**Budget**	**Final Overall Score**
2	PP220034	EPS	Screening to Optimize Prevention of CRC in East Texas (STOP CRC ET)	McGaha, Paul	The University of Texas Health Center at Tyler	$2,482,127	1.8
3	PP220038	EPS	Advancing Implementation of Evidence-Based Strategies for Tobacco Prevention and HPV Vaccination in Pediatric Safety Net Settings	Montealegre, Jane R	Baylor College of Medicine	$2,499,180	2.3
4	PP220045	EBP	Inpatient Screening and Treatment for Unhealthy Alcohol Use and Tobacco Use as a means of cancer prevention	Ramesh, Jananie	The University of Texas at Austin	$999,957	2.6
5	PP220037	EPS	Project ACCESS: Increasing Access to Cervical Cancer Screening & Treatment Services in Texas	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	$2,498,445	2.9
6	PP220024	EBP	Promoting Prevention in Survivorship Care in Rural Texas	Kvale, Elizabeth	The University of Texas at Austin	$975,851	3.3
7	PP220041	EBP	Fecal Immunochemical Testing for Screening and Treatment of Occult Neoplasia (FIT-STOP)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	$999,999	4.0

Prevention Grant Award Recommendations							
Rank	**Application ID**	**Mechanism**	**Application Title**	**PD**	**PD Organization**	**Budget**	**Final Overall Score**
8	PP220051	EPS	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations-Program title: GetFIT	Mika, Virginia	University Health System	$1,999,849	4.5
9	PP220035	EBP	DEFEAT breast cancer: Delivering Education, Focused navigation, and Equitable Access throughout East Texas.	McGaha, Paul	The University of Texas Health Center at Tyler	$997,120	5.0

EBP: Evidence-Based Cancer Prevention Services
EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

PRODUCT DEVELOPMENT RESEARCH GRANT AWARD RECOMMENDATIONS

The PIC unanimously recommends approval of nine product development research grant proposals totaling $64,868,655. The recommended grant proposals were submitted in response to the *Company Relocation Product Development Awards*, *Seed Awards for Product Development Research*, and *Texas Company Product Development Awards* grant mechanisms. The Product Development Review Council (PDRC) provided the prioritized list of recommendations for the awards to the presiding officers on July 28, 2022.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these product development research proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- Are interdisciplinary or interinstitutional;
- Address federal or other major research sponsors' priorities in emerging scientific or Technology fields in the area of Cancer Prevention, or cures for cancer

- Are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- Are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state
- have a demonstrable economic development benefit to this state;
- expedite innovations and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or Technology research capabilities; and
- address the goals of the Texas Cancer Plan.

Product Development Research Grant Award Recommendations							
Rank	**Application ID**	**Mechanism**	**Applicant Company**	**PI**	**Project Title**	**Budget**	**Final Overall Score**
1	DP220039	TXCO	PLUS Therapeutics, Inc.	Sims, Andrew	Single Dose 186RNL for Leptomeningeal Metastases: Multicenter Phase 1/2a Study to Determine MTD/MFD, Safety & Efficacy, Leading to Pivotal Registrational Trial	$17,613,605	2.2
2	DP220028	SEED	Stellanova Therapeutics, Inc.	Schuler, Emmanuelle	Development of DKK3-Targeted Therapeutic Antibodies for Cancer	$3,000,000	2.3
3	DP220038	SEED	Asylia Therapeutics	Miller, John	Humanization, validation, and clinical translation of cell surface Heat shock protein 70-targeted antibody drug conjugates for T-cell non-Hodgkin lymphomas	$3,000,000	2.3

Product Development Research Grant Award Recommendations							
Rank	**Application ID**	**Mechanism**	**Applicant Company**	**PI**	**Project Title**	**Budget**	**Final Overall Score**
4	DP220055	TXCO	Atom Mines	Dorius, Kirk	Commercial-Scale Enrichment of Stable Ytterbium-176 for Production of No-carrier-added Lutetium-177 for Use in Prostate Cancer Therapy	$2,500,000	2.0
5	DP220053	TXCO	Rapamycin Holdings, Inc.	Kingman, Shannon	Development of eRapa for the treatment of Familial Adenomatous Polyposis, a rare genetic disease associated with a high risk of colorectal cancer	$16,999,999	2.7
6	DP220043	SEED	Xerient Pharm, Inc.	Taniguchi, Cullen	Oral Amifostine as an upper GI Tract Radioprotectant for Effective Radiotherapy Treatment of Pancreatic Cancer	$2,934,737	2.2
7	DP220063	SEED	InformAI, Inc.	Havelka, Jim	RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology	$1,552,000	2.2
8	DP220066	RELCO	PanTher Therapeutics, Inc.	Indolfi, Laura	Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer	$14,268,315	3.6

Product Development Research Grant Award Recommendations							
Rank	**Application ID**	**Mechanism**	**Applicant Company**	**PI**	**Project Title**	**Budget**	**Final Overall Score**
9	DP220054	SEED	NUCORE MEDICAL	Nathan, Joanna	Clinical Validation of the MiTR-core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention	$2,999,999	3.4

RELCO: Company Relocation Product Development Awards
SEED: Seed Awards for Product Development Research
TXCO: Texas Company Product Development Awards

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE CERTIFICATION – AUGUST 2022 AWARDS
DATE:	AUGUST 8, 2022

Summary and Recommendation:

As CPRIT's Chief Compliance Officer, I am responsible for reporting to the Oversight Committee regarding the agency's compliance with applicable statutory and administrative rule requirements during the grant review process. I have reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the following mechanisms:

- Recruitment of Established Investigators
- Recruitment of First-Time, Tenure-Track Faculty Members
- Texas Company Product Development Awards
- Company Relocation Product Development Awards
- Seed Awards for Product Development Research
- Evidence-Based Cancer Prevention Services
- Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

The following mechanism also received applications during this award cycle; however, did not result in recommendations to the Oversight Committee for its August 17, 2022, meeting: Tobacco Control and Lung Cancer Screening. I have conferred with staff at CPRIT and General Dynamics Information Technology (GDIT), CPRIT's contracted third-party grants administrator, regarding the academic research, product development research, and prevention awards and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the above mechanisms recommended by the Program Integration Committee (PIC) followed applicable laws and agency administrative rules. I certify the academic research, product development research, and prevention award recommendations for the Oversight Committee's consideration.

At its August 3, 2022, meeting, the PIC voted to recommend an application from Recruitment cycle 22.8 that the PIC previously deferred at its March 4, 2021, meeting. I certified the Recruitment of Established

Investigators mechanism for the May 18, 2022, Oversight Committee meeting; therefore, I will not repeat the certification here but instead will make available copies of those previous certifications.

Background:

CPRIT's Chief Compliance Officer must report to the Oversight Committee regarding compliance with the statute and the agency's administrative rules. Among the Chief Compliance Officer's responsibilities is the obligation "to ensure that all grant proposals comply with this chapter and rules adopted under this chapter before the proposals are submitted to the oversight committee for approval." Texas Health & Safety Code § 102.051(c) and (d).

CPRIT uses a compliance pedigree process to formally document compliance for the grant award process. The compliance pedigree tracks the grant application as it moves through the review process and documents compliance with applicable laws and administrative rules. A compliance pedigree is created for each application; the information related to the procedural steps listed on the pedigree is entered and attested to by GDIT employees and CPRIT employees. CPRIT relies on GDIT to accurately record a majority of the information on the pedigree from the pre-receipt stage to final Review Council recommendation. To the greatest extent possible, information reported in the compliance pedigree is imported directly from data contained in CPRIT's Application Receipt System (CARS), the grant application database managed by GDIT. This is done to minimize the opportunity for error caused by manual data entry.

No Prohibited Donations:

Although CPRIT is statutorily authorized to accept gifts and grants pursuant to Texas Health & Safety Code § 102.054, the statute prohibits CPRIT from awarding a grant to an applicant who has made a gift or grant to CPRIT, or a nonprofit organization established to provide support to CPRIT. I note that Texas Health & Safety Code § 102.251(a)(3) specifically addresses "donors from any nonprofit organization established to provide support to the institute compiled from information made available under § 102.262(c)." To the best of my knowledge, there are no nonprofit organizations that have been established to provide support to CPRIT on or after June 14, 2013, the effective date of this statutory change. The only nonprofit organization established to provide support to the Institute was the CPRIT Foundation; however, the CPRIT Foundation ceased operations and changed its name and its purpose prior to June 14, 2013. The institute has received no donations from the CPRIT Foundation made on or after June 14, 2013**.**

I have reviewed the list of donors to CPRIT maintained by CPRIT (and listed on CPRIT's website) and compared the donors to the list of applicants. No donors to CPRIT have submitted applications for grant awards during the award cycles that are the subject of this report.

Pre-Receipt Compliance:

The activities listed on a compliance pedigree in the pre-receipt stage cover the period beginning with CPRIT's approval and issuance of the Request for Applications (RFA) through the submission of grant applications. The RFA specifies a deadline and mandates that only those applications submitted electronically through CPRIT's Application Receipt System (CARS) are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally, an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may appeal to CPRIT (through the CPRIT Helpdesk that is managed by GDIT) to allow for a submission after the deadline. The program officer considers any requests for extension and may approve an extension for good cause. When a late filing request is approved, the applicant is notified, and CARS is reopened for a brief period – usually two to three hours – the next business day.

Academic Research:

All Academic Research RFAs were uploaded to the Texas.gov eGrants website. For Recruitment Cycle 22.10, two applications were received for the Recruitment of Established Investigators RFA and 10 applications were received in response to the Recruitment of First-Time, Tenure Track Faculty members RFA.

All applications were submitted through CARS.

Product Development Research:

All Product Development Research RFAs were uploaded to the Texas.gov eGrants Website. For Cycle 22.2, 10 applications were received for the Texas Company Product Development Awards RFA, eight applications were received for the Company Relocation Product Development Research Awards RFA, and 16 applications were received for the Seed Awards for Product Development Research RFA.

All applications were submitted through CARS. One applicant requested an extension to submit an application after the deadline. The program officer determined that there was good cause for the request and the deadline was extended.

Prevention:

For Prevention Cycle 22.2, CPRIT uploaded the RFAs on the Texas.gov eGrants website. For Cycle 22.2, nine applications were received for the Evidence-Based Cancer Prevention Services RFA; three applications were received for the Tobacco Control and Lung Cancer Screening RFA; four applications were received for the Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations RFA.

All applications were submitted through CARS.

Receipt, Referral, and Assignment Compliance:

Once applications have been submitted through CARS, GDIT staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, GDIT notifies the program officer, and the program officer makes the final decision whether to administratively withdraw the application. Recruitment grant applications are assigned to the Scientific Review Council members for peer review. All other academic research, product development research, and prevention applications are assigned by the peer review panel chair to their respective peer review panels. Prior to distribution of the applications, reviewers are given summary information about the applicant, including the Project Director and collaborators. Reviewers must sign a conflict of interest agreement and confirm that they do not have a conflict of interest with the application before they are provided with the full application.

The pedigrees attest that a conflict of interest statement was signed by each primary reviewer for each Grant Application.

Academic Research:

One recruitment was voluntarily withdrawn by the applicant after the SRC, but before the Program Integration Committee (PIC) meeting.

Product Development Research:

No applications were withdrawn during this cycle.

Prevention:

One application was administratively withdrawn prior to peer review.

Peer Review:

Primary reviewers (typically three) must submit written critiques for each of their assigned applications prior to the peer review meeting. Sign out sheets are used to document when a reviewer with a conflict of interest associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application.

Following the peer review meeting, each participating peer reviewer must sign a post-review peer review statement certifying that the reviewer knew of and understood CPRIT's conflict of interest policy and followed the policy for this review process. After the peer review meetings, a final score report from the review committee is delivered to the Review Council for additional review.

Academic Research:

For the Recruitment Awards, the applications are reviewed by the Scientific Review Council (SRC), which assigns two members of the SRC to be primary reviewers. I reviewed the supporting documentation, such as the sign-out sheets, third-party observer reports, and post-review peer reviewer statements. Sign out sheets are used to document when a reviewer with a conflict of interest associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application. No conflicts of interest were declared by the SRC for Recruitment Cycle 22.10.

I reviewed and confirmed that the post review conflict of interest statements were signed by the six SRC members and two ad hoc reviewers that attended the 22.10 Recruitment Review Panel meeting on May 12, 2022, and the six SRC members that attended the Scientific Review Council meeting on July 14, 2022.

<u>Product Development Research</u>:

Product Development Research awards go through a peer review teleconference screening call to determine which applications will be invited to in-person (or video teleconference) review. Those applicants that attend in-person review are once again evaluated by peer reviewers. Applicants recommended after in-person review must then go through business operations and management due diligence review and intellectual property review. ICON, a third party contractor for CPRIT, conducts the business and operations due review while intellectual property review is conducted by CPRIT's Chief Due Diligence and Patent Officer, or outside counsel. However, CPRIT's Chief Strategic Initiatives and Intellectual Property Officer, Tracey Davies, performed the intellectual property due diligence review for DP220053. Dr. Ken Smith was unable to conduct due diligence review because he is CPRIT's Chief Product Development Officer and a voting member of the PIC. Ms. Davies previously performed due diligence for CPRIT as outside counsel and reported no conflict of interest with this application. She does not vote or otherwise take any role in recommending awards to the Oversight Committee. Outside counsel performed IP due diligence review for the remaining product development applications.

The Product Development Review Council (PDRC) recommends awards after due diligence to the PIC. I have verified from GDIT documentation and the third-party observer reports that those reviewers with conflicts did not participate in review of applications for which they indicated a conflict of interest. All declared COIs left the room or disengaged from the conference call and did not participate in the discussion of relevant applications.

I also reviewed and confirmed that the post review conflict of interest statements were signed by peer review members for each panel as well as the nine PDRC members that attended the Due Diligence meeting on July 19, 2022.

<u>Prevention</u>:

Prevention applications are reviewed by peer review panels and then sent to the Prevention Review Council (PRC).

I reviewed the supporting documentation, such as the sign-out sheets, third-party observer reports, and post-review peer reviewer statements. As documented by GDIT and verified by third-party observer reports, reviewers with conflicts of interest did not participate in review of those applications. All declared COIs left the room or disengaged from the conference call and did not participate in the discussion of relevant applications.

I reviewed and confirmed that the post review conflict of interest statements were signed by 11 peer review members for Prevention Panel 1 on April 25, 2022 and the three PRC members that attended the PRC Programmatic Review meeting on June 3, 2022.

Programmatic Review:

Programmatic review is conducted by the Scientific Review Council, Prevention Review Council, and Product Development Review Council for their respective awards. Each review council creates a final list of grant applications it will recommend to the PIC for grant award slates.

To the extent that any Review Council member identified a conflict of interest, I reviewed documentation confirming that the review council member did not participate in the discussion or vote on the application(s).

I also reviewed the third-party observer reports for each Review Council meeting. The third-party observer reports document that the Review Council discussions were limited to the merits of the applications and established evaluation criteria and that conflicted reviewers, if applicable, exited the room or the conference call when the application was discussed.

For the Academic Research, Product Development Research and Prevention awards, I reviewed and confirmed that the Review Council recommendations corresponded to RFAs that had been released. I also confirmed that the pedigrees reflect the date of the Review Council meeting and that the applications were recommended by the Review Council.

<u>Academic Research</u>:

The SRC met on May 12, 2022, July 14, 2022, and August 1, 2022, to review the applications submitted for Cycle 22.10 under the Recruitment of Established Investigator, and Recruitment of First-Time, Tenure Track Faculty Members RFAs.

The SRC Chairman provided recommendation letters to the PIC and Oversight Committee Chairmen on July 20 and August 2, 2022. The July 20 letter recommended RR220094, and the August 2 letter included an additional application, RR220101, for the PIC to consider. Prior to the August 2 letter, the SRC favorably reviewed but took no action on RR220101 because of insufficient agency funds.

However, on August 1 additional funds became available enabling the SRC to recommend RR220101 to the PIC and Oversight Committee. The SRC did not make a final decision on four applications submitted during this review cycle.

Product Development Research:

For Cycle 22.2, eleven applications went through due diligence. The Product Development Review Council (PDRC) met on July 19, 2022, and after review and discussion recommended nine applications to the PIC for consideration.

The PDRC's final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

Prevention:

The Prevention Review Council (PRC) met on June 3, 2022, to consider nine applications recommended by the peer review panel following their meeting held on April 25, 2022. After review and discussion of these applications, the PRC recommended all nine applications to the Program Integration Committee (PIC) for consideration. One of the recommended applications was submitted during cycle 22.1 and reviewed earlier in the fiscal year, but the PRC took no action on the application at that time before recommending it to the PIC on June 13, 2022.

I note that on September 10, 2021, Mr. Roberts granted the Chief Prevention Officer, Ramona Magid, a waiver from the general prohibition against communicating with grant applicants, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet for each of the prevention mechanisms recommended by the PIC.

Program Integration Committee (PIC) Review:

Texas Health & Safety Code § 102.051(d) requires the Chief Compliance Officer to attend and observe the PIC meetings to ensure compliance with CPRIT's statute and administrative rules. CPRIT's statute requires that, at the time the PIC's final Grant Award recommendations are formally submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the PIC containing relevant information related to the Grant Application recommendations.

I attended the August 3, 2022, PIC meeting as an observer and confirm that the PIC review process complied with CPRIT's statute and administrative rules. All five PIC members were present for the meeting; however, Dr. Michelle Le Beau dropped off the video conference call early and did not vote

on the Product Development Research and Prevention award slates. No PIC member reported a conflict of interest with any of the grant application recommendations.

The PIC considered 21 applications that were recommended by the three review councils, including one application that the PIC deferred at its May 4, 2022, meeting. The PIC voted to recommend all 21 applications to move forward to the Oversight Committee.

A review of the CEO affidavits confirms that such affidavits were executed and provided for each grant application recommendation.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: VINCE BURGESS, CHIEF COMPLIANCE OFFICER

SUBJECT: COMPLIANCE CERTIFICATION – MAY 2022 AWARDS

DATE: MAY 5, 2022

Summary and Recommendation:

As CPRIT's Chief Compliance Officer, I am responsible for reporting to the Oversight Committee regarding the agency's compliance with applicable statutory and administrative rule requirements during the grant review process. I have reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the:

- Recruitment of Established Investigators
- Recruitment of Rising Stars
- Recruitment of First-Time, Tenure-Track Faculty Members

I have conferred with staff at CPRIT and General Dynamics Information Technology (GDIT), CPRIT's contracted third-party grants administrator, regarding the academic research awards and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the above mechanisms recommended by the Program Integration Committee (PIC) followed applicable laws and agency administrative rules. I certify the academic research award recommendations for the Oversight Committee's consideration.

Background:

CPRIT's Chief Compliance Officer must report to the Oversight Committee regarding compliance with the statute and the agency's administrative rules. Among the Chief Compliance Officer's responsibilities is the obligation "to ensure that all grant proposals comply with this chapter and rules adopted under this chapter before the proposals are submitted to the oversight committee for approval." Texas Health & Safety Code § 102.051(c) and (d).

CPRIT uses a compliance pedigree process to formally document compliance for the grant award process. The compliance pedigree tracks the grant application as it moves through the review process and documents compliance with applicable laws and administrative rules. A compliance pedigree is

created for each application; the information related to the procedural steps listed on the pedigree is entered and attested to by GDIT employees and CPRIT employees. CPRIT relies on GDIT to accurately record a majority of the information on the pedigree from the pre-receipt stage to final Review Council recommendation. To the greatest extent possible, information reported in the compliance pedigree is imported directly from data contained in CPRIT's Application Receipt System (CARS), the grant application database managed by GDIT. This is done to minimize the opportunity for error caused by manual data entry.

No Prohibited Donations:

Although CPRIT is statutorily authorized to accept gifts and grants pursuant to Texas Health & Safety Code § 102.054, the statute prohibits CPRIT from awarding a grant to an applicant who has made a gift or grant to CPRIT or a nonprofit organization established to provide support to CPRIT. I note that Texas Health & Safety Code § 102.251(a)(3) specifically addresses "donors from any nonprofit organization established to provide support to the institute compiled from information made available under § 102.262(c)." To the best of my knowledge, there are no nonprofit organizations that have been established to provide support to CPRIT on or after June 14, 2013, the effective date of this statutory change. The only nonprofit organization established to provide support to the Institute was the CPRIT Foundation; however, the CPRIT Foundation ceased operations and changed its name and its purpose prior to June 14, 2013. The institute has received no donations from the CPRIT Foundation made on or after June 14, 2013**.**

I have reviewed the list of donors to CPRIT maintained by CPRIT (and listed on CPRIT's website) and compared the donors to the list of applicants. No donors to CPRIT have submitted applications for grant awards during the award cycles that are the subject of this report.

Pre-Receipt Compliance:

The activities listed on a compliance pedigree in the pre-receipt stage cover the period beginning with CPRIT's approval and issuance of the Request for Applications (RFA) through the submission of grant applications. For the period covering these RFAs, CPRIT published the RFAs on the Texas.gov eGrants website. The RFA specifies a deadline and mandates that only those applications submitted electronically through CPRIT's Application Receipt System (CARS) are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally, an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may appeal to CPRIT (through the CPRIT Helpdesk that is managed by GDIT) to allow for a submission after the deadline. The program officer considers any requests for extension and may approve an extension for good cause. When a late filing request is approved, the applicant is notified and CARS is reopened for a brief period – usually two to three hours – the next business day.

Academic Research:

For recruitment Cycles 22.7, 22.8 and 22.9, six applications were received for the Recruitment of Established Investigators RFA, six applications were received for the Recruitment of Rising Starts RFA, and 20 applications were received in response to the Recruitment of First-Time, Tenure Track Faculty members RFA.

All Academic Research RFAs were posted on the Texas.gov eGrants website and all applications were submitted through CARS.

Receipt, Referral, and Assignment Compliance:

Once applications have been submitted through CARS, GDIT staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, GDIT notifies the program officer and the program officer makes the final decision whether to administratively withdraw the application. Recruitment grant applications and the Dissemination of CPRIT-funded Cancer Control Intervention grant applications are assigned to their respective review council members for review. All other academic research, product development research, and prevention applications are assigned by the peer review panel chair to their respective peer review panels. Prior to distribution of the applications, reviewers are given summary information about the applicant, including the Project Director and collaborators. Reviewers must sign a conflict of interest agreement and confirm that they do not have a conflict of interest with the application before they are provided with the full application.

The pedigrees attest that a conflict of interest statement was signed by each primary reviewer for each grant application.

For Cycles 22.7, 22.8, and 22.9, one recruitment application was withdrawn by the applicant prior to being reviewed by the SRC and two applications were withdrawn by the applicant after they were recommended by the Scientific Review Council (SRC) but prior to the PIC meeting.

Peer Review:

Primary reviewers (typically three) must submit written critiques for each of their assigned applications prior to the peer review meeting. After the peer review meetings, a final score report from the review committee is delivered to the Review Council for additional review. Following the peer review meeting, each participating peer reviewer must sign a post-review peer review statement certifying that the reviewer knew of and understood CPRIT's conflict of interest policy and followed the policy for this review process.

Academic Research:

For the Recruitment Awards, the applications are reviewed by the Scientific Review Council (SRC), which assigns two members of the SRC to be primary reviewers. I reviewed the supporting documentation, such as the sign-out sheets, third-party observer reports, and post-review peer reviewer statements. Sign out sheets are used to document when a reviewer with a conflict of interest associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application. One conflict of interest was declared by the SRC for recruitment cycle 22.7 and two conflicts of interest were declared by the SRC for recruitment cycle 22.8. For recruitment cycle 22.9, no conflicts of interest were declared.

I reviewed and confirmed that the post review conflict of interest statements were signed by the seven reviewers that attended the Recruitment Review Panel meeting on February 10, the six reviewers that attended the Recruitment Review Panel on March 10, and the eight reviewers that attended the Recruitment Review Panel on April 14, 2022.

Programmatic Review:

Programmatic review is conducted by the Scientific Review Council, Prevention Review Council, and Product Development Review Council for their respective awards. Each review council creates a final list of grant applications it will recommend to the PIC for grant award slates.

Academic Research:

I reviewed the third-party observer reports for each Review Council meeting. The third-party observer reports document that the Review Council discussions were limited to the merits of the applications and established evaluation criteria and that conflicted reviewers, if applicable, exited the room or the conference call when the application was discussed.

I reviewed and confirmed that the Review Council recommendations corresponded to RFAs that had been released. I also confirmed that the pedigrees reflect the date of the Review Council meeting and that the applications were recommended by the Review Council.

Because recruitment applications are assigned to the SRC, programmatic and peer review occur simultaneously when applications are reviewed by the SRC.

For Cycles 22.7, 22.8, and 22.9, one recruitment application was withdrawn by the applicant prior to being reviewed by the SRC and two applications were withdrawn by the applicant after they were recommended by the Scientific Review Council (SRC) but prior to the PIC meeting.

Program Integration Committee (PIC) Review:

Texas Health & Safety Code § 102.051(d) requires the Chief Compliance Officer to attend and observe the PIC meetings to ensure compliance with CPRIT's statute and administrative rules. CPRIT's statute requires that, at the time the PIC's final Grant Award recommendations are formally

submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the PIC containing relevant information related to the Grant Application recommendations.

I attended the May 4, 2022, PIC meeting held via videoconferencing as an observer and confirm that the PIC review process complied with CPRIT's statute and administrative rules.

The PIC considered 19 recruitment applications. Of the 19 applications, Dr. Michelle LeBeau, Chief Scientific Officer, recommended deferring 2 applications to a future PIC meeting. The remaining 17 applications were recommended by the PIC to move forward to the Oversight Committee.

A review of the CEO affidavits confirms that such affidavits were executed and provided for each Grant Application recommendation.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycles 7 through 9
Recruitment of Established Investigators

Request for Applications

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-22.1-REI

Recruitment of

Established Investigators

Please also refer to the Instructions for Applicants document, which will be posted on June 22, 2021

Application Receipt Dates:

June 22, 2021-June 20, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

6/22/21	RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas
- Develop and implement the Texas Cancer Plan

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure

Priorities Across CPRIT's 3 Programs:

- Prevention and early detection initiatives
- Translational of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, computational biology and analytic methods

- Childhood cancers
- Hepatocellular cancer
- Expand access to innovative clinical trials

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract world-class research scientists with distinguished professional careers to Texas universities and cancer research institutes to establish research programs that add research talent to the state. This award will support established academic leaders whose body of work has made an outstanding contribution to cancer research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas.

The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment. Candidates with research programs addressing CPRIT's priority areas for research are encouraged. These areas include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, computational biology and analytic methods, childhood cancers, hepatocellular cancer, and expansion of access to innovative clinical trials.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. This award honors outstanding senior investigators with proven track records of research accomplishments combined with excellence in leadership and teaching. All candidates should be recognized research or clinical investigators, held in the highest esteem by professional colleagues nationally and internationally, whose contributions have had a significant influence on their discipline and, likely, beyond. They must have clearly established themselves as exemplary faculty members with exceptional accomplishments in teaching and advising and/or basic, translational, population-based, or clinical cancer research activities. It is expected that the candidate will contribute significantly to and have a major

impact on the institution's overall cancer research initiative. Candidates will be leaders capable of initiating and developing creative ideas leading to novel solutions related to cancer detection, diagnosis, and/or treatment. They are also expected to maintain and lead a strong research group and have a stellar, high-impact publication portfolio, as well as continue to secure external funding. Furthermore, recipients will lead and inspire undergraduate and graduate students interested in pursuing research careers and will engage in collegial and collaborative relationships with others within and beyond their traditional discipline in an effort to expand the boundaries of cancer research.

Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.

Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates should be at the career level of a full professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience as vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Applications nominating individuals who carry out patient-oriented research and who have demonstrated exceptional ability to lead innovative discovery campaigns through conduct of clinical trials are appropriate for this mechanism and encouraged.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. INSTITUTIONAL COMMITMENT

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of an Established Investigator must be complemented by a strong financial institutional commitment to the recruitment. The institutional commitment should be clearly documented in the application (see section 8.2.2) and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

5. FUNDING INFORMATION

This award is up to 5 years and is not renewable. Grant support will be awarded based upon the breadth and nature of the research program proposed. Grant funds of up to $6,000,000 (total costs) for the 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years except under extraordinary circumstances with strong justification for a no-cost extension. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified and a detailed justification is provided along with an institutional plan should the additional funds not be approved. Scholars may request funds for travel for 2 project staff to attend CPRIT's conference.

Funds from this award mechanism may be used for salary support of this candidate but may not be used to construct or renovate laboratory space.

No annual limit on the number of grant application submissions by institutions has been set.

Note that the annual salary (also referred to as direct salary or institutional base salary) that an individual may be reimbursed from a CPRIT award for FY 2022 is limited to a maximum of $200,000. In other words, an individual may request salary proportional to the percent of effort

up to a maximum of $200,000. Salary does not include fringe benefits and/or facilities and administrative costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

Note: Depending on the availability of funds, nominations submitted in response to this Request for Applications (RFA) during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31, 2022) or in the first quarter of the next fiscal year (starting September 1, 2022).

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.
- There is no limit to the number of applications that an institution may submit during a review cycle.
- A candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council reviews the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's Academic Research program staff will notify the nominating institution of the Scientific Review Council's

review decision following the Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's review decision but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.

- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, **and reside in Texas for the duration of the appointment**. The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate should hold an appointment at the rank of professor (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation. The candidate must not reside in Texas at the time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Established Investigators award mechanism. Any nomination for the Recruitment of Established Investigators that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. A nomination for the Recruitment of Established Investigators that was previously submitted to CPRIT for any of the recruitment RFA mechanisms and reviewed and recommended for funding but declined by the candidate may be submitted in response to this RFA if the candidate meets the eligibility criteria described in section 6, and the application is not in the same fiscal year as the previous application. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles. Applications being resubmitted according to the criteria permitted by this section should be submitted as a new application (refer to the IFA for more details).

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (Nominator) must create a user account in the system

(which includes the Nominator's credentials and email address) to start and submit an application. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Dependent upon available funding, applications will be accepted on a continuous basis throughout FY22. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 PM central time on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application must be submitted on or before 11:59 PM central time. In the event that the 20th falls on Saturday or Sunday, applications may be submitted on or before 11:59 PM central time the following Monday. CPRIT will not extend the submission deadline. During periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. For details, please refer to the *Instructions for Applicants* document that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 6 will be administratively withdrawn without review.

8.2.1. Summary of Nomination (2,500 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

8.2.2. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of an Established Investigator Faculty should be complemented by a strongly

documented institutional commitment to the recruitment. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

The following guidelines should be followed when documenting the institutional commitment to the candidate:

- The institutional commitment should be clearly documented in the form of a letter signed by the applicant institution's president, provost, or appropriate dean and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.
- The institutional commitment letter must include the following statement regarding the institution's financial commitment required to meet the 50% match.
    - This institutional financial commitment will not be offset by funds from an investigator-initiated award received by the candidate. If an award dictates that such funds must be used for salary, the corresponding amount of institutional funds committed to pay the candidate's salary will be re-directed to allow the candidate to use them for program support.
- Institutional commitment as described above must be presented in a table (example below), that clearly identifies the salary amount, sources of salary, and any additional research support from institutional sources over the course of the CPRIT award. Note that a federal indirect cost rate credit cannot be used to demonstrate an institutional commitment to the candidate.
- Include a brief job description for the candidate should recruitment be successful.
- Describe the institutional environment and any professional commitments to the candidate including, but not limited to, dedicated personnel, access to students, space assignment, and access to shared equipment, and discuss all other agreements between the institution and the candidate.

- Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment, through development of strategic collaborations, will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research.
- Note that Texas law allows an institution of higher learning to use its federal indirect cost rate credit to comply with the requirement to demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award (see section 12). However, a federal indirect cost rate credit cannot be used to demonstrate an institutional commitment to the candidate.

Example of an acceptable Institutional Commitment table:

Candidate's Name, Institutional Commitments					
	Year 1	Year 2	Year 3	Year 4	Year 5
Salary/Benefits					
Research Support					
Administrative Support					
Moving Expenses					

Total =

Note: CPRIT acknowledges that the institutional commitments by category may change during the course of the award; however, the total financial commitment to the candidate must remain equal to or greater than 50% of the CPRIT award.

8.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department to which the candidate is being recruited. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research: While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

8.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

8.2.5. Summary of Goals and Objectives (2,000 characters)

List goals and objectives to be achieved during this award. **This section must be completed by the candidate.**

8.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate. References cited in this section should be listed in the Publications/References section (see 8.2.7).**

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.**

"I understand that I do not need to have made a commitment to <*nominating institution*> before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. I understand that requests to change the recruiting institution during the recruitment process are not allowed after the application is submitted to CPRIT."

8.2.7. Publications/References (1 Page)

Provide a concise and relevant list of publications/references cited for the application. Any appropriate citation format is acceptable; official journal abbreviations should be used.

8.2.8. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research, such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research. Biographical sketches of collaborators established in the research collaborative plan must be uploaded as part of the application. This will be in addition to the 2-page synergy plan (see IFA).

8.2.9. Publications

Provide the 5 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

8.2.10. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.11. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.12. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

8.2.13. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award. **This section of the application must be prepared by the candidate.** If the application is approved for funding, this section will be made publicly available on CPRIT's website. Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components; exceed the specified page, word, or budget limits; or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

9. APPLICATION REVIEW

9.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will review applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications recommended by the Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions is sent to the nominator.

9.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of the Department of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. **Also, of critical importance**

is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate made significant, transformative, and sustained contributions to basic, translational, clinical, or population-based cancer research? Is the candidate an established and nationally and/or internationally recognized leader in the field? Has the candidate demonstrated excellence in leadership and teaching? Has the candidate provided mentorship, inspiration, and/or professional training opportunities to junior scientists and students? Does the candidate have a strong record of research funding? Does the candidate have a publication history in high-impact journals? Does the candidate show evidence of collaborative interaction with others?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques? Does the research program integrate with and/or increase collaborative research efforts and relationships at the nominating institution?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research program? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program?

10. KEY DATES

RFA

RFA Release June 22, 2021

Application Receipt and Review Timeline

Application Receipt System opens 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 22, 2021	Continuous – dependent upon available funding	Monthly by the 15th day of the month	June 20, 2022

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements

set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. CPRIT requires funding acknowledgement to include the award grant ID on all print and visual materials that are funded in whole or in part by CPRIT grants. Examples of print and visual materials include, but are not limited to, publications, brochures, pamphlets, project websites, videos, and media materials. Grantees must have written approval from CPRIT prior to the purchase of any equipment. If the equipment is clearly defined in the grantee's budget submitted with the initiating award requirements, then approval of the grant award constitutes "prior approval" for the purchase. Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703, for specific requirements regarding the demonstration of available funding.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Academic Research.

Email: Research@cprit.texas.gov
Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
22.7 Academic Research Recruitment Review Panel
(22.7_SRC_REC)
Observation Report

Report No.	2022-02-10 22.7_SRC_REC
Program Name:	Academic Research
Panel Name:	22.7 Academic Research Recruitment Review Panel (22.7 _SRC_REC)
Panel Date:	February 10, 2022
Report Date:	February 17, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.7 Academic Research Recruitment Review Panel (22.7_SRC_REC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on February 10, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed
- Panelists: One (1) panel chair, six (6) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was one (1) Conflict of Interest (COI) identified prior to and/or during the meeting. The COI was excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

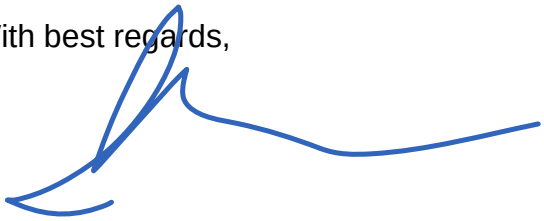
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.8 Academic Research Recruitment Review Panel
(22.8_REC)
Observation Report

Report No.	2022-03-10 22.8_REC
Program Name:	Academic Research
Panel Name:	22.8 Academic Research Recruitment Review Panel (22.8 _REC)
Panel Date:	March 10, 2022
Report Date:	March 14, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.8 Academic Research Recruitment Review Panel (22.8_REC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on March 10, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twelve (12) applications were discussed
- Panelists: One (1) panel chair, five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies and answering procedural questions

There were two (2) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

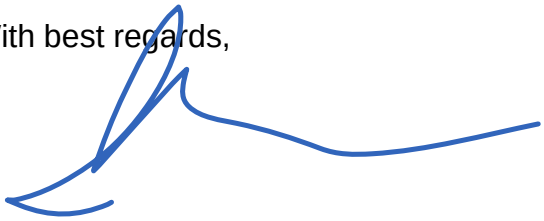
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.9 Academic Research Recruitment Review Panel
(22.9 REC)
Observation Report

Report No.	2022-04-14 22.9_REC
Program Name:	Academic Research
Panel Name:	22.9 Academic Research Recruitment Review Panel (22.9 _REC)
Panel Date:	April 14, 2022
Report Date:	April 28, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.9 Academic Research Recruitment Review Panel (22.9_REC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on April 14, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Nine (9) applications were discussed
- Panelists: One (1) panel chair, Five (5) expert reviewers, and two (2) ad-hoc reviewer
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

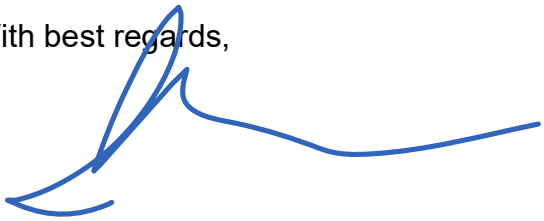
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Recruitment Cycles 22.7-22.9

Awards Announced at the May 18, and August 17, 2022, Oversight Committee Meetings

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycle 22.7 through 22.9 include: *Recruitment of Established Investigators; Recruitment of Rising Stars;* and *Recruitment of First-Time, Tenure-Track Faculty Members.*

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/Principal Investigator	Principal Investigator Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
RR220062	Gulio Draetta	The University of Texas M.D. Anderson Cancer Center	M. Tempero
RR220067	Gulio Draetta	The University of Texas M.D. Anderson Cancer Center	C. Prives
RR220068	Robert Hromas	The University of Texas Health Science Center at San Antonio	R. O'Reilly
Applications not considered by the PIC or Oversight Committee:			
No conflicts reported.			

De-Identified Overall Evaluation Scores

Recruitment of Established Investigators

Academic Research Recruitment Cycles 22.7 – 22.9

Application ID	Final Overall Evaluation Score
RR220033*	1.0
RR220051*	1.8
ad**	2.0
aa	3.0
ab	4.0
ac	4.0

* = Recommended for funding

** = The Scientific Review Council (SRC) recommended this application to the Program Integration Committee (PIC); the PIC deferred this application to a future meeting date in FY2022.

Final Overall Evaluation Scores and Rank Order Scores

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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April 25, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

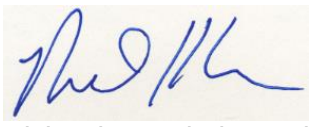
Dear Dr. Patel and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on February 10, 2022 (REC Cycle 22.7); on March 10, 2022 (REC Cycle 22.8) and on April 14, 2022 (REC Cycle 22.9) to review the applications submitted to CPRIT under the Recruitment of Established Investigators, of Rising Stars and of First-Time, Tenure Track Faculty Members.

The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation scores are stated for each grant application. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is $57,998,029. Please note that applications RR220073 and RR220059 recommended by the SRC were withdrwan prior to the Program Integration Committee meeting; therefore, the applications are not included in the rank order list on page two of this letter.

These recommendations meet the SRC's standards for funding. These include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,



Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Rank	App. ID	Mechanism	Candidate	Organization	Budget	Overall Scores
1	RR220084	RFTFM	Linde Miles	The University of Texas Southwestern Medical Center	$2,000,000	**1.0**
2	RR220087	RRS	Hans Renata	Rice University	$4,000,000	**1.0**
3	RR220068	RFTFM	Elizabeth Wasmuth	The University of Texas Health Science Center at San Antonio	$2,000,000	**1.0**
4	RR220069	RFTFM	William Hudson	Baylor College of Medicine	$2,000,000	**1.0**
5	RR220075	RFTFM	Nicholas Riley	The University of Texas at Austin	$2,000,000	**1.0**
6	RR220033	REI	Pavan Reddy	Baylor College of Medicine	$6,000,000	**1.0**
7	RR220062	RFTFM	Aria Vaishnavi	The University of Texas M. D. Anderson Cancer Center	$2,000,000	**1.0**
8	RR220065	RFTFM	Mingjie Dai	Rice University	$2,000,000	**1.4**
9	RR220072	RRS	Christine Lovly	The University of Texas M. D. Anderson Cancer Center	$4,000,000	**1.4**
10	RR220063	RRS	Ku-Lung Hsu	The University of Texas at Austin	$4,000,000	**1.7**
11	RR220051	REI	Michael Taylor	Baylor College of Medicine	$6,000,000	**1.8**
12	RR220081	RFTFM	Jonathan Clinger	Baylor University	$1,998,029	**2.0**
13	RR220086	RFTFM	Jason Schenkel	The University of Texas M. D. Anderson Cancer Center	$2,000,000	**2.0**
14	RR220088	RRS	Abdel Kareem Azab	The University of Texas Southwestern Medical Center	$2,000,000	**2.0**
15	RR220067	REI	Zhiguo Zhang	The University of Texas M. D. Anderson Cancer Center	$6,000,000	**2.0**
16	RR220070	RRS	Marios Giannakis	The University of Texas Southwestern Medical Center	$4,000,000	**2.0**
17	RR220055	RFTFM	Samantha Yruegas	Rice University	$2,000,000	**2.0**
18	RR220066	RFTFM	Deepshika Ramanan	The University of Texas M. D. Anderson Cancer Center	$2,000,000	**2.2**
19	RR220035	RFTFM	Qian Zhu	Baylor College of Medicine	$2,000,000	**2.5**

REI = Recruitment of Established Investigator
RRS = Recruitment of Rising Stars
RFTFM = Recruitmen of First-Time, Tenure Track Faculty Members

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 1
Evidence-Based Cancer Prevention Services

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Request for Applications

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA P-22.1-EBP

Evidence-Based Cancer Prevention Services

Please also refer to the Instructions for Applicants document, which will be posted on June 3, 2021

Application Receipt Opening Date: June 3, 2021

Application Receipt Closing Date: September 1, 2021

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

Rev	5/7/2021	RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and enhance the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1 Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary, and tertiary (includes survivorship) prevention interventions

CPRIT's Cross-Program Priorities:

- Prevention and early detection initiatives
- Translation of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science infrastructure

Prevention Program Priorities

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize underserved populations
- Program assessment to identify best practices, use as a quality improvement tool, and guide future program direction

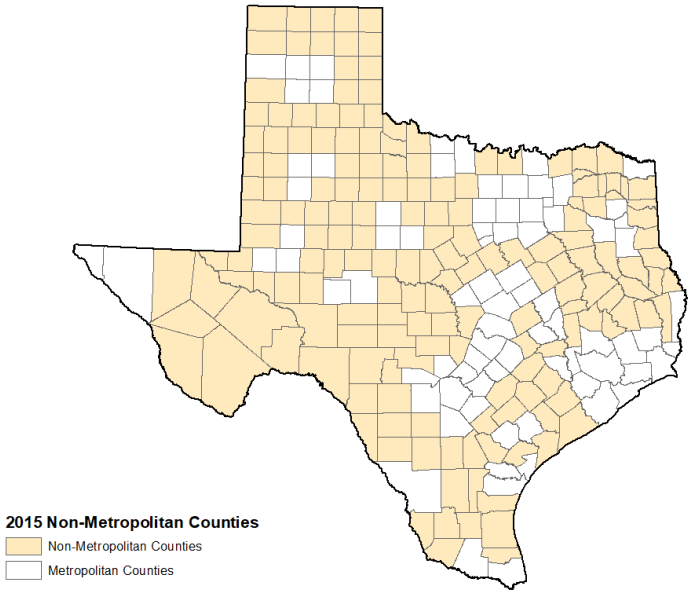
2. FUNDING OPPORTUNITY DESCRIPTION

2.1 Summary

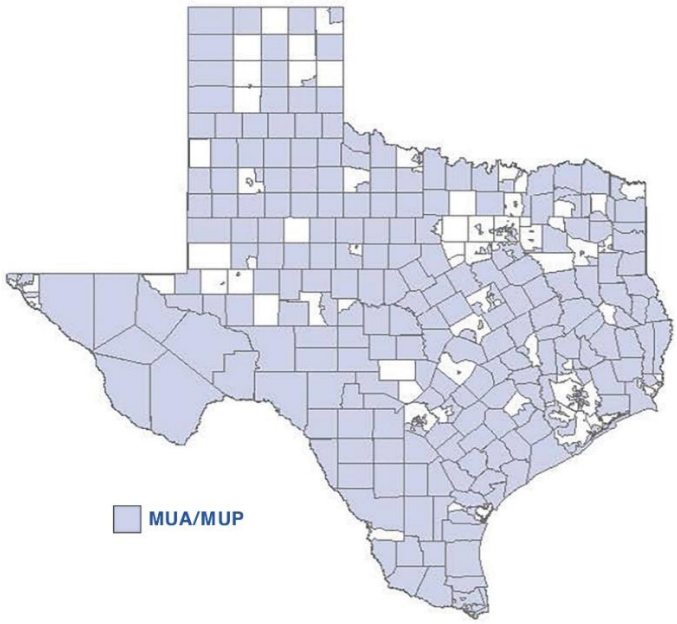
The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT fosters the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based risk reduction, early detection, and survivorship interventions.

The **Evidence-Based Cancer Prevention Services (EBP)** award mechanism seeks to fund programs that greatly challenge the status quo in cancer prevention and control services. The proposed program should be designed to reach and serve as many people as possible.

Only proposals for new projects are eligible under this mechanism. Eligible applications must include the delivery of services to nonmetropolitan (rural) and medically underserved counties in the state. These may be identified via web-based tools from the Texas Department of State Health Services and US Department of Health and Human Services respectively.



Texas Medically Underserved Areas (MUA) and Populations (MUP)



Data source: US Health Resources and Services Administration Data Warehouse, October 2019

Partnerships with other organizations that can support and leverage resources are strongly encouraged. A coordinated submission of a collaborative partnership program in which all partners have a substantial role in the proposed project is preferred.

2.2 Project Objectives

CPRIT seeks to fund projects that will do the following:

- Deliver comprehensive projects comprising all of the following: public and/or professional education, outreach, delivery of clinical services, follow-up navigation, and system and/or policy improvements.
- Offer effective and efficient systems of delivery of prevention services based on the existing body of knowledge about and evidence for cancer prevention in ways that far exceed current performance in a given service area.
- Implement policy changes and/or system improvements that are sustainable over time (eg, decrease wait times between positive screen and diagnostic tests and treatment through improved navigation, reminder systems, etc) and treatment.
- Provide tailored, culturally appropriate outreach and accurate information on early detection and prevention to the public and health care professionals that results in a health impact that can be measured.
- Deliver evidence-based survivorship services aimed at reducing the morbidity associated with cancer diagnosis and treatment.

2.3 Award Description

The Evidence-Based Cancer Prevention Services RFA solicits applications for eligible projects up to 36 months in duration that will deliver evidence-based services in cancer prevention and control to nonmetropolitan (rural) and medically underserved counties in Texas.

In addition to other primary prevention and screening/early detection services, CPRIT considers evidence-based clinical counseling services (eg, tobacco cessation, survivorship) when done on a one-on-one basis or in small groups and delivered by qualified providers as clinical services. This mechanism will fund case management/patient navigation to screening, to diagnostic testing, and to treatment. Applicants must ensure that there is access to treatment services for patients with

precancer or cancers that are detected as a result of the project and must describe the process for ensuring access to treatment services in their application.

Applicants should not request funds for any of the above components if these components are already being funded from other sources. If clinical services are being provided and paid by others, the applicant must demonstrate and report on the outcomes and services that are delivered to the people navigated by the program.

The following are required components of the project:

- **Geographic Area to be Served:** Clinical service delivery to nonmetropolitan/medically underserved area (MUA) counties is required. Service to urban/nonmedically underserved counties is allowable as long as the project proposes to also serve nonmetropolitan/medically underserved counties. Eligible projects in nonmetropolitan/medically underserved geographic areas not well served by the CPRIT portfolio (see maps at https://www.cprit.state.tx.us/our-programs/prevention/portfolio-maps) will receive priority consideration.
- **Comprehensive Projects:** Comprehensive projects include a continuum of services and systems and policy changes and comprise all of the following: Public and professional education and training, outreach, delivery of screening and diagnostic services, follow-up navigation, data collection and tracking, and systems improvement.
- **Evidence Based**: CPRIT's prevention grants are intended to fund effective and efficient systems of delivery of prevention services based on the existing body of knowledge about and evidence for cancer prevention in ways that far exceed current performance in a given service area. The provision of clinical services, including rescreening at the appropriate interval, must comply with established and current national guidelines (eg, US Preventive Services Task Force [USPSTF], American Cancer Society, etc).

If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data (eg, availability of resources and screening coverage) for the target population and target service region are required. If no baseline data exist, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish a baseline.

Clinical Service and Community Partner Networks. If applicable to the proposed project, applicants are encouraged to coordinate and describe a collaboration of clinical service providers and community partners that can deliver outreach, education, clinical, and navigation services to the most counties and the most people possible in a selected service region. Partnerships with other organizations that can support and leverage resources (ie, community-based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations, etc) are encouraged. Letters of commitment or memoranda of understanding describing their specific role in the partnership will strengthen the application.

In cases where the project proposes to work with multiple clinical providers, the Program Director (PD) should facilitate the establishment of standard protocols for all clinical service providers in the network as well as standard systems, policies, and procedures for the participating clinical service providers and organizations. These may include, but are not limited to, patient tracking and timely follow-up of all abnormal screening results and/or diagnoses of cancer.

CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based services, changes in provider practice, systems changes, and cost-effectiveness. Applicants must demonstrate how these outcomes will ultimately impact incidence, mortality, morbidity, or quality of life.

Under this RFA, CPRIT **will not** consider the following:

- **Projects focused solely on metropolitan/non–medically underserved counties.**
- **Currently or previously funded CPRIT Prevention projects.** These applicants should apply under the Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations (EPS) RFA.
- **Projects focusing solely on systems and/or policy change or solely on education and/or outreach** that do not include the delivery of cancer preventive clinical services.
- **Projects focused solely on counseling services** with no additional evidence-based clinical services.
- **Projects focusing solely on case management/patient navigation services.** Case management/patient navigation services must be paired with the delivery of a clinical cancer prevention service and reported to CPRIT. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded

project, applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.

- **Clinical tests/services proposed as part of the project that have not been recommended by the USPSTF due to lack of evidence available to draw reliable conclusions about benefits and harms of the tests. These include, but are not limited to, breast self exams, clinical breast exams, and PSA tests.**
- **New projects focusing on tobacco prevention and/or cessation for any age or computerized tomography screening for lung cancer for ages 50 to 80** should apply under CPRIT's Tobacco Control and Lung Cancer Screening RFA. For expansion projects, applicants should apply under the Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations (EPS) RFA.
- **Projects involving prevention/intervention research.** Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).
- **Resources for the treatment of cancer or viral treatment for hepatitis.**

2.4 Priorities

Types of Cancer: Applications addressing any cancer type(s) that are responsive to this RFA will be considered for funding. See section 2.5 for specific areas of emphasis.

The Prevention Program's priorities for funding include the following:

1) Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.

CPRIT programs must address underserved populations. Underserved populations are subgroups that are disproportionately affected by cancer. CPRIT-funded efforts must address 1 or more of these priority populations:

- Underinsured and uninsured individuals;
- Medically unserved or underserved populations;
- Racial, ethnic, and cultural minority populations;
- Populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened or who are significantly out of compliance

with nationally recommended screening guidelines (more than 5 years for breast/cervical cancers).

The age of the priority population and frequency of screening/rescreening for provision of clinical services described in the application must comply with established and current national guidelines (eg, USPSTF, American Cancer Society).

2) Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.

While disparities and needs exist across the state, CPRIT will also prioritize applications proposing to serve geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence. For this RFA, projects must propose to serve nonmetropolitan and/or MUAs of the state. In addition, projects addressing areas of emphasis (see section 2.5) will receive priority consideration.

Geographic and Population Balance in Current CPRIT portfolio

At the programmatic level of review conducted by the Prevention Review Council (see section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio (see https://www.cprit.state.tx.us/our-programs/prevention/portfolio-maps and https://www.cprit.state.tx.us/grants-funded?search=prevention).

2.5 Specific Areas of Emphasis

CPRIT has identified the following areas of emphasis for this cycle of awards.

Primary Prevention
HPV Vaccination
• Increasing access to, delivery of, and completion of the HPV vaccine regimen to males and females through evidence-based intervention efforts in all areas of the state.[1]
Liver Cancer
• Screening for HBV infection and HCV infection in populations at high risk of infection
• Increasing screening rates in Public Health Region (PHR) 8, 9, 10, and 11. Incidence and mortality rates are highest in PHR 10 and 11.[2]

Secondary Prevention - Screening and Early Detection Services
Colorectal Cancer
• Decreasing disparities in incidence and mortality rates of colorectal cancer in racial/ethnic populations. Blacks have the highest incidence and mortality rates, followed by non-Hispanic Whites and Hispanics.[2]
• Increasing screening/detection rates in PHR 2, 4, 5, and 9, where the highest rates of cancer incidence and mortality are found. • Decreasing incidence and mortality rates in nonmetropolitan counties. Incidence and mortality rates are higher in nonmetropolitan counties compared with metropolitan counties.[2]
Breast Cancer
• Decreasing disparities in mortality rates of breast cancer in racial/ethnic populations. The mortality rate is significantly higher in Blacks than in other populations.[2]
• Increasing screening/detection rates in medically underserved areas of the state.
Cervical Cancer
• Decreasing disparities in incidence and mortality rates of cervical cancer in racial/ethnic populations. Hispanics have the highest incidence rates while Blacks have the highest mortality rates.[2]
• Increasing screening/detection rates in medically underserved areas of the state.[2]
Tertiary Prevention – Survivorship Services
• Preventing secondary cancers and recurrence of cancer through evidence-based interventions.
• Improving quality of life of cancer survivors by managing the aftereffects of cancer, including the use of survivorship care plans.

2.6 Outcome Metrics

Applicants are required to clearly describe their assessment and evaluation methodology. The applicant is required to describe final outcome measures for the project. Output measures that are associated with the final outcome measures should be identified in the project plan and will serve as a measure of program effectiveness. Planned policy or system changes/improvements should be identified and the plan for qualitative analysis described. **Baseline data for each measure proposed are required**. In addition, applicants should describe how funds from the CPRIT grant will improve outcomes over baseline. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement to collect the data necessary to establish a baseline.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

If clinical services are being paid for and provided by others, the applicant is required to report on the number of clinical services and outcomes (eg, cancers detected) that are delivered to the people navigated by the program.

- Quarterly progress report sections include, but are not limited to, the following:
  - Summary page, including narrative on project progress (required)
  - Services, other than clinical services, provided to the public/professionals
  - Actions taken by people/professionals as a result of education or training
  - Clinical services provided (county of residence of client is required)
  - Precursors and cancers detected
- Annual and final progress report sections include, but are not limited to, the following:
  - Key accomplishments, **including qualitative analysis of policy change and/or lasting systems change**
  - Progress toward goals and outcome objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible individuals in a defined service area
  - Materials produced and publications
  - Economic impact of the project

2.7 Eligibility

- Eligible applications include only new cancer prevention projects.
- The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.

- The designated PD will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field and who resides in Texas during the time that the project is conducted.
- The applicant may submit more than 1 application, but each application must be for distinctly different services without overlap in the services provided. Applicants who do not meet this criterion will have all applications administratively withdrawn without peer review.
- If an organization has a current CPRIT grant that is the same or similar to the prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary.
- If the applicant or a partner is an existing Department of State Health Services (DSHS) contractor, CPRIT funds may not be used as a match, and the application must explain how this grant complements or leverages existing state and federal funds. DSHS contractors who also receive CPRIT funds must be in compliance with and fulfill all contractual obligations within CPRIT. CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor receiving funds from both entities.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization (or any person related to 1 or more of these individuals within the second

degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.

- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 6. All statutory provisions and relevant administrative rules can be found on the CPRIT website.

2.8 Resubmission Policy

- **One resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project or a change of title for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing**

previous critiques is advisable; however, it does not guarantee the success of the resubmission. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

2.9 Funding Information

Applicants may request any amount of funding up to a maximum of $1 million in total funding over a maximum of 36 months. Grant funds may be used to pay for clinical services, navigation services, project staff salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Applicants must ensure that there is access to treatment services for patients with precancer or cancers detected as a result of the program and must describe access to treatment.

Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the **total** award amount.

3. KEY DATES

RFA release	May 7, 2021
Online application opens	June 3, 2021, 7 AM central time
Application due	September 1, 2021, 4 PM central time
Application review	September 2021–January 2022
Award notification	February 2022
Anticipated start date	March 1, 2022

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1 *Instructions for Applicants* document

It is **imperative** that applicants read the accompanying instructions document for this RFA that will be available June 3, 2021 (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2 Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (an individual who will help manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on June 3, 2021, and must be submitted by 4 PM central time on September 1, 2021. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.3 Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.4 Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Refer to the *Instructions for Applicants* document for details. **Submissions that are missing 1 or more components or do not meet the eligibility requirements may be administratively withdrawn without review.**

4.4.1 Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need in the specific service area. Include rates of incidence, mortality, and screening in the service area compared to overall Texas rates. Describe barriers, plans to overcome these barriers, and the priority population to be served.
- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the services to be provided and the process/system for delivery of services and outreach to the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of clinical services delivered and number of people (public and/or professionals) served.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.4.2 Goals and Objectives (700 characters each)

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within both the stated Objective **and** the Measure sections (eg, Measure: 2,000 individuals, ages 9-12, will initiate HPV vaccination during the grant period). Applications may be returned for revision if the proposed metric is not included within the Measure section. Refer to the *Instructions for Applicants* document for details.

The maximum number is 3 goals with 3 outcome objectives each. Projects will be evaluated annually on progress toward outcome goals and objectives. See Appendix B for instructions on writing outcome goals and objectives.

A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target. If a baseline has not been defined, applicants are required to explain plans to establish baseline and describe method(s) of measurement.

4.4.3 Project Timeline (2 pages)

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3, and Months 1, 2, 3, etc, as applicable (eg, Year 1, Months 3-5) instead of specific months or years. Month 1 is the first full month of the grant award.

4.4.4 Project Plan (12 pages; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below.

Background: Briefly present the rationale behind the proposed services, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the priority population. Describe the race, ethnicity, age, and other defining characteristics of the population to be served.

If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the priority population and target service area are required where applicable.

Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are encouraged.

Goals and Objectives: Process objectives should be included in the project plan. Outcome goals and objectives will be entered in separate fields in CARS. However, if desired, outcome goals and objectives may be fully repeated or briefly summarized here. See Appendix B for instructions on writing goals and objectives.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services, as well as anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. Describe why this project is

nonduplicative. If an organization has a current CPRIT grant that is the same or similar to the prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary.

It is important to distinguish between Texas counties where the project proposes to deliver services and counties of residence of population served (see Appendix A for definitions and *Instructions for Applicants*). Only counties with service delivery should be listed in the Geographic Area to be Served section of the application. Projecting counties of residence of population served is not required but may be described in the project plan.

Clearly demonstrate the ability to provide the proposed service and describe how results will be improved over baseline and the ability to reach the priority population. Describe the method(s) that will be used to recall for appropriate rescreening those individuals who have been screened through this project.

If clinical services are being paid for and provided by others, the applicant must explain and report on the number of clinical services and outcomes (eg, screenings/diagnostics, vaccinations, cancer precursors, cancers detected) that are delivered to the people navigated by the program. Applicants must also clearly describe **access to treatment services** should precancer or cancer be detected. Include how and by whom any positive screening results will be delivered to a program participant.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the plan for outcome and output measurements, including qualitative analysis of policy and system changes. Describe data collection and management methods, data analyses, and anticipated results. Evaluation and reporting of results should be headed by a professional who has demonstrated expertise in the field. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, or the like. Applicants should budget accordingly for the evaluation activity and should involve that professional during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing health programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. The applicant should demonstrate how the organizational environment will

contribute to a successful project. If equipment or physical resources are required to carry out the project, the applicant should describe the availability of these resources and the organizational capacity to use equipment. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

CPRIT acknowledges that full maintenance and sustainability of projects when CPRIT funding ends may not be feasible, especially in cases involving the delivery of clinical services. However, it is important to consider sustainability early in the life cycle of a project, particularly regarding organizational characteristics and processes that are modifiable.

