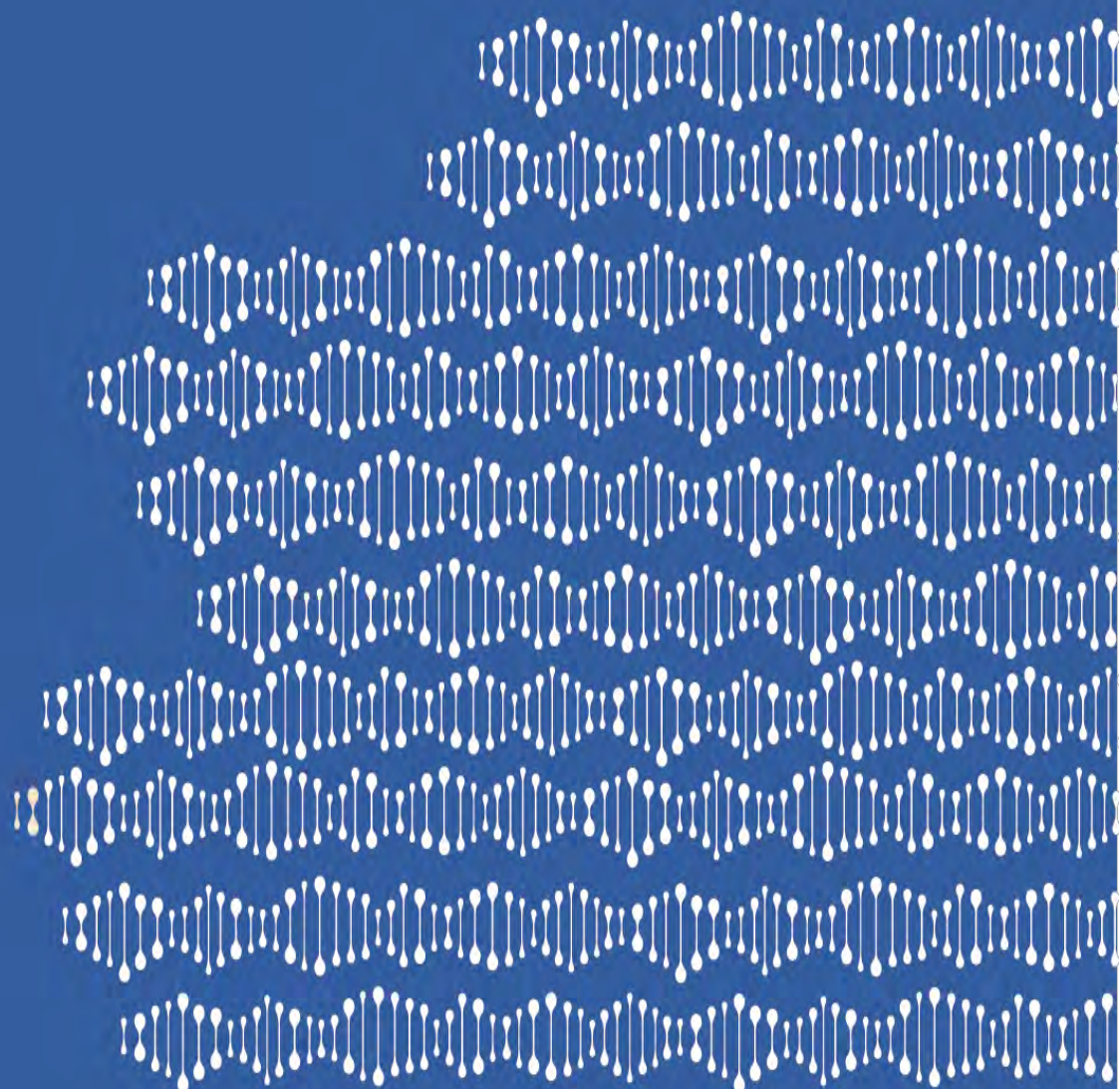




CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Proposed Grant Awards

May 20, 2015





May 6, 2015

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 42 grant applications totaling \$91,185,945 in grants. The PIC recommendations for 29 academic research grant awards, 2 product development research awards, and 11 prevention awards are attached. The program officers have prepared overviews of the academic research, product development research, and prevention program slates to assist your evaluation of the recommended awards. The overviews are intended to provide a comprehensive summary of the recommended proposals with enough detail that you should be able to understand the substance of the proposal and the reasons endorsing grant funding. All of the information reviewed by the Review Councils is available by clicking on the appropriate link in the portal. This information includes the full application, peer reviewer critiques, budget/scope change recommendations (if applicable) and the CEO affidavit for each proposal.

For the first time the PIC has a split decision on one product development research award recommendation. A majority of the PIC voted not to recommend the award. I disagreed with that decision and have prepared a minority recommendation following the process called for by CPRIT's administrative rules. My minority recommendation as well as the majority's reasoning for not recommending the grant application are on the portal.

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. Kristen Doyle, CPRIT's Interim 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 Wednesday, May 20, 2015. 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. This is particularly important because some recommendations are for publicly traded companies, which implicates state and federal securities law as described by the memorandum prepared by Ms. Doyle that is on the portal.

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 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 Award Recommendations –

The PIC unanimously recommends approval of 29 academic research grant proposals totaling \$62,066,521. The recommended grant proposals were submitted in response to one of five grant mechanisms: Core Facilities Support Awards, Multi-Investigator Research Awards, High-Impact/High-Risk Research Awards; Recruitment of First-Time, Tenure-Track Faculty; and Recruitment of Established Investigators. The PIC followed the recommendations made by the Scientific Review Council (SRC). The SRC provided the prioritized list of recommendations for the Recruitment awards to the presiding officers on April 22, 2015.

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 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 (the PIC chose this factor for Multi-Investigator Research Awards and High-Impact, High-Risk Research Awards);
- 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 Grant Award Recommendations

Rank	App ID	Mechanism	Organization	Application Title	Budget	Score
1	RP150587	MIRA	Baylor College of Medicine	The Texas Hepatocellular Carcinoma Consortium (THCCC)	\$9,771,157	1.9
2	RP150611	CFSA	The Methodist Hospital Research Institute	CPRIT Core for RNA Therapeutics and Research	\$4,845,868	2.0
3	RP150535	CFSA	The University of Texas M. D. Anderson Cancer Center	Precision Oncology Decision Support Core	\$5,999,996	2.0

Rank	App ID	Mechanism	Organization	Application Title	Budget	Score
4	RP150573	HIHRRRA	The University of Texas Southwestern Medical Center	Dynamin GTPase: A novel pro-apoptotic cancer therapeutic target	\$200,000	2.0
5	RP150632	HIHRRRA	The University of Texas Southwestern Medical Center	Acetate may be a key substrate driving growth in early stage breast cancer in patients	\$200,000	2.0
6	RP150600	CFSA	The University of Texas Health Science Center at San Antonio	The Single-Cell Biopsy and Characterization Core (SBCC) at The University of Texas Health Science at San Antonio	\$3,277,895	2.1
7	RP150551	CFSA	The University of Texas Health Science Center at Houston	Therapeutic Monoclonal Antibody Lead Optimization and Development Core	\$5,277,338	2.1
8	RP150640	HIHRRRA	The University of Texas Health Science Center at Houston	Drug Conjugates of anti-LGR5 Antibodies as Novel Therapeutics for Destroying Cancer Stem Cells	\$200,000	2.1
9	RP150676	HIHRRRA	The University of Texas Southwestern Medical Center	Identification of Novel Melanoma Metastasis Driver Genes through Transposon-Mediated Mutagenesis	\$200,000	2.1
10	RP150637	HIHRRRA	Texas A&M University System Health Science Center	Efficient Production of iPSC-Derived Mesenchymal Stem Cells to Kill Cancers by Bystander Effects from Suicide Genes	\$200,000	2.2
11	RP150648*	MIRA	Baylor College of Medicine	GATA2 and steroid receptor coactivator-2 cooperate with androgen receptor in prostate cancer progression and androgen resistance	\$6,151,179	2.3
12	RP150703	HIHRRRA	Texas A&M University System Health Science Center	Metabolomic Salivary Biomarkers for Oral Cancer Detection	\$199,999	2.6
13	RP150596	CFSA	The University of Texas Southwestern Medical Center	Bioinformatics Core Facility at UT Southwestern Medical Center	\$5,593,882	2.7

Rank	App ID	Mechanism	Organization	Application Title	Budget	Score
14	RP150720	HIHRRRA	Texas Tech University	Integrated on-chip networks for investigating exosome-mediated drug expulsion	\$200,000	2.7
15	RP150559	HIHRRRA	Texas A&M University	Small Molecules to Perturb A Novel PPI Target For Chemotherapy	\$200,000	2.7
16	RP150656	HIHRRRA	Texas Tech University Health Sciences Center	Engineered Bone Targeting Nanomedicine for Treatment of Bone Metastases from Breast Cancer	\$199,970	2.8
17	RP150578	CFSA	Texas A&M University System Health Science Center	The Combinatorial Drug Discovery Program (CDDP)	\$5,954,596	3.0
18	RP150701	HIHRRRA	Rice University	Non-invasive Colonoscopy by Molecular Imaging of Mucin Targeted Hyperpolarized Silicon Nanoparticles	\$200,000	3.0
19	RP150638	HIHRRRA	Baylor Research Institute	Elevated D-2-hydroxyglutarate precedes and promotes tumor progression in inflammatory bowel diseases	\$200,000	3.1
20	RP150590	HIHRRRA	The University of Texas Southwestern Medical Center	Identifying Inhibitors of Ascl1 to Block Growth of Malignant Neuroendocrine and Neural Tumors	\$200,000	3.2
21	RP150713	HIHRRRA	The University of Texas at Dallas	Identification of Therapeutic Targets on Breast Cancer Stem Cells	\$194,543	3.3
22	RP150696	HIHRRRA	The University of Texas Health Science Center at San Antonio	Inhibition of Breast Cancer Metastasis to the Bone by microRNA Transmission through Gap Junctions	\$200,000	3.4
23	RP150711	HIHRRRA	The University of Texas at Arlington	Biomechanical profiling of migrating brain cancer genotypes in tightly-confined space for drug screening	\$199,998	3.4

Rank	App ID	Mechanism	Organization	Application Title	Budget	Score
24	RP150574	HIHRRRA	The University of Texas Health Science Center at San Antonio	Turning on a Novel Tumor-Inhibiting Switch for Colorectal Cancer	\$200,000	3.4

*RP150648 - The peer review panel recommended the removal of a MIRA project. The budget was reduced based on the deletion of that project plus a 20% reduction of the remaining budget.

Academic Research Recruitment Grant Award Recommendations

Rank	App ID	Mechanism	Organization	Candidate	Budget Requested	Overall Score
1	RR150060**	RFT	The University of Texas Southwestern Medical Center	Dr. Randal Halfmann	\$2,000,000	1.0
2	RR150062	RFT	The University of Texas Southwestern Medical Center	Dr. Shixin Liu	\$2,000,000	1.0
3	RR150058	RFT	The University of Texas Southwestern Medical Center	Dr. Andreas Doncic	\$2,000,000	1.3
4	RR150054	REI	The University of Texas M. D. Anderson Cancer Center	Dr. Hongtu Zhu	\$4,000,000*	1.8
5	RR150059	RFT	The University of Texas Southwestern Medical Center	Dr. Maralice Conacci-Sorrell	\$2,000,000	2.0
6	RR150044	RFT	Rice University	Dr. Natalia Kirienko	\$2,000,000	2.2

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

REI = Recruitment of Established Investigators

*The award amount for this REI candidate was reduced from \$6M to \$4M at the recommendation of the SRC.

**RR150060 was withdrawn by the applicant after the meeting of the SRC but before the PIC meeting.

Product Development Research Award Recommendations –

The PIC unanimously recommends approval of two product development grant proposals totaling \$8,500,011. The recommended grant proposals were submitted in response to New Company Product Development Awards and Established Company Product Development Awards Request for Applications. The Product Development Review Council (PDRC) recommended three applications to the PIC; however, the PIC only recommended two to the Oversight Committee. The PDRC provided the prioritized list of recommendations for the product development awards to the presiding officers on April 21, 2015.

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 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;
- are interdisciplinary or interinstitutional (the PIC chose this factor for Established Company Awards);
- 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 innovation and product development, 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	Company Name	Project	Requested Budget	Overall Score
1	DP150019	Vermillion, Inc.	Development and Validation of a Second-Generation Multivariate Test for Use in Assessing Risk of Ovarian Mass Malignancy	\$7,533,011	2.4
2	DP150005	Rosellini Scientific, Inc.	Wireless Neuro-modulation Treatment for Bladder Dysfunction Secondary to Cancer	\$967,000	2.9

Rank	Application ID	Company Name	Project	Requested Budget	Overall Score
3	DP150042*	Aradigm Corp.	Development of AERx Pure Nicotine Inhaler	\$5,330,000	3.0

* DP150042 was not recommended by the PIC.

Prevention Award Recommendations –

The PIC unanimously recommends approval of 11 prevention grant proposals totaling \$20,619,413. The recommended grant proposals were submitted in response to Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition, Competitive Continuation/Expansion-Evidence-Based Cancer Prevention Services, and Evidence-Based Cancer Prevention Services Request for Applications. The PIC followed the recommendations made by the Prevention Review Council (PRC). The PRC provided the prioritized list of recommendations for the product development awards to the presiding officers on April 21, 2015.

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 proposals met the following CPRIT funding priorities:

- 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 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

App ID	Mech.	Application Title	Organization	Score	Rank Order Score	Recommended funding
PP150061	EBP-CRC	The C-SPAN Coalition: Colorectal Screening and Patient Navigation	The University of Texas Southwestern Medical Center	2.3	1	\$ 4,800,000*
PP150079	EBP	STOP HCC – Evidence-Based Hepatocellular	The University of Texas Health	2.3	2	\$ 1,488,294

App ID	Mech.	Application Title	Organization	Score	Rank Order Score	Recommended funding
		Cancer Prevention Targeting Hepatitis C Virus Infection	Science Center at San Antonio			
PP150071	EBP	FluFIT on the Frontera: Increasing Colorectal Cancer Screening on the Texas-Mexico Border	Val Verde Regional Medical Center	2.6	3	\$ 1,500,000
PP150053	CCE-EBP	BSPAN3: Breast Screening and Patient Navigation for Rural and Underserved Women across North Texas	The University of Texas Southwestern Medical Center	2.9	4	\$ 1,499,993
PP150054**	EBP-CRC	Alliance for Colorectal Cancer Testing (ACT) in Southeast Texas	The University of Texas M. D. Anderson Cancer Center	2.9	4 (rank ordered without Dr. Brownson)	\$ 2,588,774
PP150077	EBP	Media-Rich Mobile Dissemination of a Dysphagia Prevention Program for Head and Neck Cancer Patients during Radiation	The University of Texas M. D. Anderson Cancer Center	2.9	6	\$ 1,263,342
PP150086	CCE-EBP	Access to Breast and Cervical Care for West Texas (West/Central Texas)(ABCC4WT)	Angelo State University	3.9	7	\$ 1,480,898

App ID	Mech.	Application Title	Organization	Score	Rank Order Score	Recommended funding
PP150080	CCE-EBP	Empower Her To Care Expansion: Increasing Access to Breast Cancer Screening and the Continuum of Care for Underserved Texas Women	The Rose	4.1	8	\$ 1,500,000
PP150078	EBP	Cada Paso del Camino: Outreach, Education, Screening, Health Insurance Navigation, and Linkage to Treatment for Breast, Cervical, and Colorectal Cancers	MHP, Inc. Promoviendo Vidas Saludables	4.5	9	\$ 1,498,337
PP150064	CCE-EBP	University Health System Evidence-Based Colorectal Cancer Prevention Screening Program	University Health System	4.5	10	\$ 1,499,775
PP150089	CCE-EBP	Increasing Breast and Cervical Cancer Screening and Diagnostic Rates in Rural, Frontier, and Border Counties for Uninsured, Underserved Women	Texas AgriLife Extension Service	4.7	11	\$ 1,500,000

* reduce grant to \$4,800,000.Due to this being the initial coalition grant (largest grant ever awarded) and to efficiencies to be achieved with current grant that has a CRC focus.

** PRC noted concerns about ensuring navigation for follow-up and treatment. Per RFA, access to follow-up and treatment must be ensured. PRC recommends grantee be expected to track all abnormalities; providing outcomes in routine reports.

Recommendations 7 through 11 were made by the PRC based on several factors including geographic distribution and cancer type.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS
From: KRISTEN DOYLE, INTERIM CHIEF COMPLIANCE OFFICER
Subject: COMPLIANCE CERTIFICATION – MAY 2015 AWARDS
Date: MAY 6, 2015

Summary and Recommendation:

As CPRIT's Interim 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 First-Time, Tenure-Track Faculty Members
- Recruitment of Established Investigators
- Core Facilities Support Awards
- High-Impact/High-Risk Research Awards
- Multi-Investigator Research Awards
- New Company Product Development Awards
- Established Company Product Development Awards
- Competitive Continuation/Expansion-Evidence-Based Prevention Services
- Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition
- Evidence-Based Prevention Services

I have conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grants administrator, regarding 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 the above mechanisms recommended by the Program Integration Committee (PIC), followed applicable laws and agency administrative rules. I note that the following mechanisms received applications; however, none were recommended by the review councils or considered by the PIC: Recruitment of Rising Stars, Cancer Prevention Promotion and Navigation to Clinical Services, and Company Relocation Product Development Awards. I certify the academic research, prevention, and product development 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." Tex 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 SRA employees and CPRIT employees. 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 SRA. 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's accountant 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 in pre-receipt stage cover the period beginning with CPRIT's issuance of the Request for Application (RFA) through the submission of grant applications. CPRIT's administrative rules require that RFAs be publicly posted in the *Texas Register*. The RFA specifies a deadline and mandates that only those applications submitted electronically through 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 request that the deadline be extended to allow for a late submission. The applicant's request is submitted to the CPRIT Helpdesk that is managed by SRA; the program officer considers any requests for extension and may approve an extension for good cause. When an extension 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:

I note that ten applications were received in response to the Recruitment of First-Time, Tenure Track Faculty members RFA. However, one application withdrew before review by the Scientific Review Council and a second application withdrew after recommendation by the SRC but before the PIC. I reviewed the application pedigrees for the nine recruitment applicants and 159 academic research, non-recruitment applications that underwent peer review. All academic research RFAs were posted in the Texas Register. All of the applicants registered through CARS and submitted applications by the deadline. No applicants requested an extension.

Product Development Research:

Nineteen applications were received in response to the New Company RFA and five applications were received in response to the Established Company RFA. Of the applications submitted for New Company awards, two applications were withdrawn. All applicants recommended for awards paid the application fee. The product development research RFAs were published in the Texas Register and applications submitted through CARS. Three applicants requested an extension to submit applications after the deadline. The program officer determined that good cause supported two requests and the deadline was extended for the two applications. Neither of the applications that received extensions were recommended for a grant award.

Prevention:

Sixteen applications were received in response the Evidence-Based Prevention Services RFA and five were received from the Evidence-Based Prevention Services-Colorectal Cancer Prevention Coalition. However, a total of two applications, one submitted for each mechanism, withdrew before review. The RFAs were published in the Texas Register and all applications were submitted through CARS. No applicants requested an extension.

Receipt, Referral, and Assignment Compliance:

Once applications have been submitted through CARS, SRA staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, SRA notifies the program officer and the program officer makes the final decision 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 to 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.

No preliminary evaluation process was used for any mechanisms recommended to the May 2015 Oversight Committee. Of the applications received in response to 15.2 prevention RFAs, two were administratively withdrawn. Two applications were withdrawn during the 15.1 product development cycle.

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 peer reviewer critiques and supporting documentation, such as the sign-out sheets 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 conflict of interest was declared for any recruitment application reviewed by the SRC.

Academic Research applications (non-recruitment) are reviewed by peer review panels and recommended to the Scientific Review Council. As documented by SRA, reviewers with conflicts of interest did not participate in review of those applications. I reviewed supporting documentation, such as sign out sheets

I also reviewed and confirmed that the post review conflict of interest statements were signed by peer review members as well as the six SRC members that attended the SRC meeting on April 13, 2015.

Product Development Research:

Product Development Research awards go through a peer review teleconference screening call to determine which applications will be invited to in-person 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 due diligence, which is conducted by outside contractors and outside intellectual property counsel. The Product Development Review Council recommends awards after due diligence to the PIC. I have verified from SRA documentation that those reviewers with conflicts for certain applications did not participate in review of applications they indicated a conflict of interest.

I confirmed that post review conflict of interest statements were signed by peer review members.

Prevention:

Prevention applications are reviewed by peer review panels and then sent to the Prevention Review Council. Reviewers with a conflict of interest with an application did not participate in review of that application, which is documented by SRA.

I confirmed that post review conflict of interest statements were signed by peer review members.

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.

For each program, I reviewed that the recommendations correspond to RFAs that have been released and that the pedigrees reflect the date of the review council meeting and that the applications were recommended by the corresponding review council.

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 panel and review council meeting. The third-party observer reports document that the panel and review council discussions were limited to the merits of the applications and established evaluation criteria and that conflicted reviewers exited the room or the conference call when the application was discussed.

Academic Research:

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the

panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Product Development Research:

For this cycle, eight applications went through due diligence. Due to time constraints to complete the due diligence, the Product Development Review Council elected to put four applications through due diligence, which was completed in December 2014. These applications were considered by the Oversight Committee at the February 2015 meeting. The remaining four applications went through due diligence review, which was completed in February and April 2015. The Product Development Review Council recommended three of those four applications to the PIC.

Prevention:

Some applications with more favorable or equivalent scores to applications that were recommended for awards did not move forward to the PIC. As allowed in 25 T.A.C § 703.6(d)(1), the Prevention Review Council'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. The Prevention Review Council's recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the Prevention Review Council's Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

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 5, 2015, PIC meeting as an observer and confirm that the PIC review process complied with CPRIT's statute and administrative rules. The PIC considered 43 applications; 42 were recommended to move forward to the Oversight Committee. One product development research award was not recommended by four of the five PIC members. The PIC member not voting with the majority has written a minority opinion to forward to the Oversight Committee as allowed in 25 T.A.C. § 703.7(e). A review of the CEO affidavits confirms that such affidavits were executed and provided for each Grant Application recommendation.

MEMORANDUM

TO: PROGRAM INTEGRATION COMMITTEE
FROM: REBECCA GARCIA, PH.D., CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT: PREVENTION GRANT RECOMMENDATIONS
DATE: APRIL 28, 2015

Summary and Recommendation:

The CPRIT Prevention Review Council has reviewed and recommends awarding 11 prevention projects totaling \$ 20,619,413. The grant recommendations are presented in 3 slates corresponding to the following grant mechanisms:

1. **Evidence-Based Cancer Prevention Services**— 4 grants; \$5,749,973
2. **Colorectal Cancer Prevention Coalition**—2 grants; \$7,388,774
3. **Competitive Continuation/Expansion Grants**—5 grants: \$7,480,666

Background:

Four RFAs were released September 25, 2014 and applications were due December 4, 2014. Thirty seven prevention grant applications were submitted in response to the following CPRIT RFAs:

- ***Evidence-Based Cancer Prevention Services*** – For projects that provide the delivery of evidence-based prevention services (e.g., screening, survivorship services). The maximum grant award is up to \$1.5 million for up to three years.
- ***Colorectal Cancer Prevention Coalition*** -- For projects that will deliver a comprehensive and integrated colorectal cancer screening project that includes provision of screening, diagnostic, and navigation services in conjunction with outreach and education of the target population through a coalition of partners. No funding cap, up to three years.
- ***Competitive Continuation/Expansion Grants*** – For projects that propose to continue or expand highly successful projects previously or currently funded by CPRIT. The award ranges from \$150,000 to \$1.5 million depending on the type of project proposed.
- ***Cancer Prevention Promotion and Navigation to Clinical Services*** –for projects that deliver public education and outreach and navigation to cancer screening and preventive services. Maximum of \$400,000; maximum duration of 36 months.

Two applications were administratively withdrawn and peer review of the remaining 35 applications was conducted in February and April.

By statute the Prevention Program funding is limited to no more than 10% of available funding which is approximately \$28 million per fiscal year.

Evidence-Based Cancer Prevention Services Slate

Recommended projects (4): \$5,749,973

Sixteen applications were submitted in this mechanism (one was withdrawn): 4 new evidence-based prevention services projects are recommended. Of the four, two address new topics not previously covered in our portfolio of grants -- screening for hepatitis C to prevent liver cancer and head and neck cancer survivor services. The other two new projects provide screening services for breast, cervical or colorectal cancer in underserved areas of the state.

PP150079	STOP HCC –Evidence-Based Hepatocellular Cancer Prevention Targeting Hepatitis C Virus Infection	The University of Texas Health Science Center at San Antonio
----------	---	--

STOP HCC will be implemented in 12 primary care clinics in a large safety-net health system in Dallas County and in 10 primary care clinics in 9 South Texas counties, treating mostly Hispanics. STOP HCC will offer in-person and web-based educational programs for professional and public audiences. 20,000 baby boomers will be screened for hepatitis C (HCV) and HCV+ persons will be educated to promote acceptance and compliance with anti-HCV treatment. Over 200 patients will be referred for treatment for HCV through STOP HCC. Patients found to have hepatocellular cancer (HCC) will be linked to treatment resources of their affiliated cancer centers.

PP150077	Media-Rich Mobile Dissemination of a Dysphagia Prevention Program for Head and Neck Cancer Patients during Radiation	The University of Texas M. D. Anderson Cancer Center
----------	--	--

Head and neck cancer patients who are treated at the Texas Health Care Otolaryngology & Facial Plastic Surgery Associates in Fort Worth would receive specialized speech pathology services. The services would provide speech pathology functional swallow evaluation pre- and post-treatment and targeted swallowing exercises to head and neck cancer patients during radiation. They would administer the 10-session weekly behavioral program via a mobile health technology application (GuideVue) to head and neck cancer patients during radiation.

PP150071	FluFIT on the Frontera: Increasing Colorectal Cancer Screening on the Texas-Mexico Border	Val Verde Regional Medical Center
----------	---	-----------------------------------

The FluFIT on the Frontera project will provide colorectal cancer (CRC) screening education and social support in colonias and clinics, free fecal immunochemical test (FIT) kits, and navigation to appropriate free and/or discounted follow-up colonoscopies for those with positive tests. The program will be conducted in conjunction with flu vaccination clinics during flu season and community events linked with health promotion initiatives throughout the year.

PP150078	Cada Paso del Camino: Outreach, Education, Screening, Health Insurance Navigation, and Linkage to Treatment for Breast, Cervical, and Colorectal Cancers	MHP, Inc. Promoviendo Vidas Saludables
----------	--	---

The proposed Cada Paso del Camino (Every Step of the Way) project is a comprehensive prevention strategy for breast, cervical, and colorectal cancers in the Valley. Through partnerships the project will provide promotor(a) outreach and education, screening, diagnostic testing, and referrals and assistance obtaining affordable treatment. The project will focus on reaching uninsured, underserved Hispanic residents in colonias surrounding the city of Harlingen, located in Cameron County.

Colorectal Cancer Prevention Coalition

Recommended projects (2): \$7,388,774

Five applications were received in response to this new colorectal cancer coalition RFA; one was administratively withdrawn and two are being recommended for funding.

PP150061	The C-SPAN Coalition: Colorectal Screening and Patient Navigation	The University of Texas Southwestern Medical Center
----------	---	---

The project will conduct a colorectal cancer screening program among age-eligible uninsured and underinsured not up to date with screening across 20 counties. The program will leverage established collaborative relationships and expand a coalition of county partners to provide services. Using centralized cancer screening platforms already established at UTSW-MCI, they will invite eligible patients to complete CRC screening using a home-based FIT test. They will evaluate patient response to FIT testing and navigate them to needed services.

PP150054	Alliance for Colorectal Cancer Testing (ACT) in Southeast Texas	The University of Texas M. D. Anderson Cancer Center
----------	---	--

A regional coalition framework coalition involving MD Anderson and community clinics will be used to implement the ACT screening program in federally qualified health centers (FQHCs) and community clinics. Practices will be encouraged to pair colorectal cancer (CRC) screenings with the annual flu shot (Flu FIT). They will partner with the American Cancer Society (ACS) to offer professional education and support material to assist primary care physicians in providing appropriate CRC screening recommendations and initiate policy and procedure changes in primary care clinics to increase adherence to CRC screening. The project will navigate patients with positive FIT results to colonoscopy in their communities and patients diagnosed with cancer to treatment.

Competitive Continuation/Expansion Grants

Recommended projects (5): \$7,480,666

This mechanism is intended to fund the continuation or expansion of currently or previously funded projects that have demonstrated exemplary success as evidenced by progress reports and project evaluations. Of the 10 applications submitted, 5 are being recommended for funding.

PP150053	BSPAN3: Breast Screening and Patient Navigation for Rural and Underserved Women across North Texas	The University of Texas Southwestern Medical Center
----------	--	---

The goals of this renewal and expansion project are to address the persistent need by further expanding breast screening and navigation services into Ellis, Navarro, and Grayson Counties over Year 1, while continuing to provide care to under- and uninsured women across the initial 17-county rural and underserved service area. In response to unexpectedly higher demand in the initial project, BSPAN3 outreach will place particular emphasis on meeting the needs of underserved Hispanic women in these rural communities. The project will improve screening access, increase timely clinical resolution and facilitate referral to local treatment services as needed.

PP150086	Access to Breast and Cervical Care for West Texas (West/Central Texas)(ABCC4WT)	Angelo State University
----------	---	-------------------------

The proposed program has an existing network of partnerships with collaborators for breast care; cervical cancer screening is being added. This project aims to expand community collaborative breast and cervical cancer prevention services in the ABCC4WT network in the 21-county region; increase the targeted women's use of prevention counseling and resources provided by the network; increase the breast and cervical cancer screening rate in the targeted population; and provide patient navigation or comprehensive counseling through the network.

PP150080	Empower Her To Care Expansion: Increasing Access to Breast Cancer Screening and the Continuum of Care for Underserved Texas Women	The Rose
----------	---	----------

The Empower Her to Care Expansion project will continue to increase the delivery of breast cancer screening, diagnostic procedures and patient navigation services to underserved women in 34 southeast Texas counties. The expansion effort will focus on serving ten additional counties over 24 months. Services will be provided through The Rose's digital Mobile Mammography Program through partnerships with established community clinics, physicians and other organizations that offer education/outreach efforts and clinical breast exams to recruit eligible women in need of screening. Diagnostic testing, coordinated care and access to breast cancer treatment will be provided at either of The Rose's two locations.

PP150064	University Health System Evidence-Based Colorectal Cancer Prevention Screening Program	University Health System
----------	--	--------------------------

The project plans to expand to include female patients. Cultural barriers, along with financial, transportation and social concerns prevent our targeted population from obtaining CRC screening services. To overcome these barriers they propose a three-tiered screening services program. Depending on eligibility, they will offer services that will include navigation, scheduling, follow-up, transportation and home visits and procedure preparation instructions. Follow up services and results reporting will also be provided.

PP150089	Increasing Breast and Cervical Cancer Screening and Diagnostic Rates in Rural, Frontier, and Border Counties for Uninsured, Underserved Women	Texas AgriLife Extension Service
----------	---	----------------------------------

Increasing access to breast and cervical screening and diagnostic services is a significant need in rural, frontier, and border Texas counties for uninsured and underserved women. Uninsured and underserved women in 50 frontier, rural and border counties will be recruited and offered education at a Friend to Friend (FTF) event. Twenty-eight are new counties. Navigators assist with finding a provider, making an appointment, transportation to screening and diagnostic services. If cancer is found, women are offered assistance with finding treatment and financial support.

Cancer Prevention Promotion and Navigation to Clinical Services

Six applications were submitted to this mechanism; none are being recommended for funding.

Conflicts of Interest for Prevention Cycle 15.2 Applications
(Prevention Cycle 15.2 Awards Announced at May 20, 2015, 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 15.2 include *Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition*; *Evidence-Based Cancer Prevention Services*; *Cancer Prevention Promotion and Navigation to Clinical Services*, and *Competitive Continuation/Expansion-Evidence-Based Cancer Prevention Services*. 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
PP150054	Foxhall, Lewis	The University of Texas M.D. Anderson Cancer Center	Brownson, Ross; Mahoney, Martin; Cole, Kirk; Mitchell, Amy
PP150078	Arjona, Moises	MHP, Inc. Promoviendo Vidas Saludables	Cole, Kirk
PP150053	Lee, Simon Craddock	The University of Texas Southwestern Medical Center	Mitchell, Amy
PP150061	Argenbright, Keith E	The University of Texas Southwestern Medical Center	Mitchell, Amy
PP150064	Villarreal, Roberto	University Health System	Mitchell, Amy
PP150071	Larson, Adrian F	Val Verde Regional Medical Center	Mitchell, Amy
PP150077	Shinn, Eileen	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
PP150079	Turner, Barbara J	The University of Texas Health Science Center at San Antonio	Mitchell, Amy; Mulrow, Cynthia
PP150086	Ross, Linda	Angelo State University	Mitchell, Amy
PP150089	Rice, Carol A	Texas Agrilife Extension Service	Mitchell, Amy

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
Applications Not Recommended for PIC or Oversight Committee Consideration			
PP150096*	Wiechnicki, Katherine	Texas Department of State Health Services	Mahoney, Martin; Momrow, David

* = Not discussed



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 2
*Competitive Continuation/Expansion-Evidence-Based
Cancer Prevention Services*

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA P-15-CCE-2

Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services

**Please also refer to the “Instructions for Applicants” document, which will be
posted September 25, 2014**

Application Receipt Opening Date: September 25, 2014

Application Receipt Closing Date: December 4, 2014

FY 2015

Fiscal Year Award Period

September 1, 2014–August 31, 2015

TABLE OF CONTENTS

1. ABOUT CPRIT	4
2. FUNDING OPPORTUNITY DESCRIPTION	4
2.1. SUMMARY	4
2.2. PROGRAM OBJECTIVES	5
2.3. AWARD DESCRIPTION	5
2.3.1. <i>Priority Areas</i>	7
2.3.2. <i>Specific Areas of Emphasis</i>	8
2.3.3. <i>Outcome Metrics</i>	10
2.4. ELIGIBILITY	12
2.4.1 <i>Resubmission Policy</i>	14
2.5. FUNDING INFORMATION.....	14
3. KEY DATES.....	15
4. APPLICATION SUBMISSION GUIDELINES	15
4.1. SUBMISSION DEADLINE EXTENSION	15
4.2. APPLICATION COMPONENTS	16
4.2.1. <i>Abstract and Significance (5,000 characters)</i>	16
4.2.2. <i>Goals and Objectives (download template)</i>	17
4.2.3. <i>Project Timeline</i>	17
4.2.4. <i>Project Plan (15 pages maximum; fewer pages permissible)</i>	17
4.2.5. <i>People Reached (complete online)</i>	20
4.2.6. <i>People Served (complete online)</i>	20
4.2.7. <i>References</i>	20
4.2.8. <i>CPRIT Grants Summary (download template)</i>	20
4.2.9. <i>Budget and Justification (complete online)</i>	20
4.2.10. <i>Current and Pending Support and Sources of Funding (download template)</i>	21
4.2.11. <i>Biographical Sketches (download template)</i>	22
4.2.12. <i>Collaborating Organizations (complete online)</i>	22
4.2.13. <i>Letters of Commitment</i>	22
5. APPLICATION REVIEW.....	22
5.1. REVIEW PROCESS OVERVIEW	22
5.2. REVIEW CRITERIA.....	24
5.2.1. <i>Primary Evaluation Criteria</i>	24
5.2.2. <i>Secondary Evaluation Criteria</i>	26
6. AWARD ADMINISTRATION.....	27
7. CONTACT INFORMATION.....	28
7.1. HELPDESK	28
7.2. PROGRAM QUESTIONS	28
8. RESOURCES	28
9. REFERENCES.....	29
10. APPENDIX: KEY TERMS.....	29

RFA VERSION HISTORY

Rev 9/25/14 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 \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- 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.

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 will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based projects relevant to prevention through risk reduction, early detection, and survivorship.

This **Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services (CCE-EBP)** request for applications (RFA) solicits applications seeking to continue or expand projects previously or currently funded under the Evidence-Based Cancer Prevention Services mechanism. **This award mechanism is open only to previously or currently funded CPRIT Prevention projects.**

The proposed projects must continue to provide evidence-based interventions in primary, secondary, and/or tertiary cancer prevention and control. The proposed program should be designed to reach and serve as many people as possible. 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.

Applicants wanting to continue or expand previously or currently funded projects focused on public education should submit applications to the Cancer Prevention Promotion and Navigation to Clinical Services (PN) mechanism.

2.2. Program Objectives

CPRIT seeks to fund evidence-based prevention and survivorship services that will:

- Address multiple components of the cancer prevention and control continuum (e.g., provision of screening and navigation services in conjunction with outreach and education of the target population as well as healthcare provider education);
- 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;
- Offer systems and/or policy changes that are sustainable over time;
- Provide tailored, culturally appropriate outreach and accurate information on early detection, prevention, and survivorship to the public and/or healthcare professionals that result in a health impact that can be measured; and/or
- Deliver evidence-based survivorship services aimed at reducing the morbidity associated with cancer diagnosis and treatment.

2.3. Award Description

CPRIT's **Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services** grants are intended to fund continuation or expansion of currently or previously funded projects that have demonstrated exemplary success, as evidenced by progress reports and project evaluations, and desire to further enhance their impact on target populations. Detailed descriptions of **results, barriers, outcomes, and impact of the currently or previously funded project are required** (see outline of Project Plan, [Section 4.2.4](#)).

The projects proposed under this mechanism should NOT be new projects but should closely follow the intent and core elements of the currently or previously funded project. Established infrastructure/processes and fully described prior project results are required.

Improvements and expansion (e.g., new geographic area, additional services, new populations) are strongly encouraged but will require justification. Expansion of current projects into geographic areas not well served by the CPRIT portfolio (see maps at <http://www.cprit.state.tx.us/prevention/cprit-portfolio-maps/>), especially rural areas or subpopulations of urban areas that are not currently being served, will receive priority consideration. CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area). It is expected that baselines will have already been established and that continued improvement over baseline is demonstrated in the current application. However, in the case of a proposed expansion where no baseline data exist for the target population, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish a baseline. Applicants must demonstrate how these outcomes will ultimately impact cancer incidence, mortality, morbidity, or quality of life.

CPRIT also expects that applications for continuation or expansion **will not** require startup time, that applicants can demonstrate that they have overcome barriers encountered, and that applicants have identified **lasting systems changes** that improve results, efficiency, and sustainability. Leveraging of resources and plans for dissemination are expected and should be well described.

CPRIT requires applicants to deliver evidence-based interventions in at least one of the following clinical services areas (see [Section 2.3.2](#) for areas of emphasis):

- Delivery of vaccines that reduce the risk of cancer
- Evidence-based assessment and counseling services for behaviors established as increasing cancer risk
- Screening and early detection services
- Survivorship services

CPRIT considers counseling services (e.g., tobacco cessation, survivorship, exercise, and nutrition) as clinical services when provided on an individual basis or in small groups.

Applicants are **required** to conceptualize comprehensive projects **or provide a continuum of services** that would increase desired outcomes. This mechanism **will fund** case management/patient navigation if it is paired with the actual delivery of a clinical service.

Applicants offering screening services must ensure that there is access to treatment services for patients with cancers that are detected as a result of the program and describe plans to provide access to treatment services. CPRIT strongly encourages projects to include broad-based education on cancer risk reduction and health lifestyle as one component of the education curriculum. Applicants offering survivorship services should include an individual needs assessment in addition to the clinical service.

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

- **Continuation or expansion of projects originally funded under the Health Behavior Change through Public and/or Professional Education mechanisms**
- **Projects focusing on case management/patient navigation services through the treatment phase of cancer**
- **Projects utilizing State Quitline services.** Applicants proposing the utilization of Quitline services should communicate with the Tobacco Prevention and Control program prior to submitting a CPRIT grant application to discuss the services currently offered by the Texas Department of State Health Services (DSHS).
- **Resources for the treatment of cancer**
- **Prevention/intervention research.** Applicants interested in prevention research should review CPRIT's research RFAs (available at <http://www.cprit.state.tx.us>.)

2.3.1. Priority Areas

Types of Cancer: Applications addressing any cancer type(s) for which there is strong evidence of effectiveness and that are responsive to this RFA will be considered for funding.

Target Populations: The age of the target population and frequency of screening plans for provision of clinical services described in the application must comply with established and current national guidelines (e.g., U.S. Preventive Services Task Force, American Cancer Society).

Priority populations are subgroups that are disproportionately affected by cancer. Priority populations include, but are not limited to, the following:

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations

- Medically unserved or underserved populations
- Populations with low health literacy skills
- Geographic regions of the State with higher prevalence of cancer risk factors (e.g., obesity, tobacco use, alcohol misuse, unhealthy eating, sedentary lifestyle)
- Racial, ethnic, and cultural minority populations
- Any other 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).

Geographic and Population Balance Priority: For applications submitted in response to this announcement, 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 <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control> and <http://www.cprit.state.tx.us/funded-grants>).

2.3.2. Specific Areas of Emphasis

A. Primary Preventive Services

Priority will be given to projects that, through evidence-based efforts, address and can positively influence **local policy or systems change** that can lead to **sustainable change in desired health behaviors**.

Tobacco Prevention and Control

CPRIT is interested in applications focused on areas of the State

- That have higher smoking rates per capita than other areas of the State
- Where funds for tobacco use control efforts are not readily accessible from other sources

HPV Vaccination

CPRIT is interested in applications to increase access to and delivery of the HPV vaccine regimen through evidence-based intervention efforts.¹

B. Screening and Early Detection Services

Priority will be given to projects for screening and early detection of colorectal, breast, and cervical cancers.

Colorectal Cancer

- Increasing screening/detection rates in North and East Texas. The highest rates of cancer incidence and mortality are found in East and North Texas.²
- Decreasing disparities in incidence and mortality rates of colorectal cancer for racial/ethnic populations and rural communities (African Americans have the highest incidence and mortality rates, followed by non-Hispanic Whites and Hispanics).²
- Decreasing incidence and mortality rates in rural counties. Incidence and mortality rates are higher in rural counties compared with urban counties.²

Breast Cancer

- Increasing screening/detection rates in rural and medically underserved areas of the State
- Reaching women never before screened or who have not been screened in the last 5 years, if addressing breast cancer in urban areas

Cervical Cancer

- Increasing screening/detection rates for women in Texas-Mexico border counties. Women in these counties have a 31-percent higher cervical cancer mortality rate than women in nonborder counties.²
- Decreasing disparities in racial/ethnic populations. Hispanics have the highest incidence rates while African Americans have the highest mortality rates.²
- Increasing access to and delivery of the HPV vaccine¹

C. Survivorship Services

Priority for funding will be given to survivorship service projects that demonstrate a likelihood of success based on available evidence and can demonstrate and measure an improvement in quality of life in one or more of the following areas:

- Preventing secondary cancers and recurrence of cancer

- Managing the after effects of cancer and treatment to maximize quality of life and number of years of healthy life
- Minimizing preventable pain, disability, and psychosocial distress

2.3.3. Outcome Metrics

The applicant is required to describe the results (quantitative and qualitative) of the currently or previously funded project and the proposed outcome measures/metrics for the current application. Interim measures that are associated with the final outcome measures should be identified and will serve as a measure of program effectiveness and public health impact.

Applicants are required to clearly describe their assessment and evaluation methodology and to provide results and baseline data from currently or previously funded projects. Applicants should describe how funds from the proposed CPRIT grant will improve and expand outcomes from the initial project and how the current application builds on the previous work or addresses new areas of cancer prevention and control services. 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 output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

- Quarterly progress report sections include, but are not limited to:
 - Narrative on project progress (required)
 - People reached activities
 - Services, other than clinical services, provided to the public/professionals
 - Actions taken by people/professionals as a result of education or training, including percentage of people reporting sustained behavior change
 - Clinical services provided
 - Abnormal results and precursors or cancers detected
- Annual and Final progress report sections include, but are not limited to:
 - Key accomplishments, including qualitative analysis of policy change and/or lasting systems change

- Progress against goals and objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible men and women in a defined service area, for example:
 - Percentage increase over baseline in number of people served
 - Percentage increase over baseline in number of services provided
 - Completion of all required doses of vaccine
 - Number of people quitting tobacco use and sustaining healthy behavior
 - Percentage increase over baseline in cancers detected
 - Percentage increase in early-stage cancer diagnoses in a defined service area
- Materials produced and publications
- Economic impact of the project

Outcome measures/metrics (as appropriate for each project) should be reported in the annual and final reports and should include, **but are not limited to**, the following:

For Primary Preventive Services

- Percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible men and women in a defined service area
- Percentage of people reporting sustained behavior change
- Estimates of cancers prevented as a result of primary preventive services

For Screening Services

- Percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible men and women in target populations
- Percentage increase over baseline in early-stage cancer diagnoses in a defined service area

For Survivorship Services

- Percentage increase over baseline in provision of survivorship services in a defined service area
- Percentage increase over baseline in improvement in quality-of-life measures using a validated quality-of-life instrument, if such an instrument is applicable to the project

- Percentage of people reporting sustained behavior change
- Percentage of people showing clinical improvement of cancer treatment sequelae

Systems Change (for all projects)

- Qualitative analysis of policy or systems change
- Description of lasting, sustainable system changes

2.4. Eligibility

- The applicant must be a Texas-based entity that previously received CPRIT funding through Prevention Program RFAs.
- The designated Program Director (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 (e.g., qualitative or quantitative statistics) and who resides in Texas during the time that the project is conducted.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted.
- 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, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant may submit more than one continuation application, if eligible, 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. Applicants may submit a continuation application before the end of the currently funded project but should time their submission for continuation 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 continuation/expansion project. To apply for an expansion of a current project, projects must have at least one full year of results and data.

- If the applicant or a partner is an existing 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 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, and any officer or director of the grant applicant's organization, (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have 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 at <http://www.cprit.state.tx.us>.

2.4.1 Resubmission Policy

More than **one resubmission** is not 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.

2.5. Funding Information

Applicants may request any amount of funding up to a maximum of \$1.5 million in total funding over a maximum of 36 months.

The following estimates may be used as a general guide:

- Primary prevention services only: \$300,000 to \$500,000
- Screening and early detection services, including clinical services: Up to \$1.5 million (projects requesting the maximum should provide comprehensive services, demonstrate broad-based community collaboration, and serve as many people as possible)
- Survivorship services only: \$300,000 to \$500,000

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). 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 two 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.

3. KEY DATES

RFA

RFA release September 25, 2014

Application

Online application opens September 25, 2014, 7 A.M. Central Time

Application due December 4, 2014, 3 P.M. Central Time

Application review February 2015

Award

Award notification May 2015

Anticipated start date June 2015

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

4. 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 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 Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 A.M. Central Time on September 25, 2014, and must be submitted by 3 P.M. Central Time on December 4, 2014. 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.**

4.1. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail

to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.2. Application Components

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

4.2.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed and 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 upon review of this statement.

The required 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 target 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 targeted population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) to be reached and people (public and/or professionals) to be served.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.2.2. Goals and Objectives (download template)

Goals and objectives must be completed for the initial funded project and for the proposed continuation/expansion project. Enter the goals and objectives for the initial funded project in the Goals and Objectives template form. Enter the goals and objectives for the proposed continuation/expansion project in the CARS text fields. List specific goals and **measurable** objectives for each year of the project. Baseline and results for the initial funded project and baseline and method(s) of measurement for the proposed continuation/expansion project are required. Applicants must explain plans to establish baseline and describe method(s) of measurement in cases where it has not been defined.

4.2.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates.

4.2.4. Project Plan (15 pages maximum; fewer pages permissible)

The required Project Plan format follows. Applicants must include the components in the order presented below: Introduction, Project Components, Organizational Capacity and Sustainability, Dissemination/Adaptation (Table 1). The project plan must include information for both the initial funded project and the proposed continuation/expansion project.

The format of the Project Plan does not have to be a table. Information may be presented by project: The format may be initial funded project (describe the four components) followed by proposed continuation/expansion project (describe the four components). Alternatively, information may be presented by component: The format may be component 1 (describe the initial project, describe the proposed continuation/expansion project, etc.). Each section must be clearly labeled and formatted.

Table 2. Project Plan Components

PROJECT PLAN COMPONENTS	
INITIAL PROJECT	PROPOSED CONTINUATION/EXPANSION PROJECT
SECTION I: Introduction Provide the anticipated end date of the initial project. Describe the evidence-based intervention. If applicable, describe how it was adapted for the target population. Provide a summary paragraph describing the initial funded project, including the purpose, goals, outcomes, and obstacles of the project. Goals and Objectives will be completed separately in CARS and need not be provided in the project plan (Section 4.2.2). However, if desired, goals and objectives may be fully repeated or briefly summarized here.	SECTION I: Introduction Present the rationale for the project continuation/expansion and describe how results will be improved and/or expanded over the initial project. Goals and Objectives will be completed separately in CARS and need not be provided in the project plan (Section 4.2.2). However, if desired, goals and objectives may be fully repeated or briefly summarized here.
SECTION II: Project Components Briefly describe each of the following components of the initial project:	SECTION II: Project Components Briefly describe each of the following components of the proposed project:
Target population	Target population
Geographic region served Number and type of each clinical, education and navigation service delivered (see Appendix for definition)	Geographic region served Number and type of each clinical, education and navigation service proposed (see Appendix for definition)
Roles of key collaborators on the project	Roles of key collaborators on the project
Procedures that ensured access to treatment or preventive services	Procedures that ensure access to treatment or preventive services
Major system changes implemented during or as a result of project	Planned systems changes to be implemented during or as a result of project
Summary of key challenges or barriers encountered and strategies used to overcome them	Description of the impact on ultimate outcome measures (e.g., reduction of cancer incidence, mortality, and morbidity) and interim outcome measures (e.g., increase in the proportion of individuals receiving cancer screening, increase in the number of individuals demonstrating personal health behavior change); description of the plan for project evaluation and outcome measurements, including data collection and management methods, statistical analyses, and anticipated results

PROJECT PLAN COMPONENTS	
INITIAL PROJECT	PROPOSED CONTINUATION/EXPANSION PROJECT
SECTION III: Sustainability <p>Describe ongoing efforts toward sustainability. Elements contributing to organizational project sustainability may include some or all of the following:</p> <ul style="list-style-type: none"> • Developing ownership, administrative networks, and formal engagements with stakeholders • Enhancing system capacity and developing processes for each practice/location to incorporate services into its structure beyond project funding • Identifying and training of diverse resources (human, financial, material, and technological) 	SECTION III: Organizational Capacity and Sustainability <p>Describe the organization and its track record for providing services. Include information on the organization's financial stability and viability. A sustainability plan describing the continuation of the proposed intervention after CPRIT funding has ended must be included. Elements contributing to organizational project sustainability may include some or all of the following:</p> <ul style="list-style-type: none"> • Developing ownership, administrative networks, and formal engagements with stakeholders • Enhancing system capacity and developing processes for each practice/location to incorporate services into its structure beyond project funding • Identifying and training of diverse resources (human, financial, material, and technological) <p>If the PD/key staff of the proposed project differ from the initial project, provide an explanation for the change(s) and impact, if any, on the project.</p>
SECTION IV: Dissemination <p>Describe any dissemination of project results to date. Describe how the project lends itself to further dissemination and adaptation to other communities.</p>	SECTION IV: Dissemination/Adaptation <p>Describe how the project lends itself to further dissemination and adaptation to other communities and/or organizations or expansion in the same communities. Describe plans for dissemination of project results. Dissemination of positive and negative project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts.</p>

4.2.5. People Reached (complete online)

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 noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to the [Appendix](#) for definitions.

