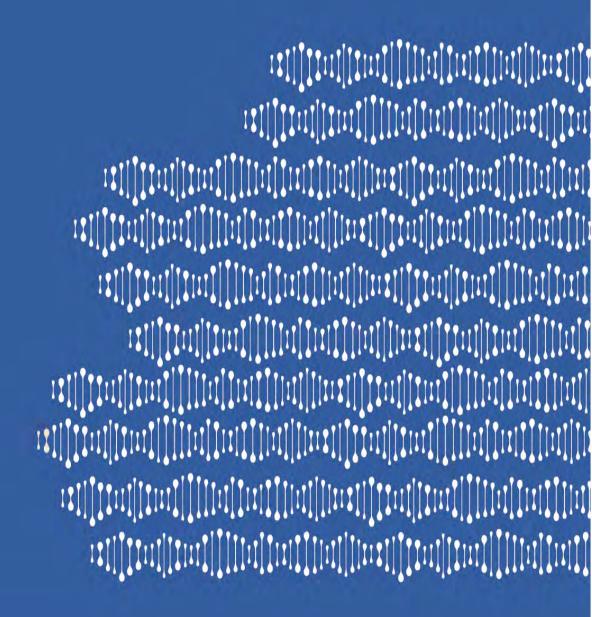
# Oversight Committee Meeting

February 18, 2015





# Summary Overview of the February 18, 2015, Oversight Committee Meeting

Please find enclosed the packet for the next meeting of the CPRIT Oversight Committee to be held on Wednesday, February 18, 2015 at 10:00 AM. This summary overview of major agenda items provides background on key issues for Committee consideration.

#### **CEO Report**

Wayne Roberts will present the CEO's report and address issues including office relocation plans, legislative activities, agency funds available for grant awards, and other issues as appropriate.

# **Chief Compliance Officer Report**

David Reisman will report on the status of required grantee reports, desk reviews and site visits.

#### **Chief Operating Officer Report**

Heidi McConnell will present the operating budget, performance measures, and debt issuance history for the first quarter of FY 2015.

#### **Chief Prevention and Communications Officer Report**

Dr. Becky Garcia will provide an update regarding the communications initiatives, including plans for the 2015 CPRIT Conference and the upcoming screening for the new Ken Burns' documentary, *Cancer: The Emperor of All Maladies*. In addition, Dr. Garcia will provide an update regarding the current prevention review cycles. Dr. Garcia will also speak to a potential collaboration on breast and cervical cancer initiatives.

#### **Chief Scientific Officer Report and Grant Award Recommendations**

Dr. Margaret Kripke will provide an update on the Academic Research Program and present the Program Integration Committee's recommendations for 54 academic research awards. Dr. Kripke will also report on the February meetings of the Advisory Committee on Childhood Cancer and the University Advisory Committee.

# **Chief Product Development Officer Program Overview and Grant Award Recommendations**

Dr. Tom Goodman will provide an update on the Product Development Research Program and present the Program Integration Committee's recommendations for four Product Development Research Awards. Dr. Goodman, Dr. Kripke, and Mr. Roberts will discuss the appropriate program for Early Translational Research Awards.

Information related to the academic research and product development grant applications recommended for funding is not publicly disclosed until the Oversight Committee meeting. The information has been made available to board members through a secure electronic portal.

Oversight Committee: William Rice, M.D., Chair | Angelos Angelou | Gerald Geistweidt | Pete Geren | Ned Holmes
Amy Mitchell | Will Montgomery | Cynthia D. Mulrow, M.D., MSc., MACP | Craig Rosenfeld, M.D.

# Appointments to the Scientific Research and Prevention Programs Committee and the Advisory Committee on Product Development (ACPD)

Mr. Roberts has appointed three new members to the CPRIT's Scientific Research and Prevention Programs Committees. Texas Health & Safety Code §102.151 requires the CEO's appointments to be approved by the Oversight Committee. A biographical sketch for each appointee is included in the board packet.

# **CPRIT Contracting and Required Contract Training**

Ms. McConnell will present an overview of CPRIT's agency contracts for goods and services, as well as proposed legislation that will affect all state agency contracting processes. Following her presentation, the Oversight Committee will view the statutorily required contract training webinar presented by the Comptroller's Office.

# Annual Report Presentations by the Advisory Committee on Childhood Cancer (ACCC) and the University Advisory Committee (UAC)

Pursuant to CPRIT's administrative rule 701.13(7), each CPRIT advisory committee is required to submit a report to the Oversight Committee regarding the activities of the committee at least annually. Both the ACCC and the UAC have elected to use the reports submitted as part of CPRIT's Program Priorities Project for the required annual reports. Committee representatives will present the reports to the Oversight Committee.

# **Grants Compliance Monitoring Contract, Internal Audit Services Contract and Contract Renewal with SRA International**

Several contracts will be presented for Oversight Committee approval. Ms. McConnell will address CPRIT staff's recommendations for proposed contracts and provide an overview of the contracting process used for each contract.

# **Changes to Agency Administrative Rules**

Kristen Doyle, General Counsel, will present proposed changes to the agency's administrative rules. Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute.

- Rule changes recommended for final adoption include changes to §703.6 to incorporate the Chief Compliance Officer in the review panel process and to §703.11 to provide additional clarity regarding matching fund requirements. These proposed changes were initially discussed at the November 19, 2014, meeting.
- Proposed rule changes recommended for publication in the *Texas Register* will affect §703.11, CPRIT's administrative rule addressing matching funds. Once the public has had the opportunity to provide input regarding the changes, the rule changes will be brought back to the Oversight Committee in May 2015 for adoption.

#### **Subcommittee Issues**

Several items related to Oversight Committee subcommittees are scheduled to be addressed at the Oversight Committee meeting including approval of the charter for the Contract Issues Subcommittee, approval of the conflict of interest waiver for CPRIT employee Donald Brandy, and subcommittee reports from the Audit Subcommittee and the Diversity Subcommittee.

#### **Annual Review of the CEO**

The Oversight Committee will conduct the annual performance evaluation of the CEO, led by the Board Governance subcommittee. Information related to the performance review will be provided to Oversight Committee members under separate cover. Pursuant to Tex. Govt. Code §551.074, the Oversight Committee may meet in closed session to conduct the performance review.



# Oversight Committee Meeting Agenda

Texas Higher Education Coordinating Board 1200 E. Anderson Lane, Austin, Texas 78752 Board Room 1.170

> February 18, 2015 10:00 a.m.

The Oversight Committee may discuss or take action regarding any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any and all purposes permitted by the Act.

# **Opening**

<ol> <li>Roll Call/Excused Absences</li> <li>Adoption of Minutes from January 20, 2015 meeting</li> </ol>	TAB 1
	TAB 1
Dealth Comment and Staff Demants	
Public Comment and Staff Reports	
4. Public Comment*	
5. Chief Executive Officer Report	TAB 2
6. Chief Compliance Officer Report	TAB 3
7. Chief Operating Officer Report	TAB 4
8. Chief Prevention and Communications Officer Report	TAB 5
<ul> <li>Communications Report</li> </ul>	
Program Activities	
9. Chief Prevention and Communications Officer Report	TAB 6
<ul> <li>Prevention Program Report</li> </ul>	
10. Chief Scientific Officer Report	<b>TAB 7</b>
<ul> <li>Academic Research Program Report</li> </ul>	
Grant Award Recommendations	
11. Chief Product Development Officer Report	TAB 8
Product Development Research Program Report	
Early Translational Research Award Program Assignment	
Grant Award Recommendations	
Request to Disburse Funds in Advance	

	12.	Scientific Research and Prevention Program Committee Appointments	TAB 9
Ageno	cy B	usiness	
	13.	Contract Management	<b>TAB 10</b>
		<ul> <li>Overview of CPRIT Contracting</li> </ul>	
		<ul> <li>Training required by Government Code §2262.0535</li> </ul>	
	14.	Advisory Committee on Childhood Cancers – Annual Report	<b>TAB 11</b>
	15.	University Advisory Committee – Annual Report	<b>TAB 12</b>
	16.	CEO Report Pursuant to Health & Safety Code § 102.260(c)	<b>TAB 13</b>
	17.	Grant Compliance Monitoring Contract	<b>TAB 14</b>
	18.	Internal Audit Services Contract	<b>TAB 15</b>
	19.	SRA International Contract Renewal for Pre- and Post-Award Grants Management Support Services	<b>TAB 16</b>
	20.	Final Order Approving Amendments to 25 T.A.C. Chapter 703	<b>TAB 17</b>
	21.	Proposed Amendments to 25 T.A.C. Chapter 703 and Authorization to Publish in the <i>Texas Register</i>	<b>TAB 18</b>
	22.	Subcommittee Business	<b>TAB 19</b>
		<ul> <li>Contract Issues Subcommittee Charter</li> </ul>	

- Audit Subcommittee Approval of Outside Employment and Conflict of Interest Disclosure/Waiver
- 23. Personnel Chief Executive Officer Evaluation, which may include discussion of Chief Scientific Officer, Chief Prevention and Communications Officer, Chief Product Development Officer, Chief Operating Officer, Chief Advisor and General Counsel, Chief Compliance Officer
- 24. Consultation with General Counsel

#### Closing

25. Future Meeting Dates and Agenda Items

**TAB 20** 

26. Adjourn

<sup>\*</sup> Anyone wishing to make public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.



# **Oversight Committee Meeting Minutes**

January 20, 2015

#### 1. Meeting Called to Order

A quorum of six being present, Dr. Rice called the Oversight Committee to order at 10:01 A.M.

#### 2. Roll Call /Excused Absences

Dr. Rice asked Amy Mitchell, Secretary of the Oversight Committee, to take attendance of the Oversight Committee. All were present except Mr. Angelou, Mr. Geren, and Mr. Holmes. Ms. Mitchell stated that Mr. Angelou, Mr. Geren, and Mr. Holmes notified CPRIT that they would be unable to attend the meeting.

#### **MOTION:**

Dr. Rice asked for a motion to approve an excused absence for Mr. Angelou, Mr. Geren, and Mr. Holmes

Motion by: Montgomery Seconded by: Rosenfeld

#### MOTION CARRIED UNANIMOUSLY

#### 3. Adoption of Minutes from the November 19, 2014, meeting.

Dr. Rice informed the committee that the minutes from the November 19, 2014, meeting were under Tab 1 in their meeting books. He asked if anyone had comments but there were none.

#### **MOTION:**

Dr. Rice called for a motion to approve the minutes of the November 19, 2014, Oversight Committee meeting.

Motion by: Montgomery Seconded by: Rosenfeld

MOTION CARRIED UNANIMOUSLY

### 4. Contract Terms for Product Development Grants

Dr. Rice recognized Mr. Roberts, Chief Executive Officer and Mr. Tom Goodman, Chief Product Development Officer, to present the contract terms for Product Development grants.

Mr. Roberts stated all the relevant information on the contract terms was in the meeting book. He thanked the Oversight Committee members who served on the Subcommittee on Economic Terms—Pete Geren, Amy Mitchell, Will Montgomery and Dr. Craig Rosenfeld—for the extra work their participation required. He then thanked the members of the advisory committee that was put together in the process of this project. He noted that the members of the Advisory Committee on Product Development were listed on page 30 of the November 19, 2014, minutes under Tab 1 in the meeting book.

The overall purpose of the project was to develop general contract terms for outstanding product development awards and for awards going forward. The overarching criteria that were addressed were that the terms: be simple and understandable; provide the state with a fair and reasonable rate of return on investment; take into account that CPRIT's involvement is only to provide financing to awardees; do not prohibit or restrict company formation and job growth in Texas; and take into account the fact that CPRIT's cost of capital is much lower than that of other investors. The terms also needed to ensure that the state would participate in any large returns if a company did expand, and were in an appropriate range for venture capital funding that was neither too permissive nor too restrictive to prevent follow-on funding. After talking with the advisory committee, Mr. Roberts stated that the recommended terms accomplish all the goals mentioned. The terms are spelled out on page 39 in the meeting book. Mr. Roberts noted that Dr. Goodman had provided a memo under Tab 2 that gave a brief justification for each one of the terms. Mr. Roberts then requested adoption of the terms as presented on behalf of the Contract Issues Subcommittee.

Dr. Rice called for any questions or comments from the full Oversight Committee members. Mr. Geistweidt asked if there were any grantees who were not companies. Ms. Doyle, General Counsel, responded that there were not at this time, and stated that these terms presented were only for product development awards. Mr. Montgomery asked that the word "company" be changed to "grantee." No further discussion was heard.

#### **MOTION:**

Dr. Rice called for a motion to approve the Product Development General Contract Terms upon the condition that the word "company" be changed to "grantee."

Motion by: Montgomery Seconded by: Rosenfeld

MOTION CARRIED UNANIMOUSLY

	Dr. Rice called for a motion to authorize with approved product development gran	the Chief Executive Officer to execute contracts tees, consistent with the approved terms.
	Motion by: Montgomery	Seconded by: Rosenfeld
		MOTION CARRIED UNANIMOUSLY
5.	Consultation with General Counsel	
	This agenda item was not taken up.	
6.	Future Meeting Dates and Agenda Iter	ms
	Dr. Rice announced the next meeting of the February 18, 2015, with the location to be	
7.	Adjourn	
	There being no further business, Dr. Rice	called for a motion to adjourn.
	Motion by: Montgomery	Seconded by: Geistweidt
		MOTION CARRIED UNANIMOUSLY
1	Meeting adjourned at 10:09 A.M.	
_		
	Signature	Date

**MOTION:** 



#### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER

Subject: AGENDA ITEM 5: CHIEF EXECUTIVE OFFICER REPORT

**Date: FEBRUARY 10, 2015** 

Behind this memo are copies of the January 9, 2015 (for December 2014), and February 4, 2015 (for January 2015), CPRIT Activities Update reports. These updates began in March 2014 to provide an overview of significant or unique staff activities that occur in the months the Oversight Committee (OC) does not meet. Some topics will be repeated or updated as needed at the quarterly meetings.

As of this writing, the Chief Executive Officer Report for the February 18, 2015, Oversight Committee meeting includes the following.

#### 1. Agency Move Update

Agency staff will pack the office on Thursday and Friday immediately after the February 18 OC meeting. The actual move to the 6<sup>th</sup> floor of the William B. Travis building will take place over the weekend. Agency staff should be available on Monday, February 23 and fully operational by Tuesday. As of this writing all of the various moving parts of the move appear on schedule. Hopefully this will not disrupt our legislative activities, however, it could.

#### 2. Update on Legislative Activities

A verbal report on the agency's legislative activities will be given. Sample materials distributed to legislators will also be provided at the February 18 OC meeting. These materials are routinely placed on the agency's website after public testimony is provided.

## 3. Report on Funds Available for Grant Awards in FY 2015

A report will be made concerning estimated funds available for grant awards for the remainder of the current fiscal year.

# 4. Other Topics May be Added as Warranted

\*\*\*\*

# CPRIT has awarded 814 grants totaling \$1146.5 million

- 135 prevention awards totaling \$121.6 million
- 679 academic research and product development awards totaling \$1024.9 million

Of the \$1024.9 million in academic research and product development awards

- 29.3% of the funding (\$300.1 million) supports clinical research projects
- 27.2% of the funding (\$278.7 million) supports translational research projects
- 24.3% of funding (\$249.4 million) supports recruitment awards
- 16.3% of the funding (\$167.2 million) supports discovery stage research projects
- 2.9% of funding (\$29.5 million) supports training programs.

CPRIT has 3 open Requests for Applications (RFAs)

• 3 Research Recruitment



#### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

**Subject:** CPRIT ACTIVITIES UPDATE – JANUARY 2015

**Date:** FEBRUARY 4, 2015

Topics in this update include: Oversight Committee preparations, Contract Management Training for Oversight Committee members, CPRIT staffing, Program updates, Compliance RFP, legislative update, ongoing projects, and outreach efforts.

# **Preparation for the February 18 Oversight Committee Meeting**

The Oversight Committee is scheduled to meet February 18 at 10:00 a.m. at the Texas Higher Education Coordinating Board. Due to legislative activities the Oversight Committee will not be able to meet in the Texas Capitol Extension until the August 2015 meeting, at the earliest. The final agenda for the Oversight Committee meeting will be posted by February 10; a tentative agenda is attached.

A major agenda item will be consideration and approval of the Program Integration Committee (PIC) award recommendations. The PIC met February 3 to review the 59 grant award recommendations (totaling approximately \$115.4 million) made by the Scientific Research and Product Development Research Review Councils.

CPRIT will send you an email with a link and password to access the PIC's recommendations via the grant award portal by February 5, 2014. The portal will have supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, and grant pedigree. Summaries of each award slate have been prepared by the Program Officers and are also available through the portal. Please allow time to complete the individual conflict of interest checks and review the supporting material.

We plan to distribute the agenda packet to Oversight Committee members electronically by COB February 11. CPRIT will hand deliver hard copies of the agenda packet to all members residing in Austin. Hard copies will be available at the Oversight Committee meeting for all out-of-town members.

Required Contract Training Will Be Held at February 18 Oversight Committee Meeting

Texas Government Code § 2262.0353 requires governing boards of all state agencies that issue contracts to complete training administered by the Comptroller by September 1, 2015. CPRIT has arranged for the required training, a 45 minute webinar, to be shown during lunch at the February 18 meeting. CPRIT will register Oversight Committee members for the statutorily required contract training webinar. Each member may receive multiple emails from the Comptroller's Office once registration begins.

Agency contracting issues will continue to be an important topic during the 84<sup>th</sup> Legislative Session; completing the required contract training now will reflect positively on CPRIT and allow me to report that the training is complete at any legislative hearings.

# **Personnel Changes and Job Openings**

CPRIT has five open positions that we are in the process of filing.

- The selection process is underway for the <u>Operations Specialist</u> position. This person will assist Lisa Nelson, Operations Manager, with personnel, office management, and grants management.
- The job posting for the vacant <u>Grant Accountant</u> position has closed; CPRIT is currently reviewing applications and will schedule interviews this month.
- The job posting for the vacant <u>Grant Specialist</u> position is open through February 13.
- Two IT positions (<u>Systems Administrator</u> and <u>Programmer</u>); one position closed January 30 and the other closing February 6.

#### **Facilities Update**

Construction is complete on CPRIT's new offices in the Travis Building and CPRIT staff is preparing for the office relocation that will take place beginning immediately after the Oversight Committee meeting on February 18. CPRIT's current office will be packed on Thursday, February 19 for the move on Friday. Agency staff should be available on Monday, February 23, and fully operational by Tuesday. As of this writing all of the various moving parts of the move appear on schedule.

This will be the second of two moves that the CPRIT staff has made since August. It is less than ideal to move the entire office twice in six months (a period that covers five Oversight Committee meetings and the start of the 84th Legislative Session). CPRIT staff managed the first move with a minimum of disruption in our operations. We expect the same for this move and plan to be fully operational as quickly as possible.

#### **CPRIT's 2014 Annual Report**

CPRIT filed the *2014 Annual Report* with the Legislature on January 30, 2015, as required by statute. It is posted on the CPRIT website and a link has been sent to Oversight Committee

members and other stakeholders. The Annual Report covers CPRIT's activities during the 2014 fiscal year (September 1, 2013 – August 31, 2014).

# **Grantee Reporting**

CPRIT staff efforts to improve monitoring, education and communication with grantees continues to have positive results. Grantees continue to file reports on a timely basis and grantee questions are answered promptly.

Additionally, CPRITs Grant Compliance Specialists are continuing to perform desk reviews on selected grantees. To date, 11 desk reviews have been completed and four desk reviews are currently being performed. The results of the desk reviews have been positive, with grantees complying with staff requests for documentation and evidence of proper policies and procedures. The Grant Compliance Specialists are also scheduled to make 10 site review visits in the coming weeks, as well as several orientation visits to new grantees. The orientation visits will entail a thorough review of CPRIT grantee reporting responsibilities and will address frequently asked questions and assist in educating the new grantee on required reporting procedures. This heightened level of customer service is expected to improve compliance reporting over the long term.

## **Matching Fund Forms**

SRA International (SRA), CPRIT's third party contractor and grants management system operator, is continuing its project to ensure that CPRIT records are complete. As you may remember, during this project SRA identified a significant number of matching fund forms from prior years among others that it was unable to locate. While CPRIT staff has located many of these forms that were not entered into the system or were unrecognized by the system, it also appears that for a period of time, due to a programming error, the grants management software did not generate a matching fund form for grantees to fill out. As result, the matching fund reports, as well as possible other reports, have not appeared on the delinquent reports list used by the Chief Compliance Officer. SRA continues to work to resolve the reporting software issues and reportedly is close to resolution. However, in the meantime it is difficult to ascertain an accurate count of missing reports.

### **Compliance Program Design Project**

CPRIT received responses from three vendors on its RFP issued to procure services to implement the proposed compliance plan. As you recall, at the November 19th Oversight Committee meeting, the authorization was given to the Audit Subcommittee for the issuance of a Request for Proposal (RFP) to implement a compliance program design adopting a 53% compliance coverage, which could require four to five new contract positions in addition to nine

agency staff. The proposals have been reviewed and the respondents are currently being interviewed. I expect to bring a recommendation for the compliance plan contract to the Oversight Committee for action on February 18.

An RFP has also recently been issued for hotline services. The responses for the hotline services are due by February 13, 2015.

#### **Internal Auditor Contract**

CPRIT received three proposals in response to a request for quote (RFQ) issued to the pool of public accounting firms listed on the Texas Multiple Award Schedule (TXMAS) on December 22, 2014. The RFQ closed on January 9, 2015. CPRIT staff is evaluating the proposals and will present a vendor recommendation to the Oversight Committee at the February 18, 2015, meeting.

# **Scientific Research Program Update**

• <u>FY2015 Individual Investigator Research Award (IIRA) Applications</u>: In response to Requests for Applications (RFAs) for Individual Investigator Research Awards (IIRAs), 393 applications were reviewed by the peer review panels, and 62 were recommended for consideration by the Scientific Review Council. The Scientific Review Council recommended that only 51 of these applications move forward for consideration by the PIC and the Oversight Committee. The numbers for each type of IIRA (targeted and untargeted) are shown below:

Success Rate by Mechanism vs. Total Reviewed*			
Mechanism	Success Rate	# Recommended	
IIRA	13.3%	36/271	
IIRACCA	17.9%	10/56	
IIRAP	7.6%	5/66	
Overall	12.9%	51/393	

<sup>\*</sup>The overall success rate for FY2014 IIRAs was 13%

Of the applications forwarded by the Scientific Review Council, 70% are untargeted, 20% are for childhood cancer, and 10% are for prevention and early detection research. These applications will be considered by the Oversight Committee at its February 18 meeting.

• <u>FY 2015 Recruitment Applications</u>: The Scientific Review Council considered five applications for recruitment awards at its last meeting and has forwarded four of these to the PIC and Oversight Committee for their consideration. These will be acted upon by the Oversight Committee at the February meeting. Additional applications have been received and will be reviewed by the Scientific Review Council in March.

- <u>FY 2015 Cycle 2 Academic Research Applications</u>: CPRIT received 100 applications in response to the High Impact-High Risk RFA, 17 applications for the Core Facility Support Awards, and 42 applications for the Multi-Investigator Research Award by the November 17 deadline. Applications have been distributed to the review panels for individual review and will be considered at the next round of peer review meetings to be held in Dallas between March 8 and 18. These applications will come to the Oversight Committee for action at the May meeting.
- Other Activities: The Academic Research Subcommittee of the Oversight Committee met on January 19, 2015 to address several items. First was our response to the white paper provided by the Advisory Committee on Childhood Cancer. Our response will be communicated to the committee during a conference call scheduled for February. The interim Chair of the Advisory Committee will present the committee's annual report to the Oversight Committee at the February meeting.

The subcommittee also discussed how the research priorities would be implemented and approved a memo announcing the priorities to the peer reviewers. They reviewed a draft of a table illustrating how the success of the prioritization would be evaluated and made suggestions for improvement. The subcommittee requested that grant slates brought to the Oversight Committee include information on how the grants fit into the priorities established by the Oversight Committee.

Finally, the subcommittee discussed the agenda for the CPRIT conference and made suggestions for the types of presenters who would be invited to give keynote addresses.

#### **Product Development Program Update**

- FY2015 Cycle 1 Product Development Research Grants: CPRIT is reviewing applications for Cycle 1 FY2015 product development awards. Of 30 applications received, the reviewers advanced eight into due diligence. The first four of these were completed and subsequently approved by the Program Integration Committee on February 3, 2015. These will be presented to the Oversight Committee on February 18, 2015. The remaining four applications are undergoing due diligence and will be taken up by the Product Development Review Council on March 13, 2015; and potentially presented to the Oversight Committee on May 20, 2015.
- <u>FY2015 Cycle 4 Product Development Request for Applications</u>: CPRIT opened the application process for three RFAs for Company Relocation, Established Company, and New Company product development awards on January 5, 2015. RFAs for this cycle specifically

targeted established product development program priorities. The application period will close on February 9, 2015. The first screening of these by the review panels will take place in late March.