Washington University in St Louis has developed a useful tool (Program Sustainability Assessment Tool) to assess program capacity for sustainability. The tool assesses several factors that contribute to program sustainability. These factors include environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communication and strategic planning. Applicants are not required to use this tool; however, it provides practical guidance on factors that should be considered and should be included in the application to describe a program's organizational capacity for sustainability.

It is expected that steps toward building capacity for the program will be taken and plans for such be briefly described in the application. The applicant should describe the factors that will contribute to the organization's capacity to facilitate sustainability.

Dissemination and Replication: Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination efforts should consider the message, source, audience, and channel (Brownson, R.C., et al. *J Pub Health Manag Pract*. 24(2):102-111, March/April 2018). Dissemination methods may include, but are not limited to, presentations at workshops and seminars, one-on-one meetings, publications, news media, social media, etc.

While passive dissemination methods are common (eg, publications, presentations at professional meetings), plans should include some active dissemination methods (eg, meetings with stakeholders, blogs, social media). Applicants should describe their dissemination plans. The plans should include the kinds of audiences to be targeted and methods for reaching the targeted audiences.

Replication by others is an additional way to disseminate the project. For applicable components, describe how the project or components of the project lend themselves to application by other communities and/or organizations in the state or expansion in the same communities. Describe what components of this project can be adapted to a larger or lower resource setting. Note that some programs may have unique resources and may not lend themselves to replication by others.

4.4.5 People Reached (Indirect Contact)

Provide the estimated overall number of people (members of the public and professionals) to be reached by the funded project. The applicant is required to itemize separately the types of indirect noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to Appendix A for definitions.

4.4.6 Number of Services Delivered (Direct Contact)

Provide the estimated overall number of services directly delivered to members of the public and to professionals by the funded project. Each individual service should be counted, regardless of the number of services one person receives. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimate provided. Refer to Appendix A for definitions.

4.4.7 Number of Clinical Services Delivered

Provide the estimated overall number of clinical services directly delivered to members of the public by the funded project. Each individual clinical service should be counted, regardless of the number of services one person receives. Separately itemize the clinical services, with estimates, that led to the calculation of the overall estimate provided. Refer to Appendix A for definitions.

4.4.8 Number of Unique People Served (Direct Contact)

Provide the estimated overall number of unique members of the public and professionals served by the funded project. One person may receive multiple services but should only be counted once here. Refer to Appendix A for definitions.

4.4.9 References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed services.

4.4.10 Resubmission Summary

Use the template provided on the CARS (https://CPRITGrants.org). Describe the approach to the resubmission and how reviewers' comments were addressed. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed.

The summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.4.11 Most Recently Funded Relevant Project Summary (if applicable) (3 pages)

Upload a summary that outlines the progress made with the most recently funded relevant CPRIT award. Applicants must describe results and outcomes of the most recently funded award and demonstrate why further funding is warranted.

Please note that a different set of reviewers from those assigned to the previously funded application may evaluate this application. Applicants should make it easy for reviewers to compare the most recently funded project with the proposed project.

In the description, include the following:

- Describe the evidence-based intervention, its purpose, and how it was implemented in the priority population. Describe any adaptations made for the population served.
- List approved goals and objectives of the most recently funded grant.
- For each objective, provide milestones/target dates and target metrics as compared to actual completion dates and metrics.
- Include a discussion of objectives not fully met. Explain any barriers encountered and strategies used to overcome these.
- For the most recently funded project, describe major activities; significant results, including major findings, developments or conclusions (both positive and negative); and key outcomes.
- Describe steps taken toward sustainability for components of the project. Fully describe systems or policy improvements and enhancements.

- Describe how project results were disseminated or plans for future dissemination of results.

4.4.12 CPRIT Grants Summary

Use the template provided on CARS (https://CPRITGrants.org). Provide a listing of **all** projects funded by the CPRIT Prevention program for the PD and the Co-PD, regardless of their connection to this application.

4.4.13 Budget and Justification

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications requesting more than the maximum allowed cost (total costs) as specified in section 2.9 will be administratively withdrawn.

Clearly describe any organizational cost sharing or pro bono contributions related to this project, as well as any attempts made or successes to secure other state/federal funds.

- **Average Cost per Person:** The average cost per person will be automatically calculated from the total cost of the project divided by the total number of unique people served (refer to Appendix A).
- **Average Cost per Service:** The average cost per service will be automatically calculated from the total cost of the project divided by the total number of services delivered (refer to Appendix A). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.
- **Average Cost per Clinical Service:** The average cost per clinical service will be automatically calculated from the total cost of the project divided by the total number of clinical services delivered (refer to Appendix A).
- **Personnel:** The individual salary cap for CPRIT awards is $200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- **Equipment:** Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not

need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.

- **Services Costs:**
  - CPRIT reimburses for services using Medicare reimbursement rates. Describe the source of funding for all services where CPRIT funds are not requested. If clinical services are being paid for and provided by others, the applicant is required to explain and report on the number of clinical services and outcomes (eg, screenings/diagnostics, vaccinations, cancer precursors, cancers detected) that are delivered to the people navigated by the program.
  - CPRIT does not allow recovery of costs related to tests that have not been recommended by the USPSTF. In several cases (eg, breast self-exams, clinical breast exams, PSA tests), the Task Force has concluded there is not enough evidence available to draw reliable conclusions about the additional benefits and harms of these tests. (See https://www.uspreventiveservicestaskforce.org/)
- **Other Expenses:**
  - **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is $25.
  - **Costs Not Related to Cancer Prevention and Control:** CPRIT does not allow recovery of any costs for services not related to cancer (eg, health physicals, HIV testing) other than those required prior to the clinical services proposed in the project.
- **Indirect/Shared Costs:** Texas law limits the amount of grant funds that may be spent on indirect/shared expenses to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules.

4.4.14 Current and Pending Support and Sources of Funding

Use the template provided on the CARS (https://CPRITGrants.org). Describe the funding source and duration of **all** current and pending support for the proposed project, including a capitalization table that reflects private investors, if any.

4.4.15 Biographical Sketches

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

- Use the Co-PD Biographical Sketch section ONLY if a Co-PD has been identified.
- The evaluation professional must provide a biographical sketch in the Evaluation Professional Biographical Sketch section.
- Up to 3 additional biographical sketches for key personnel may be provided in the Key Personnel Biographical sketch section.

Each biographical sketch must not exceed 5 pages and should use either the "Prevention Programs: Biographical Sketch" template provided on the CARS (https://CPRITGrants.org) or the NIH Biographical Sketch format. Only biographical sketches will be accepted; do not submit resumes and/or CVs. If a position is not yet filled, please upload a job description.

4.4.16 Collaborating Organizations

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (eg, evaluation, clinical services, recruitment to screening). Please be sure to also include anyone listed as key personnel and/or listed under the Current & Pending Support section.

4.4.17 Letters of Commitment (10 pages)

Applicants should provide letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program. Letters should be specific to the contribution of each organization.

5. APPLICATION REVIEW

5.1 Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in

the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2 Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1 Primary Evaluation Criteria

Impact

- Do the proposed services address an important problem or need in cancer prevention and control? Do the proposed project strategies support desired outcomes in cancer incidence, morbidity, and/or mortality? Do the proposed project strategies reach a priority population (eg, low income, minority, rural) at high risk of cancer?
- Will the project reach and serve/impact an appropriate number of people based on the budget allocated to providing services and the cost of providing services?
- If applicable, have partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than the applicant organization's effort separately?
- Does the program address adaptation, if applicable, of the evidence-based intervention to the priority population? Is the base of evidence clearly explained and referenced?

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?
- Are the overall program approach, strategy, and design clearly described and supported by established theory and practice? Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Has the applicant proposed policy changes and/or system improvements?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the priority population and culturally appropriate methods to reach the priority population clearly described?
- If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including followup for abnormal results and access to treatment?
- Does the program leverage partners and resources to maximize the reach of the services proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- If clinical services are being paid for and provided by others, does the applicant explain the methods used to collect data and report on these clinical services and outcomes?
- Does the application provide a clear and appropriate plan for data collection and management and data analyses?
- Are clear baseline data provided for the priority population, or are clear plans included to collect baseline data?
- If an evidence-based intervention is being adapted in a population where it has not been implemented or tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services?
- Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?
- Have the appropriate personnel been recruited to design, implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?
- Does the applicant describe the program's organizational capacity for sustainability?
- Does the applicant describe steps that will be taken toward building internal capacity and partnerships?
- Does the applicant describe a plan for systems changes that are sustainable over time (eg, improve results, provider practice, efficiency, cost-effectiveness)?

5.2.2 Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Replication

- Are plans for dissemination of the project's results and outcomes, including target audiences and methods, clearly described?
- Are active dissemination strategies included and described in the plan?
- Does the applicant describe whether and/or how the project lends itself to replication of all or some components of the project by others in the state?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1 Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the Helpdesk, please refer to the *Instructions for Applicants* document (posted on June 3, 2021), which provides a step-by-step guide to using CARS.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

7.2 Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8417
Email: Help@CPRITGrants.org
Website: www.cprit.texas.gov

8. RESOURCES

- The Texas Cancer Registry. https://www.dshs.texas.gov/tcr or contact the Texas Cancer Registry at the Department of State Health Services.
- The Community Guide. https://www.thecommunityguide.org/
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, R.C., Colditz G.A., and Proctor, E.K. (Editors). *Dissemination and Implementation Research in Health: Translating Science to Practice.* Oxford University Press, March 2012
- Program Sustainability Assessment Tool, copyright 2012, Washington University, St Louis, MO, https://www.sustaintool.org/about-us/
- Getting the Word Out: New Approaches for Disseminating Public Health Science Ross C. Brownson, PhD; Amy A. Eyler, PhD; Jenine K. Harris, PhD; Justin B. Moore, PhD, MS; Rachel G. Tabak, PhD, RD, **Journal of Public Health Management & Practice.** 24(2):102-111, March/April 2018. (https://journals.lww.com/jphmp/Fulltext/2018/03000/Getting_the_Word_Out___New_Approaches_for.4.aspx)
- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs. http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability. http://www.cdc.gov/pcd/issues/2014/13_0185.htm
- Cancer Prevention and Control Research Network: Putting Public Health Evidence in Action Training Workshop. http://cpcrn.org/pub/evidence-in-action/
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. https://www.cdc.gov/os/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

9. REFERENCES

1. http://www.cdc.gov/hpv/parents/questions-answers.html
2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services. https://www.cancer-rates.info/tx/

APPENDIX A: KEY TERMS

- **Activities:** A listing of the "who, what, when, where, and how" for each objective that will be accomplished
- **Capacity Building**: Any activity (eg, training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention
- **Clinical Services:** Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Other examples include genetic testing or assessments, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments, and family history screening.
- **Counties of Residence of Population Served:** Counties where the project does not plan to have a physical presence but people who live in these counties have received services. This includes counties of residence of people or places of business of professionals who participate in or receive education, navigation or clinical services. Examples include people traveling to receive services as a result of marketing and programs accessible via the website or social media. These counties may be described in the project plan and must be reported in the quarterly progress report.
- **Counties with Service Delivery:** Counties where an activity or service will occur and the project has a physical presence for the services provided. Examples include onsite outreach and educational activities and delivery of clinical services through clinics, mobile vans, or telemedicine consults. These counties must be entered in the Geographic Area to be Served section of the application.
- **Education Services:** Number of evidence-based, culturally appropriate cancer prevention and control education and outreach services delivered to the public and to health care professionals. Examples include education or training sessions (group or individual), focus groups, and knowledge assessments. One individual may receive multiple education services.

- **Evidence-Based Program:** A program that is validated by some form of documented research or applied evidence. CPRIT's website provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit https://www.cprit.state.tx.us/our-programs/prevention.
- **Goals:** Broad statements of general purpose to guide planning. Outcome goals should be few in number and focus on aspects of highest importance to the project (Appendix B).
- **Integration:** The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice.
- **Navigation Services:** Number of activities/services that offer assistance to help overcome health care system barriers in a timely and informative manner and facilitate cancer screening and diagnosis to improve health care access and outcomes. Examples include patient reminders, transportation assistance, and appointment scheduling assistance. One individual may receive multiple navigation services.
- **Number of Clinical Services:** Number of clinical services delivered directly to members of the public by the funded project. One individual may receive multiple clinical services.
- **Number of Services (Direct Contact):** Number of services delivered directly to members of the public and/or professionals—direct, interactive public or professional education, outreach, training, navigation service, or clinical service, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. One individual may receive multiple services.
- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outcomes; example: "Increase screening service provision in X population from Y% to Z% by 20xx." Baseline data for the priority population must be included as part of each objective (Appendix B). The proposed metric should be included in **both** the objective and the measure.
- **People Reached (Indirect Contact):** Number of members of the public and/or professionals reached via indirect noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals. (This category includes individuals who would

be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project).

- **Unique People Served (Direct Contact):** Number of unique members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service, or clinical service. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.

APPENDIX B: WRITING GOALS AND OBJECTIVES

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within **both** the stated Objective and the Measure sections (eg, Measure: 2,000 individuals, ages 9-12, will initiate HPV vaccination during the grant period).

The maximum number is 3 goals with 3 objectives each. Projects will be evaluated annually on progress toward **outcome** goals and objectives.

The following has been adapted with permission from Appalachia Community Cancer Network, NIH Grant U54 CA 153604:

Develop well-defined goals and objectives.

Goals provide a roadmap or plan for where a group wants to go. Goals can be long term (over several years) or short term (over several months). Goals should be based on needs of the community and evidence-based data.

Goals should be:

- Believable – situations or conditions that the group believes can be achieved
- Attainable – possible within a designated time
- Tangible – capable of being understood or realized
- On a timetable – with a completion date
- Win-Win – beneficial to individual members and the coalition

Objectives are measurable steps toward achieving the goal. They are clear statements of specific activities required to achieve the goal. The best objectives have several characteristics in common – S.M.A.R.T. + C:

- Specific – they tell how much (number or percent), who (participants), what (action or activity), and by when (date)
    - Example: 115 uninsured individuals age 50 and older will complete colorectal cancer screening by March 31, 2018.
- Measurable – specific measures that can be collected, detected, or obtained to determine successful attainment of the objective

- Example: How many screened at an event? How many completed pre/post assessment?
- Achievable – not only are the objectives themselves possible, it is likely that your organization will be able to accomplish them
- Relevant to the mission – your organization has a clear understanding of how these objectives fit in with the overall vision and mission of the group
- Timed – developing a timeline is important for when your task will be achieved
- Challenging – objectives should stretch the group to aim on significant improvements that are important to members of the community

Evaluate and refine your objectives

Review your developed objectives and determine the type and level of each using the following information:

There are 2 types of objectives:

- Outcome objectives – measure the "what" of a program; should be in the Goals and Objectives form (see section 4.4.2)
- Process objectives – measure the "how" of a program; should be in the project plan only (see section 4.4.4)

There are 3 levels of objectives:

- Community-level – objectives measure the planned community change
- Program impact – objectives measure the impact the program will have on a specific group of people
- Individual – objectives measures participant changes resulting from a specific program, using these factors:
  - Knowledge – understanding (know screening guidelines; recall the number to call for screening)
  - Attitudes – feeling about something (will consider secondhand smoke dangerous; believe eating 5 or more fruits and vegetable is important)
  - Skills – the ability to do something (complete fecal occult blood test)
  - Intentions – regarding plan for future behavior (will agree to talk to the doctor, will plan to schedule a Pap test)

- Behaviors (past or current) – to act in a particular way (will exercise 30+ minutes a day, will have a mammogram)

Well-defined outcome goals and objectives can be used to track, measure, and report progress toward achievement.

Summary Table

	Outcome – Use in Goals and Objectives	Process – Use in Project Plan only
Community-level	WHAT will change in a community ***Example:*** *As a result of CPRIT funding, fecal immunochemical tests (FIT) will be available to 1,500 uninsured individuals age 50 and over through 10 participating local clinics and doctors.*	HOW the community change will come about ***Example:*** *Contracts will be signed with participating local providers to enable uninsured individuals over age 50 have access to free colorectal cancer screening in their communities.*
Program impact	WHAT will change in the target group as a result of a particular program ***Example:*** *As a result of this project, 200 uninsured women between 40 and 49 will receive free breast and cervical cancer screening.*	HOW the program will be implemented to affect change in a group/population ***Example:*** *2,000 female clients, between 40 and 49, will receive a letter inviting them to participate in breast and cervical cancer screening.*
Individual	WHAT an individual will learn as a result of a particular program, or WHAT change an individual will make as a result of a particular program ***Example:*** *As a result of one-to-one education of 500 individuals, at least 20% of participants will participate in a smoking cessation program to quit smoking.*	HOW the program will be implemented to affect change in an individual's knowledge or actions ***Example:*** *As a result of one-to-one counseling, all participants will identify at least 1 smoking cessation service and 1 smoking cessation aid.*

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
22.1 Prevention Peer Review Meeting (22.1_PRV-PP1)
Observation Report

Report No.	2021-12-06 22.1_PRV-PP1
Program Name:	Prevention
Panel Name:	22.1 Prevention Peer Review Meeting (22.1 _PRV-PP1)
Panel Date:	December 6, 2021
Report Date:	December 15, 2021

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.1 Prevention Peer Review Meeting (22.1_PRV-PP1) meeting. The meeting was chaired by Ross Brownson and conducted via videoconference on December 6, 2021.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Nine (9) applications were discussed and six (6) applications were not discussed
- Panelists: One (1) panel chair, nine (9) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was one (1) Conflict of Interest (COI) identified prior to and/or during the meeting. The COI was excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log were provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.1 Prevention Program Assessment (22.1_PRV-PPA)
Observation Report

Report No.	2021-12-07 22.1_PRV-PPA
Program Name:	Prevention
Panel Name:	22.1 Prevention Program Assessment (22.1 _PRV-PPA)
Panel Date:	December 7, 2021
Report Date:	December 15, 2021

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.1 Prevention Program Assessment (22.1_PRV-PPA) meeting. The meeting was chaired by Stephen Wyatt and conducted via videoconference on December 7, 2021.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) applications was discussed
- Panelists: One (1) panel chair, two (2) expert reviewers, and one (1) ad-hoc expert reviewer
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no (0) Conflict of Interest (COI) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log, and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log were provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.1 Prevention Review Council Programmatic Review Meeting (22.1_PRV_PRC)
Observation Report

Report No.	2022-01-14 22.1_PRV_PRC
Program Name:	Prevention
Panel Name:	22.1 Prevention Review Council Programmatic Review Meeting (22.1 _PRV_PRC)
Panel Date:	January 14, 2022
Report Date:	January 21, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.1 Prevention Review Council Programmatic Review Meeting (22.1_PRV_PRC) meeting. The meeting was chaired by Stephen Wyatt and conducted via videoconference on January 14, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Nine (9) applications were discussed
- Panelists: One (1) panel chair, two (2) expert reviewers,
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was one (1) Conflict of Interest (COI) identified prior to and/or during the meeting. The COI was excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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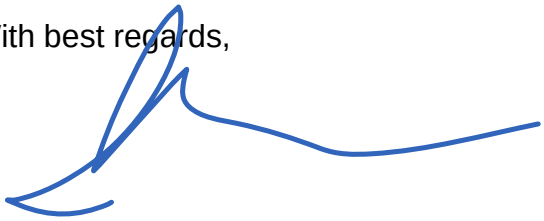
With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Prevention Review Council Programmatic Review Meeting (22.2_PRV_PRC)
Observation Report

Report No.	2022-06-03 22.2_PRV_PRC
Program Name:	Prevention
Panel Name:	22.2 Prevention Review Council Programmatic Review Meeting (22.2 _PRV_PRC)
Panel Date:	June 3, 2022
Report Date:	June 8, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Prevention Review Council Programmatic Review Meeting (22.2_PRV_PRC) meeting. The meeting was chaired by Stephen Wyatt and conducted via videoconference on June 3, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Nine (9) applications were discussed
- Panelists: One (1) panel chair, and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was one (1) Conflict of Interest (COI) identified prior to and/or during the meeting. The COI was excluded from discussions concerning applications for which there was a conflict.

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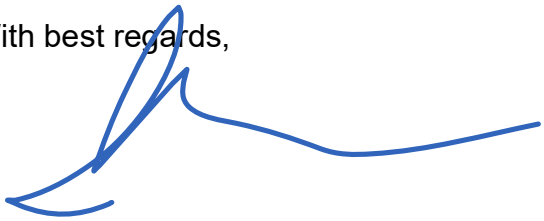
With best regards,



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Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Prevention Cycle 22.1

Awards Announced at the February 16, and August 17, 2022, Oversight Committee Meetings

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 22.1 include: *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations; Evidence-Based Cancer Prevention Services; Prevention Program Assessment;* and *Tobacco Control and Lung Cancer Screening.*

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/Program Director	Program Director Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
PP220005	Lewis Foxhall	The University of Texas M. D. Anderson Cancer Center	R. Brownson
Applications not considered by the PIC or Oversight Committee:			
No conflicts reported.			

T.A.C. Section 702.19 Waiver

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	T.A.C. § 702.19 STANDING WAIVER FOR FY 2022
DATE:	SEPTEMBER 10, 2021

Summary

This is to notify the Oversight Committee that pursuant to the authority provided to the Chief Executive Officer in T.A.C. § 702.19(e), I grant CPRIT's Chief Prevention Officer Ramona Magid a waiver from the general prohibition against communicating with grant applicants. The waiver is applicable for FY 2022 and will be effective for all prevention review cycles planned during the fiscal year. No Oversight Committee action related to this waiver is necessary.

Background and Discussion

The Chief Prevention Officer is a statutorily mandated member of the Program Integration Committee (PIC). Texas Administrative Code § 702.19 prohibits substantive communication between a grant applicant and a member of a peer review panel, the PIC, or the Oversight Committee while the application is pending a final decision. The restriction on communication prevents even the appearance of unequal treatment during the grant review process.

Traditionally, a chief program officer leads each CPRIT program with the assistance of a program manager who fields inquiries from and provides technical help to applicants completing their CPRIT grant applications. I promoted Ms. Magid to the Chief Prevention Officer position upon Dr. Becky Garcia's retirement in June 2019. However, the prevention program manager position has remained vacant since Ms. Magid's promotion. Until CPRIT fills the program manager position, she is the sole point of contact for the prevention program. The communication waiver is necessary so that Ms. Magid can assist grant applicants who have questions during the application process.

Like the FY 2021 waiver, I am granting a standing waiver for Ms. Magid for FY 2022 as long as she remains the sole point of contact for the prevention program. Approving this standing waiver does not favor any grant applicant over another. Ms. Magid will provide technical assistance only and will not comment on the substance of a grant application. CPRIT will include this waiver in the grant record for the FY 2022 prevention grant applications.

De-Identified Overall Evaluation Scores

Evidence-Based Cancer Prevention Services

Prevention Cycle 22.1

Application ID	Final Overall Evaluation Score
PP220024*	3.3
Ca	4.5
Cb	4.5
Cc	4.5
Cd	5.5
Ce	8.0

* Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

June 13, 2022

Dr. Mahendra Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Roberts and Dr. Patel,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for the FY2022 Cycle 2 Evidence-Based Cancer Prevention Services (EBP) and Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations and (EPS) grant awards.

The PRC met on June 3, 2022, to consider the applications recommended by the peer review panel following their April 25, 2022, meeting. The PRC recommends 9 projects totaling $14,443,836. One of the recommended projects, PP220024, was submitted and reviewed in FY2022 Cycle 1 but the PRC took no action on the application at that time.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PRC made no changes to the goals, project objectives, or timelines of the applications.

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary, or tertiary prevention. In making these recommendations the PRC continued to consider the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All the recommended grants address one or more of the Prevention Program priorities.

Sincerely,
Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

Attachment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Cycle 22.2 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP220036	EBP	Increasing the use of HPV vaccination services among medically underserved young adults	Roncancio, Angelica M	University of Houston	1.6	1	$991,308
PP220034	EPS	Screening to Optimize Prevention of CRC in East Texas (STOP CRC ET)	McGaha, Paul	The University of Texas Health Center at Tyler	1.8	2	$2,482,127
PP220038	EPS	Advancing Implementation of Evidence-Based Strategies for Tobacco Prevention and HPV Vaccination in Pediatric Safety Net Settings	Montealegre, Jane R	Baylor College of Medicine	2.3	3	$2,499,180
PP220045	EBP	Inpatient Screening and Treatment for Unhealthy Alcohol Use and Tobacco Use as a means of cancer prevention	Ramesh, Jananie	The University of Texas at Austin	2.6	4	$999,957
PP220037	EPS	Project ACCESS: Increasing Access to Cervical Cancer Screening & Treatment Services in Texas	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	2.9	5	$2,498,445
PP220024	EBP	Promoting Prevention in Survivorship Care in Rural Texas	Kvale, Elizabeth	The University of Texas at Austin	3.3	6	$975,851
PP220041	EBP	Fecal Immunochemical Testing for Screening and Treatment of Occult Neoplasia (FIT-STOP)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	4.0	7	$999,999
PP220051	EPS	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations- Program title: GetFIT	Mika, Virginia	University Health System	4.5	8	$1,999,849
PP220035	EBP	DEFEAT breast cancer: Delivering Education, Focused navigation, and Equitable Access throughout East Texas.	McGaha, Paul	The University of Texas Health Center at Tyler	5.0	9	$997,120

EBP: Evidence-Based Cancer Prevention Services
EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
Evidence-Based Cancer Prevention Services

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Request for Applications

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA P-22.2-EBP

Evidence-Based Cancer Prevention Services

Please also refer to the Instructions for Applicants document, which will be posted on November 15, 2021

Application Receipt Opening Date: November 15, 2021

Application Receipt Closing Date: February 9, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

Rev	10/19/2021	RFA release
Rev	12/14/2021	Clarification of survivor care clinical service requirement

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and enhance the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1 Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary, and tertiary (includes survivorship) prevention interventions

CPRIT's Cross-Program Priorities:

- Prevention and early detection initiatives
- Translation of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science infrastructure

Prevention Program Priorities

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize underserved populations
- Program assessment to identify best practices, use as a quality improvement tool, and guide future program direction

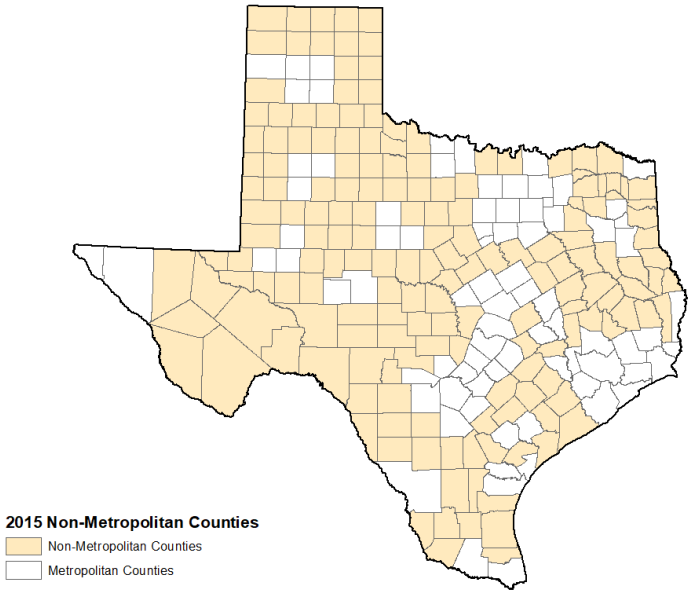
2. FUNDING OPPORTUNITY DESCRIPTION

2.1 Summary

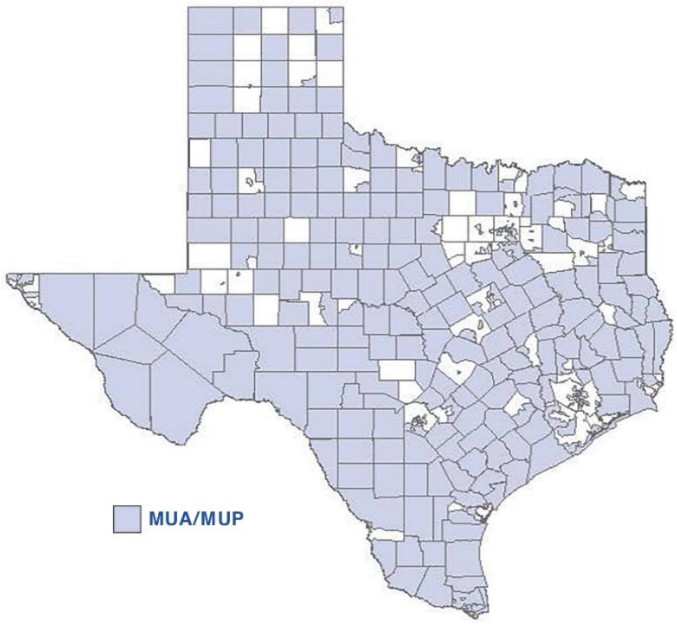
The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT fosters the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based risk reduction, early detection, and survivorship interventions.

The **Evidence-Based Cancer Prevention Services (EBP)** award mechanism seeks to fund programs that greatly challenge the status quo in cancer prevention and control services. The proposed program should be designed to reach and serve as many Texas resdients as possible.

Only proposals for new projects are eligible under this mechanism. Eligible applications must include the delivery of services to nonmetropolitan (rural) and medically underserved counties in the state. These may be identified via web-based tools from the Texas Department of State Health Services and US Department of Health and Human Services respectively.



Texas Medically Underserved Areas (MUA) and Populations (MUP)



Data source: US Health Resources and Services Administration Data Warehouse, October 2019

Partnerships with other organizations that can support and leverage resources are strongly encouraged. A coordinated submission of a collaborative partnership program in which all partners have a substantial role in the proposed project is preferred.

2.2 Project Objectives

CPRIT seeks to fund projects that will do the following:

- Deliver comprehensive projects comprising all of the following: public and/or professional education, outreach, delivery of clinical services, follow-up navigation, and system and/or policy improvements.
- Offer effective and efficient systems of delivery of prevention services based on the existing body of knowledge about and evidence for cancer prevention in ways that far exceed current performance in a given service area.
- Implement policy changes and/or system improvements that are sustainable over time (eg, decrease wait times between positive screen and diagnostic tests and treatment through improved navigation, reminder systems, etc) and treatment.
- Provide tailored, culturally appropriate outreach and accurate information on early detection and prevention to the public and health care professionals that results in a health impact that can be measured.
- Deliver evidence-based survivor care clinical services aimed at reducing the morbidity associated with cancer diagnosis and treatment.

2.3 Award Description

The Evidence-Based Cancer Prevention Services RFA solicits applications for eligible projects up to 36 months in duration that will deliver evidence-based services in cancer prevention and control to nonmetropolitan (rural) and medically underserved counties in Texas.

In addition to other primary prevention and screening/early detection services, CPRIT considers evidence-based clinical counseling services (eg, tobacco cessation, survivorship) when done on a one-on-one basis or in small groups and delivered by qualified providers as clinical services. This mechanism will fund case management/patient navigation to screening, to diagnostic testing, and to treatment. Applicants must ensure that there is access to treatment services for patients with

precancer or cancers that are detected as a result of the project and must describe the process for ensuring access to treatment services in their application.

Applicants should not request funds for any of the above components if these components are already being funded from other sources. If clinical services are being provided and paid by others, the applicant must demonstrate and report on the outcomes and services that are delivered to the people navigated by the program.

The following are required components of the project:

- **Geographic Area to be Served:** Clinical service delivery to nonmetropolitan/medically underserved area (MUA) counties is required. Service to urban/nonmedically underserved counties is allowable as long as the project proposes to also serve nonmetropolitan/medically underserved counties. Eligible projects in nonmetropolitan/medically underserved geographic areas not well served by the CPRIT portfolio (see maps at https://www.cprit.state.tx.us/our-programs/prevention/portfolio-maps) will receive priority consideration.
- **Comprehensive Projects:** Comprehensive projects include a continuum of services and systems and policy changes and comprise all of the following: Public and professional education and training, outreach, delivery of screening and diagnostic services, follow-up navigation, data collection and tracking, and systems improvement.
- **Evidence Based**: CPRIT's prevention grants are intended to fund effective and efficient systems of delivery of prevention services based on the existing body of knowledge about and evidence for prevention of both primary and secondary cancers in ways that far exceed current performance in a given service area. The provision of clinical services, including rescreening at the appropriate interval, must comply with established and current national guidelines (eg, US Preventive Services Task Force [USPSTF], American Cancer Society, etc).

If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data (eg, availability of resources and screening coverage) for the target population and target service region are required. If no baseline data exist, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish a baseline.

Clinical Service and Community Partner Networks. If applicable to the proposed project, applicants are encouraged to coordinate and describe a collaboration of clinical service providers and community partners that can deliver outreach, education, clinical, and navigation services to the most counties and the most people possible in a selected service region. Partnerships with other organizations that can support and leverage resources (ie, community-based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations, etc) are encouraged. Letters of commitment or memoranda of understanding describing their specific role in the partnership will strengthen the application.

In cases where the project proposes to work with multiple clinical providers, the Program Director (PD) should facilitate the establishment of standard protocols for all clinical service providers in the network as well as standard systems, policies, and procedures for the participating clinical service providers and organizations. These may include, but are not limited to, patient tracking and timely follow-up of all abnormal screening results and/or diagnoses of cancer.

CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based services, changes in provider practice, systems changes, and cost-effectiveness. Applicants must demonstrate how these outcomes will ultimately impact incidence, mortality, morbidity, or quality of life.

Under this RFA, CPRIT **will not** consider the following:

- **Projects focused solely on metropolitan/non–medically underserved counties.**
- **Currently or previously funded CPRIT Prevention projects.** These applicants should apply under the Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations (EPS) RFA.
- **Projects focusing solely on systems and/or policy change or solely on education and/or outreach that do not include the navigation to and delivery of cancer preventive clinical services.**
- **Projects focusing on screening the general population for genetic disposition to cancer.**
- **Projects focusing solely on case management/patient navigation services.** Case management/patient navigation services, including survivor care plans, must be paired with the delivery of a clinical cancer prevention service and reported to CPRIT, including those services delivered by another provider. Furthermore, while navigation to the point of

treatment of cancer is required when cancer is discovered through a CPRIT-funded project, applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.

- **Clinical tests/services proposed as part of the project that do not comply with established and current national guidelines and criteria and/or have not been recommended by the USPSTF due to lack of evidence available to draw reliable conclusions about benefits and harms of the tests. These include, but are not limited to, breast self exams, clinical breast exams, and PSA tests.**
- **New projects focusing on tobacco prevention and/or cessation for any age or computerized tomography screening for lung cancer for ages 50 to 80** should apply under CPRIT's Tobacco Control and Lung Cancer Screening RFA. For expansion projects, applicants should apply under the Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations (EPS) RFA.
- **Projects involving prevention/intervention research.** Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).
- **Resources for the treatment of cancer or viral treatment for hepatitis.**

2.4 Priorities

Types of Cancer: Applications addressing any cancer type(s) that are responsive to this RFA will be considered for funding. See section 2.5 for specific areas of emphasis.

The Prevention Program's priorities for funding include the following:

1) Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.

CPRIT programs must address underserved populations. Underserved populations are subgroups that are disproportionately affected by cancer. CPRIT-funded efforts must address 1 or more of these priority populations:

- Underinsured and uninsured individuals;
- Medically unserved or underserved populations;
- Racial, ethnic, and cultural minority populations;

- Populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened or who are significantly out of compliance with nationally recommended screening guidelines (more than 5 years for breast/cervical cancers).

The age of the priority population and frequency of screening/rescreening for provision of clinical services described in the application must comply with established and current national guidelines (eg, USPSTF, American Cancer Society).

2) Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.

While disparities and needs exist across the state, CPRIT will also prioritize applications proposing to serve geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence. For this RFA, projects must propose to serve nonmetropolitan and/or MUAs of the state. In addition, projects addressing areas of emphasis (see section 2.5) will receive priority consideration.

Geographic and Population Balance in Current CPRIT portfolio

At the programmatic level of review conducted by the Prevention Review Council (see section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio (see https://www.cprit.state.tx.us/our-programs/prevention/portfolio-maps and https://www.cprit.state.tx.us/grants-funded?search=prevention).

2.5 Specific Areas of Emphasis

CPRIT has identified the following areas of emphasis for this cycle of awards.

Primary Prevention
HPV Vaccination
• Increasing access to, delivery of, and completion of the HPV vaccine regimen to males and females through evidence-based intervention efforts in all areas of the state.[1]
Liver Cancer
• Screening for HBV infection and HCV infection in populations at high risk of infection
• Increasing screening rates in Public Health Region (PHR) 8, 9, 10, and 11. Incidence and mortality rates are highest in PHR 10 and 11.[2]

Secondary Prevention - Screening and Early Detection Services
Colorectal Cancer
• Decreasing disparities in incidence and mortality rates of colorectal cancer in racial/ethnic populations. Blacks have the highest incidence and mortality rates, followed by non-Hispanic Whites and Hispanics.[2]
• Increasing screening/detection rates in PHR 2, 4, 5, and 9, where the highest rates of cancer incidence and mortality are found. • Decreasing incidence and mortality rates in nonmetropolitan counties. Incidence and mortality rates are higher in nonmetropolitan counties compared with metropolitan counties.[2]
Breast Cancer
• Decreasing disparities in mortality rates of breast cancer in racial/ethnic populations. The mortality rate is significantly higher in Blacks than in other populations.[2]
• Increasing screening/detection rates in medically underserved areas of the state.
Cervical Cancer
• Decreasing disparities in incidence and mortality rates of cervical cancer in racial/ethnic populations. Hispanics have the highest incidence rates while Blacks have the highest mortality rates.[2]
• Increasing screening/detection rates in medically underserved areas of the state.[2]
Tertiary Prevention – Survivorship Services
• Preventing secondary cancers and recurrence of cancer through evidence-based interventions.
• Improving quality of life of cancer survivors by managing the aftereffects of cancer, including the use of survivorship care plans.

2.6 Outcome Metrics

Applicants are required to clearly describe their assessment and evaluation methodology. The applicant is required to describe final outcome measures for the project. Output measures that are associated with the final outcome measures should be identified in the project plan and will serve as a measure of program effectiveness. Planned policy or system changes/improvements should be identified and the plan for qualitative analysis described. **Baseline data for each measure proposed are required**. In addition, applicants should describe how funds from the CPRIT grant will improve outcomes over baseline. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement to collect the data necessary to establish a baseline.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

If clinical services are being paid for and provided by others, the applicant is required to report on the number of clinical services and outcomes (eg, cancers detected) that are delivered to the people navigated by the program.

- Quarterly progress report sections include, but are not limited to, the following:
  - Summary page, including narrative on project progress (required)
  - Services, other than clinical services, provided to the public/professionals
  - Actions taken by people/professionals as a result of education or training
  - Clinical services provided (county of residence of client is required)
  - Precursors and cancers detected
- Annual and final progress report sections include, but are not limited to, the following:
  - Key accomplishments, **including qualitative analysis of policy change and/or lasting systems change**
  - Progress toward goals and outcome objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible individuals in a defined service area
  - Materials produced and publications
  - Economic impact of the project

2.7 Eligibility

- Eligible applications include only new cancer prevention projects.
- The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.

- The designated PD will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field and who resides in Texas during the time that the project is conducted.
- The applicant may submit more than 1 application, but each application must be for distinctly different services without overlap in the services provided. Applicants who do not meet this criterion will have all applications administratively withdrawn without peer review.
- If an organization has a current CPRIT grant that is the same or similar to the prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary.
- If the applicant or a partner is an existing Department of State Health Services (DSHS) contractor, CPRIT funds may not be used as a match, and the application must explain how this grant complements or leverages existing state and federal funds. DSHS contractors who also receive CPRIT funds must be in compliance with and fulfill all contractual obligations within CPRIT. CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor receiving funds from both entities.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization (or any person related to 1 or more of these individuals within the second

degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.

- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 6. All statutory provisions and relevant administrative rules can be found on the CPRIT website.

2.8 Resubmission Policy

- **One resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project or a change of title for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing**

previous critiques is advisable; however, it does not guarantee the success of the resubmission. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

2.9 Funding Information

Applicants may request any amount of funding up to a maximum of $1 million in total funding over a maximum of 36 months. Grant funds may be used to pay for clinical services, navigation services, project staff salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Applicants must ensure that there is access to treatment services for patients with precancer or cancers detected as a result of the program and must describe access to treatment.

Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the **total** award amount.

3. KEY DATES

RFA release	October 19, 2021
Online application opens	November 15, 2021, 7 AM central time
Application due	February 9, 2022, 4 PM central time
Application review	March 2022–July 2022
Award notification	August 2022
Anticipated start date	August 31, 2022

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1 *Instructions for Applicants* document

It is **imperative** that applicants read the accompanying instructions document for this RFA that will be available November 15, 2021 (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2 Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (an individual who will help manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on November 15, 2021, and must be submitted by 4 PM central time on February 9, 2022. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.3 Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.4 Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Refer to the *Instructions for Applicants* document for details. **Submissions that are missing 1 or more components or do not meet the eligibility requirements may be administratively withdrawn without review.**

4.4.1 Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need in the specific service area. Include rates of incidence, mortality, and screening in the service area compared to overall Texas rates. Describe barriers, plans to overcome these barriers, and the priority population to be served.
- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the services to be provided and the process/system for delivery of services and outreach to the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of clinical services delivered and number of people (public and/or professionals) served.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.4.2 Goals and Objectives (700 characters each)

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within both the stated Objective **and** the Measure sections (eg, Measure: 2,000 individuals, ages 9-12, will initiate HPV vaccination during the grant period). Applications may be returned for revision if the proposed metric is not included within the Measure section. Refer to the *Instructions for Applicants* document for details.

The maximum number is 3 goals with 3 outcome objectives each. Projects will be evaluated annually on progress toward outcome goals and objectives. See Appendix B for instructions on writing outcome goals and objectives.

A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target. If a baseline has not been defined, applicants are required to explain plans to establish baseline and describe method(s) of measurement.

4.4.3 Project Timeline (2 pages)

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3, and Months 1, 2, 3, etc, as applicable (eg, Year 1, Months 3-5) instead of specific months or years. Month 1 is the first full month of the grant award.

4.4.4 Project Plan (12 pages; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below.

Background: Briefly present the rationale behind the proposed services, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the priority population. Describe the race, ethnicity, age, and other defining characteristics of the population to be served.

If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the priority population and target service area are required where applicable.

Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are encouraged.

Goals and Objectives: Process objectives should be included in the project plan. Outcome goals and objectives will be entered in separate fields in CARS. However, if desired, outcome goals and objectives may be fully repeated or briefly summarized here. See Appendix B for instructions on writing goals and objectives.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services, as well as anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. Describe why this project is

nonduplicative. If an organization has a current CPRIT grant that is the same or similar to the prevention intervention being proposed, the applicant must explain how the projects are nonduplicative or complementary.

It is important to distinguish between Texas counties where the project proposes to deliver services and counties of residence of population served (see Appendix A for definitions and *Instructions for Applicants*). Only counties with service delivery should be listed in the Geographic Area to be Served section of the application. Projecting counties of residence of population served is not required but may be described in the project plan.

Clearly demonstrate the ability to provide the proposed service and describe how results will be improved over baseline and the ability to reach the priority population. Describe the method(s) that will be used to recall for appropriate rescreening those individuals who have been screened through this project.

If clinical services are being paid for and provided by others, the applicant must explain and report on the number of clinical services and outcomes (eg, screenings/diagnostics, vaccinations, cancer precursors, cancers detected) that are delivered to the people navigated by the program. Applicants must also clearly describe **access to treatment services** should precancer or cancer be detected. Include how and by whom any positive screening results will be delivered to a program participant.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the plan for outcome and output measurements, including qualitative analysis of policy and system changes. Describe data collection and management methods, data analyses, and anticipated results. Evaluation and reporting of results should be headed by a professional who has demonstrated expertise in the field. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, or the like. Applicants should budget accordingly for the evaluation activity and should involve that professional during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing health programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. The applicant should demonstrate how the organizational environment will

contribute to a successful project. If equipment or physical resources are required to carry out the project, the applicant should describe the availability of these resources and the organizational capacity to use equipment. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

CPRIT acknowledges that full maintenance and sustainability of projects when CPRIT funding ends may not be feasible, especially in cases involving the delivery of clinical services. However, it is important to consider sustainability early in the life cycle of a project, particularly regarding organizational characteristics and processes that are modifiable.

Washington University in St Louis has developed a useful tool (Program Sustainability Assessment Tool) to assess program capacity for sustainability. The tool assesses several factors that contribute to program sustainability. These factors include environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communication and strategic planning. Applicants are not required to use this tool; however, it provides practical guidance on factors that should be considered and should be included in the application to describe a program's organizational capacity for sustainability.

It is expected that steps toward building capacity for the program will be taken and plans for such be briefly described in the application. The applicant should describe the factors that will contribute to the organization's capacity to facilitate sustainability.

Dissemination and Replication: Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination efforts should consider the message, source, audience, and channel (Brownson, R.C., et al. *J Pub Health Manag Pract*. 24(2):102-111, March/April 2018). Dissemination methods may include, but are not limited to, presentations at workshops and seminars, one-on-one meetings, publications, news media, social media, etc.

While passive dissemination methods are common (eg, publications, presentations at professional meetings), plans should include some active dissemination methods (eg, meetings with stakeholders, blogs, social media). Applicants should describe their dissemination plans. The plans should include the kinds of audiences to be targeted and methods for reaching the targeted audiences.

Replication by others is an additional way to disseminate the project. For applicable components, describe how the project or components of the project lend themselves to application by other communities and/or organizations in the state or expansion in the same communities. Describe what components of this project can be adapted to a larger or lower resource setting. Note that some programs may have unique resources and may not lend themselves to replication by others.

4.4.5 People Reached (Indirect Contact)

Provide the estimated overall number of people (members of the public and professionals) to be reached by the funded project. The applicant is required to itemize separately the types of indirect noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to Appendix A for definitions.

4.4.6 Number of Services Delivered (Direct Contact)

Provide the estimated overall number of services directly delivered to members of the public and to professionals by the funded project. Each individual service should be counted, regardless of the number of services one person receives. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimate provided. Refer to Appendix A for definitions.

4.4.7 Number of Clinical Services Delivered

Provide the estimated overall number of clinical services directly delivered to members of the public by the funded project. Each individual clinical service should be counted, regardless of the number of services one person receives. Separately itemize the clinical services, with estimates, that led to the calculation of the overall estimate provided. Refer to Appendix A for definitions.

4.4.8 Number of Unique People Served (Direct Contact)

Provide the estimated overall number of unique members of the public and professionals served by the funded project. One person may receive multiple services but should only be counted once here. Refer to Appendix A for definitions.

4.4.9 References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed services.

4.4.10 Resubmission Summary

Use the template provided on the CARS (https://CPRITGrants.org). Describe the approach to the resubmission and how reviewers' comments were addressed. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed.

The summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.4.11 Most Recently Funded Relevant Project Summary (if applicable) (3 pages)

Upload a summary that outlines the progress made with the most recently funded relevant CPRIT award. Applicants must describe results and outcomes of the most recently funded award and demonstrate why further funding is warranted.

Please note that a different set of reviewers from those assigned to the previously funded application may evaluate this application. Applicants should make it easy for reviewers to compare the most recently funded project with the proposed project.

In the description, include the following:

- Describe the evidence-based intervention, its purpose, and how it was implemented in the priority population. Describe any adaptations made for the population served.
- List approved goals and objectives of the most recently funded grant.
- For each objective, provide milestones/target dates and target metrics as compared to actual completion dates and metrics.
- Include a discussion of objectives not fully met. Explain any barriers encountered and strategies used to overcome these.
- For the most recently funded project, describe major activities; significant results, including major findings, developments or conclusions (both positive and negative); and key outcomes.
- Describe steps taken toward sustainability for components of the project. Fully describe systems or policy improvements and enhancements.

- Describe how project results were disseminated or plans for future dissemination of results.

4.4.12 CPRIT Grants Summary

Use the template provided on CARS (https://CPRITGrants.org). Provide a listing of **all** projects funded by the CPRIT Prevention program for the PD and the Co-PD, regardless of their connection to this application.

4.4.13 Budget and Justification

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications requesting more than the maximum allowed cost (total costs) as specified in section 2.9 will be administratively withdrawn.

Clearly describe any organizational cost sharing or pro bono contributions related to this project, as well as any attempts made or successes to secure other state/federal funds.

- **Average Cost per Person:** The average cost per person will be automatically calculated from the total cost of the project divided by the total number of unique people served (refer to Appendix A).
- **Average Cost per Service:** The average cost per service will be automatically calculated from the total cost of the project divided by the total number of services delivered (refer to Appendix A). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.
- **Average Cost per Clinical Service:** The average cost per clinical service will be automatically calculated from the total cost of the project divided by the total number of clinical services delivered (refer to Appendix A).
- **Personnel:** The individual salary cap for CPRIT awards is $200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- **Equipment:** Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not

need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.

- **Services Costs:**
  - CPRIT reimburses for services using Medicare reimbursement rates. Describe the source of funding for all services where CPRIT funds are not requested. If clinical services are being paid for and provided by others, the applicant is required to explain and report on the number of clinical services and outcomes (eg, screenings/diagnostics, vaccinations, cancer precursors, cancers detected) that are delivered to the people navigated by the program.
  - CPRIT does not allow recovery of costs related to tests that have not been recommended by the USPSTF. In several cases (eg, breast self-exams, clinical breast exams, PSA tests), the Task Force has concluded there is not enough evidence available to draw reliable conclusions about the additional benefits and harms of these tests. (See https://www.uspreventiveservicestaskforce.org/)
- **Other Expenses:**
  - **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is $25.
  - **Costs Not Related to Cancer Prevention and Control:** CPRIT does not allow recovery of any costs for services not related to cancer (eg, health physicals, HIV testing) other than those required prior to the clinical services proposed in the project.
- **Indirect/Shared Costs:** Texas law limits the amount of grant funds that may be spent on indirect/shared expenses to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules.

4.4.14 Current and Pending Support and Sources of Funding

Use the template provided on the CARS (https://CPRITGrants.org). Describe the funding source and duration of **all** current and pending support for the proposed project, including a capitalization table that reflects private investors, if any.

4.4.15 Biographical Sketches

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

- Use the Co-PD Biographical Sketch section ONLY if a Co-PD has been identified.
- The evaluation professional must provide a biographical sketch in the Evaluation Professional Biographical Sketch section.
- Up to 3 additional biographical sketches for key personnel may be provided in the Key Personnel Biographical sketch section.

Each biographical sketch must not exceed 5 pages and should use either the "Prevention Programs: Biographical Sketch" template provided on the CARS (https://CPRITGrants.org) or the NIH Biographical Sketch format. Only biographical sketches will be accepted; do not submit resumes and/or CVs. If a position is not yet filled, please upload a job description.

4.4.16 Collaborating Organizations

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (eg, evaluation, clinical services, recruitment to screening). Please be sure to also include anyone listed as key personnel and/or listed under the Current & Pending Support section.

4.4.17 Letters of Commitment (10 pages)

Applicants should provide letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program. Letters should be specific to the contribution of each organization.

5. APPLICATION REVIEW

5.1 Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in

the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2 Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1 Primary Evaluation Criteria

Impact

- Do the proposed services address an important problem or need in cancer prevention and control? Do the proposed project strategies support desired outcomes in cancer incidence, morbidity, and/or mortality? Do the proposed project strategies reach a priority population (eg, low income, minority, rural) at high risk of cancer?
- Will the project reach and serve/impact an appropriate number of people based on the budget allocated to providing services and the cost of providing services?
- If applicable, have partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than the applicant organization's effort separately?
- Does the program address adaptation, if applicable, of the evidence-based intervention to the priority population? Is the base of evidence clearly explained and referenced?

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?
- Are the overall program approach, strategy, and design clearly described and supported by established theory and practice? Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Has the applicant proposed policy changes and/or system improvements?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the priority population and culturally appropriate methods to reach the priority population clearly described?
- If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including followup for abnormal results and access to treatment?
- Does the program leverage partners and resources to maximize the reach of the services proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- If clinical services are being paid for and provided by others, does the applicant explain the methods used to collect data and report on these clinical services and outcomes?
- Does the application provide a clear and appropriate plan for data collection and management and data analyses?
- Are clear baseline data provided for the priority population, or are clear plans included to collect baseline data?
- If an evidence-based intervention is being adapted in a population where it has not been implemented or tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services?
- Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?
- Have the appropriate personnel been recruited to design, implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?
- Does the applicant describe the program's organizational capacity for sustainability?
- Does the applicant describe steps that will be taken toward building internal capacity and partnerships?
- Does the applicant describe a plan for systems changes that are sustainable over time (eg, improve results, provider practice, efficiency, cost-effectiveness)?

5.2.2 Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Replication

- Are plans for dissemination of the project's results and outcomes, including target audiences and methods, clearly described?
- Are active dissemination strategies included and described in the plan?
- Does the applicant describe whether and/or how the project lends itself to replication of all or some components of the project by others in the state?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1 Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the Helpdesk, please refer to the *Instructions for Applicants* document (posted on November 15, 2021), which provides a step-by-step guide to using CARS.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

7.2 Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8417
Email: Help@CPRITGrants.org
Website: www.cprit.texas.gov

8. RESOURCES

- The Texas Cancer Registry. https://www.dshs.texas.gov/tcr or contact the Texas Cancer Registry at the Department of State Health Services.
- The Community Guide. https://www.thecommunityguide.org/
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, R.C., Colditz G.A., and Proctor, E.K. (Editors). *Dissemination and Implementation Research in Health: Translating Science to Practice.* Oxford University Press, March 2012
- Program Sustainability Assessment Tool, copyright 2012, Washington University, St Louis, MO, https://www.sustaintool.org/about-us/
- Getting the Word Out: New Approaches for Disseminating Public Health Science Ross C. Brownson, PhD; Amy A. Eyler, PhD; Jenine K. Harris, PhD; Justin B. Moore, PhD, MS; Rachel G. Tabak, PhD, RD, **Journal of Public Health Management & Practice.** 24(2):102-111, March/April 2018. (https://journals.lww.com/jphmp/Fulltext/2018/03000/Getting_the_Word_Out___New_Approaches_for.4.aspx)
- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs. http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability. http://www.cdc.gov/pcd/issues/2014/13_0185.htm
- Cancer Prevention and Control Research Network: Putting Public Health Evidence in Action Training Workshop. http://cpcrn.org/pub/evidence-in-action/
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. https://www.cdc.gov/os/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

9. REFERENCES

1. http://www.cdc.gov/hpv/parents/questions-answers.html
2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services. https://www.cancer-rates.info/tx/

APPENDIX A: KEY TERMS

- **Activities:** A listing of the "who, what, when, where, and how" for each objective that will be accomplished
- **Capacity Building**: Any activity (eg, training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention
- **Clinical Services:** Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Other examples include genetic testing or assessments, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments, and family history screening.
- **Counties of Residence of Population Served:** Counties where the project does not plan to have a physical presence but people who live in these counties have received services. This includes counties of residence of people or places of business of professionals who participate in or receive education, navigation or clinical services. Examples include people traveling to receive services as a result of marketing and programs accessible via the website or social media. These counties may be described in the project plan and must be reported in the quarterly progress report.
- **Counties with Service Delivery:** Counties where an activity or service will occur and the project has a physical presence for the services provided. Examples include onsite outreach and educational activities and delivery of clinical services through clinics, mobile vans, or telemedicine consults. These counties must be entered in the Geographic Area to be Served section of the application.
- **Education Services:** Number of evidence-based, culturally appropriate cancer prevention and control education and outreach services delivered to the public and to health care professionals. Examples include education or training sessions (group or individual), focus groups, and knowledge assessments. One individual may receive multiple education services.

- **Evidence-Based Program:** A program that is validated by some form of documented research or applied evidence. CPRIT's website provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit https://www.cprit.state.tx.us/our-programs/prevention.
- **Goals:** Broad statements of general purpose to guide planning. Outcome goals should be few in number and focus on aspects of highest importance to the project (Appendix B).
- **Integration:** The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice.
- **Navigation Services:** Number of activities/services that offer assistance to help overcome health care system barriers in a timely and informative manner and facilitate cancer screening and diagnosis to improve health care access and outcomes. Examples include patient reminders, transportation assistance, and appointment scheduling assistance. One individual may receive multiple navigation services.
- **Number of Clinical Services:** Number of clinical services delivered directly to members of the public by the funded project. One individual may receive multiple clinical services.
- **Number of Services (Direct Contact):** Number of services delivered directly to members of the public and/or professionals—direct, interactive public or professional education, outreach, training, navigation service, or clinical service, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. One individual may receive multiple services.
- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outcomes; example: "Increase screening service provision in X population from Y% to Z% by 20xx." Baseline data for the priority population must be included as part of each objective (Appendix B). The proposed metric should be included in **both** the objective and the measure.
- **People Reached (Indirect Contact):** Number of members of the public and/or professionals reached via indirect noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals. (This category includes individuals who would

be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project).

- **Unique People Served (Direct Contact):** Number of unique members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service, or clinical service. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.

APPENDIX B: WRITING GOALS AND OBJECTIVES

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within **both** the stated Objective and the Measure sections (eg, Measure: 2,000 individuals, ages 9-12, will initiate HPV vaccination during the grant period).

The maximum number is 3 goals with 3 objectives each. Projects will be evaluated annually on progress toward **outcome** goals and objectives.

The following has been adapted with permission from Appalachia Community Cancer Network, NIH Grant U54 CA 153604:

Develop well-defined goals and objectives.

Goals provide a roadmap or plan for where a group wants to go. Goals can be long term (over several years) or short term (over several months). Goals should be based on needs of the community and evidence-based data.

Goals should be:

- Believable – situations or conditions that the group believes can be achieved
- Attainable – possible within a designated time
- Tangible – capable of being understood or realized
- On a timetable – with a completion date
- Win-Win – beneficial to individual members and the coalition

Objectives are measurable steps toward achieving the goal. They are clear statements of specific activities required to achieve the goal. The best objectives have several characteristics in common – S.M.A.R.T. + C:

- Specific – they tell how much (number or percent), who (participants), what (action or activity), and by when (date)
    - Example: 115 uninsured individuals age 50 and older will complete colorectal cancer screening by March 31, 2018.
- Measurable – specific measures that can be collected, detected, or obtained to determine successful attainment of the objective

- Example: How many screened at an event? How many completed pre/post assessment?
- Achievable – not only are the objectives themselves possible, it is likely that your organization will be able to accomplish them
- Relevant to the mission – your organization has a clear understanding of how these objectives fit in with the overall vision and mission of the group
- Timed – developing a timeline is important for when your task will be achieved
- Challenging – objectives should stretch the group to aim on significant improvements that are important to members of the community

Evaluate and refine your objectives

Review your developed objectives and determine the type and level of each using the following information:

There are 2 types of objectives:

- Outcome objectives – measure the "what" of a program; should be in the Goals and Objectives form (see section 4.4.2)
- Process objectives – measure the "how" of a program; should be in the project plan only (see section 4.4.4)

There are 3 levels of objectives:

- Community-level – objectives measure the planned community change
- Program impact – objectives measure the impact the program will have on a specific group of people
- Individual – objectives measures participant changes resulting from a specific program, using these factors:
  - Knowledge – understanding (know screening guidelines; recall the number to call for screening)
  - Attitudes – feeling about something (will consider secondhand smoke dangerous; believe eating 5 or more fruits and vegetable is important)
  - Skills – the ability to do something (complete fecal occult blood test)
  - Intentions – regarding plan for future behavior (will agree to talk to the doctor, will plan to schedule a Pap test)

- Behaviors (past or current) – to act in a particular way (will exercise 30+ minutes a day, will have a mammogram)

Well-defined outcome goals and objectives can be used to track, measure, and report progress toward achievement.