4.2.6. People Served (complete online)

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

4.2.7. 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.

4.2.8. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of any CPRIT-funded projects of the PD or Co-PD, except for the initial funded project that is the basis for this CCE application, regardless of their connection to this application. Progress for the initial project will be detailed in the Goals and Objectives template form (see [Section 4.2.2](#)) and need not be repeated here. Applications that are missing this document and have a PD and/or Co-PD with previous or current CPRIT funds will be administratively withdrawn prior to peer review.

4.2.9. Budget and Justification (complete online)

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, education and outreach 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 2.5](#) will be administratively withdrawn.

- **Cost per Person Served:** The cost per person served will be automatically calculated from the total cost of the project divided by the total number of people (both public and professionals) served (refer to the [Appendix](#)).
- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to two 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.
- **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 target 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.
 - **Indirect Costs:** It is CPRIT's policy **not** to allow recovery of indirect costs for prevention programs.
 - **Costs Not Related to Cancer Prevention and Control:** CPRIT does not allow recovery of any costs for services not related to cancer (e.g., health physicals, HIV testing).

4.2.10. Current and Pending Support and Sources of Funding (download template)

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. Information for the initial funded project need not be included.

4.2.11. Biographical Sketches (download template)

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.

The evaluation professional must provide a biographical sketch.

Up to three additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

4.2.12. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide one or more components essential to the success of the program (e.g., evaluation, clinical services, recruitment to screening, etc.).

4.2.13. Letters of Commitment

Applicants should provide letters of commitment and/or memorandums of understanding from community organizations, key faculty, or any other component essential to the success of the program.

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

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed using a two-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 one 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 the Prevention 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 703.6–703.8.

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 Committee is comprised of 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 pre-applications 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? Will the proposed outcomes have a significant impact on cancer incidence, morbidity, and/or mortality?
- Will the project reach and serve an appropriate number of people based on the budget allocated to providing services and the cost of providing services?
- Does the proposed continuation/expansion project build on its initial results (baseline) and continue to demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it go beyond the initial project to address what the applicant has learned or explore new partnerships, new audiences, or improvements to systems?

- Does the program address known gaps in prevention services and avoid duplication of effort?

Previous Project Performance

- Does the proposed continuation project demonstrate a high likelihood of success based on the initial project's results and outcomes?
- Has the applicant sufficiently described results and findings of the currently or previously funded application?

Project Strategy and Feasibility

- Does the proposed project provide prevention interventions or services specified in the RFA?
- Are the overall program approach, strategy, and design clearly described and supported by established theory and practice? Are the base of evidence and any necessary adaptations clearly defined and referenced?
- 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?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the target population and culturally appropriate methods to reach the target 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 listed for both the initial project and the proposed continuation project? Does the applicant provide the baseline and results or method(s) of measurement?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?

- Does the application provide a clear and appropriate plan for data collection and management, statistical analyses, and interpretation of results to follow, measure, and report on the project's outcomes?
- If an evidence-based intervention is being adapted in a population where it has not been tried/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 Capacity

- 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 implement, evaluate, and complete the project? Is the appropriate infrastructure already in place?
- Does the applicant provide evidence of compelling project progress of the already-funded project? If not, has the applicant addressed obstacles and strategies to overcome those obstacles?

Sustainability

- Is the organization structurally and financially stable and viable?
- Are there feasible plans to sustain some or all of the project beyond the funded timeframe of this award?
- Are there feasible plans to integrate the program into existing and sustainable systems?

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 Scalability (Expansion)

- Are plans for dissemination of the project's results and outcomes, including barriers encountered and successes achieved, clearly described?
- Does the applicant clearly describe how the project lends itself to dissemination to or adaptation and application by other communities and/or organizations in the State or expansion in the same communities?

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, which are available at <http://www.cprit.state.tx.us>. Applicants are advised to review CPRIT's Administrative Rules regarding 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. 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 e-mail 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 by September 25, 2014), which provides a step-by-step guide to using CARS.

Dates of operation: September 25, 2014, to December 4, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 A.M. to 4 P.M. Central Time
Wednesday, 8 A.M. to 4 P.M. Central Time

Tel: 866-941-7146

E-mail: 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: 512-305-8422

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

8. RESOURCES

- The Texas Cancer Registry: <http://www.dshs.state.tx.us/tcr>
- The Community Guide <http://www.thecommunityguide.org/index.html>
- 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/>
- 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
- Moore DE. *A Framework for Outcomes Evaluation in the Continuing Professional Development of Physicians*. In: Davis D, Barnes BE, Fox R, eds. *The Continuing Professional Development of Physicians: From Research to Practice*. Chicago, Ill: American Medical Association; 2003.
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>.
- Brownson, RC, Colditz GA, and Proctor, EK (Editors), *Dissemination and Implementation Research in Health: Translating Science to Practice*. Oxford University Press, March 2012.

9. REFERENCES

1. <http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm>
2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services: <http://www.dshs.state.tx.us/tcr/default.shtm>

10. APPENDIX: KEY TERMS

- **Activities:** A listing of the “who, what, when, where, and how” for each objective that will be accomplished.
- **Clinical Services** – Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a healthcare practitioner in an office, clinic, or healthcare 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.

- **Education Services** – Number of evidence-based, culturally appropriate cancer prevention and control education and outreach services delivered to the public and to healthcare professionals. Examples include education or training sessions (group or individual), focus groups, and knowledge assessments.
- **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 <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.
- **Goals:** Broad statements of general purpose to guide planning. Goals should be few in number and focus on aspects of highest importance to the project.
- **Navigation Services** – Number of unique activities/services that offer assistance to help overcome healthcare system barriers in a timely and informative manner and facilitate cancer screening and diagnosis to improve healthcare access and outcomes. Examples include patient reminders, transportation assistance, and appointment scheduling assistance.
- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outputs and outcomes. Example: “Increase screening service provision in X population from Y percent to Z percent by 20xx.” Baseline data for the target population must be included as part of each objective.
- **People Reached:** Number of members of the public and/or professionals reached via 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.

- **People Served:** Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service delivery, or clinical service delivery, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. 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 (e.g., X people screened for cervical cancer after referral to Y indigent care program as a result of CPRIT-funded navigation services performed by the project).

Third Party Observer Reports

CPRIT Prevention Peer Review Panel Observation Report

Report #2015-215

Panel Name: FY15 Prevention Peer Review 1

Panel Date: February 23-24, 2015

Report Date: February 25, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is Prevention Peer Review Panel 1 review of prevention program applications. The meeting was chaired by Ross Brownson and held in person at the Hyatt Regency in downtown Dallas, TX on February 23-24, 2015.

Panel Observation Objectives and Scope

This third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- Peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Prevention Peer Review meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Ross Brownson on February 23 and February 24, 2015.

The independent observer noted the following during our observation:

- Fourteen prevention applications were discussed and evaluated by the Prevention Peer Review Panel 1 to determine which grants would receive CPRIT funding.
- Eight panel members, two advocate reviewers, three CPRIT staff members, and five SRA employees were present for the peer review meeting.
- No conflicts of interest were identified prior to or during the meeting.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Peer Review Panel Observation Report

Report #2015-216

Panel Name: FY15 Prevention Peer Review Panel 2

Panel Date: February 24-25, 2015

Report Date: February 25, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is Prevention Peer Review Panel 2 review of prevention program applications. The meeting was chaired by Nancy Lee and held in person at the Hyatt Regency in downtown Dallas, TX on February 24 and February 25, 2015.

Panel Observation Objectives and Scope

This third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- Peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Prevention Peer Review meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Nancy Lee on February 24 and February 25, 2015.

The independent observer noted the following during our observation:

- Fourteen prevention applications were discussed and evaluated by the Prevention Peer Review Panel 2 to determine which grants would receive CPRIT funding.
- Eight panel members, three CPRIT staff members, one Oversight Committee member, and four SRA employees were present for the panel meeting.

- Four conflict of interest were identified prior to or during the meeting. Only one of the four applications with conflicts of interest were discussed. The reviewer with the conflict of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Review Council Observation Report

Report #2015-227

Panel Name: FY15.2 Prevention Review Council
Programmatic Review

Panel Date: April 17, 2015

Report Date: April 22, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council Programmatic Review Meeting for FY15 funding. The meeting was chaired by Stephen Wyatt and held via teleconference on April 17, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Prevention Review Council meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Stephen Wyatt on April 17, 2015.

The independent observer noted the following during our observation:

- Fourteen applications were discussed within the Prevention Review Council Programmatic Review Meeting to determine which grants would receive CPRIT funding.
- Three council members, two CPRIT staff members, and two SRA employees were present for the meeting.

- One conflict of interest was identified prior to or during the meeting. The reviewer with the conflict of interest did not participate in the ranking of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the Council's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 15.2 Applications
(Prevention Cycle 15.2 Awards Announced at May 20, 2015, 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 15.2 include *Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition*; *Evidence-Based Cancer Prevention Services*; *Cancer Prevention Promotion and Navigation to Clinical Services*, and *Competitive Continuation/Expansion-Evidence-Based Cancer Prevention Services*. 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
PP150054	Foxhall, Lewis	The University of Texas M.D. Anderson Cancer Center	Brownson, Ross; Mahoney, Martin; Cole, Kirk
PP150078	Arjona, Moises	MHP, Inc. Promoviendo Vidas Saludables	Cole, Kirk
Applications Not Recommended for PIC or Oversight Committee Consideration			
PP150096*	Wiechnicki, Katherine	Texas Department of State Health Services	Mahoney, Martin; Momrow, David

* = Not discussed

De-Identified Overall Evaluation Scores

Competitive Continuation/Expansion-Evidence-Based Cancer Prevention Services

Prevention Cycle 15.2

Application ID	Final Overall Evaluation Score
PP150053*	2.9
LA	3.7
PP150086*	3.9
PP150080*	4.1
PP150064*	4.5
PP150089*	4.7
LB	4.8
LC	4.9
LD	5.0
LE	5.5

*=Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

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

Dear Mr. Roberts and Dr. Rice,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list submitted proposals in response to CPRIT requests for applications (RFA) released for the second review cycle of FY2015. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals, in addition to the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants. However, the PRC did recommend a change to the funding amount for PP150061, proposing a reduction in funding from the requested \$5.393 million to \$4.8 million. This reduction is proposed based upon this being the initial "coalition RFA" award and due to likely efficiencies to be achieved with a current CPRIT Prevention grant to Dr. Argenbright.

The funding available for this cycle is \$20,668,032; the PRC is recommending awards totaling \$20,619,413. 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 also considered 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. Although the Oversight Committee's program priorities were not adopted at the time these RFAs were released, all the recommended grants address one or more of the new Prevention Program priorities.

Sincerely,

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

App ID	Mech.	Application Title	PD	Organization	Total Funding request	Score	Rank Order Score
PP150061	EBP-CRC	The C-SPAN Coalition: Colorectal Screening and Patient Navigation	Argenbright, Keith E	The University of Texas Southwestern Medical Center	5,393,275	2.3	1
PP150079	EBP	STOP HCC –Evidence-Based Hepatocellular Cancer Prevention Targeting Hepatitis C Virus Infection	Turner, Barbara J	The University of Texas Health Science Center at San Antonio	1,488,294	2.3	2
PP150071	EBP	FluFIT on the Frontera: Increasing Colorectal Cancer Screening on the Texas-Mexico Border	Larson, Adrian F	Val Verde Regional Medical Center	1,500,000	2.6	3
PP150053	CCE-EBP	BSPAN3: Breast Screening and Patient Navigation for Rural and Underserved Women across North Texas	Lee, Simon Craddock	The University of Texas Southwestern Medical Center	1,499,993	2.9	4
PP150054	EBP-CRC	Alliance for Colorectal Cancer Testing (ACT) in Southeast Texas	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	2,588,774	2.9	4 (rank ordered without Dr. Brownson)
PP150077	EBP	Media-Rich Mobile Dissemination of a Dysphagia Prevention Program for Head and Neck Cancer Patients during Radiation	Shinn, Eileen	The University of Texas M. D. Anderson Cancer Center	1,263,342	2.9	6

PP150086	CCE-EBP	Access to Breast and Cervical Care for West Texas (West/Central Texas)(ABCC4WT)	Ross, Linda	Angelo State University	1,480,898	3.9	7
PP150080	CCE-EBP	Empower Her To Care Expansion: Increasing Access to Breast Cancer Screening and the Continuum of Care for Underserved Texas Women	Joseph, Bernice	The Rose	1,500,000	4.1	8
PP150078	EBP	Cada Paso del Camino: Outreach, Education, Screening, Health Insurance Navigation, and Linkage to Treatment for Breast, Cervical, and Colorectal Cancers	Arjona, Moises	MHP, Inc. Promoviendo Vidas Saludables	1,498,337	4.5	9
PP150064	CCE-EBP	University Health System Evidence-Based Colorectal Cancer Prevention Screening Program	Villarreal, Roberto	University Health System	1,499,775	4.5	10
PP150089	CCE-EBP	Increasing Breast and Cervical Cancer Screening and Diagnostic Rates in Rural, Frontier, and Border Counties for Uninsured, Underserved Women	Rice, Carol A	Texas AgriLife Extension Service	1,500,000	4.7	11



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 2
Evidence-Based Cancer Prevention Services

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA P-15-EBP-2

Evidence-Based Cancer Prevention Services

**Please also refer to the “Instructions for Applicants” document, which will be
posted September 25, 2014**

Application Receipt Opening Date: September 25, 2014

Application Receipt Closing Date: December 4, 2014

FY 2015

Fiscal Year Award Period

September 1, 2014–August 31, 2015

TABLE OF CONTENTS

1. ABOUT CPRIT	4
2. FUNDING OPPORTUNITY DESCRIPTION	4
2.1. SUMMARY	4
2.2. PROGRAM OBJECTIVES	5
2.3. AWARD DESCRIPTION	5
2.3.1. <i>Priority Areas</i>	7
2.3.2. <i>Specific Areas of Emphasis</i>	8
2.3.3. <i>Outcome Metrics</i>	10
2.4. ELIGIBILITY	11
2.4.1. <i>Resubmission Policy</i>	13
2.5. FUNDING INFORMATION.....	13
3. KEY DATES.....	14
4. APPLICATION SUBMISSION GUIDELINES	14
4.1. SUBMISSION DEADLINE EXTENSION	14
4.2. APPLICATION COMPONENTS	15
4.2.1. <i>Abstract and Significance (5,000 characters)</i>	15
4.2.2. <i>Goals and Objectives</i>	16
4.2.3. <i>Project Timeline</i>	16
4.2.4. <i>Project Plan (15 pages maximum; fewer pages permissible)</i>	16
4.2.5. <i>People Reached (complete online)</i>	18
4.2.6. <i>People Served (complete online)</i>	18
4.2.7. <i>References</i>	18
4.2.8. <i>Resubmission Summary (if applicable; download template)</i>	18
4.2.9. <i>CPRIT Grants Summary (download template)</i>	18
4.2.10. <i>Budget and Justification (complete online)</i>	19
4.2.11. <i>Current and Pending Support and Sources of Funding (download template)</i>	20
4.2.12. <i>Biographical Sketches (download template)</i>	20
4.2.13. <i>Collaborating Organizations (complete online)</i>	20
4.2.14. <i>Letters of Commitment</i>	20
5. APPLICATION REVIEW	21
5.1. REVIEW PROCESS OVERVIEW	21
5.2. REVIEW CRITERIA.....	22
5.2.1. <i>Primary Evaluation Criteria</i>	23
5.2.2. <i>Secondary Evaluation Criteria</i>	25
6. AWARD ADMINISTRATION.....	25
7. CONTACT INFORMATION.....	27
7.1. HELPDESK	27
7.2. PROGRAM QUESTIONS	27
8. RESOURCES.....	27
9. REFERENCES.....	28
10. APPENDIX: KEY TERMS.....	28

RFA VERSION HISTORY

Rev 9/25/14 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 \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- 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.

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 will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based services relevant to prevention through risk reduction, early detection, and survivorship.

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.

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. Program Objectives

CPRIT seeks to fund projects that will:

- Address multiple components of the cancer prevention and control continuum (e.g., provision of screening and navigation services in conjunction with outreach and education of the target population as well as healthcare provider education);
- 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;
- Offer systems and/or policy changes that are sustainable over time;
- Provide tailored, culturally appropriate outreach and accurate information on early detection and prevention to the public and healthcare professionals that result 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 request for applications (RFA) solicits applications for projects up to 36 months in duration that will deliver evidence-based services in at least one of the following cancer prevention and control areas. For this cycle, CPRIT is accepting new applications **limited to**:

- Delivery of vaccines that reduce the risk of cancer
- Tobacco cessation interventions
- Screening and early detection services at the following anatomic sites for which there is strong evidence of effectiveness—breast, cervical, and/or colorectal cancers
- Survivorship services

In addition to other primary prevention and screening/early detection services, CPRIT considers counseling services (e.g., tobacco cessation, survivorship, exercise, and nutrition) when done on a one-on-one basis or in small groups as clinical services.

This mechanism will fund case management/patient navigation if it is paired with the delivery of a clinical service (e.g., human papillomavirus [HPV] vaccination, screening). Applicants offering screening services must ensure that there is access to treatment services for patients with cancers that are detected as a result of the program and must describe access to treatment services in their application.

CPRIT's services grants are intended to fund prevention interventions that have a demonstrated evidence base and are culturally appropriate for the target population.

CPRIT recognizes that evidence-based services have been developed but not implemented or tested in all populations or service settings. In such cases, other forms of evidence (e.g., preliminary evaluation or pilot project data) that the proposed service is appropriate for the population and has a high likelihood of success must be provided. The applicant must fully describe the base of evidence and any plans to adapt and evaluate the implementation of the program for the specific audience or situation.

Comprehensive projects are required. Comprehensive projects include a continuum of services and systems and/or policy changes and comprise all or some of the following: Public and/or professional education and training, patient support of behavior modification, outreach, delivery of clinical services, and followup navigation.

This RFA encourages traditional and nontraditional partnerships as well as leveraging of existing resources and dollars from other sources. The applicant should coordinate and describe a collaborative partnership program in which all partners have a substantial role in the proposed project. Letters of commitment describing their role in the partnership are required from all partners.

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 focusing solely on systems and/or policy change or solely on education and/or outreach** that do not include the delivery of services

- **Projects focusing solely on case management/patient navigation services.** Case management/patient navigation services must be paired with the delivery of a clinical service. 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.
- **Projects for continuation/expansion of a currently or previously funded project.** Applications for continuation/expansion should be submitted in response to the Competitive Continuation/Expansion RFA.
- **Projects utilizing State Quitline services.** Applicants proposing the utilization of Quitline services should communicate with the Tobacco Prevention and Control program prior to submitting a CPRIT grant application to discuss the services currently offered by the Texas Department of State Health Services (DSHS).
- **Projects focusing on computerized tomography (CT) screening for lung cancer**
- **Projects involving prevention/intervention research.** Applicants interested in prevention research should review CPRIT's research RFAs (available at <http://www.cprit.state.tx.us>).

2.3.1. Priority Areas

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

Target Populations: The age of the target population and frequency of screening plans for provision of clinical services described in the application must comply with established and current national guidelines (e.g., U.S. Preventive Services Task Force (USPSTF), American Cancer Society).

Priority populations are subgroups that are disproportionately affected by cancer. Priority populations include, but are not limited to, the following:

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations
- Medically unserved or underserved populations

- Populations with low health literacy skills
- Geographic regions or populations of the State with higher prevalence of cancer risk factors (e.g., obesity, tobacco use, alcohol misuse, unhealthy eating, sedentary lifestyle)
- Racial, ethnic, and cultural minority populations
- Any other 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).

Geographic and Population Priority: For applications submitted in response to this announcement, at the programmatic level of review conducted by 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 <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control/> and <http://www.cprit.state.tx.us/funded-grants/>)

2.3.2. Specific Areas of Emphasis

A. Primary Preventive Services

Priority will be given to projects that, through evidence-based efforts, address and can positively influence **local policy or systems change** that can lead to **sustainable change in desired health behaviors**.

Tobacco Prevention and Control

CPRIT is interested in applications focused on areas of the State

- That have higher smoking rates per capita than other areas of the State
- Where funds for tobacco use control efforts are not readily accessible from other sources

HPV Vaccination

CPRIT is interested in applications to increase access to and delivery of the HPV vaccine regimen through evidence-based intervention efforts.¹

B. Screening and Early Detection Services

Priority will be given to projects for screening and early detection of colorectal, breast, and cervical cancers.

Colorectal Cancer

- Increasing screening/detection rates in North and East Texas. The highest rates of cancer incidence and mortality are found in East and North Texas.²
- Decreasing disparities in incidence and mortality rates of colorectal cancer for racial/ethnic populations and rural communities (African Americans have the highest incidence and mortality rates, followed by non-Hispanic Whites and Hispanics.)²
- Decreasing incidence and mortality rates in rural counties. Incidence and mortality rates are higher in rural counties compared with urban counties.²

Breast Cancer

- Increasing screening/detection rates in rural and medically underserved areas of the State
- Reaching women never before screened or who have not been screened in the last 5 years, if addressing breast cancer in urban areas

Cervical Cancer

- Increasing screening/detection rates for women in Texas-Mexico border counties; women in these counties have a 31-percent higher cervical cancer mortality rate than women in nonborder counties.²
- Decreasing disparities in racial/ethnic populations. Hispanics have the highest incidence rates, while African Americans have the highest mortality rates.²
- Increasing access to and delivery of the HPV vaccine.¹

C. Survivorship Services

Priority for funding will be given to survivorship service projects that demonstrate a likelihood of success based on available evidence and can demonstrate and measure an improvement in quality of life in one or more of the following areas:

- Preventing secondary cancers and recurrence of cancer

- Managing the after effects of cancer and treatment to maximize quality of life and number of years of healthy life
- Minimizing preventable pain, disability, and psychosocial distress

2.3.3. Outcome Metrics

The applicant is required to describe final outcome measures for the project. Interim measures that are associated with the final outcome measures should be identified and will serve as a measure of program effectiveness and public health impact. Applicants are required to clearly describe their assessment and evaluation methodology. **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 output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

- Quarterly progress report sections include, but are not limited to:
 - Narrative on project progress (required)
 - People reached activities
 - Services, other than clinical services, provided to the public/professionals
 - Actions taken by people/professionals as a result of education or training, including percentage of people reporting sustained behavior change
 - Clinical services provided
 - Abnormal results and precursors or cancers detected
- Annual and Final progress report sections include, but are not limited to:
 - Key accomplishments, including qualitative analysis of policy change and/or lasting systems change

- Progress against goals and objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible men and women in a defined service area; for example:
 - Percentage increase over baseline in number of people served
 - Percentage increase over baseline in number of services provided
 - Completion of all required doses of vaccine
 - Number of people quitting tobacco use and sustaining healthy behavior
 - Percentage increase over baseline in cancers detected
 - Percentage increase in early-stage cancer diagnoses in a defined service area
- Materials produced and publications
- Economic impact of the project

2.4. Eligibility

- 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 designated Program Director (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 (e.g., qualitative or quantitative statistics) and who resides in Texas during the time that the project is conducted.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.
- 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, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant may submit more than one 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 the applicant or a partner is an existing 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 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, and any officer or director of the grant applicant's organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have 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 at <http://www.cprit.state.tx.us>.

2.4.1. Resubmission Policy

More than **one resubmission** is not 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.

2.5. Funding Information

Applicants may request any amount of funding up to a maximum of \$1.5 million in total funding over a maximum of 36 months. 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). 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 two 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.

3. KEY DATES

RFA

RFA release September 25, 2014

Application

Online application opens September 25, 2014, 7 A.M. Central Time

Application due December 4, 2014, 3 P.M. Central Time

Application review February 2015

Award

Award notification May 2015

Anticipated start date June 2015

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

4. 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 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 Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 A.M. Central Time on September 25, 2014, and must be submitted by 3 P.M. Central Time on December 4, 2014. 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.**

4.1. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail

to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.2. 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 one or more components or do not meet the eligibility requirements will be administratively withdrawn without review.

4.2.1. 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 required 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 target 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 targeted population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) reached and people (public and/or professionals) served.
- **Innovation:** Describe the creative components of the proposed project and how it differs from current programs or services being provided.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.2.2. Goals and Objectives

List specific goals and **measurable** objectives for each year of the project. A baseline and method(s) of measurement are required for each objective. Applicants must explain plans to establish baseline and describe method(s) of measurement in cases where a baseline has not been defined.

4.2.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates.

4.2.4. Project Plan (15 pages maximum; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below. Applications not following the required format will be administratively withdrawn.

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 target population. 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 target 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 appreciated.

Goals and Objectives (optional): Goals and Objectives will be entered in separate fields in CARS and need not be provided in the project plan. However, if desired, goals and objectives may be fully repeated or briefly summarized here.

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, creative, or unique. Clearly demonstrate the ability to provide the proposed service, describe how results will be improved over baseline and the ability to reach the target population. Applicants must also clearly describe plans to ensure access to treatment services should cancer be detected.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the impact on ultimate outcome measures and interim outcome measures as outlined in [Section 2.3.3](#). Describe the plan for outcome measurements, including data collection and management methods, statistical analyses, and anticipated results. Evaluation and reporting of outcomes must be headed by a professional who has demonstrated expertise in the field of program evaluation, intervention science, cancer screening, and/or behavioral risk reduction. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, 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 Capacity and Sustainability: Describe the organization and its track record for providing services. Include information on the organization's financial stability and viability. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memorandums of understanding) or commitments (via letters of commitment) in place. A sustainability plan describing the continuation of the proposed program or service after CPRIT funding has ended must be included.

Elements of organizational project sustainability may include, but are not limited to, the following:

- Developing ownership, administrative networks, and formal engagements with stakeholders
- Enhancing system capacity and developing processes for each practice/location to incorporate services into its structure beyond project funding
- Identifying and training of diverse resources (human, financial, material, and technological)

Dissemination and Scalability (Expansion): Describe how the project lends itself to dissemination to or application by other communities and/or organizations in the State or expansion in the same communities. Describe plans for dissemination of positive and negative project results and outcomes. 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 methods may include, but are not limited to, presentations, publications, abstract submissions, and professional journal articles, etc.

4.2.5. People Reached (complete online)

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 noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to the [Appendix](#) for definitions.

4.2.6. People Served (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be served by the funded project. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimates provided. Refer to the [Appendix](#) for definitions.

4.2.7. 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.

4.2.8. Resubmission Summary (if applicable; download template)

Describe the approach to the resubmission and how reviewers' comments were addressed. 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.

4.2.9. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of **all** CPRIT-funded projects of the PD or Co-PD, regardless of their connection to this application. Indicate how the current application builds on the previous work or addresses new areas of cancer prevention and control services. Applications that are missing this document and for which CPRIT records show a PD and/or Co-PD with previous or current CPRIT funds will be administratively withdrawn.

4.2.10. Budget and Justification (complete online)

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 2.5](#) will be administratively withdrawn.

- **Cost Per Person Served:** The cost per person served will be automatically calculated from the total cost of the project divided by the total number of people (both public and professionals) served (refer to [Appendix](#)). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.
- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to two 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.
- **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 target 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.
 - **Indirect Costs:** It is CPRIT's policy not to allow recovery of indirect costs for prevention programs.

- **Costs Not Related to Cancer Prevention and Control:** CPRIT does not allow recovery of any costs for services not related to cancer (e.g., health physicals, HIV testing).

4.2.11. Current and Pending Support and Sources of Funding (download template)

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. Information for the initial funded project need not be included.

4.2.12. Biographical Sketches (download template)

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.

The evaluation professional must provide a biographical sketch.

Up to three additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

4.2.13. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide one or more components essential to the success of the program (e.g., evaluation, clinical services, recruitment to screening, etc.).

4.2.14. Letters of Commitment

Applicants should provide letters of commitment and/or memorandums of understanding from community organizations, key faculty, or any other component essential to the success of the program.

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

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed using a two-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 one 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 703.6–703.8.

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 is comprised of 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 and Innovation

- 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? Does the proposed project demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it take evidence-based interventions and apply them in innovative ways to explore new partnerships, new audiences, or improvements to systems?
- Does the program address adaptation, if applicable, of the evidence-based intervention to the target population? Is the base of evidence clearly explained and referenced?
- Does the program address known gaps in prevention services and avoid duplication of effort?
- If applicable, have collaborative partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than the applicant organization's effort separately?
- Will the project reach and serve an appropriate number of people based on the budget allocated to providing services and the cost of providing services?

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?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the target population and culturally appropriate methods to reach the target 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?
- Does the application provide a clear and appropriate plan for data collection and management, statistical analyses, and interpretation of results to follow, measure, and report on the project's outcomes?
- Are clear baseline data provided for the target 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 Capacity

- 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 implement, evaluate, and complete the project?

Sustainability

- Is the organization structurally and financially stable and viable?
- Are there feasible plans to sustain some or all of the project beyond the funded timeframe of this award?
- Are there feasible plans to integrate the program into existing and sustainable systems?

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 Scalability

- Are plans for dissemination of the project's results and outcomes, including barriers encountered and successes achieved, clearly described?
- Does the project or do some components of the project lend themselves to scalability/expansion by others in the State? If so, does the application describe a plan for doing so?

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, which are available at www.cprit.state.tx.us. 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 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 e-mail 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 by September 25, 2014), which provides a step-by-step guide to using CARS.

Dates of operation: September 25, 2014 to December 4, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 A.M. to 4 P.M. Central Time
Wednesday, 8 A.M. to 4 P.M. Central Time

Tel: 866-941-7146

E-mail: 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: 512-305-8422

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

8. RESOURCES

- The Texas Cancer Registry: <http://www.dshs.state.tx.us/tcr>
- The Community Guide <http://www.thecommunityguide.org/index.html>
- 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, RC, Colditz GA, and Proctor, EK (Editors), *Dissemination and Implementation Research in Health: Translating Science to Practice*. Oxford University Press, March 2012.
- 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

9. REFERENCES

1. <http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm>
2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services, <http://www.dshs.state.tx.us/tcr/default.shtm>

10. APPENDIX: KEY TERMS

- **Activities:** A listing of the “who, what, when, where, and how” for each objective that will be accomplished.
- **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.
- **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.
- **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

<http://www.cpr.it.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.

- **Goals:** Broad statements of general purpose to guide planning. Goals should be few in number and focus on aspects of highest importance to the project.
- **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.
- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outputs and outcomes; example: “Increase screening service provision in X population from Y percent to Z percent by 20xx.” Baseline data for the target population must be included as part of each objective.
- **People Reached:** Number of members of the public and/or professionals reached via 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.
- **People Served:** Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service delivery, or clinical service delivery, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. 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 (e.g., X people screened for cervical cancer after referral to Y indigent care program as a result of CPRIT-funded navigation services performed by the project).

Third Party Observer Reports

CPRIT Prevention Peer Review Panel Observation Report

Report #2015-215

Panel Name: FY15 Prevention Peer Review 1

Panel Date: February 23-24, 2015

Report Date: February 25, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is Prevention Peer Review Panel 1 review of prevention program applications. The meeting was chaired by Ross Brownson and held in person at the Hyatt Regency in downtown Dallas, TX on February 23-24, 2015.

Panel Observation Objectives and Scope

This third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- Peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Prevention Peer Review meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Ross Brownson on February 23 and February 24, 2015.

The independent observer noted the following during our observation:

- Fourteen prevention applications were discussed and evaluated by the Prevention Peer Review Panel 1 to determine which grants would receive CPRIT funding.
- Eight panel members, two advocate reviewers, three CPRIT staff members, and five SRA employees were present for the peer review meeting.
- No conflicts of interest were identified prior to or during the meeting.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Peer Review Panel Observation Report

Report #2015-216

Panel Name: FY15 Prevention Peer Review Panel 2

Panel Date: February 24-25, 2015

Report Date: February 25, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is Prevention Peer Review Panel 2 review of prevention program applications. The meeting was chaired by Nancy Lee and held in person at the Hyatt Regency in downtown Dallas, TX on February 24 and February 25, 2015.

Panel Observation Objectives and Scope

This third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- Peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Prevention Peer Review meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Nancy Lee on February 24 and February 25, 2015.

The independent observer noted the following during our observation:

- Fourteen prevention applications were discussed and evaluated by the Prevention Peer Review Panel 2 to determine which grants would receive CPRIT funding.
- Eight panel members, three CPRIT staff members, one Oversight Committee member, and four SRA employees were present for the panel meeting.

- Four conflict of interest were identified prior to or during the meeting. Only one of the four applications with conflicts of interest were discussed. The reviewer with the conflict of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Review Council Observation Report

Report #2015-227

Panel Name: FY15.2 Prevention Review Council
Programmatic Review

Panel Date: April 17, 2015

Report Date: April 22, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council Programmatic Review Meeting for FY15 funding. The meeting was chaired by Stephen Wyatt and held via teleconference on April 17, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Prevention Review Council meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Stephen Wyatt on April 17, 2015.

The independent observer noted the following during our observation:

- Fourteen applications were discussed within the Prevention Review Council Programmatic Review Meeting to determine which grants would receive CPRIT funding.
- Three council members, two CPRIT staff members, and two SRA employees were present for the meeting.

- One conflict of interest was identified prior to or during the meeting. The reviewer with the conflict of interest did not participate in the ranking of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the Council's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 15.2 Applications
(Prevention Cycle 15.2 Awards Announced at May 20, 2015, 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 15.2 include *Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition*; *Evidence-Based Cancer Prevention Services*; *Cancer Prevention Promotion and Navigation to Clinical Services*, and *Competitive Continuation/Expansion-Evidence-Based Cancer Prevention Services*. 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
PP150054	Foxhall, Lewis	The University of Texas M.D. Anderson Cancer Center	Brownson, Ross; Mahoney, Martin; Cole, Kirk
PP150078	Arjona, Moises	MHP, Inc. Promoviendo Vidas Saludables	Cole, Kirk
Applications Not Recommended for PIC or Oversight Committee Consideration			
PP150096*	Wiechnicki, Katherine	Texas Department of State Health Services	Mahoney, Martin; Momrow, David

* = Not discussed

De-Identified Overall Evaluation Scores

Evidence-Based Prevention Services

Prevention Cycle 15.2

Application ID	Final Overall Evaluation Score
PP150079*	2.3
PP150071*	2.6
PP150077*	2.9
MA	4.4
PP150078*	4.5
MB	4.7
MC	4.8
MD	5.3
ME	5.3
MG	5.3
MH	5.4
MI	5.8
MJ	6.3
MK	6.6
ML	6.8

*=Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

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

Dear Mr. Roberts and Dr. Rice,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list submitted proposals in response to CPRIT requests for applications (RFA) released for the second review cycle of FY2015. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals, in addition to the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants. However, the PRC did recommend a change to the funding amount for PP150061, proposing a reduction in funding from the requested \$5.393 million to \$4.8 million. This reduction is proposed based upon this being the initial "coalition RFA" award and due to likely efficiencies to be achieved with a current CPRIT Prevention grant to Dr. Argenbright.

The funding available for this cycle is \$20,668,032; the PRC is recommending awards totaling \$20,619,413. 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 also considered 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. Although the Oversight Committee's program priorities were not adopted at the time these RFAs were released, all the recommended grants address one or more of the new Prevention Program priorities.

Sincerely,

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

App ID	Mech.	Application Title	PD	Organization	Total Funding request	Score	Rank Order Score
PP150061	EBP-CRC	The C-SPAN Coalition: Colorectal Screening and Patient Navigation	Argenbright, Keith E	The University of Texas Southwestern Medical Center	5,393,275	2.3	1
PP150079	EBP	STOP HCC –Evidence-Based Hepatocellular Cancer Prevention Targeting Hepatitis C Virus Infection	Turner, Barbara J	The University of Texas Health Science Center at San Antonio	1,488,294	2.3	2
PP150071	EBP	FluFIT on the Frontera: Increasing Colorectal Cancer Screening on the Texas-Mexico Border	Larson, Adrian F	Val Verde Regional Medical Center	1,500,000	2.6	3
PP150053	CCE-EBP	BSPAN3: Breast Screening and Patient Navigation for Rural and Underserved Women across North Texas	Lee, Simon Craddock	The University of Texas Southwestern Medical Center	1,499,993	2.9	4
PP150054	EBP-CRC	Alliance for Colorectal Cancer Testing (ACT) in Southeast Texas	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	2,588,774	2.9	4 (rank ordered without Dr. Brownson)
PP150077	EBP	Media-Rich Mobile Dissemination of a Dysphagia Prevention Program for Head and Neck Cancer Patients during Radiation	Shinn, Eileen	The University of Texas M. D. Anderson Cancer Center	1,263,342	2.9	6

PP150086	CCE-EBP	Access to Breast and Cervical Care for West Texas (West/Central Texas)(ABCC4WT)	Ross, Linda	Angelo State University	1,480,898	3.9	7
PP150080	CCE-EBP	Empower Her To Care Expansion: Increasing Access to Breast Cancer Screening and the Continuum of Care for Underserved Texas Women	Joseph, Bernice	The Rose	1,500,000	4.1	8
PP150078	EBP	Cada Paso del Camino: Outreach, Education, Screening, Health Insurance Navigation, and Linkage to Treatment for Breast, Cervical, and Colorectal Cancers	Arjona, Moises	MHP, Inc. Promoviendo Vidas Saludables	1,498,337	4.5	9
PP150064	CCE-EBP	University Health System Evidence-Based Colorectal Cancer Prevention Screening Program	Villarreal, Roberto	University Health System	1,499,775	4.5	10
PP150089	CCE-EBP	Increasing Breast and Cervical Cancer Screening and Diagnostic Rates in Rural, Frontier, and Border Counties for Uninsured, Underserved Women	Rice, Carol A	Texas AgriLife Extension Service	1,500,000	4.7	11



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 2
***Evidence-Based Cancer Prevention Services-Colorectal
Cancer Prevention Coalition***

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA P-15-EBP-CRC-1

Evidence-Based Cancer Prevention Services Colorectal Cancer Prevention Coalition

**Please also refer to the “Instructions for Applicants” document, which will be
posted September 25, 2014**

Application Receipt Opening Date: September 25, 2014

Application Receipt Closing Date: December 4, 2014

FY 2015

September 1, 2014 – August 31, 2015

TABLE OF CONTENTS

1. ABOUT CPRIT	4
2. FUNDING OPPORTUNITY DESCRIPTION	4
2.1. SUMMARY	4
2.2. PROJECT OBJECTIVES	5
2.3. AWARD DESCRIPTION	5
2.3.1. <i>Priority Areas</i>	8
2.3.2. <i>Specific Areas of Emphasis</i>	8
2.3.3. <i>Outcome Metrics</i>	9
2.4. ELIGIBILITY	10
2.4.1. <i>Applicant Organization</i>	10
2.5. FUNDING INFORMATION	12
3. KEY DATES.....	13
4. APPLICATION SUBMISSION GUIDELINES	13
4.1. SUBMISSION DEADLINE EXTENSION	14
4.2. APPLICATION COMPONENTS	14
4.2.1. <i>Abstract and Significance (5,000 characters)</i>	14
4.2.2. <i>Goals and Objectives</i>	15
4.2.3. <i>Project Timeline</i>	15
4.2.4. <i>Project Plan (30 pages maximum; fewer pages permissible)</i>	15
4.2.5. <i>People Reached (complete online)</i>	17
4.2.6. <i>People Served (complete online)</i>	17
4.2.7. <i>References</i>	17
4.2.8. <i>CPRIT Grants Summary (download template)</i>	17
4.2.9. <i>Budget and Justification (complete online)</i>	18
4.2.10. <i>Current and Pending Support and Sources of Funding (download template)</i>	19
4.2.11. <i>Biographical Sketches (download template)</i>	19
4.2.12. <i>Collaborating Organizations (complete online)</i>	19
4.2.13. <i>Letters of Commitment</i>	19
5. APPLICATION REVIEW.....	20
5.1. REVIEW PROCESS OVERVIEW	20
5.2. REVIEW CRITERIA	21
5.2.1. <i>Primary Evaluation Criteria</i>	22
5.2.2. <i>Secondary Evaluation Criteria</i>	24
6. AWARD ADMINISTRATION.....	24
7. CONTACT INFORMATION.....	26
7.1. HELPDESK	26
7.2. PROGRAM QUESTIONS	26
8. RESOURCES	26
9. REFERENCES.....	27
10. APPENDIX: KEY TERMS.....	27

RFA VERSION HISTORY

Rev 9/25/14 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 \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- 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.

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 will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based services relevant to prevention through risk reduction, early detection, and survivorship.

The **Evidence-Based Cancer Prevention Services Colorectal Cancer Prevention Coalition (EBP-CRC)** award mechanism seeks to fund projects that greatly challenge the status quo in colorectal cancer prevention and control services. The proposed project should be designed to reach and serve as many people as possible. Partnerships with organizations that can provide clinical services (i.e. clinics, hospitals, FQHCs) are required. In addition to partnerships with clinical service providers, partnerships with other organizations that can support and leverage resources (i.e. community-based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations) are strongly encouraged. A coordinated submission of

a collaborative coalition in which all partners have a substantial role in the proposed project is required.

The intent of this mechanism is to maximize the impact of the project by its simultaneous implementation in multiple clinical sites. Collaboration with clinical services organizations must be executed in a coordinated manner so that access to care and utilization of services are increased. The clinical service provider partners should all provide the same education, navigation, and clinical services. The intent is not to have the various sites providing different services or subset of services.

2.2. Project Objectives

CPRIT seeks to fund projects that will:

- Deliver evidence-based comprehensive colorectal cancer prevention services aimed at reducing health disparities in colorectal cancer screening, incidence, and mortality.
- Increase screening rates among persons 50 years and older and those at high risk (as defined by the American Cancer Society)¹ in identified service regions; focusing on **asymptomatic** persons for CRC, those who have not been screened before, and those who have inadequate or no health insurance coverage for CRC screening.
- Coordinate clinical service providers and other partners to create a coalition with the goal of screening and treating (for cancers or precancers detected) the most counties and the most people possible in a selected service region. For those identified with colorectal cancer or precancer through the screening exam who do not have health insurance coverage, assurance of appropriate treatment must be provided.
- Implement system changes to decrease wait time between positive screen and diagnostic test (navigation, reminder systems, etc.) and treatment. Offer systems and/or policy changes that are sustainable over time.
- Deliver uniform services, data collection and reporting from the coalition.

2.3. Award Description

This RFA solicits applications for projects up to 36 months in duration that will deliver a comprehensive and integrated colorectal cancer screening project that includes provision of

screening, diagnostic, and navigation services in conjunction with outreach and education of the target population through a coalition of partners.

The following are required project elements:

Comprehensive projects. Comprehensive projects include a continuum of services and systems and policy changes and comprise all or some of the following: Public and professional education and training, outreach, delivery of screening and diagnostic services, followup navigation, data collection and tracking and systems improvement.

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 cancers or precancers 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 all of the above components if they already are being paid from other sources.

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;

- Applicants may select the types of colorectal cancer screening tests offered but should be limited to those recommended by the U.S. Preventive Services Task Force (USPSTF)².
- Education and outreach strategies to support patient recruitment may include small media activities and one-on-one outreach or other methods known to be effective in reaching the project's priority population³.
- 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 (e.g., 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 provider and community partner coalitions. The applicant should coordinate and describe a collaboration of clinical service providers that can deliver outreach, education, screening, and navigation services to the most counties and the most people possible in a selected service region. In addition, partnerships with other organizations that can support and leverage resources (i.e., community based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations, etc.) are strongly encouraged. The applicant should coordinate and describe a coalition in which all partners have a substantial role in the proposed project. Letters of commitment or memorandums of understanding describing their role in the partnership are required from all clinical service providers and participating organizations.

Project Coordination and Technical Assistance. The overall screening program should be directed and overseen by the Program Director who is responsible for establishing and managing an integrated and collaborative coalition of clinical service providers and other community partners. A leader at each clinical project site is required and should be designated with a title of “Project Lead.”

- The Program Director must establish any necessary subcontracts or memoranda of understanding with project partners and clinical service providers.
- The Program Director must facilitate the establishment of standard protocols for all clinical service providers in the coalition (e.g. offering choice of test options, such as fecal immunochemical test (FIT) first, FIT/Flu etc.), as well as standard systems, policies, and procedures for the participating clinical service providers and organizations. These include, but are not limited to, patient tracking and timely followup of all abnormal screening results and/or diagnoses of cancer.
- The Program Director must also provide means to regularly communicate with Project Leads to discuss progress and barriers, resolve potential problems, and provide technical assistance as needed throughout the duration of the project.
- The Program Director is responsible for 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. The applicant should project a realistic and feasible 3-year increase in the CRC screening rate.

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

- **Projects focusing solely on systems and/or policy change or solely on education and/or outreach** that do not include the delivery of services
- **Projects focusing solely on case management/patient navigation services.** Case management/patient navigation services must be paired with the delivery of a clinical service. 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.

2.3.1. Priority Areas

Types of Cancer: Only projects proposing prevention and early detection of colorectal cancer and precancer will be considered.

Target Populations: The age of the target population and frequency of screening plans for provision of clinical services described in the application must comply with established and current national guidelines of the U.S. Preventive Services Task Force.

Priority populations are subgroups that are disproportionately affected by cancer. Priority populations include, but are not limited to, the following:

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations
- 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.

2.3.2. Specific Areas of Emphasis

Data compiled by the Texas Cancer Registry on colorectal cancer highlight needs in the following areas:

- Increasing screening/detection rates in North and East Texas. The highest rates of colorectal cancer incidence and mortality are found in East and North Texas.⁴

- Decreasing disparities in incidence and mortality rates of colorectal cancer for racial/ethnic populations and rural communities (African Americans have the highest incidence and mortality rates, followed by non-Hispanic Whites and Hispanics.)⁴
- Decreasing incidence and mortality rates for colorectal cancer in rural counties. Incidence and mortality rates are higher in rural counties compared with urban counties.⁴

2.3.3. Outcome Metrics

The applicant is required to describe final outcome measures for the project. Interim measures that are associated with the final outcome measures should be identified and will serve as a measure of program effectiveness and public health impact. Applicants are required to clearly describe their assessment and evaluation methodology. **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 used to collect the data necessary to establish a baseline.

- Reporting Requirements
- Funded projects are required to report output and outcome metrics through the submission of quarterly progress reports, annual reports, and a final report.
- Quarterly progress report sections include, but are not limited to:
 - Narrative on project progress, including formation and management of the coalition, (required).
 - People reached through project activities
 - Services, other than clinical services, provided to the public/professionals
 - Actions taken by people/professionals as a result of education or training, including percentage of people reporting sustained behavior change
 - Clinical services provided
 - Abnormal results and precursors or cancers detected
- Annual and Final progress report sections include, but are not limited to:
 - Key accomplishments, including:
 - qualitative analysis of policy change and/or lasting systems change
 - effectiveness of the coalition

- Progress against goals and objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible men and women in a defined service area; for example:
 - Percentage increase over baseline in number of people served
 - Percentage increase over baseline in number of services provided
 - Percentage increase over baseline in cancers and precancers detected
 - Percentage increase in early-stage cancer diagnoses in a defined service area
 - Percentage increase in navigation to treatment
- Materials produced and publications
- Economic impact of the project

2.4. Eligibility

2.4.1. Applicant Organization

- 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 designated Project Director (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 (e.g., qualitative or quantitative statistics) and who resides in Texas during the time that the project is conducted.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.
- 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, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.

- The applicant may submit more than one 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.
- The PD or coalition partners may have a current CPRIT grant for CRC screening but must describe how this new grant complements their current grant. Outcomes and progress on the current grant must be described in the Grants Summary form (See [Section 4.2.8](#)). Organizations that have current CRC screening grants may also opt to transition their current project to a new coalition grant if awarded. Funds cannot be transferred from one project to another. The CPRIT Prevention Program will work with the PD of the current grant to provide guidance and ensure a smooth transition.
- Additional 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 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, and any officer or director of the grant applicant's organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have 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 at <http://www.cprit.state.tx.us>.

2.5. Funding Information

CPRIT expects that funding requests will vary depending on the proposed geographic coverage and number of people served. Applicants may request any amount of funding over a maximum of 36 months. A significant proportion of funds is expected to be used for program delivery and the cost per person served to be reasonable and well justified.

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). 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 two 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.

3. KEY DATES

RFA

RFA release September 25, 2014

Application

Online application opens September 25, 2014, 7 A.M. Central Time

Application due December 4, 2014, 3 P.M. Central Time

Application review February 2015

Award

Award notification May 2015

Anticipated start date June 2015

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

4. 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 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 Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 A.M. Central Time on September 25, 2014, and must be submitted by 3 P.M. Central Time on December 4, 2014. 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.**

4.1. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.2. Application Components

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

4.2.1. 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 required 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 target 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 targeted population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) reached and people (public and/or professionals) served.

- **Innovation:** Describe the creative components of the proposed project and how it differs from current programs or services being provided.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the State of Texas.

4.2.2. Goals and Objectives

List specific goals and **measurable** objectives for each year of the project. A baseline and method(s) of measurement are required for each objective. Applicants must explain plans to establish baseline and describe method(s) of measurement in cases where a baseline has not been defined.

4.2.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates.

4.2.4. Project Plan (30 pages maximum; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below. Applications not following the required format will be administratively withdrawn.

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 target population. 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 target 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 appreciated.

Goals and Objectives (optional): Goals and Objectives will be entered in separate fields in CARS and need not be provided in the project plan. However, if desired, goals and objectives may be fully repeated or briefly summarized here.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services as well as anticipated results. Describe why this project is nonduplicative, creative, or unique.