• Standard Revenue Sharing Terms and Conditions: The Advisory Committee for Product Development, working with CPRIT staff, recommended revised revenue sharing terms that provide for continuing State participation in revenues from blockbuster products. These terms were approved by the Oversight Committee on January 20, 2015. Counsel is preparing a revised CPRIT contract that incorporates these terms. There are currently six companies awaiting contract execution.

# **Prevention Program Update**

- <u>FY2015 Review Cycle 2</u>: Four prevention RFAs were released on September 25, 2014. Two RFAs, Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition and Cancer Prevention Promotion and Navigation to Clinical Services, are offered for the first time. Thirty-seven applications were received by the December 4 due date. We held a webinar January 21 for reviewers to discuss program priorities, features of the new RFAs and answer questions. Peer review will take place February 23-25 in Dallas. The Oversight Committee will consider recommendations forwarded by the Program Integration Committee in May.
- <u>FY2016 Review Cycle 1</u>: We are revising RFAs for a March release. Changes will include addition of the program priorities and changes to the areas of emphasis to include screening for Hepatitis B and C for the prevention of liver cancer.
- Other Activities: Prevention Review Council meetings were held January 5 and January 29. Dr. Mulrow joined the call on January 5 to discuss possible prevention interventions for liver cancer. On January 29, Dr. Garcia, Ramona Magid and David Reisman met with a prevention grantee at Methodist Medical Center in Dallas to discuss progress on their project.

#### **Communications**

In addition to finalizing the 2014 Annual Report, the Communications' activities in January include:

• A new document will be presented in conjunction with the annual report to highlight accomplishments of CPRIT's grants programs. A brochure highlighting accomplishments resulting from CPRIT's grants programs is under development and expected to be completed by mid-February.

- Planning for the November 9-10, 2015 conference is underway. An RFP for meeting
  planning services has been issued with responses due back by February 18. Ideas for topics
  and speakers are being discussed at Review Council and program Oversight Committee
  subcommittee meetings.
- We are working on a "Save the Date" announcement and other promotional efforts for a screening of Ken Burns' new documentary, *The Story of Cancer: The Emperor of All Maladies*, on March 25 at the Capitol Extension Auditorium. Dr. Rice will moderate a panel discussion of cancer experts following the screening. We are in the process of inviting the panel participants. Invitations to this advance screening and panel discussion will be extended to legislators, their staff, and cancer advocacy organizations and the public.
- Updated Fact Sheets and cards with new success stories were mailed to Oversight Committee members.
- In other activities, the communications team assisted Dr. Kripke in drafting the Op-ed that was published by the Houston Chronicle in advance of the TAMEST meeting. We sent the Council of Public University Presidents and Chancellors (CPUPC) information about CPRIT's program priorities and funding opportunities. They published this information, including CPRIT's fact sheet, in their e-newsletter on Jan. 16. University presidents were strongly encouraged to alert interested researchers to learn more about the grants process by going to CPRIT's website.

#### **Legislative Activities**

The 84<sup>th</sup> Texas Legislature convened January 13. Speaker of the House Joe Straus announced committee assignments on February 4. Lt. Governor Dan Patrick named Senate committees on January 23. A list is attached of the House and Senate Committee assignments for those committees that are likely to address CPRIT issues.

#### **Meetings**

I am scheduling meetings with legislators now that they have arrived in Austin and have organized their offices.

- Kristen Doyle and I met with Travis Broussard, Sen. Nelson's legislative director, on January 21.
- Heidi McConnell, Kristen Doyle and I met with Drew DeBerry, Governor Abbott's Policy Director and other staff, on February 2.
- I met with Rep. Drew Springer on February 4, and I am scheduled to meet with Rep. Sarah Davis on February 9, and Rep. Jason Villalba on February 9.

# **Legislation**

One bill specifically affecting CPRIT has been filed and I am aware of another that may be filed.

• Senate Bill 197 (Schwertner)-would implement an interim study recommendation from the Senate Committee on Health & Human Services which Senator Schwertner currently chairs. It instructs CPRIT to develop a plan to identify how the agency will become financially self-sufficient and operate without state funding on or after September 1, 2021 (state fiscal year 2022) which is our Sunset date. The plan must specify steps to accomplish the transition to self-sufficiency, identify sources of non-state funds on which to operate, and determine how we will structure state-funded grants until FY2022 to ensure that all grants that use state money are closed out by that date.

Bill \_\_-a bill requiring CPRIT to collaborate with the Department of State
Health Services to develop a strategic plan to significantly reduce morbidity and
mortality from human papillomavirus-associated cancer may be filed. Representatives
from MD Anderson shared a copy of the draft legislation with me and I indicated that
CPRIT would want to participate if such a bill is enacted. As far as I can determine, the
bill has not yet been filed.

In addition, CPRIT and all other state agencies will be affected by the contracting reform legislation, Senate Bill 353, filed by Senator Nelson. Although the legislation has not been enacted, Governor Abbott sent a letter to all state agencies directing agency staff to begin complying with the proposed legislation by February 1. We will provide an update to you at the February 18 Oversight Committee meeting.

# **Budget**

The Legislative Budget Board (LBB) Director presented the general appropriations bill draft to the Legislature on January 15. Governor Abbott must present a budget before his state of the state message which will occur in February 17. The LBB proposed full funding for CPRIT, but left in place several restrictions for 2016-17, including:

- LBB approval required for transfers between line items of appropriation.
- LBB contract approval is required; however, the amount requiring approval has increased from \$100,000 to \$250,000.
- No authority to carry forward CPRIT's unexpended balance from FY 2015 to FY 2016.

CPRIT will accept the first two recommendations, but plans to seek carry forward authorization. The ability to carry forward unexpended appropriations from FY 2015 to FY 2016 maximizes the available appropriations authority for grants in the prevention and research programs. Carry

forward authority for unexpended balances from one biennium to the next will allow the best use of available funding for grant awards. In FY 2014, CPRIT lapsed about \$2.9 million, which indicates the range of flexibility requested.

In addition to the carry forward authorization, CPRIT is requesting that the Legislature create the statutorily authorized interest and sinking fund in the Funds Consolidation Bill. The CPRIT Sinking Fund was established last session by SB149 as a General Revenue-Dedicated Account for deposits of revenue from patents, royalties, license fees, or other income received as a result of revenue sharing agreements in CPRIT grant awards. The revenue deposited in the account could be used only at the Legislature's discretion for debt service on bonds issued by Texas Public Finance Authority for CPRIT. However, because the account was not also created in the Funds Consolidation Bill passed that session, it was not created as a fund account in the State Treasury. Currently, all income received since June 4, 2013, is deposited in the General Revenue Fund, and is used for general governmental purposes.

#### **CPRIT Outreach**

- <u>Texas Association of Community Health Centers</u>: Dr. Garcia and Ramona Magid met with the Texas Association of Community Health Centers on January 14 to discuss funding opportunities.
- <u>CPRIT Advocates Meeting</u>: CPRIT Staff met with representatives from the American Cancer Society, the Cancer Action Network, Livestrong, and Susan G. Komen on January 21 to provide a status update on CPRIT activities and to discuss the upcoming legislative session.
- The Academy of Medicine, Engineering and Science of Texas (TAMEST): Dr. Kripke presented a lecture on January 22 in Houston at TAMEST's annual meeting, the theme of which was "Cancer: A Texas-sized Problem". Her lecture, entitled, "CPRIT: Moving Forward", described the research awards portfolio and presented the results of the OC's recent prioritization project.
- MD Anderson Cancer Center's Executive Advisory Panel (EAP): On January 23, I participated in a legislative round table discussion hosted by MD Anderson, which included representatives of major medical organizations and societies in Texas.
- <u>Annual Meeting of U.T. System Senior Women Leaders</u>: On January 23, Dr. Kripke gave the closing address at the first Annual Meeting of U.T. System Senior Women Leaders in Austin.

- American Lung Association: Dr. Kripke and I met with the national CEO of the American Lung Association and several others in Austin on January 26 to discuss potential areas of collaboration.
- <u>City of Laredo</u>: Dr. Garcia and Ramona Magid met with City of Laredo representatives on January 27 to discuss CPRIT funding opportunities.
- <u>Texas A& M University</u>: On January 28, David Reisman, Kristen Doyle, Cameron Eckel, Michael Brown and Oralia Huggins presented a training to more than 50 sponsored program office staff, principal investigators and project directors at Texas A& M University.
- Texas Gulf Coast Consortia: Dr. Kripke and I participated in a CPRIT Trainee Symposium put on by the Texas Gulf Coast Consortia in Houston on January 30. The conference focused on trainees, including poster presentations on work conducted by CPRIT-funded trainees. One trainee from each of the seven programs was selected to make an oral presentation. Dr. Kripke led a discussion with the leaders of the existing training programs to solicit input for improvements in the program that could be incorporated into the new RFA for training programs, which is expected to be released in March 2015. The program included a speaker that discussed diversity opportunities and challenges in STEM (Science, Technology, Engineering, and Math) fields.
- <u>Bridge Breast Network</u>: Pete Geren, Will Montgomery, Dr. Garcia, Ramona Magid and David Reisman attended a meeting January 30 of the Bridge Breast Network in Dallas. CPRIT was recognized for its contributions to cancer prevention.
- <u>Texas Medical Association</u>: On January 30, Heidi McConnell provided an update on CPRIT activities to TMA's Committee on Cancer.
- <u>Texas Healthcare and Bioscience Institute (THBI):</u> I participated on a panel at THBI's Summit on February 4. The panel's topic was "The Future of the Texas Life Sciences Industry".
- <u>TMC Pulse Interview</u>: I have been asked to do an interview in Houston on February 26 with the Texas Medical Center's publication TMC Pulse, again covering activities since November 2013 and the new program priorities.
- Rare Disease Day: I have been asked to be a keynote speaker for the Rare Disease Day rally at the State Capitol on February 28. The short presentation will cover my interest in rare diseases, especially rare cancers, and CPRIT's current work in rare cancers and the new priority adopted by the OC in November.

- Screening of *The Emperor of All Maladies: A Biography of Cancer*: The Capitol Extension Auditorium is reserved for a screening of Ken Burns' new documentary, *The Emperor of All Maladies: A Biography of Cancer*, on March 25. We are organizing a thirty minute panel discussion to follow the screening. Invitations to this advance screening and discussion will be extended to legislators, their staff, and cancer advocacy organizations.
- <u>Houston Technology Center (HTC)</u>: The presentation planned for December 10 was postponed to a time to be determined, probably in February. This will be an opportunity for the program chiefs and me to update their membership on CPRIT activities since our July 2014 visit and to brief them on the Program Priority Project.

#### Standing Subcommittee Meetings in January and February

The dates and times for the February subcommittee meetings are listed below:

Board Governance – February 5 at 10:00

Diversity – February 6 at 10:30

Audit – February 9 at 10:00

Prevention – February 10 at 10:00

Scientific Research – February 11 at 10:00

Product Development – February 12 at 10:00

Nominations – February 13 at 10:30

An agenda, call-in information and supporting material will be available one week prior to the meeting date. If you or your assistant did not receive a calendar invite from Mary Gerdes for subcommittee meeting dates in February, please contact Mary at <a href="majorage-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-meeting-

\*\*\*\*\*

#### CPRIT has awarded 815 grants totaling \$1.146 billion

- 135 prevention awards totaling \$121.6 million
- 680 academic research and product development awards totaling \$1.024 billion

## Of the \$1.024 billion in academic research and product development awards

- 29.0% of the funding (\$297.3 million) supports clinical research projects
- 27.2% of the funding (\$278.7 million) supports translational research projects
- 24.6% of funding (\$251.5 million) supports recruitment awards
- 16.3% of the funding (\$167.2 million) supports discovery stage research projects
- 2.9% of funding (\$29.5 million) supports training programs.

#### CPRIT has 6 Requests for Applications (RFAs) that are open or will open soon:

- 3 Product Development RFAs applications due February 9
- 3 Research Recruitment RFAs applications are continuously accepted



#### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
Subject: CPRIT ACTIVITIES UPDATE – DECEMBER 2014

Date: JANUARY 9, 2015

Topics in this update include: Oversight Committee preparations, CPRIT staffing, Program updates, Compliance RFP, Financial Status Reports, Advisory Committee meetings, CPRIT's FY2014 financial audit, legislative update, ongoing projects, and outreach efforts.

# Preparation for the January 20 Oversight Committee Meeting

The Oversight Committee is scheduled to meet January 20 at 10:00am at the offices of the Teachers Retirement System just off the Capitol Complex. Due to legislative activities the Oversight Committee will not be able to meet in the Texas Capitol Extension until the August meeting at the earliest. The final agenda for the Oversight Committee meeting will be posted by January 12; a tentative agenda is attached.

The major agenda item will be approval of standard contract terms for Product Development program awards. A staff proposal derived from discussions with the newly formed Product Development Advisory Committee will be presented to the Oversight Committee Subcommittee on Economic Terms for a recommendation to the full Oversight Committee. More information is provided in the Product Development Program update.

#### **Personnel Changes and Job Openings**

Since the November 19, 2014, Oversight Committee meeting, the new grant accountant, Dina Fletcher, resigned to take a position for which she had applied at the same time she submitted her CPRIT application.

Cathy Allen is the new Program Manager for Product Development. Cathy has been working for CPRIT since June as a grant specialist. In her new position she will assist Dr. Goodman and work directly with Product Development grantees and grant applicants, as well as take on special assignments related to Product Development activities.

The vacant grant accountant and grant specialist positions will be posted the week of January 5.

The posting for Operations Specialist closed on November 12 and the selection process for this vacancy is underway. This person will assist Lisa Nelson, Operations Manager with personnel, office management, and grants management.

CPRIT currently has 32 authorized full-time equivalent (FTE) positions, of which 27 are filled. Two of the 27 FTEs are information technology (IT) contractors. In addition to the three positions that we are currently in the process of filling, the two remaining positions are an IT and internal auditor position.

#### **Facilities Update**

Construction on CPRIT's new offices in the Travis Building is reported to be on schedule for February office relocation. Initial construction inspections occurred on December 8 and 19. Our IT staff is expected to have access for preparatory work by mid-January. The move from our temporary offices at the Moody Bank building to our permanent space is planned for February 19 and 20 after the February 18 Oversight Committee meeting.

### Financial Status Reports (FSRs) Update

Through the sustained efforts of grantees and CPRIT staff, FSRs delinquencies for all projects were erased by the last filing deadline. This positive news is the result of a significant six-month project to bring all grantees up to date related to quarterly FSRs. FSRs are submitted by grantees in order to be reimbursed with grant funds. Late FSRs mean that the grantee is not getting paid for work it is doing on the CPRIT project and CPRIT is unable to timely review the grantee's financial practices to address issues early, rather than several months after the expenditures are made. When we started this project more than 180 FSRs were past their due date. Additional resources and a restructured approach have resulted in much faster processing times for FSRs over the past several months, dropping the average review period for an FSR with all required back up information from 66 days to less than 10 days. CPRIT's Grant Accountant Team, with assistance of our grant specialists, our Chief Compliance Officer and our Chief Operating Officer, have done a tremendous job.

On a related note, you may recall that CPRIT's new administrative rule waiving reimbursement for late-filed FSRs, was effective for FSRs due November 29 (with a 30 day grace period through December). All FSRs were submitted (or requested extensions to file the information) by the deadline.

Late reports overall continued to decline, and are now less than 50. With an increase in staff, implementation of new reporting rules, education efforts and efforts to track filings, the reports are now filed on a timely basis with greater CPRIT staff attention to impending filing deadlines and individual grantee awareness of reporting requirements.

#### **Matching Funds Forms**

As reported at the November Oversight Committee meeting, SRA International, Inc. (SRA), CPRIT's third party grants management system operator, is working on a project to compile complete grant records for all CPRIT grants in its electronic database. This involves integrating grant records from CPRIT's first three years into the comprehensive grant database. Having all CPRIT grant records in one place assists compliance monitoring and grant review.

SRA identified 375 matching funds forms that it is unable to locate in its electronic database. CPRIT staff has undertaken a grant-by-grant search of our paper and electronic files and has found many of the forms identified by SRA. Some were electronically stored in CPRIT's files in such a way that SRA's initial sweep of records did not recognize the forms as matching funds forms. Other forms covered more than one year, or were not filed for periods when no grant funds were disbursed. However, a portion of the missing forms are due to a programming error that SRA recently identified. The grants management software did not generate the matching fund form to be completed by the grantee for a time period from about February to June 2014. CPRIT staff and SRA are investigating how this occurred, why the missing reports did not appear on the delinquent reports list used by the Chief Compliance Officer, and how to prevent this or similar issues from occurring again.

I and other relevant CPRIT staff discussed the matching funds form issues with the Oversight Committee officers on December 19. This work is ongoing and we expect to complete the review shortly. We will report on this at the February Oversight Committee meeting.

#### **Compliance Program Request for Proposals**

CPRIT released a Request for Proposals (RFP) in December seeking a third party contractor to assist the agency in implementing a comprehensive compliance program. Using the report prepared for CPRIT by Weaver and Tidwell LLP, a Texas-based assurance, tax, and advisory firm, staff proposed a compliance program design that requires four to five new contract positions in addition to the existing nine agency compliance-related positions. The Oversight Committee authorized the release of the RFP at its November meeting based upon the Audit Subcommittee's recommendation. Responses are due by January 16 and staff anticipates bringing a contract to the Oversight Committee in February for approval. A separate RFP will be released for hotline services.

#### **Scientific Research Program Update**

• <u>FY2015 Individual Investigator Research Award (IIRA) Applications</u>: The Research Peer Review Panels met for nearly 2 ½ weeks in late October and early November to assess 407 Individual Investigator Research applications (IIRA). Of these, 62 (15%) were

recommended for funding and will be considered by the Scientific Review Council in January. This is the first cycle that includes targeted RFAs. The applications received and the recommendations by type are as follows:

- ➤ Prevention and Early Detection IIRA applications 66 submitted, 8 (12%) recommended.
- Cancers of Children and Adolescents IIRA applications 56 submitted, 12 (21%) recommended.
- ➤ Untargeted IIRA applications 285 submitted, 42 (14.7%) recommended.
- <u>FY 2015 Recruitment Applications</u>: The Scientific Review Council will consider three applications for recruitment awards at its meeting in January.
- <u>FY 2015 High Impact-High Risk (HIHR)</u>: CPRIT received 100 applications for the HIHR RFA by the November 17 deadline. Applications have been distributed to the review panels for individual review and will be considered at the next round of peer review meetings to be held in Dallas in March.
- <u>Core Facility Support Award Applications (CFSA)</u>: CPRIT received 17 applications for the CFSA RFA. Applications have been distributed to the review panels for individual review and will be considered at the next round of peer review meetings to be held in Dallas in March
- <u>FY 2015 Multi-Investigator Research Award (MIRA)</u>: CPRIT received 42 applications for the MIRA RFA. These applications total 166 projects and 77 cores. Applications have been distributed to the review panels for individual review and will be considered at the next round of peer review meetings to be held in Dallas in March.

### **Product Development Program Update**

- FY2015 Cycle 1 Product Development Research Grants: The Product Development Review Council (PDRC) will meet in January to review the due diligence reports for four grant proposals. Based upon their review, the PDRC will make final grant recommendations and submit those to the Program Integration Committee. The PIC's recommendations are expected to be taken up at the February Oversight Committee meeting. Four other applications from this cycle are still in the due diligence review stage and any recommendations are expected to be considered at the May Oversight Committee meeting.
- <u>FY2015 Cycle 4 Product Development Request for Applications</u>: CPRIT released three RFAs for Company Relocation, Established Company, and New Company product

- development awards on December 5, 2014. These RFAs specifically target the program priorities earlier set for the Product Development Grant Program. Applications will be accepted from January 5 through February 9, 2015.
- Standard Revenue Sharing Terms and Conditions: Consultation with the Advisory Committee on Product Development and the Oversight Committee Subcommittee for Contract Terms is ongoing. A modified revenue sharing proposal that provides for continuing participation in blockbuster products was developed from the Committee's input. This proposal was discussed at a joint meeting of the Advisory Committee and the OC Subcommittee for Contract Terms on January 7, 2015. As of this writing, I expect us to present standard contract terms for approval by the full Oversight Committee on January 20, 2015.
- <u>Early Translational Research Awards</u>: A question was raised at the November 19, 2014,
   Oversight Committee meeting whether Early Translational Research Awards (ETRA) awards
   should be under the auspices of the Scientific Research Program rather than in Product
   Development. A memorandum addressing this question will be discussed at the February 18,
   2015, OC meeting.

# **Prevention Program Update**

• <u>FY2015 Review Cycle 2</u>: Four prevention RFAs were released on September 25, 2014. Two RFAs, Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition and Cancer Prevention Promotion and Navigation to Clinical Services, are offered for the first time. Thirty-seven applications were received by the December 4 due date. The applications are being checked for compliance with the RFA prior to assigning them to the peer review panels for evaluation. Peer review will occur in February in Dallas. The Oversight Committee will consider recommendations forwarded by the Program Integration Committee in May.

#### **Advisory Committees**

- Advisory Committee on Childhood Committee (ACCC): The ACCC will meet in January to discuss implementation of CPRIT's newly-adopted research priorities and ways to track implementation progress.
- <u>University Advisory Committee (UAC)</u>: Chancellor Lee Jackson has appointed David Cistola, MD to replace by Myron (Mike) Jacobson, PhD, as the University of North Texas System representative on the UAC. No action is required by the Oversight Committee because members of the UAC are statutorily appointed by the chancellors/presidents of the

designated institutions. Dr. Jacobson has 35 years of National Cancer Institute funded research with successful translation and commercialization experience. He is the founding dean of the University of North Texas System College of Pharmacy at their health science center and an expert on skin cancer. The UAC will meet in January to discuss implementation of CPRIT's newly-adopted research priorities and ways to track implementation progress.

• The Product Development Advisory Committee (PDAC): The PDAC met on January 7 to discuss the proposed term sheet for revenue sharing agreements with Product Development grants.

#### **CPRIT Bi-annual Conference to Be Held November 9 – 10, 2015**

The Legislative Budget Board approved CPRIT's request to contract with the Renaissance Austin Hotel for the 2015 Biennial Conference. The conference is to be held November 9-10, 2015, in Austin.

# **CPRIT Annual Report**

Work on the statutorily required 2014 Annual Report continues. It is due by the end of January 2015. In conjunction with the annual report a new document will be presented to highlight accomplishments of CPRIT's grants programs.

#### **CPRIT's Independent Financial Audit for FY2014**

McConnell & Jones LLP, the financial auditor, completed CPRIT's financial audit for FY 2014 and concluded that the "basic financial statements...present fairly, in all material respects, the respective financial position of...CPRIT." As part of the audit, the auditor conducted a compliance review and reported two findings. One finding relates to the Comptroller of Public Accounts financial reporting guidelines that requires CPRIT to report its payables according to fund accounting requirements but not make any adjustments to conform to U.S. GAAP standards. This is identified as a material weakness and requires instruction from the Comptroller's Financial Reporting Section to address it. The second finding reported that grantees did not provide any invoices and other details to support financial status reports (reimbursement requests) for 2 of 60 samples covering September 1, 2013 through August 31, 2014. This is identified as a significant deficiency that CPRIT has already addressed by hiring four new grant accountants and verifying grantee expenses of \$750 or more.

#### **Internal Audit Services for FY2015**

CPRIT issued a Request for Quote (RFQ) for FY 2015 internal audit services to certified public accounting firms listed on the Texas Multiple Awards Schedule (TXMAS) with responses due

by January 9, 2015. CPRIT will be issuing RFPs for Fraud, Waste, and Abuse Reporting Services (hotline services) and for Conference Planning and Coordinating Services for the 2015 conference.

#### **Implementation Status Report to State Auditor's Office**

CPRIT submitted its status update in December related to the implementation of the State Auditor's recommendations included in the January 2013 State Audit, *An Audit Report on Grant Management at the Cancer Prevention and Research Institute of Texas and Selected Grantees*. CPRIT reported that it has fully implemented all of the State Auditor's recommendations.

#### **Legislative-related Activities**

The 84<sup>th</sup> Texas Legislature convenes at noon on January 13, whereupon the House will begin organizing by electing its Speaker and adopting House rules. Based on recent history it may take a few weeks, perhaps as late as the end of January for House committees to be named. The Senate may not organize until after January 20 when the new Lieutenant Governor, Dan Patrick, officially takes office. However, Senate rules may be adopted on or soon after January 13.

