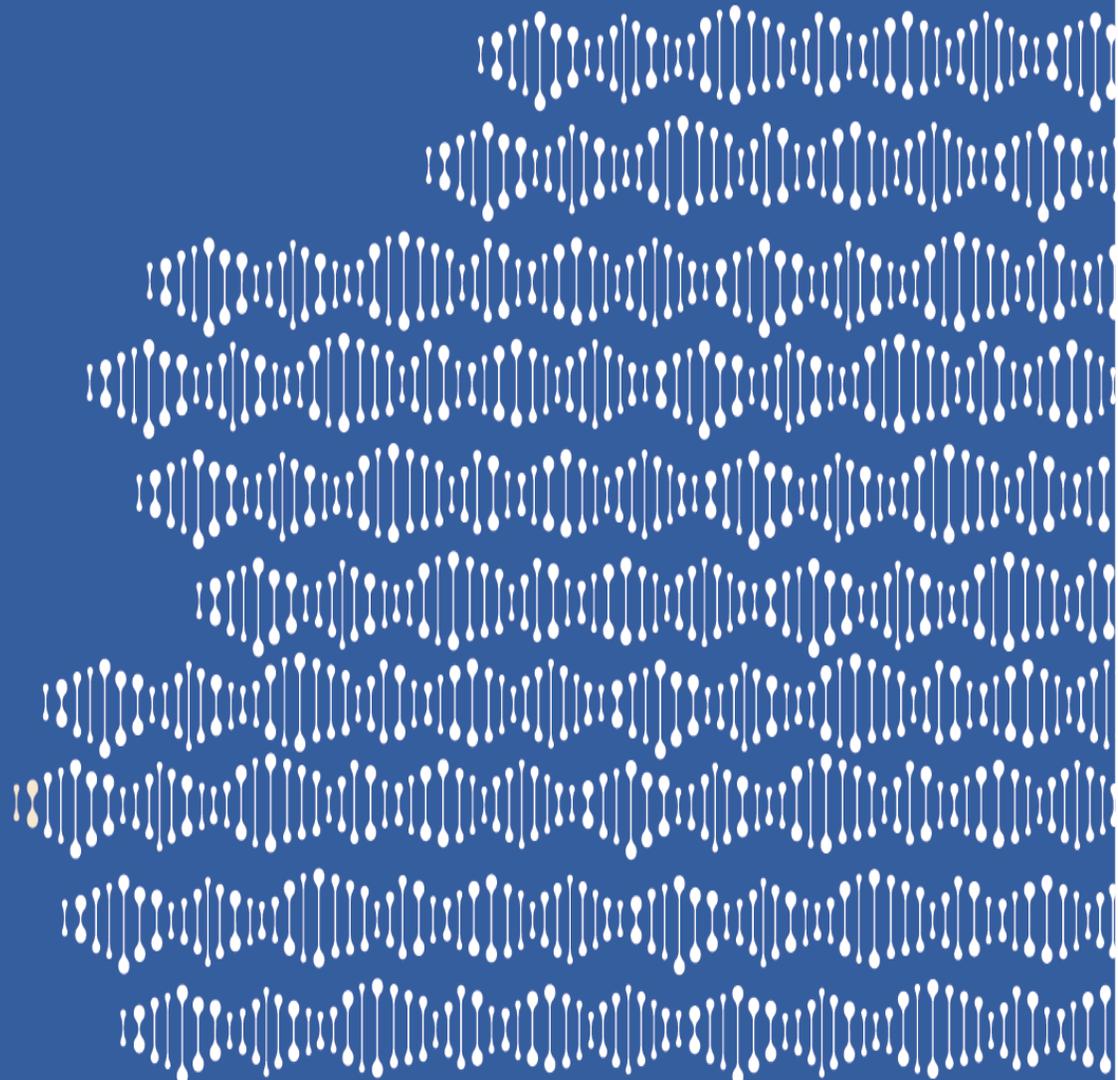




CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

# Proposed Grant Awards

November 19, 2015





# TABLE OF CONTENTS

**PIC Recommendation Letter** p.3

---

**Compliance Certification** p.21

---

**Academic Research** p.29

---

**Prevention** p.49

---

**Product Development** p.67

---







---

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

November 5, 2015

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 73 grant applications totaling \$112,009,012. The PIC recommendations for 60 academic research grant awards, 1 product development award, and 12 prevention awards are attached.

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

*For the first time the PIC has used the award deferral process set by CPRIT administrative rule § 703.7(d) to defer the decision to recommend awards for two prevention applications until a future FY 2016 meeting. PP160046 and PP160033, totaling \$2,999,657, were recommended by the Prevention Review Council (PRC). The PIC's unanimous decision conserves prevention award funds for the second FY2016 funding cycle. The two deferred applications were ranked the lowest of the prevention grants recommended for funding. After considering proposals submitted in the next cycle, the PRC may recommend funding one or both deferred applications. No Oversight Committee action is necessary at this time.*

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

The award recommendations will not be considered final until the Oversight Committee meeting on Thursday, November 19, 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.

If you have any questions or would like more information on the review process or any of the projects recommended for an award, CPRIT's staff, including myself, Dr. Kripke, Mr. Lang, and Dr. Garcia 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 60 academic research grant proposals totaling \$78,761,270. The recommended grant proposals were submitted in response to eight grant mechanisms: Individual Investigator Research Awards; Individual Investigator Research Awards for Cancer in Children and Adolescents; Individual Investigator Research Awards for Computational Biology; Individual Investigator Research Awards for Prevention and Early Detection; Research Training Awards; Recruitment of First-Time, Tenure-Track Faculty; Recruitment of Rising Stars, 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 October 26, 2015. Dr. Kolodner corrected a score for one grant, RP160268, in a letter dated October 29, 2015, which slightly affected the grant's ranking.

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;
- Expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or Technology research capabilities; and
  - This factor only applies to Individual Investigator Research Awards; Individual Investigator Research Awards for Cancer in Children and Adolescents; Individual Investigator Research Awards for Computational Biology; Individual Investigator Research Awards for Prevention and Early Detection; Recruitment of First-Time, Tenure-Track Faculty; Recruitment of Rising Stars, and Recruitment of Established Investigators
- address the goals of the Texas Cancer Plan.

## Academic Research Grant Award Recommendations

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
1	RP160157	The University of Texas Southwestern Medical Center	Cancer Intervention and Prevention Discoveries Program	\$3,993,250	RTA-Renewal	1.2
2	RP160192	Baylor College of Medicine	Decoding Cellular Heterogeneity of Malignant Glioma	\$899,701	IIRA	1.3
3	RP160451	Baylor College of Medicine	Protein Truncation Mutations in WIP1: Effects on Cancer and	\$900,000	IIRA	1.5
4	RP160180	The University of Texas Southwestern Medical Center	Development of Therapeutics Targeting Truncated Adenomatous Polyposis Coli (APC) as a Novel Prevention and Intervention Strategy for Colorectal Cancer	\$900,000	IIRA	1.8
5*	RP160237	The University of Texas M. D. Anderson Cancer Center	A novel epigenetic reader as therapeutic target in MLL-translocated pediatric leukemias	\$900,000	IIRACC A	1.8
6	RP160283	Baylor College of Medicine	Baylor College of Medicine Comprehensive Cancer Training Program	\$3,986,268	RTA-Renewal	1.9
7	RP160487	The University of Texas Health Science Center at San Antonio	Cytokine signaling in Ewing sarcoma	\$1,200,000	IIRACC A	1.9
8	RP160030	The University of Texas Southwestern Medical Center	A Randomized Controlled Trial (RCT) of Patient Navigation for Lung Cancer Screening in an Urban Safety-Net System	\$1,492,616	IIRAP	1.9
9	RP160384	Baylor College of Medicine	Promoting The Functions of Memory T cells for Adoptive T cell Therapy	\$887,676	IIRA	1.9
10	RP1	The University of Texas Southwestern Medical Center	Role of Long Non-Coding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	\$886,652	IIRA	2.0
11	RP160589	Texas AgriLife Research	Arylhydrocarbon receptor mediated modulation of colorectal cancer by microbiota	\$890,840	IIRAP	2.0
12**	RP160190	The University of Texas Southwestern Medical Center	Pediatric Radiation Oncology with Movie Induced Sedation Effect (PROMISE)	\$900,000	IIRACC A	2.0
13	RP160497	The University of Texas M. D. Anderson Cancer Center	Amplified gold nanoparticle-mediated radiosensitization of	\$899,309	IIRA	2.0
14	RP160229	The University of Texas M. D. Anderson Cancer Center	Imaging-based quantitative analysis of vascular perfusion and tissue oxygenation to improve therapy of hepatocellular carcinoma	\$885,901	IIRA	2.0
15	RP160169	The University of Texas Southwestern Medical Center	Molecular Mechanism of NLRP12- mediated Regulation of Colorectal Cancer	\$897,707	IIRA	2.1
16***	RP160249	The University of Texas Southwestern Medical Center	DIS3L2 in Childhood Wilms Tumor: Mechanism to Medicines	\$1,200,000	IIRACC A	2.1

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
17	RP160089	The University of Texas Southwestern Medical Center	Carbamoyl Phosphate Synthase-1: A new metabolic liability in non-small cell lung cancers	\$900,000	IIRA	2.1
18	RP160501	The Methodist Hospital Research Institute	De-Orphanizing TLX: Implications for Glioblastomas	\$878,969	IIRA	2.1
19	RP160622	The University of Texas Southwestern Medical Center	Computational live cell histology	\$392,779	IIRACB	2.1
20	RP160097	Baylor College of Medicine	Cancer Prevention Post-Graduate Training Program in Integrative Epidemiology	\$2,986,890	RTA	2.1
21	RP160015	The University of Texas Health Science Center at Houston	Collaborative Training of a New Cadre of Innovative Cancer Prevention Researchers	\$4,000,000	RTA-Renewal	2.1
22	RP160340	The University of Texas Southwestern Medical Center	The role of the Lats kinases in sarcomatoid renal cell	\$899,598	IIRA	2.2
23	RP160183	The University of Texas M. D. Anderson Cancer Center	Exploiting molecular and metabolic dependencies to optimize personalized therapeutic approaches	\$900,000	IIRA	2.2
24	RP160232	The University of Texas M. D. Anderson Cancer Center	Understanding Biological and Physical Factors Affecting Response to Proton Therapy to Improve its Clinical Effectiveness	\$879,362	IIRA	2.2
25	RP160022	Baylor College of Medicine	Role of Cohesin in Hematopoiesis and Myeloid Leukemia in Children with Down Syndrome	\$1,905,638	IIRACC A	2.2
26	RP160242	The University of Texas M. D. Anderson Cancer Center	Mechanisms and targeting strategies for SWI/SNF mutations in cancer	\$900,000	IIRA	2.3
27	RP160440	The University of Texas Southwestern Medical Center	Targeting the undruggable: a first-in-class inhibitor of the HIF-2 transcription factor	\$899,412	IIRA	2.3
28	RP160145	The University of Texas M. D. Anderson Cancer Center	Early Detection of Ovarian Cancer with Tumor Associated Proteins and Autoantibodies	\$1,497,595	IIRAP	2.3
29	RP160013	The University of Texas M. D. Anderson Cancer Center	Visualizing T-cell trafficking	\$900,000	IIRA	2.3
30	RP160019	The University of Texas M. D. Anderson Cancer Center	An Adaptive Personalized Clinical Trial using a Patient-Derived Xenograft Strategy to Overcome Ibrutinib Resistance in Mantle Cell	\$841,606	IIRA	2.3
31	RP160051	Texas A&M University System Health Science Center	Improving contrast for antibody-based tumor detection using PET	\$887,134	IIRA	2.3
32	RP160023	The University of Texas M. D. Anderson Cancer Center	Investigating the genetic and molecular mechanisms underlying RAS/ERK substrate network	\$900,000	IIRA	2.4
33	RP160211	The University of Texas Southwestern Medical Center	Novel tumorigenic mechanisms of the LKB1 tumor suppressor in endometrial and cervical cancer	\$896,653	IIRA	2.4