Clearly describe the coalition, its structure, key personnel and their experience, resources and facilities available from each partner, and plans to leverage existing funding and infrastructure. Also describe plans for management and technical support to the coalition including monitoring, communications, data collection, and reporting.

Clearly demonstrate the ability to provide the proposed service, describe how results will be improved over baseline and the ability to reach the target population. Applicants must also clearly describe plans to ensure access to treatment services should cancer be detected.

List in table format the types and number of each education service, navigation service, and clinical service (See [Appendix](#) for definitions) to be delivered. In addition, list the TOTAL number of all services. Treatment services are not appropriate for this award mechanism and should not be included.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the impact on ultimate outcome measures and interim outcome measures as outlined in [Section 2.3.3](#). Describe the plan for outcome measurements, including data collection and management methods, statistical analyses, and anticipated results. Evaluation and reporting of outcomes must be headed by a professional who has demonstrated expertise in the field of program evaluation, intervention science, cancer screening, and/or behavioral risk reduction. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, 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 Capacity and Sustainability: For each partner in the coalition, describe the organization and its track record for providing services. Include information on the organization's financial stability and viability. The PD's organization, acting as the coordinator, should describe their capacity to provide coordination, monitoring, reporting and technical assistance to the coalition. The coordinating organization must provide partner agreements (via

memorandums of understanding) or commitments (via letters of commitment) to ensure access to preventive services and reporting of services outcomes. A sustainability plan describing the continuation of the coalition and the proposed program or service after CPRIT funding has ended must be included.

Dissemination and Scalability (Expansion): Describe how the project lends itself to dissemination to or application by other communities and/or organizations in the State or expansion in the same communities. Describe plans for dissemination of positive and negative project results and outcomes. 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 methods may include, but are not limited to, presentations, publications, abstract submissions, and professional journal articles, etc.

4.2.5. People Reached (complete online)

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 noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to the [Appendix](#) for definitions.

4.2.6. People Served (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be served by the funded project. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimates provided. Refer to the [Appendix](#) for definitions.

4.2.7. 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.

4.2.8. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of **all** CPRIT-funded projects of the PD or Co-PD, regardless of their connection to this application. Indicate how the current application builds on the previous work or addresses new areas of cancer prevention and control services.

Applications that are missing this document and for which CPRIT records show a PD and/or Co-PD with previous or current CPRIT funds will be administratively withdrawn.

4.2.9. Budget and Justification (complete online)

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.

- **Cost Per Person Served:** The cost per person served will be automatically calculated from the total cost of the project divided by the total number of people (both public and professionals) served (refer to [Appendix](#)). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.
- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to two 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.
- **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 target 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.
 - **Indirect Costs:** It is CPRIT's policy not to allow recovery of indirect costs for prevention projects.

- **Costs Not Related to Cancer Prevention and Control:** CPRIT does not allow recovery of any costs for services not related to cancer (e.g., health physicals, HIV testing).

4.2.10. Current and Pending Support and Sources of Funding (download template)

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.

4.2.11. Biographical Sketches (download template)

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.

The evaluation professional must provide a biographical sketch.

Each Project Lead must provide a biographical sketch. Up to 10 additional biographical sketches, including the project lead biosketches, for key personnel may be provided. Each biographical sketch must not exceed two pages.

4.2.12. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide one or more components essential to the success of the project (e.g., evaluation, clinical services, recruitment to screening, etc.).

4.2.13. Letters of Commitment

Applicants should provide letters of commitment and/or memorandums of understanding from community organizations, key faculty, or any other component essential to the success of the project.

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

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed using a two-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 one 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 703.6–703.8.

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 is comprised of 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 pre-applications 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 and Innovation

- Do the proposed services address an important problem or need in colorectal cancer prevention and control? Do the proposed project strategies support desired outcomes in cancer incidence, morbidity, and/or mortality? Does the proposed project demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it take evidence-based interventions and apply them in innovative ways to explore new partnerships, new audiences, or improvements to systems?
- Does the project address adaptation, if applicable, of the evidence-based intervention to the target population?
- Does the project address known gaps in prevention services and avoid duplication of effort?
- Does the proposed coalition demonstrate that the collaborative effort will provide a greater impact on colorectal cancer prevention and control than the applicant organization's effort separately?
- Will the project reach and serve an appropriate number of people based on the budget allocated to providing services and the cost of providing services?

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?
- Are the overall project 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?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the target population and culturally appropriate methods to reach the target population clearly described?
- Does the coordinating organization demonstrate the ability to provide coordination, monitoring, reporting, and technical assistance to the coalition?

- Does the applicant demonstrate the availability of coalition resources and expertise to provide comprehensive services including case management, followup for abnormal results and access to treatment?
- Does the project leverage partners and resources to maximize the reach of the services proposed? Does the project 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?
- Does the application provide a clear and appropriate plan for data collection and management, statistical analyses, and interpretation of results to follow, measure, and report on the project's outcomes?
- Are clear baseline data provided for the proposed goals and objectives, 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 a qualitative analysis or process evaluation of the effectiveness of the coalition as well as policy or system changes described?

Organizational Capacity

- Do the coordinating organization and the coalition 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 implement, evaluate, and complete the project?

Sustainability

- Are the coalition partners structurally and financially stable and viable?
- Are there feasible plans to sustain some or all of the coalition and/or project beyond the funded timeframe of this award?
- Are there feasible plans to integrate the project into existing and sustainable systems?

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 Scalability

- Are plans for dissemination of the project's results and outcomes, including barriers encountered and successes achieved, clearly described?
- Does the project or do some components of the project lend themselves to scalability/expansion by others in the State? If so, does the application describe a plan for doing so?

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, which are available at www.cprit.state.tx.us. 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 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 e-mail 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 by September 25, 2014), which provides a step-by-step guide to using CARS.

Dates of operation: September 25, 2014 to December 4, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 A.M. to 4 P.M. Central Time
Wednesday, 8 A.M. to 4 P.M. Central Time

Tel: 866-941-7146

E-mail: 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: 512-305-8422

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

8. RESOURCES

- The Texas Cancer Registry: <http://www.dshs.state.tx.us/tcr>
- The Community Guide <http://www.thecommunityguide.org/index.html>
- 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, RC, Colditz GA, and Proctor, EK (Editors). Dissemination and Implementation Research in Health: Translating Science to Practice. Oxford University Press, March 2012.
- 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

9. REFERENCES

1. <http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-ac-s-recommendations>
2. <http://www.uspreventiveservicestaskforce.org/uspstf/uspcolo.htm>
3. <http://www.thecommunityguide.org/cancer/index.html>
4. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services <http://www.dshs.state.tx.us/tcr/default.shtm>

10. APPENDIX: KEY TERMS

- **Activities:** A listing of the “who, what, when, where, and how” for each objective that will be accomplished.
- **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.
- **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.

- **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 <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.
- **Goals:** Broad statements of general purpose to guide planning. Goals should be few in number and focus on aspects of highest importance to the project.
- **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.
- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outputs and outcomes; example: “Increase screening service provision in X population from Y percent to Z percent by 20xx.” Baseline data for the target population must be included as part of each objective.
- **People Reached:** Number of members of the public and/or professionals reached via 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.
- **People Served:** Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service delivery, or clinical service delivery, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. 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 (e.g., X

people screened for cervical cancer after referral to Y indigent care program as a result of CPRIT-funded navigation services performed by the project).

Third Party Observer Report

CPRIT Prevention Peer Review Panel Observation Report

Report #2015-215

Panel Name: FY15 Prevention Peer Review 1

Panel Date: February 23-24, 2015

Report Date: February 25, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is Prevention Peer Review Panel 1 review of prevention program applications. The meeting was chaired by Ross Brownson and held in person at the Hyatt Regency in downtown Dallas, TX on February 23-24, 2015.

Panel Observation Objectives and Scope

This third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- Peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Prevention Peer Review meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Ross Brownson on February 23 and February 24, 2015.

The independent observer noted the following during our observation:

- Fourteen prevention applications were discussed and evaluated by the Prevention Peer Review Panel 1 to determine which grants would receive CPRIT funding.
- Eight panel members, two advocate reviewers, three CPRIT staff members, and five SRA employees were present for the peer review meeting.
- No conflicts of interest were identified prior to or during the meeting.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Peer Review Panel Observation Report

Report #2015-216

Panel Name: FY15 Prevention Peer Review Panel 2

Panel Date: February 24-25, 2015

Report Date: February 25, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is Prevention Peer Review Panel 2 review of prevention program applications. The meeting was chaired by Nancy Lee and held in person at the Hyatt Regency in downtown Dallas, TX on February 24 and February 25, 2015.

Panel Observation Objectives and Scope

This third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- Peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Prevention Peer Review meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Nancy Lee on February 24 and February 25, 2015.

The independent observer noted the following during our observation:

- Fourteen prevention applications were discussed and evaluated by the Prevention Peer Review Panel 2 to determine which grants would receive CPRIT funding.
- Eight panel members, three CPRIT staff members, one Oversight Committee member, and four SRA employees were present for the panel meeting.

- Four conflict of interest were identified prior to or during the meeting. Only one of the four applications with conflicts of interest were discussed. The reviewer with the conflict of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Review Council Observation Report

Report #2015-227

Panel Name: FY15.2 Prevention Review Council
Programmatic Review

Panel Date: April 17, 2015

Report Date: April 22, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council Programmatic Review Meeting for FY15 funding. The meeting was chaired by Stephen Wyatt and held via teleconference on April 17, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Prevention Review Council meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Stephen Wyatt on April 17, 2015.

The independent observer noted the following during our observation:

- Fourteen applications were discussed within the Prevention Review Council Programmatic Review Meeting to determine which grants would receive CPRIT funding.
- Three council members, two CPRIT staff members, and two SRA employees were present for the meeting.

- One conflict of interest was identified prior to or during the meeting. The reviewer with the conflict of interest did not participate in the ranking of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the Council's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 15.2 Applications
(Prevention Cycle 15.2 Awards Announced at May 20, 2015, 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 15.2 include *Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition*; *Evidence-Based Cancer Prevention Services*; *Cancer Prevention Promotion and Navigation to Clinical Services*, and *Competitive Continuation/Expansion-Evidence-Based Cancer Prevention Services*. 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
PP150054	Foxhall, Lewis	The University of Texas M.D. Anderson Cancer Center	Brownson, Ross; Mahoney, Martin; Cole, Kirk
PP150078	Arjona, Moises	MHP, Inc. Promoviendo Vidas Saludables	Cole, Kirk
Applications Not Recommended for PIC or Oversight Committee Consideration			
PP150096*	Wiechnicki, Katherine	Texas Department of State Health Services	Mahoney, Martin; Momrow, David

* = Not discussed

De-Identified Overall Evaluation Scores

Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition

Prevention Cycle 15.2

Application ID	Final Overall Evaluation Score
PP150061*	2.3
PP150054*	2.9
NA	5.0
NB	6.6

*=Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

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

Dear Mr. Roberts and Dr. Rice,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list submitted proposals in response to CPRIT requests for applications (RFA) released for the second review cycle of FY2015. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals, in addition to the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants. However, the PRC did recommend a change to the funding amount for PP150061, proposing a reduction in funding from the requested \$5.393 million to \$4.8 million. This reduction is proposed based upon this being the initial "coalition RFA" award and due to likely efficiencies to be achieved with a current CPRIT Prevention grant to Dr. Argenbright.

The funding available for this cycle is \$20,668,032; the PRC is recommending awards totaling \$20,619,413. 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 also considered 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. Although the Oversight Committee's program priorities were not adopted at the time these RFAs were released, all the recommended grants address one or more of the new Prevention Program priorities.

Sincerely,

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

App ID	Mech.	Application Title	PD	Organization	Total Funding request	Score	Rank Order Score
PP150061	EBP-CRC	The C-SPAN Coalition: Colorectal Screening and Patient Navigation	Argenbright, Keith E	The University of Texas Southwestern Medical Center	5,393,275	2.3	1
PP150079	EBP	STOP HCC –Evidence-Based Hepatocellular Cancer Prevention Targeting Hepatitis C Virus Infection	Turner, Barbara J	The University of Texas Health Science Center at San Antonio	1,488,294	2.3	2
PP150071	EBP	FluFIT on the Frontera: Increasing Colorectal Cancer Screening on the Texas-Mexico Border	Larson, Adrian F	Val Verde Regional Medical Center	1,500,000	2.6	3
PP150053	CCE-EBP	BSPAN3: Breast Screening and Patient Navigation for Rural and Underserved Women across North Texas	Lee, Simon Craddock	The University of Texas Southwestern Medical Center	1,499,993	2.9	4
PP150054	EBP-CRC	Alliance for Colorectal Cancer Testing (ACT) in Southeast Texas	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	2,588,774	2.9	4 (rank ordered without Dr. Brownson)
PP150077	EBP	Media-Rich Mobile Dissemination of a Dysphagia Prevention Program for Head and Neck Cancer Patients during Radiation	Shinn, Eileen	The University of Texas M. D. Anderson Cancer Center	1,263,342	2.9	6

PP150086	CCE-EBP	Access to Breast and Cervical Care for West Texas (West/Central Texas)(ABCC4WT)	Ross, Linda	Angelo State University	1,480,898	3.9	7
PP150080	CCE-EBP	Empower Her To Care Expansion: Increasing Access to Breast Cancer Screening and the Continuum of Care for Underserved Texas Women	Joseph, Bernice	The Rose	1,500,000	4.1	8
PP150078	EBP	Cada Paso del Camino: Outreach, Education, Screening, Health Insurance Navigation, and Linkage to Treatment for Breast, Cervical, and Colorectal Cancers	Arjona, Moises	MHP, Inc. Promoviendo Vidas Saludables	1,498,337	4.5	9
PP150064	CCE-EBP	University Health System Evidence-Based Colorectal Cancer Prevention Screening Program	Villarreal, Roberto	University Health System	1,499,775	4.5	10
PP150089	CCE-EBP	Increasing Breast and Cervical Cancer Screening and Diagnostic Rates in Rural, Frontier, and Border Counties for Uninsured, Underserved Women	Rice, Carol A	Texas AgriLife Extension Service	1,500,000	4.7	11



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150053
Competitive Continuation/Expansion
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 *Competitive Continuation/Expansion Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 10 applications for this RFA. The application was assigned to 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:

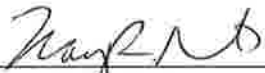
- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating 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

One application in response to this RFA with a more favorable score than those recommended was not recommended by the Prevention Review Council (PRC). As allowed in 25 T.A.C § 703.6(d)(1), the PRC'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. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

- 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

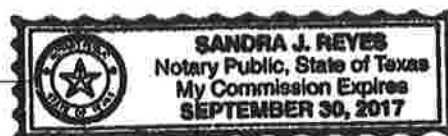
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP150053
APPLICATION TITLE BSPAN3: Breast Screening and Patient Navigation for Rural and Underserved Women across North Texas
APPLICANT NAME Lee, Simon Craddock
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Prevention Panel 2

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/27/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/27/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/27/15
	Date application submitted	12/01/14	03/27/15
	Method of submission	CARS	03/27/15
	Within receipt period	YES	03/27/15
	Appeal to submit application after CARS closed	N/A	03/27/15
	Appeal for late application submission accepted	N/A	03/27/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/27/15
	Donation(s) made to CPRIT/foundation	NO	03/27/15
	Assigned to primary reviewers	01/08/15	03/27/15
	Applicant notified of review panel assignment	01/26/15	03/27/15
	Primary Reviewer 1 COI signed	12/29/14	03/27/15
	Primary (Advocate) Reviewer 2 COI signed	12/23/14	03/27/15
	Primary Reviewer 3 COI signed	12/28/14	03/27/15
	Primary Reviewer 4 COI signed	12/26/14	03/27/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	02/09/15	03/27/15
	Primary (Advocate) Reviewer 2 critique submitted	02/08/15	03/27/15
	Primary Reviewer 3 critique submitted	02/03/15	03/27/15
	Primary Reviewer 4 critique submitted	02/09/15	03/27/15
	COI indicated by non-primary reviewer	NONE	03/27/15
	COI recused from participation	N/A	03/27/15
	Discussed at Peer Review Meeting	YES	03/27/15
	Peer Review Meeting	02/24/15-02/25/15	03/27/15
	Post review statements signed	03/02/15	03/27/15
	Third Party Observer Report	02/25/15	03/27/15
	Score report delivered to CPO	03/03/15	03/27/15
	Recommended for PRC Review	YES	03/27/15
4. Final PRC Recommendation	COI indicated by PRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150064
Competitive Continuation/Expansion
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 *Competitive Continuation/Expansion Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 10 applications for this RFA. The application was assigned to 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

One application in response to this RFA with a more favorable score than those recommended was not recommended by the Prevention Review Council (PRC). As allowed in 25 T.A.C § 703.6(d)(1), the PRC'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. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

- 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

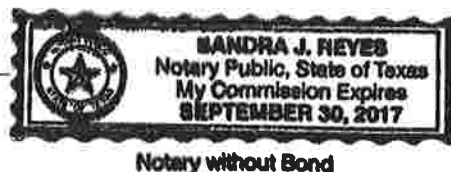
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP150064
APPLICATION TITLE University Health System Evidence-Based Colorectal Cancer Prevention Screening Program
APPLICANT NAME Villarreal, Roberto
ORGANIZATION University Health System
PANEL NAME Prevention Panel 1

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/26/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/26/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/26/15
	Date application submitted	12/04/14	03/26/15
	Method of submission	CARS	03/26/15
	Within receipt period	YES	03/26/15
	Appeal to submit application after CARS closed	N/A	03/26/15
	Appeal for late application submission accepted	N/A	03/26/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/26/15
	Donation(s) made to CPRIT/foundation	NO	03/26/15
	Assigned to primary reviewers	01/08/15	03/26/15
	Applicant notified of review panel assignment	01/26/15	03/26/15
	Primary Reviewer 1 COI signed	12/23/14	03/26/15
	Primary (Advocate) Reviewer 2 COI signed	12/23/14	03/26/15
	Primary Reviewer 3 COI signed	01/23/15	03/26/15
	Primary Reviewer 4 COI signed	12/30/14	03/26/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	02/10/15	03/26/15
	Primary (Advocate) Reviewer 2 critique submitted	01/22/15	03/26/15
	Primary Reviewer 3 critique submitted	02/10/15	03/26/15
	Primary Reviewer 4 critique submitted	02/07/15	03/26/15
	COI indicated by non-primary reviewer	NONE	03/26/15
	COI recused from participation	N/A	03/26/15
	Discussed at Peer Review Meeting	YES	03/26/15
	Peer Review Meeting	02/23/15-02/24/15	03/26/15
	Post review statements signed	03/03/15	03/26/15
	Third Party Observer Report	02/25/15	03/26/15
	Score report delivered to CPO	03/03/15	03/26/15
4. Final PRC Recommendation	Recommended for PRC Review	YES	03/26/15
	COI indicated by PRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
5. PIC Review	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
6. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150080
Competitive Continuation/Expansion
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 *Competitive Continuation/Expansion Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 10 applications for this RFA. The application was assigned to 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

One application in response to this RFA with a more favorable score than those recommended was not recommended by the Prevention Review Council (PRC). As allowed in 25 T.A.C § 703.6(d)(1), the PRC'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. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

- 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


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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

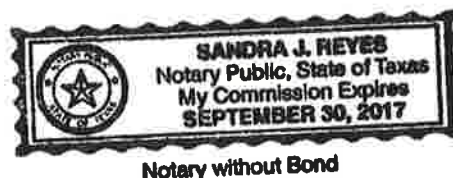
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP150080
APPLICATION TITLE Empower Her To Care Expansion: Increasing Access to Breast Cancer Screening and the Continuum of Care for Underserved Texas Women
APPLICANT NAME Joseph, Bernice
ORGANIZATION The Rose
PANEL NAME Prevention Panel 2

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/27/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/27/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/27/15
	Date application submitted	12/04/14	03/27/15
	Method of submission	CARS	03/27/15
	Within receipt period	YES	03/27/15
	Appeal to submit application after CARS closed	N/A	03/27/15
	Appeal for late application submission accepted	N/A	03/27/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/27/15
	Donation(s) made to CPRIT/foundation	NO	03/27/15
	Assigned to primary reviewers	01/08/15	03/27/15
	Applicant notified of review panel assignment	01/26/15	03/27/15
	Primary Reviewer 1 COI signed	01/03/15	03/27/15
	Primary (Advocate) Reviewer 2 COI signed	12/23/14	03/27/15
	Primary Reviewer 3 COI signed	01/06/15	03/27/15
	Primary Reviewer 4 COI signed	12/26/14	03/27/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	02/09/15	03/27/15
	Primary (Advocate) Reviewer 2 critique submitted	02/08/15	03/27/15
	Primary Reviewer 3 critique submitted	02/01/15	03/27/15
	Primary Reviewer 4 critique submitted	01/30/15	03/27/15
	COI indicated by non-primary reviewer	NONE	03/27/15
	COI recused from participation	N/A	03/27/15
	Discussed at Peer Review Meeting	YES	03/27/15
	Peer Review Meeting	02/24/15-02/25/15	03/27/15
	Post review statements signed	03/02/15	03/27/15
	Third Party Observer Report	02/25/15	03/27/15
	Score report delivered to CPO	03/03/15	03/27/15
4. Final PRC Recommendation	Recommended for PRC Review	YES	03/27/15
	COI indicated by PRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
5. PIC Review	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
6. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150086
Competitive Continuation/Expansion
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 *Competitive Continuation/Expansion Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 10 applications for this RFA. The application was assigned to 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

One application in response to this RFA with a more favorable score than those recommended was not recommended by the Prevention Review Council (PRC). As allowed in 25 T.A.C § 703.6(d)(1), the PRC'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. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

- 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

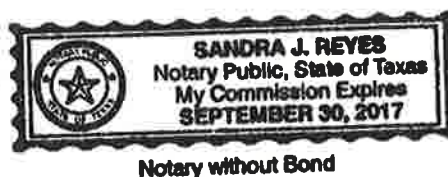
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP150086
APPLICATION TITLE Access to Breast and Cervical Care for West Texas
 (West/Central Texas)(ABCC4WT)
APPLICANT NAME Ross, Linda
ORGANIZATION Angelo State University
PANEL NAME Prevention Panel 2

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/27/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/27/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/27/15
	Date application submitted	12/04/14	03/27/15
	Method of submission	CARS	03/27/15
	Within receipt period	YES	03/27/15
	Appeal to submit application after CARS closed	N/A	03/27/15
	Appeal for late application submission accepted	N/A	03/27/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/27/15
	Donation(s) made to CPRIT/foundation	NO	03/27/15
	Assigned to primary reviewers	01/08/15	03/27/15
	Applicant notified of review panel assignment	01/26/15	03/27/15
	Primary Reviewer 1 COI signed	01/04/15	03/27/15
	Primary (Advocate) Reviewer 2 COI signed	12/23/14	03/27/15
	Primary Reviewer 3 COI signed	12/26/14	03/27/15
	Primary Reviewer 4 COI signed	01/05/15	03/27/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	02/09/15	03/27/15
	Primary (Advocate) Reviewer 2 critique submitted	02/08/15	03/27/15
	Primary Reviewer 3 critique submitted	02/06/15	03/27/15
	Primary Reviewer 4 critique submitted	02/16/15	03/27/15
	COI indicated by non-primary reviewer	NONE	03/27/15
	COI recused from participation	N/A	03/27/15
	Discussed at Peer Review Meeting	YES	03/27/15
	Peer Review Meeting	02/24/15-02/25/15	03/27/15
	Post review statements signed	03/02/15	03/27/15
	Third Party Observer Report	02/25/15	03/27/15
	Score report delivered to CPO	03/03/15	03/27/15
	Recommended for PRC Review	YES	03/27/15
4. Final PRC Recommendation	COI indicated by PRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150089
Competitive Continuation/Expansion
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 *Competitive Continuation/Expansion Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 10 applications for this RFA. The application was assigned to 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

One application in response to this RFA with a more favorable score than those recommended was not recommended by the Prevention Review Council (PRC). As allowed in 25 T.A.C § 703.6(d)(1), the PRC'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. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

- 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

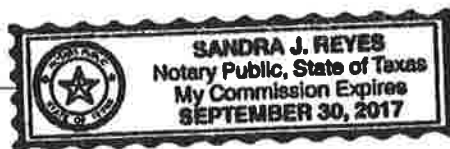
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP150089
APPLICATION TITLE Increasing Breast and Cervical Cancer Screening and Diagnostic Rates in Rural, Frontier, and Border Counties for Uninsured, Underserved Women
APPLICANT NAME Rice, Carol
ORGANIZATION Texas AgriLife Extension Service
PANEL NAME Prevention Panel 1

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/26/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/26/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/26/15
	Date application submitted	12/04/14	03/26/15
	Method of submission	CARS	03/26/15
	Within receipt period	YES	03/26/15
	Appeal to submit application after CARS closed	N/A	03/26/15
	Appeal for late application submission accepted	N/A	03/26/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/26/15
	Donation(s) made to CPRIT/foundation	NO	03/26/15
	Assigned to primary reviewers	01/08/15	03/26/15
	Applicant notified of review panel assignment	01/26/15	03/26/15
	Primary Reviewer 1 COI signed	12/23/14	03/26/15
	Primary (Advocate) Reviewer 2 COI signed	12/29/14	03/26/15
	Primary Reviewer 3 COI signed	01/06/15	03/26/15
	Primary Reviewer 4 COI signed	12/23/14	03/26/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	01/26/15	03/26/15
	Primary (Advocate) Reviewer 2 critique submitted	02/16/15	03/26/15
	Primary Reviewer 3 critique submitted	02/09/15	03/26/15
	Primary Reviewer 4 critique submitted	02/10/15	03/26/15
	COI indicated by non-primary reviewer	NONE	03/26/15
	COI recused from participation	N/A	03/26/15
	Discussed at Peer Review Meeting	YES	03/26/15
	Peer Review Meeting	02/23/15-02/24/15	03/26/15
	Post review statements signed	03/03/15	03/26/15
	Third Party Observer Report	02/25/15	03/26/15
	Score report delivered to CPO	03/03/15	03/26/15
	Recommended for PRC Review	YES	03/26/15
4. Final PRC Recommendation	COI indicated by PRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150071
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 *Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 16 applications, including 1 that was withdrawn, for this RFA. The application was assigned to 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

Two applications in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As allowed in 25 T.A.C. § 703.6(d)(1), the PRC'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. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

- 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

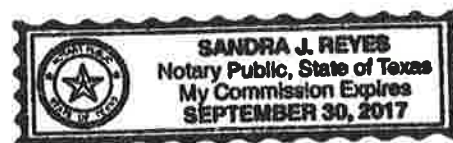
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP150071
APPLICATION TITLE FluFIT on the Frontera: Increasing Colorectal Cancer Screening on the Texas-Mexico Border
APPLICANT NAME Larson, Adrian
ORGANIZATION Val Verde Regional Medical Center
PANEL NAME Prevention Panel 2

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/27/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/27/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/27/15
	Date application submitted	12/04/14	03/27/15
	Method of submission	CARS	03/27/15
	Within receipt period	YES	03/27/15
	Appeal to submit application after CARS closed	N/A	03/27/15
	Appeal for late application submission accepted	N/A	03/27/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/27/15
	Donation(s) made to CPRIT/foundation	NO	03/27/15
	Assigned to primary reviewers	01/08/15	03/27/15
	Applicant notified of review panel assignment	01/26/15	03/27/15
	Primary Reviewer 1 COI signed	01/04/15	03/27/15
	Primary (Advocate) Reviewer 2 COI signed	01/05/15	03/27/15
	Primary Reviewer 3 COI signed	01/05/15	03/27/15
	Primary Reviewer 4 COI signed	01/03/15	03/27/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	02/09/15	03/27/15
	Primary (Advocate) Reviewer 2 critique submitted	02/08/15	03/27/15
	Primary Reviewer 3 critique submitted	02/08/15	03/27/15
	Primary Reviewer 4 critique submitted	02/09/15	03/27/15
	COI indicated by non-primary reviewer	NONE	03/27/15
	COI recused from participation	N/A	03/27/15
	Discussed at Peer Review Meeting	YES	03/27/15
	Peer Review Meeting	02/24/15-02/25/15	03/27/15
	Post review statements signed	03/02/15	03/27/15
	Third Party Observer Report	02/25/15	03/27/15
	Score report delivered to CPO	03/03/15	03/27/15
	Recommended for PRC Review	YES	03/27/15
4. Final PRC Recommendation	COI indicated by PRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to a conflict of interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150077
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 *Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 16 applications, including 1 that was withdrawn, for this RFA. The application was assigned to 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


Two applications in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As

allowed in 25 T.A.C § 703.6(d)(1), the PRC'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. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

- 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


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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

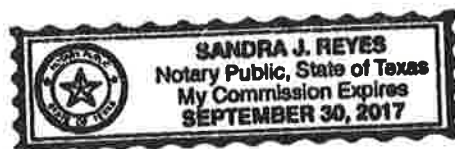
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP150077
APPLICATION TITLE Media-Rich Mobile Dissemination of a Dysphagia Prevention Program for Head and Neck Cancer Patients during Radiation
APPLICANT NAME Shinn, Eileen
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Prevention Panel 1

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/26/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/26/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/26/15
	Date application submitted	12/04/14	03/26/15
	Method of submission	CARS	03/26/15
	Within receipt period	YES	03/26/15
	Appeal to submit application after CARS closed	N/A	03/26/15
	Appeal for late application submission accepted	N/A	03/26/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/26/15
	Donation(s) made to CPRIT/foundation	NO	03/26/15
	Assigned to primary reviewers	01/08/15	03/26/15
	Applicant notified of review panel assignment	01/26/15	03/26/15
	Primary Reviewer 1 COI signed	12/30/14	03/26/15
	Primary (Advocate) Reviewer 2 COI signed	12/29/14	03/26/15
	Primary Reviewer 3 COI signed	01/04/15	03/26/15
	Primary Reviewer 4 COI signed	12/23/14	03/26/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	02/09/15	03/26/15
	Primary (Advocate) Reviewer 2 critique submitted	02/16/15	03/26/15
	Primary Reviewer 3 critique submitted	02/04/15	03/26/15
	Primary Reviewer 4 critique submitted	01/30/15	03/26/15
	COI indicated by non-primary reviewer	NONE	03/26/15
	COI recused from participation	N/A	03/26/15
	Discussed at Peer Review Meeting	YES	03/26/15
	Peer Review Meeting	02/23/15-02/24/15	03/26/15
	Post review statements signed	03/03/15	03/26/15
	Third Party Observer Report	02/25/15	03/26/15
	Score report delivered to CPO	03/03/15	03/26/15
	Recommended for PRC Review	YES	03/26/15
4. Final PRC Recommendation	COI indicated by PRC member	NONE	04/26/15
	COI recused from participation	N/A	04/26/15
	PRC Meeting	04/17/15	04/26/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/26/15
	PRC Chair Notification to PIC and OC	04/21/15	04/26/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to a conflict of interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150078
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 *Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 16 applications, including 1 that was withdrawn, for this RFA. The application was assigned to 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

Two applications in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As

allowed in 25 T.A.C § 703.6(d)(1), the PRC'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. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

- 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

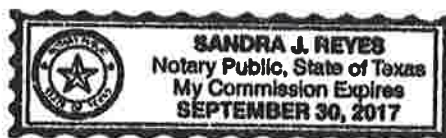
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP150078

APPLICATION TITLE Cada Paso del Camino: Outreach, Education, Screening, Health Insurance Navigation, and Linkage to Treatment for Breast, Cervical, and Colorectal Cancers

APPLICANT NAME Arjona, Moises
ORGANIZATION MHP, Inc. Promoviendo Vidas Saludables
PANEL NAME Prevention Panel 1

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/26/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/26/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/26/15
	Date application submitted	12/04/14	03/26/15
	Method of submission	CARS	03/26/15
	Within receipt period	YES	03/26/15
	Appeal to submit application after CARS closed	N/A	03/26/15
	Appeal for late application submission accepted	N/A	03/26/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/26/15
	Donation(s) made to CPRIT/foundation	NO	03/26/15
	Assigned to primary reviewers	01/08/15	03/26/15
	Applicant notified of review panel assignment	01/26/15	03/26/15
	Primary Reviewer 1 COI signed	01/06/15	03/26/15
	Primary (Advocate) Reviewer 2 COI signed	12/23/14	03/26/15
	Primary Reviewer 3 COI signed	12/23/14	03/26/15
	Primary Reviewer 4 COI signed	12/30/14	03/26/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	02/10/15	03/26/15
	Primary (Advocate) Reviewer 2 critique submitted	01/27/15	03/26/15
	Primary Reviewer 3 critique submitted	02/09/15	03/26/15
	Primary Reviewer 4 critique submitted	02/08/15	03/26/15
	COI indicated by non-primary reviewer	NONE	03/26/15
	COI recused from participation	N/A	03/26/15
	Discussed at Peer Review Meeting	YES	03/26/15
	Peer Review Meeting	02/23/15-02/24/15	03/26/15
	Post review statements signed	03/03/15	03/26/15
	Third Party Observer Report	02/25/15	03/26/15
	Score report delivered to CPO	03/03/15	03/26/15
	Recommended for PRC Review	YES	03/26/15
4. Final PRC Recommendation	COI indicated by PRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
5. PIC Review	COI indicated by PIC member	K. Cole	05/05/15
	COI recused from participation	YES	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150079
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 *Evidence-Based Cancer Prevention Services Request for Applications (RFA)*. CPRIT received 16 applications, including 1 that was withdrawn, for this RFA. The application was assigned to 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


Two applications in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As

allowed in 25 T.A.C § 703.6(d)(1), the PRC'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. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

- 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


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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

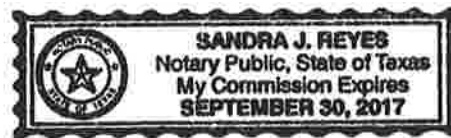
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP150079
APPLICATION TITLE STOP HCC –Evidence-Based Hepatocellular Cancer Prevention Targeting Hepatitis C Virus Infection
APPLICANT NAME Turner, Barbara
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Prevention Panel 1

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/26/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/26/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/26/15
	Date application submitted	12/04/14	03/26/15
	Method of submission	CARS	03/26/15
	Within receipt period	YES	03/26/15
	Appeal to submit application after CARS closed	N/A	03/26/15
	Appeal for late application submission accepted	N/A	03/26/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/26/15
	Donation(s) made to CPRIT/foundation	NO	03/26/15
	Assigned to primary reviewers	01/08/15	03/26/15
	Applicant notified of review panel assignment	01/26/15	03/26/15
	Primary Reviewer 1 COI signed	01/04/15	03/26/15
	Primary (Advocate) Reviewer 2 COI signed	12/29/14	03/26/15
	Primary Reviewer 3 COI signed	12/30/14	03/26/15
	Primary Reviewer 4 COI signed	12/23/14	03/26/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	01/29/15	03/26/15
	Primary (Advocate) Reviewer 2 critique submitted	02/16/15	03/26/15
	Primary Reviewer 3 critique submitted	02/09/15	03/26/15
	Primary Reviewer 4 critique submitted	02/10/15	03/26/15
	COI indicated by non-primary reviewer	NONE	03/26/15
	COI recused from participation	N/A	03/26/15
	Discussed at Peer Review Meeting	YES	03/26/15
	Peer Review Meeting	02/23/15-02/24/15	03/26/15
	Post review statements signed	03/03/15	03/26/15
	Third Party Observer Report	02/25/15	03/26/15
	Score report delivered to CPO	03/03/15	03/26/15
4. Final PRC Recommendation	Recommended for PRC Review	YES	03/26/15
	COI indicated by PRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
5. PIC Review	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
	PIC review meeting	05/05/15	05/05/15
6. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to a conflict of interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150054
Evidence-Based Cancer Prevention Services
Colorectal Cancer Prevention Coalition

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 *Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition* Request for Applications (RFA). CPRIT received five applications, including one that was withdrawn, for this RFA. The application was assigned to 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."



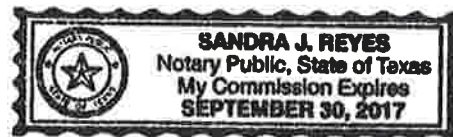
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition (EBP-CRC)
APPLICATION ID PP150054
APPLICATION TITLE Alliance for Colorectal Cancer Testing (ACT) in Southeast Texas
APPLICANT NAME Foxhall, Lewis
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Prevention Panel 2

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/27/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/27/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/27/15
	Date application submitted	12/04/14	03/27/15
	Method of submission	CARS	03/27/15
	Within receipt period	YES	03/27/15
	Appeal to submit application after CARS closed	N/A	03/27/15
	Appeal for late application submission accepted	N/A	03/27/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/27/15
	Donation(s) made to CPRIT/foundation	NO	03/27/15
	Assigned to primary reviewers	01/08/15	03/27/15
	Applicant notified of review panel assignment	01/26/15	03/27/15
	Primary Reviewer 1 COI signed	01/03/15	03/27/15
	Primary (Advocate) Reviewer 2 COI signed	01/05/15	03/27/15
	Primary Reviewer 3 COI signed	01/04/15	03/27/15
	Primary Reviewer 4 COI signed	01/05/15	03/27/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	02/09/15	03/27/15
	Primary (Advocate) Reviewer 2 critique submitted	02/06/15	03/27/15
	Primary Reviewer 3 critique submitted	02/09/15	03/27/15
	Primary Reviewer 4 critique submitted	02/08/15	03/27/15
	COI indicated by non-primary reviewer	Brownson, Ross	03/27/15
	COI recused from participation	YES	03/27/15
	COI indicated by non-primary reviewer	Mahoney, Martin	03/27/15
	COI recused from participation	YES	03/27/15
	Discussed at Peer Review Meeting	YES	03/27/15
	Peer Review Meeting	02/24/15-02/25/15	03/27/15
	Post review statements signed	03/02/15	03/27/15
	Third Party Observer Report	02/25/15	03/27/15
	Score report delivered to CPO	03/03/15	03/27/15
	Recommended for PRC Review	YES	03/27/15
4. Final PRC Recommendation	COI indicated by PRC member	Brownson, Ross	04/23/15
	COI recused from participation	YES	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
5. PIC Review	COI indicated by PIC member	K. Cole	05/05/15
	COI recused from participation	YES and M. Kripke*	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to a conflict of interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150061
Evidence-Based Cancer Prevention Services
Colorectal Cancer Prevention Coalition

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 *Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition* Request for Applications (RFA). CPRIT received five applications, including one that was withdrawn, for this RFA. The application was assigned to 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


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."



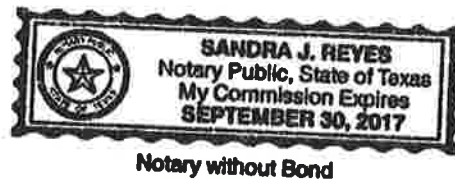
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition (EBP-CRC)
APPLICATION ID PP150061
APPLICATION TITLE The C-SPAN Coalition: Colorectal Screening and Patient Navigation
APPLICANT NAME Argenbright, Keith
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Prevention Panel 1

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	10/31/14	03/26/15
	CPRIT Application Receipt System (CARS) opened	09/25/14	03/26/15
	CPRIT Application Receipt System (CARS) closed	12/04/14	03/26/15
	Date application submitted	12/03/14	03/26/15
	Method of submission	CARS	03/26/15
	Within receipt period	YES	03/26/15
	Appeal to submit application after CARS closed	N/A	03/26/15
	Appeal for late application submission accepted	N/A	03/26/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	03/26/15
	Donation(s) made to CPRIT/foundation	NO	03/26/15
	Assigned to primary reviewers	01/08/15	03/26/15
	Applicant notified of review panel assignment	01/26/15	03/26/15
	Primary Reviewer 1 COI signed	12/23/14	03/26/15
	Primary (Advocate) Reviewer 2 COI signed	12/23/14	03/26/15
	Primary Reviewer 3 COI signed	01/23/15	03/26/15
	Primary Reviewer 4 COI signed	01/04/15	03/26/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	02/10/15	03/26/15
	Primary (Advocate) Reviewer 2 critique submitted	02/01/15	03/26/15
	Primary Reviewer 3 critique submitted	02/10/15	03/26/15
	Primary Reviewer 4 critique submitted	01/30/15	03/26/15
	COI indicated by non-primary reviewer	NONE	03/26/15
	COI recused from participation	N/A	03/26/15
	Discussed at Peer Review Meeting	YES	03/26/15
	Peer Review Meeting	02/23/15-02/24/15	03/26/15
	Post review statements signed	03/03/15	03/26/15
	Third Party Observer Report	02/25/15	03/26/15
	Score report delivered to CPO	03/03/15	03/26/15
	Recommended for PRC Review	YES	03/26/15
4. Final PRC Recommendation	COI indicated by PRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	PRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
	PRC Chair Notification to PIC and OC	04/21/15	04/23/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: MARGARET KRIPKE, PH.D.
SUBJECT: FY15, CYCLE 2 RESEARCH AWARDS
DATE: APRIL 22, 2015

The applications recommended for funding have been reviewed and approved by the CPRIT Scientific Review Council (SRC), as well as the Program Integration Committee (PIC). Applications were submitted in response to three scientific research award mechanism Request for Applications (RFAs): Core Facilities Support Awards (RFA R-15-CFSA-2), High Impact/High Risk Research Awards (RFA R-15-HIHR-2), and Multi-Investigator Research Awards (RFA R-15-MIRA-2). One hundred and fifty-nine applications were received in total for all three mechanisms (CFSA – 17, HIHR – 100, and MIRA – 42). No applications were administratively rejected or withdrawn by the applicant, and all 159 were reviewed. Twenty-four applications are being recommended for funding, for a combined amount of \$50,066,421.

Core Facilities Support Awards (RFA R-15-CFSA-2)

Applications Submitted as Resubmission:	1
Applications Receiving Full Review:	17
Applications Recommended:	6
Total Funding Request:	\$30,949,575

The aim of Core Facility Support Awards is to promote the establishment or enhancement of core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for cancer patients and survivors. 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 survivorship. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, cure, or quality of life. This award provides cancer researchers access to appropriate research infrastructure, instrumentation, and technical expertise necessary to achieve their research objectives. A wide variety of facilities can be supported, including, but not limited to, chemistry, high-throughput screening, biomedical imaging, proteomics, protein structure, molecular biology, genomics, metabolomics, animal physiology/metabolism, cell sorting, bioengineering, clinical research support, bioinformatics, and the like.

The maximum duration for this award mechanism is 5 years. Applicants may request a maximum of \$3,000,000 in total costs for the first 2 years and up to \$1,000,000 in total costs for each subsequent year for a total of \$6,000,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. Six applications were recommended to the Scientific Review Council for their consideration, and the SRC voted to recommend that all six to be considered for approval by the Oversight Committee. CPRIT caps the number of CFSA applications that may be submitted by a particular institution. Without the mandatory caps, CPRIT would likely receive many more CFSA applications.

Questions considered by reviewers included the following: Is the need for the facility justified? Is it necessary and appropriate for the research projects? Will the state-of-the-art facility directly support and impact cancer research programs at the institution and in the region? How will the availability of the facility offer incipient research projects by investigators at various career stages the opportunity to develop? Will the facility make the user group more competitive for external funding? Are the projects at the forefront of cancer research? Are the projects of significance in reducing cancer incidence, morbidity, or mortality? Is there sufficient technical expertise for optimal use of the facility?

High Impact/High Risk Research Awards (RFA R-15-HIHR-2)

Applications submitted as Resubmissions:	10
Applications Receiving Full Review:	100
Applications Recommended:	16
Total Funding Request:	\$3,194,510

The aim of this RFA is to provide short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. The intent is to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. Applications may address any research topic related to cancer biology, causation, prevention, detection, screening, or treatment. Areas of interest include laboratory research, translational studies, population-based and/or clinical investigations. Awards are made in the amount of up to \$100,000 for each of two years.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. Sixteen applications were recommended to the Scientific Review Council for their consideration, and the SRC voted to recommend that all sixteen to be considered for approval by the Oversight Committee. CPRIT caps the number of HIHR applications that may be submitted by a particular institution. Without the mandatory caps, CPRIT would likely receive many more HIHR applications.

Questions considered by reviewers included the following: Is the application clearly responsive to the RFA and specifically to the HIHR Research Award mechanism? What is the innovative potential of the project? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important under-or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field? Does the proposed research have a clearly defined hypothesis or goal that is supported by a sound scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed? Does the applicant investigator demonstrate the required creativity,

expertise, experience, and accomplishments to make a significant contribution to the research? Does the proposed research have a high degree of relevance to cancer?

Multi-Investigator Research Awards (RFA R-15-MIRA-2)

Applications submitted as Renewals:	N/A
Applications Receiving Full Review:	42
Applications Recommended:	2
Total Funding Request:	\$15,922,336

Multi-Investigator Research Awards are intended to support the creation of integrated programs of collaborative and cross-disciplinary research among multiple investigators. These should be equivalent to program projects, research centers, NCI SPOREs, multi-institutional clinical trial networks, or other types of collaborative interactions. Teams will focus on critical areas of cancer research, especially those that have been inadequately addressed by research up to this point or for which there may be an absence of an established paradigm or technical framework. Laboratory research, translational studies, clinical, and population-based investigations may be supported. Awards are expected to promote a cooperative environment that fosters intensive interaction among members in all aspects of the research program. This approach is expected to transform the research process through the integration of basic and/or clinical disciplines, leading to the aggressive translation of scientific discoveries into tools and applications that have the potential to make a significant impact on cancer incidence, detection, treatment, and/or survivorship.

The maximum duration for this award mechanism is 5 years. Applicants may request a maximum of \$10,000,000 in total costs.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. Two applications were recommended to the Scientific Review Council for their consideration. Peer Review Panel members recommended that one application only be funded with the removal of a MIRA project that resulted in the budget being reduced based on the funds allocated to that project, and then an additional 20% be reduced from the remaining budget. The SRC voted to recommend that both be considered for approval by the Oversight Committee with the recommended changes.

Questions considered by reviewers included the following: Does the proposed research have a high degree of relevance to reduce the burden of cancer? What is the innovative potential of the program? Does the program propose new paradigms or challenge existing ones? Does the program develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed? Does the proposed project provide strong synergistic activities as part of a multidisciplinary collaboration? If core facilities are described, are they necessary and sufficient to support the project in achieving the overall goals proposed? Has the project assembled the best qualified collaborative and multidisciplinary teams to achieve the proposed goals?

Overall SRC and PIC Research Program Recommendation

The SRC voted to recommend all 24 applications that were presented by the Peer Review Panels and to accept the modifications in work scope and budget as recommended. This recommendation was

forwarded by the Chair of the SRC to the Program Integration Committee and to the Oversight Committee. The Program Integration Committee met to discuss applications on May 5, 2015 and voted to recommend all applications in the order in which they were presented by the SRC. The PIC accepted all of the modifications in work scope and budget as recommended, and forwarded their recommendation to the Oversight Committee for final approval.

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: MARGARET KRIPKE, PH.D.
SUBJECT: FY15 RECRUITMENT AWARDS
DATE: APRIL 22, 2015

The applications recommended for funding by the CPRIT Scientific Review Council (SRC) have been reviewed and approved by the Program Integration Committee (PIC). Applications were submitted in response to Recruitment of Established Investigator (REI), Recruitment for First-Time, Tenure Track Faculty Members (RFT), and Recruitment of Rising Stars (RRS) Request for Applications. Twelve applications were received in total (Recruitment of Established Investigator (REI) - 1, Recruitment for First-Time, Tenure Track Faculty Members (RFT) - 10, and Recruitment of Rising Stars (RRS) - 1). One RFT application was withdrawn prior to the assignments for review and the other 11 applications were reviewed. Six applications were recommended for funding by the SRC, however, one recruit has withdrawn prior to the PIC and the Oversight Committee meetings. Four applications for Recruitment of First-Time, Tenure-Track Faculty Members and one for Recruitment of Established Investigators have been recommended for a combined amount of \$12,000,000. The SRC reduced the amount of the REI grant from \$6,000,000 to \$4,000,000 based on the recommendations of the primary reviewers. The candidate for the Recruitment of Rising Stars mechanism was not selected.

Recruitment of Established Investigators (RFA R-15-REI)

Applications Reviewed:	1
Applications Recommended:	1
Total Funding Request:	\$4,000,000

The aim of this RFA is to recruit outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas. Award: Up to \$6M over a period of five years.

The applications were evaluated and scored by the 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, 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.

Questions that were considered by reviewers include: 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?

Established Investigator candidate recommended by the Scientific Review Council is:

Hongtu Zhu, Ph.D., is being recruited to the The University of Texas M.D. Anderson Cancer Center from the Department of Biostatistics and Biomedical Research at the University of North Carolina at Chapel Hill. Dr. Zhu develops statistical models for the analysis and integration of biochemical, behavioral, clinical, genetic, and imaging data. His important contributions to statistics relate to latent variable models, missing data problems, neuroinformatics, statistical analysis of neuroimaging data, diagnostic methods, and big-data integration. Dr. Zhu's dedication to training quantitative scientists will make him a valuable faculty member and mentor of postdoctoral fellows at M.D. Anderson. His expertise and experience will strengthen the biostatistical collaborations with researchers in the Department of Cancer Imaging Systems and with clinical researchers who use diagnostic imaging modalities at M.D. Anderson Cancer Center.

Recruitment of First-Time, Tenure-Track Faculty Members (RFA R-15-RFT)

Applications Reviewed:	9
Applications Recommended:	4
Total Funding Request:	\$8,000,000

The aim of this RFA is to recruit and support 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 of 4 years.

The applications were evaluated and scored by the 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, 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.

Questions that were considered by reviewers include: 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 of independence?

Four candidates are being recommended for First-time Faculty Awards, 3 at The University of Texas Southwestern Medical Center and 1 from Rice University. Below is a listing of these candidates with their associated expertise. All have outstanding training and records of achievement and a strong commitment to cancer research.