Summary Table

	Outcome – Use in Goals and Objectives	Process – Use in Project Plan only
Community-level	WHAT will change in a community ***Example:*** *As a result of CPRIT funding, fecal immunochemical tests (FIT) will be available to 1,500 uninsured individuals age 50 and over through 10 participating local clinics and doctors.*	HOW the community change will come about ***Example:*** *Contracts will be signed with participating local providers to enable uninsured individuals over age 50 have access to free colorectal cancer screening in their communities.*
Program impact	WHAT will change in the target group as a result of a particular program ***Example:*** *As a result of this project, 200 uninsured women between 40 and 49 will receive free breast and cervical cancer screening.*	HOW the program will be implemented to affect change in a group/population ***Example:*** *2,000 female clients, between 40 and 49, will receive a letter inviting them to participate in breast and cervical cancer screening.*
Individual	WHAT an individual will learn as a result of a particular program, or WHAT change an individual will make as a result of a particular program ***Example:*** *As a result of one-to-one education of 500 individuals, at least 20% of participants will participate in a smoking cessation program to quit smoking.*	HOW the program will be implemented to affect change in an individual's knowledge or actions ***Example:*** *As a result of one-to-one counseling, all participants will identify at least 1 smoking cessation service and 1 smoking cessation aid.*

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Prevention Peer Review Meeting (22.2 PRV-PP1)
Observation Report

Report No.	2022-04-25 22.2_PRV-PP1
Program Name:	Prevention
Panel Name:	22.2 Prevention Peer Review Meeting (22.2 _PRV-PP1)
Panel Date:	April 25, 2022
Report Date:	April 28, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Prevention Peer Review Meeting (22.2_PRV-PP1) meeting. The meeting was chaired by Nancy Lee and conducted via videoconference on April 25, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twelve (12) applications were discussed and three (3) applications were not discussed
- Panelists: One (1) panel chair, ten (10) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Prevention Review Council Programmatic Review Meeting (22.2_PRV_PRC)
Observation Report

Report No.	2022-06-03 22.2_PRV_PRC
Program Name:	Prevention
Panel Name:	22.2 Prevention Review Council Programmatic Review Meeting (22.2 _PRV_PRC)
Panel Date:	June 3, 2022
Report Date:	June 8, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Prevention Review Council Programmatic Review Meeting (22.2_PRV_PRC) meeting. The meeting was chaired by Stephen Wyatt and conducted via videoconference on June 3, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Nine (9) applications were discussed
- Panelists: One (1) panel chair, and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was one (1) Conflict of Interest (COI) identified prior to and/or during the meeting. The COI was excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

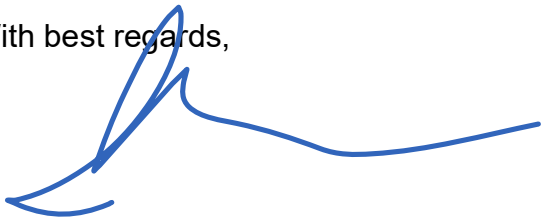
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Prevention Cycle 22.2

Awards Announced at the August 17, 2022, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 22.2 include: *Evidence-Based Cancer Prevention Services* and *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations.*

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/Principal Investigator	Principal Investigator Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
PP220037	Schmeler, Kathleen	The University of Texas M.D. Anderson Cancer Center	Brownson, Ross
Applications not considered by the PIC or Oversight Committee:			
No reported COIs.			

T.A.C. Section 702.19 Waiver

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	T.A.C. § 702.19 STANDING WAIVER FOR FY 2022
DATE:	SEPTEMBER 10, 2021

Summary

This is to notify the Oversight Committee that pursuant to the authority provided to the Chief Executive Officer in T.A.C. § 702.19(e), I grant CPRIT's Chief Prevention Officer Ramona Magid a waiver from the general prohibition against communicating with grant applicants. The waiver is applicable for FY 2022 and will be effective for all prevention review cycles planned during the fiscal year. No Oversight Committee action related to this waiver is necessary.

Background and Discussion

The Chief Prevention Officer is a statutorily mandated member of the Program Integration Committee (PIC). Texas Administrative Code § 702.19 prohibits substantive communication between a grant applicant and a member of a peer review panel, the PIC, or the Oversight Committee while the application is pending a final decision. The restriction on communication prevents even the appearance of unequal treatment during the grant review process.

Traditionally, a chief program officer leads each CPRIT program with the assistance of a program manager who fields inquiries from and provides technical help to applicants completing their CPRIT grant applications. I promoted Ms. Magid to the Chief Prevention Officer position upon Dr. Becky Garcia's retirement in June 2019. However, the prevention program manager position has remained vacant since Ms. Magid's promotion. Until CPRIT fills the program manager position, she is the sole point of contact for the prevention program. The communication waiver is necessary so that Ms. Magid can assist grant applicants who have questions during the application process.

Like the FY 2021 waiver, I am granting a standing waiver for Ms. Magid for FY 2022 as long as she remains the sole point of contact for the prevention program. Approving this standing waiver does not favor any grant applicant over another. Ms. Magid will provide technical assistance only and will not comment on the substance of a grant application. CPRIT will include this waiver in the grant record for the FY 2022 prevention grant applications.

De-Identified Overall Evaluation Scores

Evidence-Based Cancer Prevention Services

Prevention Cycle 22.2

Application ID	Final Overall Evaluation Score
PP220036*	1.6
PP220045*	2.6
PP220041*	4.0
PP220035*	5.0
Da	5.2
Db	5.3
Dc	5.5
Dd	7.3

* Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

June 13, 2022

Dr. Mahendra Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Roberts and Dr. Patel,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for the FY2022 Cycle 2 Evidence-Based Cancer Prevention Services (EBP) and Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations and (EPS) grant awards.

The PRC met on June 3, 2022, to consider the applications recommended by the peer review panel following their April 25, 2022, meeting. The PRC recommends 9 projects totaling $14,443,836. One of the recommended projects, PP220024, was submitted and reviewed in FY2022 Cycle 1 but the PRC took no action on the application at that time.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PRC made no changes to the goals, project objectives, or timelines of the applications.

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary, or tertiary prevention. In making these recommendations the PRC continued to consider the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All the recommended grants address one or more of the Prevention Program priorities.

Sincerely,
Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

Attachment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Cycle 22.2 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP220036	EBP	Increasing the use of HPV vaccination services among medically underserved young adults	Roncancio, Angelica M	University of Houston	1.6	1	$991,308
PP220034	EPS	Screening to Optimize Prevention of CRC in East Texas (STOP CRC ET)	McGaha, Paul	The University of Texas Health Center at Tyler	1.8	2	$2,482,127
PP220038	EPS	Advancing Implementation of Evidence-Based Strategies for Tobacco Prevention and HPV Vaccination in Pediatric Safety Net Settings	Montealegre, Jane R	Baylor College of Medicine	2.3	3	$2,499,180
PP220045	EBP	Inpatient Screening and Treatment for Unhealthy Alcohol Use and Tobacco Use as a means of cancer prevention	Ramesh, Jananie	The University of Texas at Austin	2.6	4	$999,957
PP220037	EPS	Project ACCESS: Increasing Access to Cervical Cancer Screening & Treatment Services in Texas	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	2.9	5	$2,498,445
PP220024	EBP	Promoting Prevention in Survivorship Care in Rural Texas	Kvale, Elizabeth	The University of Texas at Austin	3.3	6	$975,851
PP220041	EBP	Fecal Immunochemical Testing for Screening and Treatment of Occult Neoplasia (FIT-STOP)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	4.0	7	$999,999
PP220051	EPS	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations- Program title: GetFIT	Mika, Virginia	University Health System	4.5	8	$1,999,849
PP220035	EBP	DEFEAT breast cancer: Delivering Education, Focused navigation, and Equitable Access throughout East Texas.	McGaha, Paul	The University of Texas Health Center at Tyler	5.0	9	$997,120

EBP: Evidence-Based Cancer Prevention Services
EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Request for Applications

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA P-22.2-EPS

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

Please also refer to the Instructions for Applicants document, which will be posted on November 15, 2021

Application Receipt Opening Date: November 15, 2021

Application Receipt Closing Date: February 9, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

Rev	10/19/2021	RFA release
Rev	12/14/2021	Clarification of survivor care clinical service requirement

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1 Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary, and tertiary (includes survivorship) prevention interventions

CPRIT's Cross-Program Priorities:

- Prevention and early detection initiatives
- Translation of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science infrastructure

Prevention Program Priorities

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize underserved populations
- Prioritize program assessment to identify best practices, use as a quality improvement tool, and guide future program direction

2. FUNDING OPPORTUNITY DESCRIPTION

2.1 Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT fosters the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based risk reduction, early detection, and survivorship interventions.

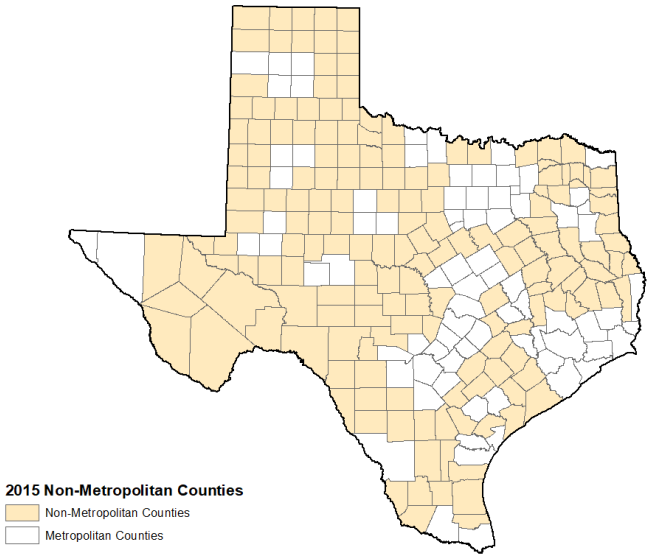
This award mechanism seeks to support the coordination and expansion of evidence-based services to prevent or screen for cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models to prevent and control these cancers. Delivery of clinical services is restricted to residents of Texas.

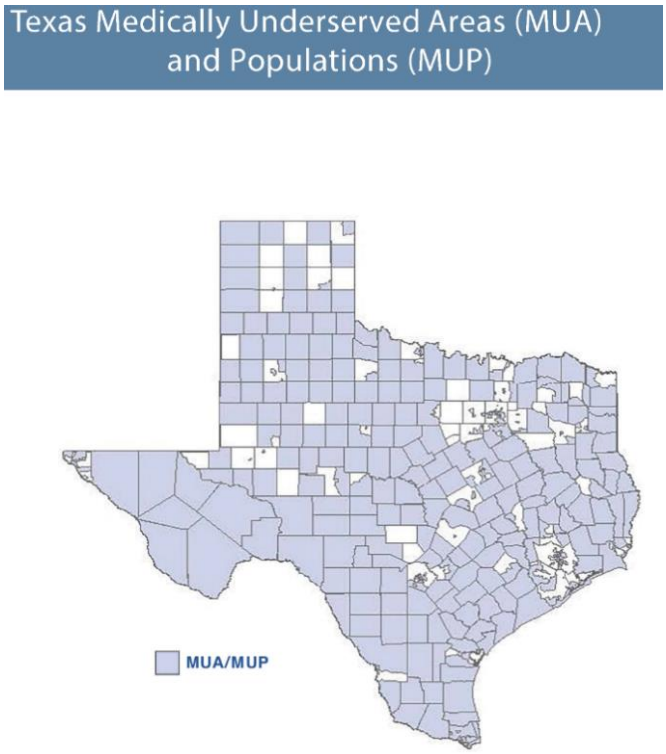
Eligible applicants include only those with currently or previously funded CPRIT Prevention projects.

Initial Expansion: For the first expansion application, eligible applicants should propose to expand their programs to include additional types of prevention clinical services or to expand current clinical services into additional counties. In either case, the expansion must include the delivery of services to nonmetropolitan (rural) and/or medically underserved counties in the state. These may

be identified via web-based tools from the Texas Department of State Health Services and US Department of Health and Human Services.

Maintenance Expansion: For a subsequent expansion, additional clinical services and/or expansion to additional counties is optional; however, the counties and the services offered in the first expansion should not be decreased. The number of clinical services delivered during the maintenance expansion must be increased substantially if no further geographic or clinical service expansion is proposed.





Data source: US Health Resources and Services Administration Data Warehouse, October 2019

2.2 Project Objectives

CPRIT seeks to fund initial expansion evidence-based prevention projects that will do the following:

- Expand an eligible CPRIT project by adding and integrating the delivery of 1 or more of the following to an existing project:
  - Screenings, rescreenings, and diagnostics for breast, cervical, colorectal, lung cancers; hepatitis C virus; genetic risk factors.
  - Vaccinations against HPV and hepatitis B virus.
  - Evidence-based interventions focused on tobacco prevention (prevent tobacco use or sustained abstinence) and tobacco cessation among youth and/or adults.
  - Evidence-based primary prevention or survivor care clinical services aimed at reducing the morbidity associated with cancer diagnosis and treatment.
- Expand an eligible CPRIT project by adding and integrating the delivery of services to additional nonmetropolitan and/or medically underserved counties.

CPRIT seeks to fund maintenance expansion evidence-based prevention projects that will do the following:

- Maintain, at a minimum, clinical service delivery and geographic area expansion as proposed in the previously funded expansion project. Further expansion of clinical services and geographic area is optional.
- Substantially increase the number of clinical services delivered if no further expansion is proposed.

Both initial and maintenance expansion evidence-based prevention projects funded by CPRIT will do the following:

- Coordinate the resources (clinical service providers, community organizations, etc) in nonmetropolitan and medically underserved areas (MUAs) to increase the availability of services and, where providers are available, help connect people with their local health care providers.
- Leverage the infrastructure, networks, and resources that have been put in place by CPRIT-supported projects while minimizing start-up time.
- Deliver comprehensive projects comprising all of the following: public and/or professional education, outreach, delivery of clinical services, navigation services, and system and/or policy improvements.
- Offer effective and efficient systems of delivery of prevention services based on the existing body of knowledge about, and evidence for, cancer prevention in ways that far exceed current performance in a given service area.
- Implement policy changes and/or system improvements that are sustainable over time (eg, decrease wait times between positive screen and diagnostic tests and treatment through improved navigation, reminder systems, etc).

2.3 Award Description

CPRIT's **Expansion of Cancer Prevention Services** grants are intended to fund the expansion of eligible projects that have demonstrated exemplary success, as evidenced by progress reports and project evaluations, and desire to further enhance their impact on priority populations. Detailed descriptions of **established infrastructure**, **results, barriers, outcomes, and impact of the most recently funded project are required** (see outline of Project Plan, section 4.4.4).

Projects in the last year of a current grant or previously funded projects may apply for this expansion. Programs must have at least 1 full year of data to report before applying (see section 2.7 eligibility criteria).

This mechanism will fund case management/patient navigation to cancer prevention services, to diagnostic testing, and to treatment. Applicants must ensure that there is access to treatment services for patients with precancer or cancers that are detected as a result of the project and must describe in detail the process for ensuring access to treatment services in their application.

Applicants should not request funds for any of the above components if these components are already being funded from other sources. If clinical services are being provided and paid by others, the applicant must explain and report on the outcomes and services that are delivered to the people navigated by the program.

The following are required components of the project:

- **Initial Expansion:** Expansion to nonmetropolitan/MUA counties and/or offering additional clinical services are required for an initial expansion. To qualify for this Expansion RFA, CPRIT requires applicants to either add the delivery of 1 or more of the following clinical services to their project or to expand to additional nonmetropolitan and/or MUA counties.
    - Screenings and rescreenings for breast, cervical, colorectal, lung cancers; hepatitis C virus; genetic risk factors
    - Vaccinations against HPV; hepatitis B virus
    - Evidence-based interventions focused on tobacco prevention (prevent tobacco use or sustained abstinence) and tobacco cessation among youth and/or adults
    - Evidence-based primary prevention or survivor care clinical services aimed at reducing the morbidity associated with cancer diagnosis and treatment

Expansion of eligible projects into nonmetropolitan/medically underserved geographic areas not well served by the CPRIT portfolio (see maps at https://www.cprit.texas.gov/our-programs/prevention/portfolio-maps) will receive priority consideration.

- **Maintenance Expansion:** The clinical service and/or geographic expansion from the previously funded CPRIT expansion project must be maintained, at a minimum. Further expansion is optional. If no further expansion of clinical services and/or geography is

proposed, the number of clinical services delivered must be substantially increased from the initial expansion.

- **Comprehensive Projects:** Comprehensive projects include a continuum of services and systems and policy changes and comprise all of the following: Public and/or professional education and training, outreach, delivery of screening and diagnostic services, navigation services, data collection and tracking, and systems improvement.
- **Evidence Based**: CPRIT's service grants are intended to fund effective and efficient systems of delivery of prevention services based on the existing body of knowledge about and evidence for cancer prevention in ways that far exceed current performance in a given service area. The provision of clinical services, including rescreening at the appropriate interval, must comply with established and current national guidelines (eg, US Preventive Services Task Force [USPSTF], American Cancer Society, Centers for Medicare and Medicaid Services [CMS], etc).

If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data (eg, availability of resources and screening coverage) for the target population and target service region are required. If no baseline data exist, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish a baseline.

Clinical Service and Community Partner Networks. Applicants are encouraged to coordinate and describe a coalition of clinical service providers and community partners that can deliver outreach, education, clinical, and navigation services to the most counties and the most people possible in a selected service region. Partnerships with other organizations that can support and leverage resources (ie, community-based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations, etc) are encouraged. Letters of commitment or memoranda of understanding describing their specific role in the partnership will strengthen the application. Leveraging of the infrastructure, existing networks, and other resources that were established for the eligible CPRIT-funded project are expected and should be well described.

Project Coordination and Technical Assistance. The overall program should be directed and overseen by the Program Director (PD) who is responsible for establishing and managing the network. Responsibilities of the PD include the following:

- Establishing any necessary subcontracts or memoranda of understanding with project partners and clinical service providers;
- Regularly communicating with partners to discuss progress and barriers, resolve potential problems, and provide technical assistance as needed throughout the duration of the project;
- Meeting all reporting requirements. CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based services, changes in provider practice, systems changes, and cost-effectiveness.

If applicable, in cases where the project proposes to work with multiple clinical providers, the PD should facilitate the establishment of standard protocols for all clinical service providers in the network as well as standard systems, policies, and procedures for the participating clinical service providers and organizations. These may include, but are not limited to, patient tracking and timely follow-up of all abnormal screening results and/or diagnoses of cancer.

Under this RFA, CPRIT **will not** consider the following**:**

- **Continuation of currently funded projects.** Projects must include the required expansion criteria detailed in the RFA.
- **New projects focusing solely on tobacco prevention and/or cessation for any age; these applicants** should apply under CPRIT's Tobacco Control and Lung Cancer Screening RFA.
- **New projects focusing on computerized tomography screening for lung cancer.** Applicants with new projects including lung cancer CT screening should apply under CPRIT's Tobacco Control and Lung Cancer Screening RFA.
- **New evidence-based cancer prevention services projects;** these applicants should apply under CPRIT's Evidence-Based Cancer Prevention Services RFA.
- **Projects that do not comply with established and current national guidelines and criteria (eg, USPSTF, American Cancer Society, CMS).**

- **Clinical tests/services proposed as part of the project that have not been recommended by the USPSTF due to lack of evidence available to draw reliable conclusions about benefits and harms of the tests. These include, but are not limited to, breast self-exams, clinical breast exams, and PSA tests.**
- **Projects focused solely on systems and/or policy change or solely on education and/or outreach that do not include the navigation to and delivery of cancer preventive clinical services.**
- **Projects focusing solely on case management/patient navigation services through the treatment phase of cancer.** Case management/patient navigation services, including survivor care plans, must be paired with the delivery of a clinical cancer prevention service and reported to CPRIT.
- **Projects focusing on screening the general population for genetic disposition to cancer.**
- **Resources for the treatment of cancer or viral treatment for hepatitis.**
- **Prevention/intervention research.** Applicants interested in prevention research should review CPRIT's Academic Research RFAs (available at http://www.cprit.texas.gov).

2.4 Priorities

Types of Cancer: Applications addressing the services listed in section 2.2 Project Objectives and that are responsive to this RFA will be considered for funding. See section 2.5 for specific areas of emphasis.

The Prevention Program's priorities for funding include the following:

1) **Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.**

CPRIT programs must address underserved populations. Underserved populations are subgroups that are disproportionately affected by cancer. CPRIT-funded efforts must address 1 or more of these priority populations:

- Underinsured and uninsured individuals
- Medically unserved or underserved populations
- Racial, ethnic, and cultural minority populations

- Populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened or who are significantly out of compliance with nationally recommended screening guidelines (more than 5 years for breast/cervical cancers).

The age of the priority population and frequency of screening for provision of clinical services described in the application must comply with established and current national guidelines (eg, USPSTF, American Cancer Society).

2) Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.

While disparities and needs exist across the state, CPRIT will also prioritize applications proposing to serve geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence. For this RFA, projects must propose to serve nonmetropolitan and/or MUAs of the state. In addition, projects addressing areas of emphasis (see section 2.5) will receive priority consideration.

Geographic and Population Balance in Current CPRIT portfolio

At the programmatic level of review conducted by the Prevention Review Council (see section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio (see https://www.cprit.texas.gov/our-programs/prevention/portfolio-maps and https://www.cprit.texas.gov/grants-funded?search=prevention).

2.5 Specific Areas of Emphasis

Applications addressing any of the services listed in section 2.2 and that are responsive to this RFA will be considered. For those services, CPRIT has identified the following areas of emphasis for this cycle of awards.

Primary Prevention
HPV Vaccination
• Increasing access to, delivery of, and completion of the HPV vaccine regimen to males and females through evidence-based intervention efforts in all areas of the state.[1]

Tobacco Prevention and Control
• Vulnerable and high-risk populations, including people with mental illness, history of substance abuse, youth, and pregnant women, that have higher tobacco usage rates than the general population.
• Areas that have higher smoking rates per capita than other areas of the state. Public Health Regions (PHR) 2, 4, 5, 8, and 9 have significantly higher tobacco use among adults than in other regions of the state.
Liver Cancer
• Screening for HBV infection and HCV infection in populations at high risk of infection.
• Increasing screening rates in PHR 8, 9, 10, and 11. Incidence and mortality rates are highest in PHR 10 and 11.[2]
Secondary Prevention - Screening and Early Detection Services
Colorectal Cancer
• Decreasing disparities in incidence and mortality rates of colorectal cancer in racial/ethnic populations. Blacks have the highest incidence and mortality rates, followed by non-Hispanic Whites and Hispanics.[2]
• Increasing screening/detection rates in PHR 2, 4, 5, and 9, where the highest rates of cancer incidence and mortality are found. • Decreasing incidence and mortality rates in nonmetropolitan counties. Incidence and mortality rates are higher in nonmetropolitan counties compared with metropolitan counties.[2]
Lung Cancer
• Decreasing disparities in incidence and mortality rates of lung cancer in racial/ethnic populations. Blacks have higher mortality rates than Hispanics and non-Hispanic Whites.
• Increasing screening/detection rates in PHR 2, 4, and 5, where the highest rates of cancer incidence and mortality are found.
Breast Cancer
• Decreasing disparities in mortality rates of breast cancer in racial/ethnic populations. The mortality rate is significantly higher in Blacks than in other populations.[2]
• Increasing screening/detection rates in medically underserved areas of the state.
Cervical Cancer
• Decreasing disparities in incidence and mortality rates of cervical cancer in racial/ethnic populations. Hispanics have the highest incidence rates while Blacks have the highest mortality rates.[2]
• Increasing screening/detection rates in medically underserved areas of the state.

2.6 Outcome Metrics

Applicants are required to clearly describe their assessment and evaluation methodology. The applicant is required to describe final outcome measures for the project. Output measures that are associated with the final outcome measures should be identified in the project plan and will serve as a measure of program effectiveness. Planned policy or system changes/improvements should be identified and the plan for qualitative analysis described. **Baseline data for each measure proposed are required**. In addition, applicants should describe how funds from the CPRIT grant will improve outcomes over baseline. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement to collect the data necessary to establish a baseline.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

If clinical services are being paid for and provided by others, the applicant is required to report on the number of clinical services and outcomes (eg, screenings/diagnostics, vaccinations, cancer precursors, cancers detected) that are delivered to the people navigated by the program.

- Quarterly progress report sections include, but are not limited to, the following:
  - Summary page, including narrative on project progress (required);
  - Services, other than clinical services, provided to the public/professionals;
  - Actions taken by people/professionals as a result of education or training;
  - Clinical services provided (county of residence of client is required); and
  - Precursors and cancers detected.

- Annual and final progress report sections include, but are not limited to, the following:
  - Key accomplishments, **including qualitative analysis of policy change and/or lasting systems change**;
  - Progress toward goals and outcome objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible individuals in a defined service area;
  - Materials produced and publications; and
  - Economic impact of the project.

2.7 Eligibility

- Eligible applicants include only those with currently or previously funded CPRIT Prevention projects that comply with established and current national guidelines, including tobacco cessation, lung cancer screening, primary prevention, and survivorship projects previously funded through other Prevention Program RFAs (see CPRIT Evidence-Based Cancer Prevention Services and Tobacco Control and Lung Cancer Screening RFAs).
- To justify the expansion, applicants must leverage the infrastructure and networks of the most recently funded CPRIT project.
- Applicants may submit an expansion application before the end of the currently funded project but should time their submission during the last year of the current project to ensure minimal overlap of funding. Unexpended funds from the original project will not carry forward to the expansion project. To apply for an expansion of a current project, projects must have at least 1 full year of results and data.
- The applicant must be a Texas-based entity that previously received CPRIT funding through Prevention Program RFAs.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted.
- The designated PD will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field and who resides in Texas during the time that the project is conducted.
- If the applicant or a partner is an existing Department of State Health Services (DSHS) contractor, CPRIT funds may not be used as a match, and the application must explain how this grant complements or leverages existing state and federal funds. DSHS contractors who also receive CPRIT funds must be in compliance with and fulfill all contractual obligations within CPRIT. CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor receiving funds from both entities.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT

funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.

- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization, (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.
- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way (whether slated to receive salary or compensation under the grant award or not) are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 6. All statutory provisions and relevant administrative rules can be found on the CPRIT website.

2.8 Resubmission Policy

- **One resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project or a change of title for a project that was previously

submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.

- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

2.9 Funding Information

The amount of funding that applicants may request is dependent on the primary focus of the project and on the type of expansion (see section 2.2 and section 2.3). Use the table below to determine the maximum amount of funding and the maximum number of years that may be requested.

Project Focus	Expansion Type	Maximum Amount of Funding	Maximum Duration
Cancer screenings/diagnostics	Initial	$2 million	3 years
Cancer screenings/diagnostics	Maintenance	$2.5 million	5 years
Healthy living/obesity control	Initial or Maintenance	$1 million	3 years
HPV/hepatitis B screening and vaccination/hepatitis C screening	Initial	$2 million	3 years
HPV/hepatitis B screening and vaccination/hepatitis C screening	Maintenance	$2.5 million	5 years
Survivor care	Initial or Maintenance	$1 million	3 years
Tobacco cessation	Initial or Maintenance	$2 million	3 years

Lung cancer screening and tobacco cessation	Initial	$2 million	3 years
Lung cancer screening and tobacco cessation	Maintenance	$2.5 million	5 years

A **significant expansion** in the geographic area and/or clinical services provided for the initial expansion, or number of clinical services delivered for any subsequent expansion, as described in section 2.3, is required. Grant funds may be used to pay for clinical services, navigation services, salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Applicants must ensure that there is access to treatment services for patients with precancers or cancers that are detected as a result of the program and must describe access to treatment services in their application.

Requests for funds to support construction or renovation or requests to support lobbying will not be approved under this mechanism. Cost sharing for equipment purchases is encouraged. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT funding should not be used to replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the **total** award amount.

3. KEY DATES

RFA release	October 19, 2021
Online application opens	November 15, 2021, 7 AM central time
Application due	February 9, 2022, 4 PM central time
Application review	March 2022–July 2022
Award notification	August 2022
Anticipated start date	August 31, 2022

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1 *Instructions for Applicants* document

It is **imperative** that applicants read the accompanying instructions document for this RFA that will be available November 15, 2021 (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2 Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (an individual who will help manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on November 15, 2021, and must be submitted by 4 PM central time on February 9, 2022. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.3 Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.4 Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Refer to the *Instructions for Applicants* document for details.

Submissions that are missing 1 or more components or do not meet the eligibility requirements may be administratively withdrawn without review.

4.4.1 Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need in the specific service area. Include rates of incidence, mortality, and screening in the service area compared to overall Texas rates. Describe barriers, plans to overcome these barriers, and the priority population to be served.
- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the services to be provided and the process/system for delivery of services and outreach to the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of clinical services delivered and number of people (public and/or professionals) served.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.4.2 Goals and Objectives (700 characters each)

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within both the stated Objective **and** the Measure sections (eg, Measure: 2,000 individuals, age 9-12, will initiate HPV vaccination during the grant period). Applications may be returned for revision if the proposed metric is not included within the Measure section. Refer to the *Instructions for Applicants* document for details.

The maximum number is 3 goals with 3 outcome objectives each. Projects will be evaluated annually on progress toward outcome goals and objectives. See Appendix B for instructions on writing outcome goals and objectives.

A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target. If a baseline has not been defined, applicants are required to explain plans to establish baseline and describe method(s) of measurement.

4.4.3 Project Timeline (2 pages)

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3 and Months 1, 2, 3, etc, as applicable (eg, Year 1, Months 3-5), instead of specific months or years. Month 1 is the first full month of the grant award.

4.4.4 Project Plan (12 pages; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below.

Background: Briefly present the rationale behind the proposed service, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the priority population. Describe the race, ethnicity, age, and other defining characteristics of the population to be served.

If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the priority population and target service area are required where applicable.

Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are encouraged.

Goals and Objectives: Process objectives should be included in the project plan. Outcome goals and objectives will be entered in separate fields in CARS. However, if desired, outcome goals and objectives may be fully repeated or briefly summarized here. See Appendix B for instructions on writing goals and objectives.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services as well as anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. Describe why this project is nonduplicative. Describe how the proposed project leverages the infrastructure, networks, and resources that have been put in place by the most recently funded CPRIT project while minimizing start-up time.

Clearly describe and differentiate between the ongoing project components in the previous project and any new components; include counties served and number of clinical services provided in the original or initial expansion project as compared to the current application.

It is important to distinguish between Texas counties where the project proposes to deliver services and counties of residence of population served (see Appendix A for definitions and *Instructions for Applicants*). Only counties with service delivery should be listed in the Geographic Area to be Served section of the application. Projecting counties of residence of population served is not required but may be described in the project plan.

Clearly demonstrate the ability to provide the proposed service and describe how results will be improved over baseline and the ability to reach the priority population. Describe the method(s) that will be used to recall for appropriate rescreening those individuals who have been screened through this project. Describe any planned policy changes or system improvements.

If clinical services are being paid for and provided by others, the applicant must explain and report on the number of clinical services and outcomes (eg, screenings/diagnostics, vaccinations, cancer precursors, cancers detected) that are delivered to the people navigated by the program. Applicants must also clearly and thoroughly describe **access to treatment** services should precancer or cancer be detected. Include how and by whom any positive screening results will be delivered to a program participant.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the plan for outcome and output measurements, including qualitative analysis of policy and system changes. Describe data collection and management methods, data analyses, and anticipated results. Evaluation and reporting of results should be headed by a professional who has demonstrated expertise in the field. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, or the like. Applicants should budget

accordingly for the evaluation activity and should involve that professional during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing health programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. The applicant should demonstrate how the organizational environment will contribute to a successful project. If equipment or physical resources are required to carry out the project, the applicant should describe the availability of these resources and the organizational capacity to use the equipment. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

CPRIT acknowledges that full maintenance and sustainability of projects when CPRIT funding ends may not be feasible, especially in cases involving the delivery of clinical services. However, it is important to consider sustainability early in the life cycle of a project, particularly regarding organizational characteristics and processes that are modifiable.

Washington University in St Louis has developed a useful tool (Program Sustainability Assessment Tool) to assess program capacity for sustainability. The tool assesses several factors that contribute to program sustainability. These factors include environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communication, and strategic planning. Applicants are not required to use this tool; however, it provides practical guidance on factors that should be considered and should be included in the application to describe a program's organizational capacity for sustainability.

It is expected that steps toward building sustainability capacity for the program will be taken and plans for such be briefly described in the application. The applicant should assess and describe the factors that will contribute to the organization's capacity to facilitate sustainability.

Dissemination and Replication: Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination efforts should consider the message, source, audience, and channel (Brownson, R.C., et al. *J Pub Health Manag Pract*. 24(2):102-111,

March/April 2018). Dissemination methods may include, but are not limited to, presentations at workshops and seminars, one-on-one meetings, publications, news media, social media, etc.

While passive dissemination methods are common (eg, publications, presentations at professional meetings), plans should include some active dissemination methods (eg, meetings with stakeholders, blogs, social media). Applicants should describe their dissemination plans. The plans should include the kinds of audiences to be targeted and methods for reaching the targeted audiences.

Replication by others is an additional way to disseminate the project. For applicable components, describe how the project or components of the project lend themselves to application by other communities and/or organizations in the state or expansion in the same communities. Describe what components of this project can be adapted to a larger or lower-resource setting. Note that some programs may have unique resources and may not lend themselves to replication by others.

4.4.5 People Reached (Indirect Contact)

Provide the estimated overall number of people (members of the public and professionals) to be reached by the funded project. The applicant is required to itemize separately the types of indirect noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to Appendix A for definitions.

4.4.6 Number of Services Delivered (Direct Contact)

Provide the estimated overall number of services directly delivered to members of the public and to professionals by the funded project. Each individual service should be counted, regardless of the number of services one person receives. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimate provided. Refer to Appendix A for definitions.

4.4.7 Number of Clinical Services Delivered

Provide the estimated overall number of clinical services directly delivered to members of the public by the funded project. Each individual clinical service should be counted, regardless of the number of services one person receives. Separately itemize the clinical services, with estimates, that led to the calculation of the overall estimate provided. Refer to Appendix A for definitions.

4.4.8 Number of Unique People Served (Direct Contact)

Provide the estimated overall number of unique members of the public and professionals served by the funded project. One person may receive multiple services but should only be counted once here. Refer to Appendix A for definitions.

4.4.9 References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed services.

4.4.10 Resubmission Summary

Use the template provided on the CARS (https://CPRITGrants.org). Describe the approach to the resubmission and how reviewers' comments were addressed. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed.

The summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.4.11 Most Recently Funded Relevant Project Summary (3 pages)

Upload a summary that outlines the progress made with the most recently funded relevant CPRIT award. Applicants must describe results and outcomes of the most recently funded relevant award and demonstrate why further funding is warranted.

Please note that a different set of reviewers from those assigned to the previously funded application may evaluate this application. Applicants should make it easy for reviewers to compare the most recently funded relevant project with the proposed expansion project.

In the description include the following:

- Describe the evidence-based intervention, its purpose, and how it was implemented in the priority population. Describe any adaptations made for the population served.
- List approved goals and objectives of the most recently funded grant.

- For each objective, provide milestones/target dates and target metrics as compared to actual completion dates and metrics.
- Include a discussion of objectives not fully met. Explain any barriers encountered and strategies used to overcome these.
- For the most recently funded relevant project, describe major activities; significant results, including major findings, developments, or conclusions (both positive and negative); and key outcomes. If the project has not yet ended, provide projections for completion dates and final metrics.
- Describe steps taken toward sustainability for components of the project. Fully describe systems or policy improvements and enhancements.
- Describe how project results were disseminated or plans for future dissemination of results.

4.4.12 CPRIT Grants Summary

Use the template provided on the CARS (https://CPRITGrants.org). Provide a listing of **all** projects funded by the CPRIT Prevention program for the PD and the Co-PD, regardless of their connection to this application.

4.4.13 Budget and Justification

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications requesting more than the maximum allowed cost (total costs) as specified in section 2.9 will be administratively withdrawn.

Clearly describe any organizational cost-sharing or pro-bono contributions related to this project, as well as any attempts made or successes to secure other state/federal funds.

- **Average Cost per Service:** The average cost per service will be automatically calculated from the total cost of the project divided by the total number of services delivered (refer to Appendix A). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.

- **Average Cost per Person:** The average cost per person will be automatically calculated from the total cost of the project divided by the total number of unique people served (refer to Appendix A).
- **Average Cost per Clinical Service:** The average cost per clinical service will be automatically calculated from the total cost of the project divided by the total number of clinical services delivered (refer to Appendix A).
- **Personnel:** The individual salary cap for CPRIT awards is $200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- **Equipment:** Equipment having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.
- **Services Costs:**
    - CPRIT reimburses for services using Medicare reimbursement rates. Describe the source of funding for all services where CPRIT funds are not requested. If clinical services are being paid for and provided by others, the applicant is required to explain and report on the number of clinical services and outcomes (eg, screenings/diagnostics, vaccinations, cancer precursors, cancers detected) that are delivered to the people navigated by the program.
    - CPRIT does not allow recovery of costs related to tests that have not been recommended by the USPSTF, including breast self-exams, clinical breast exams, and PSA tests; the Task Force has concluded there is not enough evidence available to draw reliable conclusions about the additional benefits and harms of these tests. (See https://www.uspreventiveservicestaskforce.org/)
- **Other Expenses:**
    - **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant.

CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is $25.

- **Costs Not Related to Cancer Prevention and Control:** CPRIT does not allow recovery of any costs for services not related to cancer (eg, health physicals, HIV testing) other than those required prior to the clinical services proposed in the project.

- **Indirect/Shared Costs:** Texas law limits the amount of grant funds that may be spent on indirect/shared expenses to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules.

4.4.14 Current and Pending Support and Sources of Funding

Use the template provided on the CARS (https://CPRITGrants.org). Describe the funding source and duration of **all** current and pending support for the proposed project, including a capitalization table that reflects private investors, if any.

4.4.15 Biographical Sketches

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

- Use the Co-PD Biographical Sketch section ONLY if a Co-PD has been identified.
- The evaluation professional must provide a biographical sketch in the Evaluation Professional Biographical sketch section.
- Up to 3 additional biographical sketches for key personnel may be provided in the Key Personnel Biographical Sketch section.

Each biographical sketch must not exceed 5 pages and should use either the "Prevention Programs: Biographical Sketch" template provided on the CARS (https://CPRITGrants.org) or the NIH Biographical Sketch format. Only biographical sketches will be accepted; do not submit resumes and/or CVs. If a position is not yet filled, please upload a job description.

4.4.16 Collaborating Organizations

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (eg, evaluation, clinical services, recruitment to screening). Please be sure to also include anyone listed as key personnel and/or listed under the Current & Pending Support section.

4.4.17 Letters of Commitment (10 pages)

Applicants should provide letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program. Letters should be specific to the contribution of each organization.

5. APPLICATION REVIEW

5.1 Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and

eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2 Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1 Primary Evaluation Criteria

Impact

- Do the proposed services address an important problem or need in cancer prevention and control? Do the proposed project strategies support desired outcomes in cancer incidence, morbidity, and/or mortality? Do the proposed project strategies reach a priority population (eg, low income, minority, rural) at high risk of cancer?
- For the proposed expansion, does the project build on its initial results (baseline)? Does it go beyond the initial project to address what the applicant has learned or explore new partnerships, new audiences, or improvements to systems?
- Will the project reach and serve/impact an appropriate number of people based on the budget allocated to providing services and the cost of providing services?
- If applicable, have partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than the applicant organization's effort separately?
- Does the program address adaptation, if applicable, of the evidence-based intervention to the priority population? Is the base of evidence clearly explained and referenced?

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?
- Are the overall program approach, strategy, and design clearly described and supported by established theory and practice? Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Has the applicant proposed policy changes and/or system improvements?

- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the priority population and culturally appropriate methods to reach the priority population clearly described?
- If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including follow-up for abnormal results and access to treatment?
- Does the program leverage partners and resources to maximize the reach of the services proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

- Are specific outcome goals and measurable objectives for each year of the project provided?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- If clinical services are being paid for and provided by others, does the applicant explain the methods used to collect data and report on these clinical services and outcomes?
- Does the application provide a clear and appropriate plan for data collection and management and data analyses?
- Are clear baseline data provided for the priority population, or are clear plans included to collect baseline data?
- If an evidence-based intervention is being adapted in a population where it has not been implemented or tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services?

- Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?
- Have the appropriate personnel been recruited to design, implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?
- Does the applicant describe their current activities and the program's organizational capacity for sustainability?
- Does the applicant describe steps that will be taken toward building internal capacity and partnerships?
- Does the applicant describe a plan for systems changes that are sustainable over time; eg, improve results, provider practice, efficiency, cost-effectiveness?

5.2.2 Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Replication

- Are plans for dissemination of the project's results and outcomes, including target audiences and methods, clearly described?
- Are active dissemination strategies included and described in the plan?
- Does the applicant describe whether and/or how the project lends itself to replication of all or some components of the project by others in the state?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has

approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1 Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the helpdesk, please refer to the *Instructions for Applicants* document (posted on November 15, 2021), which provides a step-by-step guide to using CARS.

Hours of operation:	Monday through Friday, 8 AM to 6 PM central time
Tel:	866-941-7146
Email:	Help@CPRITGrants.org

7.2 Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel:	512-305-8417
Email:	Help@CPRITGrants.org
Website:	www.cprit.texas.gov

8. RESOURCES

- The Texas Cancer Registry. https://www.dshs.texas.gov/tcr or contact the Texas Cancer Registry at the Department of State Health Services.
- The Community Guide. https://www.thecommunityguide.org/
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, R.C., Colditz G.A., and Proctor, E.K. (Editors). *Dissemination and Implementation Research in Health: Translating Science to Practice.* Oxford University Press, March 2012
- Program Sustainability Assessment Tool, copyright 2012, Washington University, St Louis, MO, https://www.sustaintool.org/about-us/
- Getting the Word Out: New Approaches for Disseminating Public Health Science. Ross C. Brownson, PhD; Amy A. Eyler, PhD; Jenine K. Harris, PhD; Justin B. Moore, PhD, MS; Rachel G. Tabak, PhD, RD, *Journal of Public Health Management & Practice***.** 24(2):102-111, March/April 2018. (https://journals.lww.com/jphmp/Fulltext/2018/03000/Getting_the_Word_Out___New_Approaches_for.4.aspx)
- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs. http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability. http://www.cdc.gov/pcd/issues/2014/13_0185.htm
- Cancer Prevention and Control Research Network: Putting Public Health Evidence in Action Training Workshop. http://cpcrn.org/pub/evidence-in-action/
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. https://www.cdc.gov/os/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

9. REFERENCES

1. http://www.cdc.gov/hpv/parents/questions-answers.html
2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services. https://www.cancer-rates.info/tx/

APPENDIX A: KEY TERMS

- **Activities:** A listing of the "who, what, when, where, and how" for each objective that will be accomplished.
- **Capacity Building:** Any activity (eg, training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention.
- **Clinical Services:** Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Other examples include genetic testing or assessments, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments, and family history screening.
- **Counties of Residence of Population Served:** Counties where the project does not plan to have a physical presence but people who live in these counties have received services. This includes counties of residence of people or places of business of professionals who participate in or receive education, navigation, or clinical services. Examples include people traveling to receive services as a result of marketing and programs accessible via the website or social media. These counties may be described in the project plan and must be reported in the quarterly progress report.
- **Counties with Service Delivery:** Counties where an activity or service will occur and the project has a physical presence for the services provided. Examples include onsite outreach and educational activities and delivery of clinical services through clinics, mobile vans, or telemedicine consults. These counties must be entered in the Geographic Area to be Served section of the application.
- **Education Services:** Number of evidence-based, culturally appropriate cancer prevention and control education and outreach services delivered to the public and to health care professionals. Examples include education or training sessions (group or individual), focus groups, and knowledge assessments. One individual may receive multiple education services.

- **Evidence-Based Program:** A program that is validated by some form of documented research or applied evidence. CPRIT's website provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit https://www.cprit.state.tx.us/our-programs/prevention.
- **Goals:** Broad statements of general purpose to guide planning. Outcome goals should be few in number and focus on aspects of highest importance to the project. (Appendix B)
- **Integration:** The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice.
- **Navigation Services:** Number of unique activities/services that offer assistance to help overcome health care system barriers in a timely and informative manner and facilitate cancer screening and diagnosis to improve health care access and outcomes (Examples include patient reminders, transportation assistance, and appointment scheduling assistance). One individual may receive multiple navigation services.
- **Number of Clinical Services:** Number of clinical services delivered directly to members of the public by the funded project. One individual may receive multiple clinical services.
- **Number of Services (Direct Contact):** Number of services delivered directly to members of the public and/or professionals—direct, interactive public or professional education, outreach, training, navigation service, or clinical service, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. One individual may receive multiple services.
- **Objectives:** Specific, measurable, actionable, realistic, and timely projections for outcomes; example: "Increase screening service provision in X population from Y% to Z% by 20xx." Baseline data for the priority population must be included as part of each objective. (Appendix B). The proposed metric should be included in **both** the objective and the measure (eg, Measure: 2,000 individuals, age 9-12, will initiate HPV vaccination during the grant period).
- **People Reached (Indirect Contact):** Number of members of the public and/or professionals reached via indirect noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service

announcements, newsletters, and journals. (This category includes individuals who would be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project).

- **Unique People Served (Direct Contact):** Number of unique members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service, or clinical service. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.

APPENDIX B: WRITING GOALS AND OBJECTIVES

List only major **outcome goals** and **measurable objectives** for each year of the project. **Do not include process objectives**; these should be described in the project plan only. Include the proposed metric within **both** the stated objective and the measure (eg, Measure: 2,000 individuals, age 9-12, will initiate HPV vaccination during the grant period).

The maximum number is 3 goals with 3 objectives each. Projects will be evaluated annually on progress toward **outcome** goals and objectives.

The following guide has been adapted with permission from Appalachia Community Cancer Network, NIH Grant U54 CA 153604:

Develop well-defined goals and objectives.

Goals provide a roadmap or plan for where a group wants to go. Goals can be long term (over several years) or short term (over several months). Goals should be based on needs of the community and evidence-based data.

Goals should be:

- Believable – situations or conditions that the group believes can be achieved
- Attainable – possible within a designated time
- Tangible – capable of being understood or realized
- On a timetable – with a completion date
- Win-Win – beneficial to individual members and the coalition

Objectives are measurable steps toward achieving the goal. They are clear statements of specific activities required to achieve the goal. The best objectives have several characteristics in common – S.M.A.R.T. + C:

- Specific – they tell how much (number or percent), who (participants), what (action or activity), and by when (date)
    - Example: 115 uninsured individuals age 50 and older will complete colorectal cancer screening by March 31, 2018.
- Measurable – specific measures that can be collected, detected, or obtained to determine successful attainment of the objective

- Example: How many screened at an event? How many completed pre/post assessment?
- Achievable – not only are the objectives themselves possible, it is likely that your organization will be able to accomplish them
- Relevant to the mission – your organization has a clear understanding of how these objectives fit in with the overall vision and mission of the group
- Timed – developing a timeline is important for when your task will be achieved
- Challenging – objectives should stretch the group to aim on significant improvements that are important to members of the community

Evaluate and refine your objectives

Review your developed objectives and determine the type and level of each using the following information:

There are 2 types of objectives:

- Outcome objectives – measure the "what" of a program; should be in the Goals and Objectives form (see section 4.4.2)
- Process objectives – measure the "how" of a program; should be in the project plan only (see section 4.4.4)

There are 3 levels of objectives:

- Community-level – objectives measure the planned community change
- Program impact – objectives measure the impact the program will have on a specific group of people
- Individual – objectives measures participant changes resulting from a specific program, using these factors:
  - Knowledge – understanding (know screening guidelines; recall the number to call for screening)
  - Attitudes – feeling about something (will consider secondhand smoke dangerous; believe eating 5 or more fruits and vegetable is important)
  - Skills – the ability to do something (complete fecal occult blood test)
  - Intentions – regarding plan for future behavior (will agree to talk to the doctor, will plan to schedule a Pap test)

- Behaviors (past or current) – to act in a particular way (will exercise 30+ minutes a day, will have a mammogram)

Well-defined outcome goals and objectives can be used to track, measure, and report progress toward achievement.

Summary Table

	Outcome – Use in Goals and Objectives	Process – Use in Project Plan only
Community-level	WHAT will change in a community ***Example:*** *As a result of CPRIT funding, fecal immunochemical tests (FIT) will be available to 1,500 uninsured individuals age 50 and over through 10 participating local clinics and doctors.*	HOW the community change will come about ***Example:*** *Contracts will be signed with participating local providers to enable uninsured individuals over age 50 have access to free colorectal cancer screening in their communities.*
Program impact	WHAT will change in the target group as a result of a particular program ***Example:*** *As a result of this project, 200 uninsured women between 40 and 49 will receive free breast and cervical cancer screening.*	HOW the program will be implemented to affect change in a group/population ***Example:*** *2,000 female clients, between 40 and 49, will receive a letter inviting them to participate in breast and cervical cancer screening.*
Individual	WHAT an individual will learn as a result of a particular program, or WHAT change an individual will make as a result of a particular program ***Example:*** *As a result of one-to-one education of 500 individuals, at least 20% of participants will participate in a smoking cessation program to quit smoking.*	HOW the program will be implemented to affect change in an individual's knowledge or actions ***Example:*** *As a result of one-to-one counseling, all participants will identify at least 1 smoking cessation service and 1 smoking cessation aid.*

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Prevention Peer Review Meeting (22.2 PRV-PP1)
Observation Report

Report No.	2022-04-25 22.2_PRV-PP1
Program Name:	Prevention
Panel Name:	22.2 Prevention Peer Review Meeting (22.2 _PRV-PP1)
Panel Date:	April 25, 2022
Report Date:	April 28, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Prevention Peer Review Meeting (22.2_PRV-PP1) meeting. The meeting was chaired by Nancy Lee and conducted via videoconference on April 25, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twelve (12) applications were discussed and three (3) applications were not discussed
- Panelists: One (1) panel chair, ten (10) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Prevention Review Council Programmatic Review Meeting (22.2_PRV_PRC)
Observation Report

Report No.	2022-06-03 22.2_PRV_PRC
Program Name:	Prevention
Panel Name:	22.2 Prevention Review Council Programmatic Review Meeting (22.2 _PRV_PRC)
Panel Date:	June 3, 2022
Report Date:	June 8, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Prevention Review Council Programmatic Review Meeting (22.2_PRV_PRC) meeting. The meeting was chaired by Stephen Wyatt and conducted via videoconference on June 3, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Nine (9) applications were discussed
- Panelists: One (1) panel chair, and two (2) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: One (1)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was one (1) Conflict of Interest (COI) identified prior to and/or during the meeting. The COI was excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

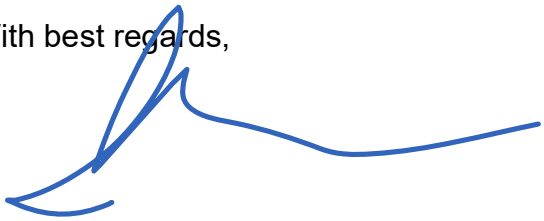
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Prevention Cycle 22.2

Awards Announced at the August 17, 2022, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 22.2 include: *Evidence-Based Cancer Prevention Services* and *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations.*

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/Principal Investigator	Principal Investigator Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
PP220037	Schmeler, Kathleen	The University of Texas M.D. Anderson Cancer Center	Brownson, Ross
Applications not considered by the PIC or Oversight Committee:			
No reported COIs.			

T.A.C. Section 702.19 Waiver

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	T.A.C. § 702.19 STANDING WAIVER FOR FY 2022
DATE:	SEPTEMBER 10, 2021

Summary

This is to notify the Oversight Committee that pursuant to the authority provided to the Chief Executive Officer in T.A.C. § 702.19(e), I grant CPRIT's Chief Prevention Officer Ramona Magid a waiver from the general prohibition against communicating with grant applicants. The waiver is applicable for FY 2022 and will be effective for all prevention review cycles planned during the fiscal year. No Oversight Committee action related to this waiver is necessary.

Background and Discussion

The Chief Prevention Officer is a statutorily mandated member of the Program Integration Committee (PIC). Texas Administrative Code § 702.19 prohibits substantive communication between a grant applicant and a member of a peer review panel, the PIC, or the Oversight Committee while the application is pending a final decision. The restriction on communication prevents even the appearance of unequal treatment during the grant review process.

Traditionally, a chief program officer leads each CPRIT program with the assistance of a program manager who fields inquiries from and provides technical help to applicants completing their CPRIT grant applications. I promoted Ms. Magid to the Chief Prevention Officer position upon Dr. Becky Garcia's retirement in June 2019. However, the prevention program manager position has remained vacant since Ms. Magid's promotion. Until CPRIT fills the program manager position, she is the sole point of contact for the prevention program. The communication waiver is necessary so that Ms. Magid can assist grant applicants who have questions during the application process.

Like the FY 2021 waiver, I am granting a standing waiver for Ms. Magid for FY 2022 as long as she remains the sole point of contact for the prevention program. Approving this standing waiver does not favor any grant applicant over another. Ms. Magid will provide technical assistance only and will not comment on the substance of a grant application. CPRIT will include this waiver in the grant record for the FY 2022 prevention grant applications.

De-Identified Overall Evaluation Scores

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

Prevention Cycle 22.2

Application ID	Final Overall Evaluation Score
PP220034*	1.8
PP220038*	2.3
PP220037*	2.9
PP220051*	4.5

* Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

June 13, 2022

Dr. Mahendra Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

Dear Mr. Roberts and Dr. Patel,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for the FY2022 Cycle 2 Evidence-Based Cancer Prevention Services (EBP) and Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations and (EPS) grant awards.

The PRC met on June 3, 2022, to consider the applications recommended by the peer review panel following their April 25, 2022, meeting. The PRC recommends 9 projects totaling $14,443,836. One of the recommended projects, PP220024, was submitted and reviewed in FY2022 Cycle 1 but the PRC took no action on the application at that time.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PRC made no changes to the goals, project objectives, or timelines of the applications.

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary, or tertiary prevention. In making these recommendations the PRC continued to consider the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All the recommended grants address one or more of the Prevention Program priorities.

Sincerely,
Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

Attachment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Cycle 22.2 Recommended Prevention Program Awards

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP220036	EBP	Increasing the use of HPV vaccination services among medically underserved young adults	Roncancio, Angelica M	University of Houston	1.6	1	$991,308
PP220034	EPS	Screening to Optimize Prevention of CRC in East Texas (STOP CRC ET)	McGaha, Paul	The University of Texas Health Center at Tyler	1.8	2	$2,482,127
PP220038	EPS	Advancing Implementation of Evidence-Based Strategies for Tobacco Prevention and HPV Vaccination in Pediatric Safety Net Settings	Montealegre, Jane R	Baylor College of Medicine	2.3	3	$2,499,180
PP220045	EBP	Inpatient Screening and Treatment for Unhealthy Alcohol Use and Tobacco Use as a means of cancer prevention	Ramesh, Jananie	The University of Texas at Austin	2.6	4	$999,957
PP220037	EPS	Project ACCESS: Increasing Access to Cervical Cancer Screening & Treatment Services in Texas	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	2.9	5	$2,498,445
PP220024	EBP	Promoting Prevention in Survivorship Care in Rural Texas	Kvale, Elizabeth	The University of Texas at Austin	3.3	6	$975,851
PP220041	EBP	Fecal Immunochemical Testing for Screening and Treatment of Occult Neoplasia (FIT-STOP)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	4.0	7	$999,999
PP220051	EPS	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations- Program title: GetFIT	Mika, Virginia	University Health System	4.5	8	$1,999,849
PP220035	EBP	DEFEAT breast cancer: Delivering Education, Focused navigation, and Equitable Access throughout East Texas.	McGaha, Paul	The University of Texas Health Center at Tyler	5.0	9	$997,120

EBP: Evidence-Based Cancer Prevention Services
EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
Company Relocation Product Development Awards

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA C-22.2-RELCO

Company Relocation Product Development Research Awards

Please also refer to the Instructions for Applicants document, which will be posted on December 1, 2021

Application Receipt Opening Date: December 1, 2021

Application Receipt Closing Date: January 26, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

Rev	11/3/2021	RFA release

1. KEY POINTS

This Company Relocation Product Development Research Award mechanism is governed by the following guidelines:

- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools. Products must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- For therapeutics, Product Development Research award funding supports preclinical research and early clinical research necessary to demonstrate initial clinical safety and efficacy (typically phase 1, phase 2A).
- Recipient companies must commit to be Texas based (see section 8.1) and must have a chief executive officer (CEO) as part of the applicant's management team prior to submitting an application. The Cancer Prevention and Research Institute of Texas (CPRIT) requires the use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-state entities.
- CPRIT requires recipient companies to raise a portion of the total project budget from external sources. For a company receiving an initial CPRIT award, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the recipient company. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds should, whenever possible, be spent in Texas. A company's matching funds must be dedicated to the CPRIT-funded project but may be spent outside of Texas.
- For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company. More details on the matching funds requirements are provided below.
    - A grantee approved for 1 or more product development grants that together total a commitment of $20 million or less must dedicate to each grant project $1 of their own funds for every $2 of CPRIT grant award funds.
    - A grantee approved for a product development grant award that causes the total amount of committed CPRIT product development grant award funds to exceed $20 million must increase their matching fund obligation to $1 for every $1

contributed by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under the matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.

  - A company approved for a grant award that would result in more than $30 million in CPRIT product development grant funds must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

- Applicants may request up to $20 million in CPRIT funds. CPRIT receives many more applications each year than available funds can support. While all requests for funding must be well justified, a funding request at or near the maximum amount will be heavily scrutinized. Such a request must be exceptionally well justified to warrant dedicating a large percentage of CPRIT's product development research budget to the applicant's project.
- Funding will be tranched and tied to the achievement of contract-specified milestones. The contract-specific milestones are the Goals & Objectives submitted by the applicant within the proposal. The progress-based release of funds will be dependent upon the completion of the applicant's proposed Goals & Objectives for each project year.
- All award contracts include a revenue-sharing agreement. **A copy of the revenue-sharing agreement can be found at www.cprit.texas.gov in the Product Development Research Program section.** Other contract provisions are specified in CPRIT's Administrative Rules, which are also available at www.cprit.texas.gov.
- An application last submitted but not funded (including resubmission) before December 4, 2019), may be submitted as a new application, even if it was previously resubmitted (see section 8.2).
- Applicant companies are limited to 1 submission per cycle across all CPRIT Product Development award mechanisms.

2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2.1. Product Development Research Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. CPRIT has established overarching principles and each of CPRIT's 3 grantmaking programs (Academic Research, Prevention and Product Development Research) have established program-specific priorities. Additional priorities focused at the intersection of the 3 programs have also been established and outlined below. The Product Development Research Program's principles and priorities guide CPRIT staff and the Product Development Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to RFAs.

CPRIT's Established Principles:

- Scientific excellence and impact on cancer

- Increasing the life sciences infrastructure

CPRIT's Academic Research, Prevention, and Product Development Research Cross-Program Priorities:

- Prevention and early detection initiatives
- Translation of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science infrastructure

CPRIT's Product Development Research Priorities:

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits not currently available; ie, disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early-stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas institutions • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff, to lead to seed clusters of life science expertise at various Texas locations • Providing appropriate return on Texas taxpayer investment

A full description of CPRIT's program priorities may be found at http://priorities.cprit.texas.gov/.

3. EXECUTIVE SUMMARY

CPRIT will foster cancer research as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. This RFA solicits applications for the research and development of innovative products addressing critically important needs related to diagnosis, prevention, and/or treatment of cancer and the product development infrastructure needed to support these efforts. CPRIT encourages applicants who seek to apply or develop state-of-the-art products, services (eg, contract research organization services), technologies, tools, and/or resources for cancer research, prevention, or treatment. The award mechanism described in this RFA is designed to encourage the relocation of existing oncology-focused companies or a substantial portion of their business to Texas. CPRIT expects

outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. The overall goal of this award program is to improve outcomes of patients with cancer by accelerating the development of groundbreaking therapeutics, diagnostics, and tools with a primary focus on Texas-centric programs.

4. MECHANISM OF SUPPORT

The goal of the Company Relocation Product Development Research Award is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will provide companies or limited partnerships that are willing to relocate all or a substantial portion of their business to Texas with the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award is intended to support companies that will be staffed with a majority of Texas-based employees, including C-level executives.

5. OBJECTIVES

The State of Texas seeks to attract industry partners in the field of cancer care to advance economic development and cancer care efforts in the state. The goal of this award mechanism is to recruit to Texas companies with proven management teams who are focused on exceptional product opportunities to improve cancer care. These companies must presently be domiciled outside of Texas and have sufficient personnel to operate the Texas-based research and/or development activities of the company and, along with appropriate management, must be willing to relocate to or be hired and remain in Texas for a specified period after funding.