# **Legislation**

One bill affecting CPRIT has been filed and I am aware of another that may be filed.

• Senate Bill 197 (Schwertner)-would implement an interim study recommendation from the Senate Committee on Health & Human Services which Senator Schwertner currently chairs. It instructs CPRIT to develop a plan to identify how the agency will become financially self-sufficient and operate without state funding on or after September 1, 2021 (state fiscal year 2022) which is our Sunset date. The plan must specify steps to accomplish the transition to self-sufficiency, sources of non-state funds on which to operate, and how we will structure state-funded grants until FY2022 to ensure that all grants that use state money are closed out by that date.

Bill \_\_-a bill requiring CPRIT to collaborate with the Department of State Health Services to develop a strategic plan to significantly reduce morbidity and mortality from human papillomavirus-associated cancer may be filed. Representatives from MD Anderson shared a copy of the draft legislation with me and I indicated that CPRIT would want to participate if such a bill is enacted. As far as I can determine, the bill has not yet been filed.

#### Budget

No information exists concerning proposed appropriations from the Legislative Budget Board or the Governor's Office nor do I expect to hear anything until January 17 at the earliest when the

director of the LBB is required to provide budget estimates to the Legislature. A full general appropriations bill draft must be presented by the LBB director to the Legislature by January 20. However, the estimates and budget <u>may</u> be provided sooner than those deadlines.

Governor-Elect Abbott must present a budget before his state of the state message which will occur in late January or early February. Governor Perry may or may not choose to submit a budget before leaving office on January 20.

I hope to begin meeting with legislators as they arrive and get organized in their offices. Arranging meetings during this transition time is difficult.

#### **CPRIT Outreach**

- The University of Texas Institute for Computational Engineering and Sciences: Drs. Rice and Kripke attended a meeting on December 11, 2014, at The University of Texas Institute for Computational Engineering and Sciences in Austin to discuss applications of computational biology and modeling in medicine. This was the first of several meetings to develop a new RFA in computational biology, which is one of CPRIT's new priority areas.
- <u>HOPE Clinic</u>: Dr. Kripke and Michael Brown attended the 20th Anniversary Celebration of the HOPE clinic in Houston on December 12, 2014. The event was sponsored by the Asian American Health Coalition of Houston. Dr. Kripke gave the keynote address entitled, "CPRIT: A New Focus on Prevention and Health Disparities".
- <u>Capital Tonight</u>: I appeared on Time Warner Cable's "Capital Tonight" on December 16 to update viewers on CPRIT activities since my previous appearance in August 2013. The conversation focused largely on accomplishments since November 2013 after the naming of the new OC members and the recently adopted program priorities.
- <u>Kalon Biotherapeutics Ceremony</u>: Dr. Goodman and I traveled to College Station on December 18 to attend the ceremony announcing the acquisition of Kalon Biotherapeutics by FUJIFILM Diosynth Biotechnologies U.S.A., a subsidiary of FUJIFILM Corp. Kalon, a biopharmaceutical contract manufacturing organization that produces vaccines and therapeutics, is a CPRIT grantee. In his remarks at the signing ceremony Governor Perry acknowledged the participation of CPRIT in reaching this acquisition and praised CPRIT's efforts.
- <u>Texas A&M</u>: Dr. Garcia and Ramona Magid visited two Texas A&M grantees in December to review the projects' status and explore components of projects that may be candidates for replication by others.

- MD Anderson Cancer Center's Executive Advisory Panel (EAP): I am invited to participate in an exchange of information between MD Anderson and representatives of major medical organizations and societies in Texas. This discussion will occur in Houston on January 23.
- Texas Gulf Coast Consortia: Dr. Kripke and I will participate in a CPRIT Trainee Symposium put on by the Texas Gulf Coast Consortia in Houston on January 30. The conference will focus on trainees. There will also be poster presentations on work conducted by CPRIT-funded trainees and one trainee from each of the seven programs will make an oral presentation. Dr. Kripke will lead a discussion with the leaders of the existing training programs to solicit input for improvements in the program that could be incorporated into the new RFA for training programs, which is expected to be released in March 2015. There may be a speaker to discuss diversity opportunities and challenges in STEM (Science, Technology, Engineering, and Math) fields. Anyone interested in training programs in cancer research in Texas is encouraged to attend. Please let Dr. Kripke know if you wish to participate.
- <u>Bridge Breast Network</u>: Pete Geren, Will Montgomery and Dr. Garcia will attend a meeting January 30 of the Bridge Breast Network in Dallas where it is expected that CPRIT will be recognized for its contributions to cancer prevention.
- <u>Texas Healthcare and Bioscience Institute (THBI)</u>: THBI invited me to sit on a panel at its Summit on February 4. The panel's topic will be "The Future of the Texas Life Sciences Industry". Considerable legislative participation and attendance is expected.
- <u>TMC Pulse Interview</u>: I have been asked to do an interview in Houston on February 26 with the Texas Medical Center's publication TMC Pulse, again covering activities since November 2013 and the new program priorities.
- Rare Disease Day: I have been asked to be a keynote speaker for the Rare Disease Day rally at the State Capitol on February 28. The short presentation will cover my interest in rare diseases, especially rare cancers, and CPRIT's current work in rare cancers and the new priority adopted by the OC in November.
- Screening of *The Emperor of All Maladies: A Biography of Cancer*: The Capitol Extension Auditorium is reserved for a screening of Ken Burns' new documentary, *The Emperor of All Maladies: A Biography of Cancer*, on March 25. We intend to organize a thirty minute panel discussion to follow the screening. Invitations to this advance screening and discussion will be extended to legislators, their staff, and cancer advocacy organizations.
- <u>Houston Technology Center (HTC):</u> the presentation planned for December 10 was postponed to a time to be determined, probably in February. This will be an opportunity for

the program chiefs and me to update their membership on CPRIT activities since our July 2014 visit and to brief them on the Program Priority Project.

### Standing Subcommittee Meetings in January and February

The dates and times for the February subcommittee meetings are listed below:

Board Governance – February 5 at 10:00

Diversity – February 6 at 10:30

Audit – February 9 at 10:00

Prevention – February 10 at 10:00

Scientific Research – February 11 at 10:00

Product Development – February 12 at 10:00

Nominations – February 13 at 10:30

An agenda, call-in information and supporting material will be sent to the subcommittee one week prior to the meeting date. If you or your assistant did not receive a calendar invite from Mary Gerdes for subcommittee meeting dates in February, please contact Mary at <a href="mailto:mgerdes@cprit.state.tx.us">mgerdes@cprit.state.tx.us</a>.

\*\*\*\*\*

#### CPRIT has awarded 815 grants totaling \$1.146 billion

- 135 prevention awards totaling \$121.6 million
- 630 academic research and product development awards totaling \$1.024 billion

Of the \$1.024 billion in academic research and product development awards

- 29.0% of the funding (\$297.3 million) supports clinical research projects
- 27.2% of the funding (\$278.7 million) supports translational research projects
- 24.6% of funding (\$251.5 million) supports recruitment awards
- 16.3% of the funding (\$167.2 million) supports discovery stage research projects
- 2.9% of funding (\$29.5 million) supports training programs.

CPRIT has 6 Requests for Applications (RFAs) that are open or will open soon:

- 3 Product Development RFAs applications due February 9
- 3 Research Recruitment RFAs applications are continuously accepted

### CPRIT MANAGEMENT DASHBOARD FISCAL YEAR 2015

	SEPT	ОСТ	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (YTD)
ACCOUNTABILITY														
Announced Grant Awards			32										32	
New Grant Contracts Signed	11	14	47	19	21								112	
New Grant Contracts In Negotiation			26										26	
Grant Reimbursements Processed (#)	2	434	0	11	109								556	
Grant Reimbursements Processed (\$)	\$ 3,919,524	\$ 30,454,155	\$ -	\$ 2,501,374	\$ 10,721,494								\$ 47,596,547	
Revenue Sharing Payments Received	\$ 1,000	\$ -	\$ -	\$ 7,456	\$ 6,208								\$ 14,664	\$ 2,181,406
<b>Total Grants Contracted (\$)</b>	\$ 8,316,567	\$ 21,311,777	\$43,594,810	\$ 14,713,321	\$ 23,311,979								\$ 111,248,454	
Grants Awarded (#)/Applications Rec'd (#)	12%	12%	12%	12%	12%									
Debt Issued (\$)/Funding Awarded (\$)	51%	51%	53%	53%	53%									
Grantee Compliance Trainings/Monitoring Visits	1	1	0	0	2								4	
Awards with Delinquent Reimbursement Submission (FSR)						9								
Awards with Delinquent Matching			16			2								
Funds Verification Awards with Delinquent Progress														
Report Submission			10			14								
IA Agency Operational Recommendations Implemented	2	3	6	6	7									
IA Agency Operational Recommendations In Progress	13	12	9	9	8									
IA Grantee Recommendations Implemented	0	1	1	1	1									
IA Grantee Recommendations In Progress	20	19	19	19	19									
Open RFAs	7	13	10	10	6									
<b>Prevention Applications Received</b>	0	0	0	35	0								35	540
Product Development Applications Received	0	0	0	0	0								0	252
Research Applications Received	10	0	161	2	4				1				177	3,960
Help Desk Calls/Emails	230	240	210	184	149								1,013	
MISSION														
RESEARCH PROGRAM														
Number of Research Grant			7										7	
Awarded (Annual) Recruited Scientists Announced														0.4
														84
Recruited Scientists Accepted  Recruited Scientists Contracted														81 65
Published Articles on CPRIT-													0	05
Funded Projects (#)														
Jobs Created & Maintained (#)													0	

### CPRIT MANAGEMENT DASHBOARD FISCAL YEAR 2015

			•			T	T			ı	•		•	•
	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (YTD)
Trainees in CPRIT-Funded Training													0	
Programs (#) Open Clinical Trials (#)														F2
Number of Patents Resulting from														53
Research													0	
Number of Patent Applications													0	
Number of Investigational New Drugs													0	
DRODUCT DEVELOPMENT					1			1						
PRODUCT DEVELOPMENT PROGRAM														
Number of Product Development														
Grant Awarded (Annual)			20										20	
Life Science Companies Recruited (in TX)														2
Published Articles on CPRIT- Funded Projects													0	
Number of Jobs Created & Maintained													0	
Open Clinical Trials (#)														7
Number of Patents Resulting from Research													0	
Number of Patent Applications													0	
Number of Investigational New Drugs													0	
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)			5										5	
People Served by CPRIT-Funded Prevention and Control Activities			1,972,406										1,972,406	
People Served through CPRIT- Funded Education and Training			1,005,173										1,005,173	
People Served through CPRIT- Funded Clinical Services			967,233										967,233	
runueu Chnical Services														
TRANSPARENCY														
Total Website Hits (Sessions)	6,610	7,275	8,202	5,101	5,844								33,032	
Total Unique Visitors to Website (Users)	4,811	5,143	5,628	3,852	4,195								23,629	



### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: DAVID A. REISMAN, CHIEF COMPLIANCE OFFICER

Subject: CHIEF COMPLIANCE OFFICER REPORT

Date: FEBRUARY 9, 2015

The Chief Compliance Officer is responsible for creating, supporting, and promoting an effective Ethics and Compliance Program and assuring the CPRIT Oversight Committee that controls are in place to prevent, detect and mitigate compliance risk. CPRIT's Administrative Rule 701.7, provides in part that, "The Chief Compliance Officer is responsible and will be held accountable for apprising the Oversight Committee and the Chief Executive Officer of the institutional compliance functions and activities." The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules and agency policies (701.7(c)(2)(A)). In addition, the compliance officer must inquire into and monitor the timely submission status of required grant recipient reports and notify the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

### **Monitoring Submission Status of Required Grant Recipient Reports:**

As of February 6, 2015, the date the report was run, information regarding delinquent grant recipient reports was as follows:

• 4 grant projects, either active or in close out, at 4 separate entities, have not filed required quarterly financial status reports (FSRs) by the deadline. At the last Oversight Committee meeting on November 19, 2014, I reported that 43 grant projects had not filed required FSRs by the deadline.

At the last Oversight Committee meeting it was noted that in addition to those above, other FSRs were pending filing upon submission and approval of the currently delinquent FSR; the total number of past due FSRs at the last meeting was 46, at the prior meeting in August it was 180, that number is currently 0.

• Six grant projects, either active or in close out, have not filed required progress reports by the deadline. All grant projects must file annual progress reports; Prevention program projects are also required to file quarterly progress reports. Annual progress reports must be filed with CPRIT within 60 days following the anniversary of the contract effective date.

Additionally, the grant specialists and the grant accountants have continued reviewing and processing incoming reports and reaching out to grantees to expeditiously resolve filing issues. As a result, significant progress has been made in identifying and processing these past due reports.

At the last meeting, a total of 76 outstanding reports existed. As of February 6, 2015, the date this report was run, that number has been reduced to 43. It should be noted, that the grants management software (CGMS) that the agency uses to manage the filing of reports, has still not completed its reconciliation for all reports. As a result, some grantees have been unable to file select annual financial reports through our system and it's uncertain how many of those reports are still due, including matching funds certification forms, for a period now lasting several months. It remains unclear when the reconciliation is expected to be completed. It may be that we need to receive reports in an alternative format until the issue is resolved. This is not a desirable approach.

### **Grantee Desk Reviews and Site Visits**

The grant compliance specialists have continued with desk reviews of grantees. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify grantees expend funds in compliance with specific grant requirements and guidelines. A total of 16 desk reviews have been completed to date, and there are currently 4 active desk reviews. Desk-based reviews may target the following areas:

- Grantee administrative and/or operating policies and procedures
- Grantee financial policies and procedures
- Project budget and payroll records and time reporting records
- Project accounting records to include general ledger records
- Project financial expenditure records and supporting documentation
- Programmatic reports, financial reports, progress reports, inventory reports
- Single Audit Reports and/or Single Audit Determination forms and records

The grant compliance specialists also have 10 on-site reviews scheduled starting the following week. Also, on Wednesday, February 11, 2015, the grant compliance specialists will be traveling to visit a product development grantee, which recently changed ownership, to orient the new management on reporting and compliance laws and regulations. The specialists will also be assisting the grantee file past due reports to come into compliance.



### **MEMORANDUM**

**TO:** CPRIT OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

**SUBJECT:** CPRIT FINANCIAL OVERVIEW FOR FY 2015, QUARTER 1

**DATE:** FEBRUARY 10, 2014

### FY 2015, Quarter 1 Operating Budget

For the first three months of FY 2015, CPRIT expended approximately \$1 million between the Indirect Administration and Grant Review and Award Operations strategies primarily in staff salaries and prepayment of six months of rent for the current leased space in the Moody Bank Building.

During this period, CPRIT received \$1,000 in revenue sharing payments which was deposited into the General Revenue Fund (0001).

### FY 2015, Quarter 1 Performance Measures

In January 2015, CPRIT reported to the LBB on the two output measures that have quarterly reporting requirements, number of people served by CPRIT prevention and control activities and the number of entities performing cancer research relocating to Texas. The other four measures are only reported after the end of the fiscal year.

### **Debt Issuance History**

CPRIT has not issued any additional debt in the past two months since reporting to you on November 19, 2014, that the Texas Public Finance Authority issued \$57.6 million on CPRIT's behalf on November 5, 2014. The total debt issued to date remains approximately \$606.4 million.

Attachments: FY 2015 Quarterly Financial Report

FY 2015 Performance Measure Report

# Cancer Prevention and Research Institute of Texas FY 2015 Quarterly Financial Report

As of November 30, 2014

Indirect /	Administration (	D 1 1 \
manect A	AUITIIIIISU AUION I	D.T.T.1

					Actual Expenditures &			Estimated	
		2015		% of Total	<b>Grant Encumbrances</b>	Remaining	Percent	Expenditures	
		Appropriated	2015 Budgeted	Budget	(FYTD)	Budget	Expended	(YTD)	Lapse/Overspent
1001	Salaries and Wages	\$ 1,571,528	\$ 1,571,528		\$ 262,160	1,309,368	17%	\$ 349,547	\$ 1,221,981
1002	Other Personnel Costs	50,000	50,000		4,385	45,615	9%	5,846	44,154
2001	Professional Fees and Services	867,290	767,290		29,640	737,650	4%	39,521	727,769
2003	Consumable Supplies	25,750	25,750		-	25,750	0%	-	25,750
2004	Utilities	63,648	63,648		94	63,554	0%	125	63,523
2005	Travel	24,176	24,176		6,479	17,697	27%	8,638	15,538
2006	Rent - Building	181,875	181,875		142,965	38,910	79%	190,621	(8,746)
2007	Rent-Machine and Other	29,644	29,644		772	28,872	3%	1,029	28,615
2009	Other Operating Expenses	456,500	456,500		22,600	433,900	5%	30,133	426,367
5000	Capital	95,000	95,000		7,043	87,957	0%	-	95,000
	Subtotal - Indirect Administration (B.1.1.)	\$ 3,365,411	\$ 3,265,411	1.10%	\$ 476,139	\$ 2,789,272	15%	\$ 625,461	\$ 2,639,950

**Grant Review and Award Operations (A.1.3.)** 

						Actu	ual Expenditures &				Estimated		
		2	2015		% of Total	Gra	nt Encumbrances	1	Remaining	Percent	Expenditures		
		Appro	opriated	2015 Budgeted	Budget		(FYTD)		Budget	Expended	(YTD)	Laps	e/Overspent
1001	Salaries and Wages	\$ 2	,654,617	2,654,617		\$	556,444	\$	2,098,173	21%	\$ 741,926	\$	1,912,691
1002	Other Personnel Costs		100,000	100,000			6,654		93,346	0%	8,872		91,128
2001	Professional Fees and Services	12	,942,211	13,042,211			-		13,042,211	0%	-		13,042,211
2003	Consumable Supplies		-	-			-		-	0%	-		-
2005	Travel		35,000	35,000			13,451		21,549	38%	17,935		17,065
2006	Rent - Building		32,400	32,400			8,822		23,578	27%	11,762		20,638
2007	Rent-Machine and Other		5,013	5,013			-		5,013	0%	-		5,013
2009	Other Operating Expenses		=	-			-		-	0%	-		
	Subtotal - Grant Operations (A.1.3.)	\$ 15	,769,241	\$ 15,869,241	5.34%	\$	585,371	\$	15,283,870	4%	\$ 780,495	\$	15,088,746

### Grants

	2015 Appropriated	2	2015 Budgeted	% of Total Budget	Actual Expenditu Grant Encumbra (FYTD)		Remaining Budget	Percent Expended	Ехре	timated enditures (YTD)	Lap	se/Overspent
Grants - Prevention (A.1.2) Grants - Research (A.1.1.)	\$ 29,037,567 248,929,227	\$ \$	29,037,567 248,929,227		\$	- -	\$ 29,037,567 \$ 248,929,227	0% 0%	\$	- -	\$	29,037,567 248,929,227
Subtotal - Grants	\$ 277,966,794	\$	277,966,794	93.56%	\$	-	\$ 277,966,794	0%	\$	-	\$	277,966,794
Grand Totals	\$ 297,101,446	\$	297,101,446	100.00%	\$ 1,063	1,510	\$ 296,039,936	0%	\$	1,405,956	\$	295,695,490

<sup>\* 2015</sup> Appropriated and budgeted includes a transfer from strategy A.1.1. (Research) into strategies A.1.3. (Grant Operations) and B.1.1. (Indirect Administration) approved by the Legislative Budget Board pursuant to the 2014-15 General Appropriation Act, CPRIT Rider 5, Transfer Authority.

## Cancer Prevention and Research Institute of Texas FY 2015 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	400,000	178,669				178,669	141.79%
Number of Entities Relocating to TX for Cancer Research Related Projects	7.00	0.00				0.00	0.00%
Percentage of Texas Regions w/ Cancer Prevention Services and Activities Initiated	100%	N/A	N/A	N/A	N/A	0%	0%
Annual Age-adjusted Cancer Mortality Rate	176.5	N/A	N/A	N/A	N/A	0	0.00%
Number of Published Articles on CPRIT- Funded Research Projects	400	N/A	N/A	N/A	N/A	0	0.00%
Number of New Jobs Created and Maintained	200	N/A	N/A	N/A	N/A	0	0.00%

### **Variance Explanations**

### Number of People Served by Institute Funded Prevention and Control Activities

CPRIT grantees deliver these education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter.

### Number of Entities Relocating to TX for Cancer Research Related Projects

Thisoutput is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive and award and actually relocate operations to Texas.



### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: REBECCA GARCIA, PH.D. CHIEF PREVENTION AND

**COMMUNICATIONS OFFICER** 

**Subject:** COMMUNICATIONS UPDATE

**Date:** FEBRUARY 18, 2015

The following report provides an overview of the agency's communications activities from Oct. 2014 through Jan. 2015.

### EARNED MEDIA

The communications team worked with and pitched individual publications and reporters to secure positive coverage for CPRIT, including coordinating interviews with the *Houston Chronicle* and the *Austin Business Journal* regarding the Oversight Committee's Program Priorities Project. A story about CPRIT's "restart" is in the works with the *Texas Tribune*.

Additionally, in advance of her appearance at the TAMEST conference, the communications team assisted with Dr. Kripke in drafting the Op-ed that was published in the *Houston Chronicle*.

**Grant Awards Announcement:** Following the Oversight Committee's approval, on Nov. 19, 2014, CPRIT distributed a press release to and pitched local, regional and national media announcing the awarding of 20 product development grants, five prevention grants and seven research grants which resulted in some of the coverage as represented below.

**Coverage:** (Nov. 1, 2014 – Jan. 31, 2015)

- 8 articles featured CPRIT
- 35 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

**Coverage Highlights:** (see clipped articles following report)

- Jan. 22, 2015, *Houston Chronicle*, Op-Ed: Cancer Research Should Look More at Prevention
- Dec. 26, 2014, *Austin Business Journal*, UT-Austin Researchers Get \$4.9M in CPRIT Grants to Fight Cancer
- Dec. 25, 2014, San Antonio Express-News, Local Cancer Research Receives \$4 Million
- Dec. 1, 2014, *Houston Chronicle*, Cancer Agency Shifting Priorities

• Nov. 28, 2014, San Antonio Business Journal, CTRC Gets More Funding from CPRIT

### **SOCIAL MEDIA**

The communications team restarted outreach through CPRIT's established social media channels, including Facebook, Twitter and YouTube posting and linking to CPRIT-generated content as well as relevant content from grantees, advocates and other trusted sources.

### ANNUAL REPORT

The 2014 Annual Report has been sent to the legislature as required by statute. It is also posted on the CPRIT website and a link was sent to other stakeholders.

### **CPRIT MESSAGES AND ACCOMPLISHMENTS**

A brochure highlighting accomplishments resulting from CPRIT's grants programs is under development and expected to be completed by late February. A CPRIT Overview slide deck is available and can be customized for presentations. In addition, the communications team is working on speeches that can also be quickly tailored for specific audiences when speaking opportunities arise.

### PBS CANCER DOCUMENTARY OPPORTUNITY

A "Save the Date" announcement and other promotional efforts for a screening of a new documentary from Ken Burns, *Cancer: The Emperor of All Maladies*, on March 25 at the Capitol Extension Auditorium are being developed. Dr. Rice will moderate a panel discussion of cancer experts following the screening. We are in the process of inviting the panel participants. Invitations to this advance screening and panel discussion will be extended to legislators, their staff, and cancer advocacy organizations and the public.

### **CPRIT 2015 CONFERENCE**

Planning for the Nov. 9-10, 2015 conference is underway. An RFP for meeting planning services has been issued with responses due back by Feb. 18. Ideas for topics and speakers are being discussed at Review Council and program OC subcommittee meetings.

### PROGRAM PRIORITIES PROJECT

Following the Oversight Committee's approval of the priorities, the communications team finalized and published the report on CPRIT's website.

### **RFA RELEASES**

Announcements regarding the release of new product development RFAs were sent out via CPRIT's available communications channels.

### ADDITIONAL OUTREACH

Council of Public University Presidents and Chancellors (CPUPC) was provided information about CPRIT's program priorities and funding opportunities. They published this information,

including CPRIT's fact sheet, in their e-newsletter on Jan. 16. University presidents were strongly encouraged to alert interested researchers to learn more about the grants process by going to CPRIT's website.

On Jan. 21 we met with representatives from the American Cancer Society, LIVESTRONG, and Komen for the Cure to update them on CPRIT activities over the past year.

# Cancer research should look more at prevention

By Margaret Kripke

With progress in finding cures still so slow, early detection and keeping it from starting are crucial.

Sometime today, about 325 people in our state will be told they have carcer. Weddings are about to be missed, reunious are about to be canceled and vacations persponed as medical appairs ments and procedures dominate their lives.