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
34	RP160319	The University of Texas Southwestern Medical Center	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast	\$884,315	IIRA	2.4
35	RP160124	The University of Texas Health Science Center at San Antonio	Chemoprevention of Colon Cancer by Anti-inflammatory Blockade Using Neem	\$899,617	IIRAP	2.4
36	RP160188	The University of Texas M. D. Anderson Cancer Center	Regulation of infiltration and function of tumor-resident CD8 T	\$828,060	IIRA	2.4
37	RP160255	The University of Texas Southwestern Medical Center	Structural and Functional Analyses of the Spindle Checkpoint	\$900,000	IIRA	2.5
38	RP160307	The University of Texas Southwestern Medical Center	Targeting Metastatic Pathways	\$900,000	IIRA	2.5
39	RP160517	The University of Texas M. D. Anderson Cancer Center	Exosomal DNA as a surrogate biomarker for early diagnosis and therapeutic stratification in pancreatic cancer	\$891,938	IIRA	2.5
40	RP160345	Baylor College of Medicine	Engineering T cells to ensure specificity for tumor cells and their environment	\$900,000	IIRA	2.5
41	RP160482	The University of Texas M. D. Anderson Cancer Center	Nanoparticle Targeted STAT3 Immune Expression	\$888,429	IIRA	2.6
42	RP160121	The University of Texas M. D. Anderson Cancer Center	Clinical Safety and Efficacy of Third party, fucosylated, cord blood derived regulatory T cells to prevent graft versus host disease	\$900,000	IIRA	2.6
43	RP160520	The University of Texas Southwestern Medical Center	Effect of Chest Radiation Therapy on Cardiomyocyte Turnover	\$897,570	IIRAP	2.6
44	RP160268	The University of Texas Southwestern Medical Center	DNA damage-induced small non-coding RNAs: mechanism and their role in cancer development	\$900,000	IIRA	2.7
45	RP160512	The University of Texas Health Science Center at San Antonio	Integrin-mediated IL-18 signaling in the prevention and treatment of inflammation-associated colorectal cancer	\$859,620	IIRA	2.7
46	RP160577	Baylor Research Institute	A novel function of Itch in controlling IL-17-induced inflammation in colon cancer	\$900,000	IIRA	2.7
47	RP160617	The University of Texas at Dallas	Optimizing therapeutic strategies against lung cancer using Multi-Modality	\$899,999	IIRA	2.7
48	RP160493	The University of Texas Southwestern Medical Center	Characterization and pharmacological targeting of the oncogenic activity of Jumonji	\$899,997	IIRA	2.8
49	RP160054	Baylor College of Medicine	The CTC Circulator Phenotype: Insights into Mechanisms of Breast Cancer Dormancy	\$884,332	IIRA	2.9
50	RP160235	The University of Texas Health Science Center at Houston	Regulation of tumor aggressiveness and immune suppression in lung adenocarcinoma	\$900,000	IIRA	2.9

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
51	RP160150	The University of Texas M. D. Anderson Cancer Center	Radiogenomic Screen to Identify Novel Proliferation-associated Glioblastoma Genomic Therapeutic Targets: Discovery and Mechanistic Validation Study	\$897,627	IIRA	3.0
52	RP160460	Rice University	High resolution imaging for early and better detection of bladder	\$873,765	IIRAP	3.0
53	RP160471	The University of Texas M. D. Anderson Cancer Center	Identifying new epigenetic vulnerabilities in pancreatic	\$900,000	IIRA	3.1
54	RP160462	Baylor College of Medicine	Systematic identification of small molecule inhibitors that manipulate telomerase activities	\$898,288	IIRA	3.2
55	RP160035	Baylor College of Medicine	The role of Prdm16 and histone H3 lysine 9 methyltransferase complex in MDS	\$872,157	IIRA	3.2

\*RP160237 - The peer review panel recommended reducing the budget to \$300,000 per year for 3 years for a total of \$900,000 based on the scope and depth of the work proposed.

\*\*RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to \$300,000 per year for 3 years for a total of \$900,000. The final score was based on revised scope with full deletion of Aim 4.

\*\*\*RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to \$300,000 per year for 4 years for a total of \$1,200,000.

### Academic Research Recruitment Grant Award Recommendations

Rank	App ID	Candidate	Organization/Company	Mech.	Budget Requested	Overall Score
1	RR160019	Dung-fang Lee	The University of Texas Health Science Center at Houston	RFT	\$2,000,000	1.0
2	RR160020	Wei Yang	The University of Texas at Austin	REI	\$6,000,000	1.0
3	RR160022	Andrew D. Rhim	The University of Texas M. D. Anderson Cancer Center	RRS	\$4,000,000	1.8
4	RR160017	Zhijie Liu	The University of Texas Health Science Center at San Antonio	RFT	\$2,000,000	2.5
5	RR160021	Nidhi Sahni	The University of Texas M. D. Anderson Cancer Center	RFT	\$2,000,000	2.5

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

REI = Recruitment of Established Investigators

RRS = Recruitment of Rising Stars

**Product Development Research Award Recommendation –**

The PIC unanimously recommends approval of one product development grant proposal totaling \$20,000,000. The recommended grant proposal was submitted in response to the New Company Product Development Award Request for Applications. The Product Development Council (PDRC) recommended one application to the PIC. The PDRC provided its recommendation to the presiding officers on October 26, 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 ;
- strengthen and enhance fundamental science in cancer research;
- Ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional (the PIC chose this factor for Established Company Awards);
- address federal or other major research sponsors’ priorities in emerging scientific or technology fields in the area of cancer prevention, or cures for cancer;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;
- have a demonstrable economic development benefit to this state;
- expedite 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 Recommendation**

<b>Rank</b>	<b>Application ID</b>	<b>Company Name</b>	<b>Project</b>	<b>Requested Budget</b>	<b>Overall Score</b>
1	DP150127	Ruga Corporation	Engineered AXL Decoy Receptor for Treatment of AML & Solid Tumors	\$20,000,000	2.2

## **Prevention Award Recommendations –**

The PIC unanimously recommends approval of 12 prevention grant proposals totaling \$13,247,742. 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, Cancer Prevention Promotion and Navigation to Clinical Services, Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions; and Evidence-Based Cancer Prevention Services Request for Applications. The PIC followed the recommendations made by the Prevention Review Council (PRC), including deferring two applications to a future PIC meeting. The PRC provided the prioritized list of recommendations for the prevention awards to the presiding officers on October 27, 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 prevention 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**

See pages 9-18 for the prevention grant award recommendations.

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160049	CCE-EBP	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	\$1,500,000	1.9			1	
PP160047	CCE-EBP	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and cervical cancer among Latinas	Savas, Lara S	The University of Texas Health Science Center at Houston	\$1,387,005	2.7	Steps that will be taken to assess actual # of screenings and vaccinations for participants in educational sessions are not explained. It appears that only women completing the surveys will be followed. Evaluation of outcomes for all	Changes not recommended-PRC reviewed peer review comments and determined those comments did NOT impact decision to recommend or impact rank order	2	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							participants is not provided, only provided for women completing surveys. Budget is unclear about number of screenings that will be paid for; number of financially supported screening isn't clearly stated.			
PP160042	EBP	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra-Medina, Deborah	The University of Texas Health Science Center at San Antonio	\$1,295,493	2.8	Outcomes evaluation doesn't have baseline and % increase noted. A highly intensive program is being implemented and the high cost is a barrier. If the cost is reduced, the	changes not recommended- PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	3	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							applicability of the proposed approach may be enhanced. Reviewers would like the applicants to clarify why the increase in the budget from the previous grant to this grant. Why has the per person cost increased so much?			
PP160032	PN	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese	Chen, Lei-Shih	Texas A&M University	\$399,993	3.0	Findings from this study should be applied to follow-up treatment for the participants. Plans for this are lacking and should be provided.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	4	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
		Americans in Texas								
PP160056	PN	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundation	\$379,698	3.0	Should be clarified that \$25 gift card is not being offered to change the behavior of the participants.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	5	
PP160010	EBP	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,409,909	3.1	Ask applicants why they do not plan to vaccinate young adults on college campuses. In addition, students	changes not recommended-PRC reviewed peer review comments and determined they did not impact	6	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							could be used to help with recruitment	decision to recommend or impact rank order		
PP160048	DI	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	\$300,000	3.1			7	
PP160023	EBP-CRC	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$2,299,753	3.3	Recommendation was made in previous application that providing FIT isn't evidence-based for people who are at significant risk for CRC; this isn't consistent with ACS guidelines. Ask how they came	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	8	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							up with \$275/colonoscopy			
PP160036	CCE-EBP	Establishing a Comprehensive Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Association	\$1,101,986	3.3	Request that the applicant provides a leadership plan that includes input from the three communities being targeted: Vietnames, Korean, and Filipino	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	9	
PP160027	EBP	Improving Service Delivery to Cancer Survivors in	Foxhall, Lewis E	The University of Texas M. D. Anderson	\$1,374,127	3.5	Not clear how project will add to what is already happening in clinic. This is a large, complex project and not clear how	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to	10	Recommended out of score order above one with higher score due to

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
		Primary Care Settings		Cancer Center			it will be managed on a daily basis. Budget is weak and justification for some of the positions is lacking	recommend or impact rank order		ROI and cancer type
PP160051	DI	Dissemination of an Evidence-Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez, Maria E	The University of Texas Health Science Center at Houston	\$299,778	3.6	List of current awards doesn't specify PD participation; it should be verified that PD isn't overcommitted. Budget seems somewhat personnel heavy and accounts for a large majority of overall costs; careful review of personnel and their exact roles and responsibilities and whether or not	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	11	Recommended out of score order above one with higher score due to type of program

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							any of the services are duplicative may be warranted.			
PP160011	CCE-EBP	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson, Gail E	The University of Texas Health Science Center at San Antonio	\$1,500,000	2.7			12	Recommended but ranked out of score order due to 1) ROI may be limited; large numbers need to be screened to identify at risk pop.

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160046	EBP	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in high-risk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	\$1,499,668	2.2			13	Recommended but out of score order due to 1) geography-several HPV grants in Harris county, 2) ROI-costs for education vs services
PP160033	CCE-EBP	Increasing cancer control behaviors among the underserved: A collaboration with Texas 2-1-1 programs	Fernandez, Maria E	The University of Texas Health Science Center at Houston	\$1,499,989	2.4			14	Recommended but out of score order due to 1) geography-several HPV grants in Harris county, 2) cancer type-availability of breast and cervical services 3) ROI-costs for

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
										education vs services
				Initial funding (Rank #1-12)	\$13,247,742					
				(Rank #13+14)	\$2,999,657					
				2nd funding	\$16,247,399					



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

---

---

**MEMORANDUM**

---

---

**To:** OVERSIGHT COMMITTEE MEMBERS  
**From:** VINCE BURGESS, CHIEF COMPLIANCE OFFICER  
**Subject:** COMPLIANCE CERTIFICATION – NOVEMBER 2015 AWARDS  
**Date:** NOVEMBER 04, 2015

---

**Summary and Recommendation:**

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

- Recruitment of First-Time, Tenure-Track Faculty Members
- Recruitment of Established Investigators
- Recruitment of Rising Stars
- Individual Investigator Research Awards
- Individual Investigator Research Awards for Computational Biology
- Individual Investigator Research Awards for Cancer in Children and Adolescents
- Individual Investigator Research Awards for Prevention and Early Detection
- Research Training Awards
- New Company Product Development Awards
- Evidence-Based Prevention Services
- Competitive Continuation/Expansion-Evidence-Based Prevention Services
- Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition
- Cancer Prevention Promotion and Navigation to Clinical Services
- Dissemination of CPRIT-funded Cancer Prevention and Control Interventions

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: Established Company Product Development Awards 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." Texas Health & Safety Code § 102.051(c) and (d).