- **Shixin Liu, Ph.D.** (UTSW) - Single-molecule, fluorescence spectroscopy, force spectroscopy, molecular motors, gene regulation
- **Andreas Doncic, M.D.** (UTSW) - Systems biology, mathematical modeling, image analysis, microscopy, microfluidics, molecular biology and genetics (budding yeast)
- **Maralice Conacci-Sorrell, M.D., Ph.D.**, (UTSW) - Myc, hypoxia, chemotherapeutic resistance, metastasis, acetylation, colon cancer
- **Natalia Kirienko, Ph.D.** (Rice) - C. elegans as a cancer model, mitophagy, autophagy

Conflicts of Interest for Academic Research Cycle 15.2 Applications
(Academic Research Cycle 15.2 Awards Announced at May 20, 2015, 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 Academic Research Cycle 15.2 include *Core Facilities Support Awards*, *High Impact/High Risk Research Awards*, and *Multi-Investigator 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP150535	Meric-Bernstam, Funda	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150551	An, Zhiqiang	The University of Texas Health Science Center at Houston	Mitchell, Amy
RP150559	Burgess, Kevin	Texas A&M University	Mitchell, Amy
RP150573	Schmid, Sandra	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150574	Li, Rong	The University of Texas Health Science Center at San Antonio	Mitchell, Amy
RP150578	Davies, Peter	Texas A&M University System Health Science Center	Mitchell, Amy
RP150587	El-Serag, Hashem	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher; Mitchell, Amy
RP150587-C1	Marrero, Jorge	The University of Texas Southwestern Medical Center	Barlow, William; Kushi, Lawrence; Li, Christopher; Mitchell, Amy
RP150587-C2	Feng, Ziding	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kushi, Lawrence; Li, Christopher; Mitchell, Amy

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150587-P1	Kanwal, Fasiha	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher; Mitchell, Amy
RP150587-P2	El-Serag, Hashem	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-P3	Moore, David	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher; Mitchell, Amy
RP150587-P4	Baretta, Laura	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kushi, Lawrence; Li, Christopher; Mitchell, Amy
RP150587-P5	Singal, Amit	The University of Texas Southwestern Medical Center	Barlow, William; Kushi, Lawrence; Li, Christopher; Mitchell, Amy
RP150590	Johnson, Jane	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150596	Danuser, Gaudenz	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150611	Cooke, John	The Methodist Hospital Research Institute	Sukumar, Saraswati; Mitchell, Amy
RP150632	Bachoo, Robert	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150637	Bartosh, Thomas	Texas A&M University System Health Science Center	Mitchell, Amy
RP150638	Theiss, Arianne	Baylor Research Institute	Mitchell, Amy
RP150640	Carmon, Kendra	The University of Texas Health Science Center at Houston	Mitchell, Amy
RP150648	O'Malley, Bert	Baylor College of Medicine	Costello, Joseph; Mitchell, Amy
RP150648-C1	Ittmann, Michael	Baylor College of Medicine	Costello, Joseph; Mitchell, Amy
RP150648-P1	Tsai, Ming-Jer	Baylor College of Medicine	Costello, Joseph; Mitchell, Amy
RP150648-P2	Weigel, Nancy	Baylor College of Medicine	Costello, Joseph; Mitchell, Amy

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150648-P3	O'Malley, Bert	Baylor College of Medicine	Costello, Joseph; Mitchell, Amy
RP150648-P4	Chiu, Wah	Baylor College of Medicine	Costello, Joseph; Mitchell, Amy
RP150656	Liu, Xinli	Texas Tech University Health Sciences Center	Mitchell, Amy
RP150676	O'Donnell, Kathryn	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150696	Nicholson, Bruce	The University of Texas Health Science Center at San Antonio	Mitchell, Amy
RP150701	Carson, Daniel	Rice University	Mitchell, Amy
RP150703	Cheng, Yi-Shing	Texas A&M University System Health Science Center	Mitchell, Amy
RP150711	Mohanty, Samarendra	The University of Texas at Arlington	Mitchell, Amy
RP150713	Lee, Jiyong	The University of Texas at Dallas	Mitchell, Amy
RP150720	Li, Wei	Texas Tech University	Mitchell, Amy
RP1560600	Huang, Tim	The University of Texas Health Science Center at San Antonio	Mitchell, Amy

Application ID	Applicant	Institution	Conflict Noted
Applications Not Recommended for PIC or Oversight Committee Consideration			
RP150527*	Foulds, Charles	Baylor College of Medicine	Greene, Geoffrey; Wahl, Geoffrey
RP150536*	Orlowski, Robert	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-C2*	Davis, Richard	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-C3*	Yang, Jing	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P1*	Shah, Nina	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P2*	Molldrem, Jeffrey	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150536-P3*	Nawrocki, Steffan	The University of Texas Health Science Center at San Antonio	Kast, W. Martin
RP150536-P4*	Colla, Simona	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P5*	Orlowski, Robert	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150537*	Dalby, Kevin	The University of Texas at Austin	Roberts, Charles
RP150537-C1*	Ren, Pengyu	The University of Texas at Austin	Roberts, Charles
RP150537-C2*	Ueno, Naoto	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150537-P1*	Bartholomeusz, Chandra	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150537-P2*	Bartholomeusz, Chandra	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150537-P3*	Ueno, Naoto	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150560	Suarez-Almazor, Maria	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-C1	Zhao, Hui	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-C2	Chang, Shine	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-C3	Rodriguez, Alma	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P1	Smith, Benjamin	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P2	Holmes, Holly	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150560-P3	Hwang, Jessica	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P4	Suarez-Almazor, Maria	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P5	Shih, Ya-Chen Tina	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150575	Yu, Dihua	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-C1	Sahin, Aysegul	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-P1	Yu, Dihua	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-P2	Hung, Mien-Chie	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-P3	Jiang, Ning	The University of Texas at Austin	Kast, W. Martin; Riddell, Stanley
RP150575-P4	Mittendorf, Elizabeth	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150592	Symmans, William	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-C1	Tripathy, Debu	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-C2	Davies, Peter	Texas A&M University System Health Science Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-C3	Symmans, William	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P1	Moulder, Stacy	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P2	Piwnica-Worms, Helen	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150592-P3	Mani, Sendurai	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P4	Symmans, William	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150603	Raj, Ganesh	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-C1	Kapur, Payal	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-C2	Hwang, Tae Hyun	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P1	Boothman, David	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P2	Raj, Ganesh	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P3	Hsieh, Jer-Tsong	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P4	Martinez, Elisabeth	The University of Texas Southwestern Medical Center	Costello, Karen
RP150614*	Edwards, Beatrice	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-C1*	Wagner, Elizabeth	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-C2*	Zhao, Hua	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-C3*	Amini, Behrang	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-P1*	Edwards, Beatrice	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-P2*	Villareal, Reina	Baylor College of Medicine	Barlow, William

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150614-P3*	Villareal, Dennis	Baylor College of Medicine	Barlow, William
RP150631	Gustafsson, Jan-Ake	University of Houston	Sukumar, Saraswati
RP150631-P4	Tekmal, Rajeshwar	The University of Texas Health Science Center at San Antonio	Sukumar, Saraswati
RP150650	Pandita, Tej	The Methodist Hospital Research Institute	Sukumar, Saraswati
RP150650-P3	Pandita, Tej	The Methodist Hospital Research Institute	Sukumar, Saraswati
RP150653	Maitra, Anirban	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-C1	Maitra, Anirban	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-C2	Chin, Lynda	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P1	DePinho, Ronald	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P2	Draetta, Giulio	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P3	Kalluri, Raghu	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P4	Yee, Cassian	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150657	Sherry, Dean	The University of Texas at Dallas	Zinn, Kurt
RP150664	Rawley, David	Baylor College of Medicine	Greene, Geoffrey
RP150664-C1	Mancini, Michael	Baylor College of Medicine	Greene, Geoffrey
RP150664-P1	Zhang, Xiang	Baylor College of Medicine	Greene, Geoffrey
RP150664-P2	Rowley, David	Baylor College of Medicine	Greene, Geoffrey
RP150664-P3	Farach-Carson, Cindy	Rice University	Greene, Geoffrey
RP150664-P4	Park, Dongsu	Baylor College of Medicine	Greene, Geoffrey

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150667*	Mitsiades, Nicholas	Baylor College of Medicine	Costello, Joseph
RP150674*	Kameoka, Jun	Texas A&M University	Basillion, James
RP150679*	Wang, Rongfu	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-C1*	Liu, Xuewu	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-C2*	Gee, Adrian	Baylor College of Medicine	Kast, W. Martin
RP150679-P1*	Shen, Haifa	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-P2*	Wang, Rongfu	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-P3*	Rooney, Cliona	Baylor College of Medicine	Kast, W. Martin
RP150680*	Zeng, Mingtao	Texas Tech University Health Sciences Center at El Paso	Costello, Karen
RP150681	Jayarman, Arul	Texas A&M Engineering Experiment Station	Belinsky, Steven; Fearon, Eric
RP150683	Wetter, David	Rice University	Brandon, Thomas
RP150683-C1	Li, Liang	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas
RP150683-P1	Wetter, David	Rice University	Brandon, Thomas
RP150683-P2	Fernandez, Maria	The University of Texas Health Science Center at Houston	Brandon, Thomas
RP150683-P3	Shih, Ya-Chen Tina	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas
RP150684*	Wetter, David	Rice University	Brandon, Thomas

* = Not discussed

**Conflicts of Interest for Academic Research Cycle 15.2 Recruitment Applications
(Academic Research Cycle 15.2 Recruitment Awards Announced at May 20, 2015,
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 Academic Research Cycle 15.2 include *Recruitment of First-Time, Tenure-Track Faculty Members*; *Recruitment of Established Investigators*; and *Recruitment of Rising Stars*. 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RR150044	Rossky, Peter	Rice University	Mitchell, Amy
RR150054	Dmitrovsky, Ethan	The University of Texas M. D. Anderson Cancer Center	Mitchell, Amy
RR150058	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy
RR150059	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy
RR150062¹	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy

¹ RR150062 was withdrawn by the applicant after the PIC but before the OC.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 2
Core Facilities Support Awards

Request for Applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA R-15-CFSA-2

Core Facilities Support Awards

Please also refer to the “Instructions for Applicants” document, which will be posted September 30, 2014.

Application Receipt Opening Date: September 30, 2014

Application Receipt Closing Date: November 17, 2014

FY 2015

Fiscal Year Award Period

September 1, 2014–August 31, 2015

TABLE OF CONTENTS

1. ABOUT CPRIT	4
2. RATIONALE	4
3. RESEARCH OBJECTIVES	4
4. FUNDING INFORMATION	5
5. ELIGIBILITY	6
6. RESUBMISSION POLICY	8
7. RENEWAL POLICY	8
8. RESPONDING TO THIS RFA	8
8.1. APPLICATION SUBMISSION GUIDELINES	8
8.1.1. Submission Deadline Extension	8
8.2. APPLICATION COMPONENTS	9
8.2.1. Abstract and Significance (5000 characters)	9
8.2.2. Layperson's Summary (2000 characters)	9
8.2.3. Goals and Objectives	10
8.2.4. Timeline (1 page)	10
8.2.5. Institutional Support (2 pages)	10
8.2.6. Resubmission Summary (1 page)	10
8.2.7. Renewal Summary (2 pages)	11
8.2.8. Core Facility Plan (5 pages)	11
8.2.9. Vertebrate Animals and/or Human Subjects (1 page)	11
8.2.10. Publications/References	11
8.2.11. Budget and Justification	11
8.2.12. User Group (8 pages)	12
8.2.13. Biographical Sketches (2 pages each)	13
8.2.14. Current and Pending Support	13
8.2.15. Institutional/Collaborator Support and/or Other Certification (4 pages)	13
8.2.16. Previous Summary Statement	13
9. APPLICATION REVIEW	13
9.1. REVIEW PROCESS OVERVIEW	13
9.2. CONFIDENTIALITY OF REVIEW	14
9.3. REVIEW CRITERIA	15
9.3.1. Primary Criteria	15
9.3.2. Secondary Criteria	16
10. KEY DATES	17
11. AWARD ADMINISTRATION	17
12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	18
13. CONTACT INFORMATION	18
13.1. HELPDESK	18
13.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	19

RFA VERSION HISTORY

Rev 07/14/14 RFA release

Rev 07/22/14 Revised Section 8.2.2 Layperson's Summary

- Corrected reference link about advocate reviewers to (Section 9.1)

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- 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.

2. RATIONALE

Core Facility Support Awards seek to facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. A user group of Texas-based investigators must be identified, each of whom should have supported cancer research projects that will make use of the requested facility. This requirement is not intended to exclude early career-stage investigators who have not yet secured peer-reviewed grant support. Successful applicants should be working in a research environment capable of supporting potentially high-impact cancer studies.

3. RESEARCH OBJECTIVES

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This Request for Applications (RFA) solicits applications from institutions to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer.

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 survivorship. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, cure, or quality of life. This award provides cancer researchers access to appropriate research infrastructure, instrumentation, and technical expertise necessary to achieve their research objectives. A wide variety of facilities can be supported, including, but not limited to, chemistry, high-throughput screening, biomedical imaging, proteomics, protein structure, molecular biology, genomics, metabolomics, animal physiology/metabolism, cell sorting, bioengineering, clinical research support, bioinformatics, and the like. Funds may be requested to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region.

4. FUNDING INFORMATION

The maximum duration for this award mechanism is 5 years. Applicants may request a maximum of \$3,000,000 in total costs for the first 2 years and up to \$1,000,000 in total costs for each subsequent year. Exceptions to these limits may be granted, but only if exceptionally well justified. Allowable expenses include the cost of instruments (preferably expended in the first 2 years), installation and/or necessary renovation expenses in the first year (installation/renovation expenses not to exceed 10 percent of the total first-year request), and maintenance/service contracts. Installation/renovation expenses can be requested in the first year only. Equipment should be purchased within the first 2 years. In addition, applicants may request salary support and fringe benefits for the facility director, data analysts, and technical staff; travel to scientific/technical meetings or collaborating institutions is also an allowable expense for these individuals. All of these costs and expenses must be prorated for direct use in cancer research efforts. Also allowable are funds to support the use of the facility by qualified cancer research investigators for relevant projects (research supplies and services, clinical research costs, etc). Institutions must describe the process to be used to disburse funds to support use of the facility by cancer investigators. Finally, some fraction of available funds may be used by the facility director for development of new or improved approaches to technical challenges. State law limits the amount of award funding that may be spent on indirect costs to no more than 5 percent of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization 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; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Program.
- The Principal Investigator (PI) must be the director of the facility and must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted. The PI should also hold a faculty position, preferably at the level of associate or full professor or the equivalent.
- This award must be directed by the PI. Co-PIs are not permitted.
- 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. Collaborators should have specific and well-defined roles. 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. In no event shall equipment purchased under this award leave the State of Texas.
- An institution may submit only one new, renewal, or resubmission application under this RFA during this funding cycle. For purposes of this RFA, an institution is defined as that component of a university system that has a geographically distinct campus. A PI may only resubmit an application that was previously not funded once (see [section 6](#)).
- Support for only one facility may be requested per application. Collaborative applications among institutions are permitted. However, such collaboration must not be used as a pretext for supporting more than one facility at a given institution. Further, applicants must not attempt to assemble illogical technical combinations and capabilities under one roof. Examples of illogical combinations would include protein mass spectrometry with DNA sequencing or light microscopy with magnetic resonance imaging.

The coherence of the facility and the ability of the PI/facility director to oversee all of the facility's operations will be critical components of the review process. If support is requested for an existing facility, applicants must make it clear how CPRIT support will enhance its capabilities and improve access for cancer investigators rather than simply replace ongoing institutional support.

- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to one 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 PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, 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 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. 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.state.tx.us.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than one resubmission is not permitted. An application is considered a resubmission if the proposed core facility is the same as that presented in the original submission. A change in the identity of the PI for a core facility or a change of title of the facility that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. This policy is in effect for all applications submitted to date. See [section 8.2.5](#).

7. RENEWAL POLICY

An application funded by CPRIT under this mechanism may be submitted for a competitive renewal.

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 was submitted. The PI must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will 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 September 30, 2014, and must be submitted by 3 PM central time on November 17, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.1.1. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail

to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing one or more components or do not meet the eligibility requirements listed in [section 5](#) will be administratively rejected without review.

8.2.1. Abstract and Significance (5000 characters)

Clearly explain the proposed program, including a summary of the facility to be developed, an outline of the goals of the research projects that will be supported, and an overview of institutional infrastructure and commitment. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the Core Facility Plan. Clearly address how the proposed project, if successful, will have a major impact on cancer.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly).

8.2.2. Layperson's Summary (2000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding.

Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers ([section 9.1](#)) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

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.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. 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.

8.2.5. Institutional Support (2 pages)

Each application must be accompanied by a letter of institutional support from the president or provost or equivalent indicating commitment to the program and certifying that this is the sole application submitted by this institution in response to this RFA. Furthermore, the letter should indicate support of the facility for activities not related to cancer research. An additional letter should be submitted by the person to whom the facility director reports, ensuring that the facility will be operated in a superior fashion and discussing how this will be ascertained.

8.2.6. Resubmission Summary (1 page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Core Facility Plan or modify the original Core Facility Plan and mark the changes.

However, 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.

8.2.7. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.8. Core Facility Plan (5 pages)

Background: Present the rationale and need for the facility, emphasizing the pressing problems in cancer research that will be addressed.

Instrument Details: Provide details of the equipment/instruments, if any, that will be acquired.

Technical Expertise: Describe the qualifications of the facility director and other key personnel that make them suitable to oversee the establishment and operations of the facility.

Administrative Plan: Clearly describe the plan under which the operation, sharing, time allocation, and maintenance of the facility will be administered.

Training Plan: Describe the plan to train users to use the facility and also to evaluate the results obtained.

8.2.9. Vertebrate Animals and/or Human Subjects (1 page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

8.2.10. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.11. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cpritis.state.tx.us. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2015 is \$200,000; CPRIT FY 2015 is from September 1, 2014, through August 31, 2015. Salary does not include fringe benefits and/or facilities and administrative (F&A) 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.

8.2.12. User Group (8 pages)

Provide concise descriptions of the research projects of major users of the facility. Provide a tabular summary of all users of the requested facility. List the names of all researchers, their academic appointment and affiliation, funded project title(s)/number(s) (wherever applicable), a brief description of the project(s), and approximate percentage use of the facility for direct use in cancer research efforts.

8.2.13. Biographical Sketches (2 pages each)

The PI should provide a biographical sketch that describes his/her education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI (as required by the online application receipt system). Up to 5 additional biographical sketches for key personnel from the user group may be provided. Each biographical sketch must not exceed 2 pages.

8.2.14. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI must be provided.

8.2.15. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.2.16. Previous Summary Statement

If the application is being resubmitted, 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.

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

9. APPLICATION REVIEW

9.1. Review Process Overview

All eligible applications will be evaluated using a 2-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers, using the criteria listed below. In the second stage,

applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by the Scientific 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 703.6–703.8.

9.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, Program Integration Committee 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 Peer Review Panel members and Scientific 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 Web site. **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 Program Integration Committee Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee 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. The prohibition on communication does not apply to the time period when RFAs are announced and the CPRIT Application Receipt System opens. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.3. Review Criteria

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 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.**

9.3.1. Primary Criteria

Primary 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 request for the instrument/equipment. Primary criteria include the following:

Justification of Need/Value: Is the need for the facility justified? Is it necessary and appropriate for the research projects? Will the state-of-the-art facility directly support and impact cancer research programs at the institution and in the region? How will the availability of the facility offer incipient research projects by investigators at various career stages the opportunity to develop? Will the facility make the user group more competitive for external funding?

Quality and Significance of research projects supported: Does the facility support a significant number of different, independently funded users? Are the projects at the forefront of cancer research? Are the projects of significance in reducing cancer incidence, morbidity, or mortality?

Technical Expertise: Is there sufficient technical expertise for optimal use of the facility? How well qualified is the user group to take optimal advantage of the facility and evaluate the research

results for the proposed projects? How will the facility be maintained? Is there a satisfactory training plan for new users?

Administration: Is there assurance that the facility will be managed and operated in a superior fashion? To whom does the facility director report? Is that person committed to appropriate oversight (a letter of commitment should be submitted)? Is there an adequate plan for the management of the facility, including an appropriate system for charging for services and subsidy of user fees for specific cancer-related projects and individuals (especially early career–stage investigators)? How will facility time be allocated among the projects? Have biosafety issues been addressed? Are there criteria and is there a mechanism for prioritization of user requests? Are there appropriate advisory committees?

Institutional Commitment: Is there clear institutional commitment for support of the facility for cancer research and, if applicable, for noncancer research efforts as well? Has the host institution provided an appropriate site for the facility?

9.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed project.

Secondary criteria include the following:

Research Environment: Does the team have the needed expertise and resources to accomplish all aspects of the project? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support for the project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are included in the proposed research, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release	July 24, 2014
-------------	---------------

Application

Online application opens	September 30, 2014, 7 AM central time
Application due	November 17, 2014, 3 PM central time
Application review	December 2014 - March 2015

Award

Award notification	May 2015
Anticipated start date	June 2015

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. 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, which are available at www.cprit.state.tx.us. 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 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 the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

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, Chapter 703, Section 703.11, for specific requirements regarding 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 e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation:	July 24 - November 17, 2014 (excluding public holidays)
Hours of operation:	Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time Wednesday, 8 AM to 4 PM central time
Tel:	866-941-7146
E-mail:	Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Research.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

Third Party Observer Reports

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-217

Panel Name: FY15 Basic Cancer Research-1

Panel Date: March 9, 2015

Report Date: March 10, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an out-sourced provider to function as a neutral third-party observer.

Introduction

The subject of this report is the FY15 Basic Cancer Research-1 peer review panel recommendations for funding. The meeting was chaired by Tom Curran and held at the Hyatt Regency in Dallas TX, on March 9, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at the Hyatt Regency and chaired by Tom Curran on March 9, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

The independent observer noted the following during our observation:

- Forty applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Seventeen reviewers, two advocate reviewers, two CPRIT staff members and six SRA employees were present for the meetings.
- Five conflicts of interest were identified prior to or during the meeting. The reviewer with the conflicts of interest left the room and did not participate in the review of the conflicted application.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The peer review panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-218

Panel Name: FY 15.2 Cancer Biology

Panel Date: March 10, 2015

Report Date: March 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Biology peer review of applications for FY15 funding. The meeting was chaired by Peter Jones and held at the Hyatt Regency in Dallas, TX on March 10, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Cancer Biology Review Panel meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Peter Jones on March 10, 2015.

The independent observer noted the following during our observation:

- Thirty-eight applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Fourteen peer review panel members, two advocate reviewers, two CPRIT staff members and six SRA employees were present for the meetings either in-person or by teleconference.

- Thirty-one conflicts of interest were identified prior to or during the meeting. Applications for only twenty-one conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-219

Panel Name: FY15.2 Imaging Technology and Informatics

Panel Date: March 12-13, 2015

Report Date: March 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the peer review of Imaging Technology and Informatics applications for FY15 funding. The meeting was chaired by Sam Gambhir and held at the Hyatt Regency in Dallas TX, on March 12-13, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Imaging Technology and Informatics peer review panel held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Sam Gambhir on March 12 and March 13, 2015.

The independent observer noted the following during our observation:

- Thirty-nine applications were discussed within the Imaging Technology and Informatics Peer Review Panel to determine which grants would receive CPRIT funding.
- Twenty peer review panel members, two advocate reviewers, two CPRIT staff members and five SRA employees were present for the meeting.

- Two conflicts of interest were identified prior to or during the meeting, but only one application with a conflicted reviewer was discussed during the panel. The reviewer with the conflict of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-220

Panel Name: FY15.2 Clinical & Translational Cancer Research and Translational Cancer Research

Panel Date: March 16, 2015

Report Date: March 23, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical & Translational Cancer Research and Translational Cancer Research peer review of applications for FY15 funding. The meeting was chaired by Richard O'Reilly and Margaret Tempero and held at the Hyatt Regency in Dallas TX, on March 16, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at the Hyatt Regency. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard O'Reilly and Margaret Tempero on March 16, 2015.

The independent observer noted the following during our observation:

- Thirty-one applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Twenty-eight reviewers, three advocate reviewers, two CPRIT staff members and six SRA employee were present for the meetings.

- Fifty-six conflicts of interest were identified prior to or during the meeting. Applications for fifty-two conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The independent third party was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-221

Panel Name: FY15.2 Cancer Prevention Research

Panel Date: March 17, 2015

Report Date: March 23, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research peer review of applications for FY15 funding. The meeting was chaired by Tom Sellers and held at the Hyatt Regency in Dallas TX on March 17, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Cancer Prevention Research panel meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Sellers on March 17, 2015.

The independent observer noted the following during our observation:

- Thirty-seven applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Sixteen peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA employees were present for the meeting.
- Forty-six conflicts of interest were identified prior to or during the meeting. Applications for thirty-eight conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either left

the room or did not participate telephonically and did not participate in the review of the conflicted application.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-222

Panel Name: FY15.2 Basic Cancer Research – 2

Panel Date: March 18, 2015

Report Date: March 23, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the peer review of Basic Cancer Research applications for FY15 funding. The meeting was chaired by Carol Prives and held at the Hyatt Regency in Dallas TX, on March 18, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at the Hyatt Regency on March 18, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Carol Prives.

The independent observer noted the following during our observation:

- Thirty applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Thirteen reviewers, two advocate reviewers, two CPRIT staff members and five SRA employees were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panelists' discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Review Council Observation Report

Report #2015-225

Panel Name: FY15.2 Recruitment Review Panel – 7 &
FY15.2 Scientific Research Applications

Panel Date: April 13, 2015

Report Date: April 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council's review of non-recruitment and recruitment applications for FY15 funding. The meeting was chaired by Tom Curran and held via teleconference on April 13, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council's discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Scientific Review Council meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Curran on April 13, 2015.

The independent observer noted the following during our observation:

- Thirty-four applications were discussed within the Scientific Review Council to determine which grants would receive CPRIT funding.
- Eight council members, two CPRIT staff members, and three SRA employees were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Cycle 15.2 Applications
(Academic Research Cycle 15.2 Awards Announced at May 20, 2015, 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 Academic Research Cycle 15.2 include *Core Facilities Support Awards*, *High Impact/High Risk Research Awards*, and *Multi-Investigator 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP150611	Cooke, John	The Methodist Hospital Research Institute	Sukumar, Saraswati
RP150648	O'Malley, Bert	Baylor College of Medicine	Costello, Joseph
RP150648-C1	Ittmann, Michael	Baylor College of Medicine	Costello, Joseph
RP150648-P1	Tsai, Ming-Jer	Baylor College of Medicine	Costello, Joseph
RP150648-P2	Weigel, Nancy	Baylor College of Medicine	Costello, Joseph
RP150648-P3	O'Malley, Bert	Baylor College of Medicine	Costello, Joseph
RP150648-P4	Chiu, Wah	Baylor College of Medicine	Costello, Joseph
RP150587	El-Serag, Hashem	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-C1	Marrero, Jorge	The University of Texas Southwestern Medical Center	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-C2	Feng, Ziding	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-P1	Kanwal, Fasiha	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150587-P2	El-Serag, Hashem	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-P3	Moore, David	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-P4	Baretta, Laura	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-P5	Singal, Amit	The University of Texas Southwestern Medical Center	Barlow, William; Kushi, Lawrence; Li, Christopher
Applications Not Recommended for PIC or Oversight Committee Consideration			
RP150631	Gustafsson, Jan-Ake	University of Houston	Sukumar, Saraswati
RP150631-P4	Tekmal, Rajeshwar	The University of Texas Health Science Center at San Antonio	Sukumar, Saraswati
RP150650	Pandita, Tej	The Methodist Hospital Research Institute	Sukumar, Saraswati
RP150650-P3	Pandita, Tej	The Methodist Hospital Research Institute	Sukumar, Saraswati
RP150527*	Foulds, Charles	Baylor College of Medicine	Greene, Geoffrey; Wahl, Geoffrey
RP150537*	Dalby, Kevin	The University of Texas at Austin	Roberts, Charles
RP150537-C1*	Ren, Pengyu	The University of Texas at Austin	Roberts, Charles
RP150537-C2*	Ueno, Naoto	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150537-P1*	Bartholomeusz, Chandra	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150537-P2*	Bartholomeusz, Chandra	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150537-P3*	Ueno, Naoto	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150603	Raj, Ganesh	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-C1	Kapur, Payal	The University of Texas Southwestern Medical Center	Costello, Karen

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150603-C2	Hwang, Tae Hyun	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P1	Boothman, David	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P2	Raj, Ganesh	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P3	Hsieh, Jer-Tsong	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P4	Martinez, Elisabeth	The University of Texas Southwestern Medical Center	Costello, Karen
RP150664	Rawley, David	Baylor College of Medicine	Greene, Geoffrey
RP150664-C1	Mancini, Michael	Baylor College of Medicine	Greene, Geoffrey
RP150664-P1	Zhang, Xiang	Baylor College of Medicine	Greene, Geoffrey
RP150664-P2	Rowley, David	Baylor College of Medicine	Greene, Geoffrey
RP150664-P3	Farach-Carson, Cindy	Rice University	Greene, Geoffrey
RP150664-P4	Park, Dongsu	Baylor College of Medicine	Greene, Geoffrey
RP150667*	Mitsiades, Nicholas	Baylor College of Medicine	Costello, Joseph
RP150680*	Zeng, Mingtao	Texas Tech University Health Sciences Center at El Paso	Costello, Karen
RP150681	Jayarman, Arul	Texas A&M Engineering Experiment Station	Belinsky, Steven; Fearon, Eric
RP150560	Suarez-Almazor, Maria	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-C1	Zhao, Hui	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-C2	Chang, Shine	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150560-C3	Rodriguez, Alma	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P1	Smith, Benjamin	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P2	Holmes, Holly	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P3	Hwang, Jessica	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P4	Suarez-Almazor, Maria	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P5	Shih, Ya-Chen Tina	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150614*	Edwards, Beatrice	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-C1*	Wagner, Elizabeth	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-C2*	Zhao, Hua	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-C3*	Amini, Behrang	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-P1*	Edwards, Beatrice	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-P2*	Villareal, Reina	Baylor College of Medicine	Barlow, William
RP150614-P3*	Villareal, Dennis	Baylor College of Medicine	Barlow, William
RP150683	Wetter, David	Rice University	Brandon, Thomas
RP150683-C1	Li, Liang	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas
RP150683-P1	Wetter, David	Rice University	Brandon, Thomas
RP150683-P2	Fernandez, Maria	The University of Texas Health Science Center at Houston	Brandon, Thomas

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150683-P3	Shih, Ya-Chen Tina	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas
RP150684*	Wetter, David	Rice University	Brandon, Thomas
RP150536*	Orlowski, Robert	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-C2*	Davis, Richard	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-C3*	Yang, Jing	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P1*	Shah, Nina	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P2*	Molldrem, Jeffrey	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P3*	Nawrocki, Steffan	The University of Texas Health Science Center at San Antonio	Kast, W. Martin
RP150536-P4*	Colla, Simona	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P5*	Orlowski, Robert	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150575	Yu, Dihua	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-C1	Sahin, Aysegul	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-P1	Yu, Dihua	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-P2	Hung, Mien-Chie	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-P3	Jiang, Ning	The University of Texas at Austin	Kast, W. Martin; Riddell, Stanley
RP150575-P4	Mittendorf, Elizabeth	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150592	Symmans, William	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-C1	Tripathy, Debu	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-C2	Davies, Peter	Texas A&M University System Health Science Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-C3	Symmans, William	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P1	Moulder, Stacy	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P2	Piwnica-Worms, Helen	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P3	Mani, Sendurai	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P4	Symmans, William	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150653	Maitra, Anirban	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-C1	Maitra, Anirban	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-C2	Chin, Lynda	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P1	DePinho, Ronald	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P2	Draetta, Giulio	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P3	Kalluri, Raghu	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P4	Yee, Cassian	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150679*	Wang, Rongfu	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-C1*	Liu, Xuewu	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-C2*	Gee, Adrian	Baylor College of Medicine	Kast, W. Martin
RP150679-P1*	Shen, Haifa	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-P2*	Wang, Rongfu	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-P3*	Rooney, Cliona	Baylor College of Medicine	Kast, W. Martin
RP150657	Sherry, Dean	The University of Texas at Dallas	Zinn, Kurt
RP150674*	Kameoka, Jun	Texas A&M University	Basillion, James

* = Not discussed

De-Identified Overall Evaluation Scores

Core Facilities Support Awards

Academic Research Cycle 15.2

Application ID	Final Overall Evaluation Score
RP150611*	2.0
RP150535*	2.0
RP150551*	2.1
RP150600*	2.1
RP150596*	2.7
RP150578*	3.0
A	3.2
B	3.7
C	4.0
D	4.0
E	4.3
F	4.3
G	4.7
H	4.7
I	5.1
J	5.3
K	5.3

*=Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

Ludwig Institute for
Cancer Research Ltd

April 22, 2015

Richard D. Kolodner
Ph.D.

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

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

rkolodner@ucsd.edu

San Diego Branch
UC San Diego School of
Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

T 212 450 1500
F 212 450 1555

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cpr.it.state.tx.us

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the **Core Facilities Support Awards (CFSA)**, **High Impact/High Risk Research Awards (HIHR)**, and **Multi-Investigator Research Awards (MIRA)** grant mechanisms. The SRC met on Monday, April 13, 2015 to consider the applications recommended by the peer review panels following their meetings that were held March 9-18, 2015. 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 score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to one grant application. This adjustment is listed at the end of the list of recommended projects. The total amount for the applications recommended is \$50,066,421.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, 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

Attachment

Rank	App ID	Mechanism	Organization	Application Title	Budget	Score
1	RP150587	MIRA	Baylor College of Medicine	The Texas Hepatocellular Carcinoma Consortium (THCCC)	\$9,771,157	1.9
2	RP150611	CFSA	The Methodist Hospital Research Institute	CPRIT Core for RNA Therapeutics and Research	\$4,845,868	2.0
3	RP150535	CFSA	The University of Texas M. D. Anderson Cancer Center	Precision Oncology Decision Support Core	\$5,999,996	2.0
4	RP150573	HIHRRRA	The University of Texas Southwestern Medical Center	Dynamin GTPase: A novel pro-apoptotic cancer therapeutic target	\$200,000	2.0
5	RP150632	HIHRRRA	The University of Texas Southwestern Medical Center	Acetate may be a key substrate driving growth in early stage breast cancer in patients	\$200,000	2.0
6	RP150600	CFSA	The University of Texas Health Science Center at San Antonio	The Single-Cell Biopsy and Characterization Core (SBCC) at The University of Texas Health Science at San Antonio	\$3,277,895	2.1
7	RP150551	CFSA	The University of Texas Health Science Center at Houston	Therapeutic Monoclonal Antibody Lead Optimization and Development Core	\$5,277,338	2.1
8	RP150640	HIHRRRA	The University of Texas Health Science Center at Houston	Drug Conjugates of anti-LGR5 Antibodies as Novel Therapeutics for Destroying Cancer Stem Cells	\$200,000	2.1
9	RP150676	HIHRRRA	The University of Texas Southwestern Medical Center	Identification of Novel Melanoma Metastasis Driver Genes through Transposon-Mediated Mutagenesis	\$200,000	2.1
10	RP150637	HIHRRRA	Texas A&M University System Health Science Center	Efficient Production of iPSC-Derived Mesenchymal Stem Cells to Kill Cancers by Bystander Effects from Suicide Genes	\$200,000	2.2
11	RP150648*	MIRA	Baylor College of Medicine	GATA2 and steroid receptor coactivator-2 cooperate with androgen receptor in prostate cancer progression and androgen resistance	\$6,151,179	2.3
12	RP150703	HIHRRRA	Texas A&M University System Health Science Center	Metabolomic Salivary Biomarkers for Oral Cancer Detection	\$199,999	2.6
13	RP150596	CFSA	The University of Texas Southwestern Medical Center	Bioinformatics Core Facility at UT Southwestern Medical Center	\$5,593,882	2.7
14	RP150720	HIHRRRA	Texas Tech University	Integrated on-chip networks for investigating exosome-mediated drug expulsion	\$200,000	2.7
15	RP150559	HIHRRRA	Texas A&M University	Small Molecules to Perturb A Novel PPI Target For Chemotherapy	\$200,000	2.7

16	RP150656	HIHRRRA	Texas Tech University Health Sciences Center	Engineered Bone Targeting Nanomedicine for Treatment of Bone Metastases from Breast Cancer	\$199,970	2.8
17	RP150578	CFSA	Texas A&M University System Health Science Center	The Combinatorial Drug Discovery Program (CDDP)	\$5,954,596	3.0
18	RP150701	HIHRRRA	Rice University	Non-invasive Colonoscopy by Molecular Imaging of Mucin Targeted Hyperpolarized Silicon Nanoparticles	\$200,000	3.0
19	RP150638	HIHRRRA	Baylor Research Institute	Elevated D-2-hydroxyglutarate precedes and promotes tumor progression in inflammatory bowel diseases	\$200,000	3.1
20	RP150590	HIHRRRA	The University of Texas Southwestern Medical Center	Identifying Inhibitors of Ascl1 to Block Growth of Malignant Neuroendocrine and Neural Tumors	\$200,000	3.2
21	RP150713	HIHRRRA	The University of Texas at Dallas	Identification of Therapeutic Targets on Breast Cancer Stem Cells	\$194,543	3.3
22	RP150696	HIHRRRA	The University of Texas Health Science Center at San Antonio	Inhibition of Breast Cancer Metastasis to the Bone by microRNA Transmission through Gap Junctions	\$200,000	3.4
23	RP150711	HIHRRRA	The University of Texas at Arlington	Biomechanical profiling of migrating brain cancer genotypes in tightly-confined space for drug screening	\$199,998	3.4
24	RP150574	HIHRRRA	The University of Texas Health Science Center at San Antonio	Turning on a Novel Tumor-Inhibiting Switch for Colorectal Cancer	\$200,000	3.4

*RP150648 - The peer review panel recommended the removal of a MIRA project. The budget was reduced based on the deletion of that project plus a 20% reduction of the remaining budget.

Success Rate by Panel		
Peer Review Panel	Success Rate	Score Cutoff
BCR1	14.3%	3.3
BCR2	18.2%	2.7
CB	18.2%	3.4
CPR	7.7%	1.9
CTCR/TCR	14.8%	3.0
ITI	13.9%	3.4

Success Rate by Mechanism vs. Total Reviewed*		
Mechanism	Success Rate	# Recommended
CFSA	35.3%	6/17
HIHR	16.0%	16/100
MIRA	4.8%	2/42
Overall	15.1%	24/159

Percent of Applications Recommended by SRC by Mechanism		
Mechanism	# Recommended	Percentage
CFSA	6/24	25%
HIHR	16/24	67%
MIRA	2/24	8%

Percent of Funding Recommended by SRC by Mechanism		
Mechanism	\$ Recommended	Percentage
CFSA	\$30.9	62%
HIHR	\$3.2	6%
MIRA	\$15.9	32%



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 2
High-Impact/High-Risk Research Awards

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-15-HIHR-2

High Impact/High-Risk Research Awards

**Please also refer to the Instructions for Applicants document,
which will be posted September 30, 2014**

Applications for this award mechanism are subject to institutional limits. Applicants are advised to consult with their institution's Office of Research and Sponsored Programs (or equivalent).

Application Receipt Opening Date: September 30, 2014
Application Receipt Closing Date: November 17, 2014

FY 2015

Fiscal Year Award Period

September 1, 2014–August 31, 2015

TABLE OF CONTENTS

1. ABOUT CPRIT	5
2. RATIONALE	5
3. RESEARCH OBJECTIVES	6
4. FUNDING INFORMATION	6
5. ELIGIBILITY	7
6. RESUBMISSION POLICY	8
7. RESPONDING TO THIS RFA	8
7.1. APPLICATION SUBMISSION GUIDELINES	8
7.1.1. Submission Deadline Extension	9
7.2. APPLICATION COMPONENTS	9
7.2.1. Abstract and Significance (5,000 characters)	9
7.2.2. Layperson's Summary (2,000 characters)	9
7.2.3. Goals and Objectives	10
7.2.4. Timeline (One page)	10
7.2.5. Resubmission Summary (One page)	10
7.2.6. Research Plan (Four pages)	10
7.2.7. Vertebrate Animals and/or Human Subjects (One page)	11
7.2.8. Publications/References	11
7.2.9. Budget and Justification	11
7.2.10. Biographical Sketches (Two pages each)	12
7.2.11. Current and Pending Support	12
7.2.12. Institutional/Collaborator Support and/or Other Certification (Two pages)	12
7.2.13. Previous Summary Statement	12
7.2.14. Institutional Limits	12
8. APPLICATION REVIEW	13
8.1. REVIEW PROCESS OVERVIEW	13
8.2. CONFIDENTIALITY OF REVIEW	14
8.3. REVIEW CRITERIA	15
8.3.1. Primary Criteria	15
8.3.2. Secondary Criteria	16
9. KEY DATES	16
10. AWARD ADMINISTRATION	17

11.	REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS.....	18
12.	CONTACT INFORMATION.....	18
12.1.	HELPDESK	18
12.2.	SCIENTIFIC AND PROGRAMMATIC QUESTIONS	18

RFA VERSION HISTORY

Rev 7/14/14 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 \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature and the citizens of Texas to:

- 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. RATIONALE

CPRIT High-Impact/High-Risk (HIHR) Research Awards seek to provide short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Because HIHR Research Awards are designed to support new ideas, preliminary data are not required. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. The HIHR Research Awards are expected to provide the foundation for individual or multiple investigator awards upon completion. Applicants must explain why more conventional sources of support are not available for the proposed research and how short-term funding will lead to strong applications for additional support.

Applications that might be described as “mini-R01s” will not be competitive. **The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data. There should be reasons for the idea to be plausible, but CPRIT acknowledges that most of the selected projects will ultimately fail to meet their primary goals. The rare proposals that succeed will be of sufficient importance to justify this program.** Applications may address any research topic related to cancer biology, causation, prevention, detection, screening, or treatment.

3. RESEARCH OBJECTIVES

Areas of interest include laboratory research, translational studies, population-based and/or clinical investigations. In that cancers arise from a large number of derangements of basic molecular and cellular functions, which, in turn, cause many alterations in basic biological processes, almost any aspect of biology may be relevant to cancer research, more or less directly. The *degree of relevance* to cancer research will be an important criterion for evaluation of projects for funding by CPRIT ([Section 8.3.1](#)). For example, are alterations in the process in question *primarily* responsible for oncogenesis or secondary manifestations of malignant transformation? Will understanding the process or interfering with it offer selective and useful insight into prevention, diagnosis, or treatment of cancer? *Successful applicants for funding from CPRIT will have addressed these questions satisfactorily.*

4. FUNDING INFORMATION

Applicants may request a total of \$200,000 for a period of up to 24 months (2 years), inclusive of both direct and indirect costs. Because of the nature of this funding mechanism, renewal applications will not be accepted. Follow-on applications will not be funded until the time requested for the HHR Research Award has passed. Award funds may be used to pay for salary and benefits, research supplies, equipment, and clinical costs. *Requests for funds for travel to scientific meetings are not appropriate for this funding mechanism, nor are requests for funds to support construction and/or renovation.* State law limits the amount of award funding that may be spent on indirect costs to no more than 5 percent of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism.
A public or private company is also eligible for funding under this award mechanism.
- The Principal Investigator (PI) must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and reside in Texas for the period of the time that the research that is the subject of the grant is conducted.
- A PI may submit only one new or resubmission application under this RFA during this funding cycle.
- One Co-PI may be included.
- 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. Collaborators should have specific and well-defined roles. 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 eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have 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 PI, any senior member or key personnel listed on the grant application, and 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 PI, 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.
- 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 10](#) and [Section 11](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than one resubmission is not permitted. This policy is in effect for all applications submitted to date. See [Section 7.2.5](#).

7. RESPONDING TO THIS RFA

7.1. 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 was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS.

Applications will be accepted beginning at 7 a.m. Central Time on September 30, 2014 and must be submitted by 3 p.m. Central Time on November 17, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

7.1.1. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

7.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing one or more components or that do not meet the eligibility requirements listed in [Section 5](#) will be administratively withdrawn without review.

7.2.1. Abstract and Significance (5,000 characters)

Clearly 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. Clearly address how the proposed project, if successful, will have a major impact on the field of cancer research or on the care of patients with cancer. Summarize how the proposed research creates new paradigms or challenges existing ones.

7.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer prevention research, early diagnosis or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers ([Section 8.1](#)) in evaluating the significance and impact of the proposed work.

7.2.3. Goals and Objectives

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.

7.2.4. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. 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.

7.2.5. Resubmission Summary (One page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Research Plan or modify the original Research Plan and mark the changes. However, 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.

7.2.6. Research Plan (Four pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed. Preliminary data are not required, but strong reasoning and literature support will obviously enhance the application.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

7.2.7. Vertebrate Animals and/or Human Subjects (One page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

7.2.8. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

7.2.9. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applications requesting more than \$200,000 (total costs) over a maximum period of 24 months (2 years) will be administratively withdrawn.

In preparing the requested budget, applicants should be aware of the following:

- Major equipment purchases are discouraged for this funding mechanism. 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.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. So-called grants management and facilities fees (e.g., sponsored programs fees; grants and contracts fees; electricity, gas and water; custodial fees; maintenance fees; etc.) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

7.2.10. Biographical Sketches (Two pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research.

A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to two additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

7.2.11. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a two-line summary of the goal of the project and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided.

7.2.12. Institutional/Collaborator Support and/or Other Certification (Two pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of two pages may be provided.

7.2.13. Previous Summary Statement

If the application is being resubmitted, 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.

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

7.2.14. Institutional Limits

Because a large number of submissions is anticipated, and to ensure timely and high-quality review of the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, CPRIT is imposing a limit on the number of HIHR Research Award applications that may be submitted by an institution during this review cycle.

The limit on the number of applications may seem restrictive, but experience indicates that truly innovative ideas that are appropriate for this award mechanism are uncommon. CPRIT expects institutions to initiate an internal review process and only authorize submission of the appropriate number of applications that have been judged rigorously to be responsive to this RFA. Institutional limits (which need not be fully used) are as follows: University of Texas M. D. Anderson Cancer Center, 10; Baylor College of Medicine, 10; University of Texas Southwestern Medical Center, 10; University of Texas Health Science Center at San Antonio, 5; University of Texas Health Science Center at Houston, 5; University of Texas at Austin, 5; University of Texas Medical Branch, 5; Texas A&M University, 5; Texas A&M University Health Science Center, 5; Texas Tech University, 5; Texas Tech University Health Sciences Center (combined campuses), 5; all others, 2 each.

8. APPLICATION REVIEW

8.1. Review Process Overview

All eligible applications will be evaluated using a two-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers, using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by the Scientific 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 703.6–703.8.

8.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, Program Integration Committee 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 Peer Review Panel members and Scientific 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 Web site. **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 Program Integration Committee member, a Scientific Review Panel member or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee is comprised of 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.

The prohibition on communication does not apply to the time period when pre-applications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

8.3. Review Criteria

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 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.**

8.3.1. Primary Criteria

Primary 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 study. Primary criteria include:

Significance and Impact: Is the application clearly responsive to the RFA and specifically to the HIHR Research Award mechanism? What is the innovative potential of the project? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important under- or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Responsive applications will be highly speculative or exploratory; they need not be based on preliminary data but must have the potential for high scientific payoff because of exceptionally promising ideas.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by a sound scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity, expertise, experience, and accomplishments to make a significant contribution to the research? Applicants' credentials will be evaluated in a career stage-specific fashion. Have early career stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer? This will be an important criterion for evaluation of projects for CPRIT support.

8.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research. Secondary criteria include:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are included in the proposed research, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget and Duration: Are the budget and the duration appropriate for the proposed work?

9. KEY DATES

RFA

RFA release July 14, 2014

Application

Online application opens September 30, 2014, 7 a.m. Central Time

Application due November 17, 2014, 3 p.m. Central Time

Application review December 2014/March 2015

Award

Award notification May 2015

Anticipated start date June 2015

10. 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, which are available at www.cprit.state.tx.us. 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 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 the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

11. 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, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

12. CONTACT INFORMATION

12.1. HelpDesk

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

Dates of operation: July 14 – November 17, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

12.2. Scientific and Programmatic Questions

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

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

Third Party Observer Reports

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-217

Panel Name: FY15 Basic Cancer Research-1

Panel Date: March 9, 2015

Report Date: March 10, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an out-sourced provider to function as a neutral third-party observer.

Introduction

The subject of this report is the FY15 Basic Cancer Research-1 peer review panel recommendations for funding. The meeting was chaired by Tom Curran and held at the Hyatt Regency in Dallas TX, on March 9, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at the Hyatt Regency and chaired by Tom Curran on March 9, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

The independent observer noted the following during our observation:

- Forty applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Seventeen reviewers, two advocate reviewers, two CPRIT staff members and six SRA employees were present for the meetings.
- Five conflicts of interest were identified prior to or during the meeting. The reviewer with the conflicts of interest left the room and did not participate in the review of the conflicted application.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The peer review panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-218

Panel Name: FY 15.2 Cancer Biology

Panel Date: March 10, 2015

Report Date: March 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Biology peer review of applications for FY15 funding. The meeting was chaired by Peter Jones and held at the Hyatt Regency in Dallas, TX on March 10, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Cancer Biology Review Panel meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Peter Jones on March 10, 2015.

The independent observer noted the following during our observation:

- Thirty-eight applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Fourteen peer review panel members, two advocate reviewers, two CPRIT staff members and six SRA employees were present for the meetings either in-person or by teleconference.

- Thirty-one conflicts of interest were identified prior to or during the meeting. Applications for only twenty-one conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-219

Panel Name: FY15.2 Imaging Technology and Informatics

Panel Date: March 12-13, 2015

Report Date: March 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the peer review of Imaging Technology and Informatics applications for FY15 funding. The meeting was chaired by Sam Gambhir and held at the Hyatt Regency in Dallas TX, on March 12-13, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Imaging Technology and Informatics peer review panel held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Sam Gambhir on March 12 and March 13, 2015.

The independent observer noted the following during our observation:

- Thirty-nine applications were discussed within the Imaging Technology and Informatics Peer Review Panel to determine which grants would receive CPRIT funding.
- Twenty peer review panel members, two advocate reviewers, two CPRIT staff members and five SRA employees were present for the meeting.

- Two conflicts of interest were identified prior to or during the meeting, but only one application with a conflicted reviewer was discussed during the panel. The reviewer with the conflict of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-220

Panel Name: FY15.2 Clinical & Translational Cancer Research and Translational Cancer Research

Panel Date: March 16, 2015

Report Date: March 23, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical & Translational Cancer Research and Translational Cancer Research peer review of applications for FY15 funding. The meeting was chaired by Richard O'Reilly and Margaret Tempero and held at the Hyatt Regency in Dallas TX, on March 16, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at the Hyatt Regency. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard O'Reilly and Margaret Tempero on March 16, 2015.

The independent observer noted the following during our observation:

- Thirty-one applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Twenty-eight reviewers, three advocate reviewers, two CPRIT staff members and six SRA employee were present for the meetings.

- Fifty-six conflicts of interest were identified prior to or during the meeting. Applications for fifty-two conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The independent third party was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-221

Panel Name: FY15.2 Cancer Prevention Research

Panel Date: March 17, 2015

Report Date: March 23, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research peer review of applications for FY15 funding. The meeting was chaired by Tom Sellers and held at the Hyatt Regency in Dallas TX on March 17, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Cancer Prevention Research panel meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Sellers on March 17, 2015.