On a regular basis, my colleagues and l at the Cancer Prevention and Research Institute of Texas, or CPRIT, are ashed when we're going to find a curre for cancer. This is not an unreasonable question, considering that CPRIT supports more cancer research in Texas than any oliver agency, including the National Cancer Institute.

The good news in that after treatment, around two thirds of people who develop cancer remain few of the disease for free or more years. The better towers that me are already curing some cancers — one person at a time, one discovery at a fine—with new and evolving treatments. In fact, more than half of those diagnosed today will be cured of their disease.

The bad news, Inspector, is that progress is frustralingly slow. This is the to the fact that cancer is not a single discuss, but is made up of many discusses.

At last count, there were 17 differont types of breast causer alone, such of which may require a different treatment. This means it is unlikely that a single breakthrough ours is even possible. Purthermore, concers have two distinct characteristics that make them hard to treat. They can spread to other sites of the body, where they are untreatable with surgery, and ment cancers can change and become revisitant to treatment.

Much of cancer research today is formed on finding cares. This is an important goal because more effective, less book treatments are overly needed.

However, remoter the impact of making progress on preventing cancer or detecting it in its earliers stage, when it is still curable. When breast cancer is detected early, so percent of patients are cured by today's treatments. However, once it has apread to distant organs, the five-year survival rate drops to 24 percent.

Therefore, in addition to seeking new treatments for these advanced cancers, doesn't it make sense to try to reduce their numbers by developing methods to detect them earlier and even prevent them altogether?

Prevention would have a much greater impact on reducing the burden of cancer in the population than curing a small



Biagmosed with inflammatney breast cancer, Lourdes Suggs visuts radiation omeniogist Dr. Wendy Woodward at M.D. Anderson in August to plan her radiation therapy. Dr. Margaret Eriphe. CPBT's chief scientific officer, wants research to be focused more on effective approaches for prevention and early detection of capeer.

subtype of advanced current. For enample, discovering a cure for the most conmon type of long currer would climinate an percent of the deaths from this discuss, which would be a remarkable actiovement.

However, eliminating indusers use would prevent to prevent of desitts. From long cancer as well as an pervent of desitts from all cancers. While this is femilial for long cancer and samignishadance skin capear, where the casses are well recognized, little is known about low to interfere with the development of other types, of cancer at in detect them at their crutical stage.

Developing new, effective approaches for prevention and early detection of canres will require much more research for rused on these areas.

Unfortunately, these areas reveive less attention and much less funding than the search for cures. This is why prevention and early detection are among CPRITnew priorities for research funding.

We challenge the research community in Tiexas to apply their cromaterable talent to addressing these critical areas in the hope that it will eventually reduce the incidence of and improve survival from all cancers, not just in Texas, but throughout the world.

Krijske is the chief scientific officer for the Cancer Preportion and Remarch Institute of Texas.

# AUSTIN Business Journal

December 26, 2014

# A shift in treatment priorities

# WITH MORE OVERSIGHT IN PLACE, CPRIT FOCUSES FUNDING ON CANCER PREVENTION

With a year-long controversy that put its grant-giving abilities on hold until late 2013 now fading from view, the Cancer Prevention and Research Institute of Texas plans to focus its efforts on prevention and research initiatives in the coming year while also trying to commercialize academic research by steering it to startups and established businesses.

That's the word from CPRIT Executive Director Wayne Roberts, who said the agency's governing board recently approved its funding priorities that will focus on cancer prevention programs that may offer the best chance to produce results in fighting the disease.

CPRIT – which reports doling out about \$1.1 billion via \$17 grants since 2010 – will also continue to steer funding toward recruiting premiere researchers to Texas.

"To date CPRIT has supported cancer prevention, education,

screening and survivorship services to nearly 2 million Texans in every county," Roberts said. "We'll also emphasize moving research findings at Texas institutions into new companies as well as funding projects to develop new tools and technologies for cancer prevention and treatment."

The agency's most recent round of grants in November were heavy on research and prevention dollars, with \$4.9 million given to three University of Texas projects as the only money allocated for Austin.

In August the agency awarded \$7.5 million over three years to San Diego-based Curtana Pharmaceuticals to relocate to Austin and continue its work to develop treatments for adult and pediatric brain cancer tumors.

The agency's product development efforts, which provides the most oppor-

tunity for businesses to receive funding, are overseen by Tom Goodman, who joined the agency this spring. Goodman is a former vice president of business development for life sciences at Arizona Science and Technology Enterprises, a subsidiary of the Arizona State University Foundation.

Also on CPRIT's plate in 2015 is work related to a recent recommendation from Texas Senate Committee on Health and



THINKSTOCK

Human Services that said the agency should begin a transition to become self sufficient by 2021, when its funding is due to expire. CPRIT was created when voters approved spending \$3 billion in state bond money to fund cancer prevention and take advantage of the economic opportunities available in the life sciences industry.

Roberts said CPRIT will follow the direction of whatever legislation is approved by lawmakers related to its future.

"It's still early in the legislative process and the bill must be enacted so at this point quite a lot remains to be considered," he said. "We appreciate lawmakers thinking ahead and planning for the future of the agency. Planning ahead is wise, and it's what SB197 instructs us to do. We look forward to discussions."

Roberts also said several layers of oversight and review have been put in place to ensure grants are awarded properly, and avoid a repeat of allegations that board members gave preferential treatment to business associates that in turn led to the agency's major overhaul.

"All of the processes and grant-making improvements enacted by the last Legis-

lature have been adopted and are working well," Roberts said. "These include an enhanced compliance program that verifies all steps in the review process are followed, board approval of each grant award, use of a new panel to recommend awards to the governing board instead of relying upon the sole discretion of the agency director, and new conflict of interest requirements and ethics training."



"All of the ... improvements enacted by the last Legislature ... are working well."

WAYNE ROBERTS, CPRIT executive director

# San Antonio Express-News

December 25, 2014

# Local cancer research receives \$4 million

By Maria Luisa Cesar

STAFF WRITER

Cancer research can feel like walking around in a dark room, trying to find a light switch, Rong Li, a professor of molecular medicine at the University of Texas Health Science Center, said recently.

"You know that there is a light in the room and you know that there has to be some switch there to turn that light on," he said.

After seven years of groping in the darkness, Li and a team of scientists at the Cancer Therapy and Research Center, or CTRC, have found a way to switch on a protein that could inhibit the growth of tumors in "triple-negative breast cancer," a particularly aggressive form of the disease that lacks targeted treatment options.

The group, which is partnering with scientists at the University of Texas at San Antonio, recently received close to \$2 million in grant money from the Cancer Prevention & Research Institite of Texas, or CPRIT.

Another CTRC team, led by professor of obstetrics and gynecology Ratna Vadlamudi,

### RESEARCH

also recived a grant just shy of \$2 million from CPRIT to develop a drug that could prevent breast cancer cells' ability to resist drug treatments.

Li's team is preparing for preclinical trials on a drug that has been clinically tested for its ability to relieve the symptoms of hot flashes but which also might contain the right compounds to "turn on the anti-tumor activity" of an estrogen receptor called ER beta, which is present in about half of triplenegative breast cancers, Li said. The group also will design,

test, and screen other compounds that could do the same thing.
"If we can rally that anti-



UTHSC **Professor Rong** Li says research is like moving about a dark room, seeking a light switch.

tumor activity of ER beta, then it could be a very promising therapy," Li said.

A significant proportion of breast cancers are estrogen dependent, fueled by the presence of the hormone, he said. Targeted therapies often work to suppress estrogen and thus dial back the growth of harmful cells. These types of cancers have an estrogen receptor called ER alpha.

Triple-negative breast cancer, by definiton, lacks this kind of receptor and can't be treated by the same hormone therapy

but some have the ER beta receptor, which Li calls "the cinderella sister."

"It behaves in many ways like ER alpha but one particular feature of ER beta is that instead of promoting tumor growth, it inhibits it," he said.

For seven years his team including longtime collaborator and postdoctoral fellow Qinong Ye and in the past few years Stanton McHardy, a co-principal investigator and medicinal chemistry core director at the Center for Innovation in Drug Discovery at the UTSA - has been looking to see whether the receptor has a "switch" that could control the anti-tumor characteristic.

The group not only has found the switch, it knows how to flip it on, Li said. Now it's ready to

"I will say that this is still at the early stage of drug development but we have a pretty high confidence that our laboratory discovery will lay out a very solid foundation and give us a very feasible molecular handle to unleash or rally the anti-tumor activity there," he said.

Collaborating on Vadlamudi's grant are the University of Texas Southwestern Medical Center and the University of Texas at Dallas.

The funding will help us develop these first-in-class cancer therapy drugs that address the critical need of targeting therapy resistance and metastasis of breast cancer," Vadlamudi said in a news re-

His work focuses on the "mechanisms in treatmentresistant cells," according to the release. Because patients can develop a resistance to antiestrogen targeted therapies, making it easier for tumors to mutate, Vadlamudi and his team have developed a smallmolecule drug that could block or prevent drug resistance. The CPRIT grant will help researchers prepare the drug for clinical trials in patients.

Both grants will fund research and science experiments

for the next three years.
"This is a tangible confirmation of the exceptional merit of the science and clinical care provided by our CTRC scienctists and physicians," said CTRC director Ian M. Thomp-

mcesar@express-news.net Twitter: @mlcesar

# Cancer agency shifting priorities

Underfunded tumors, commercialization of therapies new focus

By Todd Ackerman

After a series of scandals threatened its existence, Texas' \$3 billion cancer-fighting agency is switching gears to emphasize underfunded, hard-to-treat tumors and the commercialization of new therapies.

The shift is reflected in a new Cancer Prevention and Research Institute of Texas report that puts a top priority on tumors that affect children and the pancreas, brain, lungs and liver. It also is reflected in a near tripling of the percentage of funding allotted to product-development efforts since the agency resumed operations following a nearly yearlong moratorium that ended in October 2013.

"These new priorities represent a way to make the most of the opportunity we have," said Rebecca Garcia, the CPRIT project leader. "Three hundred million dollars a year sounds like a lot of money, but it's nowhere near industry's \$9 billion and the National Cancer Institute's \$5 billion investments. We wanted to determine how Texas can make a difference, what are the neglected areas where we can be a player?"

Thirty-two percent of the \$337 million approved in the year since the freeze was lifted was awarded for commercialization,

CPRIT continues on A4

### By the numbers

CPRIT's new priorities: Pediatric cancer; lung, liver, brain and pancreatic cancers

Funding allotments in agency's last year

57.5% Research
32% Commercialization
10.5% Prevention

Funding allotments in agency's first four years

77% Research 12.5% Commercialization 10.5% Prevention

### FROM THE COVER

# CPRIT's mismanagement led to its reboot

CPRIT from page A1

now called product development by CPRIT leaders, up from 12.5 percent in the agency's first four years. Such grants typically fund start-up companies that attempt to move research from a researcher's lab to the marketplace.

The emphasis on children's cancers comes two years after the agency was challenged to fund such research by a 19-year-old Rice University student, James Ragan, diagnosed with bone cancer at 13. Ragan, who died this year, asked governing board members at a CPRIT meeting to remember his face, "the face of every Texan who dies from unprofitable pediatric cancer."

### No funding quota

State law requires at least to percent of CPRIT's funding go for cancer prevention, but beyond that the priorities' report gives no funding quota or target for prevention, research or commercialization. It does refer to "balancing" the portfolio across the programs.

The review of CPRIT's funding priorities was required under the 2013 bill that reformed the agency. The legislation removed its entire board and put in place safeguards to clarify conflicts of interest, strengthen oversight of grant decisions and increase transparency. The lack of such safeguards was implicated in the mismanagement of three grants worth \$56 million of taxpayer money.

The mismanagement caused the Legislature to remove CPRIT's 2014-15 funding from the state budget before reinstating it at the session's end as part of the reform bill. A Travis County grand jury indicted a high-ranking agency administrator, Jerald "Jerry" Cobbs, for allegedly deceiving bosses about an \$11 million grant that never underwent the required review. Key agency figures previously had resigned in protest or under pressure. and the freeze was imposed until the agency could restore public confidence.

"Almost any new direction is a better direction," said Glenn Smith, director of the liberal Progress Texas PAC, adding that before the reforms CPRIT had "wasted cancer research money on friends of the powerful instead of cures for cancer."

Its future, Smith said, "hinges on transparency and dogged oversight. Only time will tell."

### Lessons learned?

Dr. Leonard Zwelling, a retired oncologist who served on a 2012 advisory committee regarding CPRIT's future, criticized the report, saying it includes "no overriding strategic plan to get to (its) priorities, no listing of what has been gained by (its) expenditures." He said the new priorities don't reflect lessons learned from the agency's mistakes.

CPRIT was approved by voters in 2007 and launched in 2009. Its board approved the new priorities, seven months in the works, at a Nov. 19 meeting.

Garcia acknowledged that longstanding interest in commercialization by the state's political leadership likely influenced the process. In October 2012, Gov. Rick Perry, Lt. Gov. David Dewhurst and House Speaker Joe Straus sent CPRIT leaders a letter urging the agency to "take further steps to fulfill its statutory mission and expedite innovation that will deliver new cancer treatments to patients within three to five years." The letter noted that CPRIT had "laid a solid foundation for this endeavor by focusing its efforts and funding predominantly on basic scientific research.

CPRIT's governing board has awarded grants totaling \$337 million at six meetings since the moratorium's end. The funding includes \$193 million, or 57.5 percent, for research; \$108 million, or 32 percent, for product development; and \$35.6 million, or 10.5 percent, for prevention.

Before the moratorium, when it had awarded about \$809 million in grants, CPRIT spent about \$625 million, or 77 percent, on research; about \$98 million, or 12.5 percent, on commercialization; and about \$86 million, or 10.5 percent, on prevention. The priorities report is

The priorities report is not specific about CPRIT's new product development priorities, saying only that the agency should seek "to bridge gaps that may delay or even deny patients access to important scientific advances." It is more explicit about research priorities, calling for strategic investments to move research forward rather than simply "adding incrementally" to types of cancer research funded by other agencies.

### Research opportunities

Besides pediatric and lung, liver, pancreatic and brain cancers, the report cites opportunities for research that employs computational biology and analytic methods, and research into possible new therapies or strategies to prevent cancer from developing.

That is different from the statutorily required prevention funding, which typically goes to identified prevention or early detection efforts, such as smoking cessation programs and

The report says CPRIT will continue to fund meritorious, untargeted proposals in addition to the new focus.

CPRIT's new research riorities, not surprisingly, were hailed by experts in the targeted fields. Dr. Eugenie Kleinerman, head of M.D. Anderson Cancer Center's pediatrics divi-sion, said it will put Texas in the vanguard on children's cancers. And Dr. Ernie Hawks, head of M.D. Anderson's cancer prevention and population sci-ences, said "CPRIT is now prioritizing what most other funding agencies ignore - research into the delivery of evidence-based strategies to the broad public to reduce cancer and its risk factors.'

Garcia acknowledged CPRIT officials know the clock is ticking on the 10year program. Thanks to the new plan, she said, "we think we can have a significant impact."

todd.ackerman@chron.com twitter.com/ChronMed



November 28, 2014

# CTRC gets more funding from CPRIT

The University of Texas Health Science Center at San Antonio's Cancer Therapy & Research Center will get some additional financial help in its fight against the deadly disease.

The Austin-based Cancer Prevention and Research Institute of Texas awarded nearly \$4 million to a pair of CTRC researchers - Rong Li and Ratna Vadlamudi - who plan to use the grant money to continue their work on developing next-generation drugs to treat breast

The \$3.99 million awarded to the Health Science Center is part of \$65 million in new CPRIT money handed out in the latest funding round.

Li, professor of molecular medicine at the Health Science Center, is principal investigator on a proposal that will harness an existing drug that treats hot flashes and that has potential anti-tumor activity. The goal is to create other agents that will help the existing drug

### ► INSIDE THE NUMBERS

### \$3 billion

Amount of bonds Texas was authorized by voters to issue to establish the Cancer Prevention and Research Institute of Texas

# Number of Texas

83

academic institutions, nonprofit organizations and private companies that have received CPRIT grants

### \$1.15 billion

Amount of funding awarded by CPRIT to date

- Source: CPRIT

work with greater precision.

"It balances feasibility and innovation," Li said about the project.

Meanwhile, Vadlamudi, professor of obstetrics and gynecology at the Health Science Center, is working to develop an innovative drug that could prevent treatment resistance in breast cancer patients. Vadlamudi said the institute's funding will help researchers develop first-inclass cancer therapy drugs that "address the critical need of targeting therapy resistance and metastasis of breast cancer."

CTRC Director Ian Thompson said the

institute's latest CPRIT awards represent "tangible confirmation of the exceptional merit of the science" its researchers are engaged in.

In August, CPRIT awarded \$7.6 million in grants to the Health Science Center benefiting CTRC researchers.

"It's a substantial increase over what we have previously received," Health Science Center President Dr. William Henrich said about the August grants. "It certainly establishes the investigators who have received these funds as top-tier cancer researchers."

The Cancer Prevention and Research Institute of Texas (CPRIT), Texas PBS and KLRU-TV Austin PBS invite you to attend a special preview screening of a forthcoming PBS documentary from executive producer Ken Burns.



### **KEN BURNS PRESENTS**

# CANCER

THE EMPEROR OF ALL MALADIES

A FILM BY BARAK GOODMAN



The event will feature a half-hour segment from the six-hour documentary, along with a panel discussion of leading cancer experts from Texas.

When: Wednesday, March 25, 2015 from 6:00 p.m. to 7:30 p.m.

Where: The Texas Capitol Extension Auditorium

1100 Congress Avenue

Room E1.004, Austin, Texas 78711

RSVP: <u>cprit.us/storyofcancer</u>

The documentary will air on PBS stations across the nation on March 30, 31 and April 1.

Learn more about the film at: <a href="mailto:cancerfilms.org">cancerfilms.org</a>









# **CPRIT Overview**

February 2015

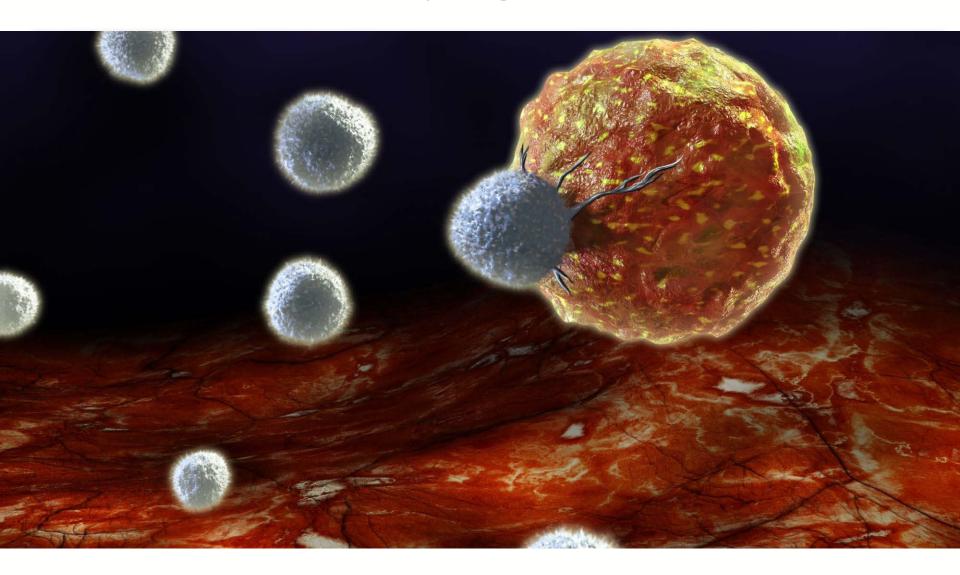
# Agenda

- 1. Cancer's Impact in Texas
- 2. CPRIT Mission and Perspective ....
- 3. CPRIT Organization and Process
- 4. CPRIT Annual Program Priorities
- 5. CPRIT Grant Programs
  - Research
  - Product Development
  - Prevention

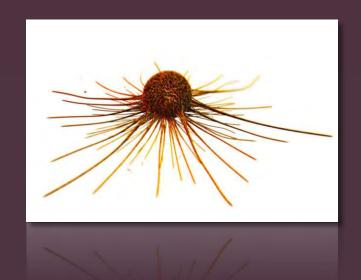


# Cancer's Impact in Texas

# 2014: 119,115 Texans newly diagnosed; 44,150 died



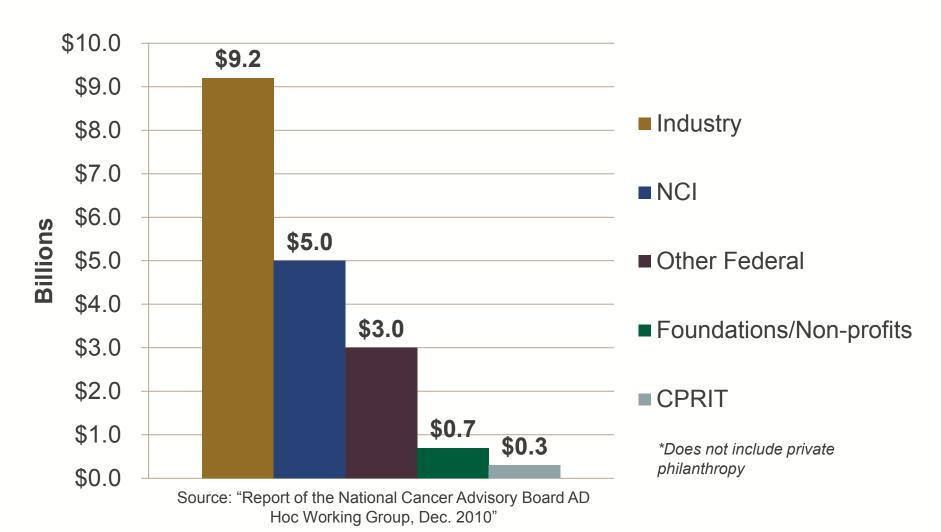
# Cancer's Enormous Human and Economic Cost to Texas



- \$161.7 billion in reduced annual spending
- \$79.8 billion in output losses annually
- 785,865 lost jobs from cancer treatment, morbidity and mortality and the associated spillover effects



# **CPRIT Funding in Perspective**





# Mission and Perspective



# CPRIT's Unique Role in the Fight Against Cancer

Purpose: CPRIT exists to reduce the burden of cancer in Texas

### **Overview:**

- Created by the Texas Legislature and citizens in 2007
- \$3 billion to expedite innovation and product development in cancer research and enhance access to evidence-based prevention programs and services

### Values:

- Investing in the most promising preventative measures, new diagnostics and innovative medicines and treatments
- Making cures for cancers possible every day advancements are happening today, one discovery at a time
- Using guidance of leading cancer experts and supporters unified in commitment to accountability



# **CPRIT's Mission and Action**

### Mission

- Create and expedite innovation in cancer research into prevention and cures
- Attract, create, or expand research capabilities
- Create high-quality new jobs in Texas
- Develop and implement the Texas Cancer Plan



Action

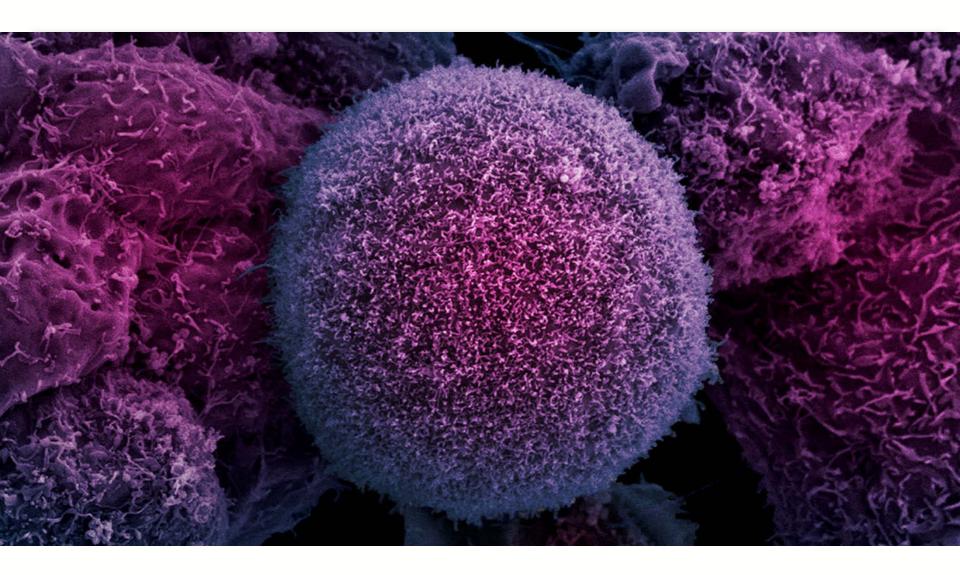
Award merit-based, peer reviewed grants to Texas-based entities and institutions for cancer-related research, product development and the delivery of cancer prevention programs and services.