CPRIT uses a compliance pedigree process to formally document compliance for the grant award process. The compliance pedigree tracks the grant application as it moves through the review process and documents compliance with applicable laws and administrative rules. A compliance pedigree is created for each application; the information related to the procedural steps listed on the pedigree is entered and attested to by 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 four applications were received in response to the Recruitment of First-Time, Tenure Track Faculty members RFA, one application was received for the Recruitment of Established Investigators RFA, and one application was received for the Recruitment of Rising Starts RFA. In response to the academic, non-recruitment RFAs, CPRIT received 504 applications. Six applications were administratively withdrawn prior to Peer Review. In addition, based on the scores of a preliminary evaluation, 211 academic, non-recruitment applications did not move forward for discussion at the in-person peer review phase. I reviewed the application pedigrees for the six recruitment applicants and 287 academic research, non-recruitment applications that underwent peer review. It should be noted that one academic research, non-recruitment application was voluntarily withdrawn by the applicant during the Peer Review process.*

*All academic research RFAs were posted in the Texas Register and all applications were submitted through CARS. Three applicants requested an extension to submit applications past the deadline. The program officer determined that good cause supported two requests and the deadline was extended. One application was denied an extension. None of the applications that requested an extension were recommended for a grant award.*

Product Development Research:

*Ten applications were received in response to the New Company RFA, five applications were received for the Company Relocation RFA, and one application was received in response to the Established Company RFA. Of the applications submitted for New Company awards, one application was administratively withdrawn prior to primary reviewer assignment. 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. One applicant requested an extension to submit the application after the deadline. The program officer determined that good cause supported the request and the deadline was extended. The application that received the extension was not recommended for a grant award.*

### Prevention:

*Six applications were received in response to the Evidence-Based Prevention Services RFA, six applications were received in response to the Competitive Continuation/Expansion-Evidence Based Cancer Prevention Services, one application was received for the Evidence-Based Prevention Services-Colorectal Cancer Prevention Coalition RFA, five applications were received for the Cancer Prevention Promotion and Navigation to Clinical Services RFA, and two were received for the Dissemination of CPRIT-funded Cancer Prevention and Control Interventions RFA. A total of two applications withdrew before review – one was withdrawn administratively and one was withdrawn by the applicant. The RFAs were published in the Texas Register and all applications were submitted through CARS. One applicant requested an extension to submit the application after the deadline. The program officer determined that good cause supported the request and the deadline was extended. The application that received the extension was not recommended for a grant award.*

### **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 whether to administratively withdraw the application. Recruitment grant applications are assigned to the Scientific Review Council members for peer review. All other academic research, product development research, and prevention applications are assigned to their respective peer review panels. Prior to distribution of the applications, reviewers are given summary information about the applicant, including the Project Director and collaborators. Reviewers must sign a conflict of interest agreement and confirm that they do not have a conflict of interest with the application before they are provided with the full application.

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

*As previously mentioned, six applications were administratively withdrawn and one was withdrawn by the applicant during the 16.1 academic research cycle. Of the applications received in response to 16.1 prevention RFAs, one was administratively withdrawn and one was withdrawn by the applicant. One application was administratively withdrawn during the 15.4 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, third-party observer reports, and post-review peer reviewer statements. Sign out sheets are used to document when a reviewer with a conflict of interest associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application. A conflict of interest was declared for one recruitment application reviewed by the SRC. The reviewer disengaged from the conference call and did not participate in the discussion of the application.*

*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 conflict of interest statements (COIs), third-party observer reports, and sign out sheets. All declared COIs left the room or disengaged from the conference call and did not participate in the discussion of relevant application(s).*

*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 Review Council meeting on October 23, 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 (PDRC) recommends awards after due diligence to the PIC. I have verified from SRA documentation that those reviewers with conflicts did not participate in review of applications for which they indicated a conflict of interest.*

*I also reviewed and confirmed that the post review conflict of interest statements were signed by peer review members as well as the seven PDRC members that attended the Review Council meeting on October 12, 2015.*

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 also reviewed and confirmed that the post review conflict of interest statements were signed by peer review members as well as the three PRC members that attended the Review Council meeting on October 23, 2015.*

**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. 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. 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 for example, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.*

*The SRC met on October 23, 2015 to consider the applications recommended by the peer review panels following their meetings that were held on September 29 – October 7, 2015. After considering success rates across panels, the SRC decided to reduce success rates in four of the panels to fall in line with the other three panels. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding.*

*Product Development Research:*

*For this cycle, three applications went through due diligence. The Product Development Review Council recommended one of those three 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 November 3, 2015, PIC meeting as an observer and confirm that the PIC review process complied with CPRIT's statute and administrative rules. The PIC considered 75 applications; 73 were recommended to move forward to the Oversight Committee. Two applications were recommended to be deferred until a subsequent PIC meeting. A review of the CEO affidavits confirms that such affidavits were executed and provided for each Grant Application recommendation.*



# Academic Research

---

## Recommendation

### Items

Academic Research Awards Summary

Review Council Chairman Letter –  
Individual Investigators & Training Awards

Review Council Chairman Letter –  
Recruitment Awards







---

CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

---

---

MEMORANDUM

---

**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** MARGARET KRIPKE, PH.D.  
**SUBJECT:** FY16, CYCLE 1 RESEARCH AWARDS  
**DATE:** NOVEMBER 3, 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 five scientific research award mechanism Request for Applications (RFAs): Individual Investigator Research Award (RFA R-16-IIRA-1), Individual Investigator Research Award for Computational Biology (RFA R-16-IIRACB-1), Individual Investigator Research Award for Cancer in Children and Adolescents (RFA R-16-IIRACCA-1), Individual Investigator Research Award for Prevention and Early Detection (RFA R-16-IIRAP-1), and Research Training Awards (RFA R-16-RTA-1). Five hundred and four applications were received in total for all mechanisms. Six applications were administratively withdrawn, and 498 were reviewed (IIRA – 347, IIRACB – 50, IIRACCA – 44, IIRAP – 44, and RTA – 13 [7 new and 6 renewal]). Fifty-five applications are being recommended for funding, for a combined amount of \$62,761,270.

**Individual Investigator Research Award (RFA R-16-IIRA-1)**

Applications Receiving Preliminary Evaluation: 347  
Applications Receiving Full Review: 135  
Applications Recommended: 39  
Total Funding Request: \$34,744,442

The aim of this RFA is to support innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. The goal of awards made in response to this RFA is to fund exceptionally innovative research projects with great potential impact that are directed by a single investigator. Areas of interest include laboratory research, translational studies, and/or clinical investigations. The degree of relevance to cancer research is an important criterion for evaluation of projects for funding. Awards are made in the amount of up to \$300,000 per year for three years for a maximum of \$900,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. Due to the large number of applications submitted for consideration, CPRIT elected to use a preliminary evaluation process to conduct an initial screening of the proposals. In the preliminary evaluation stage, the assigned reviewers focus on a subset of material presented in the application— the Abstract and

Significance, Layperson Summary, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest or have been judged to offer only modest contributions to the field of cancer research at the preliminary evaluation stage are not considered for further review.

After preliminary review, 211 (61%) of the applications were eliminated from further consideration. The remaining 136 applications were subjected to full review (one application was withdrawn after preliminary evaluation and only received a partial full review leaving a total of 135 receiving a full review), and 42 were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 39 of the 42 to be considered for approval by the Oversight Committee.

Questions considered by reviewers included the following: Will the results of this research significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for cancer patients? Is the application innovative? Does the project develop new technologies, methods, tools, or resources for cancer research or address important under-explored areas? Will the project lead to truly substantial advances in the field? Is the research plan supported by sufficient preliminary data or scientific rationale? Are the methods appropriate? Does the Principal Investigator demonstrate creativity and sufficient expertise? Does the proposed research have a high degree of relevance to cancer research?

#### **Individual Investigator Research Award for Computational Biology (RFA R-16-IIRACB-1)**

Applications Receiving Preliminary Evaluation:	N/A
Applications Receiving Full Review:	50
Applications Recommended:	1
Total Funding Request:	\$392,779

The aim of this RFA is to support innovative mathematical or computational research projects addressing questions that will advance our knowledge in any aspect of cancer. Areas of interest include data analysis of cellular pathways, microarrays, cellular imaging, cancer imaging, or genomic, proteomic, and metabolomic databases; descriptive mathematical models of cancer, as well as mechanistic models of cellular processes and interactions and use of artificial intelligence approaches to build new tools for mining cancer research and treatment databases. Awards are made in the amount of up to \$150,000 per year for three years for a maximum of \$450,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. IIRACB applications did not go through the preliminary review process. Three applications were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 1 of the 3 to be considered for approval by the Oversight Committee.

Questions considered by reviewers included the following: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the project innovative? Does the project 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 underexplored 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?

**Individual Investigator Research Award for Cancer in Children and Adolescents (RFA R-16-IIRACCA-1)**

Applications Receiving Preliminary Evaluation:	N/A
Applications Receiving Full Review:	44
Applications Recommended:	5
Total Funding Request:	\$6,105,638

The aim of this RFA is to support innovative research projects addressing questions that will advance our knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. The goal of these awards is to produce outcomes that will reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. The subject of applications addressed: the causes of cancer in children and adolescents, including genetic factors or prenatal exposure to environmental agents; identification of risk factors for cancer development; new methods for diagnosing cancers in children and/or adolescents; development of new therapies, including targeted therapies, immunotherapies, and new drugs; identification of patients at risk of developing late effects of cancer treatment; and improvements in quality of life for survivors of childhood and adolescent cancers. Awards are made in the amount of up to \$500,000 per year for four years for a maximum of \$2,000,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. IIRACCA applications did not go through the preliminary review process. Six applications were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 5 of the 6 to be considered for approval by the Oversight Committee.

Questions considered by reviewers included the following: Will the results of this research significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for cancer patients? Is the application innovative? Does the project develop new technologies, methods, tools, or resources for cancer research or address important under-explored areas? Will the project lead to truly substantial advances in the field? Is the research plan supported by sufficient preliminary data or scientific rationale? Are the methods appropriate? Does the Principal Investigator demonstrate creativity and sufficient expertise? Does the proposed research have a high degree of relevance to cancer research? Does the proposed research address cancer in children or adolescents? Is it likely to make an impact on these diseases?

**Individual Investigator Research Award for Prevention and Early Detection (RFA R-16-IIRAP-1)**

Applications Receiving Preliminary Evaluation:	N/A
Applications Receiving Full Review:	44
Applications Recommended:	6
Total Funding Request:	\$6,552,003

The aim of this RFA is to support innovative research projects addressing questions that will advance our knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. The goal of these awards is to support activities that will reduce the burden of cancer in the near or long

term. The subject of applications addressed: environmental carcinogenesis, including high-throughput methods for carcinogen detection and identification of carcinogens and their mechanisms of action; the role of microbial agents in cancer causation; cancer epidemiology; identification of populations at high risk of developing cancer; cellular and molecular alterations leading to development of precancerous lesions; approaches to prevent progression of early lesions; methods for early detection of cancer; development and testing of intervention strategies to increase access to and improve recently endorsed screening technologies for cancer; cancer-focused health services/outcomes or patient-centered outcomes research; and development and adaptation of novel interventions for effective and efficient delivery of cancer prevention and screening services. Awards are made in the amount of up to \$300,000 in total costs per year for up to 3 years for laboratory and clinical research for a maximum of \$900,000, and up to \$500,000 in total costs per year for up to 3 years for population-based research for a maximum of \$1,500,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. IIRAP applications did not go through the preliminary review process. Nine applications were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 6 of the 9 to be considered for approval by the Oversight Committee.