The independent observer noted the following during our observation:

- Thirty-seven applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Sixteen peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA employees were present for the meeting.
- Forty-six conflicts of interest were identified prior to or during the meeting. Applications for thirty-eight conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either left

the room or did not participate telephonically and did not participate in the review of the conflicted application.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-222

Panel Name: FY15.2 Basic Cancer Research – 2

Panel Date: March 18, 2015

Report Date: March 23, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the peer review of Basic Cancer Research applications for FY15 funding. The meeting was chaired by Carol Prives and held at the Hyatt Regency in Dallas TX, on March 18, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at the Hyatt Regency on March 18, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Carol Prives.

The independent observer noted the following during our observation:

- Thirty applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Thirteen reviewers, two advocate reviewers, two CPRIT staff members and five SRA employees were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panelists' discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

De-Identified Overall Evaluation Scores

High-Impact/High-Risk Research Awards

Academic Research Cycle 15.2

Application ID	Final Overall Evaluation Score
RP150573*	2.0
RP150632*	2.0
RP150640*	2.1
RP150676*	2.1
RP150637*	2.2
RP150703*	2.6
RP150720*	2.6
RP150559*	2.7
RP150656*	2.8
AA	3.0
RP150701*	3.0
RP150638*	3.1
RP150590*	3.2
RP150713*	3.3
AB	3.4
RP150574*	3.4
RP150696*	3.4
RP150711*	3.4
AC	3.5
AD	3.7
AE	3.7
AF	3.7
AG	3.7
AH	3.8
AI	3.9
AJ	3.9
AK	4.0
AL	4.0
AM	4.0
AN	4.0
AO	4.0
AP	4.0
AQ	4.0
AR	4.0
AS	4.0
AT	4.1
AU	4.2
AV	4.2
AW	4.2
AX	4.3
AY	4.3
AZ	4.3

*=Recommended for funding

Application ID	Final Overall Evaluation Score
BA	4.3
BB	4.3
BC	4.3
BD	4.3
BE	4.3
BF	4.3
BG	4.3
BH	4.5
BI	4.7
BJ	4.7
BK	4.7
BL	4.7
BM	4.7
BN	4.7
BO	4.7
BP	4.7
BQ	4.7
BR	5.0
BT	5.0
BU	5.0
BV	5.0
BW	5.0
BX	5.0
BY	5.0
BZ	5.0
CA	5.1
CB	5.3
CC	5.3
CD	5.3
CE	5.3
CF	5.3
CG	5.3
CH	5.3
CI	5.3
CJ	5.3
CK	5.3
CL	5.3
CM	5.3
CN	5.7
CO	5.7
CP	5.7
CQ	5.7
CR	6.0
CS	6.0
CT	6.0
CU	6.0

*=Recommended for funding

Application ID	Final Overall Evaluation Score
CV	6.0
CW	6.0
CX	6.0
CY	6.3
CZ	6.3
DA	6.7
DB	6.7
DC	6.7
DD	6.7
DE	7.0
DF	7.3
DG	8.0

*=Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

**Ludwig Institute for
Cancer Research Ltd**

April 22, 2015

**Richard D. Kolodner
Ph.D.**

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

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

rkolodner@ucsd.edu

San Diego Branch
UC San Diego School of
Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

**T 858 534 7804
F 858 534 7750**

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

**T 212 450 1500
F 212 450 1555**

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

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

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the **Core Facilities Support Awards (CFSA)**, **High Impact/High Risk Research Awards (HIHR)**, and **Multi-Investigator Research Awards (MIRA)** grant mechanisms. The SRC met on Monday, April 13, 2015 to consider the applications recommended by the peer review panels following their meetings that were held March 9-18, 2015. 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 score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to one grant application. This adjustment is listed at the end of the list of recommended projects. The total amount for the applications recommended is \$50,066,421.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, 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

Attachment

Rank	App ID	Mechanism	Organization	Application Title	Budget	Score
1	RP150587	MIRA	Baylor College of Medicine	The Texas Hepatocellular Carcinoma Consortium (THCCC)	\$9,771,157	1.9
2	RP150611	CFSA	The Methodist Hospital Research Institute	CPRIT Core for RNA Therapeutics and Research	\$4,845,868	2.0
3	RP150535	CFSA	The University of Texas M. D. Anderson Cancer Center	Precision Oncology Decision Support Core	\$5,999,996	2.0
4	RP150573	HIHRRRA	The University of Texas Southwestern Medical Center	Dynamin GTPase: A novel pro-apoptotic cancer therapeutic target	\$200,000	2.0
5	RP150632	HIHRRRA	The University of Texas Southwestern Medical Center	Acetate may be a key substrate driving growth in early stage breast cancer in patients	\$200,000	2.0
6	RP150600	CFSA	The University of Texas Health Science Center at San Antonio	The Single-Cell Biopsy and Characterization Core (SBCC) at The University of Texas Health Science at San Antonio	\$3,277,895	2.1
7	RP150551	CFSA	The University of Texas Health Science Center at Houston	Therapeutic Monoclonal Antibody Lead Optimization and Development Core	\$5,277,338	2.1
8	RP150640	HIHRRRA	The University of Texas Health Science Center at Houston	Drug Conjugates of anti-LGR5 Antibodies as Novel Therapeutics for Destroying Cancer Stem Cells	\$200,000	2.1
9	RP150676	HIHRRRA	The University of Texas Southwestern Medical Center	Identification of Novel Melanoma Metastasis Driver Genes through Transposon-Mediated Mutagenesis	\$200,000	2.1
10	RP150637	HIHRRRA	Texas A&M University System Health Science Center	Efficient Production of iPSC-Derived Mesenchymal Stem Cells to Kill Cancers by Bystander Effects from Suicide Genes	\$200,000	2.2
11	RP150648*	MIRA	Baylor College of Medicine	GATA2 and steroid receptor coactivator-2 cooperate with androgen receptor in prostate cancer progression and androgen resistance	\$6,151,179	2.3
12	RP150703	HIHRRRA	Texas A&M University System Health Science Center	Metabolomic Salivary Biomarkers for Oral Cancer Detection	\$199,999	2.6
13	RP150596	CFSA	The University of Texas Southwestern Medical Center	Bioinformatics Core Facility at UT Southwestern Medical Center	\$5,593,882	2.7
14	RP150720	HIHRRRA	Texas Tech University	Integrated on-chip networks for investigating exosome-mediated drug expulsion	\$200,000	2.7
15	RP150559	HIHRRRA	Texas A&M University	Small Molecules to Perturb A Novel PPI Target For Chemotherapy	\$200,000	2.7

16	RP150656	HIHRRRA	Texas Tech University Health Sciences Center	Engineered Bone Targeting Nanomedicine for Treatment of Bone Metastases from Breast Cancer	\$199,970	2.8
17	RP150578	CFSA	Texas A&M University System Health Science Center	The Combinatorial Drug Discovery Program (CDDP)	\$5,954,596	3.0
18	RP150701	HIHRRRA	Rice University	Non-invasive Colonoscopy by Molecular Imaging of Mucin Targeted Hyperpolarized Silicon Nanoparticles	\$200,000	3.0
19	RP150638	HIHRRRA	Baylor Research Institute	Elevated D-2-hydroxyglutarate precedes and promotes tumor progression in inflammatory bowel diseases	\$200,000	3.1
20	RP150590	HIHRRRA	The University of Texas Southwestern Medical Center	Identifying Inhibitors of Ascl1 to Block Growth of Malignant Neuroendocrine and Neural Tumors	\$200,000	3.2
21	RP150713	HIHRRRA	The University of Texas at Dallas	Identification of Therapeutic Targets on Breast Cancer Stem Cells	\$194,543	3.3
22	RP150696	HIHRRRA	The University of Texas Health Science Center at San Antonio	Inhibition of Breast Cancer Metastasis to the Bone by microRNA Transmission through Gap Junctions	\$200,000	3.4
23	RP150711	HIHRRRA	The University of Texas at Arlington	Biomechanical profiling of migrating brain cancer genotypes in tightly-confined space for drug screening	\$199,998	3.4
24	RP150574	HIHRRRA	The University of Texas Health Science Center at San Antonio	Turning on a Novel Tumor-Inhibiting Switch for Colorectal Cancer	\$200,000	3.4

*RP150648 - The peer review panel recommended the removal of a MIRA project. The budget was reduced based on the deletion of that project plus a 20% reduction of the remaining budget.

Success Rate by Panel		
Peer Review Panel	Success Rate	Score Cutoff
BCR1	14.3%	3.3
BCR2	18.2%	2.7
CB	18.2%	3.4
CPR	7.7%	1.9
CTCR/TCR	14.8%	3.0
ITI	13.9%	3.4

Success Rate by Mechanism vs. Total Reviewed*		
Mechanism	Success Rate	# Recommended
CFSA	35.3%	6/17
HIHR	16.0%	16/100
MIRA	4.8%	2/42
Overall	15.1%	24/159

Percent of Applications Recommended by SRC by Mechanism		
Mechanism	# Recommended	Percentage
CFSA	6/24	25%
HIHR	16/24	67%
MIRA	2/24	8%

Percent of Funding Recommended by SRC by Mechanism		
Mechanism	\$ Recommended	Percentage
CFSA	\$30.9	62%
HIHR	\$3.2	6%
MIRA	\$15.9	32%



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 2
Multi-Investigator Research Awards

Request for Applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS
RFA R-15-MIRA-2

Multi-Investigator Research Awards

**Please also refer to the “Instructions for Applicants” document, which will be
posted on September 30, 2014**

Application Receipt Opening Date: September 30, 2014

Application Receipt Closing Date: November 17, 2014

FY 2015

Fiscal Year Award Period

September 1, 2014–August 31, 2015

TABLE OF CONTENTS

1.	ABOUT CPRIT	5
2.	RATIONALE	5
3.	RESEARCH OBJECTIVES	7
4.	FUNDING INFORMATION	7
5.	ELIGIBILITY	8
6.	RESUBMISSION POLICY	10
7.	RENEWAL POLICY	10
8.	CHARACTERISTICS OF MULTI-INVESTIGATOR RESEARCH AWARDS	10
8.1.	SYNERGY	10
8.2.	LEADERSHIP	11
8.2.1.	<i>Principal Investigator (PI).....</i>	<i>11</i>
8.2.2.	<i>Co-Principal Investigator (Co-PI).....</i>	<i>11</i>
8.3.	RESEARCH PROJECTS	11
8.4.	CORE RESOURCES	12
8.5.	SELECTION OF RESEARCH PROJECTS AND CORE RESOURCES	12
8.6.	COMMITMENT OF TIME AND EFFORT	13
8.7.	PARTICIPATION ON MORE THAN 1 APPLICATION.....	13
9.	RESPONDING TO THIS RFA	14
9.1.	APPLICATION SUBMISSION GUIDELINES	14
9.1.1.	<i>Submission Deadline Extension.....</i>	<i>14</i>
9.2.	APPLICATION COMPONENTS	14
9.2.1.	<i>Abstract and Significance (10,000 characters)</i>	<i>15</i>
9.2.2.	<i>Layperson's Summary (5,000 characters).....</i>	<i>15</i>
9.2.3.	<i>Goals and Objectives (Maximum of 3 Goals and 3 Objectives per Goal for Each Project and Core) 15</i>	
9.2.4.	<i>Timeline (Maximum of 1 Page per Project and Core).....</i>	<i>16</i>
9.2.5.	<i>Overview of Overall Program (5 Pages)</i>	<i>16</i>
9.2.6.	<i>Research Project Plan (5 Pages for Each Project)</i>	<i>16</i>
9.2.7.	<i>Core Resource Plan (5 Pages for Each Core Resource).....</i>	<i>17</i>
9.2.8.	<i>Administrative Plan (5 Pages)</i>	<i>17</i>
9.2.9.	<i>Synergy Illustration.....</i>	<i>17</i>

9.2.10.	<i>Vertebrate Animals and/or Human Subjects (1 Page)</i>	17
9.2.11.	<i>Publications/References</i>	17
9.2.12.	<i>Budget and Justification</i>	17
9.2.13.	<i>Biographical Sketches (2 Pages Each)</i>	19
9.2.14.	<i>Current and Pending Support</i>	19
9.2.15.	<i>Institutional/Collaborator Support and/or Other Certification (4 Pages)</i>	19
10.	APPLICATION REVIEW	19
10.1.	REVIEW PROCESS OVERVIEW	19
10.2.	CONFIDENTIALITY OF REVIEW	20
10.3.	REVIEW CRITERIA.....	21
10.3.1.	<i>Primary Criteria</i>	21
10.3.2.	<i>Secondary Criteria</i>	23
11.	KEY DATES	23
12.	AWARD ADMINISTRATION	24
13.	REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	24
14.	CONTACT INFORMATION	25
14.1.	HELPDESK	25
14.2.	SCIENTIFIC AND PROGRAMMATIC QUESTIONS	25

RFA VERSION HISTORY

Rev 07/24/14 RFA release

Rev 09/30/14 Revised Section 6 – Resubmission Policy

- Included additional instructions and information about Resubmission not being available under this RFA

Revised Section 7 – Renewal Policy

- Included additional instructions and information about Renewal not being available under this RFA

Revised Section 9.2.14 – Current and pending Support

- Added clarification that at a minimum, current and pending support of the PI and co-PIs must be provided

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 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.

2. RATIONALE

Multi-Investigator Research Awards are intended to support the creation of integrated programs of collaborative and cross-disciplinary research among multiple investigators. These should be equivalent to program projects, research centers, NCI SPOREs, multi-institutional clinical trial networks, or other types of collaborative interactions. Teams will focus on critical areas of cancer research, especially those that have been inadequately addressed by research up to this point or for which there may be an absence of an established paradigm or technical framework. Laboratory research, translational studies, clinical, and population-based investigations may be supported. Awards are expected to promote a cooperative environment that fosters intensive interaction among members in all aspects of the research program. This approach is expected to transform the research process through the integration of basic and/or clinical disciplines, leading to the aggressive translation of scientific discoveries into tools and applications that have the potential to make a significant impact on cancer incidence, detection, treatment, and/or survivorship.

While all investigators need not be trained specifically in cancer research, this award is intended to initiate sustainable, collaborative programs of cancer research that cannot be addressed effectively by an individual researcher or a group of researchers within the same discipline.

It is aimed at research programs that, by their complexity and interdisciplinary nature, require a cross-disciplinary team approach to achieve significant progress and sustainability, thereby creating a culture for teaching and research that transcends traditional disciplinary boundaries. Clinical research or a clinical trial (Phase I, I/II, or II) may be included as part of the proposed program.

Investigators are expected to work together to develop the research plan, determine the management structure, and prepare the application. It should be clear that all investigators have a substantial level of intellectual input into the proposed program. Collectively, the members of the teams should represent the appropriate diversity of expertise necessary for addressing the research question. Effort is expected to be appropriately balanced among the investigators and their respective teams.

Applicants must present a clear plan for how they would manage and facilitate meaningful collaboration among the separate research teams to enable successful completion of the proposed research. Participating institutions must be willing to resolve potential intellectual and material property issues/conflicts and subcontracting issues and remove institutional barriers to achieving high levels of cooperation.

This funding mechanism offers an attractive opportunity for investigators to test new ideas, explore new areas, and/or implement new approaches. These types of applicant responses are desired and encouraged. However, CPRIT staff and external scientific review committees have noted a significant amount of overlap of investigators (ie, some investigators proposing to lead or participate in several new activities), thereby making it difficult to discern where the investigators' interests truly lie. In addition, some investigators have submitted very ambitious applications requesting large sums of money but with minimal evidence of commitment to the project in terms of percentage effort. This Request for Applications (RFA) attempts to curb these practices while still avoiding excessively rigid rules that might stifle innovation; therefore, applications with deviations from guidelines stated in the RFA will be examined closely. Evidence of lack of commitment or excessive fragmentation will be a significant negative factor in funding decisions.

3. RESEARCH OBJECTIVES

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This RFA solicits applications for integrated programs of collaborative and cross-disciplinary research among multiple investigators and will focus on critical research areas that will contribute meaningfully to advancing knowledge of the causes, prevention, and/or treatment of cancer. CPRIT encourages applicants who seek to develop or apply state-of-the-art technologies, tools, and/or resources for cancer research, including those with projects having potential commercialization opportunities. 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 survivorship. To fulfill this vision, applications may address any research topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or quality of life.

Because Multi-Investigator Research Awards, by definition, support collaborative research projects, this award mechanism will accommodate applications that encompass a wide variety of activities and administrative structures. Applicants may propose collaborative programs that are modest in size or those that are larger and more complex. CPRIT encourages cancer investigators from Texas to bring their best ideas forward for consideration. Creative, collaborative projects that address critical questions should leverage cancer research taking place in Texas into a leadership position from both national and international perspectives. Federal programs should not be duplicated; rather, when possible, their impact in the state of Texas should be enhanced.

4. FUNDING INFORMATION

This funding mechanism is intended to accommodate a wide variety of applications and organizational structures. Applicants may request a maximum of \$10,000,000 in total costs for a maximum period of 5 years. Exceptions to the maximum amount may be requested if extremely well justified. Funds may be used for salary and fringe benefits, research supplies, equipment, clinical costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. 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.

In an attempt to reduce the administrative difficulties in submitting programmatic and financial reports, Multi-Investigator Research Awards will be submitted as a single application. The PI will lead the project through the Administrative Core, which will be housed at the applicant institution. Individual projects and cores must be handled through subcontracts if participating institutions are located outside of the applicant institution. The applicant institution will develop the overall program budget with the assistance of individual participating institutions. Therefore, the institution that leads the Administrative Core will be responsible for coordinating subcontracts, submission of progress reports, and all related annual and financial reports. There will not be a requirement for other participating institutions to submit these reports to CPRIT.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization 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; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Program.
- The Principal Investigator (PI) and Co-Principal Investigators (Co-PIs) must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent. They must reside in Texas during the time the research that is the subject of the grant is conducted. A major criterion for successful applications will be the level of expertise of the collaborative team that has been assembled. CPRIT encourages the creation of teams composed of researchers from Texas who have stellar reputations in their given areas of expertise. If necessary, applicants must eschew institutional and regional considerations to assemble the best qualified of the state's investigators on a given subject into a superb collaborative team. Competing applications in a single area may fragment and dilute the best talent available. While CPRIT recognizes the value of competition, assembly of researchers with the best expertise for large-scale programs is encouraged to facilitate the highest level of cancer research throughout the state. CPRIT also encourages the inclusion of investigators from multiple institutions to facilitate interinstitutional collaboration.

- 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. Collaborators should have specific and well-defined roles. 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. In no event shall equipment purchased under this award leave the state of Texas.
- An individual may submit only 1 new application under this RFA.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, 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 PI, 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.
- The applicant must report whether the applicant institution or organization, the PI, 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 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. 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 12](#) and [section 13](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

CPRIT has determined that since this round of Multi-Investigator Research Awards is set up as a new award mechanism, resubmissions and renewals are not available under this RFA. All programs eligible for resubmission should be submitted as new applications.

A MIRA application that was unfunded after a single review should be submitted as a new application rather than a resubmission under this RFA. However, if a summary statement was prepared for the original application review, applicants are advised to address all noted concerns. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All previously unfunded MIRA submissions should be carefully reconstructed and take reviewers comments under consideration when submitting a new application.

7. RENEWAL POLICY

CPRIT has determined that since this round of Multi-Investigator Research Awards is set up as a new award mechanism, resubmissions and renewals are not available under this RFA. All responses should be submitted as new applications.

A project that was previously funded and would be a continuation of MIRA program activities must also be submitted as a new application under this RFA. In preparing the new application, applicants should describe and demonstrate that appropriate/adequate progress has been made on the previously funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be incorporated into the application as well as patents and efforts at product development where appropriate.

8. CHARACTERISTICS OF MULTI-INVESTIGATOR RESEARCH AWARDS

8.1. Synergy

Successful multi-investigator research programs are characterized by an exceptionally synergistic theme. Applications in response to this RFA must bring together a strong group of research projects and necessary core resources that contribute to a common goal in cancer research as a single, coherent entity.

Synergy between projects and cores to support the overall objective of the proposed program and the multidisciplinary focus of each project and core are essential aspects of the award mechanism.

It is envisioned that these research programs, once established, will interact extensively with each other and, if possible, with newly formed or established companies interested in bringing specific, Texas-based cancer discoveries to the market for the benefit of patients with cancer everywhere. To the extent possible, plans for such interactions should be developed and described.

8.2. Leadership

8.2.1. Principal Investigator (PI)

The overall research program will be directed and overseen by a PI. The PI is responsible for developing and managing an integrated and collaborative research environment that permits uninterrupted progress of the research projects regardless of distinct geographic locations of collaborators within the state. The PI must direct the required administrative core (see [section 8.4](#) and [section 9.2.8](#)). The PI is responsible for the submission of the application, all reporting requirements, and all budgeting decisions.

8.2.2. Co-Principal Investigator (Co-PI)

Each research project and core resource within the overall research program must be directed by a single individual designated as a Co-PI on the application for the overall research program. The Co-PI will be responsible for the research activities of his or her research project(s) and/or core resource(s) within the framework and goals of the overall research program. The PI may also direct a research project and/or core resource. Projects and cores located outside of the PI's institution must be supported through a subcontract with the applicant institution.

8.3. Research Projects

Research projects (also referred to as *projects* in this RFA) will challenge existing paradigms; develop or employ novel concepts, approaches, methodologies, tools, or technologies for the proposed cancer research area; or address important underexplored or unexplored areas. CPRIT seeks to support original and innovative projects. The thrust of the Multi-Investigator Research Awards mechanism is to support research projects that lead to truly substantial advances in the field rather than add modest increments of insight. Projects that modestly extend current lines of research will not be considered for this award.

Each project must be poised individually to make significant contributions to the field of cancer research as well as be complementary to the overall research program. Application of a single approach to multiple forms of cancer does not justify a request for multiple research projects.

The guidelines for research projects are as follows:

- Minimum: 3 projects
- Maximum: 5 projects
- Each research project must be directed by the PI or by a Co-PI. The PI or a Co-PI can direct only 1 project within the Multi-Investigator Research Award application.

8.4. Core Resources

Supporting core resources (also referred to as *cores* in this RFA) constitute integral components of multi-investigator research programs by providing the expertise and/or infrastructure essential to the completion of the individual research projects. Examples of core resources include, but are not limited to, administrative core, tissue/specimen core, sequencing/bioinformatics core, histopathology core, and imaging core. All applications submitted in response to this RFA must include an administrative core that comprehensively coordinates all activities proposed within the objectives of the projects and cores and is directed by the PI.

The guidelines for core resources are as follows:

- Minimum: Administrative core
- Maximum: 3 technical cores
- A maximum of 4 cores is permitted (ie, the administrative core and 3 technical cores).
- Each core must be directed by the PI or by a Co-PI. A Co-PI can direct 1 project and/or 1 technical core. The PI can direct 1 project and/or technical core in addition to the administrative core. The administrative core must be directed by the PI.
- Cores should include clear descriptions of the projects they are designed to support.
- Projects and cores are subject to different review criteria (see [section 10.3](#)). Research projects must **not** be submitted as cores in an attempt to circumvent the limitation on the number of research projects that may be submitted as part of a single Multi-Investigator Research Award application.

8.5. Selection of Research Projects and Core Resources

The PI is expected not only to coordinate and develop the overall research program but also to *limit the number of projects and cores* to only those that are considered highly meritorious and significant within the context of the entire application. The collaborative impact, merit, and feasibility of all the projects—not the cores—will determine whether an application for a Multi-Investigator Research Award receives support. Investigators are strongly discouraged from

including weaker projects in an effort to obtain a higher level of funding. Rather, inclusion of fewer, highly focused projects is strongly recommended.

8.6. Commitment of Time and Effort

Investigators are expected to commit *significant percentage effort* to research projects and cores. The PI should commit a minimum of 15 % effort to the research program. A project/core lead (ie, the PI or a Co-PI) should commit at least 10 % effort for each project and/or core that he or she directs.

Note: CPRIT requires that the percentage effort of the PI and/or Co-PI(s) remain the same in every year of support requested unless there is a corresponding change in the budget and level of activity of the project/core directed by the PI or the Co-PI(s) in question.

CPRIT recognizes that multi-investigator programs will vary significantly in size and scope; thus, a single guideline for commitment of time and effort is not appropriate for all applications. Applications should exhibit a reasonable correlation between time commitment and funds requested unless there are special circumstances, which must be explained. In addition, it should be clear from the other support information provided that the investigator will be able to achieve the required percentage effort and what activities may have to be contracted or curtailed to achieve the required percentage effort for the application submitted.

8.7. Participation on More than 1 Application

CPRIT is concerned that many investigators appear frequently as part of several different research programs, which makes it difficult to discern the investigators' commitment to a given project. CPRIT believes that this leads to weaker, less competitive applications. Therefore, CPRIT urges investigators to be named on only 1 Multi-Investigator Research Award application in a given funding cycle, regardless of their role. However, CPRIT recognizes that specific individuals directing and/or participating in core resources (eg, biostatistics, bioinformatics, or histopathology cores) may be involved in multiple research studies.

A common set of tools may be applied in more than 1 situation, leading to economies of scale (but **not** duplications of budgets). Thus, exceptions to investigators being listed on only 1 application may be made if compelling justification for such exceptions and assurance of commitment (usually in the form of percentage effort) is provided. Reductions in percentage effort will usually not be approved after an application is funded unless there have been major changes in scope and, therefore, in budget.

9. RESPONDING TO THIS RFA

9.1. 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 was submitted. The PI must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. The Co-PI does not have to create a user account in CARS; the Co-PI will be added to the application by the PI. Please refer to the *Instructions for Applicants (IFA)* document for the instructions on adding Co-PIs to an application. The IFA document will be available when the application receipt system opens. Applications will be accepted beginning at 7 AM central time on September 30, 2014, and must be submitted by 3 PM central time on November 17, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

9.1.1. 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 e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records. Please note that deadline extension requests are very rarely approved.

9.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the IFA document for details 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 5](#) will be administratively rejected without review.

9.2.1. Abstract and Significance (10,000 characters)

Clearly explain the question or problem to be addressed by the proposed overall research program and the approach to its answer or solution. Address how the proposed research, if successful, will have a major impact on the field of cancer research or on the care of patients with cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. State the synergistic value that the individual research projects and core resources present to the goals of the overall application. Summarize the proposed core resources. Clearly state the project(s) that the core resources will support and the synergistic value they provide to the goals of the research project(s).

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly).

9.2.2. Layperson's Summary (5,000 characters)

Provide a layperson's summary of the proposed program. Describe, in simple, nontechnical terms, the overall goals of the proposed program, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers ([section 10.1](#)) in evaluating the significance and impact of the proposed work.

9.2.3. Goals and Objectives (Maximum of 3 Goals and 3 Objectives per Goal for Each Project and Core)

Provide a list of 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. Goals and objectives should be listed for the overall project as well as for each project and core separately. Projects and cores should be labeled numerically (AC for the Administrative Core, Project 1 to Project 5, and Core 1 to Core 3) and be clearly identified. Goals and objectives for cores should indicate the project(s) to be supported.

Goals and objectives for the overall project should be listed under Administrative Core and prepared by the PI.

9.2.4. Timeline (Maximum of 1 Page per Project and Core)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. Timelines should be listed for the overall program as well as for each project and core separately. Projects and cores should be labeled numerically (AC for the Administrative Core, Project 1 to Project 5, and Core 1 to Core 3) and be clearly identified. Timeline for the overall project should be listed under Administrative Core and prepared by the PI.

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.

9.2.5. Overview of Overall Program (5 Pages)

Background: Present the rationale behind the proposed research program, emphasizing the pressing problem in cancer research that will be addressed.

Research Strategy: Describe the objectives of the research program and briefly summarize each component project and core resource.

Synergy: Describe how individual component projects provide synergistic value to the research program.

9.2.6. Research Project Plan (5 Pages for Each Project)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

Synergy: Describe how the project provides synergistic value to the entire research program.

9.2.7. Core Resource Plan (5 Pages for Each Core Resource)

Background: Present the rationale behind the proposed core resource.

Support Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data demonstrating the capabilities of the core are encouraged but not required.

Synergy: Describe how the core resource provides synergistic value to the research program.

9.2.8. Administrative Plan (5 Pages)

Describe the organizational and management structure that will be established to efficiently, effectively, and comprehensively manage all aspects of the research program. State how the leaders of individual projects and cores (ie, the PI and the Co-PIs) will communicate and discuss results, report progress, and resolve potential problems throughout the duration of the research program.

9.2.9. Synergy Illustration

Provide a diagrammatic representation of interactions between the Administrative Core, all research projects, and all core resources of the proposed research program.

9.2.10. Vertebrate Animals and/or Human Subjects (1 Page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for IRB approval or exemption and recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

9.2.11. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

9.2.12. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- One budget will be submitted on behalf of the entire program and will include costs for individual projects and cores. Individual budgets will not be submitted in the application system, but there should be a budget breakdown for each project and core resource. For programs that have outside institutions participating, a subcontract must be executed for that institution to receive CPRIT funds.
- 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.
- 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.cpritis.state.tx.us. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2015 is \$200,000; CPRIT FY 2015 is from September 1, 2014, through August 31, 2015.

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.

9.2.13. Biographical Sketches (2 Pages Each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI (as required by the online application receipt system) and each individual leading a project or core. Biosketches for individuals leading projects and cores should be labeled numerically (Project 1 to Project 5 and Core 1 to Core 3) and be clearly identified. Up to 5 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages. Appropriate templates will be provided in CARS.

9.2.14. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and co-PIs must be provided.

9.2.15. Institutional/Collaborator Support and/or Other Certification (4 Pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

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

10. APPLICATION REVIEW

10.1. Review Process Overview

All eligible applications will be evaluated using a 2-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers, using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and

recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities.

Applications approved by the Scientific 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 703.6–703.8.

10.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, 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 Peer Review Panel members and Scientific 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 Scientific Review Panel 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 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 prior to the opening of CARS. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

10.3. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review panels will evaluate and score each project and core individually according to the primary criteria 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 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.**

10.3.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work in each project and core as well as the overall program as described in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact of Overall Program: What is the innovative potential of the program? Does the program propose new paradigms or challenge existing ones? Does the program develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Investigators and biomedical personnel must want and need to know the results of CPRIT-funded research because such knowledge will change the ways in which they conduct their own research or approach and care for their patients. Programs that modestly extend current lines of research will not be considered for this award.

Research Plan for Research Projects: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed? Does the proposed project provide strong synergistic activities as part of a multidisciplinary collaboration? See [section 8.1](#).

Project Leader for Research Projects: Does the project leader demonstrate the required creativity, expertise, experience, and accomplishments to achieve the goals of the research project? Has the project leader devoted a sufficient amount of his or her time (percentage effort) to this project?

Synergy and Collaborative Teams: Does the proposed project provide strong synergistic activities as part of a multidisciplinary collaboration? That is, is the value of this program significantly greater than the sum of its parts? If core facilities are described, are they necessary and sufficient to support the project in achieving the overall goals proposed? Has the project assembled the best qualified collaborative and multidisciplinary teams to achieve the proposed goals? Are the levels of effort of the key personnel appropriate as outlined in [section 8.6](#)?

Relevance of Research Projects: Does the proposed research have a high degree of relevance to reduce the burden of cancer? This will be an important criterion for evaluation of projects for CPRIT support.

Sufficiency and Capability of Core Resources: Is the proposed core resource necessary? Does it have the needed facilities and sufficient resources to support the proposed research project(s) in accomplishing the proposed goals? Does it provide strong synergistic activities as part of a multidisciplinary collaboration? Is there a mechanism for prioritizing the work of the core?

Core Resources Leader: Does the core leader demonstrate the required expertise and experience to direct the core resource in supporting the research project(s)? Has the core leader devoted a sufficient amount of his or her time (percentage effort) to this resource?

Administrative Plan: Is the proposed organizational and management structure capable of comprehensively overseeing and coordinating all aspects and activities of the proposed research program?

Administrative Core Leader: Does the core leader demonstrate the required expertise and experience to direct the research program? Has the core leader devoted a sufficient amount of his or her time (percentage effort) to this activity? Are there plans for coordination of the program and for facilitating interactions among the program components?

10.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed project. Secondary criteria include the following:

Research Environment: Does the team have the needed expertise, facilities, and resources to accomplish all aspects of the project? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support for the research team and the project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are included in the proposed research, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

11. KEY DATES

RFA

RFA release	July 24, 2014
-------------	---------------

Application

Online application opens	September 30, 2014, 7 AM central time
Application due	November 17, 2014, 3 PM central time
Application review	December 2014-March 2015

Award

Award notification	May 2015
Anticipated start date	June 2015

12. 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, which are available at www.cprit.state.tx.us. 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 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 the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

13. 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, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding.

14. CONTACT INFORMATION

14.1. HelpDesk

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

Dates of operation: July 24-November 17, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time
Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

14.2. Scientific and Programmatic Questions

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

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

Third Party Observer Reports

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-217

Panel Name: FY15 Basic Cancer Research-1

Panel Date: March 9, 2015

Report Date: March 10, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an out-sourced provider to function as a neutral third-party observer.

Introduction

The subject of this report is the FY15 Basic Cancer Research-1 peer review panel recommendations for funding. The meeting was chaired by Tom Curran and held at the Hyatt Regency in Dallas TX, on March 9, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at the Hyatt Regency and chaired by Tom Curran on March 9, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

The independent observer noted the following during our observation:

- Forty applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Seventeen reviewers, two advocate reviewers, two CPRIT staff members and six SRA employees were present for the meetings.
- Five conflicts of interest were identified prior to or during the meeting. The reviewer with the conflicts of interest left the room and did not participate in the review of the conflicted application.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The peer review panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-218

Panel Name: FY 15.2 Cancer Biology

Panel Date: March 10, 2015

Report Date: March 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Biology peer review of applications for FY15 funding. The meeting was chaired by Peter Jones and held at the Hyatt Regency in Dallas, TX on March 10, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Cancer Biology Review Panel meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Peter Jones on March 10, 2015.

The independent observer noted the following during our observation:

- Thirty-eight applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Fourteen peer review panel members, two advocate reviewers, two CPRIT staff members and six SRA employees were present for the meetings either in-person or by teleconference.

- Thirty-one conflicts of interest were identified prior to or during the meeting. Applications for only twenty-one conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-219

Panel Name: FY15.2 Imaging Technology and Informatics

Panel Date: March 12-13, 2015

Report Date: March 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the peer review of Imaging Technology and Informatics applications for FY15 funding. The meeting was chaired by Sam Gambhir and held at the Hyatt Regency in Dallas TX, on March 12-13, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Imaging Technology and Informatics peer review panel held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Sam Gambhir on March 12 and March 13, 2015.

The independent observer noted the following during our observation:

- Thirty-nine applications were discussed within the Imaging Technology and Informatics Peer Review Panel to determine which grants would receive CPRIT funding.
- Twenty peer review panel members, two advocate reviewers, two CPRIT staff members and five SRA employees were present for the meeting.

- Two conflicts of interest were identified prior to or during the meeting, but only one application with a conflicted reviewer was discussed during the panel. The reviewer with the conflict of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-220

Panel Name: FY15.2 Clinical & Translational Cancer Research and Translational Cancer Research

Panel Date: March 16, 2015

Report Date: March 23, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical & Translational Cancer Research and Translational Cancer Research peer review of applications for FY15 funding. The meeting was chaired by Richard O'Reilly and Margaret Tempero and held at the Hyatt Regency in Dallas TX, on March 16, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at the Hyatt Regency. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard O'Reilly and Margaret Tempero on March 16, 2015.

The independent observer noted the following during our observation:

- Thirty-one applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Twenty-eight reviewers, three advocate reviewers, two CPRIT staff members and six SRA employee were present for the meetings.

- Fifty-six conflicts of interest were identified prior to or during the meeting. Applications for fifty-two conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The independent third party was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-221

Panel Name: FY15.2 Cancer Prevention Research

Panel Date: March 17, 2015

Report Date: March 23, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research peer review of applications for FY15 funding. The meeting was chaired by Tom Sellers and held at the Hyatt Regency in Dallas TX on March 17, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Cancer Prevention Research panel meeting held in-person and telephonically. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Sellers on March 17, 2015.

The independent observer noted the following during our observation:

- Thirty-seven applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Sixteen peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA employees were present for the meeting.
- Forty-six conflicts of interest were identified prior to or during the meeting. Applications for thirty-eight conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either left

the room or did not participate telephonically and did not participate in the review of the conflicted application.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Peer Review Panel Observation Report

Report #2015-222

Panel Name: FY15.2 Basic Cancer Research – 2

Panel Date: March 18, 2015

Report Date: March 23, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the peer review of Basic Cancer Research applications for FY15 funding. The meeting was chaired by Carol Prives and held at the Hyatt Regency in Dallas TX, on March 18, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at the Hyatt Regency on March 18, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Carol Prives.

The independent observer noted the following during our observation:

- Thirty applications were discussed within the Scientific Peer Review Panel to determine which grants would receive CPRIT funding.
- Thirteen reviewers, two advocate reviewers, two CPRIT staff members and five SRA employees were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panelists' discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Review Council Observation Report

Report #2015-225

Panel Name: FY15.2 Recruitment Review Panel – 7 &
FY15.2 Scientific Research Applications

Panel Date: April 13, 2015

Report Date: April 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council's review of non-recruitment and recruitment applications for FY15 funding. The meeting was chaired by Tom Curran and held via teleconference on April 13, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council's discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Scientific Review Council meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Curran on April 13, 2015.

The independent observer noted the following during our observation:

- Thirty-four applications were discussed within the Scientific Review Council to determine which grants would receive CPRIT funding.
- Eight council members, two CPRIT staff members, and three SRA employees were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.

- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Cycle 15.2 Applications
(Academic Research Cycle 15.2 Awards Announced at May 20, 2015, 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 Academic Research Cycle 15.2 include *Core Facilities Support Awards*, *High Impact/High Risk Research Awards*, and *Multi-Investigator 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP150611	Cooke, John	The Methodist Hospital Research Institute	Sukumar, Saraswati
RP150648	O'Malley, Bert	Baylor College of Medicine	Costello, Joseph
RP150648-C1	Ittmann, Michael	Baylor College of Medicine	Costello, Joseph
RP150648-P1	Tsai, Ming-Jer	Baylor College of Medicine	Costello, Joseph
RP150648-P2	Weigel, Nancy	Baylor College of Medicine	Costello, Joseph
RP150648-P3	O'Malley, Bert	Baylor College of Medicine	Costello, Joseph
RP150648-P4	Chiu, Wah	Baylor College of Medicine	Costello, Joseph
RP150587	El-Serag, Hashem	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-C1	Marrero, Jorge	The University of Texas Southwestern Medical Center	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-C2	Feng, Ziding	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-P1	Kanwal, Fasiha	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150587-P2	El-Serag, Hashem	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-P3	Moore, David	Baylor College of Medicine	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-P4	Baretta, Laura	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kushi, Lawrence; Li, Christopher
RP150587-P5	Singal, Amit	The University of Texas Southwestern Medical Center	Barlow, William; Kushi, Lawrence; Li, Christopher
Applications Not Recommended for PIC or Oversight Committee Consideration			
RP150631	Gustafsson, Jan-Ake	University of Houston	Sukumar, Saraswati
RP150631-P4	Tekmal, Rajeshwar	The University of Texas Health Science Center at San Antonio	Sukumar, Saraswati
RP150650	Pandita, Tej	The Methodist Hospital Research Institute	Sukumar, Saraswati
RP150650-P3	Pandita, Tej	The Methodist Hospital Research Institute	Sukumar, Saraswati
RP150527*	Foulds, Charles	Baylor College of Medicine	Greene, Geoffrey; Wahl, Geoffrey
RP150537*	Dalby, Kevin	The University of Texas at Austin	Roberts, Charles
RP150537-C1*	Ren, Pengyu	The University of Texas at Austin	Roberts, Charles
RP150537-C2*	Ueno, Naoto	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150537-P1*	Bartholomeusz, Chandra	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150537-P2*	Bartholomeusz, Chandra	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150537-P3*	Ueno, Naoto	The University of Texas M.D. Anderson Cancer Center	Roberts, Charles
RP150603	Raj, Ganesh	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-C1	Kapur, Payal	The University of Texas Southwestern Medical Center	Costello, Karen

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150603-C2	Hwang, Tae Hyun	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P1	Boothman, David	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P2	Raj, Ganesh	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P3	Hsieh, Jer-Tsong	The University of Texas Southwestern Medical Center	Costello, Karen
RP150603-P4	Martinez, Elisabeth	The University of Texas Southwestern Medical Center	Costello, Karen
RP150664	Rawley, David	Baylor College of Medicine	Greene, Geoffrey
RP150664-C1	Mancini, Michael	Baylor College of Medicine	Greene, Geoffrey
RP150664-P1	Zhang, Xiang	Baylor College of Medicine	Greene, Geoffrey
RP150664-P2	Rowley, David	Baylor College of Medicine	Greene, Geoffrey
RP150664-P3	Farach-Carson, Cindy	Rice University	Greene, Geoffrey
RP150664-P4	Park, Dongsu	Baylor College of Medicine	Greene, Geoffrey
RP150667*	Mitsiades, Nicholas	Baylor College of Medicine	Costello, Joseph
RP150680*	Zeng, Mingtao	Texas Tech University Health Sciences Center at El Paso	Costello, Karen
RP150681	Jayarman, Arul	Texas A&M Engineering Experiment Station	Belinsky, Steven; Fearon, Eric
RP150560	Suarez-Almazor, Maria	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-C1	Zhao, Hui	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-C2	Chang, Shine	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150560-C3	Rodriguez, Alma	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P1	Smith, Benjamin	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P2	Holmes, Holly	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P3	Hwang, Jessica	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P4	Suarez-Almazor, Maria	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150560-P5	Shih, Ya-Chen Tina	The University of Texas M.D. Anderson Cancer Center	Paskett, Electra
RP150614*	Edwards, Beatrice	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-C1*	Wagner, Elizabeth	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-C2*	Zhao, Hua	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-C3*	Amini, Behrang	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-P1*	Edwards, Beatrice	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150614-P2*	Villareal, Reina	Baylor College of Medicine	Barlow, William
RP150614-P3*	Villareal, Dennis	Baylor College of Medicine	Barlow, William
RP150683	Wetter, David	Rice University	Brandon, Thomas
RP150683-C1	Li, Liang	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas
RP150683-P1	Wetter, David	Rice University	Brandon, Thomas
RP150683-P2	Fernandez, Maria	The University of Texas Health Science Center at Houston	Brandon, Thomas

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150683-P3	Shih, Ya-Chen Tina	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas
RP150684*	Wetter, David	Rice University	Brandon, Thomas
RP150536*	Orlowski, Robert	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-C2*	Davis, Richard	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-C3*	Yang, Jing	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P1*	Shah, Nina	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P2*	Molldrem, Jeffrey	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P3*	Nawrocki, Steffan	The University of Texas Health Science Center at San Antonio	Kast, W. Martin
RP150536-P4*	Colla, Simona	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150536-P5*	Orlowski, Robert	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin
RP150575	Yu, Dihua	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-C1	Sahin, Aysegul	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-P1	Yu, Dihua	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-P2	Hung, Mien-Chie	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150575-P3	Jiang, Ning	The University of Texas at Austin	Kast, W. Martin; Riddell, Stanley
RP150575-P4	Mittendorf, Elizabeth	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150592	Symmans, William	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-C1	Tripathy, Debu	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-C2	Davies, Peter	Texas A&M University System Health Science Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-C3	Symmans, William	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P1	Moulder, Stacy	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P2	Piwnica-Worms, Helen	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P3	Mani, Sendurai	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150592-P4	Symmans, William	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Niedzwiecki, Donna
RP150653	Maitra, Anirban	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-C1	Maitra, Anirban	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-C2	Chin, Lynda	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P1	DePinho, Ronald	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P2	Draetta, Giulio	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P3	Kalluri, Raghu	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley
RP150653-P4	Yee, Cassian	The University of Texas M.D. Anderson Cancer Center	Kast, W. Martin; Riddell, Stanley

* = Not discussed

Application ID	Applicant	Institution	Conflict Noted
RP150679*	Wang, Rongfu	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-C1*	Liu, Xuewu	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-C2*	Gee, Adrian	Baylor College of Medicine	Kast, W. Martin
RP150679-P1*	Shen, Haifa	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-P2*	Wang, Rongfu	The Methodist Hospital Research Institute	Kast, W. Martin
RP150679-P3*	Rooney, Cliona	Baylor College of Medicine	Kast, W. Martin
RP150657	Sherry, Dean	The University of Texas at Dallas	Zinn, Kurt
RP150674*	Kameoka, Jun	Texas A&M University	Basillion, James

* = Not discussed

De-Identified Overall Evaluation Scores

Multi-Investigator Research Awards

Academic Research Cycle 15.2

Application ID	Final Overall Evaluation Score
RP150587*	1.9
RP150648*	2.3
EA	2.5
EB	2.5
EC	3.3
ED	3.3
EE	3.5
EF	3.5
EG	3.6
EH	3.7
EI	3.7
EJ	3.7
EK	3.7
EL	3.7
EM	3.8
EN	3.9
EO	3.9
EP	3.9
EQ	4.0
ER	4.0
ES	4.1
ET	4.1
EU	4.1
EV	4.2
EW	4.3
EX	4.3
EY	4.3
EZ	4.4
FA	4.4
FB	4.4
FC	4.7
FD	4.7
FE	4.8
FF	4.9
FG	4.9
FH	5.0
FI	5.1
FJ	5.1
FK	5.3
FL	5.3
FM	5.5
FN	5.5

*=Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

**Ludwig Institute for
Cancer Research Ltd**

April 22, 2015

**Richard D. Kolodner
Ph.D.**

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

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

rkolodner@ucsd.edu

San Diego Branch
UC San Diego School of
Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

**T 858 534 7804
F 858 534 7750**

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

**T 212 450 1500
F 212 450 1555**

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cpr.it.state.tx.us

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the **Core Facilities Support Awards (CFSA)**, **High Impact/High Risk Research Awards (HIHR)**, and **Multi-Investigator Research Awards (MIRA)** grant mechanisms. The SRC met on Monday, April 13, 2015 to consider the applications recommended by the peer review panels following their meetings that were held March 9-18, 2015. 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 score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to one grant application. This adjustment is listed at the end of the list of recommended projects. The total amount for the applications recommended is \$50,066,421.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, 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

Attachment

Rank	App ID	Mechanism	Organization	Application Title	Budget	Score
1	RP150587	MIRA	Baylor College of Medicine	The Texas Hepatocellular Carcinoma Consortium (THCCC)	\$9,771,157	1.9
2	RP150611	CFSA	The Methodist Hospital Research Institute	CPRIT Core for RNA Therapeutics and Research	\$4,845,868	2.0
3	RP150535	CFSA	The University of Texas M. D. Anderson Cancer Center	Precision Oncology Decision Support Core	\$5,999,996	2.0
4	RP150573	HIHRRRA	The University of Texas Southwestern Medical Center	Dynamin GTPase: A novel pro-apoptotic cancer therapeutic target	\$200,000	2.0
5	RP150632	HIHRRRA	The University of Texas Southwestern Medical Center	Acetate may be a key substrate driving growth in early stage breast cancer in patients	\$200,000	2.0
6	RP150600	CFSA	The University of Texas Health Science Center at San Antonio	The Single-Cell Biopsy and Characterization Core (SBCC) at The University of Texas Health Science at San Antonio	\$3,277,895	2.1
7	RP150551	CFSA	The University of Texas Health Science Center at Houston	Therapeutic Monoclonal Antibody Lead Optimization and Development Core	\$5,277,338	2.1
8	RP150640	HIHRRRA	The University of Texas Health Science Center at Houston	Drug Conjugates of anti-LGR5 Antibodies as Novel Therapeutics for Destroying Cancer Stem Cells	\$200,000	2.1
9	RP150676	HIHRRRA	The University of Texas Southwestern Medical Center	Identification of Novel Melanoma Metastasis Driver Genes through Transposon-Mediated Mutagenesis	\$200,000	2.1
10	RP150637	HIHRRRA	Texas A&M University System Health Science Center	Efficient Production of iPSC-Derived Mesenchymal Stem Cells to Kill Cancers by Bystander Effects from Suicide Genes	\$200,000	2.2
11	RP150648*	MIRA	Baylor College of Medicine	GATA2 and steroid receptor coactivator-2 cooperate with androgen receptor in prostate cancer progression and androgen resistance	\$6,151,179	2.3
12	RP150703	HIHRRRA	Texas A&M University System Health Science Center	Metabolomic Salivary Biomarkers for Oral Cancer Detection	\$199,999	2.6
13	RP150596	CFSA	The University of Texas Southwestern Medical Center	Bioinformatics Core Facility at UT Southwestern Medical Center	\$5,593,882	2.7
14	RP150720	HIHRRRA	Texas Tech University	Integrated on-chip networks for investigating exosome-mediated drug expulsion	\$200,000	2.7
15	RP150559	HIHRRRA	Texas A&M University	Small Molecules to Perturb A Novel PPI Target For Chemotherapy	\$200,000	2.7

16	RP150656	HIHRRRA	Texas Tech University Health Sciences Center	Engineered Bone Targeting Nanomedicine for Treatment of Bone Metastases from Breast Cancer	\$199,970	2.8
17	RP150578	CFSA	Texas A&M University System Health Science Center	The Combinatorial Drug Discovery Program (CDDP)	\$5,954,596	3.0
18	RP150701	HIHRRRA	Rice University	Non-invasive Colonoscopy by Molecular Imaging of Mucin Targeted Hyperpolarized Silicon Nanoparticles	\$200,000	3.0
19	RP150638	HIHRRRA	Baylor Research Institute	Elevated D-2-hydroxyglutarate precedes and promotes tumor progression in inflammatory bowel diseases	\$200,000	3.1
20	RP150590	HIHRRRA	The University of Texas Southwestern Medical Center	Identifying Inhibitors of Ascl1 to Block Growth of Malignant Neuroendocrine and Neural Tumors	\$200,000	3.2
21	RP150713	HIHRRRA	The University of Texas at Dallas	Identification of Therapeutic Targets on Breast Cancer Stem Cells	\$194,543	3.3
22	RP150696	HIHRRRA	The University of Texas Health Science Center at San Antonio	Inhibition of Breast Cancer Metastasis to the Bone by microRNA Transmission through Gap Junctions	\$200,000	3.4
23	RP150711	HIHRRRA	The University of Texas at Arlington	Biomechanical profiling of migrating brain cancer genotypes in tightly-confined space for drug screening	\$199,998	3.4
24	RP150574	HIHRRRA	The University of Texas Health Science Center at San Antonio	Turning on a Novel Tumor-Inhibiting Switch for Colorectal Cancer	\$200,000	3.4

*RP150648 - The peer review panel recommended the removal of a MIRA project. The budget was reduced based on the deletion of that project plus a 20% reduction of the remaining budget.