Academic Research

Prevention

Product
Development
Research

# CPRIT has invested more than \$1 billion through more than 800 grants



# Organization and Process

# Oversight Committee Members

William Rice, M.D.

Chair

Austin

Appointed by Governor Perry

Term: 9/26/13 - 1/31/17

**Gerald Geistweidt** 

Mason

Appointed by Governor Perry

Term: 9/26/13 - 1/31/15

**Angelos Angelou** 

Austin

Appointed by Governor Perry

Term: 9/26/13 - 1/31/19

**Pete Geren** 

Vice-Chair

Fort Worth

Appointed by Speaker Straus

Term: 10/22/13 - 1/31/19

Cynthia D. Mulrow, M.D., MSc., MACP

San Antonio

Appointed by Speaker Straus

Term: 10/22/13 – 1/31/15

Will Montgomery

Dallas

Appointed by Speaker Straus

Term: 11/20/13 – 1/31/17

Amy Mitchell

**Secretary** 

Austin

Appointed by Lt. Gov. Dewhurst

Term: 9/26/13 - 1/31/15

Craig Rosenfeld, M.D.

Dallas

Appointed by Lt. Gov. Dewhurst

Term: 9/26/13 – 1/31/17

**Ned Holmes** 

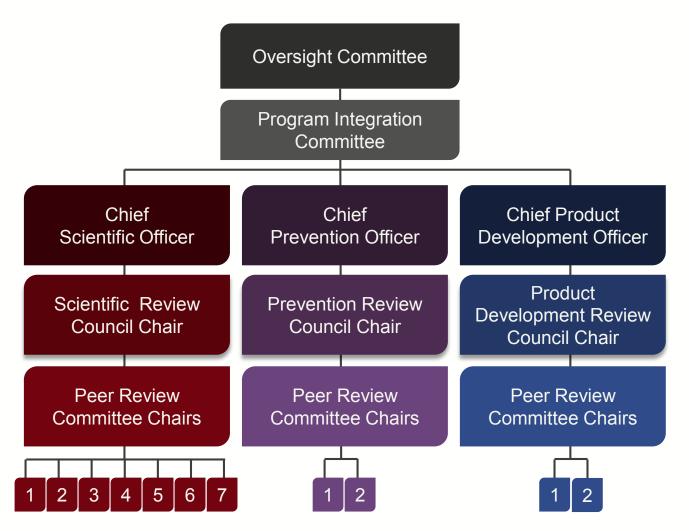
Houston

Appointed by Lt. Gov. Dewhurst

Term: 9/26/13 - 1/31/19



# Peer Review Structure





# **Annual Program Priorities**



# **Program Priorities**

# Scope

Oversight Committee
establishes annual
priorities at two levels of
grant making process

### **Priorities Within Each**

**Program:** Inform staff and Peer Review Councils on the development and issuance of programspecific RFAs and evaluation of applications

### **Priorities Across Three**

**Programs:** Inform the PIC on balancing the portfolio across the research, prevention and product development programs



**2015 Across Program Priorities** 

- Prevention and early detection initiatives
- Early translational research
- Enhance Texas' research capacity and life science infrastructure

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# Research Program

# **Principles**

Scientific excellence
and impact on
cancer
Targeting
underfunded areas
Increasing the life
sciences
infrastructure

# \*

Cancer Prevention & Research Institute of Texas

# 2015 Research Program Priorities

- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Rare and intractable cancers, including childhood cancers
- Cancers of importance in Texas
- Research to move basic science toward its application
- Recruit outstanding cancer researchers to Texas

# Product Development Program

# **Principles**

Development of commercial products to diagnose and treat cancer

Creation of good, highpaying jobs for Texans

Sound financial return on the monies invested

Development of Texas high tech life sciences business environment



# 2015 Product Development Program Priorities

- Funding projects at Texas companies and relocating companies that are most likely to bring important products to the market
- Providing funding that promotes the translation of research at Texas institutions into new companies able to compete in the marketplace
- Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment, and prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# **Principles**

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

# **2015 Prevention Program Priorities**

- Prioritize areas of greatest need, greatest potential for impact
- Focus on underserved populations
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist



INSTITUTE OF TEXAS

# Grant Programs



# Research Program

Goals **Grants** 

- Discover new information about cancer that can lead to prevention, early detection and cures
- Translate new and practical advances in cancer diagnosis and treatment
- Increase the prominence and stature of Texas in the fight against cancer



existing discoveries into

**Portfolio** Research

- Research Grants:
  - 637 awarded
  - \$785,115,599 granted
- > Researcher Recruitment Grants:
  - 84 recruited (including 3 pending); 62 contracts executed
  - \$249,459,916 granted

# Research Program

Goals **Grants** 

**Mechanisms** 

Research

- Discover new information about cancer that can lead to prevention, early detection and cures
- Translate new and existing discoveries into practical advances in cancer diagnosis and treatment
- Increase the prominence and stature of Texas in the fight against cancer



**Research Grants:** 

- Individual Investigator Research Awards (IIRA)
- High Impact-High Risk Research Awards (HIHR)
- Multi-Investigator Research Awards (MIRA)
- Core Facilities Support Awards (CFSA)
- Shared Instrumentation Awards (SIA)
- Research Training Awards (RTA)

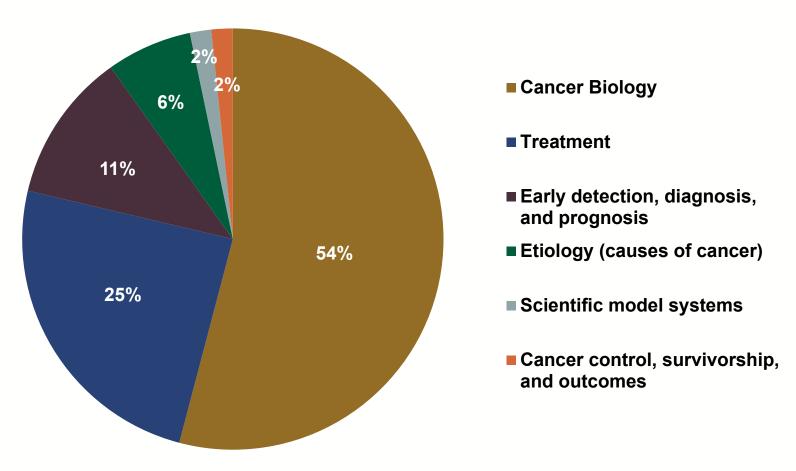
## **Research Recruitment Grants:**

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

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# Research: Current Portfolio

# **Distribution of Funded Grants by Research Area**





# Research Program

# **Scholar Recruitment Awards\***

As of December 2014

Award Mechanism	# of Recruits	Total Award Amounts
Recruitment of Established Investigators	18	\$102.7M
Recruitment of First-Time, Tenure-Track Faculty	52	\$102.6M
Recruitment of Missing Links	3	\$ 5.9M
Recruitment of Rising Stars	8	\$26.3M
TOTALS:	81	\$237.5M

<sup>\*</sup>Fully executed contracts



# RESEARCH PROGRAM: Enhancing Research Superiority in Texas

### **GRANT:**

Dr. Elizabeth Ward's work at UT Southwestern Medical Center focuses on breast cancer and the ability of certain antibodies to inhibit the growth of breast cancer cells.

## **RESULT:**

In a recent study, the antibodies prevented the growth factor receptors in breast cancer cells from receiving the signals that stimulate tumor growth.

Antibodies are also being tested on prostate cancer cells, which share one of the same growth factor receptors as breast cancer cells.

A provisional patent has been filed on the antibodies.



# Product Development Program

**Portfolio** 

**Product Development** 

Goals **Grants** 

- To improve patient care through expedited innovation and product development
- To foster economic development in Texas' emerging life sciences industry and the creation of high-quality new jobs in this state
- To provide a direct return, through intellectual property and revenue sharing, on the investments made by Texans



- > Product Development Grants:
  - 42 awarded
  - Over \$239 million granted
  - Over \$360 million invested in R&D with matching funds
  - ~170 direct jobs created by **CPRIT-funded projects**

# Product Development Program

Mechanisms

**Product Development** 

**Goals** Grants

- To improve patient care through expedited innovation and product development
- To foster economic development in Texas' emerging life sciences industry and the creation of high-quality new jobs in this state
- To provide a direct return, through intellectual property and revenue sharing, on the investments made by Texans



 Established Company Product Development Awards

- New Company Product Development Awards
- Company Relocation Product Development Awards
- Early Translational Research Awards

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# PRODUCT DEVELOPMENT PROGRAM: Moving Science into the Clinic; Supporting New Therapies

### **GRANT:**

DNAtrix modified the common cold virus in ways to develop a virus-based therapy for the treatment of one of the most aggressive types of brain cancer.

### **RESULT:**

In human trials, Delta-24-RGC showed a remarkable ability to hunt and kill tumors, and to improve the survival rates of patients.

If additional clinical trials prove successful, the FDA is expected to approve the product.

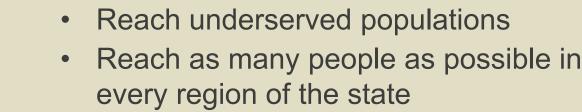


**Principles** 

**Prevention** 

Goals Focus

- Prevent and reduce cancer risk, mitigate effects
- Serve populations in greatest need
- Build capacity by promoting innovations and best practices across Texas



# > Evidence-Based

 Primary, secondary, tertiary prevention

> Deliver a program or service to Texans

Not prevention research

# > Results oriented

 Measurable public health impact in ways that exceed current performance in a given service area



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Portfolio

**Prevention** 

**Goals** Grants

- Prevent and reduce cancer risk, mitigate effects
- Serve populations in greatest need
- Build capacity by promoting innovations and best practices across Texas



- 135 awarded
- \$121,570,507 granted
- 1.9 million Texans served



Mechanisms

**Prevention** 

Goals Grants

- Prevent and reduce cancer risk, mitigate effects
- Serve populations in greatest need
- Build capacity by promoting innovations and best practices across Texas



- Health Behavior Change Through Public Education
- Competitive Continuation/Expansion Grants



Cancer Prevention & Research Institute of Texas

# PREVENTION PROGRAM: Reaching Underserved Populations; Saving Lives

### **GRANT:**

Project led by Dr. Carol Rice at Texas A&M AgriLife Extension Service targets underserved women in 50 counties to help them get breast and cervical cancer screenings.

### **RESULT:**

Screenings of 3,157 women have detected 198 abnormalities, including 42 cancer pre-cursors.

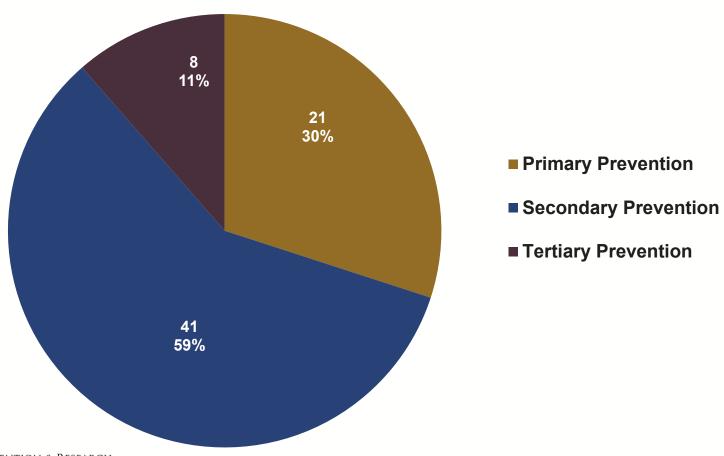
Indicating the high demand for services, the project's outreach has impacted 7,590 women in nearly three years—more than twice the goal.



# **Number of Projects by Prevention Type**

59 Active Prevention Grants

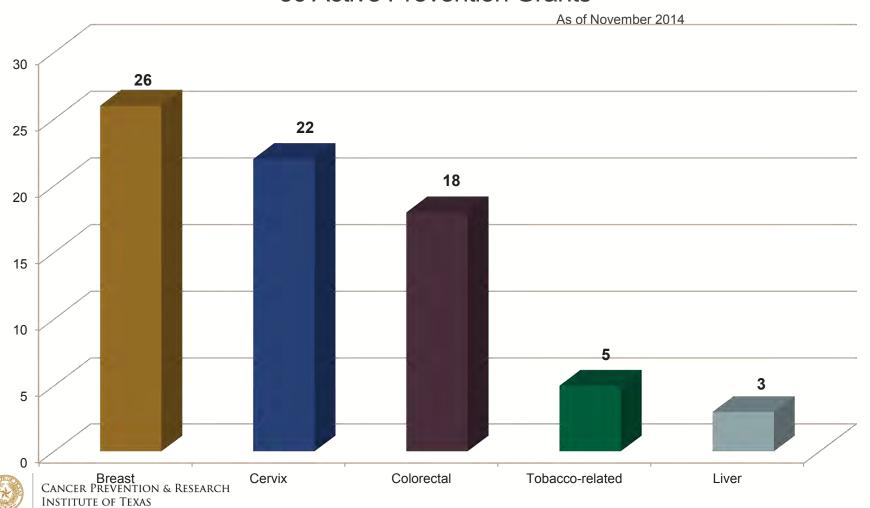
As of November 2014



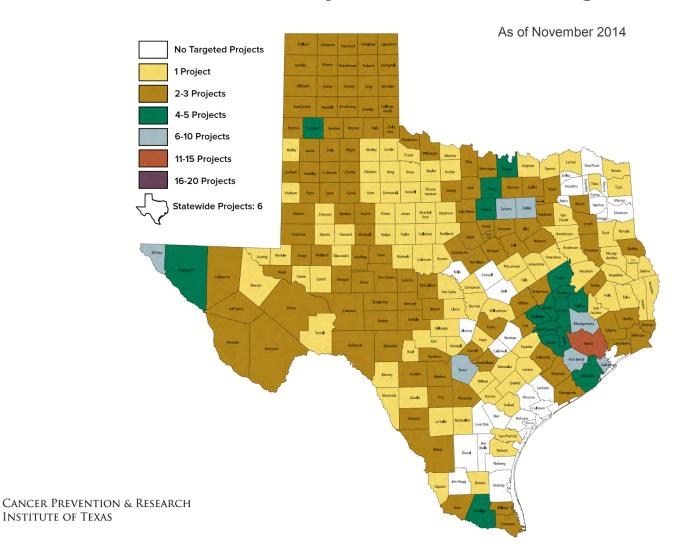


# **Number of Active Grants by Cancer Type**

59 Active Prevention Grants



# **Counties Served by CPRIT Prevention Programs**





# **CPRIT Overview**

February 2015

Presented To:

Name of Group or Organization

### **CPRIT GRANTEE HIGHLIGHTS**

While advancements in cancer research, prevention and product development can take years, we are already realizing some incredible returns on the investments CPRIT has made in Texas. CPRIT is playing a critical role in advancing innovation in all three areas and CPRIT's impact will continue to grow far beyond the progress we see today.

# PREVENTION Reaching Underserved Populations, Saving Lives

**Grantee:** Dr. Abbey Berenson, The University of Texas Medical Branch at Galveston

**Project:** HPV Vaccinations

Dr. Berenson's project targeted low income pregnant women to take advantage of opportunities for prevention when these women accessed the health care system. This program targeted populations that typically have very low HPV vaccination rates by implementing standing orders for postpartum HPV vaccination(s) during regular doctors'

visits associated with pre and postpartum care.

**Impact:** This program has increased the HPV vaccination rates from 9% to 83% in this clinic

population in the very first year of operation.

**Grantee:** Dorothy Gibbons, The Rose (Houston)

**Project:** Breast Cancer Screenings

The Rose's *Empower Her to Care* project increases mammography screening within the underserved minorities in 24 Texas counties through an expanded Mobile Mammography Outreach program. The program does this by providing free, easy to access breast cancer screening in the neighborhoods where the women work and live, increasing public

awareness of the importance of identifying cancer in its earliest chances.

**Impact:** To date, the project has served 5,044 women; 1,800 of these women had never before

been screened.

**Grantee:** Texas Tech University Health Sciences Center at El Paso

**Project:** Colorectal Screenings

Collaborating with more than 20 organizations, has developed Project ACCION, a bilingual program that provides free education and screening services for a high-risk,

underserved population.

**Impact:** Through the program, thousands have received education and screening. To date, 36

people had small lesions in the colon detected and seven were found to have cancer and

steered into treatment.

**Grantee:** The University of Texas Southwestern Medical Center

**Project:** *Identifying Patients with Hereditary Breast-Ovarian Cancer and Lynch Syndrome* 

Through the only telemedicine program of its kind in Texas, genetic counseling is provided to populations who have never received services with the goal of identifying patients with Hereditary Breast-Ovarian Cancer (HBOC) and Lynch syndrome, two of

the most commonly inherited cancer predisposition syndromes.

**Impact:** In the first 20 months, more than 61,000 underserved women were screened for HBOC

risk and more than 500 underserved patients with colon and uterine cancer were tested for Lynch syndrome. Additional funding from CPRIT will expand the reach of this project

from six to 22 counties in North Texas.

**Grantee:** Dr. Carol Rice, Texas A&M AgriLife Extension Service

**Project:** Breast and Cervical Cancer Screenings in Rural, Frontier and Border Counties

Targets underserved women in 50 counties to help them get breast and cervical cancer

screenings.

**Impact:** Screenings of 3,157 women have detected 198 abnormalities, including 42 cancer pre-

cursors. Indicating the high demand for services, the project's outreach has impacted

7,590 women in nearly three years—more than twice the goal.

**Grantee:** Dr. Samir Gupta, The University of Texas Southwestern Medical Center

**Project:** Colorectal Cancer Screenings

Dr. Gupta tested outreach strategies to find the best way to screen uninsured populations for colorectal cancer, which included FIT test or colonoscopy. For this uninsured population served by a safety net hospital, results showed that screening was twice as

high for at home FIT text vs. colonoscopy and much more cost effective.

**Impact:** This project resulted in successful new methods to reach uninsured populations with

preventative measures.

### RESEARCH

### Enhancing Research Superiority in Texas; Supporting Groundbreaking Science

**Grantee:** Dr. James Allison, The University of Texas M.D. Anderson Center

**Project:** *CPRIT Scholar: Recruitment of Established Investigator* 

With the help of a CPRIT recruitment grant, M.D. Anderson brought noted researcher Jim Allison, Ph.D. to Texas. Allison's research has exposed ways to unleash the body's immune-system warriors, called T cells, against cancer cells. His groundbreaking discovery earned him the 2014 Breakthrough Prize in Life Sciences among many other

distinguished recognitions.

**Impact:** Dr. Allison's work has opened a new field of immunotherapy and improved the survival

of patients with advanced melanoma, and is now being extended to other types of cancer.

**Grantee:** Dr. Craig Malloy, The University of Texas Southwestern Medical Center

**Project:** Discovering New Technologies to Fight Breast and Brain Cancers

Dr. Malloy's grant created a partnership between Texas A&M University engineers and clinicians and researchers at the University of Texas Southwestern Medical Center to develop new measuring tools to improve locating biomarkers in breast cancer and

malignancies of the brain.

**Impact:** This study resulted in a patent application for the newly created breast coil and an

agreement with Samsung Research America in Dallas to develop new technologies in this

area.

**Grantee:** Dr. Zeina Nahleh, Texas Tech University Health Science Center in El Paso

**Project:** Bringing Clinical Trials to the El Paso-Area Latino Community

This project establishes a Cancer Clinical Research facility at Texas Tech University Health Sciences Center in El Paso. This center will allow activation of currently funded cancer-related projects, development of an educational and community outreach office to expand patient awareness and education of cancer programs, and to establish a new cancer database for sharing key data with Texas clinical oncology clinical trials consortia.

**Impact:** The project benefits a population that was previously underserved for cancer care and

underrepresented in clinical trials nationwide.

**Grantee:** Dr. Elizabeth Ward, The University of Texas Southwestern Medical Center

**Project:** Switching off Breast Cancer Tumor Growth

Focuses on breast cancer and the ability of certain antibodies to inhibit the growth of

breast cancer cells.

**Impact:** In a recent study, the antibodies prevented the growth factor receptors in breast cancer

cells from receiving the signals that stimulate tumor growth. Antibodies are also being tested on prostate cancer cells, which share one of the same growth factor receptors as

breast cancer cells. A provisional patent has been filed on the antibodies.

### **CLINICAL TRIALS: Studying New, Innovative Cancer Treatments**

30 different drugs and vaccines are currently in clinical trials, along with nine cell therapies that harness the body's immune system to attack and kill cancerous cells.

- **Hak Choy,** *Technology-Directed Advances in Radiation Therapy of Lung Cancer*New technologies in radiation therapy are being tested, which may allow higher doses of radiation to be delivered in fewer treatments with fewer side effects.
- Louis Chrystal, Chemo-Immunotherapy For Relapsed or Refractory Nasopharyngeal Carcinoma

This study is testing a combination of chemotherapy to reduce the size of the tumor, followed by immunotherapy to remove remaining cells in cancers induced by a virus (Epstein-Barr).

- Carlos Beccera, Novel Dendritic Cell Vaccine Therapy for Pancreatic Cancer
   Patients with pancreatic cancer are being immunized against their cancer using dendritic cells—
   cells of the immune system that initiate an immune response. The study involves improving the
   effectiveness of these dendritic cell vaccines.
- Laurence Cooper, Clinical Application of Umbilical Cord Blood-Derived Designer T Cells Genetically modified T cells have been engineered to attack tumors in patients with aggressive leukemias and lymphomas.

# PRODUCT DEVELOPMENT Moving Science into the Clinic; Supporting New Therapies

**Grantee:** Mirna Therapeutics, Inc.

**Project:** Cancer Treatment Including Drug Discovery/Development and Clinical Trials

With CPRIT funding, scientists at Mirna Therapeutics, Inc. were among the first to investigate tumor suppressor miRNAs as a new therapeutic approach in the treatment of cancer. Preclinical studies across a range of tumors strongly indicated that miRNA-based therapeutics represent a potent new class of anticancer drugs. The company has now been the first to advance a promising miRNA therapy into a human clinical trial for liver

cancer.

**Impact:** If confirmed through further clinical testing, the Mirna therapeutic will be the first of a

new class of anticancer drugs with improved therapeutic performance and tolerability for

the patient.

**Grantee:** Apollo Endosurgery

**Project:** *Medical Devices for the Treatment of Cancerous Lesions and the Gastrointestinal Tract* 

Apollo Endosurgery has developed a surgical device that enables a new procedure to remove early stage lesions from the colon, esophagus and stomach. Prior to the introduction of this device, physicians were limited in their ability to treat a suspicious lesion during a routine colonoscopy. This device allows multiple stages and sizes of lesions to be treated endoscopically, rather than by more invasive surgical procedures.

**Impact:** Early detection and removal of cancerous and pre-cancerous lesions dramatically

improve patient outcomes. By facilitating lesion removal, the Apollo technology is a

significant new benefit to patients.

**Grantee:** Rules-Based Medicine

**Project:** Cancer Biology and Genetics Including Oncogenesis Genomics and Proteomics

Rules-Based Medicine is developing automated, multiplexed immunoassays (tests) for cancer related proteins. When many of these individual assays or tests are taken together from a single analysis, their results can show unique patterns. These patterns can be useful in early cancer diagnosis, prognosis, as well as potentially monitoring how people

respond to therapies.

**Impact:** Novel biomarkers for cancer detection and monitoring provide benefits for both research

and patient care. The company was acquired by Myriad Genetics and is continuing to

operate its Austin office.

**Grantee:** CerRx, Inc.

**Project:** Novel Ceramide-Modulating Therapeutics for Cancer Use

Developing drugs that trick cancer cells into overproducing toxic waxes, called ceramides, which cells need to grow and divide. When the ceramides increase to a certain level, the cancer cells die. CerRx has a pipeline of such drugs, which work synergistically

against many cancer types in laboratory testing.

**Impact:** Clinical testing has already shown that one of the drugs can eliminate the cancers of some

patients with relapsed lymphomas. CerRx will use its CPRIT funding to advance these

drugs to market by conducting additional clinical trials in Texas.

**Grantee:** DNAtrix

**Project:** Clinical Development and Commercialization of Oncolytic Adenovirus for Treating

Malignant Glioma

Modified the common cold virus in ways to develop a virus-based therapy for the

treatment of one of the most aggressive types of brain cancer.

**Impact:** In human trials, Delta-24-RGC showed a remarkable ability to hunt and kill tumors, and

to improve the survival rates of patients. If additional clinical trials prove successful, the

FDA is expected to approve the product.



### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: REBECCA GARCIA, PHD, CHIEF PREVENTION AND

**Subject:** COMMUNICATIONS OFFICER

Date: PREVENTION PROGRAM UPDATE

**FEBRUARY 10, 2015** 

The following report provides an overview of the Prevention Program activities from Oct. 2014 through Jan. 2015

### Prevention

- <u>FY2015 Review Cycle 2</u>: We released four prevention RFAs on September 25, 2014, two of which are new. Thirty seven applications were received by the due date of December 4, 2014, two were administratively withdrawn and 35 assigned to the panels. We held a webinar January 21 for reviewers to discuss features of the new RFAs and answer questions. Peer review will take place February 23-25 in Dallas. The Oversight Committee will consider recommendations forwarded by the PIC in May.
- <u>FY2016 Review Cycle 1</u>: We are revising RFAs for a March release. Changes will include the addition of the program priorities and changes to the areas of emphasis to include screening for Hepatitis B and C for the prevention of liver cancer.

### • Other Activities:

- The College of American Pathologists (CAP) Foundation and CPRIT are discussing a collaboration to fund and implement CAP's *See, Test & Treat* programs for underserved populations in Texas. *See, Test & Treat* is a community based cervical and breast cancer screening program organized by pathologists in partnership with medical facilities (FQHC clinics and hospitals). The program is unique in that it provides same-day results, some follow-up care on the day of the program and a plan of action for further treatment if required.
- Prevention Review Council meetings were held January 5 and January 29. Dr. Mulrow joined the call on January 5 to discuss possible prevention interventions for liver cancer.
- Ramona Magid and I met with the Texas Association of Community Health Centers on January 14 and with representatives from the City of Laredo to discuss CPRIT's funding opportunities.
- On January 29, Ramona Magid, David Reisman and I met with a prevention grantee at Methodist Medical Center in Dallas to discuss progress on their project.

- Pete Geren, Will Montgomery, Ramona Magid, David Reisman and I attended a meeting January 30 of the Bridge Breast Network in Dallas. CPRIT was recognized for its contributions to cancer prevention.
- The OC Prevention Subcommittee met February 10 and discussed FY16 cycle 1 RFAs, the CAP proposed working arrangement, and program priorities metrics.

Memo Subject Page 2



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Conflict of Interest Disclosure – Oversight Committee Members For Applications Recommended for Consideration at February 18, 2015, Open Meeting

### **Conflict of Interest Disclosure - Amy Mitchell**

Academic	Research	(55)
Academic	IX CSCal CII	しつショ

RP150006, RP150014, RP150030, RP150032, RP150053, RP150079, RP150081, RP150084, RP150093, RP150094, RP150102, RP150129, RP150148, RP150164, RP150166, RP150179, RP150195, RP150197, RP150224, RP150228, RP150230, RP150231, RP150232, RP150235, RP150242, RP150245, RP150277, RP150282, RP150292, RP150293, RP150301, RP150316, RP150319, RP150334, RP150343, RP150346, RP150356, RP150386, RP150403, RP150405, RP150408, RP150416, RP150421, RP150440, RP150445, RP150449, RP150451, RP150454, RP150456, RP150485, RP150498, RR150025, RR150032, RR150033, RR150038

### **Conflict of Interest Disclosure - Angelos Angelou**

Amy Mitchell, Secretary, Oversight Committee

Academic Research (1)	
RP150346	
By my signature, this list of reported conflicts of interest shall be included of conflicts of interest reported by Oversight Committee members for grantecommendations considered at the November 19, 2014, Oversight Comm	nt award
Dr. William Rice, Presiding Officer, Oversight Committee	Date

Date



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

February 6, 2015

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 59 grant applications totaling \$115,464,359 in grants. The PIC recommendations for 55 scientific research grant awards and four product development awards are attached.

Dr. Margaret Kripke, CPRIT's Chief Scientific Officer and Dr. Tom Goodman, CPRIT's Chief Product Development Officer, have prepared overviews of the scientific research and product development program slates to assist your evaluation of the recommended awards. The overviews are intended to provide a comprehensive summary of the recommended proposals with enough detail that you should be able to understand the substance of the proposal and the reasons endorsing grant funding.

In addition to the comprehensive overviews, all of the information reviewed by the Review Councils is available by clicking on the appropriate link in the portal. This information includes the full application, peer reviewer critiques, and the CEO affidavit for each proposal.

The approval of these grant recommendations is governed by a statutory process that requires two-thirds of the members present and voting to approve each recommendation. David Reisman, 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 Wednesday, February 18, 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 and Dr. Goodman 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 55 academic research grant proposals totaling \$66,922,094. The recommended grant proposals were submitted in response to one of five grant mechanisms: Individual Investigator Research Awards; Individual Investigator Research Awards for Cancer in Children and Adolescents; Individual Investigator Research Awards for Prevention and Early Detection; Recruitment of First-Time, Tenure-Track Faculty; and Recruitment of Rising Stars. 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 January 8, 2015.

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

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

### **Academic Research Grant Award Recommendations**

App ID	Award Mechanism	Organization	Application Title	Budget
RP150006	IIRACCA	The University of Texas M. D. Anderson Cancer Center	Defining and Treating Targetable Lesions in AYA Acute Lymphoblastic Leukemia	\$1,989,950
RP150014	IIRAP	The University of Texas Health Science Center at Houston	Multi-component interventions for patients and providers to increase HPV vaccination in a network of pediatric clinics in Houston, TX	\$2,498,986
RP150030	IIRA	The University of Texas M. D. Anderson Cancer Center	Exploring molecular and immune mechanisms of response and resistance to combined BRAF/MEK inhibition in patients with high-risk resectable	\$900,000
RP150032	IIRACCA	Baylor College of Medicine	Developing New Combinatory Therapies for Pediatric High Grade Glioma	\$1,945,940
RP150053	IIRA	The University of Texas Southwestern Medical Center	Mechanisms of nuclear import and export in cancer	\$900,000
RP150079	IIRA	The University of Texas M. D. Anderson Cancer Center	Elucidating the evolution of the premalignant airway genome in space and time	\$886,173

RP150081	IIRACCA	Baylor College of Medicine	Genetic susceptibility to testicular germ cell tumors	\$1,406,791
RP150084	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of PTEN feedback mechanism in cancer	\$900,000
RP150093	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting 17q23 amplicon in HER2- positive Breast Cancer	\$828,242
RP150094	IIRA	The University of Texas M. D. Anderson Cancer Center	Investigating the regulation of miRNA and lncRNAs by p63 in mammary tumor progression and metastasis	\$900,000
RP150102	IIRA	The University of Texas M. D. Anderson Cancer Center	Genome stability and immune diversity controlled by the POLQ pathway	\$900,000
RP150129	IIRACCA	Baylor College of Medicine	Drug Discovery and Mechanistic Studies of Protein Methylation Targeting Leukemia	\$1,733,813
RP150148	IIRA	The University of Texas M. D. Anderson Cancer Center	Identifying Drivers of Lung Metastasis in Triple Negative Breast Cancer	\$899,637
RP150164	IIRACCA	The University of Texas Southwestern Medical Center	Using imaging and computational tools to improve risk stratification in children with bone cancer	\$1,290,442
RP150166	IIRA	The University of Texas Health Science Center at San Antonio	Prostate Cancer Chemoprevention with Resveratrol	\$900,000
RP150179	IIRA	The University of Texas M. D. Anderson Cancer Center	Regulation of dormancy of metastatic prostate cancer cells by bone microenvironment	\$900,000
RP150195	IIRAP	The University of Texas M. D. Anderson Cancer Center	Mechanisms of DHA and EPA differential effects on colon cancer chemoprevention	\$920,926
RP150197	IIRA	Baylor College of Medicine	Understanding How NCOA6 Suppresses Endometrial Cancer by Inhibiting the Wnt/beta-Catenin Pathway	\$886,524
RP150224	IIRA	The University of Texas M. D. Anderson Cancer Center	Discovering the molecular mechanisms that determine replicative lifespan	\$892,104
RP150228	IIRAP	The University of Texas M. D. Anderson Cancer Center	Varenicline and Combined NRT for Initial Smoking Cessation and Rescue Treatment in Smokers: A Randomized Pilot Trial	\$1,493,464
RP150230	IIRA	The University of Texas Health Science Center at Houston	Counteracting tumor evasion of antibody immunity by a novel therapeutic strategy	\$900,000
RP150231	IIRA	The University of Texas M. D. Anderson Cancer Center	Function of Fibroblasts and Collagen I in Pancreas Cancer	\$898,811
RP150232	IIRA	Baylor College of Medicine	The Role of Progesterone Receptor in Early Stage Breast Cancer.	\$864,661
RP150235	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of TBK1 in Regulating Dendritic Cell Function and Antitumor Immunity.	\$876,958
RP150242	IIRA	The University of Texas Southwestern Medical Center	Functional and structural characterization of a small chemical compound that arrests glioma stem cell growth with high activity and specificity	\$900,000
RP150245	IIRA	The University of Texas M. D. Anderson Cancer Center	EGFR Arginine Methylations: Biomarkers for Cetuximab Resistance in colon cancer	\$900,000
RP150277	IIRA	The University of Texas Health Science Center at San Antonio	Vertical targeting of the B cell receptor in leukemia and lymphoma	\$899,879

RP150282	IIRA	The University of Texas M. D. Anderson Cancer Center	Mechanisms of de novo and acquired resistance to therapeutic treatment of bone-metastatic prostate cancer	\$900,000
RP150292	IIRA	Baylor College of Medicine	Broad Shortening of 3' UTRs in Human Cancers: Methods, Target Genes and Functional Consequences	\$900,000
RP150293	IIRA	The University of Texas M. D. Anderson Cancer Center	Identification of clinically relevant targets for radiosensitization	\$899,280
RP150301	IIRACCA	The University of Texas M. D. Anderson Cancer Center	Epigenetics in Medulloblastoma Development and Therapeutics	\$1,871,708
RP150316	IIRA	The University of Texas M. D. Anderson Cancer Center	T-cell activating immunotherapy for indolent B-cell malignancies	\$852,595
RP150319	IIRA	The University of Texas M. D. Anderson Cancer Center	Leukemia inhibitory factor receptor signaling and function in cancer	\$900,000
RP150334	IIRACCA	Baylor College of Medicine	Personalized Functionalization of Pediatric High Grade Glioma	\$1,820,319
RP150343	IIRACCA	University of Houston	An ultra-sensitive nanomagnetic sensor for the early detection of anaplastic large cell lymphoma	\$1,929,710
RP150346	IIRA	The University of Texas at Austin	Targeting Twist1 for Prevention and Treatment of Non-Melanoma Skin Cancer	\$900,000
RP150356	IIRA	The University of Texas Southwestern Medical Center	Peripheral nerve tolerance to single- session stereotactic irradiation	\$897,779
RP150386	IIRA	The University of Texas Southwestern Medical Center	A Phase I Trial of Stereotactic HYpofractionateD RadioAblative (HYDRA) Treatment of Advanced Laryngeal Cancer	\$860,540
RP150403	IIRA	The University of Texas M. D. Anderson Cancer Center	On the role of DEAR1 in the regulation of cell polarity and progression from DCIS to invasive breast cancer	\$899,846
RP150405	IIRA	The University of Texas M. D. Anderson Cancer Center	Tumor Cell Epithelial-Mesenchymal Transition in Regulating Immunosuppression and Metastasis in Lung Cancer	\$900,000
RP150408	IIRA	The University of Texas Health Science Center at San Antonio	Cellular mechanisms of chemotherapy- induced peripheral neuropathy	\$844,746
RP150416	IIRACCA	Texas Tech University Health Sciences Center	Translational Investigations On Fenretinide and Safingol For Pediatric Cancer Use	\$1,999,415
RP150421	IIRAP	Texas Engineering Experiment Station	High-throughput Screening and Detection of Circulating Tumor Cells	\$1,135,450
RP150440	IIRA	Baylor College of Medicine	Effects of hormonal therapy on subclonal evolution of breast tumors with ESR1 mutations	\$899,805
RP150445 **	IIRACCA	The University of Texas Health Science Center at San Antonio	Ewing's sarcoma, a homologous recombination defective disease	\$2,000,000
RP150449	IIRAP	The University of Texas Medical Branch at Galveston	Noninvasive multiscale imaging for optical biopsy in epithelial cancers	\$852,748
RP150451 ***	IIRA	Baylor College of Medicine	SRC-2 driven "Metabolic Switch" in metastatic prostate cancer- Prognostic and Therapeutic implications	\$900,000

RP150454	IIRA	Texas A&M University	Tumor Suppression Through the cGAMP/STING Pathway	\$900,000
RP150456	IIRA	The University of Texas Southwestern Medical Center	TAMU-UT Southwestern Partnership for Breast Imaging and Spectroscopy at 7 Tesla	\$897,311
RP150485	IIRA	The University of Texas Southwestern Medical Center	Translating Online Adaptive Radiotherapy from Lab to Clinical Practice	\$858,356
RP150498	IIRA	The University of Texas Southwestern Medical Center	Harnessing the Cytosolic DNA Sensing Pathway for Cancer Immunotherapy	\$889,185

<sup>\*</sup> RP150053 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$900,000.

### **Academic Research Recruitment Grant Award Recommendations**

App ID	Organization/Company	Candidate	Mechanism	Budget Requested
	The University of Texas			_
RR150032	Southwestern Medical Center	Dr. Jenna L. Jewell	RFT	\$2,000,000
	The University of Texas			
RR150033	Southwestern Medical Center	Dr. Vincent S. Tagliabracci	RFT	\$2,000,000
	The University of Texas			
RR150025	Southwestern Medical Center	Dr. H. Charles Manning	RRS	\$4,000,000
RR150038	Texas A&M University	Dr. Jonathan T. Sczepanski	RFT	\$2,000,000

<sup>\*</sup>RRS = Recruitment of Rising Star, RFT = Recruitment of First Time Tenure Track, REI = Recruitment of Established Investigator

<sup>\*\*</sup>RP150445 - Budget will be adjusted down during contracting to accommodate a reduction in personnel and associated supplies and materials as recommended by the peer review panel. The total amount requested was \$2,000,000.

<sup>\*\*\*</sup>RP150451 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$900,000.

<sup>\*\*\*\*</sup>RP150408 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$844,746.

### **Product Development Award Recommendations –**

The PIC unanimously recommends approval of four product development grant proposals totaling \$48,452,265. The recommended grant proposals were submitted in response to the New Company Product Development Awards Request for Applications. The PIC followed the recommendations made by the Product Development Review Council (PDRC). The PDRC provided the prioritized list of recommendations for the product development awards to the presiding officers on January 21, 2015.

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

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- 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 Grant Award Recommendations

Application ID	Company Name	Project	Requested Budget
DP150021	NanoTx Therapeutics	Development of Rhenium Nanoliposomes for Cancer Therapy	\$ 2,000,000
DP150029	Immatics Biotechnologies	Personalized Cellular Immunotherapy against Novel Cancer Targets	\$19,652,175
DP150031	Medicenna Therapeutics, Inc.	A Multi-Targeted Approach for Recurrent Glioblastoma and Other Aggressive Cancers: Exploiting the Potential of IL-4 Fusion Proteins Treatment of Cancer	\$14,140,090
DP150039	Armada Pharmaceuticals, Inc.	New Company Formation for the Development of Anti-Cancer Antibody – Drug Conjugate Therapeutics	\$12,750,000



#### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS

FROM: MARGARET KRIPKE, PH.D., CHIEF SCIENTIFIC OFFICER

**SUBJECT:** UPDATE OF RESEARCH ACTIVITIES

**DATE:** FEBRUARY 18, 2015

#### **Research Grants**

Research Applications 15.1. In response to our RFAs for Individual Investigator Research Awards (IIRAs), 393 applications were reviewed by the peer review panels, and 62 were recommended for consideration by the Scientific Review Council. The Scientific Review Council recommended that only 51 of these applications move forward for consideration by the PIC and OC. The numbers for each type of IIRA (targeted and untargeted) are shown below:

Success Ra	te by Mechanism vs.	Total Reviewed*
Mechanism	Success Rate	# Recommended
IIRA	13.3%	36/271
IIRACCA	17.9%	10/56
IIRAP	7.6%	5/66
Overall	12.9%	51/393

<sup>\*</sup>The overall success rate for FY2014 IIRAs was 13%

Of the applications forwarded by the SRC, 70% are untargeted, 20% are for childhood cancer, and 10% are for prevention and early detection. These applications will be considered by the OC later in this meeting.

<u>Research Applications 15.2</u>. For the second round of funding in FY15, RFAs were released for High Impact-High Risk (HIHR) awards, Core Facility Support Awards (CFSA), and Multi-investigator Research Awards (MIRA). The number of applications in each category that were distributed to the review panels is shown below:

High Impact-High Risk (HIHR) Research Awards - 100 Core Facility Support Awards (CFSA) - 17 Multi-investigator Research Awards (MIRA) - 42

These applications are currently under review by the peer reviewers, and the panels will meet In Dallas to discuss them between March 8 and 18. These applications will come to the OC for action at the May meeting.

<u>Research Applications 16.1</u>. The next round of RFAs will be released at the end of February, 2015. It will include an RFA for new and renewal applications for Research Training Awards, untargeted Individual Investigator Research Awards (IIRAs), and three targeted IIRAs for

Childhood and Adolescent Cancers, Prevention and Early Detection, and Computational Biology.

<u>Recruitment Applications</u>. The SRC considered 5 applications for recruitment awards at its last meeting and forwarded 4 of these to the PIC and OC for their consideration. One of the four recruits has declined the award prior to the consideration of the OC. These will be acted upon by the OC later in this meeting. Additional applications have been received and will be reviewed by the SRC in March.

#### **Research Subcommittee**

The Research Subcommittee of the OC met on January 19, 2015 to address several items. First was our response to the white paper provided by the Advisory Committee on Childhood Cancers. Our response was communicated to the committee during a teleconference on February 2, 2015. The ad interim Chair of the committee will present the committee's annual report to the OC at this meeting.

#### **Meeting of the University Advisory Committee**

The University Advisory Committee met on February 5 to provide input into our new RFA on Computational Biology and elect a new co-chair. MaryAnn Ottinger, Ph.D., Associate Vice Chancellor for Research, University of Houston System was elected and will present the committee's annual report to the OC at this meeting.

#### **Meeting of the Advisory Committee Childhood Cancers**

The Advisory Committee Childhood Cancers met on February 2 to discuss the CPRIT program priorities project. Gail Tomlinson, M.D., Ph.D., Professor of Pediatrics, Greehey Distinguished Chair in Genetics and Cancer, Division Director, Pediatric Hematology-Oncology at The University of Texas Health Science Center at San Antonio will present the committee's annual report.

#### **Other Activities**

On January 30, 2015, Dr. Kripke, Mr. Roberts, and Mr. Brown attended a Trainee Day for all trainees supported by CPRIT training awards. The meeting was held at the Rice University Collaborative Research Building in Houston and was sponsored by the Gulf Coast Consortia. Presentations and poster sessions by trainees were highlighted and were most impressive. A discussion was held with the training program leaders to obtain their input concerning the value and policies of the training programs. This discussion was very helpful for us in preparing the new RFA for Training Awards.

Dr. Kripke presented a lecture to The Academy of Medicine, Engineering and Science of Texas on January 22 in Houston at their annual meeting, the theme of which was "Cancer: A Texas-sized Problem". Her lecture, entitled, "CPRIT: Moving Forward", described the research awards portfolio and presented the results of the OC's recent prioritization project. On January 23, Dr. Kripke gave the closing address at the first Annual Meeting of U.T. System Senior Women Leaders in Austin. On February 12, Dr. Kripke gave a plenary lecture at the 12<sup>th</sup> Annual M.D.Anderson Survivorship Research Symposium entitled, "Survivorship Research: How CPRIT Can Help".

Research Area	14	4.1	1	5.1	14.	1	15.3	1
	#	%	#	%	\$	%	\$	%
Cancer Biology	38	50%	26	51%	\$28.7M	53%	\$25.3M	44%
Cancer Control and Survivorship	1	1%	0	0%	\$0.8M	1%	\$0.0M	0%
Early detection, diagnosis, and prognosis	10	13%	5	10%	\$6.7M	12%	\$6.1M	11%
Etiology (causes of cancer)	5	7%	1	2%	\$3.6M	7%	\$1.4M	3%
Prevention	0	0%	4	8%	\$0.0M	0%	\$5.8M	10%
Scientific model systems	2	3%	1	2%	\$0.5M	1%	\$1.9M	3%
Treatment	20	26%	14	27%	\$14.0M	26%	\$16.4M	29%
Total	76	100%	51	100%	\$54.3M	100%	\$56.9M	100%

Program Priority Area	14	<b>1</b> .1	1	5.1	14.	1	15.1	L
	#	%	#	%	\$	%	\$	%
Childhood and Adolescent Cancer	2	4%	10	20%	\$1.7M	3%	\$17.9M	31%
Prevention and Early Detection	10**	13%	9	18%	\$6.7M	12%	\$11.9M	21%

<sup>\*\*</sup>All grants in this cell are early detection

15.1 Success Rate by Mechanism (#Recommended/Total #Reviewed)*					
	Peer Review	SRC			
Mechanism	Success Rate	Success Rate	Final Total Recommended		
IIRA	15.4%	13.3%	36/271		
IIRACCA	21.4%	17.9%	10/56		
IIRAP	12.0%	7.6%	5/66		
Overall	15.8%	12.9%	51/393		

<sup>\*</sup>The overall success rate for FY2014 IIRAs was 13%

15.1 Perce	ent of Applications Recommende	d by SRC by Mechanism
Mechanism	# Recommended	Percentage
IIRA	36/51	70.6%
IIRACCA	10/51	19.6%
IIRAP	5/51	9.8%

	Rec				Approval	Award	
Grant No.	Fname	Rec Lname	Mechanism	Institution	Date	Amount	Status
RR150009	iΣ	Chen	RFT	BCM	11/19/14	\$2,000,000	Accepted
RR150005	Melanie	Samuel	RFT	BCM	11/19/14	\$2,000,000	Accepted
00010	RR150010 Robert	Mattrey	REI	UTSW	11/19/14	\$6,000,000	Accepted
50015	RR150015 Samara	Reck-Peterson	RRS	UTSW	11/19/14	\$4,000,000	Pending - Competing Offer from Harvard - April/May decision
50016	RR150016 Andres	Leschziner	RRS	UTSW	11/19/14	\$4,000,000	Pending - Competing Offer from Harvard - April/May decision
RR150017	Issam El	Naga	RRS	UTSW	11/19/14	\$4,000,000	Pending - No decision
RR150013	Marcin	Imielinski	RFT	MDA	11/19/14	\$2,000,000	Declined
RR150012	Silvio	Gutkind	REI	MDA	11/19/14		Declined -Withdrew prior to OC approval
50032	RR150032 Jenna	Jewel	RFT	UTSW	02/18/15	\$2,000,000	Pending
50033	RR150033 Vincent	Tagliabracci	RFT	UTSW	02/18/15	\$2,000,000   Pending	Pending
50038	RR150038 Jonathan	Sczepanski	RFT	TAMU	02/18/15	\$2,000,000	Pending
50025	RR150025 Charles	Manning	RRS	UTSW	02/18/15		\$4,000,000 Declined -Withdrew prior to OC approval

## Conflicts of Interest for Acadmic Research Cycle 15.1 Applications (Academic Research Cycle 15.1 Awards Announced at February 18, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Acadmic Research Cycle 15.1 include *Individual Investigator Research Awards for Cancer in Children and Adolescents*, and *Individual Investigator Research Awards for Prevention and Early Detection*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	<b>Conflict Noted</b>
	<b>Applications Considered </b>	by the PIC and Oversight Com	mittee
RP150006	Konopleva, Marina	The University of Texas M.D. Anderson Cancer	Mullighan, Charles; Mitchell, Amy
		Center	
RP150014	Vernon, Sally	The University of Texas Health Science Center at Houston	Kushi, Lawrence; Mitchell, Amy
RP150030	Wargo, Jennifer	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150032	Li, Xiao-Nan	Baylor College of Medicine	Baker, Suzanne; Mitchell, Amy
RP150053	Chook, Yuh Min	The University of Texas Southwestern Medical Center	Houchens, David; Sonenberg, Nahum; Mitchell, Amy
RP150079/ RP150079pe	Kadara, Humam	The University of Texas M.D. Anderson Cancer Center	Mucci, Lorelei; Mitchell, Amy
RP150081	Heaney, Jason	Baylor College of Medicine	Mitchell, Amy
RP150084	Song, Min Sup	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150093	Zhang, Xinna	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150094	Flores, Elsa	The University of Texas M.D. Anderson Cancer Center	Pure, Ellen; Mitchell, Amy
RP150102	McBride, Kevin	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150129	Song, Yongcheng	Baylor College of Medicine	Mitchell, Amy
RP150148	Piwnica-Worms, Helen	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150164	Leavey, Patrick	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150166/ RP150166pe	Kumar, Addanki	The University of Texas Health Science Center at San Antonio	Kristal, Alan; Mitchell, Amy
RP150179	Lin, Sue-Hwa	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150195	Shureiqi, Imad	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150197	Xu, Jianming	Baylor College of Medicine	Mitchell, Amy
RP150224/ RP150224pe	Tyler, Jessica	The University of Texas M.D. Anderson Cancer Center	Edelmann, Winfried; Mitchell, Amy
RP150228	Cinciripini, Paul	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas; Mitchell, Amy
RP150230	An, Zhinqiang	The University of Texas Health Science Center at Houston	Mitchell, Amy
RP150231	Kalluri, Raghu	The University of Texas M.D. Anderson Cancer Center	Kripke, Margaret <sup>1</sup> ; Mitchell, Amy
RP150232/ RP150232pe	Edwards, Dean	Baylor College of Medicine	Greene, Geoffrey; Mitchell, Amy
RP150235	Sun, Shao-Cong	The University of Texas M.D. Anderson Cancer Center	Cooney, Kathleen; Mitchell, Amy

¹ Dr. Kripke is not a peer reviewer, but attends peer review meetings as an observer in her capacity as Chief Scientific Officer, which is allowed in her FY2015 COI waiver. Because of the professional relationship between the applicant and Dr. Fidler, out of extreme caution Dr. Kripke chose not to be present when the application was discussed. She also abstained from voting on the application during the PIC meeting.