Questions considered by reviewers included the following: Will the results of this research significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for cancer patients? Is the application innovative? Does the project develop new technologies, methods, tools, or resources for cancer research or address important under-explored areas? Will the project lead to truly substantial advances in the field? Is the research plan supported by sufficient preliminary data or scientific rationale? Are the methods appropriate? Does the Principal Investigator demonstrate creativity and sufficient expertise? Does the proposed research have a high degree of relevance to cancer research? Does the proposed research have a high degree of relevance to cancer prevention research or early detection?

### **Research Training Awards (RFA R-16-RTA-1)**

Applications Receiving Preliminary Evaluation:	N/A
Applications Receiving Full Review:	13 (6 renewal and 7 new)
Applications Recommended:	4 (3 renewal and 1 new)
Total Funding Request:	\$14,966,408

The aim of this RFA is to support integrated institutional research training programs to support promising individuals who seek specialized training in the area of cancer research. CPRIT expects institutions to provide trainees with broad access to research opportunities across disciplinary and departmental lines and to maintain high standards for intellectual rigor and creativity. Applications were accepted for new and renewal projects with applicants being able to submit one application for a basic science training program and one applications for a prevention training program. Awards are made in the amount of up to \$800,000 per year for five years for a maximum of \$4,000,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. IIRAP applications did not go through the preliminary review process. Five applications were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 4 of the 5 to be considered for approval by the Oversight Committee.

Questions considered by reviewers for new programs included the following: What is the likelihood that the training program will serve as a sound foundation to enhance a supported trainee's potential for, and commitment to, a productive, independent scientific research career in a cancer-related field? Will the training plan provide trainees with individualized and supervised experiences that will enable them to develop the research skills needed to be independent researchers or physician-scientists? Is the training plan customizable for students from diverse academic backgrounds and differing educational philosophies? Do the PI and mentors have excellent research qualifications and track records of mentoring that are appropriate for the proposed training program? Are high-quality individuals routinely recruited at the applicant institution's existing training programs? Are the qualifications and interests of these potential trainees appropriate for the training program described by the applicant institution? Are there sufficient numbers of highly meritorious potential trainees to fill the slots requested? Is there a plan to enhance the diversity of trainees by recruiting from underrepresented groups? Is there a high-quality institutional environment for the scientific development of trainees? Is there appropriate institutional commitment to fostering training as investigators or physician-scientists?

Questions considered by reviewers for existing programs included the following: Does the proposed continuation of the program demonstrate a high likelihood of success based on the initial program's results and outcomes? Has the applicant sufficiently described results and findings of the previously funded application? What is the likelihood that the training program will continue to serve as a sound foundation to enhance a supported trainee's potential for, and commitment to, a productive, independent scientific research career in a cancer-related field? Has the program recruited underrepresented minority trainees? Has the training plan provided, and will the plan continue to provide, trainees with individualized and supervised experiences that will enable them to develop the research skills needed to be independent researchers or physician-scientists? Is the training plan customizable for students from diverse academic backgrounds and differing educational philosophies? Do the PI and mentors have excellent research qualifications and track records of mentoring that are appropriate for the proposed training program? Have high-quality individuals been recruited into the training programs? Are the qualifications and interests of these potential trainees appropriate for the training program described by the applicant institution? Have there been sufficient numbers of highly meritorious candidates to fill the available slots? Have efforts been made to enhance the diversity of trainees by recruiting from underrepresented groups? Has appropriate progress been demonstrated by trainees? Is there a high-quality institutional environment for the scientific development of trainees? Is there appropriate institutional commitment to fostering training as investigators or physician-scientists?

### **Overall SRC and PIC Research Program Recommendation**

During the SRC discussion, it was determined that the success rates (percentage of the number recommended/number reviewed) for four panels were much higher than the rates for the other three panels and higher than the historical approval rates. It was suggested that these four panels reduce their success rates to fall in line with the other panels, and all chairs agreed to the scoring adjustments. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding.

After determining to adjust the success rates, the SRC voted to recommend 55 of the 65 applications that were presented by the Peer Review Panels and to accept any 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 November 3, 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.



---

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

---

---

### MEMORANDUM

---

**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** MARGARET KRIPKE, PH.D.  
**SUBJECT:** FY16 RECRUITMENT AWARDS, CYCLE REC 16.2 AND REC 16.3  
**DATE:** NOVEMBER 3, 2015

---

The applications recommended for funding by the CPRIT Scientific Review Council (SRC) have been reviewed and approved by the Program Integration Committee (PIC). The applications recommended for funding have been reviewed and approved by the CPRIT Scientific Review Council (SRC). 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 for Recruitment Cycles REC 16.2 and 16.3. Two applications were received for REC 16.2 (RFT - 2). Four applications were received for REC 16.3 (REI-1, RFT-2, and RRS-1). All six applications were reviewed, and no applications were administratively rejected for ineligibility. Five applications in total were recommended for funding by the SRC for both cycles. Three applications for Recruitment of First-Time, Tenure-Track Faculty Members, one for Recruitment of Established Investigators, and one for Recruitment of Rising Stars have been recommended for a combined amount of \$16,000,000.

#### **Recruitment of Established Investigators (RFA R-16-REI)**

Applications Reviewed:	1
Applications Recommended:	1
Total Funding Request:	\$6,000,000

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?

**Wei Yang, Ph.D.**, is an internationally known structural biologist and member of the National Academy of Sciences who is being recruited to the Department of Molecular Biosciences in the College of Natural Sciences at The University of Texas at Austin from National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Diseases. Dr. Yang has been a leader in three areas of molecular biology that relate to cancer: mismatch repair, DNA double-strand break repair, and error-prone DNA polymerases. Within each field she has set the bar for the highest achievements in structural biology, including solving the first structures of several classes of novel DNA repair enzymes. Recently, she pioneered the new field of enzyme catalysis within crystals, enabling real-time molecular movies of enzymatic reactions with DNA polymerases to visualize transition states for the first time. Dr. Yang plans an ambitious range of new projects at UT-Austin that will use cryo-electron microscopy, single-molecule fluorescent technologies, and small molecule screening to take her cancer-related interests to the next level.

#### **Recruitment of Rising Stars (RFA R-16-RRS)**

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

The aim of this RFA is to recruit outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research. Award: Up to \$4 million over a period of 5 years.

These applications were evaluated and scored by the SRC to determine the candidate's 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 extraordinary accomplishments during his or her initial years of independent research? Does the candidate show promise of making important contributions with significant impact to basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated strong self-direction, motivation, and commitment for transformative cancer research?

**Andrew D. Rhim, M.D.**, is being recruited from the University of Michigan, Department of Internal Medicine/Gastroenterology and Cancer Center to The University of Texas M.D. Anderson Cancer Center, Department of Gastroenterology in the Division of Internal Medicine. Dr. Rhim is an exceptional basic scientist that was selected among 19 outstanding candidates to receive this year's MDACC Physician Scientist Award based on the strength of his achievements and potential to be a leader in cancer research. He published paradigm-shifting first-author papers in Cell and Cancer Cell

and obtained highly competitive peer reviewed grants from NIH, Doris Duke Charitable Foundation, and American Academy of Cancer Research. In recognition of past and current research, Dr. Rhim was recognized with the 2014 Young Physician Scientist Award from the American Society of Clinical Investigation. Dr. Rhim is also an accomplished translational researcher, evidenced by multiple ongoing clinical trials of novel biomarkers of subclinical pancreatic cancer. Dr. Rhim's expertise will be utilized to establish the only high risk pancreatic cancer clinic in the State of Texas and to build a robust and innovative program focused on endogenous DNA and RNA editing in cancer. Dr. Rhim is an outstanding physician scientist who will bring enormous strength to the MDACC burgeoning clinical and basic research programs in pancreatic cancer.

### **Recruitment of First-Time, Tenure-Track Faculty Members (RFA R-16-RFT)**

Applications Reviewed:	4
Applications Recommended:	3
Total Funding Request:	\$6,000,000

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?

Three First-Time, Tenure-Track Faculty Member Award candidates are being recommended for recruitment: one to The University of Texas Health Science Center at Houston, one to The University of Texas Health Science Center at San Antonio, and one The University of Texas M.D. Anderson Cancer Center. Listed below is the candidate with his associated expertise. Each has had outstanding training, an excellent record of achievement, and a strong commitment to cancer research.

- **Dung-fang Lee, Ph.D.**, (UTHSC-H) – osteosarcoma, p53 systems biology, stem-cell biology, iPSC technology, Li-Fraumeni syndrome, genome editing, cell signaling, tumor suppressor genes
- **Zhijie (Jason) Liu, Ph.D.**, (UTHSC-SA) - breast cancer, estrogen receptor, transcription regulation, hormone resistance
- **Nidhi Sahni, Ph.D.**, (UTMDA) - Cancer Sys Biology, Molecular Genetics, Bioinformatics/Computational Biology, Interactive Networks, Cancer Therapeutics, Oncology Signaling Pathways, Proteomics, Coding/Non-Coding Genomic Variation

San Diego

**Ludwig Institute for  
Cancer Research Ltd**

October 29, 2015

**Richard D. Kolodner  
Ph.D.**

Director, San Diego Branch

Head, Laboratory of  
Cancer Genetics  
San Diego Branch

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

[rkolodner@ucsd.edu](mailto: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

Mr. Pete Geren  
Oversight Committee Presiding Officer  
Cancer Prevention and Research Institute of Texas  
Via email to [pgcprit@sidrichardson.org](mailto:pgcprit@sidrichardson.org)

Mr. Wayne R. Roberts  
Chief Executive Officer  
Cancer Prevention and Research Institute of Texas  
Via email to [wroberts@cprit.state.tx.us](mailto:wroberts@cprit.state.tx.us)

Dear Mr. Geren and Mr. Roberts,

In reviewing the list of recommended applications, we were made aware of one minor error in scoring. Application RP160268 was assigned a score of 2.6 in the list, and the actual score should be 2.7. This recommended application was initially placed in row 41 and now appears in row 44. The change of score is reflected in the attached revised list. This does not change the outcome of the SRC recommendation.

Sincerely yours,



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

San Diego

**Ludwig Institute for  
Cancer Research Ltd**

October 29, 2015

**Richard D. Kolodner  
Ph.D.**

Director, San Diego Branch

Head, Laboratory of  
Cancer Genetics  
San Diego Branch

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

[rkolodner@ucsd.edu](mailto: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

Mr. Pete Geren  
Oversight Committee Presiding Officer  
Cancer Prevention and Research Institute of Texas  
Via email to [pgcprit@sidrichardson.org](mailto:pgcprit@sidrichardson.org)

Mr. Wayne R. Roberts  
Chief Executive Officer  
Cancer Prevention and Research Institute of Texas  
Via email to [wroberts@cprit.state.tx.us](mailto:wroberts@cprit.state.tx.us)

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the **Individual Investigator Research Awards (IIRA)**, **Individual Investigator Research Awards for Computational Biology (IIRACB)**, **Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)**, **Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)**, **Research Training Awards (RTA)**, and **Research Training Awards - Renewal (RTA-R)** grant mechanisms. The SRC met on Friday, October 23, 2015 to consider the applications recommended by the peer review panels following their meetings that were held September 29 – October 7, 2015. During the SRC discussion, it was determined that the success rates (percentage of the number recommended/number reviewed) for four panels were much higher than the rates for the other three panels and higher than the historical approval rates. It was suggested that these four panels reduce their success rates to fall in line with the other panels, and all chairs agreed to the scoring adjustments. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded after adjustments were made based on success rates.

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 three grant applications. These adjustments with justifications are listed at the end of the list of recommended projects. The total amount for the applications recommended is \$62,761,270.