Success Rate by Panel		
Peer Review Panel	Success Rate	Score Cutoff
BCR1	14.3%	3.3
BCR2	18.2%	2.7
CB	18.2%	3.4
CPR	7.7%	1.9
CTCR/TCR	14.8%	3.0
ITI	13.9%	3.4

Success Rate by Mechanism vs. Total Reviewed*		
Mechanism	Success Rate	# Recommended
CFSA	35.3%	6/17
HIHR	16.0%	16/100
MIRA	4.8%	2/42
Overall	15.1%	24/159

Percent of Applications Recommended by SRC by Mechanism		
Mechanism	# Recommended	Percentage
CFSA	6/24	25%
HIHR	16/24	67%
MIRA	2/24	8%

Percent of Funding Recommended by SRC by Mechanism		
Mechanism	\$ Recommended	Percentage
CFSA	\$30.9	62%
HIHR	\$3.2	6%
MIRA	\$15.9	32%



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 2
Recruitment of Established Investigators

Request for Applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-15-REI-2

**Recruitment of
Established Investigators**

**Please also refer to the Instructions for Applicants document, which will be
posted on September 2, 2014**

Application Receipt Dates:

September 2, 2014-August 31, 2015

Fiscal Year Award Period

September 1, 2014-August 31, 2015 (FY 2015)

TABLE OF CONTENTS

1. ABOUT CPRIT	4
2. RATIONALE	4
3. RECRUITMENT OBJECTIVES.....	4
4. FUNDING INFORMATION	6
5. ELIGIBILITY	6
6. RESUBMISSION POLICY	8
7. RESPONDING TO THIS RFA	8
7.1. APPLICATION SUBMISSION GUIDELINES	8
7.2. APPLICATION COMPONENTS	9
7.2.1. <i>Summary of Nomination (2,000 characters)</i>	9
7.2.2. <i>Institutional Commitment (2 pages)</i>	9
7.2.3. <i>Letter of Support from Department Chair (1 page)</i>	10
7.2.4. <i>Curriculum Vitae (CV)</i>	10
7.2.5. <i>Summary of Goals and Objectives</i>	10
7.2.6. <i>Research (4 pages)</i>	11
7.2.7. <i>Publications</i>	11
7.2.8. <i>Timeline (1 page)</i>	11
7.2.9. <i>Current and Pending Support</i>	11
7.2.10. <i>Research Environment (1 page)</i>	12
7.2.11. <i>Descriptive Biography (Up to 2 pages)</i>	12
8. APPLICATION REVIEW	12
8.1. REVIEW PROCESS	12
8.2. CONFIDENTIALITY OF REVIEW	13
8.3. REVIEW CRITERIA	13
9. KEY DATES.....	15
10. AWARD ADMINISTRATION.....	15
11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS.....	16
12. CONTACT INFORMATION.....	16
12.1. HELPDESK	16
12.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	17

RFA VERSION HISTORY

Rev 9/2/14 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 \$3 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.

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.

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.

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, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. FUNDING INFORMATION

This is a 5-year award 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 million (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. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified. **Grant funds may be used for salary support of this candidate but may not be used to construct or renovate laboratory space.** Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50% of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support and endowment for the individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

5. 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.
- Candidates who have already accepted a position at the recruiting institution are not eligible for a recruitment award as an investment by CPRIT is obviously not necessary. Such individuals may, however, apply for other CPRIT grant awards, as appropriate.
- 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 not primarily based in Texas. 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. Prior to final approval of an award, the candidate must provide the same certification.
- 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. Prior to final approval of an award, the candidate must provide the same certification.
- 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. Prior to final approval of an award, the candidate must provide the same certification.

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 10](#) and [Section 11](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. 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. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

7. RESPONDING TO THIS RFA

7.1. 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 to start and submit an application. Furthermore, the Authorized Signing Official (ASO), 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.

Applications will be accepted on a continuous basis and reviewed monthly. To manage the timely review of nominations for each evaluation period, the application submitted by the 20th day of each month will be reviewed by the 15th day of the following month. For the most immediate submission period, nominations will be accepted beginning at 7 AM central time on September 2, 2014, and must be submitted by 3 PM central time on September 20, 2014, to be reviewed by October 15, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

7.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details 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 5](#) will be administratively withdrawn without review.

7.2.1. 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.

7.2.2. Institutional Commitment (2 pages)

Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. **The institutional commitment must state the total award amount requested.** Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean.

The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the

institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

Start-up Package: Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.

Endowment Equivalents: The principal of an endowment may not be included as part of the institutional match, but endowment income over the lifetime of the award may be included.

Rent: Amount for recovery of occupying facility space (ie, “rent”) is not a permitted institutional commitment item.

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

Provide the letter of support from and signed by the chair of the department that the candidate is being recruited to. 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.

7.2.4. Curriculum Vitae (CV)

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

7.2.5. Summary of Goals and Objectives

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

7.2.6. 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 must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.**

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. Requests to change the recruiting institution during the recruitment process are inappropriate."

7.2.7. 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.

7.2.8. 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.

7.2.9. 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.

7.2.10. 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.

7.2.11. 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.

8. APPLICATION REVIEW

8.1. 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 discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment.

Applications approved by 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, Chapter 703, Sections 703.6–703.8.

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 are sent to the nominator.

8.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, Program Integration Committee 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, 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 Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee 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.

8.3. 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 some 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?

9. KEY DATES

RFA

RFA Release

September 2, 2014

Application Receipt and Review Timeline

Application Receipt System opens, 7 AM CT	Application Receipt	Anticipated Application Review
September 2, 2014	Continuous	Monthly by the 15 th day of the month

10. 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 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, which are available at www.cprit.state.tx.us.

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 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 the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

11. 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, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

12. CONTACT INFORMATION

12.1. HelpDesk

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

Dates of operation: September 2, 2014, onward (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time
Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

12.2. 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 Research.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Scientific Review Council Observation Report

Report #2015-225

Panel Name: FY15.2 Recruitment Review Panel- 7

Panel Date: April 13, 2015

Report Date: April 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council's review of Recruitment applications for FY15 funding. The meeting was chaired by Tom Curran and held via teleconference on April 13, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council's discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Curran on April 13, 2015.

The independent observer noted the following during our observation:

- Ten applications were discussed within the Recruitment Review Panel to determine which grants would receive CPRIT funding.
- Seven council members, two CPRIT staff members, and three SRA employees were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

There were no noted conflicts of interest from either the Scientific Review Council or the Program Integration Committee.

De-Identified Overall Evaluation Scores

Recruitment of Established Investigators

Academic Research Recruitment Cycle 15.2

Application ID	Final Overall Evaluation Score
RR150054*	1.8

*=Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

**Ludwig Institute for
Cancer Research Ltd**

April 22, 2015

**Richard D. Kolodner
Ph.D.**

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

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

rkolodner@ucsd.edu

San Diego Branch
UC San Diego School of
Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

**T 858 534 7804
F 858 534 7750**

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

**T 212 450 1500
F 212 450 1555**

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cpriti.state.tx.us

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its list of recruitment grant recommendations. The SRC met on Monday, April 13, 2015 to consider the applications submitted to CPRIT under the **Recruitment of Established Investigator, Recruitment for First-Time, Tenure Track Faculty Members and Recruitment of Rising Stars** Request for Applications. 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 score are stated for each grant application. The SRC made one change to the funding amount requested by an applicant to the Recruitment of Established Investigator RFA. There were no other changes to funding amounts, goals, timelines, or project objectives requested by other applicants. The total amount for the applications recommended is \$14,000,000.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a 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

Attachment

Rank	App ID	Mechanism	Organization	Candidate	Budget Requested	Overall Score
1	RR150060	RFT	The University of Texas Southwestern Medical Center	Dr. Randal Halfmann	\$2,000,000	1.0
2	RR150062	RFT	The University of Texas Southwestern Medical Center	Dr. Shixin Liu	\$2,000,000	1.0
3	RR150058	RFT	The University of Texas Southwestern Medical Center	Dr. Andreas Doncic	\$2,000,000	1.3
4	RR150054	REI	The University of Texas M. D. Anderson Cancer Center	Dr. Hongtu Zhu	\$4,000,000*	1.8
5	RR150059	RFT	The University of Texas Southwestern Medical Center	Dr. Maralice Conacci-Sorrell	\$2,000,000	2.0
6	RR150044	RFT	Rice University	Dr. Natalia Kirienko	\$2,000,000	2.2

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

REI = Recruitment of Established Investigators

*The award amount for this REI candidate was reduced from \$6M to \$4M at the recommendation of the SRC.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 2
*Recruitment of First-Time, Tenure-Track
Faculty Members*

Request for Applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-15-RFT-2

**Recruitment of First-Time
Tenure-Track Faculty Members**

Please also refer to the Instructions for Applicants document, which will be
posted on September 2, 2014

Application Receipt Dates:

September 2, 2014-Aug 31, 2015

Fiscal Year Award Period

September 1, 2014-August 31, 2015 (FY 2015)

TABLE OF CONTENTS

1. ABOUT CPRIT	4
2. RATIONALE	4
3. RECRUITMENT OBJECTIVES.....	5
4. FUNDING INFORMATION	5
5. ELIGIBILITY	6
6. RESUBMISSION POLICY	8
7. RESPONDING TO THIS RFA	8
7.1. APPLICATION SUBMISSION GUIDELINES	8
7.2. APPLICATION COMPONENTS	9
7.2.1. <i>Summary of Nomination (2,000 characters)</i>	9
7.2.2. <i>Institutional Commitment (3 pages)</i>	9
7.2.3. <i>Letter of Support from Department Chair (1 page)</i>	10
7.2.4. <i>Curriculum Vitae (CV)</i>	10
7.2.5. <i>Summary of Goals and Objectives</i>	10
7.2.6. <i>Research (4 pages)</i>	11
7.2.7. <i>Publications</i>	11
7.2.8. <i>Timeline (1 page)</i>	11
7.2.9. <i>Current and Pending Support</i>	11
7.2.10. <i>Letters of Recommendation</i>	12
7.2.11. <i>Research Environment (1 page)</i>	12
7.2.12. <i>Descriptive Biography (Up to 2 pages)</i>	12
8. APPLICATION REVIEW	12
8.1. REVIEW PROCESS.....	12
8.1.1. <i>Confidentiality of Review</i>	13
8.2. REVIEW CRITERIA	14
9. KEY DATES.....	15
10. AWARD ADMINISTRATION.....	15
11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS.....	16
12. CONTACT INFORMATION.....	16
12.1. HELPDESK	16
12.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	17

RFA VERSION HISTORY

Rev 9/2/14 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 \$3 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.

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.

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 is an important evaluation criterion for CPRIT funding.

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, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. FUNDING INFORMATION

This is a 4-year award 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 4-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 4 years. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified.

Grant funds may not be used for salary support of this candidate or to construct or renovate laboratory space. Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50% of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support for the individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

5. 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.
- Candidates who have already accepted a position as assistant professor tenure track at the recruiting institution are not eligible for a recruitment award as an investment by CPRIT is obviously not necessary. Such individuals may, however, apply for other CPRIT grant awards, as appropriate.
- 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 not primarily based in Texas. 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), etc. 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 they are completing postdoctoral training.
- 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. Prior to final approval of an award, the candidate must provide the same certification.
- 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. Prior to final approval of an award, the candidate must provide the same certification.
- 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. Prior to final approval of an award, the candidate must provide the same certification.

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 10](#) and [Section 11](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. 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.

7. RESPONDING TO THIS RFA

7.1. 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 to start and submit an application. Furthermore, the Authorized Signing Official (ASO), 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.

Applications will be accepted on a continuous basis and reviewed monthly. To manage the timely review of nominations for each evaluation period, the application submitted by the 20th day of each month will be reviewed by the 15th day of the following month. For the most immediate submission period, nominations will be accepted beginning at 7 AM central time on September 2, 2014, and must be submitted by 3 PM central time on September 20, 2014, to be reviewed by October 15, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

7.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details 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 5](#) will be administratively withdrawn without review.

7.2.1. 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.

7.2.2. Institutional Commitment (3 pages)

Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. **The institutional commitment must state the total award amount requested.** Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean. The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

Start-up Package: Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.

Rent: Amount for recovery of occupying facility space (ie, “rent”) is not a permitted institutional commitment item.

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

Provide the letter of support from and signed by the chair of the department that the candidate is being recruited to. 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.

7.2.4. Curriculum Vitae (CV)

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

7.2.5. Summary of Goals and Objectives

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

7.2.6. 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 must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.**

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. Requests to change the recruiting institution during the recruitment process are inappropriate."

7.2.7. 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.

7.2.8. 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.

7.2.9. 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.

7.2.10. 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.

7.2.11. 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.

7.2.12. 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.

8. APPLICATION REVIEW

8.1. 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 discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment.

Applications approved by 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, Chapter 703, Sections 703.6–703.8.

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 are sent to the nominator.

8.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, Program Integration Committee 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, 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 Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee 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.

8.2. 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 some 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 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?

9. KEY DATES

RFA

RFA Release September 2, 2014

Application Receipt and Review Timeline

Application Receipt System opens, 7 AM CT	Application Receipt	Anticipated Application Review
September 2, 2014	Continuous	Monthly by the 15 th day of the month

10. 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 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, which are available at

www.cpr.it.state.tx.us.

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 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 the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

11. 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, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

12. CONTACT INFORMATION

12.1. HelpDesk

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

Dates of operation: September 2, 2014 onward (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. central time
Wednesday, 8 a.m. to 4 p.m. central time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

12.2. 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 Research.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Scientific Review Council Observation Report

Report #2015-225

Panel Name: FY15.2 Recruitment Review Panel- 7

Panel Date: April 13, 2015

Report Date: April 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council's review of Recruitment applications for FY15 funding. The meeting was chaired by Tom Curran and held via teleconference on April 13, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council's discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Curran on April 13, 2015.

The independent observer noted the following during our observation:

- Ten applications were discussed within the Recruitment Review Panel to determine which grants would receive CPRIT funding.
- Seven council members, two CPRIT staff members, and three SRA employees were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

There were no noted conflicts of interest from either the Scientific Review Council or the Program Integration Committee.

De-Identified Overall Evaluation Scores

Recruitment of First-Time, Tenure-Track Faculty Members

Academic Research Recruitment Cycle 15.2

Application ID	Final Overall Evaluation Score
RR150060*	1.0
RR150062*	1.0
RR150058*	1.3
RR150059*	2.0
RR150044*	2.2
GA	2.8
GB	2.8
GC	2.8

RR150060 was withdrawn after recommendation by the Scientific Review Council but before the Program Integration Committee meeting.

*=Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

**Ludwig Institute for
Cancer Research Ltd**

April 22, 2015

**Richard D. Kolodner
Ph.D.**

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

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

rkolodner@ucsd.edu

San Diego Branch
UC San Diego School of
Medicine
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

**T 858 534 7804
F 858 534 7750**

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

**T 212 450 1500
F 212 450 1555**

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

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

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its list of recruitment grant recommendations. The SRC met on Monday, April 13, 2015 to consider the applications submitted to CPRIT under the **Recruitment of Established Investigator, Recruitment for First-Time, Tenure Track Faculty Members and Recruitment of Rising Stars** Request for Applications. 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 score are stated for each grant application. The SRC made one change to the funding amount requested by an applicant to the Recruitment of Established Investigator RFA. There were no other changes to funding amounts, goals, timelines, or project objectives requested by other applicants. The total amount for the applications recommended is \$14,000,000.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a 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

Attachment

Rank	App ID	Mechanism	Organization	Candidate	Budget Requested	Overall Score
1	RR150060	RFT	The University of Texas Southwestern Medical Center	Dr. Randal Halfmann	\$2,000,000	1.0
2	RR150062	RFT	The University of Texas Southwestern Medical Center	Dr. Shixin Liu	\$2,000,000	1.0
3	RR150058	RFT	The University of Texas Southwestern Medical Center	Dr. Andreas Doncic	\$2,000,000	1.3
4	RR150054	REI	The University of Texas M. D. Anderson Cancer Center	Dr. Hongtu Zhu	\$4,000,000*	1.8
5	RR150059	RFT	The University of Texas Southwestern Medical Center	Dr. Maralice Conacci-Sorrell	\$2,000,000	2.0
6	RR150044	RFT	Rice University	Dr. Natalia Kirienko	\$2,000,000	2.2

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

REI = Recruitment of Established Investigators

*The award amount for this REI candidate was reduced from \$6M to \$4M at the recommendation of the SRC.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150058
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Andreas Doncic

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, including two that were withdrawn, applications for this RFA. The 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.

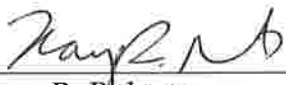
CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."



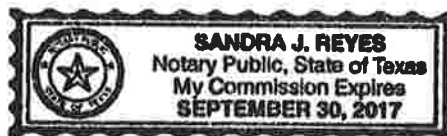
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research - Recruitment
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR150058
APPLICATION TITLE Nomination of Andreas Doncic, Ph.D. for a First-Time Tenure-Track Recruitment Award
APPLICANT NAME Fitz, John G
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 15.2 Recruitment Review Panel - 7 (15.2_RRP-7)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	09/19/14	04/23/15
	CPRIT Application Receipt Cycle opened	02/21/15	04/23/15
	CPRIT Application Receipt Cycle closed	03/20/15	04/23/15
	Date application submitted	03/13/15	04/23/15
	Method of submission	CARS	04/23/15
	Within receipt period	YES	04/23/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/23/15
	Donation(s) made to CPRIT/foundation	NO	04/23/15
	Assigned to primary reviewers	04/03/15	04/23/15
	Applicant notified of review panel assignment	N/A	04/23/15
	Primary Reviewer 1 COI signed	03/30/15	04/23/15
	Primary Reviewer 2 COI signed	03/30/15	04/23/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	04/12/15	04/23/15
	Primary Reviewer 2 critique submitted	04/12/15	04/23/15
	COI indicated by non-primary reviewer	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	Discussed at Peer Review Meeting	YES	04/23/15
	Peer Review Meeting	04/13/15	04/23/15
	Post review statements signed	04/21/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Score report delivered to CSO	04/20/15	04/23/15
4. Final SRC Recommendation	Recommended for SRC Review	YES	04/23/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Recommended for grant award	YES	04/23/15
5. PIC Review	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
6. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150044
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Natalia Kirienko

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, including two that were withdrawn, for this RFA. The 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


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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

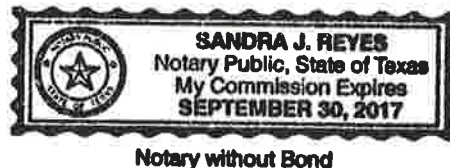
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research - Recruitment
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR150044
APPLICATION TITLE Recruitment of First-Time, Tenure Track Faculty Member -
 Dr. Natalia Kirienko
APPLICANT NAME Rossky, Peter J
ORGANIZATION Rice University
PANEL NAME 15.2 Recruitment Review Panel - 7 (15.2_RRP-7)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	09/19/14	04/23/15
	CPRIT Application Receipt Cycle opened	02/21/15	04/23/15
	CPRIT Application Receipt Cycle closed	03/20/15	04/23/15
	Date application submitted	03/19/15	04/23/15
	Method of submission	CARS	04/23/15
	Within receipt period	YES	04/23/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/23/15
	Donation(s) made to CPRIT/foundation	NO	04/23/15
	Assigned to primary reviewers	04/03/15	04/23/15
	Applicant notified of review panel assignment	N/A	04/23/15
	Primary Reviewer 1 COI signed	03/27/15	04/23/15
	Primary Reviewer 2 COI signed	03/30/15	04/23/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	04/12/15	04/23/15
	Primary Reviewer 2 critique submitted	04/12/15	04/23/15
	COI indicated by non-primary reviewer	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	Discussed at Peer Review Meeting	YES	04/23/15
	Peer Review Meeting	04/13/15	04/23/15
	Post review statements signed	04/21/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Score report delivered to CSO	04/20/15	04/23/15
	Recommended for SRC Review	YES	04/23/15
4. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150062
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Shixin 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, including two that were withdrawn, for this RFA. The 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

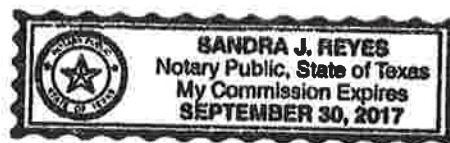
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research - Recruitment
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR150062
APPLICATION TITLE Nomination of Shixin Liu, Ph.D. for a CPRIT First-Time Tenure-Track Recruitment Award
APPLICANT NAME Fitz, John G
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 15.2 Recruitment Review Panel - 7 (15.2_RRP-7)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	09/19/14	04/23/15
	CPRIT Application Receipt Cycle opened	02/21/15	04/23/15
	CPRIT Application Receipt Cycle closed	03/20/15	04/23/15
	Date application submitted	03/17/15	04/23/15
	Method of submission	CARS	04/23/15
	Within receipt period	YES	04/23/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/23/15
	Donation(s) made to CPRIT/foundation	NO	04/23/15
	Assigned to primary reviewers	04/03/15	04/23/15
	Applicant notified of review panel assignment	N/A	04/23/15
	Primary Reviewer 1 COI signed	04/03/15	04/23/15
	Primary Reviewer 2 COI signed	03/27/15	04/23/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	04/06/15	04/23/15
	Primary Reviewer 2 critique submitted	04/12/15	04/23/15
	COI indicated by non-primary reviewer	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	Discussed at Peer Review Meeting	YES	04/23/15
	Peer Review Meeting	04/13/15	04/23/15
	Post review statements signed	04/21/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Score report delivered to CSO	04/20/15	04/23/15
	Recommended for SRC Review	YES	04/23/15
4. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150059
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Maralice Conacci-Sorrell

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, including two that were withdrawn, for this RFA. The 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

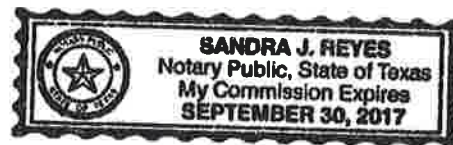
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research - Recruitment
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR150059
APPLICATION TITLE Nomination of Maralice Conacci-Sorrell, Ph.D. for a First-Time Tenure-Track Recruitment Award
APPLICANT NAME Fitz, John G
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 15.2 Recruitment Review Panel - 7 (15.2_RRP-7)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	09/19/14	04/23/15
	CPRIT Application Receipt Cycle opened	02/21/15	04/23/15
	CPRIT Application Receipt Cycle closed	03/20/15	04/23/15
	Date application submitted	03/14/15	04/23/15
	Method of submission	CARS	04/23/15
	Within receipt period	YES	04/23/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/23/15
	Donation(s) made to CPRIT/foundation	NO	04/23/15
	Assigned to primary reviewers	04/03/15	04/23/15
	Applicant notified of review panel assignment	N/A	04/23/15
	Primary Reviewer 1 COI signed	03/30/15	04/23/15
	Primary Reviewer 2 COI signed	03/27/15	04/23/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	04/13/15	04/23/15
	Primary Reviewer 2 critique submitted	04/12/15	04/23/15
	COI indicated by non-primary reviewer	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	Discussed at Peer Review Meeting	YES	04/23/15
	Peer Review Meeting	04/13/15	04/23/15
	Post review statements signed	04/21/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Score report delivered to CSO	04/20/15	04/23/15
	Recommended for SRC Review	YES	04/23/15
4. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150054
Recruitment of Established Investigators
Nomination of Dr. Hongtu Zhu

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).

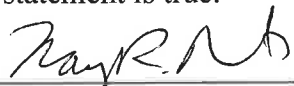
My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators* Request for Applications (RFA). CPRIT received one application for this RFA. The 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


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."



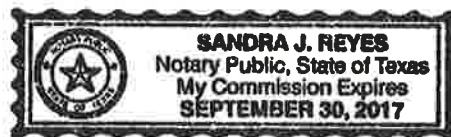
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research - Recruitment
AWARD MECHANISM Recruitment of Established Investigators (REI)
APPLICATION ID RR150054
APPLICATION TITLE Recruitment of Established Investigator - Dr. Hongtu Zhu, Ph.D.
APPLICANT NAME Dmitrovsky, Ethan
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME 15.2 Recruitment Review Panel - 7 (15.2_RRP-7)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	09/19/14	04/23/15
	CPRIT Application Receipt Cycle opened	02/21/15	04/23/15
	CPRIT Application Receipt Cycle closed	03/20/15	04/23/15
	Date application submitted	03/18/15	04/23/15
	Method of submission	CARS	04/23/15
	Within receipt period	YES	04/23/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/23/15
	Donation(s) made to CPRIT/foundation	NO	04/23/15
	Assigned to primary reviewers	04/03/15	04/23/15
	Applicant notified of review panel assignment	N/A	04/23/15
	Primary Reviewer 1 COI signed	03/27/15	04/23/15
	Primary Reviewer 2 COI signed	03/30/15	04/23/15
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	04/05/15	04/23/15
	Primary Reviewer 2 critique submitted	04/12/15	04/23/15
	COI indicated by non-primary reviewer	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	Discussed at Peer Review Meeting	YES	04/23/15
	Peer Review Meeting	04/13/15	04/23/15
	Post review statements signed	04/21/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Score report delivered to CSO	04/20/15	04/23/15
	Recommended for SRC Review	YES	04/23/15
4. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/26/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
5. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to a conflict of interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150648
Multi-Investigator Research 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 *Multi-Investigator Research Awards* Request for Applications (RFA). CPRIT received 42 applications for this RFA. The application was assigned the Cancer Biology panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

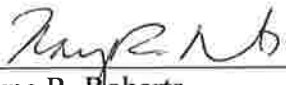
An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

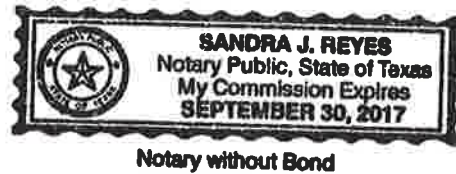


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM Multi Investigator Research Awards (MIRA)
APPLICATION ID RP150648
APPLICATION TITLE GATA2 and Steroid Receptor Coactivator-2 Cooperate with Androgen Receptor in Prostate Cancer Progression and Androgen Resistance
APPLICANT NAME O'Malley, Bert
ORGANIZATION Baylor College of Medicine
PANEL NAME Cancer Biology (CB)

Category	Consent/Requirement	Reviewer	Attention Date
1. Pre-Receipt	RFA published in Texas Register	04/03/14	04/02/15
	CPRIT Application Receipt System (CARS) opened	06/02/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Data registration submitted	11/14/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/02/15
2. Receipt, Referral, and Assignment	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	OVERALL MIRA PROJECT		
	Primary Reviewer 1 COI signed	12/18/14	04/02/15
	Primary Reviewer 2 COI signed	12/18/14	04/02/15
	Primary Reviewer 3 COI signed	12/22/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	02/08/15	04/07/15
	PROJECT 1:		
	Primary Reviewer 1 COI signed	12/18/14	04/02/15
	Primary Reviewer 2 COI signed	12/18/14	04/07/15
	Primary Reviewer 3 COI signed	12/22/14	04/02/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	PROJECT 2:		
	Primary Reviewer 1 COI signed	12/18/14	04/07/15
	Primary Reviewer 2 COI signed	12/18/14	04/02/15
	Primary Reviewer 3 COI signed	01/20/15	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	PROJECT 3:		
	Primary Reviewer 1 COI signed	12/18/14	04/07/15
	Primary Reviewer 2 COI signed	12/18/14	04/02/15
	Primary Reviewer 3 COI signed	12/22/14	04/02/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	PROJECT 4:		
	Primary Reviewer 1 COI signed	12/24/14	04/02/15
	Primary Reviewer 2 COI signed	12/21/14	04/07/15
	Primary Reviewer 3 COI signed	01/20/15	04/02/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	CORE 1:		
	Primary Reviewer 1 COI signed	12/18/14	04/02/15
	Primary Reviewer 2 COI signed	12/18/14	04/02/15
	Primary Reviewer 3 COI signed	02/20/15	04/02/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
4. Peer Review Meeting	OVERALL MIRA PROJECT		
	Primary Reviewer 1 critique submitted	01/21/15	04/07/15
	Primary Reviewer 2 critique submitted	01/22/15	04/02/15
	Primary Reviewer 3 critique submitted	02/22/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	02/26/15	04/07/15
	PROJECT 1:		
	Primary Reviewer 1 critique submitted	02/17/15	04/02/15
	Primary Reviewer 2 critique submitted	02/17/15	04/07/15
	Primary Reviewer 3 critique submitted	02/22/15	04/02/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	PROJECT 2:		
	Primary Reviewer 1 critique submitted	02/17/15	04/07/15
	Primary Reviewer 2 critique submitted	02/14/15	04/02/15
	Primary Reviewer 3 critique submitted	02/23/15	04/02/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	PROJECT 3:		
	Primary Reviewer 1 critique submitted	02/22/15	04/07/15
	Primary Reviewer 2 critique submitted	02/17/15	04/02/15
	Primary Reviewer 3 critique submitted	02/24/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/02/15
	PROJECT 4:		
	Primary Reviewer 1 critique submitted	02/18/15	04/02/15
	Primary Reviewer 2 critique submitted	02/22/15	04/07/15
	Primary Reviewer 3 critique submitted	02/22/15	04/02/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	CORE 1:		
	Primary Reviewer 1 critique submitted	02/22/15	04/07/15
	Primary Reviewer 2 critique submitted	02/17/15	04/02/15
	Primary Reviewer 3 critique submitted	02/22/15	04/02/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/02/15
	COI indicated by non-primary reviewer	Castello, Joseph	04/02/15
	COI recused from participation	YES	04/02/15
	Discussed at Peer Review Meeting	YES	04/02/15
	Peer Review Meeting	03/30/15	04/07/15
	Post review statements signed	03/11/15	04/07/15
	Third Party Observer Report	03/13/15	04/07/15
	Score report delivered to CRO	04/01/15	04/02/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC members	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/22/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and QC	04/22/15	04/23/15
	COI indicated by PIC members	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	COI Notifications to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NONE or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made by CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150587
Multi-Investigator Research 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 *Multi-Investigator Research Awards* Request for Applications (RFA). CPRIT received 42 applications for this RFA. The application was assigned the Cancer Prevention Research panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


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."

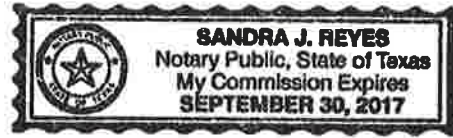

Wayne R. Roberts,

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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

FY 2015
CYCLE 3
PROGRAM Research
AWARD MECHANISM Multi-Investigator Research Awards (MIRA)
APPLICATION ID: RP150587
APPLICATION TITLE The Texas Hepatocellular Carcinoma Consortium (THCC)
APPLICANT NAME El Serag, Hashem
ORGANIZATION Baylor College of Medicine
FUND NAME Cancer Prevention Research (CPR)

Category	Event/Action/Approval	Primary Review	Secondary Review
1. Pre-Review	AAA submitted to Texas Region	08/03/14	08/07/15
	CRIT Application Review System (CAR) opened	08/03/14	08/07/15
	CRIT Application Review System (CAR) closed	11/17/14	08/07/15
	CRIT Application submitted	11/17/14	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
2. Review, Referral, and Assignment	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
3. Review, Referral, and Assignment	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
4. Peer Review Meeting	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
5. Final SMC Recommendation	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
6. Post-Review	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
7. Oversight Committee Approval	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15
	CRIT Application submitted	08/07/15	08/07/15

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150559
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Basic Cancer Research 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


I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

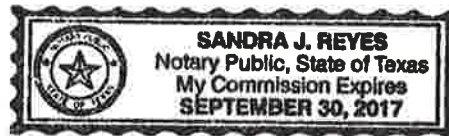


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150559
APPLICATION TITLE Small Molecules to Perturb A Novel PPI Target For Chemotherapy
APPLICANT NAME Burgess, Kevin
ORGANIZATION Texas A&M University
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/17/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/12/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/18/14	04/07/15
	Primary Reviewer 2 COI signed	12/24/14	04/07/15
	Primary Reviewer 3 COI signed	12/18/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	12/24/15	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/27/15	04/07/15
	Primary Reviewer 2 critique submitted	03/02/15	04/07/15
	Primary Reviewer 3 critique submitted	03/02/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/15/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/18/15	04/07/15
	Post review statements signed	04/01/15	04/07/15
	Third Party Observer Report	03/23/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
5. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150573
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Basic Cancer Research 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


I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


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."

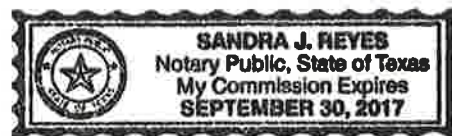


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2015
 CYCLE 2
 PROGRAM Research
 AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
 APPLICATION ID RP150573
 APPLICATION TITLE Dynamin GTPase: A Novel Pro-Apoptotic Cancer
 Therapeutic Target
 APPLICANT NAME Schmid, Sandra
 ORGANIZATION The University of Texas Southwestern Medical Center
 PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/13/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/12/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	03/05/15	04/07/15
	Primary Reviewer 2 COI signed	12/22/14	04/07/15
	Primary Reviewer 3 COI signed	12/24/14	04/07/15
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 COI signed	12/18/14	04/07/15
	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
4. Peer Review Meeting	Applicant notified of outcome	N/A	04/07/15
	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	03/07/15	04/07/15
	Primary Reviewer 2 critique submitted	03/01/15	04/07/15
	Primary Reviewer 3 critique submitted	03/02/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/13/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/18/15	04/07/15
	Post review statements signed	04/01/15	04/07/15
	Third Party Observer Report	03/23/15	04/07/15
5. Final SRC Recommendation	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
6. PIC Review	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
7. Oversight Committee Approval	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150574
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Cancer Biology panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

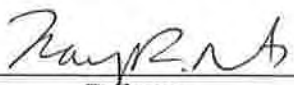
An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

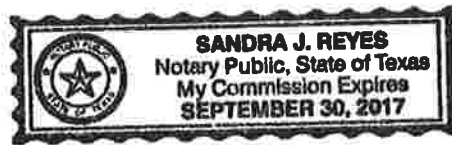


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150574
APPLICATION TITLE Turning on a Novel Tumor-Inhibiting Switch for Colorectal Cancer
APPLICANT NAME Li, Rong
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/13/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/25/14	04/07/15
	Primary Reviewer 2 COI signed	12/19/14	04/07/15
	Primary Reviewer 3 COI signed	12/18/14	04/07/15
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 COI signed	02/10/15	04/07/15
	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
4. Peer Review Meeting	Applicant notified of outcome	N/A	04/07/15
	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/16/15	04/07/15
	Primary Reviewer 2 critique submitted	02/23/15	04/07/15
	Primary Reviewer 3 critique submitted	02/02/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/05/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/10/15	04/07/15
	Post review statements signed	03/11/15	04/07/15
	Third Party Observer Report	03/13/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150590
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Basic Cancer Research 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


I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.


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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

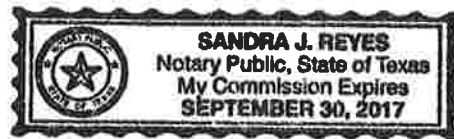
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150590
APPLICATION TITLE Identifying Inhibitors of Ascl1 to Block Growth of Malignant Neuroendocrine and Neural Tumors
APPLICANT NAME Johnson, Jane
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/13/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	12/18/14	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/21/14	04/07/15
	Primary Reviewer 2 COI signed	12/18/14	04/07/15
	Primary Reviewer 3 COI signed	12/25/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	12/19/14	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/23/15	04/07/15
	Primary Reviewer 2 critique submitted	02/22/15	04/07/15
	Primary Reviewer 3 critique submitted	02/19/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	02/28/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/09/15	04/07/15
	Post review statements signed	03/16/15	04/07/15
	Third Party Observer Report	03/10/15	04/08/15
	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
5. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
6. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150696
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Cancer Biology panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRRRA)
APPLICATION ID RP150696
APPLICATION TITLE Inhibition of Breast Cancer Metastasis to the Bone by microRNA Transmission through Gap Junctions
APPLICANT NAME Nicholson, Bruce
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/17/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/24/14	04/07/15
	Primary Reviewer 2 COI signed	12/25/14	04/07/15
	Primary Reviewer 3 COI signed	12/19/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	02/08/15	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/22/15	04/07/15
	Primary Reviewer 2 critique submitted	02/21/15	04/07/15
	Primary Reviewer 3 critique submitted	02/23/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	02/27/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/10/15	04/07/15
	Post review statements signed	03/11/15	04/07/15
	Third Party Observer Report	03/13/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OC		04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150632
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Basic Cancer Research 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

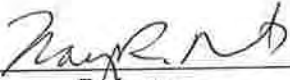
I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


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."

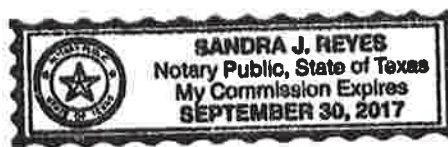


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150632
APPLICATION TITLE Acetate May Be a Key Substrate Driving Growth in Early Stage Breast Cancer in Patients
APPLICANT NAME Bachoo, Robert
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/17/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/12/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/29/14	04/07/15
	Primary Reviewer 2 COI signed	12/26/14	04/07/15
	Primary Reviewer 3 COI signed	12/19/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	12/18/15	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	03/18/15	04/07/15
	Primary Reviewer 2 critique submitted	03/02/15	04/07/15
	Primary Reviewer 3 critique submitted	03/08/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/13/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/18/15	04/07/15
	Post review statements signed	04/01/15	04/07/15
	Third Party Observer Report	03/23/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
5. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
6. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150637
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Basic Cancer Research 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

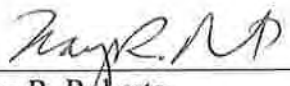
An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

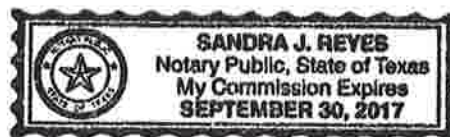


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150637
APPLICATION TITLE Efficient Production of iPSC-Derived Mesenchymal Stem Cells to Kill Cancers by Bystander Effects from Suicide Genes
APPLICANT NAME Bartosh, Thomas
ORGANIZATION Texas A&M University System Health Science Center
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/13/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/21/14	04/07/15
	Primary Reviewer 2 COI signed	12/20/14	04/07/15
	Primary Reviewer 3 COI signed	12/19/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	12/19/14	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/23/15	04/07/15
	Primary Reviewer 2 critique submitted	02/18/15	04/07/15
	Primary Reviewer 3 critique submitted	02/04/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/03/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/09/15	04/07/15
	Post review statements signed	03/16/15	04/07/15
	Third Party Observer Report	03/10/15	04/08/15
	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
5. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
6. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150638
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Cancer Biology panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

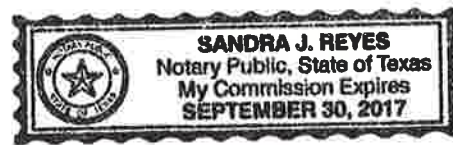


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150638
APPLICATION TITLE Elevated D-2-Hydroxyglutarate Precedes and Promotes Tumor Progression in Inflammatory Bowel Diseases
APPLICANT NAME Theiss, Arianne
ORGANIZATION Baylor Research Institute
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/11/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/24/14	04/07/15
	Primary Reviewer 2 COI signed	12/26/14	04/07/15
	Primary Reviewer 3 COI signed	12/21/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	02/08/15	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	01/30/15	04/07/15
	Primary Reviewer 2 critique submitted	02/22/15	04/07/15
	Primary Reviewer 3 critique submitted	02/22/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	02/27/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/10/15	04/07/15
	Post review statements signed	03/11/15	04/07/15
	Third Party Observer Report	03/13/15	04/07/15
5. Final SRC Recommendation	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
6. PIC Review	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
7. Oversight Committee Approval	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150640
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the combined review panel of Clinical & Translational Cancer Research and Translational Cancer Research 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

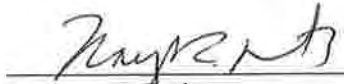
An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

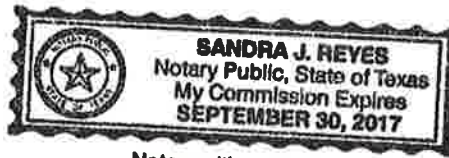


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2015
 CYCLE 2
 PROGRAM Research
 AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
 APPLICATION ID RP150640
 APPLICATION TITLE Drug Conjugates of anti-LGR5 Antibodies as Novel Therapeutics for Destroying Cancer Stem Cells
 APPLICANT NAME Carmon, Kendra
 ORGANIZATION The University of Texas Health Science Center at Houston
 PANEL NAME Clinical / Translational Cancer Research (CTCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/14/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/21/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/19/14	04/07/15
	Primary Reviewer 2 COI signed	12/22/14	04/07/15
	Primary Reviewer 3 COI signed	12/18/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	01/12/15	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/27/15	04/07/15
	Primary Reviewer 2 critique submitted	03/15/15	04/07/15
	Primary Reviewer 3 critique submitted	02/26/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/15/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/16/15	04/07/15
	Post review statements signed	03/30/15	04/07/15
	Third Party Observer Report	03/23/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
5. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
6. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150656
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Cancer Biology panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

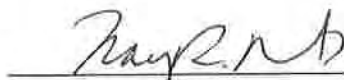
An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

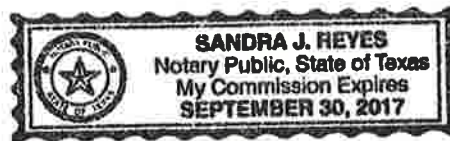


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150656
APPLICATION TITLE Engineered Bone Targeting Nanomedicine for Treatment of Bone Metastases from Breast Cancer
APPLICANT NAME Liu, Xinli
ORGANIZATION Texas Tech University Health Sciences Center
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/13/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/24/14	04/07/15
	Primary Reviewer 2 COI signed	12/18/14	04/07/15
	Primary Reviewer 3 COI signed	02/20/15	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	02/10/15	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	01/30/15	04/07/15
	Primary Reviewer 2 critique submitted	02/21/15	04/07/15
	Primary Reviewer 3 critique submitted	02/23/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/05/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/10/15	04/07/15
	Post review statements signed	03/11/15	04/07/15
	Third Party Observer Report	03/13/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150676
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Cancer Biology panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."



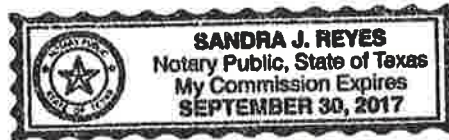
Wayne R. Roberts,

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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRRRA)
APPLICATION ID RP150676
APPLICATION TITLE Identification of Novel Melanoma Metastasis Driver Genes through Transposon-Mediated Mutagenesis
APPLICANT NAME O'Donnell, Kathryn
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/14/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/25/14	04/07/15
	Primary Reviewer 2 COI signed	12/19/14	04/07/15
	Primary Reviewer 3 COI signed	12/18/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	02/08/15	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/22/15	04/07/15
	Primary Reviewer 2 critique submitted	02/23/15	04/07/15
	Primary Reviewer 3 critique submitted	02/21/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	02/27/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/10/15	04/07/15
	Post review statements signed	03/11/15	04/07/15
	Third Party Observer Report	03/13/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150701
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150701
APPLICATION TITLE Non-invasive Colonoscopy by Molecular Imaging of Mucin Targeted Hyperpolarized Silicon Nanoparticles
APPLICANT NAME Carson, Daniel
ORGANIZATION Rice University
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/08/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/08/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/08/15
	Date application submitted	11/17/14	04/08/15
	Method of submission	CARS	04/08/15
	Within receipt period	YES	04/08/15
	Appeal to submit application after CARS closed	N/A	04/08/15
	Appeal for late application submission accepted	N/A	04/08/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/08/15
	Donation(s) made to CPRIT/foundation	NO	04/08/15
	Assigned to primary reviewers	01/09/15	04/08/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/22/14	04/08/15
	Primary Reviewer 2 COI signed	12/18/14	04/08/15
	Primary Reviewer 3 COI signed	12/22/14	04/08/15
	Primary (Advocate) Reviewer 4 COI signed	12/18/14	04/08/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/08/15
	Primary Reviewer 2 critique submitted	N/A	04/08/15
	Primary Reviewer 3 critique submitted	N/A	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/08/15
	COI indicated by non-primary reviewer	N/A	04/08/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/08/15
	Recommended for full review	N/A	04/08/15
	Applicant notified of outcome	N/A	04/08/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/08/15
	Primary Reviewer 1 COI signed	N/A	04/08/15
	Primary Reviewer 2 COI signed	N/A	04/08/15
	Primary Reviewer 3 COI signed	N/A	04/08/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/08/15
	Primary Reviewer 1 critique submitted	02/16/15	04/08/15
	Primary Reviewer 2 critique submitted	02/23/15	04/08/15
	Primary Reviewer 3 critique submitted	02/09/15	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	03/09/15	04/08/15
	COI indicated by non-primary reviewer	NONE	04/08/15
	COI recused from participation	N/A	04/08/15
	Discussed at On-Site Meeting	YES	04/08/15
	Peer Review Meeting	03/12/15-03/13/15	04/08/15
	Post review statements signed	03/17/15	04/08/15
	Third Party Observer Report	03/13/15	04/08/15
	Score report delivered to CSO	04/01/15	04/08/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/08/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OCT	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150703
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Basic Cancer Research 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

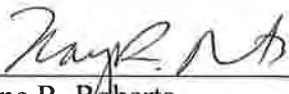
An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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.

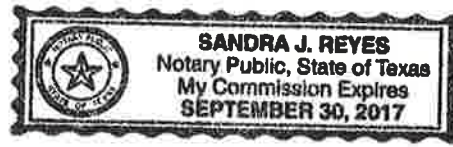
This statement is true."


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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150703
APPLICATION TITLE Metabolomic Salivary Biomarkers for Oral Cancer Detection
APPLICANT NAME Cheng, Yi-Shing
ORGANIZATION Texas A&M University System Health Science Center
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/17/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/12/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/18/14	04/07/15
	Primary Reviewer 2 COI signed	12/19/14	04/07/15
	Primary Reviewer 3 COI signed	12/19/14	04/07/15
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 COI signed	12/18/14	04/07/15
	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
4. Peer Review Meeting	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/27/15	04/07/15
	Primary Reviewer 2 critique submitted	03/08/15	04/07/15
	Primary Reviewer 3 critique submitted	03/15/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/13/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/18/15	04/07/15
	Post review statements signed	04/01/15	04/07/15
5. Final SRC Recommendation	Third Party Observer Report	03/23/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
6. PIC Review	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
7. Oversight Committee Approval	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150711
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150711
APPLICATION TITLE Biomechanical Profiling of Migrating Brain Cancer Genotypes in Tightly-Confin ed Space for Drug Screening
APPLICANT NAME Mohanty, Samarendra
ORGANIZATION The University of Texas at Arlington
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/08/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/08/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/08/15
	Date application submitted	11/17/14	04/08/15
	Method of submission	CARS	04/08/15
	Within receipt period	YES	04/08/15
	Appeal to submit application after CARS closed	N/A	04/08/15
	Appeal for late application submission accepted	N/A	04/08/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/08/15
	Donation(s) made to CPRIT/foundation	NO	04/08/15
	Assigned to primary reviewers	01/09/15	04/08/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/29/14	04/08/15
	Primary Reviewer 2 COI signed	12/22/14	04/08/15
	Primary Reviewer 3 COI signed	12/19/14	04/08/15
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 COI signed	12/18/14	04/08/15
	Primary Reviewer 1 critique submitted	N/A	04/08/15
	Primary Reviewer 2 critique submitted	N/A	04/08/15
	Primary Reviewer 3 critique submitted	N/A	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/08/15
	COI indicated by non-primary reviewer	N/A	04/08/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/08/15
	Recommended for full review	N/A	04/08/15
4. Peer Review Meeting	Applicant notified of outcome	N/A	04/08/15
	Assigned to primary reviewers	N/A	04/08/15
	Primary Reviewer 1 COI signed	N/A	04/08/15
	Primary Reviewer 2 COI signed	N/A	04/08/15
	Primary Reviewer 3 COI signed	N/A	04/08/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/08/15
	Primary Reviewer 1 critique submitted	03/11/15	04/08/15
	Primary Reviewer 2 critique submitted	02/04/15	04/08/15
	Primary Reviewer 3 critique submitted	02/20/15	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	03/10/15	04/08/15
	COI indicated by non-primary reviewer	NONE	04/08/15
	COI recused from participation	N/A	04/08/15
	Discussed at On-Site Meeting	YES	04/08/15
	Peer Review Meeting	03/12/15-03/13/15	04/08/15
	Post review statements signed	03/17/15	04/08/15
	Third Party Observer Report	03/13/15	04/08/15
	Score report delivered to CSO	04/01/15	04/08/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/08/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150713
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards Request for Applications (RFA)*. CPRIT received 100 applications for this RFA. The application was assigned to the Basic Cancer Research 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."



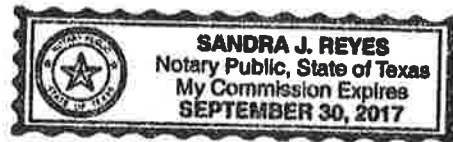
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150713
APPLICATION TITLE Identification of Therapeutic Targets on Breast Cancer Stem Cells
APPLICANT NAME Lee, Jiyong
ORGANIZATION The University of Texas at Dallas
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/17/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/18/14	04/07/15
	Primary Reviewer 2 COI signed	12/19/14	04/07/15
	Primary Reviewer 3 COI signed	01/05/15	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	12/20/14	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	01/24/15	04/07/15
	Primary Reviewer 2 critique submitted	01/28/15	04/07/15
	Primary Reviewer 3 critique submitted	03/04/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/04/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/09/15	04/07/15
	Post review statements signed	03/16/15	04/07/15
	Third Party Observer Report	03/10/15	04/08/15
	Score report delivered to CSO	04/01/15	04/07/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
6. PIC Review	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
7. Oversight Committee Approval	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150720
High-Impact/High-Risk Research 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 *High-Impact/High-Risk Research Awards* Request for Applications (RFA). CPRIT received 100 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."