The long-term objective of this award is to support commercially oriented therapeutic and medical technology products, diagnostic or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA should be the intent to further the research and development of products that would

eventually be approved and marketed for the diagnosis, prevention, and/or treatment of cancer. Eligible products or services include—but are not limited to—therapeutics (eg, small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques.

CPRIT seeks to maximize the clinical impact of our funding. Hence, we focus investment in translational research and development activities, including the following eligible stages:

- Studies that establish preclinical proof of concept
- GLP studies to support INDs
- Phase 1 to establish safety and a maximally tolerated dose
- Phase 2 studies to determine safety and efficacy in initial targeted patient populations (up to 100 patients)

CPRIT typically does not fund efforts outside of these parameters. We do not consider studies larger than what are described as "translational" and, hence, such studies are outside the scope of our interest. Companies that have clinically demonstrated safety and efficacy should be able to acquire necessary capital via other sources. By exception, later clinical trials or later-stage product development projects may be considered where exceptional circumstances warrant CPRIT investment.

CPRIT's objectives and program priorities are established by its Oversight Committee. Consistent with the above, these priorities include "funding projects at Texas companies and relocating companies that are most likely to bring important products to the market." A full description of CPRIT's program priorities may be found at http://priorities.cprit.texas.gov/.

6. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development project proposed. Requested funds must be well justified. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property (IP) acquisition and protection, external consultants and service providers, travel in support of the project, and other appropriate research and development costs, subject to certain limitations set forth by Texas law. If a company is working on multiple

projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the state. Texas law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

For companies receiving an initial CPRIT award, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the company. The demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be fulfilled on a year-by-year basis.

For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company.

A grantee approved for 1 or more product development grants that together total a commitment of $20 million or less must dedicate to each grant project $1 of their own funds for every $2 of CPRIT grant award funds.

A grantee approved for a product development grant award that causes the total amount of committed CPRIT product development grant award funds to exceed $20 million must increase their matching fund obligation to $1 for every $1 contributed by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives three product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under the matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.

A company approved for a grant award that would result in more than $30 million in CPRIT product development grant funds must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

7. KEY DATES

RFA release	November 3, 2021
Online application opens	December 1, 2021, 7 AM central time
Applications due	January 26, 2022, 4 PM central time
Invitations to present sent	March 2022
Notifications sent if not invited	March 2022
Presentations to CPRIT*	April 2022
Award Notification	August 2022
Anticipated Start Date	September 2022

***** Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

8. ELIGIBILITY

8.1. Applicants

- Either for-profit or nonprofit companies may apply. However, nonprofit companies must intend to bring a product to market. Applications may be submitted prior to company formation, but company formation must be completed before award receipt. Applicants will be required to provide a data universal numbering system (DUNS) number before award receipt.
- Applicants may be located outside the State of Texas when the application is submitted and reviewed. However, CPRIT requires the grant applicant to demonstrate that it will relocate to Texas as a condition of the grant award. A company is considered to be Texas based if it currently fulfills or commits to fulfilling a majority of the following criteria:

    1. The US headquarters is physically located in Texas.
    2. The chief executive officer resides in Texas.
    3. A majority of the company's personnel, including at least 2 other C-level employees (or equivalent) reside in Texas.
    4. Manufacturing activities take place in Texas.
    5. At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.

6. At least 1 clinical trial site is in Texas.
7. The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

In exceptional circumstances, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.

- Unless otherwise specified by the award contract, the company must fulfill all location requirements identified in the application within 1 year of receiving the initial disbursement of funds. Failure to maintain compliance with the location criteria will result in consequences ranging from suspension of grant funding to early termination of the grant contract and repayment of grant funds.
- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools. Project must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- An application last submitted (including resubmissions) before December 4, 2019), may be submitted as a new application, even if it was previously resubmitted.
- CPRIT is releasing 3 Product Development RFAs in this funding cycle. Please note that in any given application round, applicants are allowed to apply for only 1 Product Development award (TXCO, RELCO, or SEED). Applicants are advised to review each RFA and select the program that best fits their development status.
- Only 1 coapplicant may be included on the application. For the Product Development Research Program, a coapplicant is an individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. If so designated by the applicant organization, coapplicants share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple applicants are named, each is responsible and accountable for the proper conduct of the project, program, or activity, including the submission of all required reports. The presence of more than 1 applicant on an application or award diminishes neither the responsibility nor the accountability of any individual applicant.

- An applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, or any company officer or director (or any person related to 1 or more of these individual within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or other individuals are ineligible to receive federal grant funds or have had a grant terminated for cause, the applicant may be contacted to provide more information.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although the applicant need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

8.2. Resubmission Policy

- An application previously submitted to CPRIT within the last 2 years (after December 4, 2019) but not funded may be resubmitted once and must follow all resubmission guidelines. **An application that was last submitted before December 4, 2019, may be submitted as a new application, even if the most recent submittal (prior to December 4, 2019), was a resubmission.** For additional clarity regarding the 22.2

application cycle, this means that an application that was last submitted during or before the 20.1 cycle is considered a new application. In contrast, an application that was last submitted during or after the 20.2 cycle is considered a resubmission. It is expected that significant progress will have been made on the project; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to submit an application with such modest changes.

- An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. An application that was administratively withdrawn by the applicant or by CPRIT prior to review by the review panel is not considered a submission for purposes of CPRIT's resubmission policy.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received an overall numerical score of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

9. APPLICATION REVIEW

9.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. In general, a greater extent of commitment to establishing research and/or development functions in Texas will be viewed more favorably by CPRIT.

However, it is left to the applicant's judgment to make a case for what they consider to be a sufficient extent of commitment to Texas.

CPRIT requires the submission of a comprehensive development plan (see section 10.4.7) and a detailed business plan (see section 10.4.8). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and development plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made via the review process described below.

9.2. Review Process

- **Product Development and Scientific Review:** Applications that pass initial administrative review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of applicants may be invited to deliver in-person presentations to the review panel.
- **Due Diligence Review:** Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—IP, management, regulatory, manufacturing, and market assessments. Please note that CPRIT may request to review any correspondence that an applicant has conducted with regulatory agencies (eg, the FDA) as part of the diligence process. Following the due diligence review, applications may be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and IP reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.
- **Program Integration Committee Review:** Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities

set by the Oversight Committee, portfolio balance across programs, and available funding.

- **Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Peer Review Panel members, Product Development Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Any form of communication regarding any aspect of a pending application is prohibited between the applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the

particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

Attached to this RFA is a list of more detailed questions considered by CPRIT reviewers when assessing therapeutic applications (Appendix 1, "Reviewer Evaluation Guidelines for Therapeutics") and when assessing medical devices, diagnostics, and/or tools (Appendix 2, "Reviewer Evaluations Guidelines for Medical Devices and Diagnostics"). Applicants are encouraged to review these documents and, to the extent possible, address the questions within their application.

9.3.1. Primary Criteria

Primary review criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed program.

The criteria provided below are designed to provide an **overview** of topics that may be pertinent to the assessment of applications during peer review. Specific criteria applied to evaluate a given application will depend on the type of product described by the applicant (eg, therapeutic versus medical device). **Detailed descriptions of the specific criteria employed for different product classes are provided in the appendices to this RFA.**

Primary review criteria are heavily weighted in determining the quality of an application. Reviewers provide numerical scores for these topic areas when evaluating applications. Primary criteria are intended to address the following topics:

- Significance and Impact
- Unmet Medical Need
- Product Validation/Proof of Concept
- Safety
- Preclinical Strength/Development to Date
- Development Plan
- Competitive Landscape
- Intellectual Property
- Business/Commercial Aspects
- Management and Staffing
- Production/Manufacturing Plan
- Overview of Clinical/Regulatory Plan

More details regarding these topics can be found in the appendices to this document.

9.3.2. Secondary Criteria

Secondary review criteria contribute to the global score assigned to the application and are not assigned individual numerical scores. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include the following:

- Budget and Duration of Support

Please see appendices for more details.

10. SUBMISSION GUIDELINES

Applicants are advised to review carefully all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available on December 1, 2021. Applications that

are missing 1 or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

10.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The applicant must create a user account in the system to start and submit an application. The coapplicant, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. It is acceptable (and not uncommon) for the applicant to also serve as the designated ASO. However, if the applicant intends to also serve as the ASO, the system requires that the applicant and the ASO have 2 different accounts and usernames. Applications will be accepted beginning at 7 AM central time on December 1, 2021 and must be submitted by 4 PM central time on January 26, 2022. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

10.2. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. Late submissions are permitted only in exceptional instances, usually for technology failures in the CARS. It is imperative that applicants allow sufficient time to familiarize themselves with the application format and instructions to avoid unexpected issues. The applicant's failure to adequately plan is not sufficient grounds to justify approval of a late submission.

Peer review schedules are set far in advance and do not accommodate receipt of an application days after the deadline. Therefore, potential applicants that are unable to meet the deadline due to issues such as travel, sabbaticals, conferences, prolonged illness, or other leave, etc, should not request additional time to submit an application but should instead consider submitting the application in the next review cycle.

A request to extend the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records and are intended to allow an applicant to complete and submit an incomplete application that has already been started in CARS. If a request for extension is approved, then CARS will be reopened for an additional 2 hours to allow an applicant with an unsubmitted application to complete and submit it. Applicants are also urged to initiate the registration process on CARS a minimum of 5 business days prior to deadline to ensure enough time to complete and submit an application.

10.3. Product Development Review Fee

All applicants must submit a nonrefundable fee of $1,000 for review of Product Development Research applications. Payment should be made by check or money order payable to Cancer Prevention and Research Institute of Texas; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. Unless a request to submit a late fee has been approved by CPRIT, all payments must be postmarked by the application submission deadline and mailed as described below.

Checks may be mailed via the US Postal Service to the following address:

Cancer Prevention and Research Institute of Texas
PO Box 12097
Austin, Texas 78711

Contact name: Michelle Huddleston
Phone 1-512-305-8420

Mail sent via a delivery services (ie, FedEx, UPS, etc) will need to use this address:

Cancer Prevention and Research Institute of Texas
Wm B Travis State Office Building
1701 N Congress Ave Ste 6-127
Austin, Texas 78701

Contact name: Michelle Huddleston
Phone 1-512-305-8420

10.4. Application Components

Applicants are advised to minimize repetition among application components to the extent possible. In addition, applicants should use discretion in cross-referencing sections in order to maximize the amount of information presented within the page limits.

Please note that letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc, are **not** required or requested. Please do not submit letters of support as part of your application package. **Any such information will be removed from your application before review**.

10.4.1. Abstract and Significance (5,000-character maximum)

Coherently explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Address how the proposed project, if successful, will have a major impact on the care of patients with cancer. Describe how this application provides a path for acquiring proof-of-principle data necessary for next-stage commercial development. Clearly explain the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

10.4.2. Layperson's Summary (1,500-character maximum)

Provide a summary of the proposed project using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Describe the overall goals of the project, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The layperson's summary will also be used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

10.4.3. Goals and Objectives (maximum of 1,200 characters each)

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. Identify time-specific references as follows: Year 1, Quarter 1 (Y1Q1), Y1Q2, etc. Do not specify actual calendar dates as this can be confusing when dates change.

10.4.4. Timeline (1-page maximum)

Provide a visual depiction of anticipated major milestones to be tracked in the form of a Gantt chart. Identify time-specific references as follows: Y1Q1, Y1Q2, etc, as opposed to naming specific months and years. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

10.4.5. Slide Presentation (10-page maximum)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with 1 slide filling each landscape-oriented page. The slides should succinctly capture all essential elements of the application and should stand alone.

10.4.6. Resubmission Summary (1-page maximum)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

Note: An application submitted or resubmitted before December 4, 2019, may be submitted as a new application, even if it was previously resubmitted. For the "new" applications, no summary is required.

10.4.7. Development Plan (12-page maximum)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. **Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims**. Outline the steps to be taken during the proposed period of the award, including the design of the translational and/or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches to these risks. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The development plan should include a defined **product profile (PP).** The format for the PP should be a target product profile (TPP) in the case of a therapeutic, or analogous document for a medical device, in vitro diagnostic, or service that projects a clear path to full commercialization. The PP provides a statement of the *overall intent* of the product development program and gives information about the product *at a particular time* in development. Usually, the PP is organized according to the key sections in the product package insert for a drug or biologic or medical device labeling and links development activities to specific concepts intended for inclusion in the product labeling. CPRIT recognizes that many applications are early in the development process and that not all elements of the PP will be known at the time of application. Consequently, not only does the PP serve as a snapshot in time of the development status of the program, but it additionally serves as an aspirational target upon eventual commercialization. The PP should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- Identification of a target that is applicable to human cancer treatment. Is intervention with this target likely to lead to a therapeutic, medical device, diagnostic, or service that could be useful in the treatment of cancer?
- Selection of a lead compound, assay, or device technology based on the target. Is the identification of potential developmental candidates based on a set of in vitro tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of pharmacodynamic parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?

- Description of a high-level clinical development plan detailing each of the clinical studies supporting marketing approval (phase 1, 2, and 3) the preclinical work is meant to support. Designing the preclinical program requires an understanding of the duration of the clinical studies required by regulatory authorities. Consequently, a brief outline of each of the phase 1, phase 2, and phase 3 studies necessary to obtain regulatory approval and reimbursement funding must be sketched out prior to deciding which toxicology studies would be required.

Applicants developing cancer therapeutics are encouraged to become familiar with FDA guidance documents for submission of applications related to new product development. These documents provide a standard framework for new drug submissions and biologic license applications to the FDA. Utilizing this framework helps ensure that the submission to CPRIT contains all relevant elements and is optimally organized.

Additionally, for therapeutics, the following apply:

Intended route of administration and dosing regimen. Is the intended route of administration and dosing regimen consistent with accepted convention and medical need for the therapeutic, or will the use of this new agent require a paradigm shift (more frequent or less frequent dosing, new route or method of administration), and if so, what impact will it have on current standard of care?

Optimization of the lead to ensure desired characteristics, including, but not limited to, the following studies:

- Indication of the threshold of both the safety and efficacy necessary to be a competitive product when the product is introduced
- Absorption, distribution, metabolism, excretion, including, but not limited to, relevant studies based on route of administration
- Safety (studies as mandated by ICH guidelines)
- Biomarkers (assays) that potentially target specific patient populations for clinical trials
- Biomarkers (assays) that can serve as potential pharmacodynamic markers of clinical activity during early clinical trials designed to demonstrate proof of concept
- Proposed current good manufacturing practice (including estimated costs) that can be scalable from phase 1 through phase 2. Include information on whether there are plans for possible formulation.

The FDA's website provides "Common Technical Documents" (CTDs, see https://www.ich.org/page/ctd) for guidance documents. There are 3 CTDs covering safety, efficacy, and quality. This guidance presents a standard format for the preparation of a well-structured application. Applicants may condense or summarize the CTD format as they deem appropriate to meet page limitations.

While originally intended for regulatory authorities, these formats are also applicable for a CPRIT application. Many of our reviewers have extensive pharmaceutical development expertise and are familiar with these standard formats. Hence, utilizing the CTD format will simplify the review and ensure that the application contains all of the relevant elements.

CPRIT recognizes that many applications are early in the product development process. Hence, not all elements of the CTD will be known at time of CPRIT application. We encourage applicants to complete as much of the Safety and Efficacy CTD sections as possible and to follow the submission format prescribed.

References for the Development Plan section should be provided as a stand-alone document that will be separately uploaded into CARS. In the interests of brevity include only the most pertinent and current literature. While references will not count toward the Development Plan section page limit, it is essential to be concise and to select only those references relevant to the development plan. **Do not use the references to circumvent Development Plan section page limits by including data analysis or other nonbibliographic material.**

The development plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, the development plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred. Please avoid redundancy!

10.4.8. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies typically need to raise substantial funds from private sources to fully fund development. Hence, we require companies to provide a business plan that summarizes the rationale for investing in this project. Private investors will seek a financial return on their investment. They will need to be convinced that this project has high investment return potential

based on its risk profile. They typically focus on market opportunity size, development path, and key risk issues.

Successful applicants will provide a thoughtful, careful, and succinct rationale explaining why this program is an appropriate investment of CPRIT and private funds. Note that if the company is selected to undergo due diligence, additional information (such as the company's interactions with regulatory agencies like the FDA, etc) to support the application may be requested at that time. Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

Please provide an overview of the business rationale for investing in this project. The business rationale overview will be 2 pages maximum. In addition, please provide summaries of the following key development issues with a maximum of 1 page each.

1. **Product and Market:** Provide an overview of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care, ie, primary therapy, second-line therapy, adjunctive to current therapies, etc. Information on patient populations and market segments is helpful.
2. **Competition and Value Proposition:** Provide an overview of the competitive environment (current and future) and how the envisioned product will compete in the marketplace. Provide information on how the clinical utility (efficacy, safety, cost, etc) of this therapy compares with current and potential future therapies. A clear delineation of competitive advantages and data demonstrating these advantages are helpful.
3. **Clinical and Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities and the regulatory pathway for major markets. Please describe how this is driven by interactions with the FDA, if possible. The regulatory plan should include regulatory communications (including all interactions to date with the FDA) and strategy, with clarity provided on regulatory matters and current regulatory strategies.
4. **Pricing and Reimbursement:** Provide an overview of the product cost and anticipated revenue. Cost, price, and reimbursement references from similar products are helpful. An

overview of how the company plans to obtain CMS and private insurance reimbursement approval is also helpful.

5. **Commercial Strategy:** Provide an overview of your financial projections and how you will generate a return on this investment. Describe how the company plans to bring the product to market. Information on physicians to be targeted, sales channels, etc, is helpful. Alternatively, many drugs are acquired by large pharma firms in the late development stages. If the company plans to seek acquisition, please provide an overview of similar transactions. Provide a brief assessment of current competition.
6. **Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated. Key risk issues typically include efficacy versus competitors, toxicity, clinical trials, FDA approval, dosage and delivery, CMC synthesis, changing competitive environment, etc.
7. **Funding to Date:** Provide an overview of the funding received, including a list of funding sources and a comprehensive capitalization table that should comprise all parties who have investments, stock, or rights in the company. A template exemplifying an appropriate capitalization table is provided among the application materials and MUST be used when completing your application. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.
8. **Intellectual Property:** Provide a concise discussion of the IP issues related to the project. List any relevant issued patents and patent applications. Please include the titles and dates the patents were issued/filed/published. List any licensing agreements that the company has signed that are relevant to this application.
9. **Key Personnel Located in Texas and Any Key Management Located Outside of Texas:** For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, current geographic location (in particular, whether they are located within Texas) and any other information considered essential for evaluation of qualifications. Key personnel are the Principal Investigator/Project Director as well as other individuals who contribute to the development or the execution of the project in a substantive, measurable way. *Substantive* means they have a critical role in the overall

success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project. *Measurable* means that they devote a specified percentage of time to the project. The indicated time is an obligatory commitment, regardless of whether or not they request salaries or compensation. "Zero percent" effort or "TBD" or "as needed" are not acceptable levels of involvement for those designated as key personnel. While all participants that meet these criteria should be identified as "key," it is expected that the number of key personnel will be kept to a minimum.

The entire Business Plan section shall typically comprise a maximum of 11 pages: a 2-page overview and nine, 1-page key issue summaries. Please avoid redundancy. Note that the section "Funding to Date" above may exceed this 1-page limit if necessary.

10.4.9. Biographical Sketches of Key Scientific Personnel (8-page maximum)

Provide a biographical sketch for up to 4 key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. You may use either the provided "Product Development Research Programs: Biographical Sketch" template or the NIH biographical sketch format. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see section 10.4.8]).

10.4.10. Relocation Commitment to Texas (1-page maximum)

Provide a timetable with key dates indicating the applicant's plan and commitment to relocate the company to Texas. In addition, describe which personnel and management will be headquartered in Texas.

10.4.11. Budget

In preparing the requested budget, applicants should be aware of the following:

- Each award mechanism allows for up to a 3-year funding program with an opportunity for extension after the term expires. **The budget must be aligned with the proposed milestones.** Financial support will be awarded based upon the breadth and nature of the project proposed. Requested funds must be well justified. Funding will be tranched and milestone driven.

- CPRIT considers equipment to be items having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit. If awarded, management of your grant will be facilitated if specific equipment is clearly identified in the application using plain language. **Equipment not listed in the applicant's budget must be specifically approved by CPRIT subsequent to the award contract**.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.
- The total amount of CPRIT funds allowed for an annual salary of an individual for FY 2022 is $200,000. In other words, an individual may request salary proportional to the percent effort up to a maximum of $200,000. Salary amounts in excess of this limit must be paid from matching funds. Salary does not include fringe benefits. CPRIT FY 2022 is from September 1, 2021, through August 31, 2022. Additionally, adjustments of up to a 3% increase in annual salary are permitted for Years 2 and 3 up to the cap of $200,000. The salary cap may be revised at CPRIT's discretion.

The Budget section is composed of 4 subtabs that must be completed:

A. **Budget for All Project Personnel:** Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all personnel participating on this project. If funding is requested for a role that is not currently occupied, applicant should note "new hire" as name.

B. **Detailed Budget for Year 1:** This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs in the first year of the project. Direct cost categories include Travel, Equipment, Supplies, Contractual (Subaward/Services Contracts), or Other. Applicants will be required to itemize costs.

C. **Budget for Entire Proposed Period of Performance:** This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs for all subsequent years. Amounts for *Budget Year 1* will be automatically populated based on the information provided on the previous subtabs; namely, *Budget for*

All Project Personnel and *Detailed Budget for Year 1*.

D. Budget Justification: Please specify your CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds. Use of the provided Budget Justification template is mandatory. Please specify each line item from your CPRIT budget as well as other funds (including matching funds). Provide a compelling justification for the budget for each line item of the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. **If travel costs will include out-of-state or international travel, make that clear here.** The budget must be aligned with the proposed milestones.

11. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and IP rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10 to 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT utilizes 2 methods of disbursement of grant funds: (1) reimbursement and (2) advancement. Under the reimbursement method, the grantee is expected to finance its operations with its own working capital. Under the advancement method, CPRIT disburses grant funds in

advance of the grantee incurring expenses. Grantees must be approved by the Oversight Committee to receive advancement of funds. Please see chapter 8 of the CPRIT Grant Policies & Procedures Guide for additional details regarding the disbursement of grant funds.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

Project Revenue Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement, which can be found at www.cprit.texas.gov and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has appropriate matching funds. For companies receiving an initial CPRIT award, the company must contribute $1.00 in matching funds for every $2.00 awarded by CPRIT. For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company. See section 6 ("Funding Information") of the RFA for more details. Matching funds need not be in hand when the application is submitted, nor does the entire amount of matching funds for the full 3 years of the project need to be available at the start of the grant. However, the appropriate amount of matching funds for each specific tranche must be obtained before each tranche of CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703,

section 703.11, for specific requirements associated with the requirement to demonstrate available funds.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific and product development aspects of applications. **Before contacting the helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. In addition, for Frequently Asked Programmatic Questions, please go here and for Frequently Asked Technical Questions, please go here.**

Hours of operation:	Monday through Friday, 8 AM to 6 PM central time
Tel:	866-941-7146 (toll free in the United States only—international applicants should use the email address below)
Email:	Help@CPRITGrants.org

13.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Product Development Research Program Senior Manager.

Tel:	512-305-7676
Email:	Help@CPRITGrants.org
Website:	**www.cprit.texas.gov**

14. APPENDIX

14.1. Reviewer Evaluation Guidelines for Therapeutics

Primary Review Criteria (Scored)

Unmet Medical Need: Target Product Profile (TPP)

- Assuming successful accomplishment of development objectives, as reflected in the target product profile, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Target Validation

- If this is a "targeted" agent, to what extent has the target been validated, eg, through knockdown studies and/or pharmacological intervention?
- Has engagement of the target with the agent been demonstrated by biochemical assay? What is the potency of the agent?
- Are there validated downstream pharmacodynamic (PD) markers of target modulation? How extensive is the in vitro evidence for expected PD effects? Has the agent shown biologically significant modulation of the target in vivo, especially in tumor tissue?
- Is the target uniquely or substantially overexpressed by tumor versus normal cells?
- Does the target represent an activating mutation? If so, has binding of the agent to the target and other activating mutations been characterized?
- Has the company's demonstration of target validation been externally/independently confirmed?
- Are there known mechanisms of resistance to the modulation of this target? If so, has the company proposed possible mitigation/preemptive approaches, such as combination chemotherapy?

Preclinical Characterization: Pharmacodynamic Proof of Concept

- Considering in vivo preclinical pharmacodynamic characterization and the patient populations or subpopulation(s) representing the initial clinical indication(s) for the drug, what is the clinical relevance of the preclinical models? To elaborate, were in vivo/xenograft studies carried out in cell line-based models or PDX-derived models? In how many such models have studies been carried out? To what extent do these models reflect standard of care (SOC) for refractory versus drug-naive tumors? At the time of treatment initiation, were tumors established and measurable, or was treatment initiated shortly after tumor inoculation?
- Was antitumor activity predominantly growth inhibition or tumor regression? Were sustained complete remissions or "cures" achieved in the majority of animals and models? Were comparisons with optimally dosed SOC agents made? Where the agent is intended to be added to the SOC, is there compelling evidence of in vitro/in vivo synergy with SOC agents?
- Have results of preclinical pharmacodynamic studies carried out by the company been externally/independently confirmed?
- Overall, considering clinical relevance and study results, how strong is the preclinical efficacy profile of the agent?
- How strongly does the preclinical pharmacodynamic profile support the clinical efficacy expectations reflected in the TPP?

Preclinical Characterization: Safety

- How extensive is the in vitro and in vivo preclinical safety characterization carried out so far?
- Has the agent undergone CEREP-type screening for interactions with targets with known safety liabilities, eg, CYP 450, hERG?
- Considering potency and target selectivity, what is the potential both for off-target and pharmacologically on-target deleterious effects?
- Can exposures associated with substantial antitumor efficacy/PD effects be achieved safely in vivo?

- Do preclinical pharmacokinetics (PK) studies indicate potential for clinical safety issues, eg, accumulation, variability, lack of dose proportionality?
- Have PK/PD issues been investigated with alternate dosing schedules in order to optimize the therapeutic index of the agent?
- Are there any issues with the distribution or metabolism of the agent?
- Overall, are results of safety characterization carried out so far such that the agent can be considered reasonably derisked from a safety perspective, or are there red flags? Alternatively, is the extent of preclinical safety characterization carried out so far insufficient to address this question?

Pharmaceutical Properties/Chemistry and Pharmacy

- In the case of agents intended for oral absorption, are there any issues with water solubility? Do formulation studies indicate the feasibility of oral administration?
- Were Lipinski-type criteria applied during the lead optimization process such that the lead compound has demonstrated properties that make it likely to be an orally active drug in humans?
- Are there any issues with the stability of the drug substance or the drug product?
- Is there scope for further lead optimization through structure activity studies?
- In the case of biologicals, has a high-quality cell line been developed yet? Are yields acceptable? Does the purification process appear reasonable and scalable?
- Have analytical methods been adequately developed?
- Has the (lead) protein been adequately characterized biochemically, immunogenetically, and biophysically? Has absence of aggregate formation been demonstrated in stability studies?

Development Plan/Regulatory Aspects

- Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
- Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions (United States/European Union)? Do development proposals reflect specific regulatory authority input, eg, from pre-IND interactions? Alternatively, has regulatory authority interaction been insufficient so far?

- In the case of clinical studies, are patient populations adequately described and consistent with those representing the initial target indication(s)?
- Are efficacy end points appropriate for study designs? Is the sample size statistically adequately justified in terms of the target effect size?
- In the case of potentially pivotal clinical trials, moreover, are the proposed primary efficacy end points and target effect sizes consistent with regulatory precedence?
- Considering target indication prevalence, will the agent qualify for orphan drug designation? If so, does the applicant intend to apply for this?
- Has the applicant demonstrated reasonable diligence in researching patient availability, competitive clinical trial activity, and recruitment issues such that patient enrollment projections can be considered realistic?
- Will the proposed programs advance development of the agent to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding?
- Are development milestones clear and adequately described? Is the overall project timeline realistic?

Competitive Analysis

- Has the applicant carried out a comprehensive and realistic analysis of the likely strengths and weaknesses of the agent compared to clinically relevant competitive products, including potentially competitive agents in development?
- Are the applicant's assumptions regarding the strengths and weaknesses of the agent relative to likely competitors reasonable, considering the preclinical efficacy and safety data on the agent generated so far?

Intellectual Property/Freedom to Operate

- Have IP and freedom-to-operate aspects been addressed in the application?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate?

Chemistry, Manufacturing, and Controls (CMC)

- How advanced is CMC and manufacturing development?
- Are there any sourcing issues?
- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- Are there significant technical difficulties within CMC/manufacturing scale up still to be addressed?

Business/Commercial Aspects

- Does the applicant need to raise further funds for the CPRIT matching requirement? In this case, how realistic are the applicant's assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program of studies reasonably support such expectations?
- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and CMC/manufacturing? If not, are there plans to address such deficiencies?
- Has the applicant demonstrated appropriate engagement of outside development expertise through, for example, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

14.2. Reviewer Evaluation Guidelines for Medical Devices and Diagnostics

Primary Review Criteria (Scored)

Unmet Medical Need

- Assuming successful accomplishment of development objectives, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Product Validation

- Technical Validation: Has the product or technology been successfully validated, ie, prototyped, built and tested in ex vivo, animal, or clinical settings?
- Have biological proof of principle and product mechanism of action been demonstrated?
- Have efficacy and safety in an accepted in vitro or animal model been demonstrated?
- Clinical Validation: Are clinical trials required to demonstrate product performance? If so, have they been planned or conducted?
- Biological Risk: What are the risks to the patients, eg, toxicology, biological, interactions with other therapies?

Production/Manufacturing

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- How advanced is manufacturing development?
- Are there any sourcing issues?

Intellectual Property/Freedom to Operate

- Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique know-how, etc?
- Does the company have issued patents? If not, have they conducted freedom-to-operate and patentability analysis?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use), and duration of patent life, how strong is the IP?

- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate, if required?

Market Opportunity

- Does the product address a clearly defined unmet need; lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?
- Are target indication and market clearly defined?
- Is channel to market available? Does the company understand the entire value chain and all constituencies involved in procuring and utilizing the product?
- Does the company understand the clinical pathway that leads to utilizing the product?
- Is market opportunity of significant size and lucrative enough to justify investment?
- Has the applicant demonstrated time or cost savings?
- How does product fit with the existing "ecosystem"; ie, are the benefits provided worth the time and cost of implementing the new approach?

Competition

- Is this a "Whole Product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
- Is value proposition clearly delineated, ie, improve efficacy, improve safety, reduce cost, or improve convenience?
- Has the company demonstrated its value proposition versus competition?
- Has the company conducted a competitive analysis? Does it provide a comprehensive, realistic assessment of strengths and weakness versus competition based on the data generated to date?

Development Plan/Regulatory Aspects

- Have a comprehensive development plan and market entry strategy been developed? How realistic are these plans?
- Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as product engineering, clinical development, regulatory affairs, manufacturing, etc? If not, are there plans to address such deficiencies?
- Has the applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Business/Commercial Aspects

- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration, and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?
- Has the company clearly anticipated pricing strategy and reimbursement environment?
- Is the projected return on investment congruent with investment opportunity and risks?

Funding

- Is investor interest in this sector sufficient to fund the company through profitability?
- Does the applicant already have available funds to meet the CPRIT matching requirement, or do they need to raise additional funds? In this case, how realistic are assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Have likely acquirers been identified by the applicant?
- Does the company have the resources to support required activities while fundraising?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program reasonably support such expectations?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Does the applicant demonstrate an understanding of the Texas spending requirement for CPRIT funds?

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel 1
(22.2_PDR_PDP_1)
Observation Report

Report No.	2022-03-21 22.2_PDR_PDP_1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel 1 (22.2 _PDR_PDP_1)
Panel Date:	March 21, 2022
Report Date:	March 29, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel 1 (22.2_PDR_PDP_1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on March 21, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and six (6) applications were not discussed
- Panelists: One (1) panel chair, four (4) PDRC members, eight (8) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Four (4)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The applications for which there were COIs were not discussed.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

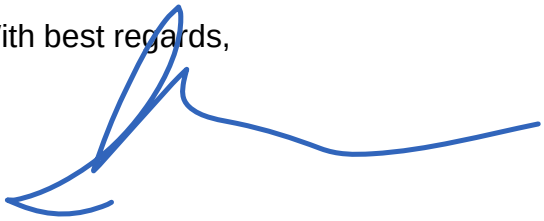
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel_2
(22.2_PRD_PDP_2)
Observation Report

Report No.	2022-03-22 22.2_PRD_PDP_2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel_2 (22.2 _PRD_PDP_2)
Panel Date:	March 22, 2022
Report Date:	March 29, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel_2 (22.2_PRD_PDP_2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on March 22, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Thirteen (13) applications were discussed and five (5) applications were not discussed
- Panelists: One (1) panel chair, three (3) PDRC members, nine (9) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) Conflicts of Interest (COIs) identified prior to and/or during the meeting. There were two (2) COIs on the application discussed and five (5) COIs on the applications not discussed. Those with COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

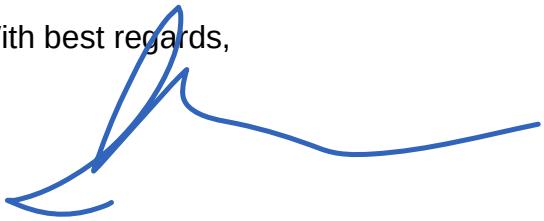
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel-1 (22.2 PDR-PDP1)
Observation Report

Report No.	2022-04-11 22.2_PDR-PDP1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel-1 (22.2 _PDR-PDP1)
Panel Date:	April 11, 2022 and April 12, 2022
Report Date:	June 8, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel-1 (22.2_PDR-PDP1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on April 11, 2022 and April 12, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed and nine (9) applications were not discussed
- Panelists : One (1) panel chair, four (4) PDRC members eight (8) expert reviewers, and two (2) advocate reviewers were present on both days
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) on day 1 and six (6) on day 2
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2) were present on both days
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

In total there were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meetings over two days. COI(s) were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

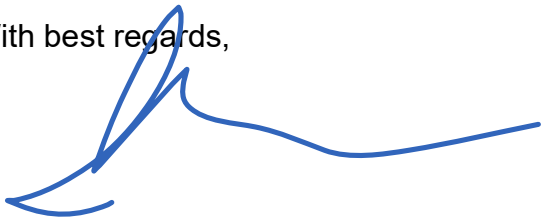
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



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Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel-2 (22.2 PDR-PDP2)
Observation Report

Report No.	2022-04-13 22.2_PDR-PDP2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel-2 (22.2 _PDR-PDP2)
Panel Date:	April 13, 2022 and April 14, 2022
Report Date:	June 8, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel-2 (22.2_PDR-PDP2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on April 13, 2022 and April 14, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Eight (8) applications were discussed and ten (10) applications were not discussed
- Panelists: One (1) panel chair, three (3) PDRC members, ten (10) expert reviewers, and two (2) advocate reviewers on both days
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Seven (7) on day 1 and five (5) on day 2
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2) on both days
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) Conflicts of Interest (COIs) identified prior to and/or during the meeting. COI(s) were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

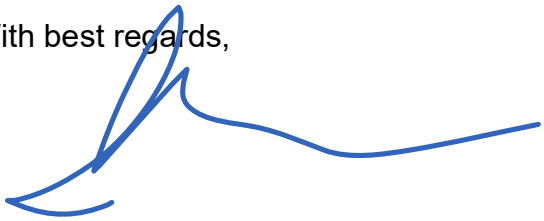
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Duligence Panel-1 (22.2_PDR_DDP1)
Observation Report

Report No.	2022-07-13 22.2_PDR_DDP1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Duligence Panel-1 (22.2 _PDR_DDP1)
Panel Date:	July 13, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Due Duligence Panel-1 (22.2_PDR_DDP1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on July 13, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Five (5) applications were discussed
- Panelists: One (1) panel chair, three (3) expert reviewers, and four (4) PDRC members
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- ICON Due Diligence Evaluators: Five (5)
- ICON Due Diligence Evaluators did only provide input when requested

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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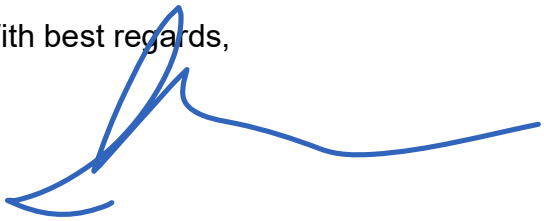

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Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Duligence Panel-2 (22.2_PDR_DDP2)
Observation Report

Report No.	2022-07-14 22.2_PDR_DDP2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Duligence Panel-2 (22.2 _PDR_DDP2)
Panel Date:	July 14, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Due Duligence Panel-2 (22.2_PDR_DDP2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on July 14, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: One (1) panel chair, Four (4) expert reviewers, and three (3) PDRC members
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Four (4)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- ICON Due Diligence Evaluators: Three (3)
- ICON Due Diligence Evaluators did only provide input when requested

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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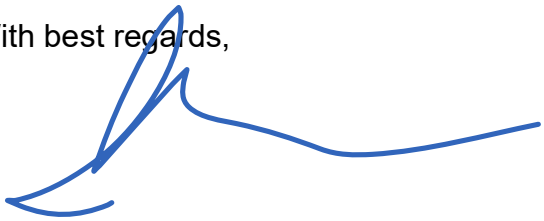

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Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Diligence Ranking (22.2_PDR_DD Ranking)
Observation Report

Report No.	2022-07-19 22.2_PDR_DD Ranking
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Diligence Ranking (22.2 _PDR_DD Ranking)
Panel Date:	July 19, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Due Diligence Ranking (22.2_PDR_DD Ranking) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on July 19, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and one (1) applications were not discussed
- Panelists: One (1) panel chair, one (1) vice chair, and seven (7) PDRC Members
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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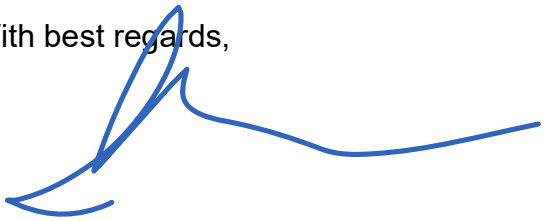

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
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Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Product Development Research Cycle 22.2

Awards Announced at the August 17, 2022, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 22.2 include: *Seed Awards for Product Development Research; Company Relocation Product Development Research Awards;* and *Texas Company Product Development Research Awards.*

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/Principal Investigator	Principal Investigator Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
No reported COIs.			
Applications not considered by the PIC or Oversight Committee:			
DP220058	Vicci Korman	Veravas, Inc.	Steven Weinstein
DP220060	Eric Rothe	Tiburon Bio, Inc.	Elaine Jones
DP220061	Chen Liu	CHEN LIU	Steven Weinstein
DP220042	David Arthur	Salarius Pharmaceuticals, Inc.	Kristine Swiderek
DP220050	Amos Ofer	EnCellX Inc.	Michael Cheng
DP220052	Timothy Coleman	Nemucore Medical Innovations, Inc.	Alan West, Lior Braunstein, Lee Greenberger, Michael Cheng
DP220056	Douglas Baum	QSAM Biosciences Inc.	Roy Cosan

High Level Summary of Due Diligence

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- StellaNova Therapeutics, Inc. for $3,000,000.

The PDRC did not recommend any contract contingencies for this award.

StellaNova Therapeutics, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

StellaNova Therapeutics Inc. is a Houston-based company based around research conducted at MD Anderson Cancer Center demonstrating that cells in the tumor microenvironment of pancreatic cancer (PDAC) and triple negative breast cancer (TNBC) produce Dickkopf-3 (DKK3) that acts on neighboring cancer cells to stimulate their growth, metastasis and resistance to standard therapy.

Novel therapies are urgently needed for pancreatic cancer and triple negative breast cancer, two of the most aggressive cancers with no effective cure. For pancreatic cancer, 4,420 Texans and 60,000 Americans are diagnosed each year and only 7% are expected to survive 5 years. Triple negative breast cancer is also aggressive, affecting 3,000 women in Texas and 42,000 in the US annually, with a disproportionate impact on African American and Hispanic women. Given the lack of effective therapies for these diseases, the successful development of DKK3-targeted therapy has the potential to be practice-changing for the field.

StellaNova is developing novel antibodies to block DKK3 (anti-DKK3 mAb). Anti-DKK3 mAb inhibited tumor growth in mice and produced long-term survival with no toxicity. For TNBC, treatment also reduced lung and brain metastases. Anti-DKK3 mAb is effective either alone or in combination with immunotherapy. Preclinical models validated the importance of DKK3 on the genetic and pharmacological levels, revealing that (1) DKK3 knockout inhibited PDAC tumor growth and metastasis, and increased survival in the KPC model, and (2) anti-DKK3 mAb (JM6-6-1) inhibited PDAC progression and metastasis, increased survival, and promoted an influx of CD8+ T cells into the “immunologically cold” tumor microenvironment. StellaNova will generate a high-quality producer cell line and generate cGMP qualified Master Cell Bank (MCB) for the large-scale production of the Development Candidate Humanized anti-DKK3 antibody which can be used for IND enabling GLP toxicity studies. These studies will be used for a cGMP 2000-L scale batch production that will be used in Phase 1/1B clinical trials.

Select Reviewer Comments

"The preclinical data establishing DKK3 as a possible therapeutic target in pancreatic cancer from Dr Hwang's lab are excellent. JM6-6- 1, a murine DKK3 neutralizing antibody, has been evaluated in a wide range of mouse models (granted preliminary data presented in very small tumors initially). These data seem promising."

"This is a very solid application arising from work done by top-notch, world-class cancer biology researchers at MD Anderson."

"The company appears to have excellent team with requisite skills and knowledge to move this project forward, including experienced CRO and mAb expertise. Stellanova is part of SPOROS Bioventures portfolio, who is well known to CPRIT for other parallel initiatives, and appears well organized in supporting this type of development."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Asylia Therapeutics, Inc. for $3,000,000.

The PDRC did not recommend any contract contingencies for this award.

Asylia Therapeutics, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Asylia Therapeutics, Inc. is a Houston-based, privately held development stage biopharmaceutical company which received a CPRIT award in 2020. Asylia is developing antibody therapies for cancer based on the discovery of the central role of heat shock protein-70 (HSP70) in tumor antigen presentation, immune activation and cellular stress responses.

Asylia discovered two entirely novel monoclonal antibodies with distinct mechanisms of action. ASY-77A targets the extracellular, soluble form of HSP70 released from cancer cells in complex with tumor-derived antigenic peptides (currently funded CPRIT SEED grant) and 239-87, targeting the cell surface form of HSP70, which is the focus of this proposal.

Asylia is developing an antibody drug conjugate (ADC) based on antibody 239-87, that recognizes the cell surface form of HSP70. Treatment with 239-87 resulted in prolonged eradication (cures) of several cancer types in mice transplanted with human cancer cells. Asylia plans to humanize and optimize mouse mAb, 239-87 to be able to manufacture cell line to produce the antibody, as well as to optimize a linker to connect the antibody to the drug. Asylia will also improve process development for ASY-87 to perform IND-enabling toxicology studies. The company will produce an ADC conjugate that can be tested for safety and efficacy in cancer patients who are failing current therapies in cancers, in particular those with T-cell lymphoma. Encouraging initial trial results will support the broader testing in other tumor types with high cell surface HSP70 expression such as Myeloma and Breast Cancer.

Select Reviewer Comments

“*Targeting HSP70 could have a wide range of cancer applications. Based on preclinical data that it shows highest expression in T-cell lymphoma, they wish to start there. T-cell lymphoma has a very high unmet need.”*

"In summary, this is a very professionally prepared application by a highly competent management team. CsHSP-70 is a promising new cancer therapeutic target with considerable preclinical validation as well as supporting clinical outcomes correlations."

"Additional in vivo preclinical studies in combination with an HDAC inhibitor and in combination with BV are planned. Not only do these approaches provide a potential backup strategy in PTCL, but they may set the stage for a post (accelerated) approval confirmatory study, and moreover, may pave the way for integration of the agent with SOC agents for earlier lines of therapy."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Xerient Pharma, Inc. for $2,934,737.

The PDRC did not recommend any contract contingencies for this award.

Xerient Pharma, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Xerient is a Houston-based startup dedicated to the development of an orally administered tablet that releases very efficient radioprotectant molecule in the duodenum. Xerient demonstrated that it is possible to repurpose an FDA-approved radioprotectant, and reformulate it in a tablet with a targeted-delivery and in-body-monitoring functionalities to allow very efficacious radiation therapy.

Pancreatic cancer cannot be cured without surgery. Nearly 90% of patients present with unresectable disease (locally advanced + metastatic), leaving patients and clinicians with very few treatment options once chemotherapy is completed. Radiation therapy cannot substitute for surgery because of morbid radiotoxicity to the nearby intestines that occurs before the tumor is controlled. Thus, treatment-related gastrointestinal (GI) radiation toxicity may be the single greatest barrier to improving treatment responses for unresectable pancreatic cancer. There are no known medications that can selectively protect the intestines from the side effects of treatment-related GI radiation toxicity.

Amifostine is a well-known therapeutic and is the only FDA-approved radioprotector, but it has significant toxicity when given intravenously (the only approved route of administration). Orally delivered amifostine is a pro-drug that is activated in the small intestine by endogenous intestinal alkaline phosphatases. If administered just prior to radiation, the active metabolite, WR-1065, is then produced locally in the gut and protects the intestinal tissue during radiation, then is rapidly degraded. Orally administered amifostine is highly efficacious and enables ablative radiation therapy to pancreatic tumors, which triples survival in a murine model. Oral amifostine coupled with ablative radiotherapy can be a curative treatment in selected patients with unresectable pancreatic cancer.

Xerient intends to develop and test an enteric-coated version of amifostine (EC-amifostine) that maximizes payload delivery in the duodenum in a timeframe relevant to radiotherapy that will be

clinically efficacious with targeted delivery and monitoring functionalities. Xerient will complete GLP toxicology studies, allowing the company to proceed with a clinical Phase I safety trial in humans. Xerient will evaluate the activity and tolerability of EC-amifostine in a canine model and confirm that amifostine can protect intestinal tissue from radiation in a porcine model.

Select Reviewer Comments

"The molecule is well known and studied and FDA approved as a radioprotectant when given IV."

"Many patients with pancreatic cancer would definitely benefit from radiotherapy, but because of the toxicity to the duodenum, it is not used. The ability to deliver safe and effective doses of targeted radiotherapy would be of great potential benefit to these patients who have few therapeutic options."

"If successful, this product could have fast uptake as SOC in radiation centers with new possibility of benefit to pancreatic cancer radiotherapy."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- InformAI, Inc. for $1,552,000.

The PDRC did not recommend any contract contingencies for this award.

InformAI, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

InformAI Inc. is a Houston-based company focusing on AI solutions that speed up medical diagnosis at the point-of-case and improve radiologist productivity. With 360 degrees of radiation access and delivering a wide range of beam intensities, a nearly infinite number of avenues exist to target a malignant lesion while minimizing off-target effects. Deep learning methods are well-positioned to optimize this process, identifying radiation plans that deliver a therapeutic radiation dose to cancer while optimally minimizing unwanted radiation exposure to healthy tissue and neighboring organs.

InformAI proposes to create RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for planning Radiation Oncology in the head and neck region. To date, a minimally viable business prototype has been created, led by work out of The University of Texas Southwestern Medical Center's Medical Artificial Intelligence and Automation Laboratory in collaboration with the Department of Radiation Oncology.

Preliminary testing and validation efforts of the model are promising. InformAI has entered into a Sponsored Research Agreement with UT Southwestern to lead the product scaling, validating, technological hardening, regulatory approval, and commercialization efforts necessary to transform this prototype technology into a finished business offering.

Deep learning methods are well-positioned to optimize the creation of radiation plans that deliver a therapeutic radiation dose to cancer while optimally minimizing unwanted radiation exposure to healthy tissue and neighboring organs. A deep learning radiation planning tool could solve current pain points in the radiation oncology workflow, improving the safety, efficiency, quality, and usability of multiple product modalities. According to the company, no products available on the market leverage deep learning methods to create the 'first pass' radiation treatment plan.

InformAI intends to expand its dataset including acquiring access to additional 400 head and neck segmented and annotated head and neck de-identified patient scans. Inform AI will validate

its label claims through clinical research with the purpose of preparing for the FDA regulatory approval process. InformAI will also ensure that its product is widely, if not universally, integrable with all TPS used in the routine practice of radiation oncology.

Select Reviewer Comments

"There is a clear unmet need in radiation oncology addressed in this proposal with the use of AI to help create more efficient and automated dose plans and associated organ segmentation. There is a clear value proposition to patients and oncologist in improving the efficiency and the accuracy of the dose plans for the clinicians."

"This approach has the potential to make radiation planning faster and more accurate than current standards of care. This is rendered possible by recent and current informatics advances, and it is likely that AI will affect the medical practice also in areas other than radiation therapy, thus the submission is well positioned in the future stream of innovative approaches."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- NUCORE Medical for $2,999,999.

The PDRC recommended the following contract contingency for this award. Agreements to assign all IP assets related to the tissue coring/resection device originally created and developed by Precision Thoracic, LLC and Ethicon, Inc. to NuCore Medical, Inc. should be completed, and the transaction concluded, prior to execution of the contract with CPRIT

NUCORE Medical

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Nucore Inc. is a Houston-based medical device company resulting from a multi-year collaboration between J&J's Center for Medical Device Innovation @ The Texas Medical Center and California-based Precision Thoracic to innovate novel technologies focused on the early interception, diagnosis, and treatment of lung cancer.

Early interception of suspicious lung nodules, by nature, means dealing with small, amorphic, and heterogeneous nodules that are extremely challenging to diagnose with current needle biopsy techniques. Surgical wedge resection (i.e. open or VATS) is an option, but these complex procedures unnecessarily sacrifice large quantities of functional lung tissue and can often expose fragile patients to unjustified surgical risks. Clinicians need a tool that can provide a minimally invasive, tissue sparing, targeted resection of suspicious small and intermediate-sized lung nodules, facilitating definitive diagnosis.

Nucore has developed Minimally-invasive Targeted Resection (MiTR-core™), the first medical device designed to safely remove lung nodules in a simple, quick, and minimally invasive procedure. The MiTR-core procedure will enable clinicians to remove suspicious nodules upon initial detection, will provide a definitive diagnosis of the nodule, spare healthy lung tissue, and in the event of cancer, provide direct access to the site of the nodule for further targeted therapy.

MiTR-core™ is a tissue-sparing transthoracic nodulectomy tool for CT-guided targeting of a suspicious nodule followed by minimally invasive access, coring, resection, and RF-based sealing of the lung to prevent blood and air leaks. The amount of diagnostically viable tissue extracted using MiTR-core is more than 2,000 times greater than the tissue extracted using existing needle techniques. In addition to facilitating greater specificity and sensitivity, the

specimen size will allow for rapid characterization of the cancer and, potentially, real-time sequencing.

The Nucore team has advanced MiTR-core from a concept to functional prototypes and rigorously tested it on the bench and in a series of nine acute porcine studies. MiTR-core has successfully demonstrated proof-of-concept in 2 chronic porcine studies. The company will strengthen its clinical and commercial case for MiTR-core through clinical data analytics (e.g. clinical outcome and cost databases, retrospective chart review, prospective multi-center registry trial), prepare for a First-in-Human study through regulatory submission, and manufacture clinical build devices and advance the device through a First-in-Human study.

Select Reviewer Comments

"*With financial support of $4.5 million from JNJ's Center for Medical Device Innovation, Nucore Inc, a Houston-based company, has developed a biopsy device that is much less invasive than wedge resection, essentially eliminates the false-negative/indeterminate issue associated with fine-needle biopsy, and by virtue of a tissue sealing feature, does so with minimal to no complications of hemothorax and pneumothorax, in effect, addressing the follow-up definitive diagnostic barriers to LDCT lung cancer screening uptake noted above."*

"This device could be really useful in terms of yielding actionable results in a far less invasive procedure than currently available."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- PLUS Therapeutics for $17,613,605.

The PDRC did not recommended any contract contingencies for this award. The award recommendation to PLUS Therapeutics is contingent on the successful completion of amending the License Agreement between PLUS Therapeutics and NanoTX.

PLUS Therapeutics

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Plus Therapeutics is a publicly listed company based in Austin. Plus is developing a Rhenium-186 NanoLiposome (186RNL), which is a novel radiotherapeutic to combat several cancers including recurrent glioblastoma, 186RNL is safe and well-tolerated while delivering a radiation dose to the tumor that is up to 15 times higher than typically achievable with standard radiation therapy. Plus is developing 186RNL to treat leptomeningeal metastases. Leptomeningeal Metastases (LM) are a rare but typically fatal complication of advanced cancer that affects the fluid-lined structures of the central nervous system. LM are diagnosed in 5% of cancer patients.

The investigational product is BMEDA-chelated Rhenium-186 NanoLiposome (186RNL). Rhenium-186 is an ideal radionuclide for CNS cancers such as LM because of its long 90-hour half-life, beta particles' short ~2mm path length, low dose rate, and high radiation density that overwhelms proliferating cellular innate DNA repair mechanisms. For 186RNL treatment of LM in humans, PLUS has obtained FDA Fast Track designation and IND clearance and will pursue FDA Orphan Drug and Breakthrough Therapy designations in the future.

The purpose of the two-part, Texas-based multicenter (The University of Texas Health Science Center San Antonio, The University of Texas Southwestern Medical Center, and The University of Texas MD Anderson Cancer Center) Phase clinical trial is to characterize the safety, tolerability, PK, dosimetry, and antitumor activity of 186RNL administered intrathecally, via an intraventricular catheter system (Ommaya reservoir), as a single agent in 61 LM subjects. If successful, PLUS intends to seek FDA investigational new drug (IND) clearance to initiate and complete a Phase 2 pivotal trial in 120 subjects (final N subject to data and statistical analysis plan) with leptomeningeal metastases to support a new drug application (NDA) submission with the FDA.

The company expects 186RNL to deliver a much higher and more targeted dose of radiation during a single administration compared to traditional RTs; have a high safety margin with minimal risk of bone marrow suppression; may be able to treat all LM patients, unlike some other therapies that rely on tumor targeting technology for a subset of patients; ease of administration with well-accepted and currently utilized access technology.

Plus intends to complete parts 1 and 2 of a Multicenter Phase 1 Clinical Trial of IT-Delivered 186RNL to treat LM, which will include compiling safety data, identifying a maximum tolerated dose, assess the safety, tolerability, efficacy of 186RNL in subjects with LM for Phase 2 pivotal clinical trial. Plus intends to complete Multicenter Phase 2 Clinical Trial of IT-Delivered 186RNL to treat LM, which will lead to preparations for filing an NDA submission to the FDA.

Select Reviewer Comments

"*This tackles the issue of leptomeningeal metastasis with no therapy at the moment. IND has been filed and cleared by the FDA. In spite of some weaknesses about lack of preclinical data particularly in combination therapy for some models, the application remains solid and promising."*

"*The strengths are high unmet need albeit a very small population. Data in GBM are encouraging. There is FDA green light for the next clinical trial. The competition is limited, and the biomarker strategy if executed should improve targeting the most likely to respond..."*

"The intended product is currently already in clinical trials in glioblastoma and overall de-risks the intended product, clinical strategy, and the company."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Atom Mines for $2,500,000.

The PDRC did not recommend any contract contingencies for this award.

Atom Mines

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Atom Mines is a small Austin-based company which utilized a Magnetically Activated and Guided Isotope Separation ("MAGIS") technology developed at The University of Texas at Austin, which will enable the production of the stable isotope Ytterbium-176 (176Yb) needed to make the radio-isotope Lutetium-177 (177Lu). 177Lu is an effective beta-therapy agent approved for certain neuroendocrine cancers and soon to be approved for prostate cancer, the second leading cause of cancer death in men, with clinical trials underway for a range of cancers. 177Lu can be used to target small tumors and dispersed, inoperable metastatic cancer using precise delivery molecules. 176Yb is currently only available in small quantities from Russia and that supply is uncertain due to geopolitics and competition for limited production capacity.

Ytterbium-176 (176Yb) is the stable precursor required to make carrier-free 177Lu, and 176Yb is currently only available in very limited quantities from Russia. Russian supplies have remained limited due to competition for production capacity for other isotopes, while global demand has more than doubled. This supply is in jeopardy due to deteriorating geopolitics, corruption, and competition for limited calutron separation capacity.

A reliable, domestic source of pure 176Yb is required to produce sufficient carrier-free 177Lu to support FDA-approved drugs and ongoing cancer research, trials, and therapies in Texas and globally. Novartis has two products Pluvicta and Lutathera which utilize 177Lu. Atom Mines utilizes an isotope separation developed by Prof. Mark G. Raizen at The University of Texas at Austin. Magnetically Activated and Guided Isotope Separation ("MAGIS") uses lasers to temporarily magnetize atoms that is then followed by separation with arrays of magnets.

Atom Mines LLC has fully demonstrated 176Yb enrichment to medical-grade purity of 99.5%. MAGIS will enable domestic commercial production of 176Yb, as well as other rare isotopes for widespread medical use. Atom Mines intends to scaleup 176Yb production initially to 200 grams; validate purity of routine batches and of 177Lu produced by industry partner and

irradiators. Atom plans to scale up to 500 grams within three years and ultimately to kilogram quantities, which will support tens of thousands of doses for prostate cancer therapy per year.

Select Reviewer Comments

"*Indeed, the Department of Energy openly recognizes the lack of separation capabilities in the United States and the need for new domestic capabilities. The company has demonstrated that Novartis has a need for this material to develop and test novel prostate cancer therapy and has a production site in Texas, as well as a global distribution partnership with a German company, Eckert and Ziegler, which has invested in the company."*

"Atom Mines will use the efficiency of MAGIS technology to greatly reduce the cost of separating stable isotopes and make important medical isotopes for therapeutics already approved or in the process of approval."

"There is no risk in this proposal short of not being able to meet the demand at commercial scale since several possible therapeutics may use this radiotherapeutic approach."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Rapamycin Holdings, Inc. for $16,999,999.

The PDRC recommended the following contract contingency for this award. Emtora's relationship with Southwest Research Institute with regard to intellectual property and manufacturing for the new formulation of eRapa should be specified.

Rapamycin Holdings, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Emtora Biosciences (formerly Rapamycin Holdings Inc.) is a San Antonio company that has developed eRapa, a novel form of the FDA-approved active ingredient rapamycin. Rapamycin has previously shown promise in treating gastrointestinal diseases and in cancer prevention, but is limited by toxicity. eRapa is targeted to the colon and is delivered at lower doses, resulting in lower toxicity. The company is developing eRapa to prevent colorectal cancer in patients with Familial Adenomatous Polyposis (FAP). In 2019, Emtora received a CPRIT Product Development (SEED) award for a Phase IIa study of eRapa in FAP, which is currently underway.

Data supports that rapamycin augments the immune system, prevents cancer in cancer-prone animal models, and prolongs health and life span. It has been demonstrated that rapamycin reduces the percentage of CD4 and CD8 T lymphocytes that express PD-1 (exhaustion marker), which inhibits T cell signaling and is more highly expressed with age and exposure to cancer. The results of Emtora's Phase I clinical trials in prostate cancer indicate that e-Rapa is safe and well-tolerated at all doses and schedules tested; more tolerable at intermittent dosing schedules; has no adverse effect on quality of life; has a consistent and predictable absorption profile (unlike rapamycin); produces measurable and favorable changes in the immune system; and no patients on eRapa experienced disease progression during the study.

Emtora proposes to manufacture drug product to support the addition of a fourth cohort in the current Phase IIa study of eRapa in FAP. The proposal would expand and complete the CPRIT-funded Phase IIa study of eRapa in Familial Adenomatous Polyposis (FAP) and prepare for and execute Randomized Placebo-Controlled Trial of eRapa in FAP.

Select Reviewer Comments

“*This new encapsulated rapamycin formulation, eRapa, is targeted specifically to the colon and is delivered at a consistent and lower dosage, not only reducing toxicities but also capitalizing on the potential of partial inhibition of the mechanistic target of rapamycin (mTOR) to act as a chemopreventive agent*.”

“*The applicant has a good standing with CPRIT through a previous Seed Award, has received ODD, has an open IND, and is currently in phase 2a clinical trials in FAP. As such, the proposal is highly de-risked.”*

RELCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- PanTher Therapeutics, Inc. for $14,268,315.