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	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
1	RP160157	The University of Texas Southwestern Medical Center	Cancer Intervention and Prevention Discoveries Program	\$3,993,250	RTA-Renewal	1.2
2	RP160192	Baylor College of Medicine	Decoding Cellular Heterogeneity of Malignant Glioma	\$899,701	IIRA	1.3
3	RP160451	Baylor College of Medicine	Protein Truncation Mutations in WIP1: Effects on Cancer and Hematopoiesis	\$900,000	IIRA	1.5
4	RP160180	The University of Texas Southwestern Medical Center	Development of Therapeutics Targeting Truncated Adenomatous Polyposis Coli (APC) as a Novel Prevention and Intervention Strategy for Colorectal Cancer	\$900,000	IIRA	1.8
5*	RP160237	The University of Texas M. D. Anderson Cancer Center	A novel epigenetic reader as therapeutic target in MLL-translocated pediatric leukemias	\$900,000	IIRACC A	1.8
6	RP160283	Baylor College of Medicine	Baylor College of Medicine Comprehensive Cancer Training Program	\$3,986,268	RTA-Renewal	1.9
7	RP160487	The University of Texas Health Science Center at San Antonio	Cytokine signaling in Ewing sarcoma	\$1,200,000	IIRACC A	1.9
8	RP160030	The University of Texas Southwestern Medical Center	A Randomized Controlled Trial (RCT) of Patient Navigation for Lung Cancer Screening in an Urban Safety-Net System	\$1,492,616	IIRAP	1.9
9	RP160384	Baylor College of Medicine	Promoting The Functions of Memory T cells for Adoptive T cell Therapy	\$887,676	IIRA	1.9
10	RP160318	The University of Texas Southwestern Medical Center	Role of Long Non-Coding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions	\$886,652	IIRA	2.0

11	RP160589	Texas AgriLife Research	Arylhydrocarbon receptor mediated modulation of colorectal cancer by microbiota metabolites	\$890,840	IIRAP	2.0
12**	RP160190	The University of Texas Southwestern Medical Center	Pediatric Radiation Oncology with Movie Induced Sedation Effect (PROMISE)	\$900,000	IIRACC A	2.0
13	RP160497	The University of Texas M. D. Anderson Cancer Center	Amplified gold nanoparticle-mediated radiosensitization of tumors	\$899,309	IIRA	2.0
14	RP160229	The University of Texas M. D. Anderson Cancer Center	Imaging-based quantitative analysis of vascular perfusion and tissue oxygenation to improve therapy of hepatocellular carcinoma	\$885,901	IIRA	2.0
15	RP160169	The University of Texas Southwestern Medical Center	Molecular Mechanism of NLRP12-mediated Regulation of Colorectal Cancer	\$897,707	IIRA	2.1
16***	RP160249	The University of Texas Southwestern Medical Center	DIS3L2 in Childhood Wilms Tumor: Mechanism to Medicines	\$1,200,000	IIRACC A	2.1
17	RP160089	The University of Texas Southwestern Medical Center	Carbamoyl Phosphate Synthase-1: A new metabolic liability in non-small cell lung cancers	\$900,000	IIRA	2.1
18	RP160501	The Methodist Hospital Research Institute	De-Orphanizing TLX: Implications for Glioblastomas	\$878,969	IIRA	2.1
19	RP160622	The University of Texas Southwestern Medical Center	Computational live cell histology	\$392,779	IIRACB	2.1
20	RP160097	Baylor College of Medicine	Cancer Prevention Post-Graduate Training Program in Integrative Epidemiology	\$2,986,890	RTA	2.1
21	RP160015	The University of Texas Health Science Center at Houston	Collaborative Training of a New Cadre of Innovative Cancer Prevention Researchers	\$4,000,000	RTA-Renewal	2.1
22	RP160340	The University of Texas Southwestern Medical Center	The role of the Lats kinases in sarcomatoid renal cell carcinoma	\$899,598	IIRA	2.2
23	RP160183	The University of Texas M. D. Anderson Cancer Center	Exploiting molecular and metabolic dependencies to optimize personalized therapeutic approaches for melanomas	\$900,000	IIRA	2.2
24	RP160232	The University of Texas M. D. Anderson Cancer Center	Understanding Biological and Physical Factors Affecting Response to Proton Therapy to Improve its Clinical Effectiveness	\$879,362	IIRA	2.2
25	RP160022	Baylor College of Medicine	Role of Cohesin in Hematopoiesis and Myeloid Leukemia in Children with Down Syndrome	\$1,905,638	IIRACC A	2.2
26	RP160242	The University of Texas M. D. Anderson Cancer Center	Mechanisms and targeting strategies for SWI/SNF mutations in cancer	\$900,000	IIRA	2.3
27	RP160440	The University of Texas Southwestern Medical Center	Targeting the undruggable: a first-in-class inhibitor of the HIF-2 transcription factor	\$899,412	IIRA	2.3

San Diego

28	RP160145	The University of Texas M. D. Anderson Cancer Center	Early Detection of Ovarian Cancer with Tumor Associated Proteins and Autoantibodies	\$1,497,595	IIRAP	2.3
29	RP160013	The University of Texas M. D. Anderson Cancer Center	Visualizing T-cell trafficking	\$900,000	IIRA	2.3
30	RP160019	The University of Texas M. D. Anderson Cancer Center	An Adaptive Personalized Clinical Trial using a Patient-Derived Xenograft Strategy to Overcome Ibrutinib Resistance in Mantle Cell Lymphoma	\$841,606	IIRA	2.3
31	RP160051	Texas A&M University System Health Science Center	Improving contrast for antibody-based tumor detection using PET	\$887,134	IIRA	2.3
32	RP160023	The University of Texas M. D. Anderson Cancer Center	Investigating the genetic and molecular mechanisms underlying RAS/ERK substrate network	\$900,000	IIRA	2.4
33	RP160211	The University of Texas Southwestern Medical Center	Novel tumorigenic mechanisms of the LKB1 tumor suppressor in endometrial and cervical cancer	\$896,653	IIRA	2.4
34	RP160319	The University of Texas Southwestern Medical Center	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	\$884,315	IIRA	2.4
35	RP160124	The University of Texas Health Science Center at San Antonio	Chemoprevention of Colon Cancer by Anti-inflammatory Blockade Using Neem	\$899,617	IIRAP	2.4
36	RP160188	The University of Texas M. D. Anderson Cancer Center	Regulation of infiltration and function of tumor-resident CD8 T cells by IL-15	\$828,060	IIRA	2.4
37	RP160255	The University of Texas Southwestern Medical Center	Structural and Functional Analyses of the Spindle Checkpoint	\$900,000	IIRA	2.5
38	RP160307	The University of Texas Southwestern Medical Center	Targeting Metastatic Pathways	\$900,000	IIRA	2.5
39	RP160517	The University of Texas M. D. Anderson Cancer Center	Exosomal DNA as a surrogate biomarker for early diagnosis and therapeutic stratification in pancreatic cancer	\$891,938	IIRA	2.5
40	RP160345	Baylor College of Medicine	Engineering T cells to ensure specificity for tumor cells and their environment	\$900,000	IIRA	2.5
41	RP160482	The University of Texas M. D. Anderson Cancer Center	Nanoparticle Targeted STAT3 Immune Expression	\$888,429	IIRA	2.6
42	RP160121	The University of Texas M. D. Anderson Cancer Center	Clinical Safety and Efficacy of Third party, fucosylated, cord blood derived regulatory T cells to prevent graft versus host disease	\$900,000	IIRA	2.6
43	RP160520	The University of Texas Southwestern Medical Center	Effect of Chest Radiation Therapy on Cardiomyocyte Turnover	\$897,570	IIRAP	2.6
44	RP160268	The University of Texas Southwestern Medical Center	DNA damage-induced small non-coding RNAs: mechanism and their role in cancer development	\$900,000	IIRA	2.7

45	RP160512	The University of Texas Health Science Center at San Antonio	Integrin-mediated IL-18 signaling in the prevention and treatment of inflammation-associated colorectal cancer	\$859,620	IIRA	2.7
46	RP160577	Baylor Research Institute	A novel function of Itch in controlling IL-17-induced inflammation in colon cancer	\$900,000	IIRA	2.7
47	RP160617	The University of Texas at Dallas	Optimizing therapeutic strategies against lung cancer using Multi-Modality Imaging	\$899,999	IIRA	2.7
48	RP160493	The University of Texas Southwestern Medical Center	Characterization and pharmacological targeting of the oncogenic activity of Jumonji enzymes	\$899,997	IIRA	2.8
49	RP160054	Baylor College of Medicine	The CTC Circulator Phenotype: Insights into Mechanisms of Breast Cancer Dormancy	\$884,332	IIRA	2.9
50	RP160235	The University of Texas Health Science Center at Houston	Regulation of tumor aggressiveness and immune suppression in lung adenocarcinoma	\$900,000	IIRA	2.9
51	RP160150	The University of Texas M. D. Anderson Cancer Center	Radiogenomic Screen to Identify Novel Proliferation-associated Glioblastoma Genomic Therapeutic Targets: Discovery and Mechanistic Validation Study	\$897,627	IIRA	3.0
52	RP160460	Rice University	High resolution imaging for early and better detection of bladder cancer	\$873,765	IIRAP	3.0
53	RP160471	The University of Texas M. D. Anderson Cancer Center	Identifying new epigenetic vulnerabilities in pancreatic cancer	\$900,000	IIRA	3.1
54	RP160462	Baylor College of Medicine	Systematic identification of small molecule inhibitors that manipulate telomerase activities	\$898,288	IIRA	3.2
55	RP160035	Baylor College of Medicine	The role of Prdm16 and histone H3 lysine 9 methyltransferase complex in MDS	\$872,157	IIRA	3.2

\*RP160237 - The peer review panel recommended reducing the budget to \$300,000 per year for 3 years for a total of \$900,000 based on the scope and depth of the work proposed.

\*\*RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to \$300,000 per year for 3 years for a total of \$900,000. The final score was based on revised scope with full deletion of Aim 4.

\*\*\*RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to \$300,000 per year for 4 years for a total of \$1,200,000.

<b>Success Rate by Panel</b>		
Peer Review Panel	Success Rate	Score Cutoff
BCR1	10%	2.3
BCR2	11%	3.2
CB	9%	3.2
CPR	9%	2.4
CTCR/TCR	13%	2.7
ITI	11%	3.0

<b>Success Rate by Mechanism vs. Total Reviewed</b>		
Mechanism	Success Rate	# Recommended
IIRA	11%	39/347
IIRACB	2%	1/50
IIRACCA	11%	5/44
IIRAP	13%	6/44
RTA	14%	1/7
RTA-R	50%	3/6
Overall	11%	55/498

<b>Percent of Applications Recommended by Mechanism vs. Total Recommended</b>		
Mechanism	# Recommended	Percentage
IIRA	39/55	71%
IIRACB	1/55	2%
IIRACCA	5/55	9%
IIRAP	6/55	11%
RTA	1/55	2%
RTA-R	3/55	5%
Overall	55/55	100%

San Diego

Ludwig Institute for  
Cancer Research Ltd

October 26, 2015

Richard D. Kolodner  
Ph.D.

Director, San Diego Branch

Head, Laboratory of  
Cancer Genetics  
San Diego Branch

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

Mr. Pete Geren  
Oversight Committee Chair  
Cancer Prevention and Research Institute of Texas  
Via email to [pgcpnit@sidrichardson.org](mailto:pgcpnit@sidrichardson.org)

Mr. Wayne R. Roberts  
Chief Executive Officer  
Cancer Prevention and Research Institute of Texas  
Via email to [wroberts@cprnit.state.tx.us](mailto:wroberts@cprnit.state.tx.us)

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its list of recruitment grant recommendations. The SRC met on Monday, October 19, 2015 to consider the applications submitted to CPRIT under the **Recruitment of Established Investigator, Recruitment of Rising Stars, and Recruitment for First-Time, Tenure Track Faculty Members** Request for Applications for Recruitment Cycles REC 16.2 and 16.3. 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. There were no changes to funding amounts, goals, timelines, or project objectives requested by other applicants. The total amount for the applications recommended is \$16,000,000.