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150242	Parada, Luis	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150245	Hung, Mien-Chie	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150277	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	Mitchell, Amy
RP150282	Gallick, Gary	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150292	Li, Wei	Baylor College of Medicine	Mitchell, Amy
RP150293	Skinner, Heath	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150301	Gopalakrishnan, Vidya	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150316	Neelapu, Sattva	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150319	Ma, Li	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150334	Deneen, Benjamin	Baylor College of Medicine	Baker, Suzanne; Mitchell, Amy
RP150343	Willson, Richard	University of Houston	Mitchell, Amy
RP150346	DiGiovanni, John	The University of Texas at Austin	Angelou, Angelos; Mitchell, Amy
RP150356/ RP150356pe	Medin, Paul	The University of Texas Southwestern Medical Center	Wu, Anna; Mitchell, Amy
RP150386	Schwartz, David	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150403	Killary, Ann	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RP150405	Gibbons, Don	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy

Application ID	Applicant	Institution	Conflict Noted
RP150408	Stockand, James	The University of Texas Health Science Center at San Antonio	Mitchell, Amy
RP150416	Maurer, Barry	Texas Tech University Health Science Center	Mitchell, Amy
RP150421	Ugaz, Victor	Texas Engineering Experiment Station	Mitchell, Amy
RP150440	Fuqua, Suzanne	Baylor College of Medicine	Fearon, Eric; Greene, Geoffrey; Lawlor, Elizabeth; Roberts, Charles; Mitchell, Amy
RP150440pe	Fuqua, Suzanne	Baylor College of Medicine	Knudsen, Karen; Greene, Geoffrey; Lawlor, Elizabeth; Roberts, Charles; Mitchell, Amy
RP150445	Bishop, Alexander	The University of Texas Health Science Center at San Antonio	Mitchell, Amy
RP150449	Vargas, Gracie	The University of Texas Medical Branch at Galveston	Mitchell, Amy
RP150451/ RP150451pe	Sreekumar, Arun	Baylor College of Medicine	Costello, Joseph; Mitchell, Amy
RP150454	Li, Pingwei	Texas A&M University	Mitchell, Amy
RP150456	Malloy, Craig	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150485	Jiang, Steve	The University of Texas Southwestern Medical Center	Mitchell, Amy
RP150498	Chen, Zhijian	The University of Texas Southwestern Medical Center	Mitchell, Amy
Applicat	ions Not Recommended fo	r PIC or Oversight Committee	e Consideration
RP150022*	Zhao, Hua	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150041*/ RP150041pe	Pati, Debananda	Baylor College of Medicine	Bhardwaj, Nina; Manfredi, James
RP150046pe	Kim, Jung-whan	The University of Texas at Dallas	Knudsen, Karen

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150064pe	Davies, Michael	The University of Texas M.D. Anderson Cancer Center	McMahon, Martin
RP150069*/ RP150069pe	Bhattarai, Shanta	The University of Texas M.D. Anderson Cancer Center	Berbeco, Ross
RP150082*	Nyitray, Alan	The University of Texas Health Science Center at Houston	Brandon, Thomas
RP150095pe	Kurie, Jonathan	The University of Texas M.D. Anderson Cancer Center	Belinsky, Steven
RP150128*/ RP150128pe	Wenzel, Pamela	The University of Texas Health Science Center at Houston	DeClerck, Yves
RP150150*	Wu, Xifeng	The University of Texas M.D. Anderson Cancer Center	Hunter, Kent
RP150154*/ RP150154pe	Paull, Tanya	The University of Texas at Austin	Tomkinson, Alan
RP150165*/ RP150165pe	Hassan, Manal	The University of Texas M.D. Anderson Cancer Center	Petersen, Gloria
RP150167pe	Gong, Zihua	The University of Texas M.D. Anderson Cancer Center	Bardeesy, Nabeel; Petrini, John
RP150173*	Bi, Xiaohong	The University of Texas Health Science Center at Houston	Mitchell, Duane
RP150175/ RP150175pe	Kundra, Vikas	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150186pe	Keyomarsi, Khandan	The University of Texas M.D. Anderson Cancer Center	Martinez, Maria
RP150188*	Rakheja, Dinesh	The University of Texas Southwestern Medical Center	Lawlor, Elizabeth
RP150201	Hamann, Heidi	The University of Texas Southwestern Medical Center	Barlow, William

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150216*/ RP150216pe	Pinney, Kevin	Baylor University	Mitchell, Duane
RP150219*/ RP150219pe	Post, Sean	The University of Texas M.D. Anderson Cancer Center	Tomkinson, Alan
RP150222*/ RP150222pe	Han, Arum	Texas Engineering Experiment Station	Nie, Shuming
RP150225/ RP150225pe	Bondy, Melissa	Baylor College of Medicine	Martinez, Maria
RP150234	Feng, Ziding	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kristal, Alan; Li, Christopher
RP150251pe	Gunaratne, Preethi	University of Houston	Costello, Joseph
RP150252pe	Cho, Sang	The University of Texas M.D. Anderson Cancer Center	Berbeco, Ross
RP150254*	McNeill, Lorna	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas
RP150259*/ RP150259pe	Zheng, Yanbin	The University of Texas Southwestern Medical Center	Greene, Geoffrey
RP150262*	Beretta, Laura	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kristal, Alan; Li, Christopher
RP150273*/ RP150273pe	Raj, Ganesh	The University of Texas Southwestern Medical Center	Greene, Geoffrey
RP150273pe	Raj, Ganesh	The University of Texas Southwestern Medical Center	Knudsen, Karen
RP150308pe	Nahleh, Zeina	Texas Tech University Health Sciences Center El Paso	Barlow, William
RP150335pe	Lizee, Gregory	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150344*/ RP150344pe	Mitsiades, Nicholas	Baylor College of Medicine	Roberts, Charles
RP150361	Maitra, Anirban	The University of Texas M.D. Anderson Cancer Center	Niedzwiecki, Donna

Application ID	Applicant	Institution	<b>Conflict Noted</b>	
RP150379*	Li, Donghui	The University of Texas M.D. Anderson Cancer Center	Petersen, Gloria	
RP150384*	Arun, Banu	The University of Texas M.D. Anderson Cancer Center	Li, Christopher	
RP150394pe	Mancini, Michael	Baylor College of Medicine	Greene, Geoffrey	
RP150399*	Patel, Darpan	The University of Texas Health Science Center at San Antonio	Kristal, Alan	
RP150404*/ RP150404pe	Glisson, Bonnie	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan	
RP150418*/ RP150418pe	Wang, Wei	Texas Tech University Health Sciences Center	Chen, Xinbin	
RP150422*	Jayaraman, Arul	Texas A&M University	Greene, Geoffrey	
RP150424/ RP150424pe	Aromougame, Asaithamby	The University of Texas Southwestern Medical Center	Berbeco, Ross	
RP150433	Taguchi, Ayumu	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Li, Christopher; Petersen, Gloria; Kristal, Alan	
RP150471pe	Castrillon, Diego	The University of Texas Southwestern Medical Center	Bardeesy, Nabeel	
RP150479*	Chan, Lawrence	Baylor College of Medicine	Williams, Bart	
RP150499*	Decuzzi, Paolo	The Methodist Hospital Research Institute	Rutt, Brian	
RP150500*	Vokes, Steven	The University of Texas at Austin	Chazin, Walter	
RP150516/ RP150516pe	Liu, Mingyao	Texas A&M University System Health Science Center	Williams, Bart	



# **CEO Affidavit Supporting Information**

FY 2015—Cycle 1
Individual Investigator Research Awards

## **Request for Applications**



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS RFA R-15-IIRA-1

### **Individual Investigator Research Awards**

Please also refer to the Instructions for Applicants document, which will be posted on May 15, 2014

**Application Receipt Opening Date: May 15, 2014 Application Receipt Closing Date: June 26, 2014** 

FY 2015

Fiscal Year Award Period September 1, 2014–August 31, 2015

#### **TABLE OF CONTENTS**

1.	. ABO	OUT CPRIT	5
2.	. RAT	TIONALE	5
3.	. RES	EARCH OBJECTIVES	6
4.	. FUN	DING INFORMATION	6
5.	. ELIC	GIBILITY	7
6.	. RES	UBMISSION POLICY	8
7.	. REN	EWAL POLICY	8
8.	. RES	PONDING TO THIS RFA	9
	8.1.	APPLICATION SUBMISSION GUIDELINES	9
	8.1.1.	Submission Deadline Extension	9
	8.2.	APPLICATION COMPONENTS	9
	8.2.1.	Abstract and Significance (5,000 characters)	9
	8.2.2.	Layperson's Summary (2,000 characters)	10
	8.2.3.	Goals and Objectives	10
	8.2.4.	Timeline (One page)	10
	8.2.5.	Resubmission Summary (One page)	11
	8.2.6.	Renewal Summary (Two pages)	11
	8.2.7.	Research Plan (Ten pages)	11
	8.2.8.		
	8.2.9.	Publications/References	12
	8.2.10	9. Budget and Justification	12
	8.2.1	I. Biographical Sketches (Two pages each)	13
	8.2.12	2. Current and Pending Support	13
	8.2.13	, T. G. J. L. L. G. J. L.	
	8.2.12		
	8.2.13		
9.	. APP	LICATION REVIEW	14
	9.1.	Preliminary Evaluation	14
	9.2.	Full Peer Review	15
	9.3.	CONFIDENTIALITY OF REVIEW	15
	9.4.	Review Criteria	16
	9.4.1.	Primary Criteria	17

	9.4.2	Secondary Criteria	17
10.	K	EY DATES	18
11.	A	WARD ADMINISTRATION	18
12.	R	EQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	19
13.	C	ONTACT INFORMATION	20
13	3.1.	HelpDesk	20
13	3 2	SCIENTIFIC AND PROGRAMMATIC OUESTIONS	20

#### **RFA VERSION HISTORY**

Rev 3/31/14 RFA release

Rev 5/13/14 Revised Section 8.2 Application Components

- Added Section 8.2.14 Clinical Trial Plan
- Information on Previous Summary Statement moved to Section 8.2.15

#### 1. ABOUT CPRIT

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

CPRIT is charged by the Texas Legislature to:

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

#### 2. RATIONALE

The goals of the CPRIT Research Grants Program are to support the discovery of new information about cancer that can lead to prevention, early detection, and cures and to translate new and existing discoveries into practical advances in cancer diagnosis and treatment. CPRIT encourages applications that seek new fundamental knowledge about cancer and cancer development as well as those attempting to develop state-of-the-art technologies, tools, computational models, and/or resources for cancer research, including those with potential commercialization opportunities. This award allows experienced or early career-stage cancer researchers the opportunity to explore new methods and approaches for investigating a question of importance that has been inadequately addressed or for which there may be an absence of an established paradigm or technical framework. CPRIT will look with special favor on new approaches to be taken or new areas of investigation to be explored by established investigators and on supporting the research programs of the most promising investigators at the beginning of their research careers. Applicants need not be trained specifically in cancer research. Indeed, CPRIT strongly encourages investigators from other fields, including the mathematical and computational modeling, physical, chemical, and engineering sciences, to bring their expertise to bear on the exceptionally challenging problems posed by cancer. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure.

To fulfill this vision, applications may address any topic or issue related to cancer, including cancer biology, computational modeling, and systems biology, causation, prevention, detection or screening, treatment, or cure. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies. Access to a clinical environment and interaction with translational cancer physician-scientists are highly desirable.

#### 3. RESEARCH OBJECTIVES

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This Request for Applications (RFA) solicits applications for 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. Applications that include collaboration with computational modeling teams are welcomed. In that cancers arise from a large number of derangements of basic molecular and cellular functions and, in turn, cause many alterations in basic biological processes, almost any aspect of biology may be relevant to cancer research, more or less directly. The degree of relevance to cancer research will be an important criterion for evaluation of projects for funding by CPRIT (Section 9.4.1). For example, are alterations in the process in question *primarily* responsible for oncogenesis or secondary manifestations of malignant transformation? Will understanding the process or interfering with it offer selective and useful insight into prevention, diagnosis, or treatment of cancer? Successful applicants for funding from CPRIT will have addressed these questions satisfactorily.

#### 4. FUNDING INFORMATION

Applicants may request a maximum of \$300,000 in total costs per year for up to 3 years for research. Exceptions to these limits may be requested if extremely well justified (see Section 8.2.10). Applications funded in this cycle will be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism.

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

#### 5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization
  that conducts research is eligible to apply for funding under this award mechanism.

  A public or private company is not eligible for funding under this award mechanism;
  these entities must use the appropriate award mechanism(s) under CPRIT's Product
  Development Program.
- The Principal Investigator (PI) must have a doctoral degree, including M.D., Ph.D.,
   D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may not submit applications to this RFA and to RFA-R-15-IIRACCA-1 or RFA R-15-IIRAP-1. Only one IIRA, IIRACCA, or IIRAP application per cycle is allowed. A PI may submit only one new or resubmission application under this RFA during this funding cycle. If submitting a renewal application, a PI may submit both a new or resubmission application and a renewal application under this RFA during this funding cycle.
- Because this award mechanism is intended to support research directed by a single investigator, only one Co-PI may be included.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Collaborators should have specific and well-defined roles. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the
  applicant institution or organization, including the PI, any senior member or key
  personnel listed on the grant application, and any officer or director of the grant
  applicant's institution or organization (or any person related to one or more of these
  individuals within the second degree of consanguinity or affinity), has not made and will
  not make a contribution to CPRIT or to any foundation specifically created to benefit
  CPRIT.

- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in <a href="Section 11">Section 11</a> and <a href="Section 12">Section 12</a>. All statutory provisions and relevant administrative rules can be found at <a href="www.cprit.state.tx.us">www.cprit.state.tx.us</a>.

#### 6. RESUBMISSION POLICY

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

#### 7. RENEWAL POLICY

An application funded by CPRIT under this mechanism may be submitted for a competitive renewal. This policy is in effect for all awards submitted to date. See <u>Section 8.2.6</u>. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See <u>Section 9.2</u>.

#### 8. RESPONDING TO THIS RFA

#### 8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<a href="https://CPRITGrants.org">https://CPRITGrants.org</a>). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 a.m. Central Time on May 15, 2014, and must be submitted by 3 p.m. Central Time on June 26, 2014. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

#### 8.1.1. Submission Deadline Extension

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

#### **8.2.** Application Components

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

#### 8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the Research Plan.

Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (e.g., that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly). Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see Section 9.1).

#### 8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (Section 9.2) in evaluating the significance and impact of the proposed work.

#### 8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success

#### 8.2.4. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications.

If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

#### 8.2.5. Resubmission Summary (One page)

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

**Note:** An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Research Plan or modify the original Research Plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

#### 8.2.6. Renewal Summary (Two pages)

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

#### 8.2.7. Research Plan (Ten pages)

**Background:** Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

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

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

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

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

#### 8.2.9. Publications/References

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

#### 8.2.10. Budget and Justification

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

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

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

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at <a href="www.cprit.state.tx.us">www.cprit.state.tx.us</a>. So-called grants management and facilities fees (e.g., sponsored programs fees; grants and contracts fees; electricity, gas and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

• The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2015 is \$200,000; CPRIT FY 2015 is from September 1, 2014, through August 31, 2015. Salary does not include fringe benefits and/or facilities and administrative (F&A) costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

#### 8.2.11. Biographical Sketches (Two pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to two additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

#### 8.2.12. Current and Pending Support

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

#### 8.2.13. Institutional/Collaborator Support and/or Other Certification (Four pages)

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

#### 8.2.14. Clinical Trial Plan

If you are planning to conduct clinical trials as part of your proposed project, please submit required documentation as a single PDF file via e-mail to the CPRIT HelpDesk at <a href="help@CPRITgrants.org">help@CPRITgrants.org</a>. In this document, please include the clinical trial protocol, informed consent document, and a letter of drug availability from the sponsor if the trial is using an investigational drug. CPRIT may require institutional review board (IRB) approval prior to the initiation of funding.

#### 8.2.15. Previous Summary Statement

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

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

#### 9. APPLICATION REVIEW

#### 9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

#### 9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a two-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

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

#### 9.3. Confidentiality of Review

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

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

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

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

#### 9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

#### 9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the 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 application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important 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? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

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

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

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

#### 9.4.2. Secondary Criteria

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

Secondary criteria include the following:

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

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

**Budget:** Is the budget appropriate for the proposed work?

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

#### 10. KEY DATES

#### **RFA**

RFA release March 31, 2014

#### **Application**

Online application opens May 15, 2014, 7 a.m. Central Time
Application due June 26, 2014, 3 p.m. Central Time

Application review October - November 2014

#### Award

Award notification January 2015
Anticipated start date March 2015

#### 11. AWARD ADMINISTRATION

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

Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

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

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>.

#### 12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11, for specific requirements regarding demonstration of available funding.

#### 13. CONTACT INFORMATION

#### 13.1. HelpDesk

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

**Dates of operation:** March 31– June 26, 2014 (excluding public holidays)

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

Wednesday, 8 a.m. to 4 p.m. Central Time

**Tel:** 866-941-7146

E-mail: Help@CPRITGrants.org

#### 13.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

E-mail: Help@CPRITGrants.org

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

## **Third Party Observer Report**

## CPRIT Basic Cancer Research Peer Review Panel Report

Report #2015-211

Panel Name: Basic Cancer Research-1

Panel Date: November 6, 2014 Report Date: November 17, 2014

#### **Background**

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

#### Introduction

The subject of this report is the Basic Cancer Research-1 peer review panel finalization of recommended prevention program applications. The meeting was chaired by Tom Curran and held at the Hyatt Regency in Dallas TX, on November 6, 2014.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the peer review panel meeting held at the Hyatt Regency and chaired by Tom Curran on November 6, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- 24 applications were discussed within the Prevention Review Council for their review and approval.
- Fifteen reviewers, two advocate reviewers, two CPRIT staff members and six SRA employee were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

#### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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

## CPRIT Basic Cancer Research Review Council Report

Report #2015-209

Panel Name: Basic Cancer Research 2

Panel Date: October 30, 2014-October 31, 2014

Report Date: October 31, 2014

#### **Background**

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

#### Intro duction

The subject of this report is the Basic Cancer Research review of applications for FY15 funding. The meeting was chaired by Carol Prives and held at the Hyatt Regency in Dallas, TX on October 30 and October 31, 2014.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the in-person Basic Cancer Research Panel final scoring of applications held October 30, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 19 applications were discussed within the Basic Cancer Research Panel for their review and approval.
- Three CPRIT staff members and seven SRA employees were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.

• The Council members' discussions were limited to the application evaluation criteria.

#### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

# CPRIT Cancer Biology Review Council Report

Report #2015-210

Panel Name: Cancer Biology

Panel Date: November 3, 2014 Report Date: November 3, 2014

#### **Background**

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

#### Intro duction

The subject of this report is the Cancer Biology review of applications for FY15 funding. The meeting was chaired by Peter Jones and held at the Hyatt Regency in Dallas TX, on November 3, 2014.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the in-person Cancer Biology final scoring of applications held November 3, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 18 applications were discussed within the Basic Cancer Research Panel for their review and approval.
- Three CPRIT staff members and five SRA employees were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

## CPRIT Cancer Prevention Research Panel Review Report

Report #2015-208

Panel Name: Cancer Prevention Research

Panel Date: October 28, 2014 Report Date: November 17, 2014

#### **Background**

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

#### Introduction

The subject of this report is the Cancer Prevention Research Panel finalization of recommended prevention program applications. The meeting was chaired by Tom Sellers and held at the Hyatt Regency in Dallas TX on October 28, 2014.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the Cancer Prevention Research Panel meeting held at the Hyatt Regency and chaired by Tom Sellers on October 28, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 20 applications were discussed within the Cancer Prevention Research Panel for their review and approval.
- Eighteen panel members, two advocate reviewers, five CPRIT staff members, and six SRA employees were
  present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

## CPRIT Imaging Technology and Informatics Review Council Report

Report #2015-207

Panel Name: Imaging Technology and Informatics

Panel Date: October 27, 2014 Report Date: October 27, 2014

#### **Background**

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

#### Intro duction

The subject of this report is the Imaging Technology and Informatics review of applications for FY15 funding. The meeting was chaired by Sam Gambhir and held at the Hyatt Regency in Dallas TX, on October 27, 2014.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the in-person Imaging Technology and Informatics Panel final scoring of applications held October 27, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 21 applications were discussed within the Imaging Technology and Informatics Panel for their review and approval.
- Two CPRIT staff members and six SRA employees were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

## CPRIT Peer Review Panel Report

### Report #2015-212

Panel Name: Translational Cancer Research & Clinical and

Translational Cancer Research

Panel Date: November 11, 2014 Report Date: November 17, 2014

#### **Background**

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

#### Introduction

The subject of this report is the Translational Cancer Research panel & Clinical and Translational Cancer Research panel review of applications for FY15 funding. The joint meeting was co-chaired by Richard O'Reilly and Margaret Tempero, and held on November 11, 2014 at the Hyatt Regency in Dallas, TX.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the in-person Translational Cancer Research & Clinical and Translational Cancer Research joint meeting held November 11, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- Over the course of the panel meeting, seventeen Translational Cancer Research applications and seven Clinical and Translational Cancer Research applications were discussed for their review and approval
- Twenty-one review panel members, three advocate reviewers, two CPRIT staff members, and five SRA
  employees were present for the in-person panel meeting. Seven panel members were on teleconference. A
  total of twenty-eight panelists participated in the meeting.

- Multiple conflicts of interests (COIs) were identified prior to the panel meeting. All COIs were noted and left the room.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

# CPRIT Scientific Review Council Observation Report

Report #2015-213

Panel Name: FY15 Scientific Review Council Meeting -

Recruitment Program Applications

Panel Date: January 6, 2015 Report Date: January 7, 2015

#### **Background**

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

#### Introduction

The subject of this report is the Scientific Review Council review of recruitment program applications. The meeting was chaired by Richard Kolodner and held over the phone on January 6, 2015.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on January 6, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- Five recruitment applications were discussed and evaluated by the Scientific Review Council to determine
  which grants would receive CPRIT funding.
- Six council members, two CPRIT staff members, and two SRA employees were present for the Council
  meeting over the phone.