The PDRC recommended the following contract contingency for this award.
1) Clinical data from the Australian clinical trial (ongoing at time of application submission)
2) A clear and detailed clinical development plan
3) A timeline for manufacturing higher doses of the drug product needed for the Phase 1b/2
4) A plan with timetable for hiring in Texas
5) Information on whether the company will be able to execute the project based on its previous pre-IND meeting with the FDA, which was held several years ago, or whether a new one will be needed.

PanTher Therapeutics, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

PanTher Therapeutics is a clinical stage oncology company working on treatments for solid tumors. The company is currently based in Cambridge, Massachusetts, and will relocate to Texas if it receives a CPRIT award.

PanTher's novel approach looks to significantly increase drug accumulation at the tumor site, while dramatically reducing systemic side effects to improve antitumor activity, preserve quality of life and lower overall healthcare costs. PanTher's PTM-101 product is a laparoscopically delivered, fully degradable film. This product has the potential to improve tumor response and reduce pancreatic tumors to allow for curative resection.

PanTher's first product, PTM-101, is a drug eluting delivery implant intended to provide paclitaxel directly onto the tumor. PTM-101 is composed of paclitaxel and a bioresorbable polymer poly (lacticco-glycolic acid) (PLGA). The PTM-101 implant is minimally invasively inserted via a trocar during diagnostic laparoscopy and surgically placed directly onto the peritumoral area. PanTher's platform has demonstrated pre-clinical validation – enabling chemotherapy to penetrate 40 times deeper and reach 5-fold higher concentration inside the tumor mass when compared to systemic delivery.

The PLGA ingredients biodegrade over time, resulting in the sustained release of paclitaxel directly towards the tumor, thereby providing localized treatment. The PLGA polymer

biodegrades into lactic and glycolic acids, which are metabolized naturally. For controlled and sustained release of paclitaxel, PTM-101 will be comprised of two different layers of PLGA. The non-tumor facing side of PTM-101 consists of 75:25 PLGA and the tumor facing side of PTM-101 contains paclitaxel incorporated into 50:50 PLGA polymer. The PLGA 50:50 will fully degrade in approximately 1 month (35 days), resulting in Paclitaxel release directly onto the tumor mass.

PanTher's proposal is for the initiation and completion of a Phase Ib/II trial in the US and Australia to build upon the current first-in-man trial to assess efficacy. Over the course of discussions with the FDA, PTM-101 has been deemed a combination product with drug primary mode of action and cleared to use the 505(b)(2) accelerated path to the clinic with a well-defined understanding of the IND package requirements.

PanTher has addressed and completed the majority of testing to be included in the IND submission as part of the ethics approval to start the phase 1 in Australia. The first-year development plan will focus on expansion of the already validated CMC and GMP manufacturing processes for the dose-escalated PTM-101, as well as completing GLP tox studies. Upon IND clearance from the FDA, PanTher will focus on the enrollment and completion of the Phase Ib/2 trial in the US and Australia, in partnership with MD Anderson and other clinical sites.

Select Reviewer Comments

"*The approach significantly increases drug accumulation at the site, while dramatically reducing systemic side effects to improve antitumor activity and preserve quality of life, provide pretreatment before surgery or improvement for tumors that are nonresectable."*

"The application has a number of strengths including the following: (1) prior phase 1 results, (2) sound management and development teams, (3) significant financial backing, (4) straightforward CMC development pathway due to the experience with paclitaxel and PLGA, and (5) lack of competition of locally administered therapies in pancreatic cancer."

De-Identified Overall Evaluation Scores

Company Relocation Product Development Awards

Product Development Research Cycle 22.2

The Product Development Review Council (PDRC) recommended an application with a less favorable score than two other applications that it did not recommend within this mechanism. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

Application ID	Final Overall Evaluation Score
DP220066*	3.6
a	3.3
b	3.3
c	4.7
d	4.7
e	6.7
f	6.7
g	8.7

* Recommended for grant award

Final Overall Evaluation Scores and Rank Order Scores

July 27, 2022

Dr. Mahendra Patel
CPRIT Oversight Committee Chair
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
CPRIT Program Integration Committee Chair
Via email to wroberts@cprit.texas.gov

Dr. Patel and Mr. Roberts,

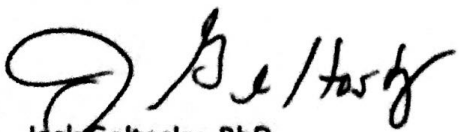
On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 22.2 grant award cycle. The PDRC convened on July 19, 2022, and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Atom Mines, InformAI Inc., Xerient Pharma Inc., PLUS Therapeutics, Inc., Stellanova Therapeutics, Asylia Therapeutics, Rapamycin Holdings Inc., NUCORE Medical and PanTher Therapeutics. The attached table reflects the ranked award recommendation for the nine (9) grant applications.

The PDRC did not make any changes to timelines or budgets for the nine (9) projects recommended for funding. However, two (2) recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP220053 and DP220054 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP220066 related to clinical data, timelines and development plans. Dr. Smith will address the proposed contingencies with the PIC and the Oversight Committee.

I also note that at its July 19, 2022, 22.2 Due Diligence Meeting, the PDRC took "No Action" on one (1) application for CPRIT FY 2022 award budget reasons and to receive additional information. We anticipate that the PDRC will make an award recommendation, if any, regarding this pending application for your consideration as early as the September 2022 Oversight Committee meeting.

Each of the companies included in the PDRC's recommendation reflets 50+ hours of individual review panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,



Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

FY22.2 Product Development Review Council Recommendations

Ranking	ID	Mechanism	Type	PI Last Name	Organization	Application Title	Score from Peer Review
1	DP220039	TXCO Therapeutics	Resubmission	Sims, A.	PLUS Therapeutics, Inc.	Single-Dose 186RNL for Leptomeningeal Metastases: Multicenter Phase 1/2a Study to Determine MTD/MFD, Safety and Efficacy, Leading to Pivotal Registrational Trial	2.2
2	DP220028	SEED Therapeutics	Resubmission	Schuler, E.	Stellanova Therapeutics, Inc.	Development of DKK3-Targeted Therapeutic Antibodies for Cancer	2.3
3	DP220038	SEED Therapeutics	New	Miller, J.	Asylia Therapeutics	Humanization, Validation, and Clinical Translation of Cell Surface Heat Shock Protein 70-Targeted Antibody-Drug Conjugates for T-Cell Non-Hodgkin Lymphomas	2.3
4	DP220055	TXCO MD&D	New	Dorius, K.	Atom Mines	Commercial-Scale Enrichment of Stable Ytterbium-176 for Production of No-Carrier-Added Lutetium-177 for Use in Prostate Cancer Therapy	2.0
5	DP220053	TXCO Therapeutics	New	Kingman, S.	Rapamycin Holdings Inc.	Development of eRapa for the Treatment of Familial Adenomatous Polyposis, a Rare Genetic Disease Associated With a High Risk of Colorectal Cancer	2.7
6	DP220043	SEED Therapeutics	New	Taniguchi, C.	Xerient Pharma Inc.	Oral Amifostine as an Upper GI Tract Radioprotectant for Effective Radiotherapy Treatment of Pancreatic Cancer	2.2
7	DP220063	SEED MD&D	New	Havelka, J.	InformAI Inc.	RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology	2.2
8	DP220066	RELCO Therapeutics	New	Indolfi, L.	PanTher Therapeutics, Inc	Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer	3.6
9	DP220054	SEED MD&D	New	Nathan, J.	NUCORE MEDICAL	Clinical Validation of the MiTR Core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention	3.4

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
Seed Awards for Product Development Research

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA C-22.2-SEED

SEED Awards for Product Development Research

Please also refer to the Instructions for Applicants document, which will be posted on December 1, 2021

Application Receipt Opening Date: December 1, 2021

Application Receipt Closing Date: January 26, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

Rev	11/3/2021	RFA release

1. KEY POINTS

This SEED Award for Product Development Research (SEED Award) mechanism is governed by the following guidelines:

- This grant mechanism is open to company applicants to fund the development of therapeutics, devices, or tools designed to lessen the burden of cancer. The aim of the SEED Award is to narrow the funding gap (sometimes referred to as the "valley of death") between discovery and commercial development, with a focus on Texas-based oncology startups. All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools. Products must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- In the case of therapeutics, Product Development Research award funding supports preclinical research that advances a project toward clinical evaluation. Examples of typical drug development activities that are eligible for funding by the SEED Award mechanism include target validation studies, lead optimization, confirmation of preliminary efficacy and safety findings in further preclinical tests, and demonstration of manufacturability.
- Recipient companies must currently be or commit to be Texas based (see section 8.1) and must have a chief executive officer (CEO) as part of the applicant's management team prior to submitting an application. If an applicant is not currently based in Texas, they must commit to relocating to Texas by meeting the Texas-based location criteria (see section 8.1) within 1 year of receiving the award. The Cancer Prevention and Research Institute of Texas (CPRIT) requires the use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-state entities.
- CPRIT requires recipient companies to raise a portion of the total project budget from external sources. For a company receiving an initial CPRIT award, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the recipient company. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds should, whenever possible, be spent in Texas. A company's matching funds must be dedicated to the CPRIT-funded project but may be spent outside of Texas.

- For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company. More details on the matching funds requirements are provided below.
    - A grantee approved for 1 or more product development grants that together total a commitment of $20 million or less must dedicate to each grant project $1 of their own funds for every $2 of CPRIT grant award funds.
    - A grantee approved for a product development grant award that causes the total amount of committed CPRIT product development grant award funds to exceed $20 million must increase their matching fund obligation to $1 for every $1 contributed by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives three product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under the matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.
    - A company approved for a grant award that would result in more than $30 million in CPRIT product development grant funds must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.
- Applicants may request up to $3.0 million in CPRIT funds. Please note that CPRIT receives many more applications each year than available funds can support. Therefore, only the most meritorious applicants are awarded.
- Funding will be tranched and tied to the achievement of contract-specified milestones. The contract-specific milestones are the Goals & Objectives submitted by the applicant within the proposal. The progress-based release of funds will be dependent upon the completion of the applicant's proposed Goals & Objectives for each project year.
- All award contracts include a revenue-sharing agreement. **A copy of the revenue-sharing agreement can be found at www.cprit.texas.gov in the Product Development Research Program section.** Other contract provisions are specified in CPRIT's Administrative Rules, which are also available at www.cprit.texas.gov.

- An application last submitted, but not funded (including resubmission), before December 4, 2019, may be submitted as a new application, even if it was previously resubmitted (see section 8.2).
- Applicant companies are limited to 1 submission per cycle across all CPRIT Product Development award mechanisms.

2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2.1. Product Development Research Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. CPRIT has established overarching principles and each of CPRIT's 3 grantmaking programs (Academic Research, Prevention, and Product Development Research) have established program-specific priorities. Additional priorities focused at the intersection of the 3

programs have also been established and outlined below. The Product Development Research Program's principles and priorities guide CPRIT staff and the Product Development Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to RFAs.

CPRIT's Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure

CPRIT's Academic Research, Prevention, and Product Development Research Cross-Program Priorities:

- Prevention and early detection initiatives
- Translation of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science infrastructure

CPRIT's Product Development Research Priorities:

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits not currently available, ie, disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early-stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas institutions • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff, to lead to seed clusters of life science expertise at various Texas locations • Providing appropriate return on Texas taxpayer investment

A full description of CPRIT's program priorities may be found at http://priorities.cprit.texas.gov/.

3. EXECUTIVE SUMMARY

CPRIT will foster cancer research as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. This RFA solicits

applications for the research and development of innovative products with potential to address critically important needs related to treatment, diagnosis, and/or prevention of cancer and the product development infrastructure needed to support these efforts. CPRIT encourages applicants who seek to apply or develop state-of-the-art products, services (eg, contract research organization services), technologies, tools, and/or resources for cancer research, prevention, or treatment. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer treatment, prevention, detection or screening. The overall goal of this award program is to improve outcomes of patients with cancer by accelerating the development of groundbreaking therapeutics, diagnostics and tools with a primary focus on Texas-centric programs.

The ideal applicant will be a company that has developed compelling preclinical/discovery stage data around a novel target, compound, device, etc, that warrants further development efforts to establish preclinical proof of concept (POC) on the road to commercialization. These data can arise from the following efforts: discovery and validation of a novel target specific to one or more defined tumor type(s); evidence that preclinical modulation of the target is associated with tumor cell killing or tumor growth inhibition (via both in vitro and in vivo studies if possible); discovery and preliminary biological characterization of an early lead compound, including a biological, or prototype device; establishment of a non-GLP safety profile; definition of a potential therapeutic window; characterization of the synthetic route and manufacturing process; etc. In addition, it is important, when possible, to establish reproducibility in another laboratory. The SEED Award aims to provide the funding such that the company is positioned to begin IND/IDE-enabling studies to support filing the IND/IDE (or equivalent).

4. MECHANISM OF SUPPORT

The SEED Award for Product Development Research is intended to support company formation, as well as early development of novel oncology therapeutics, devices, or tools as described above. A further purpose of the SEED Award is to narrow the funding gap (sometimes referred to as the “valley of death”) between discovery and commercial development, with a focus on Texas-based oncology startups.

SEED Award investments provide companies or limited partnerships located and headquartered in Texas with the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award is intended to support companies that will be staffed with a majority of Texas-based employees, including C-level executives.

5. OBJECTIVES

The long-term objective of this award is to support the development of commercially viable therapeutic and medical technology products, diagnostic- or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA should be the intent to further the research and development of products that would eventually be marketed for the treatment, diagnosis, and/or prevention of cancer. Eligible products or services include—but are not limited to—therapeutics (eg, small molecules and biologics), diagnostics, medical devices, and potential breakthrough technologies, including software and research discovery techniques.

The objective of the SEED Award program is to start with an interesting technology and to progress it toward a commercially viable business opportunity, ie, make it more attractive to private funding agents. Typically, applicants have completed the following activities:

- Identified a novel therapeutic, diagnostic technology, or clinical tool and shown a biological effect
- Replicated/verified the research in a second model and in a second lab
- Conducted preliminary safety and toxicology testing (in the case of therapeutic agents)
- Shown the product can be manufactured at small scale or as a prototype
- Assessed the business opportunity and organized a business plan that begins to address key issues (clinical utility, target market, financial plan, IP strategy, technical challenges, etc) and lays out a preliminary development plan (formulation, toxicology, scale up, IND-enabling studies, phase 1 clinical trials, regulatory pathway, etc).
- Established key preclinical development milestones through IND submission
- Initiated a patent application
- Established a company

CPRIT's objectives and program priorities are established by its Oversight Committee. Consistent with the above, these priorities include "funding projects at Texas companies and relocating companies that are most likely to bring important products to the market." A full description of CPRIT's program priorities may be found at http://priorities.cprit.texas.gov/.

6. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development project proposed. Requested funds must be well justified. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property (IP) acquisition and protection, external consultants and service providers, travel in support of the project, and other appropriate research and development costs, subject to certain limitations set forth by Texas law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are only used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the state. Texas law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

For companies receiving an initial CPRIT award, CPRIT will award $2.00 for every $1.00 contributed in matching funds by the company. The demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be fulfilled on a year-by-year basis.

For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company.

A grantee approved for 1 or more product development grants that together total a commitment of $20 million or less must dedicate to each grant project $1 of their own funds for every $2 of CPRIT grant award funds.

A grantee approved for a product development grant award that causes the total amount of committed CPRIT product development grant award funds to exceed $20 million must increase their matching fund obligation to $1 for every $1 contributed by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under the matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.

A company approved for a grant award that would result in more than $30 million in CPRIT product development grant funds must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

7. KEY DATES

RFA release	November 3, 2021
Online application opens	December 1, 2021, 7 AM central time
Applications due	January 26, 2022, 4 PM central time
Invitations to present sent	March 2022
Notifications sent if not invited	March 2022
Presentations to CPRIT*	April 2022
Award Notification	August 2022
Anticipated Start Date	September 2022

***** Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

8. ELIGIBILITY

8.1. Applicants

- Either for-profit or nonprofit companies may apply. However, nonprofit companies must intend to bring a product to market. Applications may be submitted prior to company

formation, but company formation must be completed before award receipt. Applicants will be required to provide a data universal numbering system (DUNS) number before award receipt.

- Award recipients must be Texas-based. A company is considered to be Texas-based if it currently fulfills or commits to fulfilling a majority of the following criteria:

  1. The US headquarters are physically located in Texas.
  2. The chief executive officer resides in Texas.
  3. A majority of the company's personnel, including at least 2 other C-level employees (or equivalent) reside in Texas.
  4. Manufacturing activities take place in Texas.
  5. At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
  6. At least 1 clinical trial site is in Texas.
  7. The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

  In exceptional circumstances, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.
- Unless otherwise specified by the award contract, the company must fulfill all location requirements identified in the application within 1 year of receiving the initial disbursement of funds. Failure to maintain compliance with the location criteria will result in consequences ranging from suspension of grant funding to early termination of the grant contract and repayment of grant funds.
- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools. Project must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- An application last submitted before December 4, 2019, may be submitted as a new application, even if it was previously resubmitted.
- CPRIT is releasing 3 Product Development RFAs in this funding cycle. Please note that in any given application round, applicants will typically only be allowed to apply for 1 Product Development Award (TXCO, RELCO, or SEED) at a time. Applicants are

advised to review each RFA and select the program that best fits their development status.

- Only 1 coapplicant may be included on the application. For the Product Development Research Program, a coapplicant is an individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. If so designated by the applicant organization, coapplicants share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple applicants are named, each is responsible and accountable for the proper conduct of the project, program, or activity, including the submission of all required reports. The presence of more than 1 applicant on an application or award diminishes neither the responsibility nor the accountability of any individual applicant.
- An applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, or any company officer or director (or any person related to 1 or more of these individual within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or other individuals are ineligible to receive federal grant funds or have had a grant terminated for cause, the applicant may be contacted to provide more information.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although the applicant need not demonstrate the ability to comply with these contractual requirements

at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

8.2. Resubmission Policy

- An application previously submitted to CPRIT within the last 2 years (ie, after December 4, 2019) but not funded may be resubmitted once and must follow all resubmission guidelines. **An application that was last submitted before December 4, 2019, may be submitted as a new application.** For additional clarity regarding the 22.2 application cycle, this means that an application that was last submitted during the 20.1 cycle is considered a new application. In contrast, an application that was last submitted during or after the 20.2 cycle is considered a resubmission. It is expected that significant progress will have been made on the project; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to submit an application with such modest changes.
- An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. An application that was administratively withdrawn by the applicant or by CPRIT prior to review by the review panel is not considered a submission for purposes of CPRIT's resubmission policy.
- CPRIT will consider a first-time SEED award application to be a new application for the purposes of the resubmission policy, even if the application was previously submitted for a TXCO or RELCO award within the past 2 years.
- Applicants who choose to resubmit should carefully consider the reasons provided by CPRIT reviewers for lack of prior success. Applications that received an overall numerical score of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the

resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

9. APPLICATION REVIEW

9.1. Overview

Applications will be assessed based on evaluation of the quality of the research project and the potential to improve diagnosis, prevention, or treatment outcomes in cancer patients. CPRIT requires the submission of a comprehensive development plan (see section 10.4.7) and a business plan (see section 10.4.8). CPRIT review of applications will encompass the commercial viability, product feasibility, scientific merit, and the potential suggested by preclinical results so far for therapeutic impact addressing unmet medical need. Applications will be reviewed by an integrated panel of individuals with expertise in biotechnology, basic/translational/clinical cancer research as well as in the regulatory approval processes for therapeutics, devices, and diagnostics. In addition, cancer patient advocates will participate in the review process.

Funding decisions are made via the review process described below.

9.2. Review Process

- **Product Development and Scientific Review:** Applications that pass initial administrative review are assigned to independent CPRIT Product Development Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of applicants may be invited to deliver in-person presentations to the review panel.
- **Due Diligence Review:** Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—IP, management team strength, regulatory aspects, manufacturability, preliminary preclinical safety and efficacy profiles, and proposals for further preclinical development that are

intended to advance the project to the point where IND-enabling studies can be initiated. Please note that CPRIT may request to review any correspondence that an applicant has conducted with regulatory agencies (eg, the FDA) as part of the diligence process. Following the due diligence review, applications may be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and IP reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.

- **Program Integration Committee Review:** Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.
- **Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Peer Review Panel members, Product Development Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Any form of communication regarding any aspect of a pending application is prohibited between the applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

Attached to this RFA is a list of more detailed questions considered by CPRIT reviewers when assessing therapeutic applications (Appendix 1, "Reviewer Evaluation Guidelines for Therapeutics") and when assessing medical devices, diagnostics, and/or tools (Appendix 2, "Reviewer Evaluations Guidelines for Medical Devices and Diagnostics"). Applicants are encouraged to review these documents and, to the extent possible, address the questions within their application.

CPRIT recognizes that some, perhaps much of the preclinical characterization alluded to in previous sections in the context of SEED Award eligibility may not be available at this

stage of development. We encourage applicants to be as thorough as possible in describing their current stage of development.

9.3.1. Primary Criteria

The objective of a SEED Award is to fund the work necessary to advance the project to the point where IND-enabling studies can be initiated or, in the case of diagnostics/tools, to complete appropriate prototyping and validation work and position the company to raise private capital. As an example, in the case of drug candidates, specific technical activities the SEED Award mechanism can fund may include the following:

- Performing target validation
- Conducting lead optimization
- Performing target and cellular potency studies
- Developing and validating biomarker/pharmacodynamic marker assays
- Determining pharmacokinetic and exposure parameters; determining whether concentrations that result in significant cell death or tumor growth inhibition in vitro can be safely achieved in vivo; establishing in vivo pharmacodynamic proof of concept
- Evaluating biopharmaceutical properties (absorption/bioavailability, distribution, metabolism, and clearance in rodents and nonrodents)
- Optimizing synthetic/bioengineering route
- Developing a prototype clinical formulation
- Expanding preclinical safety characterization in non-GLP studies
- Expanding in vivo preclinical efficacy characterization in tumor models, including where feasible patient-derived xenograft models, that most closely approximate the initial target indication

SEED Awards may be used to carry out comparable activities for other classes of applications such as medical devices or diagnostics.

Specific business activities the SEED Award mechanism can fund may include the following:

- Competitive analysis
- Extent of unmet need
- Target product profile

- Description of development plans including integrated project milestones
- Preparation of clinical development plan
- IP development plans

Primary review criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a flaw in the significance and/or design of the proposed program.

The criteria provided below are designed to provide an **overview** of topics that may be pertinent to the assessment of applications during peer review. Specific criteria applied to evaluate a given application will depend on the type of product described by the applicant, eg, therapeutic versus medical device. **Detailed descriptions of the specific criteria employed for different product classes are provided in the appendices to this RFA.**

Primary review criteria are heavily weighted in determining the quality of an application. Reviewers provide numerical scores for these topic areas when evaluating applications. Primary criteria are intended to address the following topics:

- Significance and Impact
- Unmet Medical Need
- Product Validation/Proof of Concept
- Safety
- Preclinical Strength/Development to Date
- Development Plan
- Competitive Landscape
- Intellectual Property
- Business/Commercial Aspects
- Management and Staffing
- Production/Manufacturing Plan
- Overview of Clinical/Regulatory Plan

More details regarding these topics can be found in the appendices to this document.

9.3.2. Secondary Criteria

Secondary review criteria contribute to the global score assigned to the application and are not assigned individual numerical scores. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include the following:

- Budget and Duration of Support

Please see appendices for more details.

10. SUBMISSION GUIDELINES

Applicants are advised to review carefully all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available on December 1, 2021. Applications that are missing 1 or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

10.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The applicant must create a user account in the system to start and submit an application. The coapplicant, if applicable, must also create a user account to participate in the application. Furthermore, the Application Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. It is acceptable (and not uncommon) for the applicant to also serve as the designated ASO. However, if the applicant intends to also serve as the ASO, the system requires that the applicant and the ASO have 2 different accounts and usernames. Applications will be accepted beginning at 7 AM central time on December 1, 2021 and must be submitted by 4 PM central time on January 26, 2022. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

10.2. Submission Deadline Extensions

The submission deadline may be extended upon a showing of good cause. Late submissions are permitted only in exceptional instances, usually for technology failures in the CARS. It is imperative that applicants allow sufficient time to familiarize themselves with the application format and instructions to avoid unexpected issues. The applicant's failure to adequately plan is not sufficient grounds to justify approval of a late submission.

Peer review schedules are set far in advance and do not accommodate receipt of an application days after the deadline. Therefore, potential applicants that are unable to meet the deadline due to issues such as travel, sabbaticals, conferences, prolonged illness or other leave, etc, should not request additional time to submit an application but should instead consider submitting the application in the next review cycle.

A request to extend the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records and are intended to allow an applicant to complete and submit an incomplete application that has already been started in CARS. If a request for extension is approved, then CARS will be reopened for an additional 2 hours to allow an applicant with an unsubmitted application to complete and submit it. Applicants are also urged to initiate the registration process on CARS a minimum of 5 business days prior to deadline to ensure enough time to complete and submit an application.

10.3. Product Development Review Fee

All applicants must submit a nonrefundable fee of $500 for review of Product Development Research SEED applications. Payment should be made by check or money order payable to Cancer Prevention and Research Institute of Texas; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. Unless a request to submit a late fee has been approved by CPRIT, all payments must be postmarked by the application submission deadline and mailed as described below.

Checks may be mailed via the US Postal Service to the following address:

Cancer Prevention and Research Institute of Texas
PO Box 12097
Austin, Texas 78711

Contact name: Michelle Huddleston

Phone 1-512-305-8420

Mail sent via a delivery services (ie, FedEx, UPS, etc) will need to use this address:

Cancer Prevention and Research Institute of Texas

Wm B Travis State Office Building

1701 N Congress Ave Ste 6-127

Austin, Texas 78701

Contact name: Michelle Huddleston

Phone 1-512-305-8420

10.4. Application Components

Applicants are advised to minimize repetition among application components to the extent possible. In addition, applicants should use discretion in cross-referencing sections in order to maximize the amount of information presented within the page limits.

Please note that letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc, are **not** required or requested. Please do not submit letters of support as part of your application package. **Any such information will be removed from your application before review**.

10.4.1. Abstract and Significance (5,000-character maximum)

Coherently explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Describe the unmet medical need addressed by the proposed project and describe how the proposed project, if successful, will have a major impact on the care of patients with cancer. Describe how this application provides a path for acquiring proof-of-principle data necessary for next-stage commercial development. Clearly explain the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

10.4.2. Layperson's Summary (1,500-character maximum)

Provide a summary of the proposed project using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Describe the overall goals of the project, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The layperson's summary will also be used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

10.4.3. Goals and Objectives (maximum of 1,200 characters each)

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. Identify time-specific references as follows: Year 1, Quarter 1 (Y1Q1), Y1Q2, etc. Do not specify actual calendar dates as this can be confusing when dates change.

10.4.4. Timeline (1-page maximum)

Provide a visual depiction of anticipated major milestones to be tracked in the form of a Gantt chart. Identify time-specific references as follows: Y1Q1, Y1Q2, etc, as opposed to naming specific months and years. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. When appropriate, provide go/no-go decision points along the timeline. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

10.4.5. Slide Presentation (10-page maximum)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with 1 slide filling each landscape-oriented page. The slides should succinctly capture all essential elements of the application and should stand alone.

10.4.6. Resubmission Summary (1-page maximum)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

Note: An application submitted before December 4, 2019, may be submitted as a new application, even if it was previously resubmitted. For "new" applications, no resubmission summary is required.

10.4.7. Development Plan (12-page maximum)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. **Describe the label claims that the company ultimately hopes to make and describe the plan to gather evidence to support these claims**. Outline the steps to be taken during the proposed period of the award, including the design of the translational and/or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches to these risks. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The development plan should include a defined **product profile (PP).** The format for the PP should be a target product profile (TPP) in the case of a therapeutic, or analogous document for a medical device, in vitro diagnostic, or service that projects a clear path to full commercialization. The PP provides a statement of the *overall intent* of the product development program and gives information about the product *at a particular time* in development. Usually, the PP is organized according to the key sections in the product package insert for a drug or biologic (but not medical device or diagnostic labeling, which must be developed by the applicant in an analogous fashion) and links development activities to specific concepts intended for inclusion in the product labeling. CPRIT recognizes that many applications are early in the development process and that not all elements of the PP will be known at the time of application. Consequently, not

only does the PP serve as a snapshot in time of the development status of the program, but it additionally serves as an aspirational target upon eventual commercialization. The PP should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- Identification of a target that is applicable to human cancer treatment. Is intervention with this target likely to lead to a therapeutic, medical device, diagnostic, or service that could be useful in the treatment or prevention of cancer?
- Selection of a lead compound, assay, or device technology based on the target. Is the identification of potential developmental candidates based on a set of in vitro tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of pharmacodynamic parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?
- Description of a high-level clinical development plan detailing each of the clinical studies supporting marketing approval (phase 1, 2, and 3) the preclinical work is meant to support. Designing the preclinical program requires an understanding of the duration of the clinical studies required by regulatory authorities. Consequently, a brief outline of each of the phase 1, phase 2, and phase 3 studies necessary to obtain regulatory approval and reimbursement funding must be sketched out prior to deciding which toxicology studies would be required.

Applicants developing cancer therapeutics are encouraged to become familiar with FDA guidance documents for submission of applications related to new product development. These documents provide a standard framework for new drug submissions and biologic license applications to the FDA. Utilizing this framework helps ensure that the submission to CPRIT contains all relevant elements and is optimally organized.

Additionally, for therapeutics, the following apply:

Optimization of the lead compound to ensure desired characteristics, including, but not limited to, the following studies:

- Indication of the threshold of both the safety and efficacy necessary to be a competitive product when the product is introduced
- Absorption, distribution, metabolism, excretion, including, but not limited to, relevant studies based on route of administration

- Safety (studies as mandated by ICH guidelines)
- Biomarkers (assays) that potentially target specific patient populations for clinical trials
- Biomarkers (assays) that can serve as potential pharmacodynamic markers of clinical activity during early clinical trials designed to demonstrate proof of concept
- Proposed current good manufacturing practice (including estimated costs) that can be scalable from phase 1 through phase 2. Include information on whether there are plans for possible formulation.

References for the Development Plan section should be provided as a stand-alone document that will be separately uploaded into CARS. In the interests of brevity include only the most pertinent and current literature. While references will not count toward the Development Plan section page limit, it is essential to be concise and to select only those references relevant to the development plan. **Do not use the references to circumvent Development Plan section page limits by including data analysis or other nonbibliographic material.**

The development plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, the development plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred. Please avoid redundancy!

CPRIT recognizes much, if not most, of this information is not available at this stage of development. However, we encourage applicants to be as complete as possible in describing their current stage of development. Applicants developing diagnostics, devices, or cancer-specific services should provide analogous information relevant to their product and project.

10.4.8. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies typically need to raise substantial funds from private sources to fully fund development. Hence, we require companies to provide a business plan that summarizes the rationale for investing in this project. Private investors will seek a financial return on their investment. They will need to be convinced that this project has high investment return potential based on its risk profile. They typically focus on market opportunity size, development path, and key risk issues.

Successful applicants will provide a thoughtful, careful, and succinct rationale explaining why this program is an appropriate investment of CPRIT and private funds. Note that if the company is selected to undergo due diligence, additional information (such as the company's interactions with regulatory agencies such as the FDA, etc) to support the application may be requested at that time. Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

Please provide an overview of the business rationale for investing in this project. The business rationale overview will be 2 pages maximum. In addition, please provide summaries of the following key development issues with a maximum of 1 page each.

1. **Product and Market:** Provide an overview of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care, ie, primary therapy, second-line therapy, adjunctive to current therapies, etc. Information on patient populations and market segments is helpful.
2. **Competition and Value Proposition:** Provide an overview of the competitive environment (current and future) and how the envisioned product will compete in the marketplace.
3. **Clinical and Regulatory Plans:** Provide an overview of plans for clinical activities and the regulatory pathway for major markets. Please describe how this is driven by interactions with the FDA, if possible. The regulatory plan should include regulatory communications (including all interactions to date with the FDA) and strategy, with clarity provided on regulatory matters and current regulatory strategies.
4. **Commercial Strategy:** Provide an overview of your anticipated commercial market with a brief assessment of current competition.
5. **Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated. Key risk issues typically include efficacy versus competitors, toxicity, clinical trials, FDA approval, dosage and delivery, CMC synthesis, changing competitive environment, etc.

6. **Funding to Date:** Provide an overview of the funding received, including a list of funding sources and a comprehensive capitalization table that should comprise all parties who have investments, stock, or rights in the company. A template exemplifying an appropriate capitalization table is provided among the application materials and MUST be used when completing your application. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.

7. **Intellectual Property:** Provide a concise discussion of the IP issues related to the project. List any relevant issued patents and patent applications. Please include the titles and dates the patents were issued/filed/published. List any licensing agreements that the company has signed that are relevant to this application.

8. **Key Personnel Located in Texas and Any Key Management Located Outside of Texas:** For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications. Key personnel are the Principal Investigator/Project Director as well as other individuals who contribute to the development or the execution of the project in a substantive, measurable way. *Substantive* means they have a critical role in the overall success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project. *Measurable* means that they devote a specified percentage of time to the project. The indicated time is an obligatory commitment, regardless of whether or not they request salaries or compensation. "Zero percent" effort or "TBD" or "as needed" are not acceptable levels of involvement for those designated as key personnel. While all participants that meet these criteria should be identified as "key," it is expected that the number of key personnel will be kept to a minimum.

The entire Business Plan section shall typically comprise a maximum of 10 pages: a 2-page overview and eight, 1-page key issue summaries. Please avoid redundancy. Note that the section "Funding to Date" above may exceed this 1-page limit if necessary.

CPRIT recognizes much of this information is not available at this stage of development. However, we encourage applicants to be as complete as possible in describing their current stage of development.

10.4.9. Biographical Sketches of Key Scientific Personnel (8-page maximum)

Provide a biographical sketch for up to 4 key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. You may use either the provided "Product Development Research Programs: Biographical Sketch" template or the NIH biographical sketch format. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see section 10.4.8]).

10.4.10. Relocation Commitment to Texas (1-page maximum)

If the applicant is not currently Texas-based, provide a timetable with key dates indicating the applicant's plan and commitment to relocate the company to Texas. In addition, describe which personnel and management will be headquartered in Texas.

10.4.11. Budget

In preparing the requested budget, applicants should be aware of the following:

- Each award mechanism allows for up to a 3-year funding program with an opportunity for extension after the term expires. **The budget must be aligned with the proposed milestones.** Financial support will be awarded based upon the breadth and nature of the project proposed. Requested funds must be well justified. Funding will be tranched and milestone driven.
- CPRIT considers equipment to be items having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit. If awarded, management of your grant will be facilitated if specific equipment is clearly identified in the application using plain language. **Equipment not listed in the applicant's budget must be specifically approved by CPRIT subsequent to the award contract**.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.
- The total amount of CPRIT funds allowed for an annual salary of an individual for FY 2022 is $200,000. In other words, an individual may request salary proportional to the

percentage effort up to a maximum of $200,000. Salary amounts in excess of this limit must be paid from matching funds. Salary does not include fringe benefits. CPRIT FY 2022 is from September 1, 2021, through August 31, 2022.

Additionally, adjustments of up to a 3% increase in annual salary are permitted for Years 2 and 3 up to the cap of $200,000. The salary cap may be revised at CPRIT's discretion.

The Budget section is composed of 4 subtabs that must be completed:

A. **Budget for All Project Personnel:** Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all personnel participating on this project. If funding is requested for a role that is not currently occupied, applicant should note "new hire" as name.

B. **Detailed Budget for Year 1:** <u>This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project</u>. Provide the amount requested from CPRIT for direct costs in the first year of the project. Direct cost categories include Travel, Equipment, Supplies, Contractual (Subaward/Services Contracts), or Other. Applicants will be required to itemize costs.

C. **Budget for Entire Proposed Period of Performance:** <u>This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project</u>. Provide the amount requested from CPRIT for direct costs for all subsequent years. Amounts for *Budget Year 1* will be automatically populated based on the information provided on the previous subtabs; namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*.

D. **Budget Justification:** <u>Please specify your CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds</u>. Use of the provided Budget Justification template is mandatory. Please specify each line item from your CPRIT budget as well as other funds (including matching funds). Provide a compelling justification for the budget for each line item of the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. **If travel costs will include out-of-state or international travel, make that clear here.** The budget must be aligned with the proposed milestones.

11. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and IP rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10 to 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT utilizes 2 methods of disbursement of grant funds, (1) reimbursement and (2) advancement. Under the reimbursement method, the grantee is expected to finance its operations with its own working capital. Under the advancement method, CPRIT disburses grant funds in advance of the grantee incurring expenses. Grantees must be approved by the Oversight Committee to receive advancement of funds. Please see chapter 8 of the CPRIT Grant Policies & Procedures Guide for additional details regarding the disbursement of grant funds.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

Project Revenue Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement, which can be found at www.cprit.texas.gov and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has appropriate matching funds. For companies receiving an initial CPRIT award, the company must contribute $1.00 in matching funds for every $2.00 awarded by CPRIT. For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company. See section 6 ("Funding Information") of the RFA for more details. Matching funds need not be in hand when the application is submitted, nor does the entire amount of matching funds for the full 3 years of the project need to be available at the start of the grant. However, the appropriate amount of matching funds for each specific tranche must be obtained before each tranche of CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements associated with the requirement to demonstrate available funds.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific and product development aspects of applications. **Before contacting the helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. In addition, for Frequently Asked Programmatic Questions, please go here, and for Frequently Asked Technical Questions, please go here.**

Hours of operation:	Monday through Friday, 8 AM to 6 PM central time
Tel:	866-941-7146 (toll free in the United States only—international applicants should use the email address below)
Email:	Help@CPRITGrants.org

13.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Product Development Research Program Senior Manager.

Tel:	512-305-7676
Email:	Help@CPRITGrants.org
Website:	**www.cprit.texas.gov**

14. APPENDIX

14.1. Reviewer Evaluation Guidelines for Therapeutics

Primary Review Criteria (Scored)

The following criteria will be used by the Reviewer Panel to assess and score applications. Due to the early-stage nature of SEED projects, CPRIT reviewers are aware that not all criteria listed below will be relevant to a particular SEED application, as some development milestones will remain to be completed.

Unmet Medical Need: Target Product Profile (TPP)

- Assuming successful accomplishment of development objectives, as reflected in the target product profile, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Target Validation

- If this is a "targeted" agent, to what extent has the target been validated, eg, through knockdown studies and/or pharmacological intervention?
- Has engagement of the target with the agent been demonstrated by biochemical assay? What is the potency of the agent?
- Are there validated downstream pharmacodynamic (PD) markers of target modulation? How extensive is the in vitro evidence for expected PD effects? Has the agent shown biologically significant modulation of the target in vivo, especially in tumor tissue?
- Is the target uniquely or substantially overexpressed by tumor versus normal cells?
- Does the target represent an activating mutation? If so, has binding of the agent to the target and other activating mutations been characterized?
- Has the company's demonstration of target validation been externally/independently confirmed?

- Are there known mechanisms of resistance to the modulation of this target? If so, has the company proposed possible mitigation/preemptive approaches, such as combination therapies?

Preclinical Characterization: Pharmacodynamic Proof of Concept

- Considering in vivo preclinical pharmacodynamic characterization and the patient populations or subpopulation(s) representing the initial clinical indication(s) for the drug, what is the clinical relevance of the preclinical models? To elaborate, were in vivo/xenograft studies carried out in cell line–based models or PDX-derived models? In how many such models have studies been carried out? To what extent do these models reflect standard of care (SOC) for refractory versus drug-naive tumors? At the time of treatment initiation, were tumors established and measurable, or was treatment initiated shortly after tumor inoculation?
- Was antitumor activity predominantly growth inhibition or tumor regression? Were sustained complete remissions or "cures" achieved in the majority of animals and models? Were comparisons with optimally dosed SOC agents made? Where the agent is intended to be added to the SOC, is there compelling evidence of in vitro/in vivo synergy with SOC agents?
- Have results of preclinical pharmacodynamic studies carried out by the company been externally/independently confirmed?
- Overall, considering clinical relevance and study results, how strong is the preclinical efficacy profile of the agent?
- How strongly does the preclinical pharmacodynamic profile support the clinical efficacy expectations reflected in the TPP?

Preclinical Characterization: Safety

- How extensive is the in vitro and in vivo preclinical safety characterization carried out so far?
- Considering potency and target selectivity, what is the potential both for off-target and pharmacologically on-target deleterious effects?
- Overall, are results of safety characterization carried out so far such that the agent can be considered reasonably derisked from a safety perspective, or are there red flags?

Alternatively, is the extent of preclinical safety characterization carried out so far insufficient to address this question?

Pharmaceutical Properties/Chemistry and Pharmacy

- In the case of agents intended for oral absorption, are there any issues with water solubility? Do formulation studies indicate the feasibility of oral administration?
- Were Lipinski-type criteria applied during the lead optimization process such that the lead compound has demonstrated properties that make it likely to be an orally active drug in humans?
- Have stability studies been initiated?
- Is there scope for further lead optimization through structure-activity studies?
- In the case of biologicals, have efforts to develop a high-quality cell line been initiated? Any data on yields and scalability?
- Have analytical method development been initiated?
- Have studies to characterize the (lead) protein begun? Any stability data?

Development Plan/Regulatory Aspects

- At a high level, are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
- Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions (United States/European Union)? Do development proposals reflect specific regulatory authority input, eg, from pre-IND interactions?
- Considering target indication prevalence, will the agent qualify for orphan drug designation? If so, does the applicant intend to apply for this?
- Will the proposed programs advance development of the agent to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding?
- Are development milestones clear and adequately described? Is the overall project timeline realistic?

Competitive Analysis

- Has the applicant identified likely competitive products on the market and in development?

Intellectual Property/Freedom to Operate

- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate?

Chemistry, Manufacturing, and Controls (CMC)

- How advanced is CMC and manufacturing development?
- Are there any sourcing issues?
- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- Do any members of the company have this expertise, or are outside consultants being exclusively relied upon?

Business/Commercial Aspects

- Does the applicant need to raise further funds for the CPRIT matching requirement? In this case, how realistic are the applicant's assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and CMC/manufacturing? If not, are there plans to address such deficiencies?

- Has the applicant demonstrated appropriate engagement of outside development expertise through, for example, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

14.2. Reviewer Evaluation Guidelines for Medical Devices and Diagnostics

Primary Review Criteria (Scored)

The following criteria will be used by the Reviewer Panel to assess and score applications. Due to the early-stage nature of SEED projects, CPRIT reviewers are aware that not all criteria listed below will be relevant to a particular SEED application, as some development milestones will remain to be completed.

Unmet Medical Need

- Assuming successful accomplishment of development objectives, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Product Validation

- Technical Validation: Has the product or technology been successfully validated, ie, prototyped, built, and tested in ex vivo, animal, or clinical setting?
- Have biological proof of principle and product mechanism of action been demonstrated?
- Have efficacy and safety in an accepted in vitro or animal model been demonstrated?
- Clinical Validation: Are clinical trials required to demonstrate product performance? If so, have they been planned?
- Biological Risk: What are the risks to the patients, eg, toxicology, biological, interactions with other therapies?

Production/Manufacturing

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- How advanced is manufacturing development?
- Are there any sourcing issues?

Intellectual Property/Freedom to Operate

- Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique knowhow, etc?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use), and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has applicant secured appropriate licenses conferring freedom to operate, if required?

Market Opportunity

- Does product address a clearly defined unmet need; lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?
- Are target indication and market clearly defined?
- Does the company understand the clinical pathway that leads to utilizing the product?
- How does product fit with existing "ecosystem"; ie, are the benefits provided worth the time and cost of implementing the new approach?

Competition

- Is this a "Whole Product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
- Has the applicant identified likely competitive products on the market and in development?

Development Plan/Regulatory Aspects

- At a high level, are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
- Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as product engineering, clinical development, regulatory affairs, manufacturing, etc? If not, are there plans to address such deficiencies?
- Has applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Business/Commercial Aspects

- Does the applicant need to raise further funds for the CPRIT matching requirement? In this case, how realistic are assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Has the company anticipated pricing strategy and reimbursement environment?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Does the applicant demonstrate an understanding of the Texas spending requirement for CPRIT funds?

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel 1
(22.2_PDR_PDP_1)
Observation Report

Report No.	2022-03-21 22.2_PDR_PDP_1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel 1 (22.2 _PDR_PDP_1)
Panel Date:	March 21, 2022
Report Date:	March 29, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel 1 (22.2_PDR_PDP_1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on March 21, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and six (6) applications were not discussed
- Panelists: One (1) panel chair, four (4) PDRC members, eight (8) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Four (4)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The applications for which there were COIs were not discussed.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

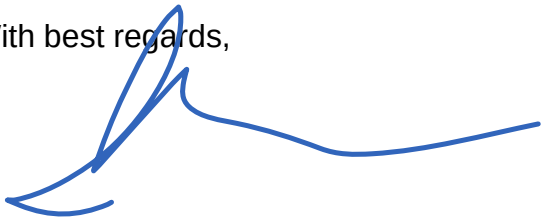
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel_2
(22.2_PRD_PDP_2)
Observation Report

Report No.	2022-03-22 22.2_PRD_PDP_2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel_2 (22.2 _PRD_PDP_2)
Panel Date:	March 22, 2022
Report Date:	March 29, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel_2 (22.2_PRD_PDP_2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on March 22, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Thirteen (13) applications were discussed and five (5) applications were not discussed
- Panelists: One (1) panel chair, three (3) PDRC members, nine (9) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) Conflicts of Interest (COIs) identified prior to and/or during the meeting. There were two (2) COIs on the application discussed and five (5) COIs on the applications not discussed. Those with COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

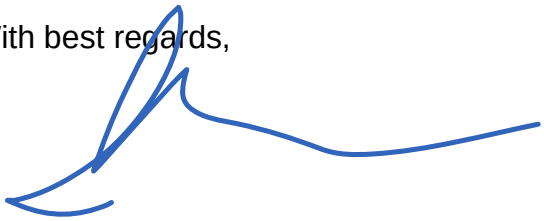
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel-1 (22.2 PDR-PDP1)
Observation Report

Report No.	2022-04-11 22.2_PDR-PDP1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel-1 (22.2 _PDR-PDP1)
Panel Date:	April 11, 2022 and April 12, 2022
Report Date:	June 8, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel-1 (22.2_PDR-PDP1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on April 11, 2022 and April 12, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed and nine (9) applications were not discussed
- Panelists : One (1) panel chair, four (4) PDRC members eight (8) expert reviewers, and two (2) advocate reviewers were present on both days
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) on day 1 and six (6) on day 2
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2) were present on both days
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

In total there were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meetings over two days. COI(s) were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

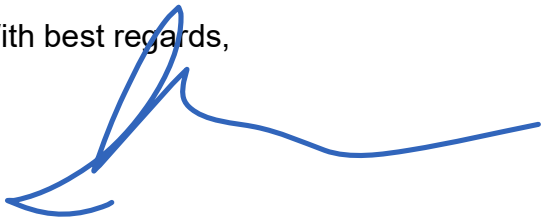
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel-2 (22.2 PDR-PDP2)
Observation Report

Report No.	2022-04-13 22.2_PDR-PDP2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel-2 (22.2 _PDR-PDP2)
Panel Date:	April 13, 2022 and April 14, 2022
Report Date:	June 8, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel-2 (22.2_PDR-PDP2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on April 13, 2022 and April 14, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Eight (8) applications were discussed and ten (10) applications were not discussed
- Panelists: One (1) panel chair, three (3) PDRC members, ten (10) expert reviewers, and two (2) advocate reviewers on both days
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Seven (7) on day 1 and five (5) on day 2
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2) on both days
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) Conflicts of Interest (COIs) identified prior to and/or during the meeting. COI(s) were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

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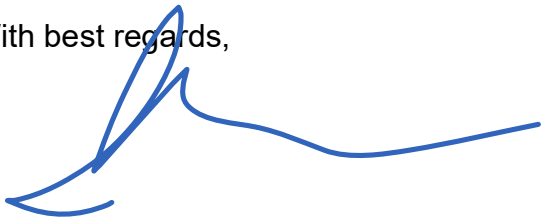

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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Duligence Panel-1 (22.2_PDR_DDP1)
Observation Report

Report No.	2022-07-13 22.2_PDR_DDP1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Duligence Panel-1 (22.2 _PDR_DDP1)
Panel Date:	July 13, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Due Duligence Panel-1 (22.2_PDR_DDP1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on July 13, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Five (5) applications were discussed
- Panelists: One (1) panel chair, three (3) expert reviewers, and four (4) PDRC members
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- ICON Due Diligence Evaluators: Five (5)
- ICON Due Diligence Evaluators did only provide input when requested

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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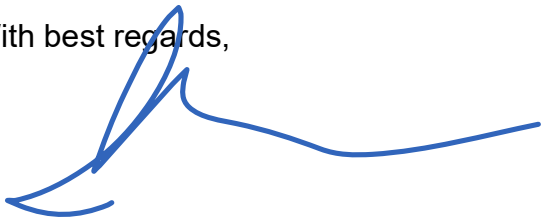

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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Duligence Panel-2 (22.2_PDR_DDP2)
Observation Report

Report No.	2022-07-14 22.2_PDR_DDP2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Duligence Panel-2 (22.2 _PDR_DDP2)
Panel Date:	July 14, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Due Duligence Panel-2 (22.2_PDR_DDP2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on July 14, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: One (1) panel chair, Four (4) expert reviewers, and three (3) PDRC members
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Four (4)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- ICON Due Diligence Evaluators: Three (3)
- ICON Due Diligence Evaluators did only provide input when requested

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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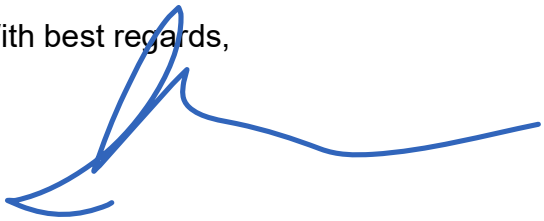

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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Diligence Ranking (22.2_PDR_DD Ranking)
Observation Report

Report No.	2022-07-19 22.2_PDR_DD Ranking
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Diligence Ranking (22.2 _PDR_DD Ranking)
Panel Date:	July 19, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Due Diligence Ranking (22.2_PDR_DD Ranking) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on July 19, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and one (1) applications were not discussed
- Panelists: One (1) panel chair, one (1) vice chair, and seven (7) PDRC Members
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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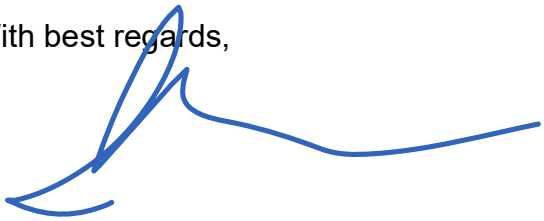

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Business & Financial Management Solutions, LLC

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Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Product Development Research Cycle 22.2

Awards Announced at the August 17, 2022, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 22.2 include: *Seed Awards for Product Development Research; Company Relocation Product Development Research Awards;* and *Texas Company Product Development Research Awards.*

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/Principal Investigator	Principal Investigator Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
No reported COIs.			
Applications not considered by the PIC or Oversight Committee:			
DP220058	Vicci Korman	Veravas, Inc.	Steven Weinstein
DP220060	Eric Rothe	Tiburon Bio, Inc.	Elaine Jones
DP220061	Chen Liu	CHEN LIU	Steven Weinstein
DP220042	David Arthur	Salarius Pharmaceuticals, Inc.	Kristine Swiderek
DP220050	Amos Ofer	EnCellX Inc.	Michael Cheng
DP220052	Timothy Coleman	Nemucore Medical Innovations, Inc.	Alan West, Lior Braunstein, Lee Greenberger, Michael Cheng
DP220056	Douglas Baum	QSAM Biosciences Inc.	Roy Cosan

High Level Summary of Due Diligence

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- StellaNova Therapeutics, Inc. for $3,000,000.

The PDRC did not recommend any contract contingencies for this award.

StellaNova Therapeutics, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

StellaNova Therapeutics Inc. is a Houston-based company based around research conducted at MD Anderson Cancer Center demonstrating that cells in the tumor microenvironment of pancreatic cancer (PDAC) and triple negative breast cancer (TNBC) produce Dickkopf-3 (DKK3) that acts on neighboring cancer cells to stimulate their growth, metastasis and resistance to standard therapy.

Novel therapies are urgently needed for pancreatic cancer and triple negative breast cancer, two of the most aggressive cancers with no effective cure. For pancreatic cancer, 4,420 Texans and 60,000 Americans are diagnosed each year and only 7% are expected to survive 5 years. Triple negative breast cancer is also aggressive, affecting 3,000 women in Texas and 42,000 in the US annually, with a disproportionate impact on African American and Hispanic women. Given the lack of effective therapies for these diseases, the successful development of DKK3-targeted therapy has the potential to be practice-changing for the field.

StellaNova is developing novel antibodies to block DKK3 (anti-DKK3 mAb). Anti-DKK3 mAb inhibited tumor growth in mice and produced long-term survival with no toxicity. For TNBC, treatment also reduced lung and brain metastases. Anti-DKK3 mAb is effective either alone or in combination with immunotherapy. Preclinical models validated the importance of DKK3 on the genetic and pharmacological levels, revealing that (1) DKK3 knockout inhibited PDAC tumor growth and metastasis, and increased survival in the KPC model, and (2) anti-DKK3 mAb (JM6-6-1) inhibited PDAC progression and metastasis, increased survival, and promoted an influx of CD8+ T cells into the “immunologically cold” tumor microenvironment. StellaNova will generate a high-quality producer cell line and generate cGMP qualified Master Cell Bank (MCB) for the large-scale production of the Development Candidate Humanized anti-DKK3 antibody which can be used for IND enabling GLP toxicity studies. These studies will be used for a cGMP 2000-L scale batch production that will be used in Phase 1/1B clinical trials.

Select Reviewer Comments

"The preclinical data establishing DKK3 as a possible therapeutic target in pancreatic cancer from Dr Hwang's lab are excellent. JM6-6- 1, a murine DKK3 neutralizing antibody, has been evaluated in a wide range of mouse models (granted preliminary data presented in very small tumors initially). These data seem promising."

"This is a very solid application arising from work done by top-notch, world-class cancer biology researchers at MD Anderson."

"The company appears to have excellent team with requisite skills and knowledge to move this project forward, including experienced CRO and mAb expertise. Stellanova is part of SPOROS Bioventures portfolio, who is well known to CPRIT for other parallel initiatives, and appears well organized in supporting this type of development."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Asylia Therapeutics, Inc. for $3,000,000.

The PDRC did not recommend any contract contingencies for this award.

Asylia Therapeutics, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Asylia Therapeutics, Inc. is a Houston-based, privately held development stage biopharmaceutical company which received a CPRIT award in 2020. Asylia is developing antibody therapies for cancer based on the discovery of the central role of heat shock protein-70 (HSP70) in tumor antigen presentation, immune activation and cellular stress responses.

Asylia discovered two entirely novel monoclonal antibodies with distinct mechanisms of action. ASY-77A targets the extracellular, soluble form of HSP70 released from cancer cells in complex with tumor-derived antigenic peptides (currently funded CPRIT SEED grant) and 239-87, targeting the cell surface form of HSP70, which is the focus of this proposal.

Asylia is developing an antibody drug conjugate (ADC) based on antibody 239-87, that recognizes the cell surface form of HSP70. Treatment with 239-87 resulted in prolonged eradication (cures) of several cancer types in mice transplanted with human cancer cells. Asylia plans to humanize and optimize mouse mAb, 239-87 to be able to manufacture cell line to produce the antibody, as well as to optimize a linker to connect the antibody to the drug. Asylia will also improve process development for ASY-87 to perform IND-enabling toxicology studies. The company will produce an ADC conjugate that can be tested for safety and efficacy in cancer patients who are failing current therapies in cancers, in particular those with T-cell lymphoma. Encouraging initial trial results will support the broader testing in other tumor types with high cell surface HSP70 expression such as Myeloma and Breast Cancer.

Select Reviewer Comments

“*Targeting HSP70 could have a wide range of cancer applications. Based on preclinical data that it shows highest expression in T-cell lymphoma, they wish to start there. T-cell lymphoma has a very high unmet need.”*

"In summary, this is a very professionally prepared application by a highly competent management team. CsHSP-70 is a promising new cancer therapeutic target with considerable preclinical validation as well as supporting clinical outcomes correlations."

"Additional in vivo preclinical studies in combination with an HDAC inhibitor and in combination with BV are planned. Not only do these approaches provide a potential backup strategy in PTCL, but they may set the stage for a post (accelerated) approval confirmatory study, and moreover, may pave the way for integration of the agent with SOC agents for earlier lines of therapy."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Xerient Pharma, Inc. for $2,934,737.

The PDRC did not recommend any contract contingencies for this award.

Xerient Pharma, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Xerient is a Houston-based startup dedicated to the development of an orally administered tablet that releases very efficient radioprotectant molecule in the duodenum. Xerient demonstrated that it is possible to repurpose an FDA-approved radioprotectant, and reformulate it in a tablet with a targeted-delivery and in-body-monitoring functionalities to allow very efficacious radiation therapy.

Pancreatic cancer cannot be cured without surgery. Nearly 90% of patients present with unresectable disease (locally advanced + metastatic), leaving patients and clinicians with very few treatment options once chemotherapy is completed. Radiation therapy cannot substitute for surgery because of morbid radiotoxicity to the nearby intestines that occurs before the tumor is controlled. Thus, treatment-related gastrointestinal (GI) radiation toxicity may be the single greatest barrier to improving treatment responses for unresectable pancreatic cancer. There are no known medications that can selectively protect the intestines from the side effects of treatment-related GI radiation toxicity.

Amifostine is a well-known therapeutic and is the only FDA-approved radioprotector, but it has significant toxicity when given intravenously (the only approved route of administration). Orally delivered amifostine is a pro-drug that is activated in the small intestine by endogenous intestinal alkaline phosphatases. If administered just prior to radiation, the active metabolite, WR-1065, is then produced locally in the gut and protects the intestinal tissue during radiation, then is rapidly degraded. Orally administered amifostine is highly efficacious and enables ablative radiation therapy to pancreatic tumors, which triples survival in a murine model. Oral amifostine coupled with ablative radiotherapy can be a curative treatment in selected patients with unresectable pancreatic cancer.

Xerient intends to develop and test an enteric-coated version of amifostine (EC-amifostine) that maximizes payload delivery in the duodenum in a timeframe relevant to radiotherapy that will be

clinically efficacious with targeted delivery and monitoring functionalities. Xerient will complete GLP toxicology studies, allowing the company to proceed with a clinical Phase I safety trial in humans. Xerient will evaluate the activity and tolerability of EC-amifostine in a canine model and confirm that amifostine can protect intestinal tissue from radiation in a porcine model.

Select Reviewer Comments

"The molecule is well known and studied and FDA approved as a radioprotectant when given IV."

"Many patients with pancreatic cancer would definitely benefit from radiotherapy, but because of the toxicity to the duodenum, it is not used. The ability to deliver safe and effective doses of targeted radiotherapy would be of great potential benefit to these patients who have few therapeutic options."

"If successful, this product could have fast uptake as SOC in radiation centers with new possibility of benefit to pancreatic cancer radiotherapy."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- InformAI, Inc. for $1,552,000.

The PDRC did not recommend any contract contingencies for this award.

InformAI, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

InformAI Inc. is a Houston-based company focusing on AI solutions that speed up medical diagnosis at the point-of-case and improve radiologist productivity. With 360 degrees of radiation access and delivering a wide range of beam intensities, a nearly infinite number of avenues exist to target a malignant lesion while minimizing off-target effects. Deep learning methods are well-positioned to optimize this process, identifying radiation plans that deliver a therapeutic radiation dose to cancer while optimally minimizing unwanted radiation exposure to healthy tissue and neighboring organs.

InformAI proposes to create RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for planning Radiation Oncology in the head and neck region. To date, a minimally viable business prototype has been created, led by work out of The University of Texas Southwestern Medical Center's Medical Artificial Intelligence and Automation Laboratory in collaboration with the Department of Radiation Oncology.

Preliminary testing and validation efforts of the model are promising. InformAI has entered into a Sponsored Research Agreement with UT Southwestern to lead the product scaling, validating, technological hardening, regulatory approval, and commercialization efforts necessary to transform this prototype technology into a finished business offering.