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	Candidate	Organization/Company	Mech.	Budget Requested	Overall Score
1	RR160019	Dung-fang Lee	The University of Texas Health Science Center at Houston	RFT	\$2,000,000	1.0
2	RR160020	Wei Yang	The University of Texas at Austin	REI	\$6,000,000	1.0
3	RR160022	Andrew D. Rhim	The University of Texas M. D. Anderson Cancer Center	RRS	\$4,000,000	1.8
4	RR160017	Zhijie Liu	The University of Texas Health Science Center at San Antonio	RFT	\$2,000,000	2.5
5	RR160021	Nidhi Sahni	The University of Texas M. D. Anderson Cancer Center	RFT	\$2,000,000	2.5

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

REI = Recruitment of Established Investigators

RRS = Recruitment of Rising Stars

# Prevention

---

## Recommendation

### Items

Prevention Awards Summary

Review Council Chairman Letter







CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

---

---

MEMORANDUM

---

---

**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** REBECCA GARCIA, PH.D., CHIEF PREVENTION AND COMMUNICATIONS OFFICER  
**SUBJECT:** PREVENTION GRANT RECOMMENDATIONS  
**DATE:** NOVEMBER 3, 2015

---

---

**Summary and Recommendation:**

The Program Integration Committee has reviewed the rank ordered list of applications submitted by the CPRIT Prevention Review Council and recommends awarding 12 projects totaling \$13,247,742. The grant recommendations are presented in five slates corresponding to the following grant mechanisms:

1. **Evidence-Based Cancer Prevention Services**
2. **Evidence-Based Cancer Prevention Services Colorectal Cancer Prevention Coalition**
3. **Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services**
4. **Cancer Prevention Promotion and Navigation to Clinical Services**
5. **Dissemination of CPRIT-Funded Cancer Control Interventions**

**Background:**

Five RFAs were released April 30, 2015 and applications were due July 9, 2015. Twenty prevention grant applications were submitted in response to the following CPRIT RFAs. One application was administratively withdrawn and peer review of the remaining 19 applications was conducted in September.

- ***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 for Evidence-Based Cancer Prevention Services*** – 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 up to three years, 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.
- ***Dissemination of CPRIT-Funded Cancer Control Interventions***- to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based

cancer prevention and control interventions across Texas. Maximum of \$300,000; maximum duration of 24 months.

All of the recommended applications address one or more of the Prevention Program priorities. Specifically, 3 of grants prioritize population and geographic areas of greatest need, 12 focus on underserved populations, and 5 focus on increased targeting of efforts to areas where significant disparities in the state exist.

### ***Evidence-Based Cancer Prevention Services Slate***

#### **Recommended projects (3): \$4,079,529**

Six applications were submitted in this mechanism. Three new evidence-based prevention services projects are recommended.

PP160042	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra-Medina, Deborah	The University of Texas Health Science Center at San Antonio
----------	--	-----------------------	--

Formative assessments will identify and understand factors that influence HPV vaccine practices of health care providers and HPV vaccine coverage in six South Texas Rural Health Services clinics that serve residents from four medically underserved rural counties (Dimmit, LaSalle, Frio and Medina). Immunization champions will be used to implement health care system based strategies such as clinic-based education and client reminders/recalls to enhance patient access to vaccine services. In addition the project will also integrate community-wide education (CE) and outreach to increase the HPV vaccine initiation and completion rates among youth by targeting health care professionals and the community.

PP160010	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston
----------	---	-------------------	---

The strategy to increase the number of adolescents and young adults vaccinated against HPV includes patient navigation services, vaccination at no cost to the patient, thorough patient tracking, reminder methods, and provider education. Multiple strategies to reach out to the entire community will be employed. In addition the project will educate regional providers in groups and individually to increase physician recommendation and vaccination rates for this vaccine throughout the community.

PP160027	Improving Service Delivery to Cancer Survivors in Primary Care Settings	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center
----------	---	------------------	--

The setting is primary care training program clinical practices that care for underserved priority patient populations. The intervention utilizes a comprehensive approach to engage cancer

survivors, oncology specialists and the primary care clinical team. Practice system changes will be implemented to identify cancer survivors currently receiving general medical care in the practices. The clinicians will obtain or develop treatment summaries and survivorship care plans for those patients. Procedures will be implemented to promote communication with treating oncologists or cancer centers to coordinate delivery of survivorship care management to reduce duplication of effort and eliminate gaps in care. The knowledge base of primary care clinicians related to survivorship care management will be assessed and further online education materials and support programs will be offered as needed.

### ***Colorectal Cancer Prevention Coalition***

#### **Recommended projects (1): \$2,299,753**

One application was received in response to the colorectal cancer coalition RFA and is being recommended for funding.

PP160023	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler
----------	--	----------------	--

The project will provide a coordinated program to increase access to and delivery of colorectal cancer (CRC) services to individuals in a 19 county area of East Texas. The program leverages a complementary, non-overlapping partnership with a federal program, focusing on the uninsured and underinsured. Multiple partnerships with existing community programs which people in this region trust have been established. The project will engage clinical colleagues in primary care who deliver medical services to many thousands of individuals in this region to assist with recruitment to the program. Through a partnership with the American Cancer Society (ACS) the program will provide CRC screening education to clinical partners, community health workers, and to eligible participants.

### ***Competitive Continuation/Expansion Grants***

#### **Recommended projects (4): \$5,488,991**

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 six applications submitted, four are being recommended for funding.

PP160049	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine
----------	---	---------------------	----------------------------

This project will expand successful navigation efforts to improve and streamline the referral of women diagnosed with cytology at sites external to the Harris Health System (HHS). The focus

of the navigation platform will be expanded with engaging the large population of Hispanic and African American women who have never been previously screened for cervical cancer despite the fact that they are actively receiving other types of primary care at an HHS facility. The streamlined navigation system is expected to navigate more than 13,500 women to timely screening and/or follow up.

PP160011	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson, Gail	The University of Texas Health Science Center at San Antonio
----------	--	-----------------	--

This project will continue and expand to cover a broader area in southernmost region of Texas, including 23 additional underserved counties and provide the cancer genetic services, thus reaching underserved and indigent patients throughout South Texas where previously no cancer genetic counseling services existed. Two additional video teleconferencing (vtel) sites along the border that can provide access to cancer genetic counseling will be added in addition to genetic counseling by telephone in selected individuals from rural areas. Members of families with a significant family history of cancer will be offered cancer screening services. The project will train mammography technicians in family history taking in additional centers and the next generation of physician providers in South Texas by partnering with a new medical school in the Rio Grande Valley.

PP160047	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and cervical cancer among Latinas	Savas, Lara	The University of Texas Health Science Center at Houston
----------	---	-------------	--

This project is an expansion and enhancement of program components that increase reach and implementation efficiencies. Guided by process and final evaluation results from the previous program, to increase reach, participation and to serve more women, the project will (1) modify education materials (2) create an alternative telephone-based education option (3) facilitate delivery of one-on-one navigation intervention with a more automated Navigation Tracking Tool, and (4) remove financial barriers for under or uninsured women ineligible for existing assistance programs. To increase program geographic expansion the project will train CHWs through a network of community CHW programs located on the South Gulf Coast of Texas.

PP160036	Establishing a Comprehensive Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Association
----------	---	------------	----------------------------

The proposed project is a joint effort of 12 Asian American (AA) community-based organizations, clinics and universities targeting Vietnamese, Chinese, Filipino and Korean

communities in Houston and Austin areas. Its four major components include: prevention/education; screening; survivorship services; and capacity building. The cancer prevention and screening components address colon, breast, cervical and liver cancer, and healthy eating. Methods of service delivery include: seminars, workshops, health fairs, newspaper articles, and TV programs, one-on-one education, and curriculum-based nutrition classes. The screening services include mammogram, Hepatitis B and C, FOBT, and Pap Smear/HPV tests. The survivorship program provides group-based interventions, patient navigation, and one-on-one support for cancer patients.

***Cancer Prevention Promotion and Navigation to Clinical Services***

**Recommended projects (2): \$779,691**

Five applications were submitted to this mechanism (one was withdrawn); two are being recommended for funding.

PP160032	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese Americans in Texas	Chen, Lei-Shih	Texas A&M University
----------	---	----------------	----------------------

In collaboration with three Asian American community organizations the program will provide colorectal cancer (CRC) prevention education, Family Health History (FHH) instruction, an FHH collection and tailored prevention messages tool, health insurance enrollment, and assistance navigating clinical services. The impact of the FHH-based program upon participants' behaviors (i.e., collecting FHH from family members, visiting doctors' offices for discussing FHH, adopting healthier lifestyles in diet, physical activity, alcohol and tobacco use, and adhering to personalized CRC screening recommendations) and theoretical mediators shaping such behaviors (i.e., knowledge, attitudes, self-efficacy, barrier, and intention) will be evaluated by pre-test, 6-, and 12-months post-intervention surveys.

PP160056	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundation
----------	--	-----------------	----------------------------------

REACH will integrate community health worker program models to deliver targeted outreach, evidence-based education, and navigation to breast and cervical cancer screening and early detection services. The project will facilitate improvements in health status and quality of life. REACH will employ members of target population that share the same social, cultural, and economic characteristics to identify the target population and use culturally appropriate evidence-based education to facilitate health promotion. REACH will provide navigation support services to assist in linkage, transportation, and completion of breast and cervical cancer prevention screenings.

## ***Dissemination of CPRIT-Funded Cancer Control Interventions***

### **Recommended projects (2): \$599,778**

Two applications were submitted to this mechanism and both are being recommended for funding.

PP160048	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center
----------	--	---------------	---

Texas A&M Health Science Center will package and disseminate Community Health Worker (CHW) components from four of its successful CPRIT-funded prevention projects related to breast, cervical, and colorectal cancer (CRC) education, navigation, and outreach. CHWs in the priority regions will have access to certified training via in-person training workshops and CHWs across the state will be able to access online training modules. Organizations with CHW programs in the priority regions will be identified as partner organizations. Through in-person training, online resources, and ongoing technical assistance, this project will equip these partner programs to implement successful cancer education and navigation programs of their own.

PP160051	Dissemination of an Evidence-Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez, Maria E	The University of Texas Health Science Center at Houston
----------	--	--------------------	--

With a CPRIT Research grant, two interventions designed to educate and to motivate Hispanic parents to vaccinate their children were developed and evaluated. This project will increase use of this program in both clinical and community settings to enhance the overall impact of the program on HPV vaccination rates across Texas. During Phase 1 (targeted dissemination for adopting agencies), the project will provide training and technical assistance for clinics and Community Health Worker (CHW) associations that have already expressed interest in implementing the *Por Nuestro Hijos* program. During Phase 2 (dissemination of PNH through clinical and community networks), the project will work closely with the Texas Department of State Health Services Breast and Cervical Cancer Services Program (BCCS) and CHW programs to increase awareness about PNH, garner interest, identify additional potential adopting clinics and CHW organizations and assess organizational readiness. Newly identified adopting clinics and organizations will then receive training and technical assistance.



Pete Geren  
Oversight Committee Presiding Officer  
Cancer Prevention and Research Institute of Texas  
Via email to [pgcprnit@sidrichardson.org](mailto:pgcprnit@sidrichardson.org)

Wayne R. Roberts  
Chief Executive Officer  
Cancer Prevention and Research Institute of Texas  
Via email to [wroberts@cprnit.state.tx.us](mailto:wroberts@cprnit.state.tx.us)

Dear Mr. Roberts and Mr. Geren,

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 of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2016. 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. When the PRC did not follow the rank ordered scores in developing its recommended funding order a justification, based upon established programmatic priorities outlined in the RFAs, is provided.