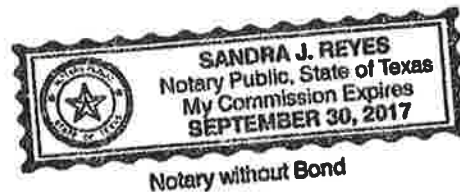
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP150720
APPLICATION TITLE Integrated On-Chip Networks for Investigating Exosome-Mediated Drug Expulsion
APPLICANT NAME Li, Wei
ORGANIZATION Texas Tech University
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/08/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/08/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/08/15
	Date application submitted	11/17/14	04/08/15
	Method of submission	CARS	04/08/15
	Within receipt period	YES	04/08/15
	Appeal to submit application after CARS closed	N/A	04/08/15
	Appeal for late application submission accepted	N/A	04/08/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/08/15
	Donation(s) made to CPRIT/foundation	NO	04/08/15
	Assigned to primary reviewers	01/09/15	04/08/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/26/14	04/08/15
	Primary Reviewer 2 COI signed	12/22/14	04/08/15
	Primary Reviewer 3 COI signed	12/19/14	04/08/15
	Primary (Advocate) Reviewer 4 COI signed	12/18/14	04/08/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/08/15
	Primary Reviewer 2 critique submitted	N/A	04/08/15
	Primary Reviewer 3 critique submitted	N/A	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/08/15
	COI indicated by non-primary reviewer	N/A	04/08/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/08/15
	Recommended for full review	N/A	04/08/15
	Applicant notified of outcome	N/A	04/08/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/08/15
	Primary Reviewer 1 COI signed	N/A	04/08/15
	Primary Reviewer 2 COI signed	N/A	04/08/15
	Primary Reviewer 3 COI signed	N/A	04/08/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/08/15
	Primary Reviewer 1 critique submitted	02/25/15	04/08/15
	Primary Reviewer 2 critique submitted	02/05/15	04/08/15
	Primary Reviewer 3 critique submitted	02/09/15	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	03/09/15	04/08/15
	COI indicated by non-primary reviewer	NONE	04/08/15
	COI recused from participation	N/A	04/08/15
	Discussed at On-Site Meeting	YES	04/08/15
	Peer Review Meeting	03/12/15-03/13/15	04/08/15
	Post review statements signed	03/17/15	04/08/15
	Third Party Observer Report	03/13/15	04/08/15
	Score report delivered to CSO	04/01/15	04/08/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/08/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150535
Core Facilities Support 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 *Core Facilities Support Awards* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

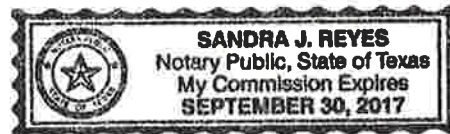


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM Core Facility Support Awards (CFSA)
APPLICATION ID RP150535
APPLICATION TITLE Precision Oncology Decision Support Core
APPLICANT NAME Meric-Bernstam, Funda
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/08/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/08/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/08/15
	Date application submitted	11/14/14	04/08/15
	Method of submission	CARS	04/08/15
	Within receipt period	YES	04/08/15
	Appeal to submit application after CARS closed	N/A	04/08/15
	Appeal for late application submission accepted	N/A	04/08/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/08/15
	Donation(s) made to CPRIT/foundation	NO	04/08/15
	Assigned to primary reviewers	01/09/15	04/08/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/22/14	04/08/15
	Primary Reviewer 2 COI signed	01/07/15	04/08/15
	Primary Reviewer 3 COI signed	12/19/14	04/08/15
	Primary (Advocate) Reviewer 4 COI signed	12/18/14	04/08/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/08/15
	Primary Reviewer 2 critique submitted	N/A	04/08/15
	Primary Reviewer 3 critique submitted	N/A	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/08/15
	COI indicated by non-primary reviewer	N/A	04/08/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/08/15
	Recommended for full review	N/A	04/08/15
	Applicant notified of outcome	N/A	04/08/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/08/15
	Primary Reviewer 1 COI signed	N/A	04/08/15
	Primary Reviewer 2 COI signed	N/A	04/08/15
	Primary Reviewer 3 COI signed	N/A	04/08/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/08/15
	Primary Reviewer 1 critique submitted	02/09/15	04/08/15
	Primary Reviewer 2 critique submitted	02/02/15	04/08/15
	Primary Reviewer 3 critique submitted	01/23/15	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	03/09/15	04/08/15
	COI indicated by non-primary reviewer	NONE	04/08/15
	COI recused from participation	N/A	04/08/15
	Discussed at On-Site Meeting	YES	04/08/15
	Peer Review Meeting	03/12/15-03/13/15	04/08/15
	Post review statements signed	03/17/15	04/08/15
	Third Party Observer Report	03/13/15	04/08/15
	Score report delivered to CSO	04/01/15	04/08/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/08/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to her Conflict of Interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150551
Core Facilities Support 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 *Core Facilities Support Awards* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to the combined review panel of Clinical & Translation Cancer Research and Translational Cancer Research panel 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

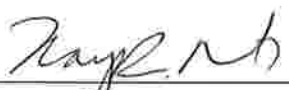
I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

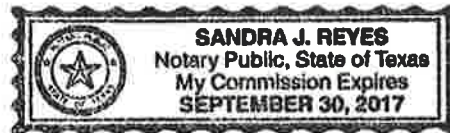


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM Core Facility Support Awards (CFSA)
APPLICATION ID RP150551
APPLICATION TITLE Therapeutic Monoclonal Antibody Lead Optimization and Development Core
APPLICANT NAME An, Zhiqiang
ORGANIZATION The University of Texas Health Science Center at Houston
PANEL NAME Clinical / Translational Cancer Research (CTCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/14/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/21/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/18/14	04/07/15
	Primary Reviewer 2 COI signed	12/23/14	04/07/15
	Primary Reviewer 3 COI signed	12/18/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	01/12/15	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/23/15	04/07/15
	Primary Reviewer 2 critique submitted	02/24/15	04/07/15
	Primary Reviewer 3 critique submitted	02/22/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/10/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/16/15	04/07/15
	Post review statements signed	03/30/15	04/07/15
	Third Party Observer Report	03/23/15	04/07/15
5. Final SRC Recommendation	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
6. PIC Review	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
7. Oversight Committee Approval	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to her Conflict of Interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150578
Core Facilities Support 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 *Core Facilities Support Awards* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to the combined review panel of Clinical & Translation Cancer Research and Translational Cancer Research 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

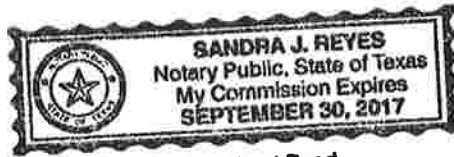


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM Core Facility Support Awards (CFSa)
APPLICATION ID RP150578
APPLICATION TITLE The Combinatorial Drug Discovery Program (CDDP)
APPLICANT NAME Davies, Peter
ORGANIZATION Texas A&M University System Health Science Center
PANEL NAME Clinical / Translational Cancer Research (CTCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/17/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/21/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	01/05/15	04/07/15
	Primary Reviewer 2 COI signed	12/24/14	04/07/15
	Primary Reviewer 3 COI signed	12/22/14	04/07/15
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 COI signed	01/21/15	04/07/15
	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
4. Peer Review Meeting	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	03/15/15	04/07/15
	Primary Reviewer 2 critique submitted	03/16/15	04/07/15
	Primary Reviewer 3 critique submitted	03/15/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/10/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/16/15	04/07/15
	Post review statements signed	03/30/15	04/07/15
5. Final SRC Recommendation	Third Party Observer Report	03/23/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
6. PIC Review	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
7. Oversight Committee Approval	COI recused from participation	M. Kripke*	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to her Conflict of Interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150596
Core Facilities Support 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 *Core Facilities Support Awards* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel 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


I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM Core Facility Support Awards (CFSA)
APPLICATION ID RP150596
APPLICATION TITLE Bioinformatics Core Facility at UT Southwestern Medical Center
APPLICANT NAME Danuser, Gaudenz
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/08/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/08/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/08/15
	Date application submitted	11/17/14	04/08/15
	Method of submission	CARS	04/08/15
	Within receipt period	YES	04/08/15
	Appeal to submit application after CARS closed	N/A	04/08/15
	Appeal for late application submission accepted	N/A	04/08/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/08/15
	Donation(s) made to CPRIT/foundation	NO	04/08/15
	Assigned to primary reviewers	01/09/15	04/08/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/19/14	04/08/15
	Primary Reviewer 2 COI signed	12/24/14	04/08/15
	Primary Reviewer 3 COI signed	12/22/14	04/08/15
	Primary (Advocate) Reviewer 4 COI signed	12/18/14	04/08/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/08/15
	Primary Reviewer 2 critique submitted	N/A	04/08/15
	Primary Reviewer 3 critique submitted	N/A	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/08/15
	COI indicated by non-primary reviewer	N/A	04/08/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/08/15
	Recommended for full review	N/A	04/08/15
	Applicant notified of outcome	N/A	04/08/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/08/15
	Primary Reviewer 1 COI signed	N/A	04/08/15
	Primary Reviewer 2 COI signed	N/A	04/08/15
	Primary Reviewer 3 COI signed	N/A	04/08/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/08/15
	Primary Reviewer 1 critique submitted	01/27/15	04/08/15
	Primary Reviewer 2 critique submitted	02/23/15	04/08/15
	Primary Reviewer 3 critique submitted	01/26/15	04/08/15
	Primary (Advocate) Reviewer 4 critique submitted	03/10/15	04/08/15
	COI indicated by non-primary reviewer	NONE	04/08/15
	COI recused from participation	N/A	04/08/15
	Discussed at On-Site Meeting	YES	04/08/15
	Peer Review Meeting	03/12/15-03/13/15	04/08/15
	Post review statements signed	03/17/15	04/08/15
	Third Party Observer Report	03/13/15	04/08/15
	Score report delivered to CSO	04/01/15	04/08/15
	Recommended for SRC Review	YES	04/08/15
5. Final SRC Recommendation	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
6. PIC Review	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to her Conflict of Interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150600
Core Facilities Support 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 *Core Facilities Support Awards* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to the combined review panel of Clinical & Translation Cancer Research and Translational Cancer Research 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

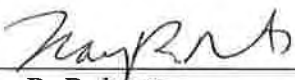
An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

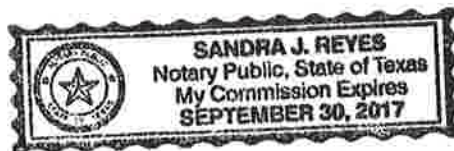


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM Core Facility Support Awards (CFSA)
APPLICATION ID RP150600

APPLICATION TITLE The Single-Cell Biopsy and Characterization Core (SBCC) at
The University of Texas Health Science at San Antonio

APPLICANT NAME Huang, Tim
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Clinical / Translational Cancer Research (CTCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/14/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/21/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/18/14	04/07/15
	Primary Reviewer 2 COI signed	12/20/14	04/07/15
	Primary Reviewer 3 COI signed	12/18/14	04/07/15
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 COI signed	01/21/15	04/07/15
	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
4. Peer Review Meeting	Applicant notified of outcome	N/A	04/07/15
	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/23/15	04/07/15
	Primary Reviewer 2 critique submitted	02/22/15	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	03/10/15	04/07/15
	COI indicated by non-primary reviewer	NONE	04/07/15
	COI recused from participation	N/A	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/16/15	04/07/15
	Post review statements signed	03/30/15	04/07/15
	Third Party Observer Report	02/23/15	04/07/15
	Score report delivered to CSO	04/01/15	04/07/15
5. Final SRC Recommendation	Recommended for SRC Review	YES	04/07/15
	COI Indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
	Recommended for grant award	YES	04/23/15
6. PIC Review	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI Indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
	PIC review meeting	05/05/15	05/05/15
7. Oversight Committee Approval	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to her Conflict of Interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP150611
Core Facilities Support 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 *Core Facilities Support Awards* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to the Basic Cancer Research 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

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

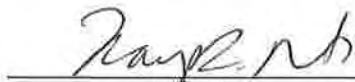
An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

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 Dr. Margaret Kripke, Chief Scientific Officer, Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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."

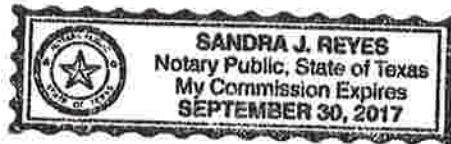


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Research
AWARD MECHANISM Core Facility Support Awards (CFSA)
APPLICATION ID RP150611
APPLICATION TITLE CPRIT Core for RNA Therapeutics and Research
APPLICANT NAME Cooke, John
ORGANIZATION The Methodist Hospital Research Institute
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	08/01/14	04/07/15
	CPRIT Application Receipt System (CARS) opened	09/30/14	04/07/15
	CPRIT Application Receipt System (CARS) closed	11/17/14	04/07/15
	Date application submitted	11/17/14	04/07/15
	Method of submission	CARS	04/07/15
	Within receipt period	YES	04/07/15
	Appeal to submit application after CARS closed	N/A	04/07/15
	Appeal for late application submission accepted	N/A	04/07/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	04/07/15
	Donation(s) made to CPRIT/foundation	NO	04/07/15
	Assigned to primary reviewers	01/09/15	04/07/15
	Applicant notified of review panel assignment	04/09/15	04/09/15
	Primary Reviewer 1 COI signed	12/18/14	04/07/15
	Primary Reviewer 2 COI signed	12/27/14	04/07/15
	Primary Reviewer 3 COI signed	12/20/14	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	12/19/14	04/07/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	04/07/15
	Primary Reviewer 2 critique submitted	N/A	04/07/15
	Primary Reviewer 3 critique submitted	N/A	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	04/07/15
	COI indicated by non-primary reviewer	N/A	04/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	04/07/15
	Recommended for full review	N/A	04/07/15
	Applicant notified of outcome	N/A	04/07/15
4. Peer Review Meeting	Assigned to primary reviewers	N/A	04/07/15
	Primary Reviewer 1 COI signed	N/A	04/07/15
	Primary Reviewer 2 COI signed	N/A	04/07/15
	Primary Reviewer 3 COI signed	N/A	04/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	04/07/15
	Primary Reviewer 1 critique submitted	02/21/15	04/07/15
	Primary Reviewer 2 critique submitted	02/23/15	04/07/15
	Primary Reviewer 3 critique submitted	02/18/15	04/07/15
	Primary (Advocate) Reviewer 4 critique submitted	02/27/15	04/07/15
	COI indicated by non-primary reviewer	Sukumar, Saraswati	04/07/15
	COI recused from participation	YES	04/07/15
	Discussed at On-Site Meeting	YES	04/07/15
	Peer Review Meeting	03/09/15	04/07/15
	Post review statements signed	03/16/15	04/07/15
	Third Party Observer Report	03/10/15	04/08/15
5. Final SRC Recommendation	Score report delivered to CSO	04/01/15	04/07/15
	Recommended for SRC Review	YES	04/07/15
	COI indicated by SRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	SRC Meeting	04/13/15	04/23/15
	Third Party Observer Report	04/13/15	04/27/15
6. PIC Review	Recommended for grant award	YES	04/23/15
	SRC Chair Notification to PIC and OC	04/22/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
7. Oversight Committee Approval	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to her Conflict of Interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: MEMBERS OF THE OVERSIGHT COMMITTEE
From: THOMAS C. GOODMAN, PhD, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject: PRODUCT DEVELOPMENT GRANT RECOMMENDATIONS
Date: MAY 6, 2015

Summary:

The Program Integration Committee has reviewed and recommended one Established Company and one New Company Product Development grant awards. The two awards total \$8,520,011. An additional New Company Product Development grant award was recommended by the Product Development Review Council, but was not recommended by a majority of the Program Integration Committee. It is the subject of a Minority Report to the Oversight Committee. This grant award would be for \$5,332,586. Each of these three potential awards is described below.

Mechanism of Support and Program Objectives:

Both the New Company and Established Company Product Development Awards share the goal of supporting the research and development of innovative products, services, and infrastructure that have significant potential to improve cancer patient care. Consistent with CPRIT's Product Development Program Priorities, both award mechanisms seek to fund projects at companies that are most likely to bring important cancer care products to the market.

New Company Awards. New Company Product Development Awards assist early-stage startup companies by providing the opportunity: (1) to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; (2) to establish infrastructure that is critical to the development of a robust industry; and (3) to fill any treatment, industry, or research gaps.

The State of Texas seeks to attract industry pioneers in the field of cancer care to advance economic development in the State. This award mechanism supports the work of new companies that intend to undertake product research and development in Texas with Texas-based employees. In determining eligibility for this award, CPRIT carefully evaluates whether applicants would have a significant presence in Texas.

Established Company Awards. Established Company Product Development Awards assist existing companies or limited partnerships, located and headquartered in Texas that have already received at least one round of professional institutional investment. The awards are given to advance specific projects at these companies to research and develop new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish or expand 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 their C-level executives.

Eligible projects include, but are not limited to, those to develop cancer therapeutics (e.g., small molecules or biologics), diagnostics, medical devices, and potential breakthrough technologies, including software and research discovery techniques. Eligible stages of research and development at awardee companies include translational research, proof-of-concept studies, and pre-clinical studies. Phase I or Phase II clinical trials are especially welcomed, as they represent opportunities for CPRIT to contribute to the advancement of projects that are closer to the marketplace.

Applications for these awards were submitted pursuant to the RFA released March 31, 2014. All applications were submitted by May 29, 2014. Peer review took place at meetings on July 15 & 16, 2014, and at in-person presentations held August 12 through 15, 2014.

Summary of the Product Development Research Slates

Applications were submitted in response to the following CPRIT RFAs:

❖ ***Established Company Product Development Awards – RFA C15-ESTCO-1***

This award mechanism seeks to support established companies that have received at least one round of professional institutional investment. Support is provided for projects at these companies in the research and development of new products for the diagnosis, treatment, or prevention of cancer. Companies must have a significant presence in Texas.

❖ ***New Company Product Development Awards – RFA C15-NEWCO-1***

This award mechanism seeks to support early-stage “start-up” companies in the research and development of new products for the diagnosis, treatment, or prevention of cancer. Companies must have a significant presence in Texas or be willing to relocate to Texas.

Applications Submitted:	30
In-Person Presentations:	17
Projects Recommended*:	2
Total Recommended:	\$8,520,011

* In Cycle 15.1, the Review Panels recommended nine applications for due diligence. One company withdrew itself from consideration because it failed to raise matching funds. Eight companies advanced to business and intellectual property due diligence examination. Due to time constraints that limited the ability of the parties performing the diligence to review all eight applications at the same time, the Product Development Review Council split the group of eight into two groups of four. The first group underwent due diligence in late 2014. After review by the Product Development Review Council and the Program Integration Committee, the first four were recommended to the Oversight Committee for awards. At its meeting of February 18, 2015, the Oversight Committee approved the Program Integration Committee's recommendations and announced the awards. These companies (NanoTx Therapeutics, Immatics Biotechnologies, Medicenna Therapeutics, and Armada Pharmaceuticals) are pending contract execution. The second group of four applications underwent due diligence that was completed in early April. The Product Development Review Council recommended three of the four applications for consideration by the Program Integration Committee. The Program Integration Committee has now further recommended two of these for approval by the Oversight Committee. A third application is the subject of a Minority Report. All three applications are described in this memorandum.

Proposed Established Company Product Development Award – Recommended by the Program Integration Committee

Vermillion, Inc.

Introduction

The management of access to care for ovarian cancer remains a serious public health challenge. Ovarian cancer is the 5th leading cause of cancer-related death in women and the most deadly form of gynecologic cancer. Numerous studies have shown that survival is improved when a patient's initial surgery is performed by a board-certified gynecologic oncologist (GO). National guidelines specify that all ovarian cancer patients should undergo surgery by an experienced GO, yet multiple studies in recent years report that just 33% of ovarian cancer surgeries were performed by these specialists. These studies highlight systemic failures posed by lack of referral and access to experienced facilities and surgeons.

Vermillion’s goal, in collaboration with MD Anderson Cancer Center, is to develop and validate a next-generation blood test (the OVA-AID test) which will improve identification and treatment of ovarian cancer in women undergoing surgery for an ovarian mass. Use of this test will increase the likelihood that ovarian cancer patients are referred to GOs and upon referral receive optimal surgery, treatment, and follow-up. Such steps have been shown to increase survival by 30%. Development and commercialization of this product is expected to improve the quality of patient care and health outcomes, while establishing additional research capabilities within both Vermillion and MD Anderson and providing future product development opportunities in Texas.

Funding Request and Risk Mitigation

Vermillion is requesting \$7,553,011 from CPRIT over a period of three years. This will be matched by \$3,776,506 for a total project cost of \$11,329,517.

To mitigate risk, CPRIT proposes to provide the money requested in three tranches. These funds would be provided in advance to enable the studies described. In the event that the agreed-upon milestones for each tranche are not achieved, CPRIT may elect either: (i) to postpone the following tranche until they are achieved, or (ii) terminate the contract, recovering any amount of unspent CPRIT funds. Milestones and timelines are described below.

First Tranche – 12 months duration – \$2,642,963

Vermillion, in collaboration with MD Anderson, plans to establish a Texas-led, multi-institutional ovarian cancer registry. This registry will consist of two separate subgroups broken down according to index surgeon (generalist or gynecologic oncologist). The registry will analyze the care for women at risk (as defined in the primary inclusion criteria) for ovarian cancer, starting at enrollment and ending one year after index surgery has taken place.

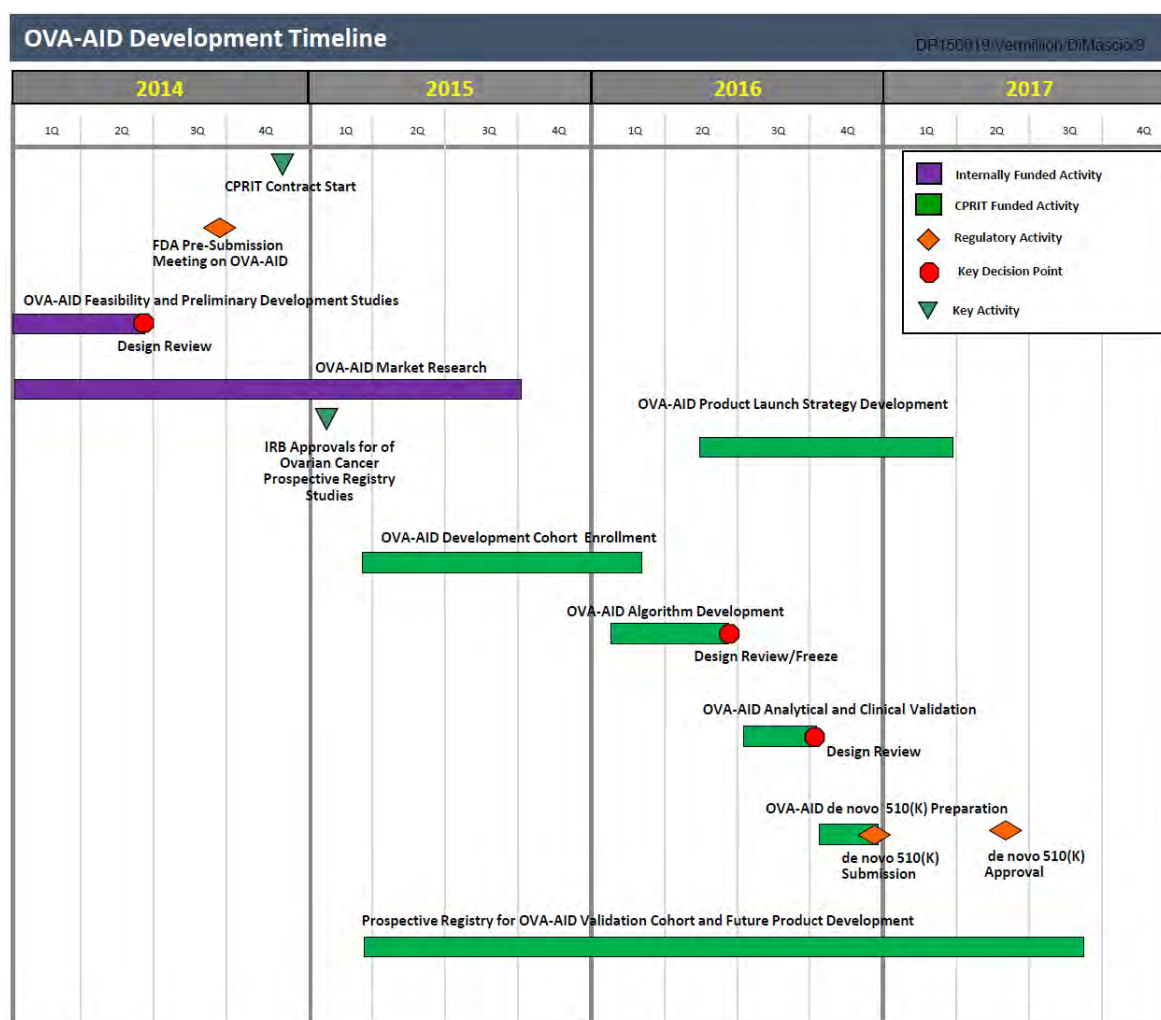
Second Tranche – 12 months duration – \$2,420,017

Following completion of sample collection from the development cohort, algorithm development activities will begin. Development samples will be tested for the final panel of biomarkers to be used in OVA-AID at ASPIRA LABS. These values will be used in algorithm development to support the agreed-upon product specifications for the OVA-AID test. This development work will be performed by Vermillion. Following successful design review of each product, the products will undergo “design freeze” prior to analytical and clinical validation. All development and validation activities will be subject to Vermillion’s quality systems and design control processes and, as appropriate, will refer to the FDA’s guidance documents.

Third Tranche – 12 months duration – \$2,490,031

Vermillion will prepare and submit an application for regulatory clearance of the OVA-AID test. As Vermillion prepares marketing applications, FDA feedback will be sought as needed in order to ensure a complete understanding of the FDA’s expectations and to avoid unnecessary delays in the approval of tests which will provide substantial benefit to ovarian cancer patients.

The OVA-AID development timeline is shown below.



Sampling of the Independent Scientific Evaluation and Recommendation

One reviewer summarized the significance and impact of this proposal with the following words: “Early and accurate diagnosis of ovarian cancer is a major challenge. Due to uncertainty in diagnosis basis on non-invasive evaluation, a large proportion of women undergo operative intervention by a general surgeon. A more precise assessment of the likelihood of ovarian cancer being present could substantially change referral patterns resulting in more women being operated upon by gynecologic oncologist. This has been associated with improved outcome in retrospective studies. Thus, the proposed biomarker work has significant implications for pattern of care in this disease.”

The Product Development Review Council, upon its review of the independent business and intellectual property due diligence performed on this application, recommended to the Program Integration Committee that the application be funded. The Program Integration Committee has now reviewed the application and recommends to the Oversight Committee that it be approved for CPRIT funding.

Proposed New Company Product Development Award – Recommended by the Program Integration Committee

Rosellini Scientific, Inc.

Introduction

Surgical resection and radiotherapy are frequently used in the treatment of prostate, cervical, and rectal cancers. While they can be life-saving therapies, these procedures often burden cancer survivors with secondary conditions such as overactive bladder (OAB). For some cancer patients and survivors, OAB symptoms are an understood and acceptable outcome of life-saving cancer therapy, while others may view the risk of urinary dysfunction as a reason to forego or substitute potentially inferior forms of treatment. There is a pressing need then for treating OAB in cancer patients and survivors, but existing treatment protocols may not be suitable for patients developing symptoms secondary to cancer or treatments directed at these malignancies.

Rosellini Scientific, a medical technology company headquartered in Dallas, is developing a small, implantable neurostimulation device (the “nUro”) to restore bladder function and improve quality of life for patients suffering from OAB as a result of their cancer therapy. The nUro Wireless Neurostimulation system combines the latest in wireless implantable technology with the clinically proven efficacy of neurostimulation to offer flexible, convenient, and cost-effective treatment. Rosellini Scientific will develop this technology in collaboration with Dr. Gary Lemack from UT Southwestern Medical Center and through the UT-Dallas incubator program. The current proposal will culminate in clinical data used to support regulatory approval of the nUro device therapy.

Funding Request and Risk Mitigation

Rosellini Scientific, Inc. is requesting \$967,000 from CPRIT over a period of three years. This will be matched by \$483,502 from other sources for a total project cost of \$1,450,502.

To mitigate risk, CPRIT proposes to provide the money requested in three tranches. These funds would be provided in advance to enable the studies described. In the event that the agreed upon milestones for each tranche are not achieved, CPRIT may elect either: (i) to postpone the following tranche until they are achieved, or (ii) terminate the contract, recovering any amount of unspent CPRIT funds. Milestones and timelines are described below.

First Tranche – 12 months duration – \$478,143

Perform biocompatibility testing and begin demonstration of clinical feasibility in an animal model.

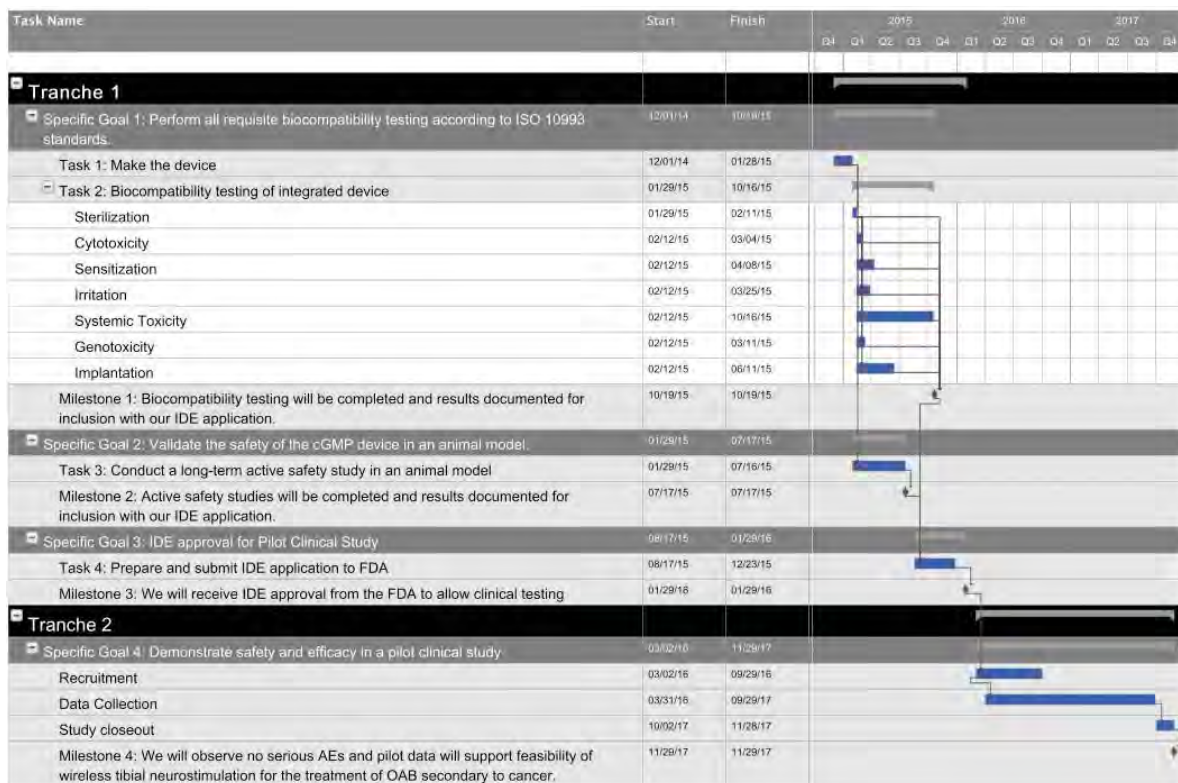
Second Tranche – 12 months duration – \$286,172

Continue animal testing and prepare and submit an IDE application to the FDA.

Third Tranche – 12 months duration – \$202,685

Demonstration of safety and feasibility through a pilot human clinical study at UT Southwestern Medical Center.

A description of the goals and milestones are described below. The two tranches described in the figure are reconfigured into three (above) based on the budget proposed.



Sampling of the Independent Scientific Evaluation and Recommendation

One reviewer summarized the significance and impact of this proposal with the following words: “The device in development has the potential to restore bladder function and improve quality of life for patients with cancer, thereby providing “supportive” care. Neurostimulation

has become a preferred choice for patients refractory to pharmacotherapy, with two currently FDA-approved devices marketed by global companies, Medtronic's InterStim and Uroplasty Urgent PC. It is not clear whether the proposed product is sufficiently different to be described as "innovative", but rather a convenient and cost-effective treatment option."

The Product Development Review Council, upon its review of the independent business and intellectual property due diligence performed on this application, recommended to the Program Integration Committee that the application be funded. The Program Integration Committee has now reviewed the application and recommends to the Oversight Committee that it be approved for CPRIT funding.

Proposed New Company Product Development Award – Not Recommended by the Program Integration Committee

Aradigm Corporation

Introduction

Smoking cessation represents an enormous opportunity to prevent human disease and, in the process of doing so, create additional tangible socioeconomic benefits. Tobacco smoking causes a third of all cancer deaths in US and the vast majority of lung cancer. Despite significant public health efforts, over 40 million people in US smoke. Although more than 50% of them try to quit every year, the long term quit rates remain low. Irresistible craving for cigarettes is a very common cause of relapse.

Aradigm has developed a pharmaceutical quality nicotine inhaler (the AERx Inhaler) and demonstrated that a single breath from it can cause a profound instantaneous and lasting (~ 4 hours) reduction in craving for cigarettes. Aradigm's inhaler is different from the electronic cigarette. It uses pure, stable nicotine. No organic solvents are inhaled, and there is no "second hand smoke". The device offers a discreet method to eliminate cravings for cigarettes. In addition, there is no perpetuating of the stigma attached to devices that are puffed on like cigarettes, or that attract naïve users, especially children, to use them in social settings. The appearance of the expected product is shown below:



AERx Inhaler

Even only modest acceptance of the device by some of the more than 1 billion smokers globally, who spend over \$ 1 trillion on tobacco products, could result in multibillion dollar revenues for the company to be domiciled in Texas - and many lives could be much improved and prolonged.

Funding Request and Risk Mitigation

Aradigm Corp. is requesting \$5,332,586 from CPRIT over a period of three years. This will be matched by \$2,667,414 from other sources for a total project cost of \$8,000,000.

To mitigate risk, CPRIT proposes to provide the money requested in three tranches. These funds would be provided in advance to enable the studies described. In the event that the agreed-upon milestones for each tranche are not achieved, CPRIT may elect either: (i) to postpone the following tranche until they are achieved, or (ii) terminate the contract, recovering any amount of unspent CPRIT funds. Milestones to be reached in each tranche of funding are described below.

First Tranche – 12 months duration – \$1,216,859

Conclude funding and initiate development activities, order materials, and enter into the necessary outsourcing contracts.

Second Tranche – 12 months duration – \$3,290,095

Conclude manufacturing for Phase 1a, quality control testing, and clinical protocol. File an IND. Recruit first clinical site, obtain IRB approval and initiate patient enrollment for a Phase 1a/2 trial.

Third Tranche – 12 months duration – \$825,632

Recruit additional centers, obtain IRB approvals, and initiate a Phase 2 study. Conclude the Phase 2 study and analyze data. Meet end of Phase 2 milestones with results to support advancing to Phase 3 development.

Sampling of the Independent Scientific Evaluation and Recommendation

One reviewer summarized the significance and impact of this proposal with the following words: “If [their] objectives could be achieved, the product could be hugely significant in terms of cancer prevention, with potential large commercial impact (billions of dollars). Smokers are addicted to nicotine and have great difficulty quitting smoking. Cigarette smoking is the leading preventable cause of death in the US, accounting for a large percentage of lung cancer and other cancers. Effective smoking cessation treatment would be enormously beneficial for individuals as well as a public health measure. However, the smoking cessation agents are difficult to develop, and the conduction of clinical trials and the marketing is very competitive with NRTs [nicotine replacement therapies] as well as non-nicotine based products.”

The Product Development Review Council, upon its review of the independent business and intellectual property due diligence performed on this application, recommended to the Program Integration Committee that this application be funded. The Program Integration Committee has now reviewed the application and recommends to the Oversight Committee that it not be approved for CPRIT funding. The present grant award application is the subject of a Minority Report from the Program Integration Committee.

Conflicts of Interest for Product Development Cycle 15.1 Applications
(Product Development Cycle 15.1 Awards Announced at May 20, 2015, 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 Cycle 15.1 include *New Company Product Development Awards*, *Company Relocation Product Development Awards*, and *Established Company Product Development Awards*. Four applications were recommended to the PIC and Oversight Committee in February 2015 while two other applications are recommended in May 2015. 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Company	Conflict Noted
Applications Considered by the PIC and Oversight Committee			
DP150031	Merchant, Fahar	Medicenna Therapeutics, Inc.	Lloyd, Ramona; Geltosky, Jack
DP150019	DiMascio, Leah	Vermillion Inc.	Mitchell, Amy
DP150042¹	Wulf, John	Aradigm Corporation	Mitchell, Amy
Applications Not Recommended for PIC or Oversight Committee Consideration			
DP150010*	Carroll, Stephen	Synergys Biotherapeutics, Inc.	Spector, Neil
DP150013	Riley, Dennis	Galera Therapeutics, Inc.	Geltosky, Jack; Spector, Neil
DP150023*	Burns, Lindsay	Pain Therapeutics, Inc.	Jones, Elaine; Saxberg, Bo
DP150036	Schmid, Steven	Vivo Biosciences, Inc.	Craig, Adam
DP150038	Kim, Jason	Molecular Templates, Inc.	Craig, Adam
DP150048	Bearss, David	Tolero Pharmaceuticals, Inc.	Craig, Adam; Saxberg, Bo; Spector, Neil

¹ DP150042 was not recommended by the PIC and not considered by the Oversight Committee.

*=Application not discussed



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 1
Established Company Product Development Awards

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA C-15-ESTCO-1

Established Company Product Development Awards

**Please also refer to the Instructions for Applicants document,
which will be posted April 28, 2014**

Application Receipt Opening Date: April 28, 2014
Application Receipt Closing Date: May 29, 2014

FY 2014

Fiscal Year Award Period

September 1, 2014–August 31, 2015

TABLE OF CONTENTS

1. KEY POINTS	5
2. ABOUT CPRIT	6
3. EXECUTIVE SUMMARY	6
4. MECHANISM OF SUPPORT.....	7
5. OBJECTIVES	7
6. FUNDING INFORMATION	8
7. KEY DATES.....	9
8. ELIGIBILITY	9
8.1. NEW APPLICATIONS.....	9
8.2. RESUBMISSION POLICY	11
8.3. RENEWAL POLICY	11
9. APPLICATION REVIEW.....	12
9.1. OVERVIEW	12
9.2. REVIEW PROCESS.....	12
9.2.1. Confidentiality of Review.....	13
9.3. REVIEW CRITERIA.....	14
9.3.1. Primary Criteria.....	15
9.3.2. Secondary Criteria.....	16
10. SUBMISSION GUIDELINES	16
10.1. ONLINE APPLICATION RECEIPT SYSTEM AND APPLICATION SUBMISSION DEADLINE	16
10.2. SUBMISSION DEADLINE EXTENSION	17
10.3. PRODUCT DEVELOPMENT REVIEW FEE	17
10.4. APPLICATION COMPONENTS	17
10.4.1. Layperson's Summary (1,500 characters)	17
10.4.2. Goals and Objectives (1,200 characters each)	18
10.4.3. Timeline (One page).....	18
10.4.4. Resubmission Summary (One page).....	18
10.4.5. Renewal Justification Summary (One page)	19

10.4.6.	<i>Executive Summary (One page)</i>	19
10.4.7.	<i>Slide Presentation (Ten pages)</i>	19
10.4.8.	<i>Scientific Plan (Ten pages)</i>	19
10.4.9.	<i>Business Plan (Fifteen pages)</i>	20
10.4.10.	<i>Biographical Sketches of Key Scientific Personnel (Eight pages)</i>	21
10.4.11.	<i>Budget and Justification</i>	22
11.	AWARD ADMINISTRATION	22
12.	REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	24
13.	CONTACT INFORMATION	24
13.1.	HELPSDESK	24
13.2.	PROGRAMMATIC QUESTIONS	24

RFA VERSION HISTORY

Rev 03/31/14 RFA release

1. KEY POINTS

This Established Company Product Development Award mechanism is governed by the following restrictions:

- Company applicants must be Texas-based companies that have already received at least one round of professional institutional investment (i.e., Series A financing or a substantive equivalent). Applicants that have not yet received a round of professional institutional investment should apply under the New Company Product Development Awards mechanism.
- Recipient companies must currently have or must commit to the following: Headquarters in Texas, the majority of staff residing in or relocated to Texas, and use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-State entities.
- Of the total program budget, the Cancer Prevention and Research Institute of Texas (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 grant funds, not at the time the application is submitted. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be designated for the CPRIT-funded project but may be spent outside of Texas.
- Funding may be tranced and will be tied to the achievement of contract-specified milestones.
- Funding award contracts will include a revenue-sharing agreement or equity to be negotiated at contract execution 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.cpritchat.state.tx.us.
- Renewal applications will be accepted (see [Section 9.3](#) and [Section 11.4.5](#)).

2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- 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.

3. APPLICANT SURVEY

CPRIT will be administering a survey to determine the operational aspects of peer review. Company representatives that anticipate submitting an application are requested to complete the survey as soon as possible, but no later than May 8, 2014. Company representatives should provide the following information: Applicant name, name of company, telephone number, email address, estimated award amount, and award mechanism. Please select only one award mechanism as only one application can be submitted per funding cycle. This information will be used for planning purposes only and will not be used for evaluation of the application. The survey is available [here](#).

4. 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 Request for Applications (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 (e.g., 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.

5. MECHANISM OF SUPPORT

The goal of the Established Company Product Development 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.

6. 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 (with the exception of infrastructure applications) should be the intent to further the research and development of products that would eventually be approved for marketing for the diagnosis, prevention, and/or treatment of cancer. Eligible products or services include—but are not limited to—therapeutics (e.g., small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques. Eligible stages of research and development include translational research, proof-of-concept studies, preclinical studies, and Phase I or Phase II clinical trials. By exception, Phase III clinical trials and later stage product development projects will be considered where circumstances warrant CPRIT investment.

7. 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 program proposed. While requested funds must be well justified, there is no limit on the amount that may be requested. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property protection, external consultants and service providers, and other appropriate research and development costs, subject to certain limitations set forth by Texas State 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 of Texas. Texas State law limits the amount of awarded funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs).

Consistent with statutory mandate, of the total program budget, 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 made on a year-by-year basis.

8. KEY DATES

RFA release	March 31, 2014
Online application opens	April 28, 2014, 7 a.m. Central Time
Applications due	May 29, 2014, 2014, 3 p.m. Central Time
Invitations to present sent	July 2014
Notifications sent if not invited	July 2014
Presentations to CPRIT*	August 2014
Award Notification	November 2014
Anticipated Start Date	December 2014

*All applicants who wish to be considered are requested to reserve these presentation dates until notified. 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.

9. ELIGIBILITY

9.1. New Applications

- Company applicants must be Texas-based companies that have already received at least one round of professional institutional investment (i.e., Series A financing or a substantive equivalent). Applicants that have not yet received a round of professional institutional investment should apply under the New Company Product Development Award mechanism.
- Recipient companies must currently have or must commit to the following: Headquarters in Texas, the majority of staff residing in or relocated to Texas, and Texas-based subcontractors and suppliers unless adequate justification is provided

for the use of out-of-State entities. To the extent that Texas-based subcontractors or collaborators are not available, non-Texas-based collaborators and subcontractors may be used. However, non-Texas-based collaborators and subcontractors are not eligible to receive funds from CPRIT unless exceptional circumstances are demonstrated and approved by CPRIT.

- An applicant may submit only one application under this RFA during this funding cycle.
- Only one co-applicant may be included on the application. Co-applicants should have specific and well-defined roles.
- A company 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 one 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.
- A company 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 company 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.
- CPRIT grants will be awarded by contract to successful company applicants. Certain contractual requirements are mandated by Texas State law or by administrative rules. Although the company 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 12](#) and [Section 13](#). All statutory provisions and relevant administrative rules can be found at www.cpr.it.state.tx.us.

9.2. Resubmission Policy

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines (see [Section 11.4.4](#)). More than one resubmission is not 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 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. 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 one-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.

9.3. Renewal Policy

A grant recipient that has previously been awarded grant funding from CPRIT may submit an application under this mechanism to be considered for a competitive renewal. The eligibility criteria described in [Section 9](#) also apply to renewal applications. In addition, note the following:

- Applicants must have received a CPRIT award, either a Company Commercialization Award (this mechanism was called Company Investment in FY 2010), a Company Formation Award, a Company Relocation Award, an

Individual Investigator Award with a commercialization component, or a High Impact/High Risk Award with a commercialization component.

- Before submitting a renewal application, applicants must consult with the Product Development Programmatic Office (see [Section 14.2](#)) to determine whether it is appropriate for their company to seek renewal funding at this time.

10. APPLICATION REVIEW

10.1. 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 scientific plan (see [Section 11.4.8](#)) and a detailed business plan (see [Section 11.4.9](#)). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and scientific 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 by the review process described below.

10.2. Review Process

- 1. Product Development and Scientific Review:** Applications that pass initial administrative compliance 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 company applicants may be invited to deliver in-person presentations to the review panel.
- 2. 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 indepth due diligence, including—but not limited to—intellectual property, management, regulatory, manufacturing, and

market assessments. Following the due diligence review, applications will be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and intellectual property reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.

- 3. 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.
- 4. 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 703.6–703.8.

10.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development 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).

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.

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 Web site. **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 company 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.

10.3. 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.**

10.3.1. Primary Criteria

Primary 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 study.

Primary criteria include the following:

Significance and Impact: Will the outcomes of this CPRIT-funded work result in the development of innovative products with significant product development potential? Will the outcome substantially impact the diagnosis, treatment, prevention of cancer, or supportive care for patients with cancer? How would competing products or services affect the value of the proposed offering?

Product: Is there demonstrated proof of relevance, and does the product fulfill a clear, unmet medical or infrastructure need? Has work been conducted that supports the advancement of the proposed product, service, or technology? Can the product be produced or manufactured in a commercially viable fashion? Is there an appropriate basis for a reimbursement strategy?

Market Plan: Is there a realistic assessment of the market size and expected penetration? Has management adequately assessed potential competitors and described how the company's offering will successfully compete with them?

Development Plan and/or Regulatory Path: Is the development plan and/or regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both a positive and a negative outcome? Does the budget appropriately support the plan?

Scientific Plan: Is the proposed product, service, and/or infrastructure based on a feasible research framework, hypothesis, and/or goal? Are the methods appropriate, and are potential research and developmental obstacles and unexpected outcomes discussed?

Management and Staffing: Does the applicant have the appropriate level of management experience to execute the stated strategy? Does the team have the needed experience or access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan?

10.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. 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: Are the budget and duration appropriate for the proposed work? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is it clear how funds will be used? Does the proposed investment fund the research and development of the proposed product, service, or technology to a point where, if the results are positive, it is likely that the project will be able to attract further financial support outside of CPRIT?

11. SUBMISSION GUIDELINES

Applicants are advised to carefully review 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 when the application receipt system opens. Applications that are missing one 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.

11.1. 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 company applicant must create a user account in the system to start and submit an application. The co-applicant, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the company 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. Applications will be accepted beginning at 7 a.m. Central Time on April 28, 2014, and must be submitted by 3 p.m. Central Time on May 29, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

11.2. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

11.3. Product Development Review Fee

All applicants must submit a fee of \$1,000 for product development review. Payment should be made by check or money order payable to CPRIT; 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 to the following address:

Cancer Prevention and Research Institute of Texas
P.O. Box 12097
Austin, TX 78711

11.4. Application Components

Applicants are advised to minimize repetition between 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.

11.4.1. Layperson's Summary (1,500 characters)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see [Section 2](#)). Would it fill a needed gap in patient care or in the development of a

sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, 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 be also used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

11.4.2. Goals and Objectives (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.

11.4.3. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. 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.

11.4.4. Resubmission Summary (One page)

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 is a resubmission only if the previous application was finalized and submitted to CPRIT. However, an application that was submitted to CPRIT to be

considered for FY 2013 Cycle 3 awards and was returned by CPRIT due to the moratorium is not considered to be a resubmission.

11.4.5. Renewal Justification Summary (One page)

If this is a renewal, upload a summary that briefly outlines the progress made with the initial CPRIT award and outlines the proposed use of renewal funding and the resulting value for Texas. Clearly indicate whether (1) the technological/scientific underpinning is the same as that evaluated during review of the company's originally funded CPRIT application or (2) whether funding is sought for the research and development of a new product or service not previously reviewed by CPRIT or represents a significant modification of the original product or service reviewed by CPRIT (either option is acceptable). If this is not a renewal, no summary is required.

11.4.6. Executive Summary (One page)

Provide an executive summary that clearly explains 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.

11.4.7. Slide Presentation (Ten pages)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with one slide filling each landscape-orientation page. The slides should succinctly capture all essential elements of the application and should stand alone.

11.4.8. Scientific Plan (Ten pages)

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 or clinical research, methods, and anticipated results. Describe potential

problems or pitfalls and alternative approaches. 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 scientific plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by the highly qualified group of reviewers. To the extent possible, the scientific 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.

11.4.9. Business Plan (Fifteen pages)

Provide a business plan covering all of the topics below in the order shown. Successful applicants will make thoughtful, careful, and economical use of the limited space. Note that if the company is selected to undergo due diligence, information to support a full intellectual property review will be requested at that time. Established Company Product Development 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.

- A. Products and Markets:** Provide a brief description 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.
- B. Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities, driven by interactions with the Food and Drug Administration (FDA), if possible. Summarize all interactions to date with the FDA.
- C. Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated.
- D. Current and Pending Support:** Describe all funding sources. Provide a complete and detailed capitalization table, which should include all parties who have investments, stock, or rights in the company. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.

- E. Financial Projections:** Provide a detailed source and use analysis of the development plan, focusing on the achievement of specific milestones.
- F. Resources Requested:** Include resources needed for research and product development and for any relocation expenses. The matching funds amount should be included in this section; however, this is the only section of the business plan that does not deal exclusively with CPRIT-requested funds.
- G. Scope of Work and Milestones:** Outline the specific goals of the project. Provide an outline of anticipated major milestones to be tracked. 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.
- H. Intellectual Property:** Provide a concise discussion of the intellectual property related to your project. List any issued patents and patent applications, along with their titles and dates they were filed/published/issued. In addition, list any licensing agreements that your company has signed that are relevant to this application.
- I. Key Personnel:** 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.
- J. Organizational Commitment to Texas:** Describe how CPRIT funding of the applicant's company would benefit the State of Texas. For example, describe how the company would create high-quality new jobs in the State and/or recruit out-of-State talent, and mention any Texas-based subcontractors and suppliers that would be used and any other unique, Texas-based resources that would be leveraged.