Deep learning methods are well-positioned to optimize the creation of radiation plans that deliver a therapeutic radiation dose to cancer while optimally minimizing unwanted radiation exposure to healthy tissue and neighboring organs. A deep learning radiation planning tool could solve current pain points in the radiation oncology workflow, improving the safety, efficiency, quality, and usability of multiple product modalities. According to the company, no products available on the market leverage deep learning methods to create the 'first pass' radiation treatment plan.

InformAI intends to expand its dataset including acquiring access to additional 400 head and neck segmented and annotated head and neck de-identified patient scans. Inform AI will validate

its label claims through clinical research with the purpose of preparing for the FDA regulatory approval process. InformAI will also ensure that its product is widely, if not universally, integrable with all TPS used in the routine practice of radiation oncology.

Select Reviewer Comments

"There is a clear unmet need in radiation oncology addressed in this proposal with the use of AI to help create more efficient and automated dose plans and associated organ segmentation. There is a clear value proposition to patients and oncologist in improving the efficiency and the accuracy of the dose plans for the clinicians."

"This approach has the potential to make radiation planning faster and more accurate than current standards of care. This is rendered possible by recent and current informatics advances, and it is likely that AI will affect the medical practice also in areas other than radiation therapy, thus the submission is well positioned in the future stream of innovative approaches."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- NUCORE Medical for $2,999,999.

The PDRC recommended the following contract contingency for this award. Agreements to assign all IP assets related to the tissue coring/resection device originally created and developed by Precision Thoracic, LLC and Ethicon, Inc. to NuCore Medical, Inc. should be completed, and the transaction concluded, prior to execution of the contract with CPRIT

NUCORE Medical

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Nucore Inc. is a Houston-based medical device company resulting from a multi-year collaboration between J&J's Center for Medical Device Innovation @ The Texas Medical Center and California-based Precision Thoracic to innovate novel technologies focused on the early interception, diagnosis, and treatment of lung cancer.

Early interception of suspicious lung nodules, by nature, means dealing with small, amorphic, and heterogeneous nodules that are extremely challenging to diagnose with current needle biopsy techniques. Surgical wedge resection (i.e. open or VATS) is an option, but these complex procedures unnecessarily sacrifice large quantities of functional lung tissue and can often expose fragile patients to unjustified surgical risks. Clinicians need a tool that can provide a minimally invasive, tissue sparing, targeted resection of suspicious small and intermediate-sized lung nodules, facilitating definitive diagnosis.

Nucore has developed Minimally-invasive Targeted Resection (MiTR-core™), the first medical device designed to safely remove lung nodules in a simple, quick, and minimally invasive procedure. The MiTR-core procedure will enable clinicians to remove suspicious nodules upon initial detection, will provide a definitive diagnosis of the nodule, spare healthy lung tissue, and in the event of cancer, provide direct access to the site of the nodule for further targeted therapy.

MiTR-core™ is a tissue-sparing transthoracic nodulectomy tool for CT-guided targeting of a suspicious nodule followed by minimally invasive access, coring, resection, and RF-based sealing of the lung to prevent blood and air leaks. The amount of diagnostically viable tissue extracted using MiTR-core is more than 2,000 times greater than the tissue extracted using existing needle techniques. In addition to facilitating greater specificity and sensitivity, the

specimen size will allow for rapid characterization of the cancer and, potentially, real-time sequencing.

The Nucore team has advanced MiTR-core from a concept to functional prototypes and rigorously tested it on the bench and in a series of nine acute porcine studies. MiTR-core has successfully demonstrated proof-of-concept in 2 chronic porcine studies. The company will strengthen its clinical and commercial case for MiTR-core through clinical data analytics (e.g. clinical outcome and cost databases, retrospective chart review, prospective multi-center registry trial), prepare for a First-in-Human study through regulatory submission, and manufacture clinical build devices and advance the device through a First-in-Human study.

Select Reviewer Comments

"*With financial support of $4.5 million from JNJ's Center for Medical Device Innovation, Nucore Inc, a Houston-based company, has developed a biopsy device that is much less invasive than wedge resection, essentially eliminates the false-negative/indeterminate issue associated with fine-needle biopsy, and by virtue of a tissue sealing feature, does so with minimal to no complications of hemothorax and pneumothorax, in effect, addressing the follow-up definitive diagnostic barriers to LDCT lung cancer screening uptake noted above."*

"This device could be really useful in terms of yielding actionable results in a far less invasive procedure than currently available."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- PLUS Therapeutics for $17,613,605.

The PDRC did not recommended any contract contingencies for this award. The award recommendation to PLUS Therapeutics is contingent on the successful completion of amending the License Agreement between PLUS Therapeutics and NanoTX.

PLUS Therapeutics

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Plus Therapeutics is a publicly listed company based in Austin. Plus is developing a Rhenium-186 NanoLiposome (186RNL), which is a novel radiotherapeutic to combat several cancers including recurrent glioblastoma, 186RNL is safe and well-tolerated while delivering a radiation dose to the tumor that is up to 15 times higher than typically achievable with standard radiation therapy. Plus is developing 186RNL to treat leptomeningeal metastases. Leptomeningeal Metastases (LM) are a rare but typically fatal complication of advanced cancer that affects the fluid-lined structures of the central nervous system. LM are diagnosed in 5% of cancer patients.

The investigational product is BMEDA-chelated Rhenium-186 NanoLiposome (186RNL). Rhenium-186 is an ideal radionuclide for CNS cancers such as LM because of its long 90-hour half-life, beta particles' short ~2mm path length, low dose rate, and high radiation density that overwhelms proliferating cellular innate DNA repair mechanisms. For 186RNL treatment of LM in humans, PLUS has obtained FDA Fast Track designation and IND clearance and will pursue FDA Orphan Drug and Breakthrough Therapy designations in the future.

The purpose of the two-part, Texas-based multicenter (The University of Texas Health Science Center San Antonio, The University of Texas Southwestern Medical Center, and The University of Texas MD Anderson Cancer Center) Phase clinical trial is to characterize the safety, tolerability, PK, dosimetry, and antitumor activity of 186RNL administered intrathecally, via an intraventricular catheter system (Ommaya reservoir), as a single agent in 61 LM subjects. If successful, PLUS intends to seek FDA investigational new drug (IND) clearance to initiate and complete a Phase 2 pivotal trial in 120 subjects (final N subject to data and statistical analysis plan) with leptomeningeal metastases to support a new drug application (NDA) submission with the FDA.

The company expects 186RNL to deliver a much higher and more targeted dose of radiation during a single administration compared to traditional RTs; have a high safety margin with minimal risk of bone marrow suppression; may be able to treat all LM patients, unlike some other therapies that rely on tumor targeting technology for a subset of patients; ease of administration with well-accepted and currently utilized access technology.

Plus intends to complete parts 1 and 2 of a Multicenter Phase 1 Clinical Trial of IT-Delivered 186RNL to treat LM, which will include compiling safety data, identifying a maximum tolerated dose, assess the safety, tolerability, efficacy of 186RNL in subjects with LM for Phase 2 pivotal clinical trial. Plus intends to complete Multicenter Phase 2 Clinical Trial of IT-Delivered 186RNL to treat LM, which will lead to preparations for filing an NDA submission to the FDA.

Select Reviewer Comments

"*This tackles the issue of leptomeningeal metastasis with no therapy at the moment. IND has been filed and cleared by the FDA. In spite of some weaknesses about lack of preclinical data particularly in combination therapy for some models, the application remains solid and promising."*

"*The strengths are high unmet need albeit a very small population. Data in GBM are encouraging. There is FDA green light for the next clinical trial. The competition is limited, and the biomarker strategy if executed should improve targeting the most likely to respond..."*

"The intended product is currently already in clinical trials in glioblastoma and overall de-risks the intended product, clinical strategy, and the company."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Atom Mines for $2,500,000.

The PDRC did not recommend any contract contingencies for this award.

Atom Mines

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Atom Mines is a small Austin-based company which utilized a Magnetically Activated and Guided Isotope Separation ("MAGIS") technology developed at The University of Texas at Austin, which will enable the production of the stable isotope Ytterbium-176 (176Yb) needed to make the radio-isotope Lutetium-177 (177Lu). 177Lu is an effective beta-therapy agent approved for certain neuroendocrine cancers and soon to be approved for prostate cancer, the second leading cause of cancer death in men, with clinical trials underway for a range of cancers. 177Lu can be used to target small tumors and dispersed, inoperable metastatic cancer using precise delivery molecules. 176Yb is currently only available in small quantities from Russia and that supply is uncertain due to geopolitics and competition for limited production capacity.

Ytterbium-176 (176Yb) is the stable precursor required to make carrier-free 177Lu, and 176Yb is currently only available in very limited quantities from Russia. Russian supplies have remained limited due to competition for production capacity for other isotopes, while global demand has more than doubled. This supply is in jeopardy due to deteriorating geopolitics, corruption, and competition for limited calutron separation capacity.

A reliable, domestic source of pure 176Yb is required to produce sufficient carrier-free 177Lu to support FDA-approved drugs and ongoing cancer research, trials, and therapies in Texas and globally. Novartis has two products Pluvicta and Lutathera which utilize 177Lu. Atom Mines utilizes an isotope separation developed by Prof. Mark G. Raizen at The University of Texas at Austin. Magnetically Activated and Guided Isotope Separation ("MAGIS") uses lasers to temporarily magnetize atoms that is then followed by separation with arrays of magnets.

Atom Mines LLC has fully demonstrated 176Yb enrichment to medical-grade purity of 99.5%. MAGIS will enable domestic commercial production of 176Yb, as well as other rare isotopes for widespread medical use. Atom Mines intends to scaleup 176Yb production initially to 200 grams; validate purity of routine batches and of 177Lu produced by industry partner and

irradiators. Atom plans to scale up to 500 grams within three years and ultimately to kilogram quantities, which will support tens of thousands of doses for prostate cancer therapy per year.

Select Reviewer Comments

"*Indeed, the Department of Energy openly recognizes the lack of separation capabilities in the United States and the need for new domestic capabilities. The company has demonstrated that Novartis has a need for this material to develop and test novel prostate cancer therapy and has a production site in Texas, as well as a global distribution partnership with a German company, Eckert and Ziegler, which has invested in the company."*

"Atom Mines will use the efficiency of MAGIS technology to greatly reduce the cost of separating stable isotopes and make important medical isotopes for therapeutics already approved or in the process of approval."

"There is no risk in this proposal short of not being able to meet the demand at commercial scale since several possible therapeutics may use this radiotherapeutic approach."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Rapamycin Holdings, Inc. for $16,999,999.

The PDRC recommended the following contract contingency for this award. Emtora's relationship with Southwest Research Institute with regard to intellectual property and manufacturing for the new formulation of eRapa should be specified.

Rapamycin Holdings, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Emtora Biosciences (formerly Rapamycin Holdings Inc.) is a San Antonio company that has developed eRapa, a novel form of the FDA-approved active ingredient rapamycin. Rapamycin has previously shown promise in treating gastrointestinal diseases and in cancer prevention, but is limited by toxicity. eRapa is targeted to the colon and is delivered at lower doses, resulting in lower toxicity. The company is developing eRapa to prevent colorectal cancer in patients with Familial Adenomatous Polyposis (FAP). In 2019, Emtora received a CPRIT Product Development (SEED) award for a Phase IIa study of eRapa in FAP, which is currently underway.

Data supports that rapamycin augments the immune system, prevents cancer in cancer-prone animal models, and prolongs health and life span. It has been demonstrated that rapamycin reduces the percentage of CD4 and CD8 T lymphocytes that express PD-1 (exhaustion marker), which inhibits T cell signaling and is more highly expressed with age and exposure to cancer. The results of Emtora's Phase I clinical trials in prostate cancer indicate that e-Rapa is safe and well-tolerated at all doses and schedules tested; more tolerable at intermittent dosing schedules; has no adverse effect on quality of life; has a consistent and predictable absorption profile (unlike rapamycin); produces measurable and favorable changes in the immune system; and no patients on eRapa experienced disease progression during the study.

Emtora proposes to manufacture drug product to support the addition of a fourth cohort in the current Phase IIa study of eRapa in FAP. The proposal would expand and complete the CPRIT-funded Phase IIa study of eRapa in Familial Adenomatous Polyposis (FAP) and prepare for and execute Randomized Placebo-Controlled Trial of eRapa in FAP.

Select Reviewer Comments

“*This new encapsulated rapamycin formulation, eRapa, is targeted specifically to the colon and is delivered at a consistent and lower dosage, not only reducing toxicities but also capitalizing on the potential of partial inhibition of the mechanistic target of rapamycin (mTOR) to act as a chemopreventive agent*.”

“*The applicant has a good standing with CPRIT through a previous Seed Award, has received ODD, has an open IND, and is currently in phase 2a clinical trials in FAP. As such, the proposal is highly de-risked.”*

RELCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- PanTher Therapeutics, Inc. for $14,268,315.

The PDRC recommended the following contract contingency for this award.
1) Clinical data from the Australian clinical trial (ongoing at time of application submission)
2) A clear and detailed clinical development plan
3) A timeline for manufacturing higher doses of the drug product needed for the Phase 1b/2
4) A plan with timetable for hiring in Texas
5) Information on whether the company will be able to execute the project based on its previous pre-IND meeting with the FDA, which was held several years ago, or whether a new one will be needed.

PanTher Therapeutics, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

PanTher Therapeutics is a clinical stage oncology company working on treatments for solid tumors. The company is currently based in Cambridge, Massachusetts, and will relocate to Texas if it receives a CPRIT award.

PanTher's novel approach looks to significantly increase drug accumulation at the tumor site, while dramatically reducing systemic side effects to improve antitumor activity, preserve quality of life and lower overall healthcare costs. PanTher's PTM-101 product is a laparoscopically delivered, fully degradable film. This product has the potential to improve tumor response and reduce pancreatic tumors to allow for curative resection.

PanTher's first product, PTM-101, is a drug eluting delivery implant intended to provide paclitaxel directly onto the tumor. PTM-101 is composed of paclitaxel and a bioresorbable polymer poly (lacticco-glycolic acid) (PLGA). The PTM-101 implant is minimally invasively inserted via a trocar during diagnostic laparoscopy and surgically placed directly onto the peritumoral area. PanTher's platform has demonstrated pre-clinical validation – enabling chemotherapy to penetrate 40 times deeper and reach 5-fold higher concentration inside the tumor mass when compared to systemic delivery.

The PLGA ingredients biodegrade over time, resulting in the sustained release of paclitaxel directly towards the tumor, thereby providing localized treatment. The PLGA polymer

biodegrades into lactic and glycolic acids, which are metabolized naturally. For controlled and sustained release of paclitaxel, PTM-101 will be comprised of two different layers of PLGA. The non-tumor facing side of PTM-101 consists of 75:25 PLGA and the tumor facing side of PTM-101 contains paclitaxel incorporated into 50:50 PLGA polymer. The PLGA 50:50 will fully degrade in approximately 1 month (35 days), resulting in Paclitaxel release directly onto the tumor mass.

PanTher's proposal is for the initiation and completion of a Phase Ib/II trial in the US and Australia to build upon the current first-in-man trial to assess efficacy. Over the course of discussions with the FDA, PTM-101 has been deemed a combination product with drug primary mode of action and cleared to use the 505(b)(2) accelerated path to the clinic with a well-defined understanding of the IND package requirements.

PanTher has addressed and completed the majority of testing to be included in the IND submission as part of the ethics approval to start the phase 1 in Australia. The first-year development plan will focus on expansion of the already validated CMC and GMP manufacturing processes for the dose-escalated PTM-101, as well as completing GLP tox studies. Upon IND clearance from the FDA, PanTher will focus on the enrollment and completion of the Phase Ib/2 trial in the US and Australia, in partnership with MD Anderson and other clinical sites.

Select Reviewer Comments

"*The approach significantly increases drug accumulation at the site, while dramatically reducing systemic side effects to improve antitumor activity and preserve quality of life, provide pretreatment before surgery or improvement for tumors that are nonresectable."*

"The application has a number of strengths including the following: (1) prior phase 1 results, (2) sound management and development teams, (3) significant financial backing, (4) straightforward CMC development pathway due to the experience with paclitaxel and PLGA, and (5) lack of competition of locally administered therapies in pancreatic cancer."

De-Identified Overall Evaluation Scores

Seed Awards for Product Development Research

Product Development Research Cycle 22.2

Application ID	Final Overall Evaluation Score
DP220063*	2.2
DP220043*	2.2
DP220028*	2.3
DP220038*	2.3
DP220054*	3.4
a**a**	4.4
a**b**	5.0
a**c**	5.0
a**d**	5.7
a**e**	6.0
a**f**	6.3
a**g**	6.3
a**h**	6.4
a**i**	6.7
A**j**	7.0
A**k**	9.0

* Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

July 27, 2022

Dr. Mahendra Patel
CPRIT Oversight Committee Chair
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
CPRIT Program Integration Committee Chair
Via email to wroberts@cprit.texas.gov

Dr. Patel and Mr. Roberts,

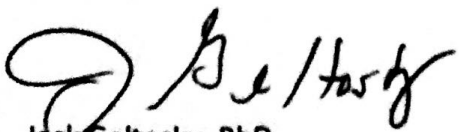
On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 22.2 grant award cycle. The PDRC convened on July 19, 2022, and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Atom Mines, InformAI Inc., Xerient Pharma Inc., PLUS Therapeutics, Inc., Stellanova Therapeutics, Asylia Therapeutics, Rapamycin Holdings Inc., NUCORE Medical and PanTher Therapeutics. The attached table reflects the ranked award recommendation for the nine (9) grant applications.

The PDRC did not make any changes to timelines or budgets for the nine (9) projects recommended for funding. However, two (2) recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP220053 and DP220054 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP220066 related to clinical data, timelines and development plans. Dr. Smith will address the proposed contingencies with the PIC and the Oversight Committee.

I also note that at its July 19, 2022, 22.2 Due Diligence Meeting, the PDRC took "No Action" on one (1) application for CPRIT FY 2022 award budget reasons and to receive additional information. We anticipate that the PDRC will make an award recommendation, if any, regarding this pending application for your consideration as early as the September 2022 Oversight Committee meeting.

Each of the companies included in the PDRC's recommendation reflets 50+ hours of individual review panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,



Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

FY22.2 Product Development Review Council Recommendations

Ranking	ID	Mechanism	Type	PI Last Name	Organization	Application Title	Score from Peer Review
1	DP220039	TXCO Therapeutics	Resubmission	Sims, A.	PLUS Therapeutics, Inc.	Single-Dose 186RNL for Leptomeningeal Metastases: Multicenter Phase 1/2a Study to Determine MTD/MFD, Safety and Efficacy, Leading to Pivotal Registrational Trial	2.2
2	DP220028	SEED Therapeutics	Resubmission	Schuler, E.	Stellanova Therapeutics, Inc.	Development of DKK3-Targeted Therapeutic Antibodies for Cancer	2.3
3	DP220038	SEED Therapeutics	New	Miller, J.	Asylia Therapeutics	Humanization, Validation, and Clinical Translation of Cell Surface Heat Shock Protein 70-Targeted Antibody-Drug Conjugates for T-Cell Non-Hodgkin Lymphomas	2.3
4	DP220055	TXCO MD&D	New	Dorius, K.	Atom Mines	Commercial-Scale Enrichment of Stable Ytterbium-176 for Production of No-Carrier-Added Lutetium-177 for Use in Prostate Cancer Therapy	2.0
5	DP220053	TXCO Therapeutics	New	Kingman, S.	Rapamycin Holdings Inc.	Development of eRapa for the Treatment of Familial Adenomatous Polyposis, a Rare Genetic Disease Associated With a High Risk of Colorectal Cancer	2.7
6	DP220043	SEED Therapeutics	New	Taniguchi, C.	Xerient Pharma Inc.	Oral Amifostine as an Upper GI Tract Radioprotectant for Effective Radiotherapy Treatment of Pancreatic Cancer	2.2
7	DP220063	SEED MD&D	New	Havelka, J.	InformAI Inc.	RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology	2.2
8	DP220066	RELCO Therapeutics	New	Indolfi, L.	PanTher Therapeutics, Inc	Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer	3.6
9	DP220054	SEED MD&D	New	Nathan, J.	NUCORE MEDICAL	Clinical Validation of the MiTR Core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention	3.4

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 2
Texas Company Product Development Awards

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Request for Applications

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA C-22.2-TXCO

Texas Company Product Development Research Awards

Please also refer to the Instructions for Applicants document, which will be posted on December 1, 2021

Application Receipt Opening Date: December 1, 2021

Application Receipt Closing Date: January 26, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

Rev 11/3/2021 RFA release

1. KEY POINTS

This Texas Company Product Development Research Award mechanism is governed by the following guidelines:

- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools. Products must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- For therapeutics, Product Development Research Award funding supports preclinical research and early clinical research necessary to demonstrate initial clinical safety and efficacy (typically phase 1, phase 2A).
- Recipient companies must currently be Texas based (see section 8.1) and must have a chief executive officer (CEO) as part of the applicant's management team prior to submitting an application. The Cancer Prevention and Research Institute of Texas (CPRIT) requires the use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-state entities.
- CPRIT requires recipient companies to raise a portion of the total project budget from external sources. For a company receiving an initial CPRIT award, CPRIT will contribute $2.00 for every $1.00 contributed in matching funds by the recipient company. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds should, whenever possible, be spent in Texas. A company's matching funds must be dedicated to the CPRIT-funded project but may be spent outside of Texas.
- For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company. More details on the matching funds requirements are provided below.
    - A grantee approved for 1 or more product development grants that together total a commitment of $20 million or less must dedicate to each grant project $1 of their own funds for every $2 of CPRIT grant award funds.
    - A grantee approved for a product development grant award that causes the total amount of committed CPRIT product development grant award funds to exceed $20 million must increase their matching fund obligation to $1 for every $1

contributed by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under the matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.

  - A company approved for a grant award that would result in more than $30 million in CPRIT product development grant funds must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

- Applicants may request up to $20 million in CPRIT funds. CPRIT receives many more applications each year than available funds can support. While all requests for funding must be well justified, a funding request at or near the maximum amount will be heavily scrutinized. Such a request must be exceptionally well justified to warrant dedicating a large percentage of CPRIT's product development research budget to the applicant's project.
- Funding will be tranched and tied to the achievement of contract-specified milestones. The contract-specific milestones are the Goals & Objectives submitted by the applicant within the proposal. The progress-based release of funds will be dependent on the completion of the applicant's proposed Goals & Objectives for each project year.
- All award contracts include a revenue-sharing agreement. **A copy of the revenue-sharing agreement can be found at www.cprit.texas.gov in the Product Development Research Program section.** Other contract provisions are specified in CPRIT's Administrative Rules, which are also available at www.cprit.texas.gov.
- An application last submitted but not funded (including resubmission) before December 4, 2019, may be submitted as a new application, even if it was previously resubmitted (see section 8.2).
- Applicant companies are limited to 1 submission per cycle across all CPRIT Product Development award mechanisms.

2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2.1. Product Development Research Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. CPRIT has established overarching principles, and each of CPRIT's 3 grantmaking programs (Academic Research, Prevention, and Product Development Research) have established program-specific priorities. Additional priorities focused at the intersection of the 3 programs have also been established and outlined below. The Product Development Research Program's principles and priorities guide CPRIT staff and the Product Development Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to RFAs.

CPRIT's Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure

CPRIT's Academic Research, Prevention, and Product Development Research Cross-Program Priorities:

- Prevention and early detection initiatives
- Translation of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science infrastructure

CPRIT's Product Development Research Priorities:

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits not currently available; ie, disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early-stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas institutions • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff, to lead to seed clusters of life science expertise at various Texas locations • Providing appropriate return on Texas taxpayer investment

A full description of CPRIT's program priorities may be found at http://priorities.cprit.texas.gov/.

3. EXECUTIVE SUMMARY

CPRIT will foster cancer research as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. This RFA solicits applications for the research and development of innovative products addressing critically important needs related to diagnosis, prevention, and/or treatment of cancer and the product development infrastructure needed to support these efforts. CPRIT encourages applicants who seek to apply or develop state-of-the-art products, services (eg, contract research organization services), technologies, tools, and/or resources for cancer research, prevention, or treatment.

CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. The overall goal of this award program is to improve outcomes of patients with cancer by accelerating the development of groundbreaking therapeutics, diagnostics, and tools with a primary focus on Texas-centric programs.

4. MECHANISM OF SUPPORT

The goal of the Texas Company Product Development Research Award is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will provide companies or limited partnerships located and headquartered in Texas with the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award is intended to support companies that will be staffed with a majority of Texas-based employees, including C-level executives.

5. OBJECTIVES

The long-term objective of this award is to support commercially oriented therapeutic and medical technology products, diagnostic- or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA should be the intent to further the research and development of products that would eventually be approved and marketed for the diagnosis, prevention, and/or treatment of cancer. Eligible products or services include—but are not limited to—therapeutics (eg, small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques.

CPRIT seeks to maximize the clinical impact of our funding. Hence, we focus investment in translational research and development activities, including the following eligible stages:

- Studies that establish preclinical proof of concept
- GLP studies to support INDs

- Phase 1 to establish safety and a maximally tolerated dose
- Phase 2 studies to determine safety and efficacy in initial targeted patient populations (up to 100 patients)

CPRIT typically does not fund efforts outside of these parameters. We do not consider studies larger than what are described as "translational," and hence, such studies are outside the scope of our interest. Companies that have clinically demonstrated safety and efficacy should be able to acquire necessary capital via other sources. By exception, later clinical trials or later-stage product development projects may be considered where exceptional circumstances warrant CPRIT investment.

CPRIT's objectives and program priorities are established by its Oversight Committee. Consistent with the above, these priorities include "funding projects at Texas companies and relocating companies that are most likely to bring important products to the market." A full description of CPRIT's program priorities may be found at http://priorities.cprit.texas.gov/.

6. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development project proposed. Requested funds must be well justified. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property (IP) acquisition and protection, external consultants and service providers, travel in support of the project, and other appropriate research and development costs, subject to certain limitations set forth by Texas law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the state. Texas law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

For companies receiving an initial CPRIT award, CPRIT will award $2.00 for every $1.00 contributed in matching funds by the company. The demonstration of available matching funds

must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be fulfilled on a year-by-year basis.

For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company.

A grantee approved for 1 or more product development grants that together total a commitment of $20 million or less must dedicate to each grant project $1 of their own funds for every $2 of CPRIT grant award funds.

A grantee approved for a product development grant award that causes the total amount of committed CPRIT product development grant award funds to exceed $20 million must increase their matching fund obligation to $1 for every $1 contributed by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $20 million threshold. For example, a company receives 3 product development grant awards of $3 million, $15 million, and $8 million (in that order) over the course of several years. Under the matching funds policy, the company must dedicate $8 million in matching funds to the $8 million project (a dollar-for-dollar match obligation) because that project caused it to exceed the $20 million threshold.

A company approved for a grant award that would result in more than $30 million in CPRIT product development grant funds must contribute $2 for every $1 provided by CPRIT. The increased matching fund obligation applies to the grant award that caused the grantee to exceed the $30 million threshold.

7. KEY DATES

RFA release	November 3, 2021
Online application opens	December 1, 2021, 7 AM central time
Applications due	January 26, 2022, 4 PM central time
Invitations to present sent	March 2022
Notifications sent if not invited	March 2022
Presentations to CPRIT*	April 2022
Award Notification	August 2022
Anticipated Start Date	September 2022

***** Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

8. ELIGIBILITY

8.1. Applicants

- Either for-profit or nonprofit companies may apply. However, nonprofit companies must intend to bring a product to market. Applications may be submitted prior to company formation, but company formation must be completed before award receipt. Applicants will be required to provide a data universal numbering system (DUNS) number before award receipt.
- Award recipients must be Texas-based. A company is considered to be Texas based if it currently fulfills or commits to fulfilling a majority of the following criteria:

    1. The US headquarters are physically located in Texas.
    2. The chief executive officer resides in Texas.
    3. A majority of the company's personnel, including at least 2 other C-level employees (or equivalent) reside in Texas.
    4. Manufacturing activities take place in Texas.
    5. At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
    6. At least 1 clinical trial site is in Texas.

7. The company collaborates with a medical research organization in Texas, including a public or private institution of higher education.

In exceptional circumstances, the applicant may propose 1 or more alternative location requirements, which the Oversight Committee may approve by a majority vote in an open meeting.

- Unless otherwise specified by the award contract, the company must fulfill all location requirements identified in the application within 1 year of receiving the initial disbursement of funds. Failure to maintain compliance with the location criteria will result in consequences ranging from suspension of grant funding to early termination of the grant contract and repayment of grant funds.
- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools. Project must diagnose cancer, treat cancer, or treat sequelae specific to cancer.
- An application last submitted before December 4, 2019, may be submitted as a new application, even if it was previously resubmitted.
- CPRIT is releasing 3 Product Development RFAs in this funding cycle. Please note that in any given application round, applicants are allowed to apply for only 1 Product Development Award (TXCO, RELCO, or SEED). Applicants are advised to review each RFA and select the program that best fits their development status.
- Only 1 coapplicant may be included on the application. For the Product Development Research Program, a coapplicant is an individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. If so designated by the applicant organization, coapplicants share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple applicants are named, each is responsible and accountable for the proper conduct of the project, program, or activity, including the submission of all required reports. The presence of more than 1 applicant on an application or award diminishes neither the responsibility nor the accountability of any individual applicant.
- An applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel

listed on the application, or any company officer or director (or any person related to 1 or more of these individual within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.

- An applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. If the applicant or other individuals are ineligible to receive federal grant funds or have had a grant terminated for cause, the applicant may be contacted to provide more information.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although the applicant need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

8.2. Resubmission Policy

- An application previously submitted to CPRIT within the last 2 years (after December 4, 2019) but not funded may be resubmitted once and must follow all resubmission guidelines. **An application that was last submitted before December 4, 2019, may be submitted as a new application, even if the most recent submittal (prior to December 4, 2019), was a resubmission.** For additional clarity regarding the 22.2 application cycle, this means that an application that was last submitted during or before the 20.1 cycle is considered a new application. In contrast, an application that was last

submitted during or after the 20.2 cycle is considered a resubmission. It is expected that significant progress will have been made on the project; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to submit an application with such modest changes.

- An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. An application that was administratively withdrawn by the applicant or by CPRIT prior to review by the review panel is not considered a submission for purposes of CPRIT's resubmission policy.
- Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received an overall numerical score of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission**. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

9. APPLICATION REVIEW

9.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. CPRIT requires the submission of a comprehensive development plan (see section 10.4.7) and a detailed business plan (see section 10.4.8). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and development plans. The plans will be reviewed

by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made via the review process described below.

9.2. Review Process

- **Product Development and Scientific Review:** Applications that pass initial administrative review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of applicants may be invited to deliver in-person presentations to the review panel.
- **Due Diligence Review:** Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—IP, management, regulatory, manufacturing, and market assessments. Please note that CPRIT may request to review any correspondence that an applicant has conducted with regulatory agencies (eg, the FDA) as part of the diligence process. Following the due diligence review, applications may be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and IP reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.
- **Program Integration Committee Review:** Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.
- **Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

9.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Peer Review Panel members, Product Development Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Any form of communication regarding any aspect of a pending application is prohibited between the applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

Attached to this RFA is a list of more detailed questions considered by CPRIT reviewers when assessing therapeutic applications (Appendix 1, "Reviewer Evaluation Guidelines for Therapeutics") and when assessing medical devices, diagnostics, and/or tools (Appendix 2, "Reviewer Evaluations Guidelines for Medical Devices and Diagnostics"). Applicants are encouraged to review these documents and, to the extent possible, address the questions within their application.

9.3.1. Primary Criteria

Primary review criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed program.

The criteria provided below are designed to provide an **overview** of topics that may be pertinent to the assessment of applications during peer review. Specific criteria applied to evaluate a given application will depend on the type of product described by the applicant (eg, therapeutic versus medical device). **Detailed descriptions of the specific criteria employed for different product classes are provided in the appendices to this RFA.**

Primary review criteria are heavily weighted in determining the quality of an application. Reviewers provide numerical scores for these topic areas when evaluating applications. Primary criteria are intended to address the following topics:

- Significance and Impact
- Unmet Medical Need
- Product Validation/Proof of Concept
- Safety
- Preclinical Strength/Development to Date

- Development Plan
- Competitive Landscape
- Intellectual Property
- Business/Commercial Aspects
- Management and Staffing
- Production/Manufacturing Plan
- Overview of Clinical/Regulatory Plan

More details regarding these topics can be found in the appendices to this document.

9.3.2. Secondary Criteria

Secondary review criteria contribute to the global score assigned to the application and are not assigned individual numerical scores. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include the following:

- Budget and Duration of Support

Please see appendices for more details.

10. SUBMISSION GUIDELINES

Applicants are advised to review carefully all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available on December 1, 2021. Applications that are missing 1 or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

10.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The applicant must create a user account in the system to start and submit an application. The coapplicant, if applicable, must also create a user account to participate in the application. Furthermore, the

Application Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. It is acceptable (and not uncommon) for the applicant to also serve as the designated ASO. However, if the applicant intends to also serve as the ASO, the system requires that the applicant and the ASO have 2 different accounts and usernames. Applications will be accepted beginning at 7 AM central time on December 1, 2021 and must be submitted by 4 PM central time on January 26, 2022. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

10.2. Submission Deadline Extension

The submission deadline may be extended upon a showing of good cause. Late submissions are permitted only in exceptional instances, usually for technology failures in the CARS. It is imperative that applicants allow sufficient time to familiarize themselves with the application format and instructions to avoid unexpected issues. The applicant's failure to adequately plan is not sufficient grounds to justify approval of a late submission.

Peer review schedules are set far in advance and do not accommodate receipt of an application days after the deadline. Therefore, potential applicants that are unable to meet the deadline due to issues such as travel, sabbaticals, conferences, prolonged illness or other leave, etc, should not request additional time to submit an application but should instead consider submitting the application in the next review cycle.

A request to extend the submission deadline must be submitted via email to the CPRIT Helpdesk within 24 hours of the submission deadline. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records and are intended to allow an applicant to complete and submit an incomplete application that has already been started in CARS. If a request for extension is approved, then CARS will be reopened for an additional 2 hours to allow an applicant with an unsubmitted application to complete and submit it. Applicants are also urged to initiate the registration process on CARS a minimum of 5 business days prior to deadline to ensure enough time to complete and submit an application.

10.3. Product Development Review Fee

All applicants must submit a nonrefundable fee of $1,000 for review of Product Development Research applications. Payment should be made by check or money order payable to Cancer Prevention and Research Institute of Texas; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. Unless a request to submit a late fee has been approved by CPRIT, all payments must be postmarked by the application submission deadline and mailed as described below.

Checks may be mailed via the US Postal Service to the following address:

Cancer Prevention and Research Institute of Texas
PO Box 12097
Austin, Texas 78711

Contact name: Michelle Huddleston
Phone 1-512-305-8420

Mail sent via a delivery services (ie, FedEx, UPS, etc) will need to use this address:

Cancer Prevention and Research Institute of Texas
Wm B Travis State Office Building
1701 N Congress Ave Ste 6-127
Austin, Texas 78701

Contact name: Michelle Huddleston
Phone 1-512-305-8420

10.4. Application Components

Applicants are advised to minimize repetition among application components to the extent possible. In addition, applicants should use discretion in cross-referencing sections to maximize the amount of information presented within the page limits.

Please note that letters of commitment and/or memoranda of understanding from community organizations, key faculty, etc, are **not** required or requested. Please do not submit letters of support as part of your application package. **Any such information will be removed from your application before review**.

10.4.1. Abstract and Significance (5,000-character maximum)

Coherently explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Address how the proposed project, if successful, will have a major impact on the care of patients with cancer. Describe how this application provides a path for acquiring proof-of-principle data necessary for next-stage commercial development. Clearly explain the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

10.4.2. Layperson's Summary (1,500-character maximum)

Provide a summary of the proposed project using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Describe the overall goals of the project, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The layperson's summary will also be used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

10.4.3. Goals and Objectives (maximum of 1,200 characters each)

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success if the award is made. Identify time-specific references as follows: Year 1, Quarter 1 (Y1Q1), Y1Q2, etc. Do not specify actual calendar dates as this can be confusing when dates change.

10.4.4. Timeline (1-page maximum)

Provide a visual depiction of anticipated major milestones to be tracked in the form of a Gantt chart. Identify time-specific references as follows: Y1Q1, Y1Q2, etc, as opposed to naming

specific months and years. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

10.4.5. Slide Presentation (10-page maximum)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with 1 slide filling each landscape-oriented page. The slides should succinctly capture all essential elements of the application and should stand alone.

10.4.6. Resubmission Summary (1-page maximum)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

Note: An application submitted or resubmitted before December 4, 2019, may be submitted as a new application, even if it was previously resubmitted. For the "new" applications, no summary is required.

10.4.7. Development Plan (12-page maximum)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. **Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims**. Outline the steps to be taken during the proposed period of the award, including the design of the translational and/or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches to these risks. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The development plan should include a defined **product profile (PP)**. The format for the PP should be a target product profile (TPP) in the case of a therapeutic, or analogous document for a medical device, in vitro diagnostic, or service that projects a clear path to full commercialization. The PP provides a statement of the *overall intent* of the product development program and gives information about the product *at a particular time* in development. Usually, the PP is organized according to the key sections in the product package insert for a drug or biologic or medical device labeling and links development activities to specific concepts intended for inclusion in the product labeling. CPRIT recognizes that many applications are early in the development process and that not all elements of the PP will be known at the time of application. Consequently, not only does the PP serve as a snapshot in time of the development status of the program, but it additionally serves as an aspirational target upon eventual commercialization. The PP should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- Identification of a target that is applicable to human cancer treatment. Is intervention with this target likely to lead to a therapeutic, medical device, diagnostic, or service that could be useful in the treatment of cancer?
- Selection of a lead compound, assay, or device technology based on the target. Is the identification of potential developmental candidates based on a set of in vitro tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of pharmacodynamic parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?
- Description of a high-level clinical development plan detailing each of the clinical studies supporting marketing approval (phase 1, 2, and 3) the preclinical work is meant to support. Designing the preclinical program requires an understanding of the duration of the clinical studies required by regulatory authorities. Consequently, a brief outline of each of the phase 1, phase 2, and phase 3 studies necessary to obtain regulatory approval and reimbursement funding must be sketched out prior to deciding which toxicology studies would be required.

Applicants developing cancer therapeutics are encouraged to become familiar with FDA guidance documents for submission of applications related to new product development. These documents provide a standard framework for new drug submissions and biologic license

applications to the FDA. Utilizing this framework helps ensure that the submission to CPRIT contains all relevant elements and is optimally organized.

Additionally, for therapeutics, the following apply:

Intended route of administration and dosing regimen. Is the intended route of administration and dosing regimen consistent with accepted convention and medical need for the therapeutic, or will the use of this new agent require a paradigm shift (more frequent or less frequent dosing, new route or method of administration), and if so, what impact will it have on current standard of care?

Optimization of the lead to ensure desired characteristics, including, but not limited to, the following studies:

- Indication of the threshold of both the safety and efficacy necessary to be a competitive product when the product is introduced
- Absorption, distribution, metabolism, excretion, including, but not limited to, relevant studies based on route of administration
- Safety (studies as mandated by ICH guidelines)
- Biomarkers (assays) that potentially target specific patient populations for clinical trials
- Biomarkers (assays) that can serve as potential pharmacodynamic markers of clinical activity during early clinical trials designed to demonstrate proof of concept
- Proposed current good manufacturing practice (including estimated costs) that can be scalable from phase 1 through phase 2. Include information on whether there are plans for possible formulation.

The FDA's website provides "Common Technical Documents" (CTDs, see https://www.ich.org/page/ctd) for guidance documents. There are 3 CTDs covering safety, efficacy, and quality. This guidance presents a standard format for the preparation of a well-structured application. Applicants may condense or summarize the CTD format as they deem appropriate to meet page limitations.

While originally intended for regulatory authorities, these formats are also applicable for a CPRIT application. Many of our reviewers have extensive pharmaceutical development expertise and are familiar with these standard formats. Hence, utilizing the CTD format will simplify the review and ensure that the application contains all the relevant elements.

CPRIT recognizes that many applications are early in the product development process. Hence, not all elements of the CTD will be known at time of CPRIT application. We encourage applicants to complete as much of the Safety and Efficacy CTD sections as possible and to follow the submission format prescribed.

References for the Development Plan section should be provided as a stand-alone document that will be separately uploaded into CARS. In the interests of brevity include only the most pertinent and current literature. While references will not count toward the Development Plan section page limit, it is essential to be concise and to select only those references relevant to the development plan. **Do not use the references to circumvent Development Plan section page limits by including data analysis or other nonbibliographic material.**

The development plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by a highly qualified panel of reviewers. To the extent possible, the development plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred. Please avoid redundancy!

10.4.8. Business Plan

CPRIT can only provide a portion of the funds required to successfully develop a novel product or service. Companies typically need to raise substantial funds from private sources to fully fund development. Hence, we require companies to provide a business plan that summarizes the rationale for investing in this project. Private investors will seek a financial return on their investment. They will need to be convinced that this project has high investment return potential based on its risk profile. They typically focus on market opportunity size, development path, and key risk issues.

Successful applicants will provide a thoughtful, careful, and succinct rationale explaining why this program is an appropriate investment of CPRIT and private funds. Note that if the company is selected to undergo due diligence, additional information (such as the company's interactions with regulatory agencies like the FDA, etc) to support the application may be requested at that time. Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

Please provide an overview of the business rationale for investing in this project. The business rationale overview will be 2 pages maximum. In addition, please provide summaries of the following key development issues with a maximum of 1 page each.

1. **Product and Market:** Provide an overview of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care, ie, primary therapy, second-line therapy, adjunctive to current therapies, etc. Information on patient populations and market segments is helpful.
2. **Competition and Value Proposition:** Provide an overview of the competitive environment (current and future) and how the envisioned product will compete in the marketplace. Provide information on how the clinical utility (efficacy, safety, cost, etc) of this therapy compares with current and potential future therapies. A clear delineation of competitive advantages and data demonstrating these advantages are helpful.
3. **Clinical and Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities and the regulatory pathway for major markets. Please describe how this is driven by interactions with the FDA, if possible. The regulatory plan should include regulatory communications (including all interactions to date with the FDA) and strategy, with clarity provided on regulatory matters and current regulatory strategies.
4. **Pricing and Reimbursement:** Provide an overview of the product cost and anticipated revenue. Cost, price, and reimbursement references from similar products are helpful. An overview of how the company plans to obtain CMS and private insurance reimbursement approval is also helpful.
5. **Commercial Strategy:** Provide an overview of your financial projections and how you will generate a return on this investment. Describe how the company plans to bring the product to market. Information on physicians to be targeted, sales channels, etc, is helpful. Alternatively, many drugs are acquired by large pharma firms in the late development stages. If the company plans to seek acquisition, please provide an overview of similar transactions.
6. **Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated. Key risk issues typically include efficacy versus competitors,

toxicity, clinical trials, FDA approval, dosage and delivery, CMC synthesis, changing competitive environment, etc.

7. **Funding to Date:** Provide an overview of the funding received, including a list of funding sources and a comprehensive capitalization table that should comprise all parties who have investments, stock, or rights in the company. A template exemplifying an appropriate capitalization table is provided among the application materials and MUST be used when completing your application. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.
8. **Intellectual Property:** Provide a concise discussion of the IP issues related to the project. List any relevant issued patents and patent applications. Please include the titles and dates the patents were issued/filed/published. List any licensing agreements that the company has signed that are relevant to this application.
9. **Key Personnel Located in Texas and Any Key Management Located Outside of Texas:** For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications. Key personnel are the Principal Investigator/Project Director as well as other individuals who contribute to the development or the execution of the project in a substantive, measurable way. *Substantive* means they have a critical role in the overall success of the project and that their absence from the project would have a significant impact on executing the approved scope of the project. *Measurable* means that they devote a specified percentage of time to the project. The indicated time is an obligatory commitment, regardless of whether or not they request salaries or compensation. "Zero percent" effort or "TBD" or "as needed" are not acceptable levels of involvement for those designated as key personnel. While all participants that meet these criteria should be identified as "key," it is expected that the number of key personnel will be kept to a minimum.

The entire Business Plan section shall typically comprise a maximum of 11 pages: a 2-page overview and nine, 1-page key issue summaries. <u>Please avoid redundancy</u>. Note that the section "Funding to Date" above may exceed this 1-page limit <u>if necessary</u>.

10.4.9. Biographical Sketches of Key Scientific Personnel (8-page maximum)

Provide a biographical sketch for up to 4 key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed 2 pages. You may use either the provided "Product Development Research Programs: Biographical Sketch" template or the NIH biographical sketch format. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see section 10.4.8]).

10.4.10. Budget

In preparing the requested budget, applicants should be aware of the following:

- Each award mechanism allows for up to a 3-year funding program with an opportunity for extension after the term expires. **The budget must be aligned with the proposed milestones.** Financial support will be awarded based upon the breadth and nature of the project proposed. Requested funds must be well justified. Funding will be tranched and milestone driven.
- CPRIT considers equipment to be items having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit. If awarded, management of your grant will be facilitated if specific equipment is clearly identified in the application using plain language. **Equipment not listed in the applicant's budget must be specifically approved by CPRIT subsequent to the award contract**.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.
- The total amount of CPRIT funds allowed for an annual salary of an individual for FY 2022 is $200,000. In other words, an individual may request salary proportional to the percent effort up to a maximum of $200,000. Salary amounts in excess of this limit must be paid from matching funds. Salary does not include fringe benefits. CPRIT FY 2022 is from September 1, 2021, through August 31, 2022. Additionally, adjustments of up to a 3% increase in annual salary are permitted for Years 2 and 3 up to the cap of $200,000. The salary cap may be revised at CPRIT's discretion.

The Budget section is composed of 4 subtabs that must be completed:

A. **Budget for All Project Personnel:** Provide the name, role, appointment type, percent effort, salary requested, and fringe benefits for all personnel participating on this project. If funding is requested for a role that is not currently occupied, applicant should note "new hire" as name.

B. **Detailed Budget for Year 1:** This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs in the first year of the project. Direct cost categories include Travel, Equipment, Supplies, Contractual (Subaward/Services Contracts), or Other. Applicants will be required to itemize costs.

C. **Budget for Entire Proposed Period of Performance:** This section should only include the amount requested from CPRIT; do NOT include the amount of the matching funds or the budget for the total project. Provide the amount requested from CPRIT for direct costs for all subsequent years. Amounts for *Budget Year 1* will be automatically populated based on the information provided on the previous subtabs; namely, *Budget for All Project Personnel* and *Detailed Budget for Year 1*.

D. **Budget Justification:** Please specify your CPRIT-requested funds and other amounts that will comprise the total budget for the project, including the use of matching funds. Use of the provided Budget Justification template is mandatory. Please specify each line item from your CPRIT budget as well as other funds (including matching funds). Provide a compelling justification for the budget for each line item of the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. **If travel costs will include out-of-state or international travel, make that clear here.** The budget must be aligned with the proposed milestones.

11. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify

legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and IP rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10 to 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT utilizes 2 methods of disbursement of grant funds, (1) reimbursement and (2) advancement. Under the reimbursement method, the grantee is expected to finance its operations with its own working capital. Under the advancement method, CPRIT disburses grant funds in advance of the grantee incurring expenses. Grantees must be approved by the Oversight Committee to receive advancement of funds. Please see Chapter 8 of the CPRIT Grant Policies & Procedures Guide for additional details regarding the disbursement of grant funds.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

Project Revenue Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement, which can be found at www.cprit.texas.gov and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These

contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has appropriate matching funds. For companies receiving an initial CPRIT award, the company must contribute $1.00 in matching funds for every $2.00 awarded by CPRIT. For companies that have received more than 1 CPRIT Product Development Research award, the amount of matching funds required to be contributed by the recipient company is dependent on the total amount of CPRIT funds committed to the company. See section 6 ("Funding Information") of the RFA for more details.

Matching funds need not be in hand when the application is submitted, nor does the entire amount of matching funds for the full 3 years of the project need to be available at the start of the grant. However, the appropriate amount of matching funds for each specific tranche must be obtained before each tranche of CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements associated with the requirement to demonstrate available funds.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff are not in a position to answer questions regarding scientific and product development aspects of applications. **Before contacting the helpdesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS. In addition, for Frequently Asked Programmatic Questions, please go here, and for Frequently Asked Technical Questions, please go here.**

Hours of operation:	Monday through Friday, 8 AM to 6 PM central time
Tel:	866-941-7146 (toll free in the United States only—international applicants should use the email address below)
Email:	Help@CPRITGrants.org

13.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Product Development Research Program Senior Manager.

Tel:	512-305-7676
Email:	Help@CPRITGrants.org
Website:	**www.cprit.texas.gov**

14. APPENDIX

14.1. Reviewer Evaluation Guidelines for Therapeutics

Primary Review Criteria (Scored)

Unmet Medical Need: Target Product Profile (TPP)

- Assuming successful accomplishment of development objectives, as reflected in the target product profile, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Target Validation

- If this is a "targeted" agent, to what extent has the target been validated, eg, through knockdown studies and/or pharmacological intervention?
- Has engagement of the target with the agent been demonstrated by biochemical assay? What is the potency of the agent?
- Are there validated downstream pharmacodynamic (PD) markers of target modulation? How extensive is the in vitro evidence for expected PD effects? Has the agent shown biologically significant modulation of the target in vivo, especially in tumor tissue?
- Is the target uniquely or substantially overexpressed by tumor versus normal cells?
- Does the target represent an activating mutation? If so, has binding of the agent to the target and other activating mutations been characterized?
- Has the company's demonstration of target validation been externally/independently confirmed?
- Are there known mechanisms of resistance to the modulation of this target? If so, has the company proposed possible mitigation/preemptive approaches, such as combination chemotherapy?

Preclinical Characterization: Pharmacodynamic Proof of Concept

- Considering in vivo preclinical pharmacodynamic characterization and the patient populations or subpopulation(s) representing the initial clinical indication(s) for the drug, what is the clinical relevance of the preclinical models? To elaborate, were in vivo/xenograft studies carried out in cell line–based models or PDX-derived models? In how many such models have studies been carried out? To what extent do these models reflect standard of care (SOC) for refractory versus drug-naive tumors? At the time of treatment initiation, were tumors established and measurable, or was treatment initiated shortly after tumor inoculation?
- Was antitumor activity predominantly growth inhibition or tumor regression? Were sustained complete remissions or "cures" achieved in the majority of animals and models? Were comparisons with optimally dosed SOC agents made? Where the agent is intended to be added to the SOC, is there compelling evidence of in vitro/in vivo synergy with SOC agents?
- Have results of preclinical efficacy studies carried out by the company been externally/independently confirmed?
- Overall, considering clinical relevance and study results, how strong is the preclinical efficacy profile of the agent?
- How strongly does the preclinical pharmacodynamic profile support the clinical efficacy expectations reflected in the TPP?

Preclinical Characterization: Safety

- How extensive is the in vitro and in vivo preclinical safety characterization carried out so far?
- Has the agent undergone CEREP-type screening for interactions with targets with known safety liabilities, eg, CYP 450, hERG?
- Considering potency and target selectivity, what is the potential both for off-target and pharmacologically on-target deleterious effects?
- Can exposures associated with substantial antitumor efficacy/PD effects be achieved safely in vivo?

- Do preclinical pharmacokinetics (PK) studies indicate potential for clinical safety issues, eg, accumulation, variability, lack of dose proportionality?
- Have PK/PD issues been investigated with alternate dosing schedules in order to optimize the therapeutic index of the agent?
- Are there any issues with the distribution or metabolism of the agent?
- Overall, are results of safety characterization carried out so far such that the agent can be considered reasonably derisked from a safety perspective, or are there red flags? Alternatively, is the extent of preclinical safety characterization carried out so far insufficient to address this question?

Pharmaceutical Properties/Chemistry and Pharmacy

- In the case of agents intended for oral absorption, are there any issues with water solubility? Do formulation studies indicate the feasibility of oral administration?
- Were Lipinski-type criteria applied during the lead optimization process such that the lead compound has demonstrated properties that make it likely to be an orally active drug in humans?
- Are there any issues with the stability of the drug substance or the drug product?
- Is there scope for further lead optimization through structure-activity studies?
- In the case of biologicals, has a high-quality cell line been developed yet? Are yields acceptable? Does the purification process appear reasonable and scalable?
- Have analytical methods been adequately developed?
- Has the (lead) protein been adequately characterized biochemically, immunogenetically, and biophysically? Has absence of aggregate formation been demonstrated in stability studies?

Development Plan/Regulatory Aspects

- Are development proposals scientifically rational and sufficiently comprehensive considering development efforts and results to date?
- Does the applicant demonstrate adequate familiarity with pertaining regulatory guidelines in major jurisdictions (United States/European Union)? Do development proposals reflect specific regulatory authority input; eg, from pre-IND interactions? Alternatively, has regulatory authority interaction been insufficient so far?

- In the case of clinical studies, are patient populations adequately described and consistent with those representing the initial target indication(s)?
- Are efficacy end points appropriate for study designs? Is the sample size statistically adequately justified in terms of the target effect size?
- In the case of potentially pivotal clinical trials, moreover, are the proposed primary efficacy end points and target effect sizes consistent with regulatory precedence?
- Considering target indication prevalence, will the agent qualify for orphan drug designation? If so, does the applicant intend to apply for this?
- Has the applicant demonstrated reasonable diligence in researching patient availability, competitive clinical trial activity, and recruitment issues such that patient enrollment projections can be considered realistic?
- Will the proposed programs advance development of the agent to commercially significant milestone(s), such as might attract either partner interest or the raising of further development funding?
- Are development milestones clear and adequately described? Is the overall project timeline realistic?

Competitive Analysis

- Has the applicant carried out a comprehensive and realistic analysis of the likely strengths and weaknesses of the agent compared to clinically relevant competitive products, including potentially competitive agents in development?
- Are the applicant's assumptions regarding the strengths and weaknesses of the agent relative to likely competitors reasonable, considering the preclinical efficacy and safety data on the agent generated so far?

Intellectual Property/Freedom to Operate

- Have IP and freedom-to-operate aspects been addressed in the application?
- Considering patent type (Composition of Matter/Formulation/Manufacturing Process/Use) and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate?

Chemistry, Manufacturing, and Controls (CMC)

- How advanced is CMC and manufacturing development?
- Are there any sourcing issues?
- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- Are there significant technical difficulties within CMC/manufacturing scale up still to be addressed?

Business/Commercial Aspects

- Does the applicant need to raise further funds for the CPRIT matching requirement? In this case, how realistic are the applicant's assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program of studies reasonably support such expectations?
- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in-house personnel in such key areas as translational research, clinical development, regulatory affairs, and CMC/manufacturing? If not, are there plans to address such deficiencies?

- Has the applicant demonstrated appropriate engagement of outside development expertise through, for example, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Is it clear that no CPRIT funds will be sent out of Texas to a corporate headquarters?

14.2. Reviewer Evaluation Guidelines for Medical Devices and Diagnostics

Primary Review Criteria (Scored)

Unmet Medical Need

- Assuming successful accomplishment of development objectives, will the intended product significantly address an unmet medical need in the diagnosis, treatment (including supportive care), prognosis, or prevention of cancer?
- In terms of incidence/prevalence of the patient populations or subpopulations intended to be targeted by the development of this product, what is the extent of the unmet need?

Product Validation

- Technical Validation: Has the product or technology been successfully validated, ie, prototyped, built and tested in ex vivo, animal, or clinical setting?
- Have biological proof of principle and product mechanism of action been demonstrated?
- Have efficacy and safety in an accepted in vitro or animal model been demonstrated?
- Clinical Validation: Are clinical trials required to demonstrate product performance? If so, have they been planned or conducted?
- Biological Risk: What are the risks to the patients, eg, toxicology, biological, interactions with other therapies?

Production/Manufacturing

- Has the applicant demonstrated the likelihood that the product can be manufactured at commercial scale and with a reasonable cost of goods?
- How advanced is manufacturing development?
- Are there any sourcing issues?

Intellectual Property/Freedom to Operate

- Have barriers to entry been identified? Has a route to patentability been mapped out, eg, independent patent, first-mover advantage, unique knowhow, etc?
- Does the company have issued patents? If not, have they conducted freedom to operate and patentability analysis?

- Considering patent type (Composition of Matter/ Formulation/Manufacturing Process/Use), and duration of patent life, how strong is the IP?
- Are there opportunities for meaningful patent life extension?
- Has the applicant secured appropriate licenses conferring freedom to operate, if required?

Market Opportunity

- Does the product address a clearly defined unmet need; lack of available therapy, poor efficacy, side effects, lack of available diagnostic, safety problems, cost reduction, enhanced convenience?
- Are target indication and market clearly defined?
- Is channel to market available? Does the company understand the entire value chain and all constituencies involved in procuring and utilizing the product?
- Does the company understand the clinical pathway that leads to utilizing the product?
- Is market opportunity of significant size and lucrative enough to justify investment?
- Has the applicant demonstrated time or cost savings?
- How does product fit with existing "ecosystem"; ie, are the benefits provided worth the time and cost of implementing the new approach?

Competition

- Is this a "Whole Product," ie, a complete product or service sold to a defined customer that provides a defined value proposition?
- Is value proposition clearly delineated, ie, improve efficacy, improve safety, reduce cost, or improve convenience)?
- Has the company demonstrated its value proposition versus competition?
- Has the company conducted a competitive analysis? Does it provide a comprehensive, realistic assessment of strengths and weakness versus competition based on the data generated to date?

Development Plan/Regulatory Aspects

- Have a comprehensive development plan and market entry strategy been developed? How realistic are these plans?
- Has determination of FDA-defined device classification been completed? Is the clinical and regulatory pathway well understood and feasible?

Management Team

- Does the management team have the appropriate level of experience and track record of relevant accomplishments to execute the development and commercialization strategy?
- Does the company have experienced and appropriately accomplished in house personnel in such key areas as product engineering, clinical development, regulatory affairs, manufacturing, etc? If not, are there plans to address such deficiencies?
- Has the applicant demonstrated appropriate engagement of outside development expertise through, eg, a scientific advisory board, individual consultantships, and regulatory authority interactions?

Business/Commercial Aspects

- Considering the initial clinical indications for the product, its competitive strengths and weaknesses, and pricing/reimbursement objectives, are market/segment penetration and sales and profitability projections reasonable?
- Has the applicant articulated a coherent plan for using results on clinical end points in pivotal trials as a basis for cost-effectiveness analyses to support pricing and reimbursement?
- Has the company clearly anticipated pricing strategy and reimbursement environment?
- Is the projected return on investment congruent with investment opportunity and risks?

Funding

- Is investor interest in this sector sufficient to fund the company through profitability?
- Does the applicant already have available funds to meet the CPRIT matching requirement, or do they need to raise additional funds? In this case, how realistic are assumptions about a successful fundraising campaign? Does the applicant have a track record of success in raising development funding?
- Have likely acquirers been identified by the applicant?
- Does the company have the resources to support required activities while fundraising?
- Does the applicant indicate intentions for attracting a development partner or for outright acquisition? Do the development milestones and assumed results of the research program reasonably support such expectations?

Secondary Review Criteria (Unscored)

Budget and Duration of Support

- Are the budget and duration of support appropriate for the program of studies described in the application?
- Is there sufficient clarity in the budget proposal as to how funds will be expended?
- Is there sufficient clarity in the budget proposal as to the spending of funds in Texas?
- Do plans reflect a substantial commitment to Texas? Does the applicant demonstrate an understanding of the Texas spending requirement for CPRIT funds?