The projected funding available for this fiscal year is \$27,965,885. However, the recent interpretation that annual prevention program funding is 10% of the CPRIT awarded dollars within a fiscal year could impact the dollars available. With the second funding cycle for the fiscal year underway, the PRC opted for a conservative approach to its recommendations for this cycle. Recommendations are provided at two levels: (1) initially fund 12 projects totaling an estimated \$13,247,742 and (2) depending upon the availability of funds later in the fiscal year, fund an additional 2 projects (PP160046 and PP160033 totaling \$2,999,657).

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. All of the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

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

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160049	CCE-EBP	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	\$1,500,000	1.9			1	
PP160047	CCE-EBP	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and cervical cancer among Latinas	Savas, Lara S	The University of Texas Health Science Center at Houston	\$1,387,005	2.7	Steps that will be taken to assess actual # of screenings and vaccinations for participants in educational sessions are not explained. It appears that only women completing the surveys will be followed. Evaluation of outcomes for all participants is not provided, only provided for women completing surveys. Budget is unclear about number of screenings that will be paid for; number of financially supported	Changes not recommended-PRC reviewed peer review comments and determined those comments did NOT impact decision to recommend or impact rank order	2	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							screening isn't clearly stated.			
PP160042	EBP	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra-Medina, Deborah	The University of Texas Health Science Center at San Antonio	\$1,295,493	2.8	Outcomes evaluation doesn't have baseline and % increase noted. A highly intensive program is being implemented and the high cost is a barrier. If the cost is reduced, the applicability of the proposed approach may be enhanced. Reviewers would like the applicants to clarify why the increase in the budget from the previous grant to this grant. Why has the per person	changes not recommended- PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	3	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							cost increased so much?			
PP160032	PN	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese Americans in Texas	Chen, Lei-Shih	Texas A&M University	\$399,993	3.0	Findings from this study should be applied to follow-up treatment for the participants. Plans for this are lacking and should be provided.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	4	
PP160056	PN	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundation	\$379,698	3.0	Should be clarified that \$25 gift card is not being offered to change the behavior of the participants.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	5	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160010	EBP	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,409,909	3.1	Ask applicants why they do not plan to vaccinate young adults on college campuses. In addition, students could be used to help with recruitment	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	6	
PP160048	DI	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	\$300,000	3.1			7	
PP160023	EBP-CRC	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$2,299,753	3.3	Recommendation was made in previous application that providing FIT isn't evidence-based for people who are at significant risk for CRC; this isn't consistent with ACS guidelines. Ask how they came up with \$275/colonoscopy	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	8	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160036	CCE-EBP	Establishing a Comprehensive Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Association	\$1,101,986	3.3	Request that the applicant provides a leadership plan that includes input from the three communities being targeted: Vietnamese, Korean, and Filipino	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	9	
PP160027	EBP	Improving Service Delivery to Cancer Survivors in Primary Care Settings	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	\$1,374,127	3.5	Not clear how project will add to what is already happening in clinic. This is a large, complex project and not clear how it will be managed on a daily basis. Budget is weak and justification for some of the positions is lacking	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	10	Recommended out of score order above one with higher score due to ROI and cancer type
PP160051	DI	Dissemination of an Evidence-Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez, Maria E	The University of Texas Health Science Center at Houston	\$299,778	3.6	List of current awards doesn't specify PD participation; it should be verified that PD isn't overcommitted. Budget seems somewhat personnel heavy and accounts for a	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	11	Recommended out of score order above one with higher score due to type of program

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							large majority of voerall costs; careful review of personnel and their exact roles and responsibilities and whether or not any of the services are duplicative may be warranted.			
PP160011	CCE-EBP	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson , Gail E	The University of Texas Health Science Center at San Antonio	\$1,500,000	2.7			12	Recommended but ranked out of score order due to 1) ROI may be limited; large numbers need to be screened to identify at risk pop.
PP160046	EBP	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in high-risk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	\$1,499,668	2.2			13	Recommended but out of score order due to 1) geography-several HPV grants in Harris county, 2) ROI-costs for education vs services

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160033	CCE-EBP	Increasing cancer control behaviors among the underserved: A collaboration with Texas 2-1-1 programs	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$1,499,989	2.4			14	Recommended but out of score order due to 1) geography-several HPV grants in Harris county, 2) cancer type-availabilty of breast and cervical services 3) ROI-costs for education vs services
				Initial funding (Rank #1-12)	\$13,247,742					
				(Rank #13+14)	\$2,999,657					
				2nd funding	\$16,247,399					



# Product Development

---

## Recommendation

### Items

Product Development Awards Summary

Review Council Chairman Letter

Advance Funds Request







CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

---

---

**MEMORANDUM**

---

---

**To:** MEMBERS OF THE OVERSIGHT COMMITTEE  
**From:** MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER  
**Subject:** PRODUCT DEVELOPMENT GRANT RECOMMENDATION  
**Date:** NOVEMBER 3, 2015

---

---

**Summary of Recommendation:**

The Program Integration Committee (PIC) met on November 3, 2015, and unanimously recommends that the Oversight Committee approve a \$20,000,000 New Company product development research grant award to Ruga Corporation (Ruga), subject to certain contingencies and additional goals and objectives recommended by the Product Development Review Counsel (PDRC) and the PIC. The PIC's decision is consistent with the PDRC's recommendation conveyed by PDRC Chair Dr. Jack Geltosky to the chairs of the PIC and the Oversight Committee on October 26.

The scientific rationale underlying Ruga's proposed product development research project is highly rated by the review panel, receiving an overall score of 2.2. The project as proposed provides a more effective therapeutic option to treat acute myeloid leukemia and other aggressive cancers, including ovarian, endometrial, breast, renal and pancreatic.

In making the recommendation, the PDRC considered the company's 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.

**Background - FY 15.4 Review Cycle:**

The RFAs for the FY 2015.4 review cycle were released January 5, 2015. All applications were submitted by February 9, 2015. Peer review took place at meetings on March 26, 2015 (peer review panel conference call), April 27-28, 2015 (in-person presentations), and October 12, 2015 (due diligence review).

CPRIT received 16 applications for the FY 2015.4 review cycle. Ten applicants were invited to make in-person presentations; of those that were presented, three were moved forward to due diligence review. After consideration of the due diligence reports, the PDRC recommended one grant application, Ruga, for a grant award. As noted by Dr. Geltosky's letter, the recommendation to fund Ruga reflects 50+ hours of individual review and panel discussion of the applicant's proposal as well as the PDRC's review of the due diligence reports for Ruga.

**Mechanism of Support and Program Objectives:**

Ruga is being recommended for a New Company Product Development research award. The 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 will have a significant presence in Texas. 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.

Consistent with CPRIT's Product Development Program Priorities, the New Company mechanism funds projects at companies that are most likely to bring important cancer care products to the market. Development of the therapeutic to treat acute myelogenous leukemia aligns with CPRIT's focus on rare and pediatric cancers and those of significant unmet clinical need.

***Proposed New Company Product Development Award –  
Recommended by the Product Development Review Council***

**Ruga Corporation - \$20,000,000 New Company Product Development Research Award recommendation**

**Summary:**

The \$20,000,000 award to Ruga supports the continued development of Ruga-S6, a therapeutic targeting certain aggressive, hard to treat cases of acute myeloid leukemia (AML). The funded project will advance the AXL/GAS6 inhibitor program through completion of Phase 1 clinical studies in hematological indications with a focus on adult AML, and potentially pediatric AML as well as certain advance solid tumors (*e.g.* ovarian, endometrial, renal, and pancreatic cancers.) Grant funds will support manufacturing activities, including cell line development, assay development, process development and scale-up, and production of cGMP material. Preclinical development will include additional pharmacokinetics, toxicology, immunogenicity, and biomarker studies. During the course of this project, Ruga will file an Investigational New Drug (“IND”) application with the FDA and initiate Phase 1/2 Clinical studies, which will include both single and multiple-ascending dose studies in AML.

**AML and Ruga-S6**

AML is a cancer that begins in bone marrow and affects cells intended to mature into different types of blood cells. Approximately 18,860 new cases of AML were diagnosed in the U.S. in 2014. Ruga’s therapy targets a specific genetic mutation evident in 20% – 25% of AML cases, FMS-related tyrosine kinase 3, (“FLT3”); most of these mutations are internal tandem duplications (“ITD”). Scientists report that AML cases that are FLT3-ITD positive are more aggressive and patients are significantly more likely to relapse. FLT3-ITD positive patients treated with the standard AML therapy protocol have a median survival of less than one year, and less than five percent are cured.

FLT3-ITD positive cases of AML are characterized by the binding together of a specific protein and ligand pair. Laboratory and animal experiments show that preventing the protein, known as AXL, and the GAS6 ligand from binding together will stop the progression of AML

Building upon these discoveries, Ruga developed Ruga-S6, which works as a decoy to bind to GAS6 so that GAS6 does not bind to the actual AXL receptor. Not all AML cases have this

AXL-GAS6 complication, so Ruga has also developed a proprietary blood-based companion diagnostic that may better identify patients that will benefit from the for Ruga-S6 treatment.

According to Ruga, other companies are currently developing treatments to address this issue, however, the treatments are more toxic and have a low response rates. This means that not only are the alternative treatments less effective, but it increases the patient’s likelihood of developing resistance to other AML treatments. Ruga’s approach addresses these critical issues.

The scientific rationale underlying Ruga’s proposed product development research project is highly rated by the review panel, receiving an overall score of 2.2. The project as proposed provides a more effective therapeutic option to AML and other aggressive cancers, including ovarian, endometrial, breast, renal and pancreatic. By advancing Ruga-S6 through preclinical and clinical testing, Ruga aims provide a more effective therapeutic option for AML and other aggressive cancers, including ovarian, endometrial, breast, renal and pancreatic.

Ruga-S6 has the opportunity to seek FDA Orphan drug and Breakthrough status. The development of Ruga-S6 aligns with CPRIT’s focus on rare and pediatric cancers and those of significant unmet clinical need. If funded, Ruga will fully relocate to Texas, where it will continue the development of Ruga-S6 in partnership with Texas-based institutions, including the Texas Medical Center.

#### **Selected Reviewer Comments:**

- *“The approach used is innovative as it consists of using an engineered AXL Fx construct as a decoy receptor that acts as an antagonist to the receptor to its ligand Gas6. If successful, the outcome could substantially impact the treatment of AML as it would provide a new treatment approach.”*
- *“Beautifully written application; clear articulation of the scientific rationale, preliminary data and plans for further preclinical and clinical development.”*
- *“If it were to show efficacy in the clinic, it will be a significant new product against AML and potentially solid tumors as well. In particular, it may be useful in combination therapies to delay resistance to other therapies.”*

#### **Funding Request and Risk Mitigation**

Ruga is seeking a total of \$20 million from CPRIT if it achieves all project goals and objectives. Combined with the company’s \$10 million in matching funds, Ruga intends to advance of the

GAS6/AXL inhibitor program from late preclinical (IND-enabling studies) through early proof of concept studies (Phase 1/2) in AML and in certain aggressive solid tumors. Ruga estimates filing its IND by Q1, FY2017.

Investing in early stage translational cancer research is inherently risky. Therapies that show promise in the lab and in animals may not make a measurable difference in humans or the treatment's side effects may be so severe as to not justify the benefits. Along with the increased risk of scientific failure, human studies are more expensive than laboratory and animal studies. CPRIT addresses the risk associated with larger product development awards by tying disbursement of grant funds to achieving specific goals and objectives. The company only receives the entire amount of the award if all goals and objectives are met. Because goals are usually associated with project milestones, such as receiving FDA approval for an investigational new drug (IND) filing or completing a Phase I clinical trial, achieving all goals also means that the project is making meaningful progress on the way to becoming a treatment option.