11.4.10. Biographical Sketches of Key Scientific Personnel (Eight pages)

Provide a biographical sketch for up to four 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 two pages and

must use the “Product Development Programs: Biographical Sketch” template. (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 11.4.9](#)]).

11.4.11. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. The budget must be aligned with the proposed milestones.

In preparing the requested budget, applicants should be aware of the following:

- 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.
- Texas State law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT’s Administrative Rules, which are available at www.cprit.state.tx.us.
- The annual salary that an individual may receive under a CPRIT award for FY 2014 is \$200,000. In other words, an individual may request salary proportional to the percentage effort up to a maximum of \$200,000. Salary does not include fringe benefits. CPRIT FY 2015 is from September 1, 2014, through August 31, 2015.

12. 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 intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. 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 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 the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

Project Economics Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement 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.state.tx.us.

13. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas State law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has \$1.00 in matching funds for every \$2.00 from CPRIT. Matching funds need not be in hand when the application is submitted. However, matching funds must be obtained before 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.

14. CONTACT INFORMATION

14.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail 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 the Application Receipt System.**

Dates of operation: April 28, 2014 to May 29, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

14.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Product Development Program Director.

Tel: 512-305-8486

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

Third Party Observer Reports

CPRIT Product Development Panel Screening Review Report

Report #2014-24

Panel Name: Product Development Screening Review Panel - 1

Panel Date: July 15, 2014

Report Date: July 16, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the first Product Development Panel screening chaired by Jack Geltosky and held over the phone on July 15, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Product Development Panel screening review meeting held telephonically and chaired by Jack Geltosky on July 15, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twelve product development applications were discussed and evaluated by the first Product Development Review Panel to determine which grants would be brought forth to present.
- Twelve review panel members, five CPRIT staff members, and one SRA employee were present for the teleconference.

- Six conflicts of interest were identified prior to or during the in-person review. All panel members with conflicts of interest panel members dropped off the teleconference and did not participate in the review of the conflicted applications. The reviewers with conflicts of interest did not come back to the teleconference until receipt of an email from an SRA employee allowing them to participate in the teleconference.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Panel Screening Review Report

Report #2014-25

Panel Name: Product Development Screening Review Panel - 2

Panel Date: July 16, 2014

Report Date: July 16, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the second Product Development Panel screening chaired by David Shoemaker and held over the phone on July 16, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Product Development Panel screening review meeting held telephonically and chaired by David Shoemaker on July 16, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Thirteen product development applications were discussed and evaluated by the first Product Development Review Panel to determine which grants would be invited to present.
- Twelve review panel members, two CPRIT staff members, and one SRA employee were present for the teleconference.

- One conflict of interest was identified prior to or during the in-person review. The panel member with a conflict of interest dropped off the teleconference and did not participate in the review of the conflicted application. The reviewer with a conflict of interest did not come back to the teleconference until receipt of an email from an SRA employee allowing them to participate in the teleconference.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Review Panel Report

Report #2014-26

Panel Name: Product Development Review Panel - 1

Panel Date: August 12, 2014 – August 13, 2014

Report Date: August 13, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the in-person Product Development Panel chaired by Jack Geltosky and held August 12, 2014 – August 13, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the in-person Product Development Panel screening review meeting held August 12, 2014 – August 13, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Over the course of two days, nine product development applications were presented, discussed, and evaluated by the Product Development Review Panel to determine which grants would be recommended for due diligence review. A score cut-off is determined by the panel as to which applications will move on further for due diligence.
- Ten review panel members, two advocate reviewers, four CPRIT staff members, and three SRA employees were present for the in-person panel meeting.

- Five conflicts of interest was identified prior to the meeting; however, only two out of the five applications with conflicts of interest were discussed. The panel members with the conflicts of interest left the meeting room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Review Panel Report

Report #2014-27

Panel Name: Product Development Review Panel - 2

Panel Date: August 14, 2014 – August 15, 2014

Report Date: August 15, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the in-person Product Development Panel chaired by David Shoemaker and held August 14, 2014 – August 15, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the in-person Product Development Panel screening review meeting held August 14, 2014 – August 15, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Over the course of two days, eight product development applications were presented, discussed, and evaluated by the Product Development Review Panel to determine which grants would be recommended for due diligence review. A score cut-off is determined by the panel as to which applications will move on further for due diligence.
- Ten review panel members, two advocate reviewers, two CPRIT staff members, and three SRA employees were present for the in-person panel meeting.

- One conflict of interest was identified prior to the meeting. The panel member with the conflict of interest left the meeting room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Review Council Meeting Observation Report

Report #2015-226

Panel Name: FY15.1 Due Diligence Evaluation Meeting-2

Panel Date: April 17, 2015

Report Date: April 22, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Product Development Review Council meeting for FY15 funding. The meeting was chaired by Jack Geltosky and held via teleconference on April 17, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Product Development Review Council meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Jack Geltosky on April 17, 2015.

The independent observer noted the following during our observation:

- Four applications were discussed during the Product Development Review Council Meeting to determine which grants would receive CPRIT funding.

- Seven reviewers, two IP attorneys, three CPRIT staff members and two SRA employees were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. The reviewer with the conflict of interest dropped off the call and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the Council's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

**Conflicts of Interest for Product Development Cycle 15.1 Applications
(Product Development Cycle 15.1 Awards Announced at May 20, 2015, 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 Cycle 15.1 include *New Company Product Development Awards*, *Company Relocation Product Development Awards*, and *Established Company Product Development Awards*. Four applications were recommended to the PIC and Oversight Committee in February 2015 while three other applications are recommended in May 2015. 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Company	Conflict Noted
Applications Considered by the PIC and Oversight Committee			
DP150031	Merchant, Fahar	Medicenna Therapeutics, Inc.	Lloyd, Ramona; Geltosky, Jack
Applications Not Recommended for PIC or Oversight Committee Consideration			
DP150010*	Carroll, Stephen	Synergys Biotherapeutics, Inc.	Spector, Neil
DP150013	Riley, Dennis	Galera Therapeutics, Inc.	Geltosky, Jack; Spector, Neil
DP150023*	Burns, Lindsay	Pain Therapeutics, Inc.	Jones, Elaine; Saxberg, Bo
DP150036	Schmid, Steven	Vivo Biosciences, Inc.	Craig, Adam
DP150038	Kim, Jason	Molecular Templates, Inc.	Craig, Adam
DP150048	Bearss, David	Tolero Pharmaceuticals, Inc.	Craig, Adam; Saxberg, Bo; Spector, Neil

High Level Summary of Due Diligence

High Level Summary of CPRIT Diligence and Recommendation

Vermillion, Inc.

One reviewer summarized the significance and impact of this proposal with the following words: “Early and accurate diagnosis of ovarian cancer is a major challenge. Due to uncertainty in diagnosis based on non-invasive evaluation, a large proportion of women undergo operative intervention by a general surgeon. A more precise assessment of the likelihood of ovarian cancer being present could substantially change referral patterns resulting in more women being operated upon by a gynecologic oncologist. This has been associated with improved outcome in retrospective studies. Thus, the proposed biomarker work has significant implications for pattern of care in this disease.”

Though the Product Development Review Council identified some potential problems with: (i) the intellectual property rights relating to this technology and (ii) the terms of the agreement with MD Anderson regarding the management of the Ovarian Cancer Registry, it was concluded that these issues could be managed and that overall this was an excellent project.

The Product Development Review Council, 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.

Rosellini Scientific, Inc.

One reviewer summarized the significance and impact of this proposal with the following words: “The device in development has the potential to restore bladder function and improve quality of life for patients with cancer, thereby providing “supportive” care. Neurostimulation has become a preferred choice for patients refractory to pharmacotherapy, with two currently FDA-approved devices marketed by global companies, Medtronic’s InterStim and Uroplasty Urgent PC. It is not clear whether the proposed product is sufficiently different to be described as “innovative”, but rather a convenient and cost-effective treatment option.”

A potential problem with intellectual property grant-back rights was noted by the Product Development Review Council. This was judged, however, not to be a significant problem.

The Product Development Review Council, 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.

Aradigm Corporation

One reviewer summarized the significance and impact of this proposal with the following words: “If [their] objectives could be achieved, the product could be hugely significant in terms of cancer prevention, with potential large commercial impact (billions of dollars). Smokers are

addicted to nicotine and have great difficulty quitting smoking. Cigarette smoking is the leading preventable cause of death in the US, accounting for a large percentage of lung cancer and other cancers. Effective smoking cessation treatment would be enormously beneficial for individuals as well as a public health measure. However, the smoking cessation agents are difficult to develop, and the conduction of clinical trials and the marketing is very competitive with NRTs [nicotine replacement therapies] as well as non-nicotine based products.”

The Product Development Review Council noted that some of the patents held by Aradigm with respect to their device could be circumvented. Overall, however, the Council felt that there was little technology risk in this project and that it had the capability of moving relatively quickly to market.

The Product Development Review Council, 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.

De-Identified Overall Evaluation Scores

Established Company Product Development Awards

Product Development Cycle 15.1

Application ID	Final Overall Evaluation Score
DP150019*	2.4
a1	3.9
a2	4.3
a3	4.4
a4	4.8

*=Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

April 21, 2015

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

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

Dear Mr. Roberts and Dr. Rice:

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendations for CPRIT's Product Development Research grant awards. The companies on the attached list submitted proposals in response to CPRIT requests for applications (RFA) released for the first review cycle of FY2015. These are the final three from a total of nine awards approved by the review panels. Each recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports.

The projects are numerically ranked in the order the PDRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PDRC did not make changes to the funding amounts, goals, timelines, or project objectives requested by the applicants.

Our recommendations met the PDRC's standards for grant award funding. These standards include the companies' potential to: 1.) expedite innovation and product development in cancer research and treatments; 2.) create and expand the number of high-quality new jobs in Texas; and 3.) make a return on CPRIT's investment in cancer research.

Sincerely,

/JG/

Chair, CPRIT Product Development Review Council

Attachment

Product Development Review Council Award Recommendations FY2015, Cycle 1, Part 2

Rank	Application ID	Company Name	Project	Requested Budget	Overall Score
1	DP150019	Vermillion, Inc.	Development and Validation of a Second-Generation Multivariate Test for Use in Assessing Risk of Ovarian Mass Malignancy	\$7,533,011	2.4
2	DP150005	Rosellini Scientific, Inc.	Wireless Neuro-modulation Treatment for Bladder Dysfunction Secondary to Cancer	\$967,000	2.9
3	DP150042	Aradigm Corp.	Development of AERx Pure Nicotine Inhaler	\$5,330,000	3.0



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 1
New Company Product Development Awards

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA C-15-NEWCO-1

New Company Product Development Awards

**Please also refer to the Instructions for Applicants document,
which will be posted April 28, 2014**

Application Receipt Opening Date: April 28, 2014
Application Receipt Closing Date: May 29, 2014

FY 2014

Fiscal Year Award Period

September 1, 2014–August 31, 2015

TABLE OF CONTENTS

1. KEY POINTS	5
2. ABOUT CPRIT	6
3. APPLICANT SURVEY	6
4. EXECUTIVE SUMMARY	7
5. MECHANISM OF SUPPORT.....	7
6. OBJECTIVES	7
7. FUNDING INFORMATION	8
8. KEY DATES.....	9
9. ELIGIBILITY	9
9.1. NEW APPLICATIONS	9
9.2. RESUBMISSION POLICY	11
9.3. RENEWAL POLICY	11
10. APPLICATION REVIEW	12
10.1. OVERVIEW	12
10.2. REVIEW PROCESS.....	12
10.2.1. Confidentiality of Review	13
10.3. REVIEW CRITERIA.....	14
10.3.1. Primary Criteria.....	15
10.3.2. Secondary Criteria	16
11. SUBMISSION GUIDELINES	16
11.1. ONLINE APPLICATION RECEIPT SYSTEM AND APPLICATION SUBMISSION DEADLINE	16
11.2. SUBMISSION DEADLINE EXTENSION	17
11.3. PRODUCT DEVELOPMENT REVIEW FEE	17
11.4. APPLICATION COMPONENTS	17
11.4.1. Layperson's Summary (1,500 characters)	18
11.4.2. Goals and Objectives (1,200 characters each)	18
11.4.3. Timeline (One page).....	18
11.4.4. Resubmission Summary (One page).....	18
11.4.5. Executive Summary (One page)	19

11.4.6.	<i>Slide Presentation (Ten pages)</i>	19
11.4.7.	<i>Scientific Plan (Ten pages)</i>	19
11.4.8.	<i>Business Plan (Fifteen pages)</i>	20
11.4.9.	<i>Relocation Commitment to Texas (One page)</i>	21
11.4.10.	<i>Biographical Sketches of Key Scientific Personnel (Eight pages)</i>	22
11.4.11.	<i>Budget and Justification</i>	22
12.	AWARD ADMINISTRATION	22
13.	REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	24
14.	CONTACT INFORMATION	24
14.1.	HELPSDESK	24
14.2.	PROGRAMMATIC QUESTIONS	25

RFA VERSION HISTORY

Rev 03/31/14 RFA release

1. KEY POINTS

This New Company Product Development Award mechanism is governed by the following restrictions:

- Company applicants must be early-stage startup companies with no previous round of professional institutional investment (i.e., those that have not yet received Series A financing or a substantive equivalent). Companies at this early stage that are not currently located in Texas but intend to relocate to Texas should apply under this mechanism rather than the Company Relocation Awards mechanism.
- Recipient companies must currently have or must commit to the following: Headquarters or substantial business functions of the company in Texas; personnel sufficient to operate the Texas-based research and/or development activities of the company, along with appropriate management, relocated to or hired from within Texas.
- Of the total program budget, the Cancer Prevention and Research Institute of Texas (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 grant funds, not at the time the application is submitted. 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.
- Funding may be tranced and will be tied to the achievement of contract-specified milestones.
- Funding award contracts will include a revenue-sharing agreement or equity to be negotiated at contract execution 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.state.tx.us.

2. ABOUT CPRIT

The State of Texas has established CPRIT, which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- 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.

3. APPLICANT SURVEY

CPRIT will be administering a survey to determine the operational aspects of peer review. Company representatives that anticipate submitting an application are requested to complete the survey as soon as possible, but no later than May 8, 2014. Company representatives should provide the following information: Applicant name, name of company, telephone number, e-mail address, estimated award amount, and award mechanism. Please select only one award mechanism as only one application can be submitted per funding cycle. This information will be used for planning purposes only and will not be used for evaluation of the application. The survey is available [here](#).

4. EXECUTIVE SUMMARY

CPRIT will foster the creation of high-quality new jobs in Texas by providing financial support for a wide variety of projects relevant to cancer. This Request for Applications (RFA) is designed to support the formation of oncology-focused companies in 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 product development 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 increasing the availability of Food and Drug Administration (FDA)–approved therapeutic interventions with a primary focus on Texas-centric programs.

5. MECHANISM OF SUPPORT

The goal of the New Company Product Development Awards is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will assist early-stage startup companies by providing 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 mechanism will support companies that intend to undertake product research and development in Texas with a strong presence of Texas-based employees. In determining eligibility for this award, CPRIT will evaluate whether applicants have a significant presence in Texas or are willing to relocate to Texas.

6. 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 support the formation and establishment of new startup companies in Texas that will develop products to significantly impact cancer care. These companies must be Texas based or have personnel sufficient to operate the Texas-based research and/or development activities of the company, along with appropriate management, who are willing to relocate to or be hired and remain in Texas for a specified period after funding. Eligible products or services include—but are not limited to—therapeutics (e.g., small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques. Eligible stages of research and development include translational research, proof-of-concept studies, preclinical studies, and Phase I or Phase II clinical trials. By exception, Phase III clinical trials and later stage product development projects will be considered where circumstances warrant CPRIT investment.

7. 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 program proposed. While requested funds must be well justified, there is no limit on the amount that may be requested. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property protection, external consultants and service providers, and other appropriate research and development costs, subject to certain limitations set forth by Texas State 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 of Texas. Texas State law limits the amount of awarded funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs).

Consistent with statutory mandate, of the total program budget, 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 made on a year-by-year basis.

8. KEY DATES

RFA release	March 31, 2014
Online application opens	April 28, 2014, 7 a.m. Central Time
Applications due	May 29, 2014, 3 p.m. Central Time
Invitations to present sent	July 2014
Notifications sent if not invited	July 2014
Presentations to CPRIT*	August 2014
Award Notification	November 2014
Anticipated Start Date	December 2014

*All applicants who wish to be considered are requested to reserve these presentation dates until notified. 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.

9. ELIGIBILITY

9.1. New Applications

- Early-stage startup companies are eligible. Such companies may have received seed funding from family, friends, and/or angel investors. However, only applicants with no previous round of professional institutional investment (i.e., those that have not yet received Series A financing or a substantive equivalent) are eligible. The inclusion of a complete and detailed capitalization table is required for assessment of eligibility.
- Recipient companies must commit to the following: Headquarters or substantial functions of the company in Texas; personnel sufficient to operate the Texas-based

research and/or development activities of the company, along with appropriate management, relocated to or hired from within Texas who will remain in Texas for a specified period after funding; and use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-State entities. To the extent that Texas-based subcontractors or collaborators are not available, non-Texas-based collaborators and subcontractors may be used. However, non-Texas-based collaborators and subcontractors are not eligible to receive funds from CPRIT unless exceptional circumstances are demonstrated and approved by CPRIT.

- 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.
- An applicant may submit only one application under this RFA during this funding cycle.
- A company 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 one 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.
- A company 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 company 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.

- CPRIT grants will be awarded by contract to successful company applicants. Certain contractual requirements are mandated by Texas State law or by administrative rules. Although the company 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 12](#) and [Section 13](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

9.2. Resubmission Policy

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines (see [Section 11.4.4](#)). 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. 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 one-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.

9.3. Renewal Policy

Grant recipients that have previously received CPRIT grant funding may submit an application for competitive renewal under the Established Company Product

Development Award RFA. Before submitting a renewal application, applicants must consult with the Product Development Programmatic Office (see [Section 14.2](#)) to determine whether it is appropriate for their company to seek renewal funding at this time.

10. APPLICATION REVIEW

10.1. 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 scientific plan (see [Section 11.4.7](#)) and a detailed business plan (see [Section 11.4.8](#)). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and scientific 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 by the review process described below.

10.2. Review Process

- 1. Product Development and Scientific Review:** Applications that pass initial administrative compliance 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 company applicants may be invited to deliver in-person presentations to the review panel.
- 2. 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 indepth due diligence, including—but not limited to—intellectual property, management, regulatory, manufacturing, and market assessments. Following the due diligence review, applications will be

recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and intellectual property reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.

- 3. 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.
- 4. 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 703.6–703.8.

10.2.1. 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).

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.

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 Web site. **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 company applicant (or someone on the 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 application from further consideration for a grant award.

10.3. 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.**

10.3.1. Primary Criteria

Primary 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 study.

Primary criteria include the following:

Significance and Impact: Will the outcomes of this CPRIT-funded work result in the development of innovative products with significant product development potential? Will the outcome substantially impact the diagnosis, treatment, prevention of cancer, or supportive care for patients with cancer? How would competing products or services affect the value of the proposed offering?

Product: Is there demonstrated proof of relevance, and does the product fulfill a clear, unmet medical or infrastructure need? Has work been conducted that supports the advancement of the proposed product, service, or technology? Can the product be produced or manufactured in a commercially viable fashion? Is there an appropriate basis for a reimbursement strategy?

Market Plan: Is there a realistic assessment of the market size and expected penetration? Has management adequately assessed potential competitors and described how the company's offering will successfully compete with them?

Development Plan and/or Regulatory Path: Is the development plan and/or regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both a positive and a negative outcome? Does the budget appropriately support the plan?

Scientific Plan: Is the proposed product, service, and/or infrastructure based on a feasible research framework, hypothesis, and/or goal? Are the methods appropriate, and are potential research and developmental obstacles and unexpected outcomes discussed?

Management and Staffing: Does the applicant have the appropriate level of management experience to execute the stated strategy in Texas, especially if the headquarters of the company are not in Texas? Would the proposed team have the needed

experience or access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan?

10.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. 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: Are the budget and duration appropriate for the proposed work? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is it clear how funds will be used (Does the use of funds indicate a commitment to conducting the project work in Texas? Is it clear that no CPRIT funds will be sent to the corporate headquarters if those headquarters remain outside of Texas)? Does the proposed investment fund the research and development of the proposed product, service, or technology to a point where, if the results are positive, it is likely that the project will be able to attract further financial support outside of CPRIT?

11. SUBMISSION GUIDELINES

Applicants are advised to carefully review 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 when the application receipt system opens. Applications that are missing one 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.

11.1. 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

company applicant must create a user account in the system to start and submit an application. The co-applicant, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the company 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. Applications will be accepted beginning at 7 a.m. Central Time on April 28, 2014, and must be submitted by 3 p.m. Central Time on May 29, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

11.2. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

11.3. Product Development Review Fee

All applicants must submit a fee of \$1,000 for product development review. Payment should be made by check or money order payable to CPRIT; 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 to the following address:

Cancer Prevention and Research Institute of Texas
P.O. Box 12097
Austin, TX 78711

11.4. Application Components

Applicants are advised to minimize repetition between 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.

11.4.1. Layperson's Summary (1,500 characters)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see [Section 2](#)). Would it fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, 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 be also used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

11.4.2. Goals and Objectives (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.

11.4.3. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. 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.

11.4.4. Resubmission Summary (One page)

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 is a resubmission only if the previous application was finalized and submitted to CPRIT. However, an application that was submitted to CPRIT to be considered for FY2013 Cycle 3 awards and was returned by CPRIT due to the moratorium is not considered to be a resubmission.

11.4.5. Executive Summary (One page)

Provide an executive summary that clearly explains 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.

11.4.6. Slide Presentation (Ten pages)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with one slide filling each landscape-orientation page. The slides should succinctly capture all essential elements of the application and should stand alone.

11.4.7. Scientific Plan (Ten pages)

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 or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches. 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 scientific plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by the highly qualified group of reviewers. To the extent possible, the scientific 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.

11.4.8. Business Plan (Fifteen pages)

Provide a business plan covering all of the topics below in the order shown. Successful applicants will make thoughtful, careful, and economical use of the limited space. Note that if the company is selected to undergo due diligence, information to support a full intellectual property review will be requested at that time. New Company Product Development 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.

- A. Products and Markets:** Provide a brief description 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.
- B. Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities, driven by interactions with the FDA, if possible. Summarize all interactions to date with the FDA.
- C. Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated.
- D. Current and Pending Support:** Describe all funding sources. Provide a complete and detailed capitalization table, which should include all parties who have investments, stock, or rights in the company. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.
- E. Financial Projections:** Provide a detailed source and use analysis of the development plan, focusing on the achievement of specific milestones.

- F. Resources Requested:** Include resources needed for research and product development and for any relocation expenses. The matching funds should be included in this section; however, this is the only section of the business plan that does not deal exclusively with CPRIT-requested funds.
- G. Scope of Work and Milestones:** Outline the specific goals of the project. Provide an outline of anticipated major milestones to be tracked. 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.
- H. Intellectual Property:** Provide a concise discussion of the intellectual property related to your project. List any issued patents and patent applications along with their titles and dates they were filed/published/issued. In addition, list any licensing agreements that your company has signed that are relevant to this application.
- I. Key Personnel Located in Texas and Any Key Management Located Outside of Texas:** Present a plan for recruiting a senior management and scientific team, describing the types of expertise and skillsets that the project will require. For each key person currently on board, 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.
- J. Organizational Commitment to Texas:** Describe how CPRIT funding of the applicant's company would benefit the State of Texas. For example, describe how the company would create high-quality new jobs in the State and/or recruit out-of-State talent, and mention any Texas-based subcontractors and suppliers that would be used and any other unique, Texas-based resources that would be leveraged.

11.4.9. Relocation Commitment to Texas (One page)

If your company will be relocating to Texas, provide a timetable with key dates indicating the Applicant's plan and commitment to relocate to Texas. In addition, describe which personnel and management will be headquartered in Texas.

11.4.10. Biographical Sketches of Key Scientific Personnel (Eight pages)

Provide a biographical sketch for up to four 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 two pages and must use the “Product Development Programs: Biographical Sketch” template.

(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 11.4.8](#)]).

11.4.11. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. The budget must be aligned with the proposed milestones. In preparing the requested budget, applicants should be aware of the following:

- 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.
- Texas State law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT’s Administrative Rules, which are available at www.cprit.state.tx.us.
- The annual salary that an individual may receive under a CPRIT award for FY 2014 is \$200,000. In other words, an individual may request salary proportional to the percentage effort up to a maximum of \$200,000. Salary does not include fringe benefits. CPRIT FY 2014 is from September 1, 2014, through August 31, 2015.

12. 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 intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. 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 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 the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

Project Economics Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement 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.state.tx.us.

13. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas State law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has \$1.00 in matching funds for every \$2.00 from CPRIT. Matching funds need not be in hand when the application is submitted. However, matching funds must be obtained before CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be designated 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 demonstration of available funds.

14. CONTACT INFORMATION

14.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific and commercialization aspects of applications. **Before contacting the HelpDesk, please refer to the "Instructions for Applicants" document, which provides a step-by-step guide on using the Application Receipt System.**

Dates of operation: April 28, 2014, to May 29, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

14.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Product Development Program Director.

Tel: 512-305-8486

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

Third Party Observer Reports

CPRIT Product Development Panel Screening Review Report

Report #2014-24

Panel Name: Product Development Screening Review Panel - 1

Panel Date: July 15, 2014

Report Date: July 16, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the first Product Development Panel screening chaired by Jack Geltosky and held over the phone on July 15, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Product Development Panel screening review meeting held telephonically and chaired by Jack Geltosky on July 15, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twelve product development applications were discussed and evaluated by the first Product Development Review Panel to determine which grants would be brought forth to present.
- Twelve review panel members, five CPRIT staff members, and one SRA employee were present for the teleconference.

- Six conflicts of interest were identified prior to or during the in-person review. All panel members with conflicts of interest panel members dropped off the teleconference and did not participate in the review of the conflicted applications. The reviewers with conflicts of interest did not come back to the teleconference until receipt of an email from an SRA employee allowing them to participate in the teleconference.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Panel Screening Review Report

Report #2014-25

Panel Name: Product Development Screening Review Panel - 2

Panel Date: July 16, 2014

Report Date: July 16, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the second Product Development Panel screening chaired by David Shoemaker and held over the phone on July 16, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Product Development Panel screening review meeting held telephonically and chaired by David Shoemaker on July 16, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Thirteen product development applications were discussed and evaluated by the first Product Development Review Panel to determine which grants would be invited to present.
- Twelve review panel members, two CPRIT staff members, and one SRA employee were present for the teleconference.

- One conflict of interest was identified prior to or during the in-person review. The panel member with a conflict of interest dropped off the teleconference and did not participate in the review of the conflicted application. The reviewer with a conflict of interest did not come back to the teleconference until receipt of an email from an SRA employee allowing them to participate in the teleconference.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Review Panel Report

Report #2014-26

Panel Name: Product Development Review Panel - 1

Panel Date: August 12, 2014 – August 13, 2014

Report Date: August 13, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the in-person Product Development Panel chaired by Jack Geltosky and held August 12, 2014 – August 13, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the in-person Product Development Panel screening review meeting held August 12, 2014 – August 13, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Over the course of two days, nine product development applications were presented, discussed, and evaluated by the Product Development Review Panel to determine which grants would be recommended for due diligence review. A score cut-off is determined by the panel as to which applications will move on further for due diligence.
- Ten review panel members, two advocate reviewers, four CPRIT staff members, and three SRA employees were present for the in-person panel meeting.

- Five conflicts of interest was identified prior to the meeting; however, only two out of the five applications with conflicts of interest were discussed. The panel members with the conflicts of interest left the meeting room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Review Panel Report

Report #2014-27

Panel Name: Product Development Review Panel - 2

Panel Date: August 14, 2014 – August 15, 2014

Report Date: August 15, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the in-person Product Development Panel chaired by David Shoemaker and held August 14, 2014 – August 15, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the in-person Product Development Panel screening review meeting held August 14, 2014 – August 15, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Over the course of two days, eight product development applications were presented, discussed, and evaluated by the Product Development Review Panel to determine which grants would be recommended for due diligence review. A score cut-off is determined by the panel as to which applications will move on further for due diligence.
- Ten review panel members, two advocate reviewers, two CPRIT staff members, and three SRA employees were present for the in-person panel meeting.

- One conflict of interest was identified prior to the meeting. The panel member with the conflict of interest left the meeting room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Review Council Meeting Observation Report

Report #2015-226

Panel Name: FY15.1 Due Diligence Evaluation Meeting-2

Panel Date: April 17, 2015

Report Date: April 22, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Product Development Review Council meeting for FY15 funding. The meeting was chaired by Jack Geltosky and held via teleconference on April 17, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Product Development Review Council meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Jack Geltosky on April 17, 2015.

The independent observer noted the following during our observation:

- Four applications were discussed during the Product Development Review Council Meeting to determine which grants would receive CPRIT funding.

- Seven reviewers, two IP attorneys, three CPRIT staff members and two SRA employees were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. The reviewer with the conflict of interest dropped off the call and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the Council's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. 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 and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Product Development Cycle 15.1 Applications
(Product Development Cycle 15.1 Awards Announced at May 20, 2015, 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 Cycle 15.1 include *New Company Product Development Awards*, *Company Relocation Product Development Awards*, and *Established Company Product Development Awards*. Four applications were recommended to the PIC and Oversight Committee in February 2015 while three other applications are recommended in May 2015. 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 SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Company	Conflict Noted
Applications Considered by the PIC and Oversight Committee			
DP150031	Merchant, Fahar	Medicenna Therapeutics, Inc.	Lloyd, Ramona; Geltosky, Jack
Applications Not Recommended for PIC or Oversight Committee Consideration			
DP150010*	Carroll, Stephen	Synergys Biotherapeutics, Inc.	Spector, Neil
DP150013	Riley, Dennis	Galera Therapeutics, Inc.	Geltosky, Jack; Spector, Neil
DP150023*	Burns, Lindsay	Pain Therapeutics, Inc.	Jones, Elaine; Saxberg, Bo
DP150036	Schmid, Steven	Vivo Biosciences, Inc.	Craig, Adam
DP150038	Kim, Jason	Molecular Templates, Inc.	Craig, Adam
DP150048	Bearss, David	Tolero Pharmaceuticals, Inc.	Craig, Adam; Saxberg, Bo; Spector, Neil

High Level Summary of Due Diligence

High Level Summary of CPRIT Diligence and Recommendation

Vermillion, Inc.

One reviewer summarized the significance and impact of this proposal with the following words: “Early and accurate diagnosis of ovarian cancer is a major challenge. Due to uncertainty in diagnosis based on non-invasive evaluation, a large proportion of women undergo operative intervention by a general surgeon. A more precise assessment of the likelihood of ovarian cancer being present could substantially change referral patterns resulting in more women being operated upon by a gynecologic oncologist. This has been associated with improved outcome in retrospective studies. Thus, the proposed biomarker work has significant implications for pattern of care in this disease.”

Though the Product Development Review Council identified some potential problems with: (i) the intellectual property rights relating to this technology and (ii) the terms of the agreement with MD Anderson regarding the management of the Ovarian Cancer Registry, it was concluded that these issues could be managed and that overall this was an excellent project.

The Product Development Review Council, 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.

Rosellini Scientific, Inc.

One reviewer summarized the significance and impact of this proposal with the following words: “The device in development has the potential to restore bladder function and improve quality of life for patients with cancer, thereby providing “supportive” care. Neurostimulation has become a preferred choice for patients refractory to pharmacotherapy, with two currently FDA-approved devices marketed by global companies, Medtronic’s InterStim and Uroplasty Urgent PC. It is not clear whether the proposed product is sufficiently different to be described as “innovative”, but rather a convenient and cost-effective treatment option.”

A potential problem with intellectual property grant-back rights was noted by the Product Development Review Council. This was judged, however, not to be a significant problem.

The Product Development Review Council, 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.

Aradigm Corporation

One reviewer summarized the significance and impact of this proposal with the following words: “If [their] objectives could be achieved, the product could be hugely significant in terms of cancer prevention, with potential large commercial impact (billions of dollars). Smokers are

addicted to nicotine and have great difficulty quitting smoking. Cigarette smoking is the leading preventable cause of death in the US, accounting for a large percentage of lung cancer and other cancers. Effective smoking cessation treatment would be enormously beneficial for individuals as well as a public health measure. However, the smoking cessation agents are difficult to develop, and the conduction of clinical trials and the marketing is very competitive with NRTs [nicotine replacement therapies] as well as non-nicotine based products.”

The Product Development Review Council noted that some of the patents held by Aradigm with respect to their device could be circumvented. Overall, however, the Council felt that there was little technology risk in this project and that it had the capability of moving relatively quickly to market.

The Product Development Review Council, 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.

De-Identified Overall Evaluation Scores

New Company Product Development Awards

Product Development Cycle 15.1

Application ID	Final Overall Evaluation Score
DP150031*	2.0
DP150021*	2.0
DP150029*	2.3
DP150039*	2.4
DP150005**	2.9
DP150042**	3.0
aa1	3.9
aa2	4.2
aa3	4.4
aa4	4.5
aa5	4.8
aa6	5.5
aa7	5.8
aa8	6.3
aa9	6.5
bb1	6.7
bb2	7.0

*=Recommended and approved for funding at February 18, 2015, Oversight Committee Meeting

**=Recommended by the Product Development Review Council for the May 20, 2015, Oversight Committee Meeting

Final Overall Evaluation Scores and Rank Order Scores

April 21, 2015

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

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

Dear Mr. Roberts and Dr. Rice:

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendations for CPRIT's Product Development Research grant awards. The companies on the attached list submitted proposals in response to CPRIT requests for applications (RFA) released for the first review cycle of FY2015. These are the final three from a total of nine awards approved by the review panels. Each recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports.

The projects are numerically ranked in the order the PDRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PDRC did not make changes to the funding amounts, goals, timelines, or project objectives requested by the applicants.

Our recommendations met the PDRC's standards for grant award funding. These standards include the companies' potential to: 1.) expedite innovation and product development in cancer research and treatments; 2.) create and expand the number of high-quality new jobs in Texas; and 3.) make a return on CPRIT's investment in cancer research.

Sincerely,

/JG/

Chair, CPRIT Product Development Review Council

Attachment

Product Development Review Council Award Recommendations FY2015, Cycle 1, Part 2

Rank	Application ID	Company Name	Project	Requested Budget	Overall Score
1	DP150019	Vermillion, Inc.	Development and Validation of a Second-Generation Multivariate Test for Use in Assessing Risk of Ovarian Mass Malignancy	\$7,533,011	2.4
2	DP150005	Rosellini Scientific, Inc.	Wireless Neuro-modulation Treatment for Bladder Dysfunction Secondary to Cancer	\$967,000	2.9
3	DP150042	Aradigm Corp.	Development of AERx Pure Nicotine Inhaler	\$5,330,000	3.0



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150005
New 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).

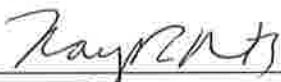
My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *New Company Product Development Awards* Request for Applications (RFA). CPRIT received 19 applications, including 2 that were withdrawn, for this RFA. The application was assigned to 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


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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

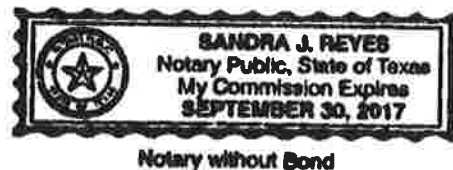
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 1
PROGRAM Product Development
AWARD MECHANISM New Company Product Development Awards (NEWCO)
APPLICATION ID DP150005
APPLICATION TITLE Wireless Neuromodulation Treatment for Bladder Dysfunction Secondary to Cancer
APPLICANT NAME Duke, Austin
ORGANIZATION Rosellini Scientific, LLC
PANEL NAME Product Development Panel-1 (PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/09/14	11/07/14
	CPRIT Application Receipt System (CARS) opened	04/28/14	11/07/14
	CPRIT Application Receipt System (CARS) closed	05/29/14	11/07/14
	Date application submitted	05/29/14	11/07/14
	Method of submission	CARS	11/07/14
	Within receipt period	YES	11/07/14
	Appeal to submit application after CARS closed	N/A	11/07/14
	Appeal for late application submission accepted	N/A	11/07/14
2. Receipt, Referral, and Assignment	Submission of application fee	YES	04/27/15
	Administrative review notification	N/A	11/07/14
	Donation(s) made to CPRIT/foundation	NO	11/07/14
	Assigned to primary reviewers	06/25/14	11/07/14
	Applicant notified of review panel assignment	07/11/14	11/07/14
	Primary Reviewer 1 COI signed	06/14/14	11/07/14
	Primary (Advocate) Reviewer 2 COI signed	06/12/14	11/07/14
	Primary Reviewer 3 COI signed	06/18/14	11/07/14
3. Peer Review: Screening Teleconference	Primary Reviewer 4 COI signed	06/19/14	11/07/14
	Primary Reviewer 1 critique submitted	07/18/14	11/07/14
	Primary (Advocate) Reviewer 2 critique submitted	07/15/14	11/07/14
	Primary Reviewer 3 critique submitted	07/15/14	11/07/14
	Primary Reviewer 4 critique submitted	07/15/14	11/07/14
	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
	Peer Review: Screening Teleconference	07/15/14	11/07/14
	Post-Screening Teleconference score report	07/15/14	11/07/14
	Post review statements signed	08/12/14	11/07/14
4. Peer Review: On-Site Meeting	Third Party Observer Report	07/16/14	11/07/14
	Recommended for On-Site Meeting	YES	11/07/14
	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
	Peer Review: On-Site Meeting	08/12/14-08/13/14	11/07/14
	Post review statements signed	08/26/14	11/07/14
	Third Party Observer Report	08/13/14	11/07/14
5. Due Dillgence and IP Review	Score report delivered to CPDO	08/30/14	11/07/14
	Recommended for due diligence and IP review	YES	11/07/14
	Final due diligence review submitted to PDRC	02/10/15	04/27/15
6. Final PDRC Recommendation	Intellectual Property conflict check	03/10/15	04/28/15
	Final intellectual property review submitted	04/07/15	04/27/15
	COI indicated by PDRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	Due Diligence Evaluation Meeting / PDRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
7. PIC Review	Recommended for grant award	YES	04/23/15
	PDRC Chair Notification to PIC and OC	04/21/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
8. Oversight Committee Approval	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150042
New 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 *New Company Product Development Awards* Request for Applications (RFA). CPRIT received 19 applications, including 2 that were withdrawn, for this RFA. The application was assigned to 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I note that the Program Integration Committee voted four to one not to recommend this application to the Oversight Committee.

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.

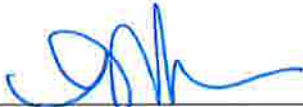
This statement is true."



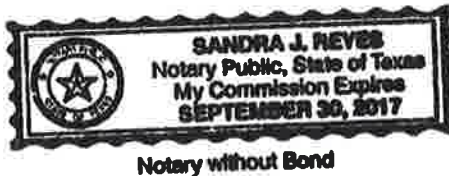
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 6th day of May, 2015,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2015
 CYCLE 1
 PROGRAM Product Development
 AWARD MECHANISM New Company Product Development Awards (NEWCO)
 APPLICATION ID DP150042
 APPLICATION TITLE AERx Pure Nicotine Inhaler
 APPLICANT NAME Wulf, John
 ORGANIZATION Aradigm Corporation
 PANEL NAME Product Development Panel-1 (PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/09/14	11/07/14
	CPRIT Application Receipt System (CARS) opened	04/28/14	11/07/14
	CPRIT Application Receipt System (CARS) closed	05/29/14	11/07/14
	Date application submitted	05/29/14	11/07/14
	Method of submission	CARS	11/07/14
	Within receipt period	YES	11/07/14
	Appeal to submit application after CARS closed	N/A	11/07/14
	Appeal for late application submission accepted	N/A	11/07/14
	Submission of application fee	YES	04/27/15
2. Receipt, Referral, and Assignment	Administrative review notification	06/20/14	11/07/14
	Donation(s) made to CPRIT/foundation	NO	11/07/14
	Assigned to primary reviewers	06/25/14	11/07/14
	Applicant notified of review panel assignment	07/11/14	11/07/14
	Primary Reviewer 1 COI signed	06/19/14	11/07/14
	Primary (Advocate) Reviewer 2 COI signed	06/13/14	11/07/14
	Primary Reviewer 3 COI signed	06/14/14	11/07/14
	Primary Reviewer 4 COI signed	06/12/14	11/07/14
3. Peer Review: Screening Teleconference	Primary Reviewer 1 critique submitted	07/15/14	11/07/14
	Primary (Advocate) Reviewer 2 critique submitted	07/18/14	11/07/14
	Primary Reviewer 3 critique submitted	07/18/14	11/07/14
	Primary Reviewer 4 critique submitted	07/15/14	11/07/14
	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
	Peer Review: Screening Teleconference	07/15/14	11/07/14
	Post-Screening Teleconference score report	07/15/14	11/07/14
	Post review statements signed	08/12/14	11/07/14
	Third Party Observer Report	07/16/14	11/07/14
4. Peer Review: On-Site Meeting	Recommended for On-Site Meeting	YES	11/07/14
	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
	Peer Review: On-Site Meeting	08/12/14-08/13/14	11/07/14
	Post review statements signed	08/26/14	11/07/14
	Third Party Observer Report	08/13/14	11/07/14
	Score report delivered to CPDO	08/30/14	11/07/14
5. Due Diligence and IP Review	Recommended for due diligence and IP review	YES	11/07/14
	Final due diligence review submitted to PDRC	02/10/15	04/27/15
	Intellectual Property conflict check	03/11/15	04/28/15
6. Final PDRC Recommendation	Final intellectual property review submitted	04/07/15	04/27/15
	COI indicated by PDRC member	NONE	04/23/15
	COI recused from participation	N/A	04/23/15
	Due Diligence Evaluation Meeting / PDRC Meeting	04/17/15	04/23/15
	Third Party Observer Report	04/22/15	04/26/15
	Recommended for grant award	YES	04/23/15
7. PIC Review	PDRC Chair Notification to PIC and OC	04/21/15	04/23/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	N/A	05/05/15
	PIC review meeting	05/05/15	05/05/15
8. Oversight Committee Approval	Recommended for grant award	NO	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150019
Established 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 *Established Company Product Development Awards* Request for Applications (RFA). CPRIT received five applications for this RFA. The application was assigned to 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

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 Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


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.

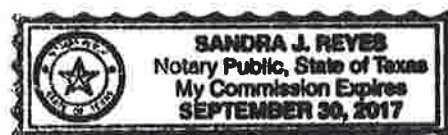
This statement is true."


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 6th day of May, 2015,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2015
 CYCLE 1
 PROGRAM Product Development
 AWARD MECHANISM Established Company Product Development Awards (ESTCO)
 APPLICATION ID DP150019
 APPLICATION TITLE Development and Validation of a Second-Generation Multivariate Test for Use in Assessing Risk of Ovarian Mass Malignancy
 APPLICANT NAME DiMascio, Leah
 ORGANIZATION Vermillion Inc.
 PANEL NAME Product Development Panel-1 (PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/09/14	11/07/14
	CPRIT Application Receipt System (CARS) opened	04/28/14	11/07/14
	CPRIT Application Receipt System (CARS) closed	05/29/14	11/07/14
	Date application submitted	05/29/14	11/07/14
	Method of submission	CARS	11/07/14
	Within receipt period	YES	11/07/14
	Appeal to submit application after CARS closed	N/A	11/07/14
	Appeal for late application submission accepted	N/A	11/07/14
2. Receipt, Referral, and Assignment	Submission of application fee	YES	04/27/15
	Administrative review notification	N/A	11/07/14
	Donation(s) made to CPRIT/foundation	NO	11/07/14
	Assigned to primary reviewers	06/25/14	11/07/14
	Applicant notified of review panel assignment	07/11/14	11/07/14
	Primary Reviewer 1 COI signed	06/14/14	11/07/14
	Primary (Advocate) Reviewer 2 COI signed	06/12/14	11/07/14
	Primary Reviewer 3 COI signed	06/13/14	11/07/14
3. Peer Review: Screening Teleconference	Primary Reviewer 4 COI signed	06/24/14	11/07/14
	Primary Reviewer 1 critique submitted	07/18/14	11/07/14
	Primary (Advocate) Reviewer 2 critique submitted	07/15/14	11/07/14
	Primary Reviewer 3 critique submitted	07/15/14	11/07/14
	Primary Reviewer 4 critique submitted	07/19/14	11/07/14
	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
	Peer Review: Screening Teleconference	07/15/14	11/07/14
	Post-Screening Teleconference score report	07/15/14	11/07/14
	Post review statements signed	08/12/14	11/07/14
4. Peer Review: On-Site Meeting	Third Party Observer Report	07/16/14	11/07/14
	Recommended for On-Site Meeting	YES	11/07/14
	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
	Peer Review: On-Site Meeting	08/12/14-08/13/14	11/07/14
	Post review statements signed	08/26/14	11/07/14
	Third Party Observer Report	08/13/14	11/07/14
5. Due Diligence and IP Review	Score report delivered to CPDO	08/30/14	11/07/14
	Recommended for due diligence and IP review	YES	11/07/14
	Final due diligence review submitted to PDRC	02/10/15	04/27/15
6. Final PDRC Recommendation	Intellectual Property conflict check	03/10/15	04/28/15
	Final intellectual property review submitted	04/07/15	04/27/15
	COI indicated by PDRC member	NONE	04/26/15
	COI recused from participation	N/A	04/26/15
	Due Diligence Evaluation Meeting / PDRC Meeting	04/17/15	04/26/15
	Third Party Observer Report	04/22/15	04/26/15
7. PIC Review	Recommended for grant award	YES	04/26/15
	PDRC Chair Notification to PIC and OC	04/21/15	04/26/15
	COI indicated by PIC member	NONE	05/05/15
	COI recused from participation	M. Kripke*	05/05/15
8. Oversight Committee Approval	PIC review meeting	05/05/15	05/05/15
	Recommended for grant award	YES	05/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

* Dr. Kripke did not vote pursuant to a conflict of interest waiver on file for FY2015 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

May 15, 2015

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 a grant contract for two companies that will be considered for Product Development grant awards at the May 20, 2015, Oversight Committee meeting. The Oversight Committee will consider the PIC's recommendation at the May 20, 2015, Oversight Committee meeting.

There is one company application that was not recommended by the PIC. The Oversight Committee may consider this application upon a motion of one of the members. If that occurs, I also request authority for CPRIT to advance funds upon execution of a grant contract for the application recommended by a minority of the PIC.

Although CPRIT disburses the majority of grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.03(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. Failure to submit the financial status reports on a timely basis will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

After consultation with Dr. Thomas Goodman, CPRIT's Chief Product Development Officer, one or more of the following reasons support advance payment of grant funds for the three companies to be considered at the May 20, 2015, meeting: 1.) a larger amount of start-up funds is needed than can be advanced from cash on hand; 2.) pre-clinical trial contracts will need to be entered into with substantial upfront payments; and/or 3.) significant equipment purchases will be needed for work to begin.

Sincerely,

A handwritten signature in dark ink, appearing to read "Wayne R. Roberts".

Wayne R. Roberts,
CPRIT Chief Executive Officer



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS
From: DR. BECKY GARCIA, DR. MARGARET KRIPKE, DR. TOM GOODMAN, COMMISSIONER KIRK COLE
Subject: DP150042 MAJORITY PIC RECOMMENDATION NOT TO FUND
Date: MAY 7, 2015

Summary and Recommendation:

The majority of PIC members voted 4-1 not to recommend DP150042, a nicotine inhaler, to the Oversight Committee. Mr. Wayne Roberts has written a minority recommendation to fund DP150042. The majority of PIC members do not recommend DP150042 because nicotine is addictive and its use for tobacco cessation is unproven and the belief that CPRIT funds would be better spent elsewhere.

Discussion:

The motion not to approve grant # DP150042, AERx Pure Nicotine Inhaler, is based on the following considerations:

Nicotine is a toxic, addictive drug. It was used as an insecticide in the past. It is reported to increase heart rate and blood pressure and affects the microvasculature. Although nicotine has not been shown to be carcinogenic on its own, it facilitates tumor growth and metastasis in animal models. These effects are thought to be due to its ability to increase production of certain growth factors and stimulate neovascularization (1-4).

The effects of long-term nicotine inhalation are not known, but concerns have been raised about its potential to affect brain development in children and adolescents.

Claims that a nicotine inhaler would lead to cessation of tobacco use are unsubstantiated at a population level in the US.

We recognize there is a high probability of technical success in manufacturing and marketing this nicotine delivery device and that it may prove effective in reducing the craving for nicotine for several hours after inhalation. However, it is our opinion that CPRIT funds would be better spent on delivering and improving smoking cessation programs or on research to determine the risks and benefits of nicotine use. It seems inappropriate for CPRIT to fund production of a device that delivers a toxic, potentially tumor-promoting drug, when tobacco companies are already funding all types of nicotine delivery devices.

1. Wong HP, Yu L, Lam EK, Tai EK, Wu WK, Cho CH (June 2007). "Nicotine promotes colon tumor growth and angiogenesis through beta-adrenergic activation". *Toxicol. Sci.* **97** (2): 279–87. [doi:10.1093/toxsci/kfm060](https://doi.org/10.1093/toxsci/kfm060). PMID 17369603.
2. Natori T, Sata M, Washida M, Hirata Y, Nagai R, Makuuchi M (October 2003). "Nicotine enhances neovascularization and promotes tumor growth". *Mol. Cells* **16** (2): 143–6. PMID 14651253.
3. Ye YN, Liu ES, Shin VY, Wu WK, Luo JC, Cho CH (January 2004). "Nicotine promoted colon cancer growth via epidermal growth factor receptor, c-Src, and 5-lipoxygenase-mediated signal pathway". *J. Pharmacol. Exp. Ther.* **308** (1): 66–72. [doi:10.1124/jpet.103.058321](https://doi.org/10.1124/jpet.103.058321). PMID 14569062.
4. Davis R, Rizwani W, Banerjee S et al. (2009). Pao, William, ed. "Nicotine promotes tumor growth and metastasis in mouse models of lung cancer". *PLoS ONE* **4** (10): e7524. Bibcode:2009PLoSO...4.7524D. [doi:10.1371/journal.pone.0007524](https://doi.org/10.1371/journal.pone.0007524). PMC 2759510. PMID 19841737.