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel 1
(22.2_PDR_PDP_1)
Observation Report

Report No.	2022-03-21 22.2_PDR_PDP_1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel 1 (22.2 _PDR_PDP_1)
Panel Date:	March 21, 2022
Report Date:	March 29, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel 1 (22.2_PDR_PDP_1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on March 21, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and six (6) applications were not discussed
- Panelists: One (1) panel chair, four (4) PDRC members, eight (8) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Four (4)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The applications for which there were COIs were not discussed.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

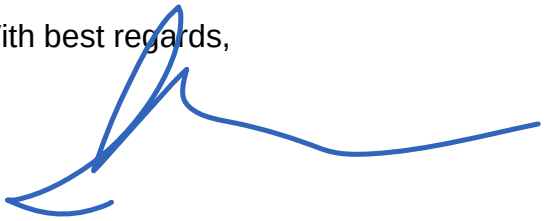
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel_2
(22.2_PRD_PDP_2)
Observation Report

Report No.	2022-03-22 22.2_PRD_PDP_2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel_2 (22.2 _PRD_PDP_2)
Panel Date:	March 22, 2022
Report Date:	March 29, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel_2 (22.2_PRD_PDP_2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on March 22, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Thirteen (13) applications were discussed and five (5) applications were not discussed
- Panelists: One (1) panel chair, three (3) PDRC members, nine (9) expert reviewers, and two (2) advocate reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) Conflicts of Interest (COIs) identified prior to and/or during the meeting. There were two (2) COIs on the application discussed and five (5) COIs on the applications not discussed. Those with COIs were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

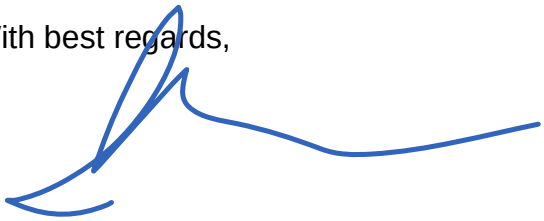
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel-1 (22.2 PDR-PDP1)
Observation Report

Report No.	2022-04-11 22.2_PDR-PDP1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel-1 (22.2 _PDR-PDP1)
Panel Date:	April 11, 2022 and April 12, 2022
Report Date:	June 8, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel-1 (22.2_PDR-PDP1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on April 11, 2022 and April 12, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Seven (7) applications were discussed and nine (9) applications were not discussed
- Panelists : One (1) panel chair, four (4) PDRC members eight (8) expert reviewers, and two (2) advocate reviewers were present on both days
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Four (4) on day 1 and six (6) on day 2
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2) were present on both days
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

In total there were three (3) Conflicts of Interest (COIs) identified prior to and/or during the meetings over two days. COI(s) were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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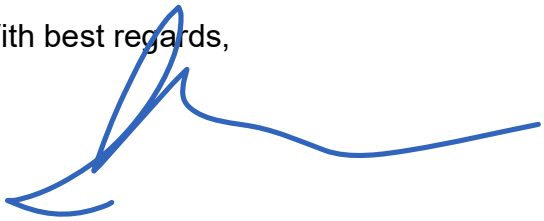

Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Panel-2 (22.2 PDR-PDP2)
Observation Report

Report No.	2022-04-13 22.2_PDR-PDP2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Panel-2 (22.2 _PDR-PDP2)
Panel Date:	April 13, 2022 and April 14, 2022
Report Date:	June 8, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Panel-2 (22.2_PDR-PDP2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on April 13, 2022 and April 14, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and

- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Eight (8) applications were discussed and ten (10) applications were not discussed
- Panelists: One (1) panel chair, three (3) PDRC members, ten (10) expert reviewers, and two (2) advocate reviewers on both days
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Seven (7) on day 1 and five (5) on day 2
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2) on both days
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were seven (7) Conflicts of Interest (COIs) identified prior to and/or during the meeting. COI(s) were excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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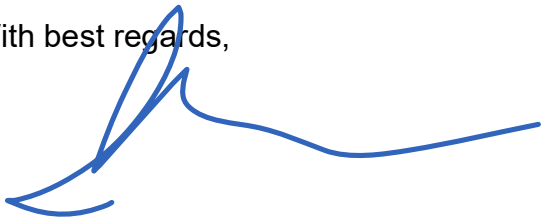

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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Duligence Panel-1 (22.2_PDR_DDP1)
Observation Report

Report No.	2022-07-13 22.2_PDR_DDP1
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Duligence Panel-1 (22.2 _PDR_DDP1)
Panel Date:	July 13, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Due Duligence Panel-1 (22.2_PDR_DDP1) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on July 13, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Five (5) applications were discussed
- Panelists: One (1) panel chair, three (3) expert reviewers, and four (4) PDRC members
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Three (3)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- ICON Due Diligence Evaluators: Five (5)
- ICON Due Diligence Evaluators did only provide input when requested

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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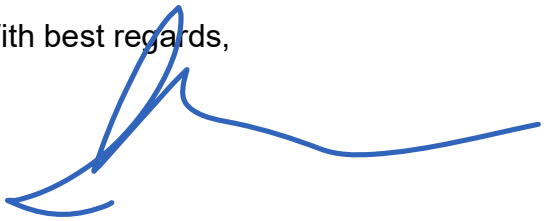

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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Duligence Panel-2 (22.2_PDR_DDP2)
Observation Report

Report No.	2022-07-14 22.2_PDR_DDP2
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Duligence Panel-2 (22.2 _PDR_DDP2)
Panel Date:	July 14, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Due Duligence Panel-2 (22.2_PDR_DDP2) meeting. The meeting was chaired by David Shoemaker and conducted via videoconference on July 14, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Six (6) applications were discussed
- Panelists: One (1) panel chair, Four (4) expert reviewers, and three (3) PDRC members
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Four (4)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions
- ICON Due Diligence Evaluators: Three (3)
- ICON Due Diligence Evaluators did only provide input when requested

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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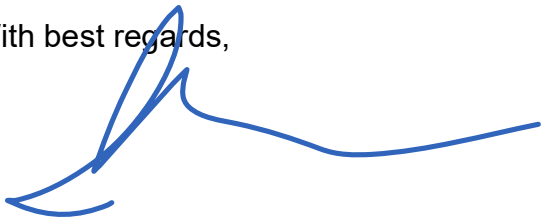

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Senior Partner
Business & Financial Management Solutions, LLC

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Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.2 Product Development Research Due Diligence Ranking (22.2_PDR_DD Ranking)
Observation Report

Report No.	2022-07-19 22.2_PDR_DD Ranking
Program Name:	Product Development Research
Panel Name:	22.2 Product Development Research Due Diligence Ranking (22.2 _PDR_DD Ranking)
Panel Date:	July 19, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.2 Product Development Research Due Diligence Ranking (22.2_PDR_DD Ranking) meeting. The meeting was chaired by Jack Geltosky and conducted via videoconference on July 19, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Two (2) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Ten (10) applications were discussed and one (1) applications were not discussed
- Panelists: One (1) panel chair, one (1) vice chair, and seven (7) PDRC Members
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Two (2)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Five (5)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There was no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

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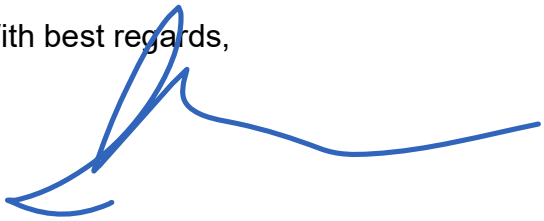

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Business & Financial Management Solutions, LLC

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Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Product Development Research Cycle 22.2

Awards Announced at the August 17, 2022, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Research Cycle 22.2 include: *Seed Awards for Product Development Research; Company Relocation Product Development Research Awards;* and *Texas Company Product Development Research Awards.*

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant/Principal Investigator	Principal Investigator Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
No reported COIs.			
Applications not considered by the PIC or Oversight Committee:			
DP220058	Vicci Korman	Veravas, Inc.	Steven Weinstein
DP220060	Eric Rothe	Tiburon Bio, Inc.	Elaine Jones
DP220061	Chen Liu	CHEN LIU	Steven Weinstein
DP220042	David Arthur	Salarius Pharmaceuticals, Inc.	Kristine Swiderek
DP220050	Amos Ofer	EnCellX Inc.	Michael Cheng
DP220052	Timothy Coleman	Nemucore Medical Innovations, Inc.	Alan West, Lior Braunstein, Lee Greenberger, Michael Cheng
DP220056	Douglas Baum	QSAM Biosciences Inc.	Roy Cosan

High Level Summary of Due Diligence

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- StellaNova Therapeutics, Inc. for $3,000,000.

The PDRC did not recommend any contract contingencies for this award.

StellaNova Therapeutics, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

StellaNova Therapeutics Inc. is a Houston-based company based around research conducted at MD Anderson Cancer Center demonstrating that cells in the tumor microenvironment of pancreatic cancer (PDAC) and triple negative breast cancer (TNBC) produce Dickkopf-3 (DKK3) that acts on neighboring cancer cells to stimulate their growth, metastasis and resistance to standard therapy.

Novel therapies are urgently needed for pancreatic cancer and triple negative breast cancer, two of the most aggressive cancers with no effective cure. For pancreatic cancer, 4,420 Texans and 60,000 Americans are diagnosed each year and only 7% are expected to survive 5 years. Triple negative breast cancer is also aggressive, affecting 3,000 women in Texas and 42,000 in the US annually, with a disproportionate impact on African American and Hispanic women. Given the lack of effective therapies for these diseases, the successful development of DKK3-targeted therapy has the potential to be practice-changing for the field.

StellaNova is developing novel antibodies to block DKK3 (anti-DKK3 mAb). Anti-DKK3 mAb inhibited tumor growth in mice and produced long-term survival with no toxicity. For TNBC, treatment also reduced lung and brain metastases. Anti-DKK3 mAb is effective either alone or in combination with immunotherapy. Preclinical models validated the importance of DKK3 on the genetic and pharmacological levels, revealing that (1) DKK3 knockout inhibited PDAC tumor growth and metastasis, and increased survival in the KPC model, and (2) anti-DKK3 mAb (JM6-6-1) inhibited PDAC progression and metastasis, increased survival, and promoted an influx of CD8+ T cells into the “immunologically cold” tumor microenvironment. StellaNova will generate a high-quality producer cell line and generate cGMP qualified Master Cell Bank (MCB) for the large-scale production of the Development Candidate Humanized anti-DKK3 antibody which can be used for IND enabling GLP toxicity studies. These studies will be used for a cGMP 2000-L scale batch production that will be used in Phase 1/1B clinical trials.

Select Reviewer Comments

"The preclinical data establishing DKK3 as a possible therapeutic target in pancreatic cancer from Dr Hwang's lab are excellent. JM6-6- 1, a murine DKK3 neutralizing antibody, has been evaluated in a wide range of mouse models (granted preliminary data presented in very small tumors initially). These data seem promising."

"This is a very solid application arising from work done by top-notch, world-class cancer biology researchers at MD Anderson."

"The company appears to have excellent team with requisite skills and knowledge to move this project forward, including experienced CRO and mAb expertise. Stellanova is part of SPOROS Bioventures portfolio, who is well known to CPRIT for other parallel initiatives, and appears well organized in supporting this type of development."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Asylia Therapeutics, Inc. for $3,000,000.

The PDRC did not recommend any contract contingencies for this award.

Asylia Therapeutics, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Asylia Therapeutics, Inc. is a Houston-based, privately held development stage biopharmaceutical company which received a CPRIT award in 2020. Asylia is developing antibody therapies for cancer based on the discovery of the central role of heat shock protein-70 (HSP70) in tumor antigen presentation, immune activation and cellular stress responses.

Asylia discovered two entirely novel monoclonal antibodies with distinct mechanisms of action. ASY-77A targets the extracellular, soluble form of HSP70 released from cancer cells in complex with tumor-derived antigenic peptides (currently funded CPRIT SEED grant) and 239-87, targeting the cell surface form of HSP70, which is the focus of this proposal.

Asylia is developing an antibody drug conjugate (ADC) based on antibody 239-87, that recognizes the cell surface form of HSP70. Treatment with 239-87 resulted in prolonged eradication (cures) of several cancer types in mice transplanted with human cancer cells. Asylia plans to humanize and optimize mouse mAb, 239-87 to be able to manufacture cell line to produce the antibody, as well as to optimize a linker to connect the antibody to the drug. Asylia will also improve process development for ASY-87 to perform IND-enabling toxicology studies. The company will produce an ADC conjugate that can be tested for safety and efficacy in cancer patients who are failing current therapies in cancers, in particular those with T-cell lymphoma. Encouraging initial trial results will support the broader testing in other tumor types with high cell surface HSP70 expression such as Myeloma and Breast Cancer.

Select Reviewer Comments

“*Targeting HSP70 could have a wide range of cancer applications. Based on preclinical data that it shows highest expression in T-cell lymphoma, they wish to start there. T-cell lymphoma has a very high unmet need.”*

"In summary, this is a very professionally prepared application by a highly competent management team. CsHSP-70 is a promising new cancer therapeutic target with considerable preclinical validation as well as supporting clinical outcomes correlations."

"Additional in vivo preclinical studies in combination with an HDAC inhibitor and in combination with BV are planned. Not only do these approaches provide a potential backup strategy in PTCL, but they may set the stage for a post (accelerated) approval confirmatory study, and moreover, may pave the way for integration of the agent with SOC agents for earlier lines of therapy."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Xerient Pharma, Inc. for $2,934,737.

The PDRC did not recommend any contract contingencies for this award.

Xerient Pharma, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Xerient is a Houston-based startup dedicated to the development of an orally administered tablet that releases very efficient radioprotectant molecule in the duodenum. Xerient demonstrated that it is possible to repurpose an FDA-approved radioprotectant, and reformulate it in a tablet with a targeted-delivery and in-body-monitoring functionalities to allow very efficacious radiation therapy.

Pancreatic cancer cannot be cured without surgery. Nearly 90% of patients present with unresectable disease (locally advanced + metastatic), leaving patients and clinicians with very few treatment options once chemotherapy is completed. Radiation therapy cannot substitute for surgery because of morbid radiotoxicity to the nearby intestines that occurs before the tumor is controlled. Thus, treatment-related gastrointestinal (GI) radiation toxicity may be the single greatest barrier to improving treatment responses for unresectable pancreatic cancer. There are no known medications that can selectively protect the intestines from the side effects of treatment-related GI radiation toxicity.

Amifostine is a well-known therapeutic and is the only FDA-approved radioprotector, but it has significant toxicity when given intravenously (the only approved route of administration). Orally delivered amifostine is a pro-drug that is activated in the small intestine by endogenous intestinal alkaline phosphatases. If administered just prior to radiation, the active metabolite, WR-1065, is then produced locally in the gut and protects the intestinal tissue during radiation, then is rapidly degraded. Orally administered amifostine is highly efficacious and enables ablative radiation therapy to pancreatic tumors, which triples survival in a murine model. Oral amifostine coupled with ablative radiotherapy can be a curative treatment in selected patients with unresectable pancreatic cancer.

Xerient intends to develop and test an enteric-coated version of amifostine (EC-amifostine) that maximizes payload delivery in the duodenum in a timeframe relevant to radiotherapy that will be

clinically efficacious with targeted delivery and monitoring functionalities. Xerient will complete GLP toxicology studies, allowing the company to proceed with a clinical Phase I safety trial in humans. Xerient will evaluate the activity and tolerability of EC-amifostine in a canine model and confirm that amifostine can protect intestinal tissue from radiation in a porcine model.

Select Reviewer Comments

"The molecule is well known and studied and FDA approved as a radioprotectant when given IV."

"Many patients with pancreatic cancer would definitely benefit from radiotherapy, but because of the toxicity to the duodenum, it is not used. The ability to deliver safe and effective doses of targeted radiotherapy would be of great potential benefit to these patients who have few therapeutic options."

"If successful, this product could have fast uptake as SOC in radiation centers with new possibility of benefit to pancreatic cancer radiotherapy."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- InformAI, Inc. for $1,552,000.

The PDRC did not recommend any contract contingencies for this award.

InformAI, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

InformAI Inc. is a Houston-based company focusing on AI solutions that speed up medical diagnosis at the point-of-case and improve radiologist productivity. With 360 degrees of radiation access and delivering a wide range of beam intensities, a nearly infinite number of avenues exist to target a malignant lesion while minimizing off-target effects. Deep learning methods are well-positioned to optimize this process, identifying radiation plans that deliver a therapeutic radiation dose to cancer while optimally minimizing unwanted radiation exposure to healthy tissue and neighboring organs.

InformAI proposes to create RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for planning Radiation Oncology in the head and neck region. To date, a minimally viable business prototype has been created, led by work out of The University of Texas Southwestern Medical Center's Medical Artificial Intelligence and Automation Laboratory in collaboration with the Department of Radiation Oncology.

Preliminary testing and validation efforts of the model are promising. InformAI has entered into a Sponsored Research Agreement with UT Southwestern to lead the product scaling, validating, technological hardening, regulatory approval, and commercialization efforts necessary to transform this prototype technology into a finished business offering.

Deep learning methods are well-positioned to optimize the creation of radiation plans that deliver a therapeutic radiation dose to cancer while optimally minimizing unwanted radiation exposure to healthy tissue and neighboring organs. A deep learning radiation planning tool could solve current pain points in the radiation oncology workflow, improving the safety, efficiency, quality, and usability of multiple product modalities. According to the company, no products available on the market leverage deep learning methods to create the 'first pass' radiation treatment plan.

InformAI intends to expand its dataset including acquiring access to additional 400 head and neck segmented and annotated head and neck de-identified patient scans. Inform AI will validate

its label claims through clinical research with the purpose of preparing for the FDA regulatory approval process. InformAI will also ensure that its product is widely, if not universally, integrable with all TPS used in the routine practice of radiation oncology.

Select Reviewer Comments

"There is a clear unmet need in radiation oncology addressed in this proposal with the use of AI to help create more efficient and automated dose plans and associated organ segmentation. There is a clear value proposition to patients and oncologist in improving the efficiency and the accuracy of the dose plans for the clinicians."

"This approach has the potential to make radiation planning faster and more accurate than current standards of care. This is rendered possible by recent and current informatics advances, and it is likely that AI will affect the medical practice also in areas other than radiation therapy, thus the submission is well positioned in the future stream of innovative approaches."

SEED

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- NUCORE Medical for $2,999,999.

The PDRC recommended the following contract contingency for this award. Agreements to assign all IP assets related to the tissue coring/resection device originally created and developed by Precision Thoracic, LLC and Ethicon, Inc. to NuCore Medical, Inc. should be completed, and the transaction concluded, prior to execution of the contract with CPRIT

NUCORE Medical

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Nucore Inc. is a Houston-based medical device company resulting from a multi-year collaboration between J&J's Center for Medical Device Innovation @ The Texas Medical Center and California-based Precision Thoracic to innovate novel technologies focused on the early interception, diagnosis, and treatment of lung cancer.

Early interception of suspicious lung nodules, by nature, means dealing with small, amorphic, and heterogeneous nodules that are extremely challenging to diagnose with current needle biopsy techniques. Surgical wedge resection (i.e. open or VATS) is an option, but these complex procedures unnecessarily sacrifice large quantities of functional lung tissue and can often expose fragile patients to unjustified surgical risks. Clinicians need a tool that can provide a minimally invasive, tissue sparing, targeted resection of suspicious small and intermediate-sized lung nodules, facilitating definitive diagnosis.

Nucore has developed Minimally-invasive Targeted Resection (MiTR-core™), the first medical device designed to safely remove lung nodules in a simple, quick, and minimally invasive procedure. The MiTR-core procedure will enable clinicians to remove suspicious nodules upon initial detection, will provide a definitive diagnosis of the nodule, spare healthy lung tissue, and in the event of cancer, provide direct access to the site of the nodule for further targeted therapy.

MiTR-core™ is a tissue-sparing transthoracic nodulectomy tool for CT-guided targeting of a suspicious nodule followed by minimally invasive access, coring, resection, and RF-based sealing of the lung to prevent blood and air leaks. The amount of diagnostically viable tissue extracted using MiTR-core is more than 2,000 times greater than the tissue extracted using existing needle techniques. In addition to facilitating greater specificity and sensitivity, the

specimen size will allow for rapid characterization of the cancer and, potentially, real-time sequencing.

The Nucore team has advanced MiTR-core from a concept to functional prototypes and rigorously tested it on the bench and in a series of nine acute porcine studies. MiTR-core has successfully demonstrated proof-of-concept in 2 chronic porcine studies. The company will strengthen its clinical and commercial case for MiTR-core through clinical data analytics (e.g. clinical outcome and cost databases, retrospective chart review, prospective multi-center registry trial), prepare for a First-in-Human study through regulatory submission, and manufacture clinical build devices and advance the device through a First-in-Human study.

Select Reviewer Comments

"*With financial support of $4.5 million from JNJ's Center for Medical Device Innovation, Nucore Inc, a Houston-based company, has developed a biopsy device that is much less invasive than wedge resection, essentially eliminates the false-negative/indeterminate issue associated with fine-needle biopsy, and by virtue of a tissue sealing feature, does so with minimal to no complications of hemothorax and pneumothorax, in effect, addressing the follow-up definitive diagnostic barriers to LDCT lung cancer screening uptake noted above."*

"This device could be really useful in terms of yielding actionable results in a far less invasive procedure than currently available."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- PLUS Therapeutics for $17,613,605.

The PDRC did not recommended any contract contingencies for this award. The award recommendation to PLUS Therapeutics is contingent on the successful completion of amending the License Agreement between PLUS Therapeutics and NanoTX.

PLUS Therapeutics

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Plus Therapeutics is a publicly listed company based in Austin. Plus is developing a Rhenium-186 NanoLiposome (186RNL), which is a novel radiotherapeutic to combat several cancers including recurrent glioblastoma, 186RNL is safe and well-tolerated while delivering a radiation dose to the tumor that is up to 15 times higher than typically achievable with standard radiation therapy. Plus is developing 186RNL to treat leptomeningeal metastases. Leptomeningeal Metastases (LM) are a rare but typically fatal complication of advanced cancer that affects the fluid-lined structures of the central nervous system. LM are diagnosed in 5% of cancer patients.

The investigational product is BMEDA-chelated Rhenium-186 NanoLiposome (186RNL). Rhenium-186 is an ideal radionuclide for CNS cancers such as LM because of its long 90-hour half-life, beta particles' short ~2mm path length, low dose rate, and high radiation density that overwhelms proliferating cellular innate DNA repair mechanisms. For 186RNL treatment of LM in humans, PLUS has obtained FDA Fast Track designation and IND clearance and will pursue FDA Orphan Drug and Breakthrough Therapy designations in the future.

The purpose of the two-part, Texas-based multicenter (The University of Texas Health Science Center San Antonio, The University of Texas Southwestern Medical Center, and The University of Texas MD Anderson Cancer Center) Phase clinical trial is to characterize the safety, tolerability, PK, dosimetry, and antitumor activity of 186RNL administered intrathecally, via an intraventricular catheter system (Ommaya reservoir), as a single agent in 61 LM subjects. If successful, PLUS intends to seek FDA investigational new drug (IND) clearance to initiate and complete a Phase 2 pivotal trial in 120 subjects (final N subject to data and statistical analysis plan) with leptomeningeal metastases to support a new drug application (NDA) submission with the FDA.

The company expects 186RNL to deliver a much higher and more targeted dose of radiation during a single administration compared to traditional RTs; have a high safety margin with minimal risk of bone marrow suppression; may be able to treat all LM patients, unlike some other therapies that rely on tumor targeting technology for a subset of patients; ease of administration with well-accepted and currently utilized access technology.

Plus intends to complete parts 1 and 2 of a Multicenter Phase 1 Clinical Trial of IT-Delivered 186RNL to treat LM, which will include compiling safety data, identifying a maximum tolerated dose, assess the safety, tolerability, efficacy of 186RNL in subjects with LM for Phase 2 pivotal clinical trial. Plus intends to complete Multicenter Phase 2 Clinical Trial of IT-Delivered 186RNL to treat LM, which will lead to preparations for filing an NDA submission to the FDA.

Select Reviewer Comments

"*This tackles the issue of leptomeningeal metastasis with no therapy at the moment. IND has been filed and cleared by the FDA. In spite of some weaknesses about lack of preclinical data particularly in combination therapy for some models, the application remains solid and promising."*

"*The strengths are high unmet need albeit a very small population. Data in GBM are encouraging. There is FDA green light for the next clinical trial. The competition is limited, and the biomarker strategy if executed should improve targeting the most likely to respond..."*

"The intended product is currently already in clinical trials in glioblastoma and overall de-risks the intended product, clinical strategy, and the company."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Atom Mines for $2,500,000.

The PDRC did not recommend any contract contingencies for this award.

Atom Mines

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Atom Mines is a small Austin-based company which utilized a Magnetically Activated and Guided Isotope Separation ("MAGIS") technology developed at The University of Texas at Austin, which will enable the production of the stable isotope Ytterbium-176 (176Yb) needed to make the radio-isotope Lutetium-177 (177Lu). 177Lu is an effective beta-therapy agent approved for certain neuroendocrine cancers and soon to be approved for prostate cancer, the second leading cause of cancer death in men, with clinical trials underway for a range of cancers. 177Lu can be used to target small tumors and dispersed, inoperable metastatic cancer using precise delivery molecules. 176Yb is currently only available in small quantities from Russia and that supply is uncertain due to geopolitics and competition for limited production capacity.

Ytterbium-176 (176Yb) is the stable precursor required to make carrier-free 177Lu, and 176Yb is currently only available in very limited quantities from Russia. Russian supplies have remained limited due to competition for production capacity for other isotopes, while global demand has more than doubled. This supply is in jeopardy due to deteriorating geopolitics, corruption, and competition for limited calutron separation capacity.

A reliable, domestic source of pure 176Yb is required to produce sufficient carrier-free 177Lu to support FDA-approved drugs and ongoing cancer research, trials, and therapies in Texas and globally. Novartis has two products Pluvicta and Lutathera which utilize 177Lu. Atom Mines utilizes an isotope separation developed by Prof. Mark G. Raizen at The University of Texas at Austin. Magnetically Activated and Guided Isotope Separation ("MAGIS") uses lasers to temporarily magnetize atoms that is then followed by separation with arrays of magnets.

Atom Mines LLC has fully demonstrated 176Yb enrichment to medical-grade purity of 99.5%. MAGIS will enable domestic commercial production of 176Yb, as well as other rare isotopes for widespread medical use. Atom Mines intends to scaleup 176Yb production initially to 200 grams; validate purity of routine batches and of 177Lu produced by industry partner and

irradiators. Atom plans to scale up to 500 grams within three years and ultimately to kilogram quantities, which will support tens of thousands of doses for prostate cancer therapy per year.

Select Reviewer Comments

"*Indeed, the Department of Energy openly recognizes the lack of separation capabilities in the United States and the need for new domestic capabilities. The company has demonstrated that Novartis has a need for this material to develop and test novel prostate cancer therapy and has a production site in Texas, as well as a global distribution partnership with a German company, Eckert and Ziegler, which has invested in the company."*

"Atom Mines will use the efficiency of MAGIS technology to greatly reduce the cost of separating stable isotopes and make important medical isotopes for therapeutics already approved or in the process of approval."

"There is no risk in this proposal short of not being able to meet the demand at commercial scale since several possible therapeutics may use this radiotherapeutic approach."

TXCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- Rapamycin Holdings, Inc. for $16,999,999.

The PDRC recommended the following contract contingency for this award. Emtora's relationship with Southwest Research Institute with regard to intellectual property and manufacturing for the new formulation of eRapa should be specified.

Rapamycin Holdings, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

Emtora Biosciences (formerly Rapamycin Holdings Inc.) is a San Antonio company that has developed eRapa, a novel form of the FDA-approved active ingredient rapamycin. Rapamycin has previously shown promise in treating gastrointestinal diseases and in cancer prevention, but is limited by toxicity. eRapa is targeted to the colon and is delivered at lower doses, resulting in lower toxicity. The company is developing eRapa to prevent colorectal cancer in patients with Familial Adenomatous Polyposis (FAP). In 2019, Emtora received a CPRIT Product Development (SEED) award for a Phase IIa study of eRapa in FAP, which is currently underway.

Data supports that rapamycin augments the immune system, prevents cancer in cancer-prone animal models, and prolongs health and life span. It has been demonstrated that rapamycin reduces the percentage of CD4 and CD8 T lymphocytes that express PD-1 (exhaustion marker), which inhibits T cell signaling and is more highly expressed with age and exposure to cancer. The results of Emtora's Phase I clinical trials in prostate cancer indicate that e-Rapa is safe and well-tolerated at all doses and schedules tested; more tolerable at intermittent dosing schedules; has no adverse effect on quality of life; has a consistent and predictable absorption profile (unlike rapamycin); produces measurable and favorable changes in the immune system; and no patients on eRapa experienced disease progression during the study.

Emtora proposes to manufacture drug product to support the addition of a fourth cohort in the current Phase IIa study of eRapa in FAP. The proposal would expand and complete the CPRIT-funded Phase IIa study of eRapa in Familial Adenomatous Polyposis (FAP) and prepare for and execute Randomized Placebo-Controlled Trial of eRapa in FAP.

Select Reviewer Comments

“*This new encapsulated rapamycin formulation, eRapa, is targeted specifically to the colon and is delivered at a consistent and lower dosage, not only reducing toxicities but also capitalizing on the potential of partial inhibition of the mechanistic target of rapamycin (mTOR) to act as a chemopreventive agent*.”

“*The applicant has a good standing with CPRIT through a previous Seed Award, has received ODD, has an open IND, and is currently in phase 2a clinical trials in FAP. As such, the proposal is highly de-risked.”*

RELCO

High Level Summary of CPRIT Product Development Diligence and Recommendation

The Product Development Review Council (PDRC) recommended that the Program Integration Committee and the Oversight Committee approve the following Seed Award for Product Development Research:

- PanTher Therapeutics, Inc. for $14,268,315.

The PDRC recommended the following contract contingency for this award.
1) Clinical data from the Australian clinical trial (ongoing at time of application submission)
2) A clear and detailed clinical development plan
3) A timeline for manufacturing higher doses of the drug product needed for the Phase 1b/2
4) A plan with timetable for hiring in Texas
5) Information on whether the company will be able to execute the project based on its previous pre-IND meeting with the FDA, which was held several years ago, or whether a new one will be needed.

PanTher Therapeutics, Inc.

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding.

PanTher Therapeutics is a clinical stage oncology company working on treatments for solid tumors. The company is currently based in Cambridge, Massachusetts, and will relocate to Texas if it receives a CPRIT award.

PanTher's novel approach looks to significantly increase drug accumulation at the tumor site, while dramatically reducing systemic side effects to improve antitumor activity, preserve quality of life and lower overall healthcare costs. PanTher's PTM-101 product is a laparoscopically delivered, fully degradable film. This product has the potential to improve tumor response and reduce pancreatic tumors to allow for curative resection.

PanTher's first product, PTM-101, is a drug eluting delivery implant intended to provide paclitaxel directly onto the tumor. PTM-101 is composed of paclitaxel and a bioresorbable polymer poly (lacticco-glycolic acid) (PLGA). The PTM-101 implant is minimally invasively inserted via a trocar during diagnostic laparoscopy and surgically placed directly onto the peritumoral area. PanTher's platform has demonstrated pre-clinical validation – enabling chemotherapy to penetrate 40 times deeper and reach 5-fold higher concentration inside the tumor mass when compared to systemic delivery.

The PLGA ingredients biodegrade over time, resulting in the sustained release of paclitaxel directly towards the tumor, thereby providing localized treatment. The PLGA polymer

biodegrades into lactic and glycolic acids, which are metabolized naturally. For controlled and sustained release of paclitaxel, PTM-101 will be comprised of two different layers of PLGA. The non-tumor facing side of PTM-101 consists of 75:25 PLGA and the tumor facing side of PTM-101 contains paclitaxel incorporated into 50:50 PLGA polymer. The PLGA 50:50 will fully degrade in approximately 1 month (35 days), resulting in Paclitaxel release directly onto the tumor mass.

PanTher's proposal is for the initiation and completion of a Phase Ib/II trial in the US and Australia to build upon the current first-in-man trial to assess efficacy. Over the course of discussions with the FDA, PTM-101 has been deemed a combination product with drug primary mode of action and cleared to use the 505(b)(2) accelerated path to the clinic with a well-defined understanding of the IND package requirements.

PanTher has addressed and completed the majority of testing to be included in the IND submission as part of the ethics approval to start the phase 1 in Australia. The first-year development plan will focus on expansion of the already validated CMC and GMP manufacturing processes for the dose-escalated PTM-101, as well as completing GLP tox studies. Upon IND clearance from the FDA, PanTher will focus on the enrollment and completion of the Phase Ib/2 trial in the US and Australia, in partnership with MD Anderson and other clinical sites.

Select Reviewer Comments

"*The approach significantly increases drug accumulation at the site, while dramatically reducing systemic side effects to improve antitumor activity and preserve quality of life, provide pretreatment before surgery or improvement for tumors that are nonresectable."*

"The application has a number of strengths including the following: (1) prior phase 1 results, (2) sound management and development teams, (3) significant financial backing, (4) straightforward CMC development pathway due to the experience with paclitaxel and PLGA, and (5) lack of competition of locally administered therapies in pancreatic cancer."

De-Identified Overall Evaluation Scores

Texas Company Product Development Awards

Product Development Research Cycle 22.2

The Product Development Review Council (PDRC) took no action an application with a less favorable score than one other application that it did not recommend within this mechanism. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio.

Application ID	Final Overall Evaluation Score
DP220055*	2.0
DP220039*	2.2
DP220053*	2.7
b**a**	3.0
b**b**[1]	3.5
b**c**	4.0
b**d**	4.3
b**e**	4.4
b**f**	5.9

[1] The PDRC took no action on this application.

* Recommended for grant award.

Final Overall Evaluation Scores and Rank Order Scores

July 27, 2022

Dr. Mahendra Patel
CPRIT Oversight Committee Chair
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
CPRIT Program Integration Committee Chair
Via email to wroberts@cprit.texas.gov

Dr. Patel and Mr. Roberts,

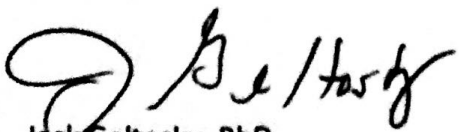
On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's Product Development Research 22.2 grant award cycle. The PDRC convened on July 19, 2022, and recommends that the Program Integration Committee and the Oversight Committee approve Product Development Research grant awards for the following applicants: Atom Mines, InformAI Inc., Xerient Pharma Inc., PLUS Therapeutics, Inc., Stellanova Therapeutics, Asylia Therapeutics, Rapamycin Holdings Inc., NUCORE Medical and PanTher Therapeutics. The attached table reflects the ranked award recommendation for the nine (9) grant applications.

The PDRC did not make any changes to timelines or budgets for the nine (9) projects recommended for funding. However, two (2) recommendations include contingencies associated with intellectual property (IP) ownership and licensing agreements, which CPRIT should address with the companies during contract negotiations. The IP due diligence reports for DP220053 and DP220054 reflect the recommended contingences. In addition, the PDRC specified a contract contingency for DP220066 related to clinical data, timelines and development plans. Dr. Smith will address the proposed contingencies with the PIC and the Oversight Committee.

I also note that at its July 19, 2022, 22.2 Due Diligence Meeting, the PDRC took "No Action" on one (1) application for CPRIT FY 2022 award budget reasons and to receive additional information. We anticipate that the PDRC will make an award recommendation, if any, regarding this pending application for your consideration as early as the September 2022 Oversight Committee meeting.

Each of the companies included in the PDRC's recommendation reflets 50+ hours of individual review panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports. Our recommendations are consistent with one or more of the priorities set by the Oversight Committee for product development grant award funding. These standards include the potential of these companies to (1) bring important products to market; (2) promote the translation of research at Texas institutions into new companies able to compete in the marketplace; and (3) develop tools and technologies of special relevance to cancer research, treatment and prevention.

Sincerely,



Jack Geltosky, PhD
Chair, CPRIT Product Development Review Committee

FY22.2 Product Development Review Council Recommendations

Ranking	ID	Mechanism	Type	PI Last Name	Organization	Application Title	Score from Peer Review
1	DP220039	TXCO Therapeutics	Resubmission	Sims, A.	PLUS Therapeutics, Inc.	Single-Dose 186RNL for Leptomeningeal Metastases: Multicenter Phase 1/2a Study to Determine MTD/MFD, Safety and Efficacy, Leading to Pivotal Registrational Trial	2.2
2	DP220028	SEED Therapeutics	Resubmission	Schuler, E.	Stellanova Therapeutics, Inc.	Development of DKK3-Targeted Therapeutic Antibodies for Cancer	2.3
3	DP220038	SEED Therapeutics	New	Miller, J.	Asylia Therapeutics	Humanization, Validation, and Clinical Translation of Cell Surface Heat Shock Protein 70-Targeted Antibody-Drug Conjugates for T-Cell Non-Hodgkin Lymphomas	2.3
4	DP220055	TXCO MD&D	New	Dorius, K.	Atom Mines	Commercial-Scale Enrichment of Stable Ytterbium-176 for Production of No-Carrier-Added Lutetium-177 for Use in Prostate Cancer Therapy	2.0
5	DP220053	TXCO Therapeutics	New	Kingman, S.	Rapamycin Holdings Inc.	Development of eRapa for the Treatment of Familial Adenomatous Polyposis, a Rare Genetic Disease Associated With a High Risk of Colorectal Cancer	2.7
6	DP220043	SEED Therapeutics	New	Taniguchi, C.	Xerient Pharma Inc.	Oral Amifostine as an Upper GI Tract Radioprotectant for Effective Radiotherapy Treatment of Pancreatic Cancer	2.2
7	DP220063	SEED MD&D	New	Havelka, J.	InformAI Inc.	RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology	2.2
8	DP220066	RELCO Therapeutics	New	Indolfi, L.	PanTher Therapeutics, Inc	Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer	3.6
9	DP220054	SEED MD&D	New	Nathan, J.	NUCORE MEDICAL	Clinical Validation of the MiTR Core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention	3.4

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit
Supporting Information

FY 2022—Cycle 10
Recruitment of First-Time, Tenure-Track Faculty Members

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Request for Applications

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-22.1-RFT

Recruitment of First-Time Tenure-Track Faculty Members

Please also refer to the Instructions for Applicants document, which will be posted on June 22, 2021

Application Receipt Dates:

June 22, 2021-June 20, 2022

FY 2022

Fiscal Year Award Period

September 1, 2021-August 31, 2022

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RFA VERSION HISTORY

6/22/21 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to $6 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas
- Develop and implement the Texas Cancer Plan

1.1. Academic Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency with regard to how the Oversight Committee directs the orientation of the agency's funding portfolio.

Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure

Priorities Across CPRIT's 3 Programs:

- Prevention and early detection initiatives
- Translational of Texas research (discoveries) to innovations
- Enhance Texas' research capacity and life science infrastructure

The program priorities for academic research adopted by the Oversight Committee include funding projects that address the following:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions

- Computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer
- Expand access to innovative clinical trials

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract very promising investigators who are pursuing their first faculty appointment at the level of assistant professor (**first-time, tenure-track faculty members**). These individuals must have demonstrated academic excellence, innovation during predoctoral and/or postdoctoral research training, commitment to pursuing cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas.

The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment. Candidates with research programs addressing **CPRIT's priority areas for research are encouraged**. These include implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions, computational biology and analytic methods, childhood cancers, hepatocellular cancer, and expansion of access to innovative clinical trials.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. All candidates are expected to have completed their doctoral and fellowship training and to have clearly demonstrated truly superior ability as evidenced by their accomplishments during training, proposed research plan, publication record, and letters of recommendation. This CPRIT-supported initiative is designed to enhance

innovative programs of excellence by providing research support for promising, early-stage investigators **seeking their first tenure-track position.**

CPRIT will provide start-up funding for newly independent investigators, with the goal of augmenting and expanding the institution's efforts in cancer research. Candidates will be expected to develop research projects within the sponsoring institution. Projects should be appropriate for a newly independent investigator and should foster the development of preliminary data that can be used to prepare applications for future independent research project grants to further both the investigator's research career and the CPRIT mission. The institution will be expected to work with each newly recruited research faculty member to design and execute a faculty career development plan consistent with his or her research emphasis. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Applications nominating individuals who are well prepared to pursue careers in patient-oriented research and who have demonstrated exceptional potential to lead innovative discovery campaigns through conduct of clinical trials are appropriate for this mechanism and encouraged.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. INSTITUTIONAL COMMITMENT

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a first-time, tenure-track faculty must therefore be complemented by a strong institutional commitment to the candidate's career development that includes financial commitments that are in addition to the CPRIT award. The institutional commitment should be clearly documented in the application (see section 8.2.2) and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to

the candidate for his or her research program by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.

5. FUNDING INFORMATION

This award is up to 5 years and is not renewable, although individuals may apply for other future CPRIT funding as appropriate. Grant funds of up to $2,000,000 (total costs) for the 5-year period may be requested. Funding is to be used by the candidate to support his or her research program. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years except under extraordinary circumstances with strong justification for a no-cost extension. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified and a detailed justification is provided along with an institutional plan should the additional funds not be approved. Scholars may request funds for travel for 2 project staff to attend CPRIT's conference.

Funds from this CPRIT award may not be used for salary support of this candidate or to construct or renovate laboratory space.

No annual limit on the number of grant application submissions by Institutions has been set.

Note: Depending on the availability of funds, nominations submitted in response to this Request for Applications (RFA) during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31, 2022) or in the first quarter of the next fiscal year (starting September 1, 2022).

6. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.

- A candidate may be nominated by only 1 institution. If more than 1 institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.
- There is no limit to the number of applications that an institution may submit during a review cycle.
- A candidate who has already accepted a position as assistant professor tenure track at the recruiting institution prior to the time that the Scientific Review Council reviews the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's Academic Research program staff will notify the nominating institution of the Scientific Review Council's review decision following the Scientific Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's review decision but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, **and reside in Texas for the duration of the appointment.** The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate must ***not*** hold an appointment at the rank of assistant professor or above (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation. Candidates holding non–tenure-track appointments at the rank of assistant professor are ***not*** eligible for this award. Examples of such appointments include research assistant professor, adjunct research assistant professor, assistant professor (non-tenure track).
- The candidate may or may not reside in Texas at the time the application is submitted and may be nominated for a faculty position at the Texas institution where he or she is completing postdoctoral training or at another Texas institution.

- *Applications nominating a candidate for a faculty position at the Texas institution where he or she is completing postdoctoral training that do not clearly demonstrate a subsequent career pathway to independence for the candidate will not be looked upon with favor.*
- Successful candidates will be offered tenure-track academic positions at the rank of assistant professor.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.texas.gov.

7. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of First-Time, Tenure-Track Faculty Members award mechanism. Any nomination for the Recruitment of First-Time, Tenure-Track Faculty Members that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (Nominator) must create a user account in the system (which includes the Nominator's credentials and email address) to start and submit an application. Furthermore, the Application Signing Official, who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Dependent upon available funding, applications will be accepted on a continuous basis throughout FY22. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 PM central time on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application must be submitted on or before 11:59 PM central time. In the event that the 20th falls on Saturday or Sunday, applications may be submitted on or before 11:59 PM central time the following Monday. CPRIT will not extend the submission deadline. During periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. For details, please refer to the *Instructions for Applicants* document that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in section 6 will be administratively withdrawn without review.

8.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

8.2.2. Institutional Commitment (3 pages)

CPRIT recruitment awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research to Texas. The funds provided by CPRIT for the recruitment of a first-time, tenure-track faculty must therefore be complemented by a strongly documented institutional commitment to the candidate's career development that includes financial commitments that are in addition to the CPRIT award.

The following guidelines should be followed when documenting the institutional commitment to the candidate:

- The institutional commitment should be clearly documented in the form of a letter signed by the applicant institution's president, provost, or appropriate dean and include the amount and sources of salary support and all additional financial support that will be available to the candidate's research program through the course of the CPRIT award. The financial commitments made to the candidate by the recruiting institution are required to be equal to or exceed 50% of the proposed CPRIT award across the course of the CPRIT award.
- The institutional commitment letter must include the following statement regarding the institution's financial commitment required to meet the 50% match.
    - This institutional financial commitment will not be offset by funds from a career transition award (K99/R00) or an investigator-initiated award received by the

candidate. If an award dictates that such funds must be used for salary, the corresponding amount of institutional funds committed to pay the candidate's salary will be redirected to allow the candidate to use them for program support.

- Institutional commitment as described above must be presented in a table (example below) that clearly identifies the salary amount, sources of salary, and any additional research support from institutional sources over the course of the CPRIT award. Note that a federal indirect cost rate credit cannot be used to demonstrate an institutional commitment to the candidate.
- Include a brief job description for the candidate should recruitment be successful.
- Describe the institutional environment and any professional commitments to the candidate including, but not limited to, dedicated personnel, access to students, space assignment, and access to shared equipment, and discuss all other agreements between the institution and the candidate.
- Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research such as a computational biologist, chemist, etc, whose prior experience has not been directly focused on cancer research.
- Note that Texas law allows an institution of higher learning to use its federal indirect cost rate credit to comply with the requirement to demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award (see section 12). However, a federal indirect cost rate credit cannot be used to demonstrate an institutional commitment to the candidate.

Example of an acceptable Institutional Commitment table:

Candidate's Name, Institutional Commitments					
	Year 1	Year 2	Year 3	Year 4	Year 5
Salary/Benefits					
Research Support					

Administrative Support					
Moving Expenses					

Total =

Note: CPRIT acknowledges that the institutional commitments by category may change during the course of the award; however, the total financial commitment to the candidate must remain equal to or greater than 50% of the CPRIT award.

8.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department to which the candidate is being recruited. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research: While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

The letter of support from the department chair must also do the following:

1. Describe how the candidate will be independent and autonomous in developing his or her research program at the institution.
2. Present a plan for mentoring that includes the design and execution of a faculty career development plan for the candidate.

8.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate. Only articles that have been published or that have been accepted for publication ("in press") should be cited.

8.2.5. Summary of Goals and Objectives (2,000 characters)

List goals and objectives to be achieved during this award. **This section must be completed by the candidate.**

8.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate. References cited in this section should be included in the Publications/References section (see 8.2.7).**

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.**

"I understand that I do not need to have made a commitment to <*nominating institution*> before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. I understand that requests to change the recruiting institution during the recruitment process are not allowed after the application is submitted to CPRIT."

8.2.7. Publications/References (1 page)

Provide a concise and relevant list of publications/references cited for the application. Any appropriate citation format is acceptable; official journal abbreviations should be used.

8.2.8. Research Collaboration/Synergy Plan (2 pages)

Institutions may provide additional information in support of a candidate's research plan to demonstrate how the institutional commitment through development of strategic collaborations will foster a candidate's cancer research. This additional information is highly encouraged when proposing a candidate with exceptional expertise and/or talent that can be directed to cancer research, such as a computational biologist, chemist, etc, whose prior experience has not been

directly focused on cancer research. Biographical sketches of collaborators established in the research collaborative plan must be uploaded as part of the application. This will be in addition to the 2-page synergy plan (see IFA).

8.2.9. Publications

Provide the 3 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

8.2.10. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.11. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted. Refer to the sample current and pending support document located in *Current Funding Opportunities* for Academic Research in CARS.

8.2.12. Letters of Recommendation

Provide 3 letters of recommendation from individuals who are in a position to detail the candidate's academic and scientific research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research.

8.2.13. Research Environment (1 page)

Clearly and concisely describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

8.2.14. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to

cancer research, and a brief overview of the candidate's goals if selected to receive the award. **This section of the application must be prepared by the candidate.** If the application is approved for funding, this section will be made publicly available on CPRIT's website. Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components; exceed the specified page, word, or budget limits; or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

9. APPLICATION REVIEW

9.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will review applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications recommended by the Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions is sent to the nominator.

9.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with

access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee member, a PIC member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of the Department of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

9.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. **Also, of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution.** It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have ***reasonable*** expectation that the recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his or her proposed research program, and his or her long-term contribution to and impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated academic excellence? Has the candidate received excellent predoctoral and postdoctoral training? Does the candidate show exceptional potential for achieving future impact on basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated a commitment to cancer research? Has the candidate demonstrated independence or the potential for independence?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will the proposed research generate preliminary data that can be used for the preparation of applications for future independent research project grants?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Letters of Recommendation: Do the letters of recommendation detail the candidate's academic and clinical research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on growing his or her research? Has the institution identified a mentor who will design and execute a faculty career development plan for the candidate?

10. KEY DATES

RFA

RFA Release June 22, 2021

Application Receipt and Review Timeline

Application Receipt System opens 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 22, 2021	Continuous – dependent upon available funding	Monthly by the 15th day of the month	June 20, 2022

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.texas.gov.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Texas Administrative Code, Title 25, Chapters 701 to 703.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. CPRIT requires funding acknowledgement to include the award grant ID on all print and visual materials that are funded in whole or in part by CPRIT grants. Examples of print and visual materials include, but are not limited to, publications, brochures, pamphlets, project websites, videos and media materials. Grantees must have written approval from CPRIT prior to the purchase of any equipment. If the equipment is clearly defined in the grantee's budget submitted with the initiating award requirements, then approval of the grant award constitutes "prior approval" for the purchase. Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, publications, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.texas.gov.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Texas Administrative Code, Title 25, Chapters 701 to 703, for specific requirements regarding the demonstration of available funding.

13. CONTACT INFORMATION

13.1. Helpdesk

Helpdesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. Helpdesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Hours of operation: Monday through Friday, 8 AM to 6 PM central time
Tel: 866-941-7146
Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Academic Research.

Email: Research@cprit.texas.gov
Website: www.cprit.texas.gov

Third Party Observer Reports

Cancer Prevention and Research Institute of Texas (CPRIT)
22.10 Academic Research - Recruitment Review Panel
(22.10_SRC_REC)
Observation Report

Report No.	2022-05-12 22.10_SRC_REC
Program Name:	Academic Research
Panel Name:	22.10 Academic Research - Recruitment Review Panel (22.10 _SRC_REC)
Panel Date:	May 12, 2022
Report Date:	May 13, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.10 Academic Research - Recruitment Review Panel (22.10_SRC_REC) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on May 12, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: Twelve (12) applications were discussed
- Panelists: One (1) panel chair, five (5) expert reviewers, and two (2) ad-hoc reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: Three (3)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were two (2) Conflicts of Interest (COIs) identified prior to and/or during the meeting. The COI was excluded from discussions concerning applications for which there was a conflict.

A list of all attendees, a sign-in log and informational materials were provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

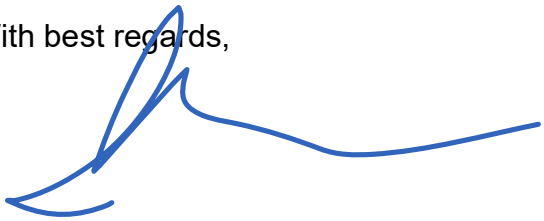
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.10 Academic Research Science Review Council
(22.10_SRC_REC_10)
Observation Report

Report No.	2022-07-14 22.10_SRC_REC_10
Program Name:	Academic Research
Panel Name:	22.10 Academic Research Science Review Council (22.10 _SRC_REC_10)
Panel Date:	July 14, 2022
Report Date:	July 20, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.10 Academic Research Science Review Council (22.10_SRC_REC_10) meeting. The meeting was chaired by Richard Kolodner and conducted via videoconference on July 14, 2022.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

One (1) BFS independent observer participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed and eleven (11) applications were not discussed
- Panelists: One (1) panel chair, five (5) expert reviewers
- Panelists' discussions were limited to the application evaluation criteria
- GDIT staff employees: One (1)
- GDIT staff did not participate in discussions concerning the merits of applications
- CPRIT staff employees: Two (2)
- CPRIT program staff participation was limited to reviewing and clarifying policies, and answering procedural questions

There were no (0) Conflicts of Interest (COIs) identified prior to and/or during the meeting.

A list of all attendees, a sign-in log and informational materials were provided by GDIT by request an hour before the meeting to aid in the observation of the objectives. COI document was not provided until the day after the meeting. A completed attendance sheet and sign-in log was provided following the meeting to confirm all attendees and COIs.

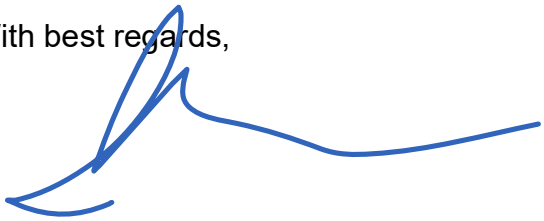
CONCLUSION

In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Cancer Prevention and Research Institute of Texas (CPRIT)
22.10 Academic Research Review Panel (22.10 Ad Hoc SRC_REC)
Observation Report

Report No.	2022-08-01 22.10_Ad Hoc SRC_REC
Program Name:	Academic Research
Panel Name:	22.10 Academic Research Review Panel (22.10 _Ad Hoc SRC_REC)
Panel Date:	August 1, 2022
Report Date:	August 3, 2022

BACKGROUND

As part of CPRIT's ongoing emphasis on continuous improvement in its grants review/management processes and to ensure panel discussions are limited to the merits of the applications and focused on established evaluation criteria, CPRIT continues to engage a third-party independent observer at all in-person and telephone conference peer review meetings. CPRIT has authorized an independent party to function as a neutral third-party observer and has engaged Business and Financial Management Solutions, LLC (BFS) for that purpose.

INTRODUCTION

The subject of this report is the 22.10 Academic Research Review Panel (22.10_Ad Hoc SRC_REC) meeting. The meeting was conducted via email on August 1, 2022, and did not have an assisgned chairperson.

PANEL OBSERVATION OBJECTIVES AND SCOPE

The third-party observation engagement was limited to observation of the following objectives:

- CPRIT's established procedure for panelists who have declared a conflict of interest is followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when an application with which there is a conflict is discussed);
- CPRIT program staff participation at meetings is limited to offering general points of information;

- CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- The panel focused on the established scoring criteria and/or making recommendations.

SUMMARY OF OBSERVATION RESULTS

Three (3) BFS independent observers participated in observing the meeting. GDIT, CPRIT's contracted third-party grant application administrator, facilitated the meeting.

The independent observers noted the following during the meeting:

- Number (#) of applications: One (1) application was discussed
- Panelists: No (0) panel chair, and seven (7) reviewers
- Panelists' discussions were limited to the application approval
- GDIT staff employees: One (1)
- GDIT staff did not participate in emails concerning the merits of applications emails for which BFS was included on the response
- CPRIT staff employees: Two (2)
- CPRIT program staff did not respond to emails for which BFS was included on the response

Per CPRIT Academic Cancer Research and Reccuirtment Review Panel policy, Conflicts of Interest (COIs) are not excluded from the setting of cutoffs for funding recommendations since there is no scoring or actual discussion of the applications. Therefore, this criteria was not evaluated.

A list of all attendees, a sign-in log and informational materials were not provided by GDIT to aid in the observation of the COI procedures and objectives. A completed attendance sheet and sign-in log was not provided following the meeting to confirm all attendees and COIs. This report is based on the receivers and respondses to an email correspondes from August 1.

CONCLUSION

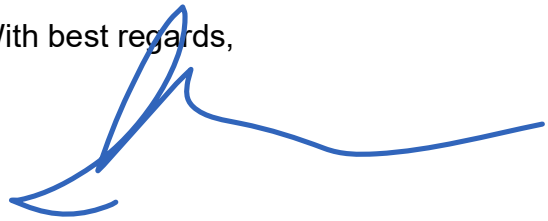
In conclusion, we observed that the activities of the meeting identified herein were limited to the identified objectives noted earlier in this report. Our observations are limited to the information made available.

BFS's third-party observation services did not include an evaluation of the appropriateness or rigor of the review panel's discussions of scientific, technical, or programmatic aspects of the applications. We were not engaged to perform an audit, the objective of which would be the expression of an opinion on the accuracy of voting and scoring. Accordingly, we will not express such an opinion. Had we performed additional

procedures; other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT, its management and its Oversight Committee members. This report is not intended to be and should not be used by anyone other than these specified parties.

With best regards,



Mara Ash, CIA, CGAP, CGFM, CMRA, CICA
Senior Partner
Business & Financial Management Solutions, LLC

cc: Vince Burgess, Chief Compliance Officer
Cameron Eckel, Attorney

Conflicts of Interest Disclosure

Conflicts of Interest Disclosure

CPRIT Academic Research Recruitment Cycle 22.10

Awards Announced at the August 17, 2022, Oversight Committee Meeting

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in *Recruitment of Established Investigators* and *Recruitment of First-Time, Tenure-Track Faculty Members.*.

All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC.

COI information used for this table was collected by General Dynamics Information Technology, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Nominator/Principal Investigator	Organization	Conflict Noted by Reviewer
Applications considered by the PIC and Oversight Committee:			
RR220094	Mary Dickinson	Baylor College of Medicine	E. Fearon
Applications not considered by the PIC or Oversight Committee:			
RR220109	Michael Blackburn	The University of Texas Health Science Center at Houston	P. Jones

De-Identified Overall Evaluation Scores

Recruitment of First-Time, Tenure-Track Faculty members

Academic Research Recruitment Cycle 22.10

Application ID	Final Overall Evaluation Score
RR220094*	1.0
RR220101*	1.0
ja˘	1.6
jb˘	1.6
jc˘	2.0
jd˘	2.2
Je	3.0
Jf	3.0
Jg	3.0
Jh	3.5

* Recommended for grant award.

˘ The Scientific Review Council did not make a final decision on this application.

Final Overall Evaluation Scores and Rank Order Scores

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Ludwig Institute for Cancer Research Ltd

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics
San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@health.ucsd.edu

San Diego Branch
UC San Diego School of Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0660
La Jolla, CA 92093-0660

T 858 534 7804
F 858 534 7750

August 2, 2022

Dr. Mahendra C. Patel
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to curingkids@gmail.com

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.texas.gov

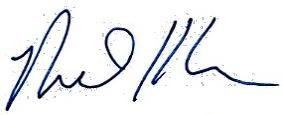
Dear Dr. Patel and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of recruitment grant recommendations. The SRC met on on May 12, 2022 (REC Cycle 22.10), July 14, 2022 (REC Cycle 22.10) and August 1, 2022 (REC Cycle 22.10) to review the applications submitted to CPRIT under the Recruitment of Established Investigators, and Recruitment of First-Time, Tenure Track Faculty Members.

The SRC recommends two applications, which are inlcuded on the attached list. The recommended funding amounts and the overall evaluation scores are stated for the grant applications. There were no recommended changes to funding amounts, goals, timelines, or project objectives requested. The total amount for the applications recommended is $4,000,000

The recommendation meets the SRC's standards for funding. These include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, commitment to cancer research and exceptional potential for achieving future impact in basic, translational, population based or clinical research.