A summary of Ruga's goals and objectives, along with the associated tranches, are set forth below. (For a complete explanation of each goal and summary, please see pages 8 – 11 of the Ruga application.) In addition, the PDRC recommends the certain contingencies, goals, and objectives be included in the grant award contract. The PDRC's recommended goals and objectives and rationale are reflected in **red** and are in addition to those already specified Ruga's application. The PIC also recommends an additional objective be included in the contract. The additional objective is related to the proposed companion diagnostic and is reflected in **blue**. With the Oversight Committee's approval, these goals and objectives will be incorporated into the "Scope of Work" for the award contract.

### **Ruga's Project Goals and Objectives:**

#### **Prior to contract execution but no later than May 1, 2016:**

- Ruga's licensing agreement with Stanford must be renegotiated. Unless CPRIT approves additional time, Ruga should provide the renegotiated license agreement to CPRIT by May 1, 2016.

*Ruga's current license agreement mandates a substantial return to Stanford (15% of all payments and milestones payments). Although CPRIT's investment in the project is significant, it is a small amount of the total capital necessary to bring the proposed therapy to patients. It is the PDRC's opinion that if the onerous license terms remain in place, it will significantly affect Ruga's ability to raise necessary follow-on funding from investors. In addition, march-in rights included in the Stanford agreement place the company at risk of losing control of the project,*

*another issue that will make prospective funders unwilling to participate in future fundraising rounds. Unless the Stanford agreement is renegotiated, CPRIT should not disburse any grant funds to the company.*

*CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the renegotiated license and advise the CPRIT CEO regarding whether to execute the contract.*

- Ruga should provide a copy of the agreement with Fuji Diosynth Biotech of Texas (FDBT) to CPRIT and follow recommendations, if any, regarding renegotiation. Should renegotiation of the FDBT agreement be necessary, it should be completed by May 1, 2016. Unless CPRIT approves additional time, Ruga should provide the renegotiated agreement to CPRIT by May 1, 2016.

*The PDRC is concerned that Ruga's agreement with FDBT may make the vector and expression system proprietary to the manufacturer with the reagents royalty-bearing. If this is the case, then Ruga must renegotiate the agreement before any grant funds are disbursed to the company to ensure that potential investors are not disincentivized. CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the FDBT agreement and advise the CPRIT CEO regarding whether to execute the contract.*

**If Ruga successfully completes the pre-contract objectives, specific Goals and Objectives, summarized below, will be included in the executed grant contract:**

#### **Year 1 Tranche \$5,063,100**

Establish Texas as the corporate headquarters for Ruga and specifically, the Texas Medical Center (TMC) as the hub for all advanced preclinical and clinical development activities for Ruga-S6. Relocating key personnel and creating new high-quality, professional jobs that are required to fully support the company's current and future operations in Texas. Develop strategic partnerships and initiate activities with Texas-based subcontractors and consultants that can provide the expertise, services, and infrastructure needed to accomplish the preclinical and clinical development of Ruga's products.

#### Year 1 Objectives

1. Initiate cell line development/engineering and process development activities with a selected contract manufacturing organization (CMO), FujiFilm Diosynth Biotechnologies Texas (FDBT), to perform all development and manufacturing activities for Ruga-S6. Key objectives of this phase of the project include identification, selection, and optimization of a high-expressing cell line suitable for further development of a robust, scalable, and current Good Manufacturing Practices (cGMP)-compliant process for

production of Ruga-S6. By the end of Year 1, FDBT will have completed cell line development, completed development of a Master Cell Bank (MCB), and produced sufficient material under non-cGMP to enable completion of GLP toxicology studies with Ruga-S6. Achieve production of their construct and formulation of the final recombinant decoy receptor Ruga plans to develop with FDBT.

*The PDRC notes that the company's proposed timeline for the IND timeline may be optimistic. Therefore, the PDRC recommends that as part of the Project Year 1 tranche Ruga achieves production of their construct and formulation of the final recombinant decoy receptor they are planning to develop with FDBT. This will prepare the company for its discussions with the FDA and planned IND submission, so as to receive the FDA's concurrence of Ruga's plan.*

*The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process.*

2. Perform IND enabling preclinical studies, including PK, PD, and biomarker studies.
3. Demonstrate successful development of the companion diagnostic test including showing sensitivity and specificity sufficient to guide use of the company's novel therapeutic compound.
4. Conduct a pre-IND meeting with the FDA.
5. Establish Ruga headquarters and operations in Texas; specifically, the Texas Medical Center (TMC) as the hub for all advanced preclinical and clinical development activities for Ruga-S6. This will be accomplished with the first six months of the Project Year 1. Key positions that will be recruited for include a full-time outward-facing CEO who is responsible for strategy and engaging with strategic partners, including potential investors and regulatory professionals, a Chief Medical Officer with a regulatory background and a demonstrated history of product(s) approval, Director of Manufacturing, and Vice President of Clinical and Regulatory Affairs, and a Program Manager to manage the development program and the consultants; in addition to administrative and other professional staff. Consultants with specialized expertise in Chemistry, Manufacturing, and Controls (CMC) for fusion proteins, preclinical, and regulatory affairs will also be retained by the company within the first year of award.

*The PDRC's strong recommendation of the proposed project is tempered by its concern regarding the ability of Ruga's current management to professionally manage the project. While the "virtual structure" approach outlined by the company is generally acceptable, the company's reliance upon contracted research personnel and the ability of the current CEO to devote time and expertise to steering the project through the FDA approval process raise questions that should be quickly addressed by the company. The company needs full-time*

*executive leadership as well as some key hires with regulatory approval expertise to interface with the contracted research personnel.*

*The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process. Ruga may consult with the Chief Product Development Officer prior to making final offers.*

### **Year 2 Tranche \$10,513,000**

Complete advanced preclinical and initiate clinical development activities required to seek approval for Ruga-S6 as a new biological drug from the FDA. Address the critical need for improved treatment options by translating Ruga-S6 into the clinic for evaluation of safety and efficacy to treat adults with AML, and specifically patient populations with genetic mutations known to contribute to more aggressive disease phenotypes (i.e. FTL3-ITD(+)), in addition to other aggressive solid tumor indications with significant unmet clinical need. Accelerate the development and availability of Ruga-S6 to these patients by optimizing clinical trial designs to enable Orphan drug and/or accelerated/Breakthrough designation with the FDA.

#### Year 2 Objectives

1. Complete GLP-toxicology study in Non-human primates.
2. Perform cGMP manufacturing to generate Ruga-S6 final drug product at 2,000L scale.
3. File IND application with the FDA.
4. Initiate Phase 1a clinical studies in adult patients with AML-FLT3(+).

### **Year 3 Tranche \$4,423,900**

Advance clinical evaluation of Ruga-S6 in adult patients with AML, and in particular AML-FLT3(+) and expand Ruga-S6 product development platform to pediatric AML as well as other cancer indications through performance of Phase 1b/2a studies in solid tumor types, such as ovarian, renal, and pancreatic cancers.

#### Year 3 Objectives

1. Complete Phase 1a clinical studies and identify expansion cohorts for Phase 1b/2a study in adult patients with AML-FLT3 subtypes.
2. Initiate Phase 1b/2a studies for Solid Tumor(s).

October 26, 2015

Via email to Wayne R. Roberts ([wroberts@cpritch.state.tx.us](mailto:wroberts@cpritch.state.tx.us)) and Pete Geren ([pgcpritch@sidrichardson.org](mailto:pgcpritch@sidrichardson.org)).

Dear Pete and Wayne,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's product development research grant awards. The PDRC recommends that the Program Integration Committee and the Oversight Committee approve a \$20,000,000 product development research grant award to Ruga Corporation (Ruga), subject to certain contingencies and additional goals and objectives recommended by the PDRC as outlined below.

This recommendation reflects 50+ hours of individual review and panel discussion of the applicant's proposal as well as the PDRC's review of the due diligence reports. Our recommendation meets the PDRC's standards for grant award funding. These standards include the company's 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.

The scientific rationale underlying Ruga's proposed product development research project is highly rated by the review panel, receiving an overall score of 2.2. The project as proposed may provide a more effective therapeutic option to acute myeloid leukemia and other aggressive cancers, including ovarian, endometrial, breast, renal and pancreatic.

The PDRC recommends the following contingencies, goals, and objectives be included in the grant award contract. The goals and objectives are in addition to those already specified by Ruga in its application.

**Prior to contract execution but no later than May 1, 2016:**

- Ruga's licensing agreement with Stanford must be renegotiated. Unless CPRIT approves additional time, Ruga should provide the renegotiated license agreement to CPRIT by May 1, 2016.

*Ruga's current license agreement mandates a substantial return to Stanford (15% of all payments and milestones payments). Although CPRIT's investment in the project is significant, it is a small amount of the total capital necessary to bring the proposed therapy to patients. It is the PDRC's opinion that if the onerous license terms remain in place, it will significantly affect Ruga's ability to raise necessary follow-on funding from investors. In addition, march-in rights included in the Stanford agreement place the company at risk of losing control of the project, another issue that will make prospective*

*fundere unwilling to participate in future fundraising rounds. Unless the Stanford agreement is renegotiated, CPRIT should not disburse any grant funds to the company.*

*CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the renegotiated license and advise the CPRIT CEO regarding whether to execute the contract.*

- Ruga should provide a copy of the agreement with Fuji Diosynth Biotech of Texas (FDBT) to CPRIT and follow recommendations, if any, regarding renegotiation. Should renegotiation of the FDBT agreement be necessary, it should be completed by May 1, 2016. Unless CPRIT approves additional time, Ruga should provide the renegotiated agreement to CPRIT by May 1, 2016.

*The PDRC is concerned that Ruga's agreement with FDBT may make the vector and expression system proprietary to the manufacturer with the reagents royalty-bearing. If this is the case, then Ruga must renegotiate the agreement before any grant funds are disbursed to the company to ensure that potential investors are not disincentivized. CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the FDBT agreement and advise the CPRIT CEO regarding whether to execute the contract.*

**Within six months of executing the award contract, Ruga must hire:**

- A Chief Medical Officer with a regulatory background and a demonstrated history of product(s) approval;
- A Program Manager to manage the development program and the consultants; and
- A full-time outward-facing CEO who is responsible for strategy and engaging with strategic partners, including potential investors and regulatory professionals.

*The PDRC's strong recommendation of the proposed project is tempered by its concern regarding the ability of Ruga's current management to professionally manage the project. While the "virtual structure" approach outlined by the company is generally acceptable, the company's reliance upon contracted research personnel and the ability of the current CEO to devote time and expertise to steering the project through the FDA approval process raise questions that should be quickly addressed by the company. The company needs full-time executive leadership as well as some key hires with regulatory approval expertise to interface with the contracted research personnel.*

*The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process. Ruga may consult with the Chief Product Development Officer prior to making final offers.*

**Within Year 1 of the project timeline, Ruga must:**

- Achieve production of their construct and formulation of the final recombinant decoy receptor Ruga plans to develop with FDBT.

*The PDRC notes that the company's proposed timeline for the IND timeline may be optimistic. Therefore, the PDRC recommends that as part of the Project Year 1 tranche Ruga achieves production of their construct and formulation of the final recombinant decoy receptor they are planning to develop with FDBT. This will prepare the company for its discussions with the FDA and planned IND submission, so as to receive the FDA's concurrence of Ruga's plan.*

*The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process.*

*Sincerely,  
/JG/*

*Jack Geltosky  
Chairman, Product Review Council*



---

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

November 16, 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 one company that will be considered for Product Development grant awards at the November 19, 2015, Oversight Committee meeting. The company has been recommended for a grant award by the Program Integration Committee (PIC). The Oversight Committee will consider the PIC's recommendation at the November 19, 2015, Oversight Committee meeting.

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 Mr. Michael Lang, CPRIT's Chief Product Development Officer, the following reason supports advance payment of grant funds for the company: pre-clinical trial contracts will need to be entered into with substantial upfront payments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Wayne R. Roberts".

Wayne R. Roberts,  
CPRIT Chief Executive Officer