Sincerely yours,



Richard D. Kolodner, Ph.D.
Chair, CPRIT Scientific Review Council

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Rank	App. ID	Mechanism	Candidate	Organization	Budget	Overall Scores
1	RR220094	RFTFM	Steven Boeynaems, Ph.D.	Baylor College of Medicine	$2,000,000	1.0
2	RR220101	RFTFM	Siqi Liu, Ph.D.	The University of Texas Southwestern Medical Center	$2,000,000	1.0

RFTFM = Recruitmen of First-Time, Tenure Track Faculty Members

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP220028
Seed Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Seed Awards for Product Development Research* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA. This application was assigned to the Product Development Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council's (PDRC) final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:47 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Product Development
MECHANISM: Seed Awards for Product Development Research
APPLICATION ID: DP220028
APPLICATION TITLE: Development of DKK3-Targeted Therapeutic Antibodies for Cancer
APPLICANT NAME: Schuler, Emmanuelle
ORGANIZATION: Stellanova Therapeutics, Inc.
PANEL NAME: 22.2 Product Development Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/24/2022**	06/28/2022
	Method of submission	**CARS**	06/28/2022
	Within receipt period	**YES**	06/28/2022
	Request for extension to submit application after CARS closed	**N/A**	06/28/2022
	Request for extension for late application submission accepted	**N/A**	06/28/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/28/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/28/2022
	Assigned to primary reviewers	**02/17/2022**	06/28/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/08/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/08/2022**	06/28/2022
	Primary Reviewer 3 COI signed	**02/08/2022**	06/28/2022
	Primary Reviewer 4 COI signed	**02/08/2022**	06/28/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/16/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 critique submitted	**03/04/2022**	06/28/2022
	Primary Reviewer 3 critique submitted	**03/11/2022**	06/28/2022
	Primary Reviewer 4 critique submitted	**03/15/2022**	06/28/2022
	COI indicated by non-primary reviewer	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Screening Teleconference Meeting	**03/21/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/22/2022**	06/27/2022
	Post review statements signed	**03/29/2022**	07/01/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/28/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Peer Review Meeting	**04/11/2022**	06/28/2022
	Peer Review Meeting End Date	**04/12/2022**	06/28/2022
	Post review statements signed	**04/26/2022**	06/28/2022
	Third Party Observer Report	**04/28/2022**	06/28/2022
	Score report delivered to CPDO	**04/21/2022**	06/28/2022
	Recommended for due diligence and IP review	**YES**	06/28/2022
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**06/16/2022**	08/03/2022
	Intellectual Property conflict check	**04/26/2022**	08/03/2022
	Final intellectual property review submitted	**06/16/2022**	08/03/2022
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	07/20/2022
	COI recused from participation	**N/A**	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	**07/13/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**N/A**	07/20/2022
	PDRC Chair Notification to PIC and OC	**07/28/2022**	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	**NONE**	07/20/2022
	COI recused from participation (Ranking Meeting)	**N/A**	07/20/2022
	PDRC Ranking Meeting	**07/19/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**YES**	07/20/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP220038
Seed Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Seed Awards for Product Development Research* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA. This application was assigned to the Product Development Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council's (PDRC) final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:47 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Product Development
MECHANISM: Seed Awards for Product Development Research
APPLICATION ID: DP220038
APPLICATION TITLE: Humanization, validation, and clinical translation of cell surface Heat shock protein 70-targeted antibody drug conjugates for T-cell non-Hodgkin lymphomas
APPLICANT NAME: Miller, John P
ORGANIZATION: Asylia Therapeutics
PANEL NAME: 22.2 Product Development Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/25/2022**	06/28/2022
	Method of submission	**CARS**	06/28/2022
	Within receipt period	**YES**	06/28/2022
	Request for extension to submit application after CARS closed	**N/A**	06/28/2022
	Request for extension for late application submission accepted	**N/A**	06/28/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/28/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/28/2022
	Assigned to primary reviewers	**02/17/2022**	06/28/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/09/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/08/2022**	06/28/2022
	Primary Reviewer 3 COI signed	**02/08/2022**	06/28/2022
	Primary Reviewer 4 COI signed	**02/08/2022**	06/28/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/22/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 critique submitted	**03/04/2022**	06/28/2022
	Primary Reviewer 3 critique submitted	**03/22/2022**	06/28/2022
	Primary Reviewer 4 critique submitted	**03/16/2022**	06/28/2022
	COI indicated by non-primary reviewer	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Screening Teleconference Meeting	**03/21/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/22/2022**	06/27/2022
	Post review statements signed	**03/29/2022**	07/01/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/28/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Peer Review Meeting	**04/11/2022**	06/28/2022
	Peer Review Meeting End Date	**04/12/2022**	06/28/2022
	Post review statements signed	**04/26/2022**	06/28/2022
	Third Party Observer Report	**04/28/2022**	06/28/2022
	Score report delivered to CPDO	**04/21/2022**	06/28/2022
	Recommended for due diligence and IP review	**YES**	06/28/2022
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**06/16/2022**	08/03/2022
	Intellectual Property conflict check	**04/26/2022**	08/03/2022
	Final intellectual property review submitted	**06/16/2022**	08/03/2022
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	07/20/2022
	COI recused from participation	**N/A**	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	**07/13/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**N/A**	07/20/2022
	PDRC Chair Notification to PIC and OC	**07/28/2022**	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	**NONE**	07/20/2022
	COI recused from participation (Ranking Meeting)	**N/A**	07/20/2022
	PDRC Ranking Meeting	**07/19/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**YES**	07/20/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP220039
Texas Company Product Development Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Texas Company Product Development Awards* Request for Applications (RFA). CPRIT received 10 applications in response to this RFA. This application was assigned to the Product Development Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

Within this grant mechanism, the Product Development Review Council (PDRC) took no action an application with a less favorable score than one other application that it did not recommend within this mechanism. The PDRC's final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:48 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Product Development
MECHANISM: Texas Company Product Development Research Awards
APPLICATION ID: DP220039
APPLICATION TITLE: Single Dose 186RNL for Leptomeningeal Metastases: Multicenter Phase 1/2a Study to Determine MTD/MFD, Safety & Efficacy, Leading to Pivotal Registrational Trial
APPLICANT NAME: Sims, Andrew
ORGANIZATION: PLUS Therapeutics, Inc.
PANEL NAME: 22.2 Product Development Panel-2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/26/2022**	06/30/2022
	Method of submission	**CARS**	06/30/2022
	Within receipt period	**YES**	06/30/2022
	Request for extension to submit application after CARS closed	**N/A**	06/30/2022
	Request for extension for late application submission accepted	**N/A**	06/30/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/11/2022**	06/30/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/30/2022
	Assigned to primary reviewers	**02/17/2022**	06/30/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/11/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/08/2022**	06/30/2022
	Primary Reviewer 3 COI signed	**02/11/2022**	06/30/2022
	Primary Reviewer 4 COI signed	**02/14/2022**	06/30/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/17/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 critique submitted	**03/16/2022**	06/30/2022
	Primary Reviewer 3 critique submitted	**03/16/2022**	06/30/2022
	Primary Reviewer 4 critique submitted	**03/17/2022**	06/30/2022
	COI indicated by non-primary reviewer	**NONE**	06/30/2022
	COI recused from participation	**N/A**	06/30/2022
	Screening Teleconference Meeting	**03/22/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/23/2022**	06/27/2022
	Post review statements signed	**03/28/2022**	06/27/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/30/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/30/2022
	COI recused from participation	**N/A**	06/30/2022
	Peer Review Meeting	**04/13/2022**	06/30/2022
	Peer Review Meeting End Date	**04/14/2022**	06/30/2022
	Post review statements signed	**05/10/2022**	06/30/2022
	Third Party Observer Report	**04/21/2022**	06/30/2022
	Score report delivered to CPDO	**04/21/2022**	06/30/2022
	Recommended for due diligence and IP review	**YES**	06/30/2022
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**06/16/2022**	08/03/2022
	Intellectual Property conflict check	**04/22/2022**	08/03/2022
	Final intellectual property review submitted	**06/16/2022**	08/03/2022
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	07/20/2022
	COI recused from participation	**N/A**	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	**07/14/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**N/A**	07/20/2022
	PDRC Chair Notification to PIC and OC	**07/28/2022**	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	**NONE**	07/20/2022
	COI recused from participation (Ranking Meeting)	**N/A**	07/20/2022
	PDRC Ranking Meeting	**07/19/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**YES**	07/20/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP220043
Seed Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Seed Awards for Product Development Research* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA. This application was assigned to the Product Development Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council's (PDRC) final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:48 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Product Development
MECHANISM: Seed Awards for Product Development Research
APPLICATION ID: DP220043
APPLICATION TITLE: Oral Amifostine as an upper GI Tract Radioprotectant for Effective Radiotherapy Treatment of Pancreatic Cancer
APPLICANT NAME: Taniguchi, Cullen M
ORGANIZATION: Xerient Pharma Inc.
PANEL NAME: 22.2 Product Development Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/26/2022**	06/28/2022
	Method of submission	**CARS**	06/28/2022
	Within receipt period	**YES**	06/28/2022
	Request for extension to submit application after CARS closed	**N/A**	06/28/2022
	Request for extension for late application submission accepted	**N/A**	06/28/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/28/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/28/2022
	Assigned to primary reviewers	**02/17/2022**	06/28/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/09/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/08/2022**	06/28/2022
	Primary Reviewer 3 COI signed	**02/08/2022**	06/28/2022
	Primary Reviewer 4 COI signed	**02/10/2022**	06/28/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/15/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 critique submitted	**02/28/2022**	06/28/2022
	Primary Reviewer 3 critique submitted	**03/13/2022**	06/28/2022
	Primary Reviewer 4 critique submitted	**03/16/2022**	06/28/2022
	COI indicated by non-primary reviewer	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Screening Teleconference Meeting	**03/21/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/22/2022**	06/27/2022
	Post review statements signed	**03/29/2022**	07/01/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/28/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Peer Review Meeting	**04/11/2022**	06/28/2022
	Peer Review Meeting End Date	**04/12/2022**	06/28/2022
	Post review statements signed	**04/26/2022**	06/28/2022
	Third Party Observer Report	**04/28/2022**	06/28/2022
	Score report delivered to CPDO	**04/21/2022**	06/28/2022
	Recommended for due diligence and IP review	**YES**	06/28/2022
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**06/16/2022**	08/03/2022
	Intellectual Property conflict check	**04/22/2022**	08/03/2022
	Final intellectual property review submitted	**06/16/2022**	08/03/2022
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	07/20/2022
	COI recused from participation	**N/A**	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	**07/13/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**N/A**	07/20/2022
	PDRC Chair Notification to PIC and OC	**07/28/2022**	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	**NONE**	07/20/2022
	COI recused from participation (Ranking Meeting)	**N/A**	07/20/2022
	PDRC Ranking Meeting	**07/19/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**YES**	07/20/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP220053
Texas Company Product Development Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Texas Company Product Development Awards* Request for Applications (RFA). CPRIT received 10 applications in response to this RFA. This application was assigned to the Product Development Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

Within this grant mechanism, the Product Development Review Council (PDRC) took no action an application with a less favorable score than one other application that it did not recommend within this mechanism. The PDRC's final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

Tracey Davies, CPRIT's Chief Strategic Initiatives and Intellectual Property Officer, performed the intellectual property due diligence review for this grant application. CPRIT has contracts with two outside counsel law firms to perform intellectual property review; however, both law firms reported conflicts of interest that prevented them from reviewing this application. Dr. Ken Smith was unable to conduct due diligence review because he is CPRIT's Chief Product Development Officer and a voting member of the PIC. Ms. Davies previously performed due diligence for CPRIT as outside counsel and reported no conflict of interest with this application. She does not vote or otherwise take any role in recommending awards to the Oversight Committee.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

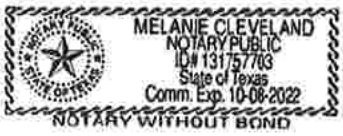
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:49 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Product Development
MECHANISM: Texas Company Product Development Research Awards
APPLICATION ID: DP220053
APPLICATION TITLE: Development of eRapa for the treatment of Familial Adenomatous Polyposis, a rare genetic disease associated with a high risk of colorectal cancer
APPLICANT NAME: Kingman, Shannon
ORGANIZATION: Rapamycin Holdings Inc.
PANEL NAME: 22.2 Product Development Panel-2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/26/2022**	06/30/2022
	Method of submission	**CARS**	06/30/2022
	Within receipt period	**YES**	06/30/2022
	Request for extension to submit application after CARS closed	**N/A**	06/30/2022
	Request for extension for late application submission accepted	**N/A**	06/30/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/11/2022**	06/30/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/30/2022
	Assigned to primary reviewers	**02/17/2022**	06/30/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/10/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/08/2022**	06/30/2022
	Primary Reviewer 3 COI signed	**02/11/2022**	06/30/2022
	Primary Reviewer 4 COI signed	**02/10/2022**	06/30/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/16/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 critique submitted	**03/16/2022**	06/30/2022
	Primary Reviewer 3 critique submitted	**03/16/2022**	06/30/2022
	Primary Reviewer 4 critique submitted	**03/16/2022**	06/30/2022
	COI indicated by non-primary reviewer	**NONE**	06/30/2022
	COI recused from participation	**N/A**	06/30/2022
	Screening Teleconference Meeting	**03/22/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/23/2022**	06/27/2022
	Post review statements signed	**03/28/2022**	06/27/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/30/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/30/2022
	COI recused from participation	**N/A**	06/30/2022
	Peer Review Meeting	**04/13/2022**	06/30/2022
	Peer Review Meeting End Date	**04/14/2022**	06/30/2022
	Post review statements signed	**05/10/2022**	06/30/2022
	Third Party Observer Report	**04/21/2022**	06/30/2022
	Score report delivered to CPDO	**04/21/2022**	06/30/2022
	Recommended for due diligence and IP review	**YES**	06/30/2022
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**06/16/2022**	08/03/2022
	Intellectual Property conflict check	**05/06/2022**	08/03/2022
	Final intellectual property review submitted	**06/16/2022**	08/03/2022
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	07/20/2022
	COI recused from participation	**N/A**	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	**07/14/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**N/A**	07/20/2022
	PDRC Chair Notification to PIC and OC	**07/28/2022**	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	**NONE**	07/20/2022
	COI recused from participation (Ranking Meeting)	**N/A**	07/20/2022
	PDRC Ranking Meeting	**07/19/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**YES**	07/20/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP220054
Seed Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Seed Awards for Product Development Research* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA. This application was assigned to the Product Development Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council's (PDRC) final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:49 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Product Development
MECHANISM: Seed Awards for Product Development Research
APPLICATION ID: DP220054
APPLICATION TITLE: Clinical Validation of the MiTR-core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention
APPLICANT NAME: Nathan, Joanna C
ORGANIZATION: NUCORE MEDICAL
PANEL NAME: 22.2 Product Development Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/26/2022**	06/28/2022
	Method of submission	**CARS**	06/28/2022
	Within receipt period	**YES**	06/28/2022
	Request for extension to submit application after CARS closed	**N/A**	06/28/2022
	Request for extension for late application submission accepted	**N/A**	06/28/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/11/2022**	06/28/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/28/2022
	Assigned to primary reviewers	**02/17/2022**	06/28/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/08/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/08/2022**	06/28/2022
	Primary Reviewer 3 COI signed	**02/07/2022**	06/28/2022
	Primary Reviewer 4 COI signed	**02/08/2022**	06/28/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/09/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 critique submitted	**03/04/2022**	06/28/2022
	Primary Reviewer 3 critique submitted	**03/15/2022**	06/28/2022
	Primary Reviewer 4 critique submitted	**03/16/2022**	06/28/2022
	COI indicated by non-primary reviewer	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Screening Teleconference Meeting	**03/21/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/22/2022**	06/27/2022
	Post review statements signed	**03/29/2022**	07/01/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/28/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Peer Review Meeting	**04/11/2022**	06/28/2022
	Peer Review Meeting End Date	**04/12/2022**	06/28/2022
	Post review statements signed	**04/26/2022**	06/28/2022
	Third Party Observer Report	**04/28/2022**	06/28/2022
	Score report delivered to CPDO	**04/21/2022**	06/28/2022
	Recommended for due diligence and IP review	**YES**	06/28/2022
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**06/16/2022**	08/03/2022
	Intellectual Property conflict check	**04/26/2022**	08/03/2022
	Final intellectual property review submitted	**06/16/2022**	08/03/2022
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	07/20/2022
	COI recused from participation	**N/A**	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	**07/13/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**N/A**	07/20/2022
	PDRC Chair Notification to PIC and OC	**07/28/2022**	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	**NONE**	07/20/2022
	COI recused from participation (Ranking Meeting)	**N/A**	07/20/2022
	PDRC Ranking Meeting	**07/19/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**YES**	07/20/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP220055
Texas Company Product Development Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Texas Company Product Development Awards* Request for Applications (RFA). CPRIT received 10 applications in response to this RFA. This application was assigned to the Product Development Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

Within this grant mechanism, the Product Development Review Council (PDRC) took no action an application with a less favorable score than one other application that it did not recommend within this mechanism. The PDRC's final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:49 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Product Development
MECHANISM: Texas Company Product Development Research Awards
APPLICATION ID: DP220055
APPLICATION TITLE: Commercial-Scale Enrichment of Stable Ytterbium-176 for Production of No-carrier-added Lutetium-177 for Use in Prostate Cancer Therapy
APPLICANT NAME: Dorius, Kirk
ORGANIZATION: Atom Mines
PANEL NAME: 22.2 Product Development Panel-2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/25/2022**	06/30/2022
	Method of submission	**CARS**	06/30/2022
	Within receipt period	**YES**	06/30/2022
	Request for extension to submit application after CARS closed	**N/A**	06/30/2022
	Request for extension for late application submission accepted	**N/A**	06/30/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/30/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/30/2022
	Assigned to primary reviewers	**02/17/2022**	06/30/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/11/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/07/2022**	06/30/2022
	Primary Reviewer 3 COI signed	**02/08/2022**	06/30/2022
	Primary Reviewer 4 COI signed	**02/07/2022**	06/30/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/15/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 critique submitted	**03/14/2022**	06/30/2022
	Primary Reviewer 3 critique submitted	**03/07/2022**	06/30/2022
	Primary Reviewer 4 critique submitted	**03/16/2022**	06/30/2022
	COI indicated by non-primary reviewer	**NONE**	06/30/2022
	COI recused from participation	**N/A**	06/30/2022
	Screening Teleconference Meeting	**03/22/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/23/2022**	06/27/2022
	Post review statements signed	**03/28/2022**	06/27/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/30/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/30/2022
	COI recused from participation	**N/A**	06/30/2022
	Peer Review Meeting	**04/13/2022**	06/30/2022
	Peer Review Meeting End Date	**04/14/2022**	06/30/2022
	Post review statements signed	**05/10/2022**	06/30/2022
	Third Party Observer Report	**04/21/2022**	06/30/2022
	Score report delivered to CPDO	**04/21/2022**	06/30/2022
	Recommended for due diligence and IP review	**YES**	06/30/2022
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**06/16/2022**	08/03/2022
	Intellectual Property conflict check	**04/26/2022**	08/03/2022
	Final intellectual property review submitted	**06/16/2022**	08/03/2022
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	07/20/2022
	COI recused from participation	**N/A**	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	**07/14/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**N/A**	07/20/2022
	PDRC Chair Notification to PIC and OC	**07/28/2022**	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	**NONE**	07/20/2022
	COI recused from participation (Ranking Meeting)	**N/A**	07/20/2022
	PDRC Ranking Meeting	**07/19/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**YES**	07/20/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP220063
Seed Awards for Product Development Research

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Seed Awards for Product Development Research* Request for Applications (RFA). CPRIT received 16 applications in response to this RFA. This application was assigned to the Product Development Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The Product Development Review Council's (PDRC) final overall rank order presented to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:49 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Product Development
MECHANISM: Seed Awards for Product Development Research
APPLICATION ID: DP220063
APPLICATION TITLE: RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology
APPLICANT NAME: Havelka, Jim
ORGANIZATION: InformAI Inc.
PANEL NAME: 22.2 Product Development Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/26/2022**	06/28/2022
	Method of submission	**CARS**	06/28/2022
	Within receipt period	**YES**	06/28/2022
	Request for extension to submit application after CARS closed	**N/A**	06/28/2022
	Request for extension for late application submission accepted	**N/A**	06/28/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/11/2022**	06/28/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/28/2022
	Assigned to primary reviewers	**02/17/2022**	06/28/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/07/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/08/2022**	06/28/2022
	Primary Reviewer 3 COI signed	**02/11/2022**	06/28/2022
	Primary Reviewer 4 COI signed	**02/09/2022**	06/28/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/14/2022**	06/28/2022
	Primary (Advocate) Reviewer 2 critique submitted	**03/04/2022**	06/28/2022
	Primary Reviewer 3 critique submitted	**03/17/2022**	06/28/2022
	Primary Reviewer 4 critique submitted	**03/22/2022**	06/28/2022
	COI indicated by non-primary reviewer	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Screening Teleconference Meeting	**03/21/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/22/2022**	06/27/2022
	Post review statements signed	**03/29/2022**	07/01/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/28/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/28/2022
	COI recused from participation	**N/A**	06/28/2022
	Peer Review Meeting	**04/11/2022**	06/28/2022
	Peer Review Meeting End Date	**04/12/2022**	06/28/2022
	Post review statements signed	**04/26/2022**	06/28/2022
	Third Party Observer Report	**04/28/2022**	06/28/2022
	Score report delivered to CPDO	**04/21/2022**	06/28/2022
	Recommended for due diligence and IP review	**YES**	06/28/2022
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**06/16/2022**	08/03/2022
	Intellectual Property conflict check	**04/22/2022**	08/03/2022
	Final intellectual property review submitted	**06/16/2022**	08/03/2022
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	07/20/2022
	COI recused from participation	**N/A**	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	**07/13/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**N/A**	07/20/2022
	PDRC Chair Notification to PIC and OC	**07/28/2022**	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	**NONE**	07/20/2022
	COI recused from participation (Ranking Meeting)	**N/A**	07/20/2022
	PDRC Ranking Meeting	**07/19/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**YES**	07/20/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CEO AFFIDAVIT
Application DP220066
Company Relocation Product Development Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Company Relocation Product Development Awards* Request for Applications (RFA). CPRIT received eight applications in response to this RFA. This application was assigned to the Product Development Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

Within this grant mechanism, the Product Development Review Council (PDRC) recommended an application with a less favorable score than one other application that it did not recommend for funding and one application that the PDRC left pending for further consideration. The PDRC's final overall rank order to the PIC and Oversight Committee recommends some applications out of score order. As allowed in 25 T.A.C. § 703.6(d)(1), the PDRC's numerical rank order is substantially based on the final overall evaluation score after the in-person presentation, but also takes into consideration the due diligence evaluation and how well the grant application achieves program priorities and the overall program portfolio.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:49 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Product Development
MECHANISM: Company Relocation Product Development Research Awards
APPLICATION ID: DP220066
APPLICATION TITLE: Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer
APPLICANT NAME: Indolfi, Laura
ORGANIZATION: PanTher Therapeutics, Inc
PANEL NAME: 22.2 Product Development Panel-2

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA approved by CPDO**	**10/29/2021**	06/27/2022
	RFA published in Texas.gov eGrants	**11/03/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) opened	**12/01/2021**	06/27/2022
	CPRIT Application Receipt System (CARS) closed	**01/26/2022**	06/27/2022
	Date application submitted	**01/26/2022**	06/30/2022
	Method of submission	**CARS**	06/30/2022
	Within receipt period	**YES**	06/30/2022
	Request for extension to submit application after CARS closed	**N/A**	06/30/2022
	Request for extension for late application submission accepted	**N/A**	06/30/2022
	Submission of application fee	**YES**	06/22/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/11/2022**	06/30/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/30/2022
	Assigned to primary reviewers	**02/17/2022**	06/30/2022
	Applicant notified of review panel assignment	**02/09/2022**	06/27/2022
	Primary Reviewer 1 COI signed	**02/10/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 COI signed	**02/07/2022**	06/30/2022
	Primary Reviewer 3 COI signed	**02/08/2022**	06/30/2022
	Primary Reviewer 4 COI signed	**02/07/2022**	06/30/2022
Screening Teleconference Meeting	**Primary Reviewer 1 critique submitted**	**03/15/2022**	06/30/2022
	Primary (Advocate) Reviewer 2 critique submitted	**03/14/2022**	06/30/2022
	Primary Reviewer 3 critique submitted	**03/07/2022**	06/30/2022
	Primary Reviewer 4 critique submitted	**03/15/2022**	06/30/2022
	COI indicated by non-primary reviewer	**NONE**	06/30/2022
	COI recused from participation	**N/A**	06/30/2022
	Screening Teleconference Meeting	**03/22/2022**	06/27/2022
	Post-Screening Teleconference score report	**03/23/2022**	06/27/2022
	Post review statements signed	**03/28/2022**	06/27/2022
	Third Party Observer Report	**03/29/2022**	06/27/2022
	Recommended for On-Site Meeting	**YES**	06/30/2022
Peer Review Meeting	**COI indicated by non-primary reviewer**	**NONE**	06/30/2022
	COI recused from participation	**N/A**	06/30/2022
	Peer Review Meeting	**04/13/2022**	06/30/2022
	Peer Review Meeting End Date	**04/14/2022**	06/30/2022
	Post review statements signed	**05/10/2022**	06/30/2022
	Third Party Observer Report	**04/21/2022**	06/30/2022
	Score report delivered to CPDO	**04/21/2022**	06/30/2022
	Recommended for due diligence and IP review	**YES**	06/30/2022
Due Diligence and IP Review	**Final due diligence review submitted to PDRC**	**06/16/2022**	08/03/2022
	Intellectual Property conflict check	**04/22/2022**	08/03/2022
	Final intellectual property review submitted	**06/16/2022**	08/03/2022
Final PDRC Recommendation	**COI indicated by PDRC member**	**NONE**	07/20/2022
	COI recused from participation	**N/A**	07/20/2022
	Due Diligence Evaluation Meeting / PDRC Meeting	**07/14/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**N/A**	07/20/2022
	PDRC Chair Notification to PIC and OC	**07/28/2022**	07/28/2022
	COI indicated by PDRC member (Ranking Meeting)	**NONE**	07/20/2022
	COI recused from participation (Ranking Meeting)	**N/A**	07/20/2022
	PDRC Ranking Meeting	**07/19/2022**	07/20/2022
	Third Party Observer Report	**07/20/2022**	07/22/2022
	Recommended for grant award	**YES**	07/20/2022
PIC Review	**COI indicated by PIC member**	**None**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP220024
Evidence Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received six applications in response to this cycle 22.1 RFA. This application was assigned to the Prevention Panel 1 for review. The Prevention Review Council (PRC) took no action on this application earlier in the fiscal year before recommending it to the PIC on June 13, 2022. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

On September 14, 2021, I notified Oversight Committee members that I granted the Chief Prevention Officer, Ramona Magid, a waiver from the general prohibition against communicating, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:49 AM CT

FY: 2022
CYCLE: 1
PROGRAM: Prevention
MECHANISM: Evidence-Based Cancer Prevention Services
APPLICATION ID: PP220024
APPLICATION TITLE: Promoting Prevention in Survivorship Care in Rural Texas
APPLICANT NAME: Kvale, Elizabeth A
ORGANIZATION: The University of Texas at Austin
PANEL NAME: 22.1_Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**05/03/2021**	01/03/2022
	RFA published in Texas.gov eGrants	**05/10/2021**	01/03/2022
	CPRIT Application Receipt System (CARS) opened	**06/03/2021**	01/03/2022
	CPRIT Application Receipt System (CARS) closed	**09/01/2021**	01/03/2022
	Date application submitted	**09/01/2021**	01/03/2022
	Method of submission	**CARS**	01/03/2022
	Within receipt period	**YES**	01/03/2022
	Request for extension to submit application after CARS closed	**N/A**	01/03/2022
	Request for extension for late application submission accepted	**N/A**	01/03/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**09/17/2021**	01/03/2022
	Donation(s) made to CPRIT / foundation	**NO**	01/03/2022
	Assigned to primary reviewers	**10/01/2021**	01/03/2022
	Applicant notified of review panel assignment	**09/29/2021**	01/03/2022
	Primary Reviewer 1 COI signed	**09/23/2021**	01/03/2022
	Primary (Advocate) Reviewer 2 COI signed	**09/24/2021**	01/03/2022
	Primary Reviewer 3 COI signed	**09/24/2021**	01/03/2022
	Primary Reviewer 4 COI signed	**09/23/2021**	01/03/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**11/22/2021**	01/03/2022
	Primary (Advocate) Reviewer 2 critique submitted	**11/18/2021**	01/03/2022
	Primary Reviewer 3 critique submitted	**11/17/2021**	01/03/2022
	Primary Reviewer 4 critique submitted	**11/08/2021**	01/03/2022
	COI indicated by non-primary reviewer	**NONE**	01/03/2022
	COI recused from participation	**N/A**	01/03/2022
	Discussed at Peer Review Meeting	**YES**	01/03/2022
	Peer Review Meeting	**12/06/2021**	01/03/2022
	Post review statements signed	**12/15/2021**	01/03/2022
	Third Party Observer Report	**12/15/2021**	01/03/2022
	Score report delivered to CPO	**12/17/2021**	01/03/2022
	Recommended for PRC review	**YES**	01/03/2022
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	01/20/2022
	COI recused from participation	**N/A**	01/20/2022
	PRC Meeting	**01/14/2022**	01/20/2022
	Third Party Observer Report	**01/21/2022**	06/24/2022
	Recommended for grant award	**Other: No Action**	01/20/2022
	PRC Chair Notification to PIC and OC	**01/18/2022**	06/24/2022
	COI indicated by PRC member (2nd Meeting)	**Other: NONE**	06/24/2022
	COI recused from participation (2nd Meeting)	**N/A**	06/24/2022
	2nd PRC Meeting	**06/03/2022**	06/24/2022
	Third Party Observer Report (2nd Meeting)	**06/08/2022**	06/24/2022
	Recommended for grant award	**YES**	06/24/2022
	PRC Chair Notification to PIC and OC (2nd Meeting)	**06/13/2022**	06/24/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP220034
Expansion of Cancer Prevention Services to
Rural and Medically Underserved Populations

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* Request for Applications (RFA). CPRIT received four applications in response to this RFA. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

On September 14, 2021, I notified Oversight Committee members that I granted the Chief Prevention Officer, Ramona Magid, a waiver from the general prohibition against communicating, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Prevention
MECHANISM: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
APPLICATION ID: PP220034
APPLICATION TITLE: Screening to Optimize Prevention of CRC in East Texas (STOP CRC ET)
APPLICANT NAME: McGaha, Paul
ORGANIZATION: The University of Texas Health Center at Tyler
PANEL NAME: 22.2 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**10/13/2021**	06/23/2022
	RFA Approved by CPO (revised)	**12/13/2021**	06/23/2022
	RFA published in Texas.gov eGrants	**10/19/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) opened	**11/15/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) closed	**02/09/2022**	06/23/2022
	Date application submitted	**02/09/2022**	06/24/2022
	Method of submission	**CARS**	06/24/2022
	Within receipt period	**YES**	06/24/2022
	Request for extension to submit application after CARS closed	**N/A**	06/24/2022
	Request for extension for late application submission accepted	**N/A**	06/24/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/24/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/24/2022
	Assigned to primary reviewers	**03/11/2022**	06/24/2022
	Applicant notified of review panel assignment	**03/09/2022**	06/23/2022
	Primary Reviewer 1 COI signed	**03/03/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 COI signed	**03/02/2022**	06/24/2022
	Primary Reviewer 3 COI signed	**03/04/2022**	06/24/2022
	Primary Reviewer 4 COI signed	**03/04/2022**	06/24/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**04/13/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 critique submitted	**04/07/2022**	06/24/2022
	Primary Reviewer 3 critique submitted	**04/13/2022**	06/24/2022
	Primary Reviewer 4 critique submitted	**04/14/2022**	06/24/2022
	COI indicated by non-primary reviewer	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	Discussed at Peer Review Meeting	**YES**	06/24/2022
	Peer Review Meeting	**04/25/2022**	06/24/2022
	Post review statements signed	**05/11/2022**	06/24/2022
	Third Party Observer Report	**04/28/2022**	06/24/2022
	Score report delivered to CPO	**05/06/2022**	06/24/2022
	Recommended for PRC review	**YES**	06/24/2022
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	PRC Meeting	**06/03/2022**	06/24/2022
	Third Party Observer Report	**06/08/2022**	06/24/2022
	Recommended for grant award	**YES**	06/24/2022
	PRC Chair Notification to PIC and OC	**06/13/2022**	06/24/2022
PIC Review	**COI indicated by PIC member**	**None**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP220035
Evidence Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received nine applications in response to this cycle 22.2 RFA, including one withdrawn application. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

On September 14, 2021, I notified Oversight Committee members that I granted the Chief Prevention Officer, Ramona Magid, a waiver from the general prohibition against communicating, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

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Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Prevention
MECHANISM: Evidence-Based Cancer Prevention Services
APPLICATION ID: PP220035
APPLICATION TITLE: DEFEAT breast cancer: Delivering Education, Focused navigation, and Equitable Access throughout East Texas.
APPLICANT NAME: McGaha, Paul
ORGANIZATION: The University of Texas Health Center at Tyler
PANEL NAME: 22.2 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**10/13/2021**	06/23/2022
	RFA Approved by CPO (revised)	**12/13/2021**	06/23/2022
	RFA published in Texas.gov eGrants	**10/19/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) opened	**11/15/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) closed	**02/09/2022**	06/23/2022
	Date application submitted	**02/09/2022**	06/24/2022
	Method of submission	**CARS**	06/24/2022
	Within receipt period	**YES**	06/24/2022
	Request for extension to submit application after CARS closed	**N/A**	06/24/2022
	Request for extension for late application submission accepted	**N/A**	06/24/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/24/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/24/2022
	Assigned to primary reviewers	**03/11/2022**	06/24/2022
	Applicant notified of review panel assignment	**03/09/2022**	06/23/2022
	Primary Reviewer 1 COI signed	**03/04/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 COI signed	**03/02/2022**	06/24/2022
	Primary Reviewer 3 COI signed	**03/03/2022**	06/24/2022
	Primary Reviewer 4 COI signed	**03/02/2022**	06/24/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**04/06/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 critique submitted	**04/17/2022**	06/24/2022
	Primary Reviewer 3 critique submitted	**04/14/2022**	06/24/2022
	Primary Reviewer 4 critique submitted	**04/12/2022**	06/24/2022
	COI indicated by non-primary reviewer	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	Discussed at Peer Review Meeting	**YES**	06/24/2022
	Peer Review Meeting	**04/25/2022**	06/24/2022
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	Third Party Observer Report	**04/28/2022**	06/24/2022
	Score report delivered to CPO	**05/06/2022**	06/24/2022
	Recommended for PRC review	**YES**	06/24/2022
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	PRC Meeting	**06/03/2022**	06/24/2022
	Third Party Observer Report	**06/08/2022**	06/24/2022
	Recommended for grant award	**YES**	06/24/2022
	PRC Chair Notification to PIC and OC	**06/13/2022**	06/24/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP220036
Evidence Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received nine applications in response to this cycle 22.2 RFA, including one withdrawn application. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

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CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

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MELANIE CLEVELAND
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ID# 131757703
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Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Prevention
MECHANISM: Evidence-Based Cancer Prevention Services
APPLICATION ID: PP220036
APPLICATION TITLE: Increasing the use of HPV vaccination services among medically underserved young adults
APPLICANT NAME: Roncancio, Angelica M
ORGANIZATION: University of Houston - Downtown
PANEL NAME: 22.2 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**10/13/2021**	06/23/2022
	RFA Approved by CPO (revised)	**12/13/2021**	06/23/2022
	RFA published in Texas.gov eGrants	**10/19/2021**	06/23/2022
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	CPRIT Application Receipt System (CARS) closed	**02/09/2022**	06/23/2022
	Date application submitted	**02/08/2022**	06/24/2022
	Method of submission	**CARS**	06/24/2022
	Within receipt period	**YES**	06/24/2022
	Request for extension to submit application after CARS closed	**N/A**	06/24/2022
	Request for extension for late application submission accepted	**N/A**	06/24/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/25/2022**	06/24/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/24/2022
	Assigned to primary reviewers	**03/11/2022**	06/24/2022
	Applicant notified of review panel assignment	**03/09/2022**	06/23/2022
	Primary Reviewer 1 COI signed	**03/04/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 COI signed	**03/06/2022**	06/24/2022
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	Primary Reviewer 4 COI signed	**03/04/2022**	06/24/2022
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	Primary Reviewer 4 critique submitted	**04/18/2022**	06/24/2022
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	COI recused from participation	**N/A**	06/24/2022
	Discussed at Peer Review Meeting	**YES**	06/24/2022
	Peer Review Meeting	**04/25/2022**	06/24/2022
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	Score report delivered to CPO	**05/06/2022**	06/24/2022
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	COI recused from participation	**N/A**	06/24/2022
	PRC Meeting	**06/03/2022**	06/24/2022
	Third Party Observer Report	**06/08/2022**	06/24/2022
	Recommended for grant award	**YES**	06/24/2022
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PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP220037
Expansion of Cancer Prevention Services to
Rural and Medically Underserved Populations

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* Request for Applications (RFA). CPRIT received four applications in response to this RFA. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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State of Texas
County of Travis

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Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Prevention
MECHANISM: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
APPLICATION ID: PP220037
APPLICATION TITLE: Project ACCESS: Increasing Access to Cervical Cancer Screening & Treatment Services in Texas
APPLICANT NAME: Schmeler, Kathleen M
ORGANIZATION: The University of Texas M. D. Anderson Cancer Center
PANEL NAME: 22.2 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**10/13/2021**	06/23/2022
	RFA Approved by CPO (revised)	**12/13/2021**	06/23/2022
	RFA published in Texas.gov eGrants	**10/19/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) opened	**11/15/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) closed	**02/09/2022**	06/23/2022
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	Method of submission	**CARS**	06/24/2022
	Within receipt period	**YES**	06/24/2022
	Request for extension to submit application after CARS closed	**N/A**	06/24/2022
	Request for extension for late application submission accepted	**N/A**	06/24/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/24/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/24/2022
	Assigned to primary reviewers	**03/11/2022**	06/24/2022
	Applicant notified of review panel assignment	**03/09/2022**	06/23/2022
	Primary Reviewer 1 COI signed	**03/04/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 COI signed	**03/06/2022**	06/24/2022
	Primary Reviewer 3 COI signed	**03/07/2022**	06/24/2022
	Primary Reviewer 4 COI signed	**03/04/2022**	06/24/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**04/16/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 critique submitted	**04/05/2022**	06/24/2022
	Primary Reviewer 3 critique submitted	**04/13/2022**	06/24/2022
	Primary Reviewer 4 critique submitted	**04/18/2022**	06/24/2022
	COI indicated by non-primary reviewer	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	Discussed at Peer Review Meeting	**YES**	06/24/2022
	Peer Review Meeting	**04/25/2022**	06/24/2022
	Post review statements signed	**05/11/2022**	06/24/2022
	Third Party Observer Report	**04/28/2022**	06/24/2022
	Score report delivered to CPO	**05/06/2022**	06/24/2022
	Recommended for PRC review	**YES**	06/24/2022
Final PRC Recommendation	**COI indicated by PRC member**	**Ross Brownson**	06/24/2022
	COI recused from participation	**YES**	06/24/2022
	PRC Meeting	**06/03/2022**	06/24/2022
	Third Party Observer Report	**06/08/2022**	06/24/2022
	Recommended for grant award	**YES**	06/24/2022
	PRC Chair Notification to PIC and OC	**06/13/2022**	06/24/2022
PIC Review	**COI indicated by PIC member**	**None**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP220038
Expansion of Cancer Prevention Services to
Rural and Medically Underserved Populations

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* Request for Applications (RFA). CPRIT received four applications in response to this RFA. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

On September 14, 2021, I notified Oversight Committee members that I granted the Chief Prevention Officer, Ramona Magid, a waiver from the general prohibition against communicating, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Prevention
MECHANISM: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
APPLICATION ID: PP220038
APPLICATION TITLE: Advancing Implementation of Evidence-Based Strategies for Tobacco Prevention and HPV Vaccination in Pediatric Safety Net Settings
APPLICANT NAME: Montealegre, Jane R
ORGANIZATION: Baylor College of Medicine
PANEL NAME: 22.2 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**10/13/2021**	06/23/2022
	RFA Approved by CPO (revised)	**12/13/2021**	06/23/2022
	RFA published in Texas.gov eGrants	**10/19/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) opened	**11/15/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) closed	**02/09/2022**	06/23/2022
	Date application submitted	**02/09/2022**	06/24/2022
	Method of submission	**CARS**	06/24/2022
	Within receipt period	**YES**	06/24/2022
	Request for extension to submit application after CARS closed	**N/A**	06/24/2022
	Request for extension for late application submission accepted	**N/A**	06/24/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/24/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/24/2022
	Assigned to primary reviewers	**03/11/2022**	06/24/2022
	Applicant notified of review panel assignment	**03/09/2022**	06/23/2022
	Primary Reviewer 1 COI signed	**03/04/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 COI signed	**03/02/2022**	06/24/2022
	Primary Reviewer 3 COI signed	**03/03/2022**	06/24/2022
	Primary Reviewer 4 COI signed	**03/04/2022**	06/24/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**04/12/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 critique submitted	**04/17/2022**	06/24/2022
	Primary Reviewer 3 critique submitted	**04/18/2022**	06/24/2022
	Primary Reviewer 4 critique submitted	**04/15/2022**	06/24/2022
	COI indicated by non-primary reviewer	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	Discussed at Peer Review Meeting	**YES**	06/24/2022
	Peer Review Meeting	**04/25/2022**	06/24/2022
	Post review statements signed	**05/11/2022**	06/24/2022
	Third Party Observer Report	**04/28/2022**	06/24/2022
	Score report delivered to CPO	**05/06/2022**	06/24/2022
	Recommended for PRC review	**YES**	06/24/2022
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	PRC Meeting	**06/03/2022**	06/24/2022
	Third Party Observer Report	**06/08/2022**	06/24/2022
	Recommended for grant award	**YES**	06/24/2022
	PRC Chair Notification to PIC and OC	**06/13/2022**	06/24/2022
PIC Review	**COI indicated by PIC member**	**None**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP220041
Evidence Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received nine applications in response to this cycle 22.2 RFA, including one withdrawn application. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

On September 14, 2021, I notified Oversight Committee members that I granted the Chief Prevention Officer, Ramona Magid, a waiver from the general prohibition against communicating, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Prevention
MECHANISM: Evidence-Based Cancer Prevention Services
APPLICATION ID: PP220041
APPLICATION TITLE: Fecal Immunochemical Testing for Screening and Treatment of Occult Neoplasia (FIT-STOP)
APPLICANT NAME: Layeequr Rahman, Rakhshanda
ORGANIZATION: Texas Tech University Health Sciences Center
PANEL NAME: 22.2 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**10/13/2021**	06/23/2022
	RFA Approved by CPO (revised)	**12/13/2021**	06/23/2022
	RFA published in Texas.gov eGrants	**10/19/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) opened	**11/15/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) closed	**02/09/2022**	06/23/2022
	Date application submitted	**02/07/2022**	06/24/2022
	Method of submission	**CARS**	06/24/2022
	Within receipt period	**YES**	06/24/2022
	Request for extension to submit application after CARS closed	**N/A**	06/24/2022
	Request for extension for late application submission accepted	**N/A**	06/24/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/24/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/24/2022
	Assigned to primary reviewers	**03/11/2022**	06/24/2022
	Applicant notified of review panel assignment	**03/09/2022**	06/23/2022
	Primary Reviewer 1 COI signed	**03/02/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 COI signed	**03/02/2022**	06/24/2022
	Primary Reviewer 3 COI signed	**03/04/2022**	06/24/2022
	Primary Reviewer 4 COI signed	**03/03/2022**	06/24/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**04/15/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 critique submitted	**04/17/2022**	06/24/2022
	Primary Reviewer 3 critique submitted	**04/19/2022**	06/24/2022
	Primary Reviewer 4 critique submitted	**04/18/2022**	06/24/2022
	COI indicated by non-primary reviewer	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	Discussed at Peer Review Meeting	**YES**	06/24/2022
	Peer Review Meeting	**04/25/2022**	06/24/2022
	Post review statements signed	**05/11/2022**	06/24/2022
	Third Party Observer Report	**04/28/2022**	06/24/2022
	Score report delivered to CPO	**05/06/2022**	06/24/2022
	Recommended for PRC review	**YES**	06/24/2022
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	PRC Meeting	**06/03/2022**	06/24/2022
	Third Party Observer Report	**06/08/2022**	06/24/2022
	Recommended for grant award	**YES**	06/24/2022
	PRC Chair Notification to PIC and OC	**06/13/2022**	06/24/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP220045
Evidence Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received nine applications in response to this cycle 22.2 RFA, including one withdrawn application. This application was assigned to the Prevention Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

On September 14, 2021, I notified Oversight Committee members that I granted the Chief Prevention Officer, Ramona Magid, a waiver from the general prohibition against communicating, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Prevention
MECHANISM: Evidence-Based Cancer Prevention Services
APPLICATION ID: PP220045
APPLICATION TITLE: Inpatient Screening and Treatment for Unhealthy Alcohol Use and Tobacco Use as a means of cancer prevention
APPLICANT NAME: Ramesh, Jananie
ORGANIZATION: The University of Texas at Austin
PANEL NAME: 22.2 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**10/13/2021**	06/23/2022
	RFA Approved by CPO (revised)	**12/13/2021**	06/23/2022
	RFA published in Texas.gov eGrants	**10/19/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) opened	**11/15/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) closed	**02/09/2022**	06/23/2022
	Date application submitted	**02/09/2022**	06/24/2022
	Method of submission	**CARS**	06/24/2022
	Within receipt period	**YES**	06/24/2022
	Request for extension to submit application after CARS closed	**N/A**	06/24/2022
	Request for extension for late application submission accepted	**N/A**	06/24/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/24/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/24/2022
	Assigned to primary reviewers	**03/11/2022**	06/24/2022
	Applicant notified of review panel assignment	**03/09/2022**	06/23/2022
	Primary Reviewer 1 COI signed	**03/02/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 COI signed	**03/02/2022**	06/24/2022
	Primary Reviewer 3 COI signed	**03/02/2022**	06/24/2022
	Primary Reviewer 4 COI signed	**03/04/2022**	06/24/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**04/12/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 critique submitted	**04/17/2022**	06/24/2022
	Primary Reviewer 3 critique submitted	**04/18/2022**	06/24/2022
	Primary Reviewer 4 critique submitted	**04/01/2022**	06/24/2022
	COI indicated by non-primary reviewer	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	Discussed at Peer Review Meeting	**YES**	06/24/2022
	Peer Review Meeting	**04/25/2022**	06/24/2022
	Post review statements signed	**05/11/2022**	06/24/2022
	Third Party Observer Report	**04/28/2022**	06/24/2022
	Score report delivered to CPO	**05/06/2022**	06/24/2022
	Recommended for PRC review	**YES**	06/24/2022
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	PRC Meeting	**06/03/2022**	06/24/2022
	Third Party Observer Report	**06/08/2022**	06/24/2022
	Recommended for grant award	**YES**	06/24/2022
	PRC Chair Notification to PIC and OC	**06/13/2022**	06/24/2022
PIC Review	**COI indicated by PIC member**	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP220051
Expansion of Cancer Prevention Services to
Rural and Medically Underserved Populations

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

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CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

On September 14, 2021, I notified Oversight Committee members that I granted the Chief Prevention Officer, Ramona Magid, a waiver from the general prohibition against communicating, pursuant to Texas Administrative Code § 702.19(e). A copy of the waiver is included in the "CEO Affidavit-Supporting Information" packet.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waiver on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-06-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 2
PROGRAM: Prevention
MECHANISM: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
APPLICATION ID: PP220051
APPLICATION TITLE: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations- Program title: GetFIT
APPLICANT NAME: Mika, Virginia
ORGANIZATION: University Health System
PANEL NAME: 22.2 Prevention Panel-1

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CPO**	**10/13/2021**	06/23/2022
	RFA Approved by CPO (revised)	**12/13/2021**	06/23/2022
	RFA published in Texas.gov eGrants	**10/19/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) opened	**11/15/2021**	06/23/2022
	CPRIT Application Receipt System (CARS) closed	**02/09/2022**	06/23/2022
	Date application submitted	**02/09/2022**	06/24/2022
	Method of submission	**CARS**	06/24/2022
	Within receipt period	**YES**	06/24/2022
	Request for extension to submit application after CARS closed	**N/A**	06/24/2022
	Request for extension for late application submission accepted	**N/A**	06/24/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**02/25/2022**	06/24/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/24/2022
	Assigned to primary reviewers	**03/11/2022**	06/24/2022
	Applicant notified of review panel assignment	**03/09/2022**	06/23/2022
	Primary Reviewer 1 COI signed	**03/03/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 COI signed	**03/06/2022**	06/24/2022
	Primary Reviewer 3 COI signed	**03/02/2022**	06/24/2022
	Primary Reviewer 4 COI signed	**03/03/2022**	06/24/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**04/14/2022**	06/24/2022
	Primary (Advocate) Reviewer 2 critique submitted	**04/04/2022**	06/24/2022
	Primary Reviewer 3 critique submitted	**04/12/2022**	06/24/2022
	Primary Reviewer 4 critique submitted	**04/12/2022**	06/24/2022
	COI indicated by non-primary reviewer	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	Discussed at Peer Review Meeting	**YES**	06/24/2022
	Peer Review Meeting	**04/25/2022**	06/24/2022
	Post review statements signed	**05/11/2022**	06/24/2022
	Third Party Observer Report	**04/28/2022**	06/24/2022
	Score report delivered to CPO	**05/06/2022**	06/24/2022
	Recommended for PRC review	**YES**	06/24/2022
Final PRC Recommendation	**COI indicated by PRC member**	**NONE**	06/24/2022
	COI recused from participation	**N/A**	06/24/2022
	PRC Meeting	**06/03/2022**	06/24/2022
	Third Party Observer Report	**06/08/2022**	06/24/2022
	Recommended for grant award	**YES**	06/24/2022
	PRC Chair Notification to PIC and OC	**06/13/2022**	06/24/2022
PIC Review	**COI indicated by PIC member**	**None**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**N/A**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR220067
Recruitment of Established Investigators
Nomination of Zhiguo Zhang, Ph.D.

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators* Request for Applications (RFA). CPRIT received six applications in response to this RFA during cycles 22.7 through 22.9. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The PIC deferred this application at its May 4, 2022, meeting, and subsequently recommended the application to the Oversight Committee on August 3, 2022.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waivers on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 8 day of August, 2022, by WAYNE R. ROBERTS.

Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 1
PROGRAM: Recruitment
MECHANISM: Recruitment of Established Investigators
APPLICATION ID: RR220067
APPLICATION TITLE: Recruitment of Established Investigators - Zhiguo Zhang
APPLICANT NAME: Draetta, Gulio
ORGANIZATION: The University of Texas M. D. Anderson Cancer Center
PANEL NAME: Recruitment FY22_Cycle 8

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**06/16/2021**	08/30/2021
	RFA published in Texas.gov eGrants	**06/22/2021**	08/30/2021
	CPRIT Application Receipt Cycle opened	**01/21/2022**	03/25/2022
	CPRIT Application Receipt Cycle closed	**02/22/2022**	03/25/2022
	Date application submitted	**02/15/2022**	03/25/2022
	Method of submission	**CARS**	03/25/2022
	Within receipt period	**YES**	03/25/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	03/25/2022
	Donation(s) made to CPRIT / foundation	**NO**	03/25/2022
	Assigned to primary reviewers	**03/03/2022**	03/25/2022
	Applicant notified of review panel assignment	**N/A**	03/25/2022
	Primary Reviewer 1 COI signed	**02/25/2022**	03/25/2022
	Primary Reviewer 2 COI signed	**02/25/2022**	03/25/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**03/09/2022**	03/25/2022
	Primary Reviewer 2 critique submitted	**03/10/2022**	03/25/2022
	COI indicated by non-primary reviewer	**Carol Prives**	03/25/2022
	COI recused from participation	**YES**	03/25/2022
	Discussed at Peer Review Meeting	**YES**	03/25/2022
	Peer Review Meeting	**03/10/2022**	03/25/2022
	Post review statements signed	**03/22/2022**	03/25/2022
	Third Party Observer Report	**03/14/2022**	03/25/2022
	Score report delivered to CSO	**03/18/2022**	03/25/2022
	Recommended for SRC review	**YES**	03/25/2022
Final SRC Recommendation	**COI indicated by SRC member**	**Carol Prives**	03/25/2022
	COI recused from participation	**YES**	03/25/2022
	SRC Meeting	**03/10/2022**	03/25/2022
	Third Party Observer Report	**03/14/2022**	03/25/2022
	Recommended for grant award	**YES**	03/25/2022
	SRC Chair Notification to PIC and OC	**04/27/2022**	04/27/2022
PIC Review	**Candidate not accepted position prior to SRC date**	**Other: Deferred**	07/27/2022
	COI indicated by PIC member	**None**	07/27/2022
	COI recused from participation	**N/A**	05/04/2022
	PIC Review Meeting	**05/04/2022**	05/04/2022
	Recommended for grant award	**Other: Deferred**	05/04/2022
	Candidate not accepted position prior to SRC date	**YES**	08/03/2022
	COI indicated by PIC member	**None**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**NO**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR220094
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Steven Boeynaems

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 10 applications in response to this RFA during cycle 22.10, including one withdrawn application. This application was assigned to the Scientific Review Council (SRC) for review. The SRC did not make a final decision on four applications submitted during this review cycle. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The SRC Chairman provided recommendation letters to the PIC and Oversight Committee Chairmen on July 20 and August 2, 2022. The July 20 letter recommended RR220094, and the August 2 letter included an additional application, RR220101, for the PIC to consider. Prior to the August 2 letter, the SRC favorably reviewed but took no action on RR220101 because of insufficient agency funds. However, on August 1 additional funds became available enabling the SRC to recommend RR220101 to the PIC and Oversight Committee.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waivers on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

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Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

Date and time exported: 08/08/2022 11:50 AM CT

FY: 2022
CYCLE: 1
PROGRAM: Recruitment
MECHANISM: Recruitment of First-Time, Tenure-Track Faculty Members
APPLICATION ID: RR220094
APPLICATION TITLE: First-Time, Tenure-Track: Dr. Steven Boeynaems
APPLICANT NAME: Dickinson, Mary
ORGANIZATION: Baylor College of Medicine
PANEL NAME: Recruitment FY22_Cycle 10

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	**RFA Approved by CSO**	**06/16/2021**	08/30/2021
	RFA published in Texas.gov eGrants	**06/22/2021**	08/30/2021
	CPRIT Application Receipt Cycle opened	**03/22/2022**	06/10/2022
	CPRIT Application Receipt Cycle closed	**04/20/2022**	06/10/2022
	Date application submitted	**04/20/2022**	06/10/2022
	Method of submission	**CARS**	06/10/2022
	Within receipt period	**YES**	06/10/2022
Receipt, Referral, and Assignment	**Administrative review notification**	**N/A**	06/10/2022
	Donation(s) made to CPRIT / foundation	**NO**	06/10/2022
	Assigned to primary reviewers	**05/03/2022**	06/10/2022
	Applicant notified of review panel assignment	**N/A**	06/10/2022
	Primary Reviewer 1 COI signed	**05/02/2022**	06/10/2022
	Primary Reviewer 2 COI signed	**04/26/2022**	06/10/2022
Peer Review Meeting	**Primary Reviewer 1 critique submitted**	**05/10/2022**	06/10/2022
	Primary Reviewer 2 critique submitted	**05/11/2022**	06/10/2022
	COI indicated by non-primary reviewer	**Eric Fearon**	06/10/2022
	COI recused from participation	**YES**	06/10/2022
	Discussed at Peer Review Meeting	**YES**	06/10/2022
	Peer Review Meeting	**05/12/2022**	06/10/2022
	Post review statements signed	**05/19/2022**	06/10/2022
	Third Party Observer Report	**05/13/2022**	06/10/2022
	Score report delivered to CSO	**05/20/2022**	06/10/2022
	Recommended for SRC review	**YES**	06/10/2022
Final SRC Recommendation	**COI indicated by SRC member**	**Eric Fearon**	06/10/2022
	COI recused from participation	**YES**	06/10/2022
	SRC Meeting	**05/12/2022**	06/10/2022
	Third Party Observer Report	**05/13/2022**	06/10/2022
	Recommended for grant award	**Other: No Action**	06/10/2022
	SRC Chair Notification to PIC and OC	**07/20/2022**	07/26/2022
	COI indicated by SRC member	**NONE**	07/26/2022
	COI recused from participation	**N/A**	07/26/2022
	SRC Meeting	**07/14/2022**	07/26/2022
	Third Party Observer Report	**07/20/2022**	07/27/2022
	Recommended for grant award	**YES**	07/26/2022
	SRC Chair Notification to PIC and OC	**07/20/2022**	07/26/2022
	SRC notification to PIC and OC	**08/02/2022**	08/03/2022
PIC Review	**Candidate not accepted asst. prof. tenure track position prior to SRC date**	**YES**	08/03/2022
	COI indicated by PIC member	**none**	08/03/2022
	COI recused from participation	**N/A**	08/03/2022
	PIC Review Meeting	**08/03/2022**	08/03/2022
	Recommended for grant award	**YES**	08/03/2022
Oversight Committee Approval	**CEO Notification to Oversight Committee**	**N/A**	
	COI Indicated by Oversight Committee member	**N/A**	
	COI Recused from participation	**N/A**	
	Donation(s) made to CPRIT / foundation	**N/A**	
	Presented to CPRIT Oversight Committee	**N/A**	
	Award approved by Oversight Committee	**NO**	
	Authority to advance funds requested	**N/A**	
	Advance authority approved by Oversight Committee	**N/A**	

Comments:

Comment	Created Date	Created By
The SRC Chairman sent an updated recommendation letter to the PIC and OC Chairmen on August 2, 2022.	**2022-08-03 16:19:20.223**	**Eckel, Cameron**

CPRIT retains the identity of the attesting party.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR220101
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Siqi Liu

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received 10 applications in response to this RFA during cycle 22.10, including one withdrawn application. This application was assigned to the Scientific Review Council (SRC) for review. The SRC did not make a final decision on four applications submitted during this review cycle. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

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- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third-party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

The SRC Chairman provided recommendation letters to the PIC and Oversight Committee Chairmen on July 20 and August 2, 2022. The July 20 letter recommended RR220094, and the August 2 letter included an additional application, RR220101, for the PIC to consider. Prior to the August 2 letter, the SRC favorably reviewed but took no action on RR220101 because of insufficient agency funds. However, on August 1 additional funds became available enabling the SRC to recommend RR220101 to the PIC and Oversight Committee.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that the following PIC member has an approved conflict of interest waivers on file for FY2022: Dr. John Hellerstedt, Department of State Health Services Commissioner, applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

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Melanie Cleveland
Notary Public, State of Texas

MELANIE CLEVELAND
NOTARY PUBLIC
ID# 131757703
State of Texas
Comm. Exp. 10-08-2022
NOTARY WITHOUT BOND

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE Date and time exported: 08/08/2022 12:19 PM CT

FY:	2022
CYCLE:	1
PROGRAM:	Recruitment
MECHANISM:	Recruitment of First-Time, Tenure-Track Faculty Members
APPLICATION ID:	RR220101
APPLICATION TITLE	Nomination of Siqi Liu, Ph.D. for a CPRIT Recruitment of a First-Time Tenure-Track Faculty Member Award
APPLICANT NAME:	Lee, W. P. Andrew
ORGANIZATION:	The University of Texas Southwestern Medical Center
PANEL NAME:	Recruitment FY22 Cycle 10

Category	Compliance Requirement	Information	Attestation Date
Pre-Receipt	RFA Approved by CSO	06/16/2021	08/30/2021
	RFA published in Texas.gov eGrants	06/22/2021	08/30/2021
	CPRIT Application Receipt Cycle opened	03/22/2022	06/10/2022
	CPRIT Application Receipt Cycle closed	04/20/2022	06/10/2022
	Date application submitted	04/19/2022	06/10/2022
	Method of submission	CARS	06/10/2022
	Within receipt period	YES	06/10/2022
Receipt, Referral, and Assignment	Administrative review notification	N/A	06/10/2022
	Donation(s) made to CPRIT / foundation	NO	06/10/2022
	Assigned to primary reviewers	05/03/2022	06/10/2022
	Applicant notified of review panel assignment	N/A	06/10/2022
	Primary Reviewer 1 COI signed	04/25/2022	06/10/2022
	Primary Reviewer 2 COI signed	05/03/2022	06/10/2022
Peer Review Meeting	Primary Reviewer 1 critique submitted	05/04/2022	06/10/2022
	Primary Reviewer 2 critique submitted	05/10/2022	06/10/2022
	COI indicated by non-primary reviewer	NONE	06/10/2022
	COI recused from participation	N/A	06/10/2022
	Discussed at Peer Review Meeting	YES	06/10/2022
	Peer Review Meeting	05/12/2022	06/10/2022
	Post review statements signed	05/19/2022	06/10/2022
	Third Party Observer Report	05/13/2022	06/10/2022
	Score report delivered to CSO	05/20/2022	06/10/2022
	Recommended for SRC review	YES	06/10/2022
Final SRC Recommendation	COI indicated by SRC member	NONE	06/10/2022
	COI recused from participation	N/A	06/10/2022
	SRC Meeting	05/12/2022	06/10/2022
	Third Party Observer Report	05/13/2022	06/10/2022
	Recommended for grant award	Other: No Action	06/10/2022
	Chair Notification to PIC and OC	07/20/2022	08/08/2022
	COI indicated by SRC member	none	08/08/2022
	COI recused from participation	N/A	08/08/2022
	SRC Meeting	08/01/2022	08/08/2022
	Third Party Observer Report	08/03/2022	08/08/2022
	Recommended for grant award	YES	08/08/2022
	SRC Chair Notification to PIC and OC	08/02/2022	08/03/2022
PIC Review	Candidate not accepted asst. prof. tenure track position prior to SRC date	YES	08/03/2022
	COI indicated by PIC member	none	08/03/2022
	COI recused from participation	N/A	08/03/2022
	PIC Review Meeting	08/03/2022	08/03/2022
	Recommended for grant award	YES	08/03/2022
Oversight Committee Approval	CEO Notification to Oversight Committee	N/A	
	COI Indicated by Oversight Committee member	N/A	
	COI Recused from participation	N/A	
	Donation(s) made to CPRIT / foundation	N/A	
	Presented to CPRIT Oversight Committee	N/A	
	Award approved by Oversight Committee	NO	
	Authority to advance funds requested	N/A	
	Advance authority approved by Oversight Committee	N/A	

Comments		
Comment	Created Date	Created By
No Comment		

CPRIT retains the identity of the attesting party.