- No conflicts of interest were identified prior to or during the call.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

### **Noted Conflicts of Interest**

# Conflicts of Interest for Scientific Research Cycle 15.1 Applications (Scientific Research Cycle 15.1 Awards Announced at February 18, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Scientific Research Cycle 15.1 include *Individual Investigator Research Awards for Cancer in Children and Adolescents*, and *Individual Investigator Research Awards for Prevention and Early Detection*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	<b>Conflict Noted</b>
	<b>Applications Considered </b>	by the PIC and Oversight Com	mittee
RP150006	Konopleva, Marina	The University of Texas M.D. Anderson Cancer	Mullighan, Charles
		Center	
RP150014	Vernon, Sally	The University of Texas Health Science Center at Houston	Kushi, Lawrence
RP150032	Li, Xiao-Nan	Baylor College of Medicine	Baker, Suzanne
RP150053	Chook, Yuh Min	The University of Texas Southwestern Medical Center	Houchens, David; Sonenberg, Nahum
RP150079/ RP150079pe	Kadara, Humam	The University of Texas M.D. Anderson Cancer Center	Mucci, Lorelei
RP150094	Flores, Elsa	The University of Texas M.D. Anderson Cancer Center	Pure, Ellen
RP150166/ RP150166pe	Kumar, Addanki	The University of Texas Health Science Center at San Antonio	Kristal, Alan
RP150224/ RP150224pe	Tyler, Jessica	The University of Texas M.D. Anderson Cancer Center	Edelmann, Winfried
RP150228	Cinciripini, Paul	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas

Application	Applicant	Institution	Conflict Noted
ID RP150231	Kalluri, Raghu	The University of Texas M.D. Anderson Cancer Center	Kripke, Margaret <sup>1</sup>
RP150232/ RP150232pe	Edwards, Dean	Baylor College of Medicine	Greene, Geoffrey
RP150235	Sun, Shao-Cong	The University of Texas M.D. Anderson Cancer Center	Cooney, Kathleen
RP150334	Deneen, Benjamin	Baylor College of Medicine	Baker, Suzanne
RP150356/ RP150356pe	Medin, Paul	The University of Texas Southwestern Medical Center	Wu, Anna
RP150440	Fuqua, Suzanne	Baylor College of Medicine	Fearon, Eric; Greene, Geoffrey; Lawlor, Elizabeth; Roberts, Charles
RP150440pe	Fuqua, Suzanne	Baylor College of Medicine	Knudsen, Karen; Greene, Geoffrey; Lawlor, Elizabeth; Roberts, Charles
RP150451/ RP150451pe	Sreekumar, Arun	Baylor College of Medicine	Costello, Joseph
Applicat	ions Not Recommended fo	r PIC or Oversight Committee	e Consideration
RP150022*	Zhao, Hua	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150041*/ RP150041pe	Pati, Debananda	Baylor College of Medicine	Bhardwaj, Nina; Manfredi, James
RP150046pe	Kim, Jung-whan	The University of Texas at Dallas	Knudsen, Karen
RP150064pe	Davies, Michael	The University of Texas M.D. Anderson Cancer Center	McMahon, Martin
RP150069*/ RP150069pe	Bhattarai, Shanta	The University of Texas M.D. Anderson Cancer Center	Berbeco, Ross
RP150082*	Nyitray, Alan	The University of Texas Health Science Center at Houston	Brandon, Thomas

¹ Dr. Kripke is not a peer reviewer, but attends peer review meetings as an observer in her capacity as Chief Scientific Officer, which is allowed in her FY2015 COI waiver. Because of the professional relationship between the applicant and Dr. Fidler, out of extreme caution Dr. Kripke chose not to be present when the application was discussed. She also abstained from voting on the application during the PIC meeting.

<sup>\* =</sup> Application not discussed

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150095pe	Kurie, Jonathan	The University of Texas M.D. Anderson Cancer Center	Belinsky, Steven
RP150128*/ RP150128pe	Wenzel, Pamela	The University of Texas Health Science Center at Houston	DeClerck, Yves
RP150150*	Wu, Xifeng	The University of Texas M.D. Anderson Cancer Center	Hunter, Kent
RP150154*/ RP150154pe	Paull, Tanya	The University of Texas at Austin	Tomkinson, Alan
RP150165*/ RP150165pe	Hassan, Manal	The University of Texas M.D. Anderson Cancer Center	Petersen, Gloria
RP150167pe	Gong, Zihua	The University of Texas M.D. Anderson Cancer Center	Bardeesy, Nabeel; Petrini, John
RP150173*	Bi, Xiaohong	The University of Texas Health Science Center at Houston	Mitchell, Duane
RP150175/ RP150175pe	Kundra, Vikas	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150186pe	Keyomarsi, Khandan	The University of Texas M.D. Anderson Cancer Center	Martinez, Maria
RP150188*	Rakheja, Dinesh	The University of Texas Southwestern Medical Center	Lawlor, Elizabeth
RP150201	Hamann, Heidi	The University of Texas Southwestern Medical Center	Barlow, William
RP150216*/ RP150216pe	Pinney, Kevin	Baylor University	Mitchell, Duane
RP150219*/ RP150219pe	Post, Sean	The University of Texas M.D. Anderson Cancer Center	Tomkinson, Alan
RP150222*/ RP150222pe	Han, Arum	Texas Engineering Experiment Station	Nie, Shuming
RP150225/ RP150225pe	Bondy, Melissa	Baylor College of Medicine	Martinez, Maria

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150234	Feng, Ziding	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kristal, Alan; Li, Christopher
RP150251pe	Gunaratne, Preethi	University of Houston	Costello, Joseph
RP150252pe	Cho, Sang	The University of Texas M.D. Anderson Cancer Center	Berbeco, Ross
RP150254*	McNeill, Lorna	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas
RP150259*/ RP150259pe	Zheng, Yanbin	The University of Texas Southwestern Medical Center	Greene, Geoffrey
RP150262*	Beretta, Laura	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kristal, Alan; Li, Christopher
RP150273*/ RP150273pe	Raj, Ganesh	The University of Texas Southwestern Medical Center	Greene, Geoffrey
RP150273pe	Raj, Ganesh	The University of Texas Southwestern Medical Center	Knudsen, Karen
RP150308pe	Nahleh, Zeina	Texas Tech University Health Sciences Center El Paso	Barlow, William
RP150335pe	Lizee, Gregory	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150344*/ RP150344pe	Mitsiades, Nicholas	Baylor College of Medicine	Roberts, Charles
RP150361	Maitra, Anirban	The University of Texas M.D. Anderson Cancer Center	Niedzwiecki, Donna
RP150379*	Li, Donghui	The University of Texas M.D. Anderson Cancer Center	Petersen, Gloria
RP150384*	Arun, Banu	The University of Texas M.D. Anderson Cancer Center	Li, Christopher
RP150394pe	Mancini, Michael	Baylor College of Medicine	Greene, Geoffrey
RP150399*	Patel, Darpan	The University of Texas Health Science Center at San Antonio	Kristal, Alan

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150404*/ RP150404pe	Glisson, Bonnie	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150418*/ RP150418pe	Wang, Wei	Texas Tech University Health Sciences Center	Chen, Xinbin
RP150422*	Jayaraman, Arul	Texas A&M University	Greene, Geoffrey
RP150424/ RP150424pe	Aromougame, Asaithamby	The University of Texas Southwestern Medical Center	Berbeco, Ross
RP150433	Taguchi, Ayumu	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Li, Christopher; Petersen, Gloria; Kristal, Alan
RP150471pe	Castrillon, Diego	The University of Texas Southwestern Medical Center	Bardeesy, Nabeel
RP150479*	Chan, Lawrence	Baylor College of Medicine	Williams, Bart
RP150499*	Decuzzi, Paolo	The Methodist Hospital Research Institute	Rutt, Brian
RP150500*	Vokes, Steven	The University of Texas at Austin	Chazin, Walter
RP150516/ RP150516pe	Liu, Mingyao	Texas A&M University System Health Science Center	Williams, Bart

### **De-Identified Overall Evaluation Scores**

# Individual Investigator Research Awards-Final Scores for Fully Reviewed Applications

Scientific Research Cycle 15.1

	Final Overall
Application ID	Score
RP150224*	1.1
RP150498*	1.2
RP150456*	1.7
RP150245*	1.8
RP150319*	1.9
RP150053*	1.9
RP150230*	1.9
RP150277*	2.0
RP150282*	2.1
RP150451*	2.1
RP150084*	2.2
RP150148*	2.2
RP150485*	2.2
RP150232*	2.3
RP150403*	2.3
RP150440*	2.3
RP150197*	2.4
RP150094*	2.4
RP150231*	2.4
RP150386*	2.4
RP150408*	2.6
RP150293*	2.7
RP150316*	2.7
RP150093*	2.8
RP150356*	2.8
RP150102*	2.9
RP150292*	2.9
RP150079*	2.9
RP150179*	3.0
RP150346*	3.0
RP150235*	3.0
RP150454*	3.0
RP150166*	3.1
RP150405*	3.1
RP150242*	3.2
RP150030*	3.2

<sup>\*=</sup>Recommended for Funding

EA 3.3 EB 3.3 EC 3.3 ED 3.4 EE 3.4 EE 3.4 EF 3.4 EG 3.4 EH 3.5 EI 3.6 EJ 3.7 EK 3.7 EK 3.7 EN 3.7 EN 3.7 EO 3.7 EP 3.7 EQ 3.7 ER 3.7 ES 3.7 ET 3.7 EV 3.7 EW 3.7 EW 3.7 EW 3.7 EV 3.7 EW 3.7 EV 3.7 EV 3.7 EV 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FF 3.9 FG 4.0 FH 4.0 FI 4.0 FM 4.0 FM 4.0		
EC 3.3 ED 3.4 EE 3.4 EE 3.4 EF 3.4 EG 3.4 EH 3.5 EI 3.6 EJ 3.7 EK 3.7 EK 3.7 EN 3.7 EN 3.7 EO 3.7 EP 3.7 EQ 3.7 ER 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EV 3.7 EV 3.7 EV 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FF 3.9 FF 3.9 FG 4.0 FH 4.0 FI 4.0 FM 4.0 FM 4.0 FM 4.0		
ED 3.4  EE 3.4  EF 3.4  EG 3.4  EH 3.5  EI 3.6  EJ 3.7  EK 3.7  EL 3.7  EM 3.7  EN 3.7  EQ 3.7  ER 3.7  ES 3.7  ET 3.7  EU 3.7  EV 3.7  EW 3.7  EW 3.7  EV 3.7  EV 3.7  EX 3.7  EX 3.7  EY 3.8  EZ 3.8  FA 3.8  FB 3.9  FC 3.9  FD 3.9  FE 3.9  FF 3.9  FG 4.0  FH 4.0  FI 4.0  FM 4.0		3.3
EE 3.4 EF 3.4 EG 3.4 EH 3.5 EI 3.6 EJ 3.7 EK 3.7 EK 3.7 EM 3.7 EN 3.7 EO 3.7 EP 3.7 EQ 3.7 ES 3.7 ES 3.7 ET 3.7 EU 3.7 EW 3.7 EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FF 3.9 FF 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FM 4.0		
EF 3.4 EG 3.4 EH 3.5 EI 3.6 EJ 3.7 EK 3.7 EK 3.7 EM 3.7 EN 3.7 EO 3.7 EP 3.7 EQ 3.7 ER 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FF 3.9 FF 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FM 4.0 FM 4.0 FM 4.0 FM 4.0	ED	3.4
EG 3.4 EH 3.5 EI 3.6 EJ 3.7 EK 3.7 EK 3.7 EL 3.7 EM 3.7 EN 3.7 EO 3.7 EQ 3.7 EQ 3.7 ES 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FF 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FM 4.0		3.4
EH 3.5  EI 3.6  EJ 3.7  EK 3.7  EK 3.7  EM 3.7  EM 3.7  EO 3.7  EQ 3.7  EQ 3.7  ES 3.7  ET 3.7  EU 3.7  EV 3.7  EW 3.7  EX 3.7  EX 3.7  EY 3.8  EZ 3.8  FA 3.8  FB 3.9  FC 3.9  FD 3.9  FF 3.9  FF 3.9  FG 4.0  FH 4.0  FI 4.0  FI 4.0  FM 4.0	EF	3.4
EI 3.6 EJ 3.7 EK 3.7 EK 3.7 EL 3.7 EM 3.7 EM 3.7 EO 3.7 EO 3.7 EQ 3.7 ER 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FF 3.9 FG 4.0 FH 4.0 FJ 4.0 FM 4.0 FM 4.0 FM 4.0 FM 4.0	EG	3.4
EJ 3.7 EK 3.7 EL 3.7 EM 3.7 EM 3.7 EN 3.7 EO 3.7 EP 3.7 EQ 3.7 ER 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FF 3.9 FF 3.9 FF 3.9 FG 4.0 FH 4.0 FJ 4.0 FM 4.0 FM 4.0 FM 4.0	EH	3.5
EK 3.7 EL 3.7 EM 3.7 EM 3.7 EN 3.7 EO 3.7 EP 3.7 EQ 3.7 ER 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EW 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FF 3.9 FF 3.9 FG 4.0 FH 4.0 FI 4.0 FM 4.0 FM 4.0 FM 4.0 FM 4.0	EI	3.6
EL 3.7 EM 3.7 EM 3.7 EN 3.7 EO 3.7 EP 3.7 EQ 3.7 ER 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FF 3.9 FF 3.9 FG 4.0 FH 4.0 FI 4.0 FK 4.0 FM 4.0 FM 4.0	EJ	3.7
EM 3.7 EN 3.7 EN 3.7 EO 3.7 EP 3.7 EQ 3.7 ER 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FK 4.0 FM 4.0 FM 4.0	EK	3.7
EN 3.7 EO 3.7 EP 3.7 EQ 3.7 EQ 3.7 ER 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FF 3.9 FF 3.9 FF 3.9 FG 4.0 FH 4.0 FI 4.0 FK 4.0 FK 4.0 FM 4.0	EL	3.7
EO 3.7 EP 3.7 EQ 3.7 ER 3.7 ER 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FF 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FK 4.0 FK 4.0 FM 4.0 FM 4.0	EM	3.7
EP       3.7         EQ       3.7         ER       3.7         ES       3.7         ET       3.7         EU       3.7         EV       3.7         EW       3.7         EX       3.7         EY       3.8         EZ       3.8         FA       3.8         FB       3.9         FC       3.9         FD       3.9         FF       3.9         FF       3.9         FG       4.0         FH       4.0         FJ       4.0         FK       4.0         FL       4.0         FM       4.0         FM       4.0	EN	3.7
EP       3.7         EQ       3.7         ER       3.7         ES       3.7         ET       3.7         EU       3.7         EV       3.7         EX       3.7         EX       3.7         EY       3.8         EZ       3.8         FA       3.8         FB       3.9         FC       3.9         FD       3.9         FE       3.9         FF       3.9         FG       4.0         FH       4.0         FJ       4.0         FK       4.0         FL       4.0         FM       4.0	EO	3.7
EQ 3.7 ER 3.7 ES 3.7 ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FK 4.0 FK 4.0 FM 4.0 FM 4.0		
ER 3.7 ES 3.7 ET 3.7 EU 3.7 EU 3.7 EW 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FI 4.0 FK 4.0 FK 4.0 FM 4.0	EQ	
ES 3.7 ET 3.7 EU 3.7 EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FI 4.0 FK 4.0 FK 4.0 FM 4.0		
ET 3.7 EU 3.7 EV 3.7 EW 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FI 4.0 FK 4.0 FK 4.0 FM 4.0		
EU 3.7 EV 3.7 EW 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FI 4.0 FK 4.0 FK 4.0 FM 4.0		
EV 3.7 EW 3.7 EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FF 3.9 FG 4.0 FH 4.0 FI 4.0 FI 4.0 FK 4.0 FK 4.0 FM 4.0 FM 4.0		
EW 3.7  EX 3.7  EY 3.8  EZ 3.8  FA 3.8  FB 3.9  FC 3.9  FD 3.9  FE 3.9  FF 3.9  FF 4.0  FH 4.0  FI 4.0  FJ 4.0  FK 4.0  FL 4.0  FM 4.0		
EX 3.7 EY 3.8 EZ 3.8 FA 3.8 FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FF 4.0 FH 4.0 FI 4.0 FJ 4.0 FK 4.0 FL 4.0 FM 4.0		
EY 3.8  EZ 3.8  FA 3.8  FB 3.9  FC 3.9  FD 3.9  FE 3.9  FF 3.9  FG 4.0  FH 4.0  FI 4.0  FJ 4.0  FK 4.0  FL 4.0  FM 4.0		
EZ 3.8  FA 3.8  FB 3.9  FC 3.9  FD 3.9  FE 3.9  FF 3.9  FG 4.0  FH 4.0  FI 4.0  FJ 4.0  FK 4.0  FL 4.0  FM 4.0		
FA 3.8  FB 3.9  FC 3.9  FD 3.9  FE 3.9  FF 3.9  FG 4.0  FH 4.0  FI 4.0  FJ 4.0  FK 4.0  FL 4.0  FM 4.0		
FB 3.9 FC 3.9 FD 3.9 FE 3.9 FF 3.9 FG 4.0 FH 4.0 FI 4.0 FJ 4.0 FK 4.0 FL 4.0 FM 4.0		
FC 3.9 FD 3.9 FE 3.9 FF 3.9 FG 4.0 FH 4.0 FI 4.0 FJ 4.0 FK 4.0 FL 4.0 FM 4.0		
FD 3.9 FE 3.9 FF 3.9 FG 4.0 FH 4.0 FI 4.0 FJ 4.0 FK 4.0 FL 4.0 FM 4.0		
FE       3.9         FF       3.9         FG       4.0         FH       4.0         FI       4.0         FJ       4.0         FK       4.0         FL       4.0         FM       4.0		
FF 3.9 FG 4.0 FH 4.0 FI 4.0 FJ 4.0 FK 4.0 FL 4.0 FM 4.0		
FG 4.0 FH 4.0 FI 4.0 FJ 4.0 FK 4.0 FL 4.0 FM 4.0		
FH 4.0 FI 4.0 FJ 4.0 FK 4.0 FL 4.0 FM 4.0		
FI       4.0         FJ       4.0         FK       4.0         FL       4.0         FM       4.0		
FJ 4.0 FK 4.0 FL 4.0 FM 4.0		
FK 4.0 FL 4.0 FM 4.0		
FL 4.0 FM 4.0		
FM 4.0		
	FN	4.0
FO 4.0	FO	4.0

<sup>\*=</sup>Recommended for Funding

FP	4.0
FQ	4.0
FR	4.0
FS	4.0
FT	4.0
FW	4.0
FX	4.0
FY	4.0
FZ	4.0
GA	4.0
GB	4.0
GC	4.0
GD	4.0
GE	4.0
GF	4.0
GG	4.0
GH	4.0
GI	4.0
GJ	4.0
GK	4.1
GL	4.1
GM	4.1
GN	4.2
GO	4.2
GP	4.2
GQ	4.3
GR	4.3
GS	4.3
GT	4.3
GU	4.3
GV	4.3
GW	4.3
GX	4.3
GY	4.3
GZ	4.3
HA	4.3
НВ	4.3
HC	4.3
HD	4.3
HE	4.3
HF	4.3
<u> </u>	

<sup>\*=</sup>Recommended for Funding

HG	4.3
НН	4.3
HI	4.3
HJ	4.3
HK	4.4
HL	4.4
HM	4.5
HN	4.6
HR	4.6
HS	4.6
HT	4.7
HU	4.7
HV	4.7
HW	4.7
HX	4.7
HY	4.7
HZ	4.7
IA	4.7
IB	4.7
IC	4.7
ID	4.8
IE	4.9
IF	5.0
IG	5.0
IH	5.0
II	5.0
IJ	5.3
IK	5.3
IL	5.3
IM	5.3
IN	5.3
Ю	5.5
IP	6.0
IQ	6.0
IR	6.0
IS	6.3
-	

## Individual Investigator Research Awards-Final Scores for Preliminary Evaluations

Scientific Research Cycle 15.1

The final overall score of a grant application that does not move forward to full review is the average of the preliminary evaluation scores received by the primary reviewers.

Application	Final Overall
ID	Score
NA	3.3
NB	3.7
NC	3.7
ND	3.7
NE	3.7
NF	3.7
NG	3.7
NH	3.7
NI	3.7
NJ	3.7
NK	3.7
NL	3.7
NM	3.7
NN	4.0
NO	4.0
NP	4.0
NQ	4.0
NR	4.0
NS	4.0
NT	4.0
NU	4.0
NV	4.0
NW	4.0
NX	4.0
NY	4.0
NZ	4.0
MA	4.0
MB	4.0
MC	4.0
MD	4.0
ME	4.0
MG	4.0
МН	4.0
MI	4.0
MJ	4.0

MK	4.0
ML	4.0
MM	4.0
MN	4.0
МО	4.0
MP	4.0
MQ	4.0
MR	4.0
MS	4.3
MT	4.3
MU	4.3
MV	4.3
MW	4.3
MX	4.3
MY	4.3
MZ	4.3
OA	4.3
ОВ	4.3
ОС	4.3
OD	4.3
OE	4.3
OF	4.3
OG	4.3
ОН	4.3
OI	4.3
Ol	4.3
ОК	4.3
OL	4.3
ОМ	4.7
ON	4.7
OP	4.7
OQ	4.7
OR	4.7
OS	4.7
ОТ	4.7
OU	4.7
ov	4.7
ow	4.7
ОХ	4.7
OY	4.7
OZ	4.7

PA	4.7
РВ	4.7
PC	5.0
PD	5.0
PE	5.0
PF	5.0
PG	5.0
PH	5.0
PI	5.0
PJ	5.0
PK	5.0
PL	5.0
PM	5.0
PN	5.0
PO	5.0
PP	5.0
PQ	5.0
PR	5.0
PS	5.0
PT	5.3
PU	5.3
PV	5.3
PW	5.3
PX	5.3
PY	5.3
PZ	5.3
QA	5.3
QB	5.3
QC	5.3
QD	5.7
QE	5.7
QF	5.7
QG	5.7
QH	5.7
QI	5.7
Ó۱	6.0
QK	6.0
QL	6.0
QM	6.0
QN	6.0
QO	6.3

QP	6.3
QQ	6.7

# Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd January 8, 2015

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Senior Advisor on Academic Affairs

New York Office

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

rkolodner@ucsd.edu

#### San Diego Branch

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

**T** 858 534 7804 **F** 858 534 7750

#### **New York Office**

28<sup>th</sup> Floor 666 Third Avenue New York, NY 10017

**T** 212 450 1500 **F** 212 450 1555

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

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

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), and Individual Investigator Research Awards for Prevention and Early Detection (IIRAP). The SRC met on Tuesday, January 6, 2015 to consider the applications recommended by the peer review panels following their meetings that were held between October 27 and November 12, 2014. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to four grants applications. These adjustments are listed at the end of the list of recommended projects.

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

Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Award Mechanism	Organization	Application Title	Budget	Overall Score
1	RP150224	IIRA	The University of Texas M. D. Anderson Cancer Center	Discovering the molecular mechanisms that determine replicative lifespan	\$892,104	1.1
2	RP150343	IIRACCA	University of Houston	An ultra-sensitive nanomagnetic sensor for the early detection of anaplastic large cell lymphoma	\$1,929,710	1.2
3	RP150498	IIRA	The University of Texas Southwestern Medical Center	Harnessing the Cytosolic DNA Sensing Pathway for Cancer Immunotherapy	\$889,185	1.2
4	RP150228	IIRAP	The University of Texas M. D. Anderson Cancer Center	Varenicline and Combined NRT for Initial Smoking Cessation and Rescue Treatment in Smokers: A Randomized Pilot Trial	\$1,493,464	1.5
5	RP150456	IIRA	The University of Texas Southwestern Medical Center	TAMU–UT Southwestern Partnership for Breast Imaging and Spectroscopy at 7 Tesla	\$897,311	1.7
6	RP150245	IIRA	The University of Texas M. D. Anderson Cancer Center	EGFR Arginine Methylations: Biomarkers for Cetuximab Resistance in colon cancer	\$900,000	1.8
7	RP150334	IIRACCA	Baylor College of Medicine	Personalized Functionalization of Pediatric High Grade Glioma	\$1,820,319	1.9
8	RP150319	IIRA	The University of Texas M. D. Anderson Cancer Center	Leukemia inhibitory factor receptor signaling and function in cancer	\$900,000	1.9
9	RP150053	IIRA	The University of Texas Southwestern Medical Center	Mechanisms of nuclear import and export in cancer	\$900,000	1.9
10	RP150230	IIRA	The University of Texas Health Science Center at Houston	Counteracting tumor evasion of antibody immunity by a novel therapeutic strategy	\$900,000	1.9
11	RP150006	IIRACCA	The University of Texas M. D. Anderson Cancer Center	Defining and Treating Targetable Lesions in AYA Acute Lymphoblastic Leukemia	\$1,989,950	1.9
12	RP150445 **	IIRACCA	The University of Texas Health Science Center at San Antonio	Ewing's sarcoma, a homologous recombination defective disease	\$2,000,000	2.0
13	RP150277	IIRA	The University of Texas Health Science Center at San Antonio	Vertical targeting of the B cell receptor in leukemia and lymphoma	\$899,879	2.0
14	RP150451 ***	IIRA	Baylor College of Medicine	SRC-2 driven "Metabolic Switch" in metastatic prostate cancer- Prognostic and Therapeutic implications	\$900,000	2.1
15	RP150282	IIRA	The University of Texas M. D. Anderson Cancer Center	Mechanisms of de novo and acquired resistance to therapeutic treatment of bone-metastatic prostate cancer	\$900,000	2.1
16	RP150148	IIRA	The University of Texas M. D. Anderson Cancer Center	Identifying Drivers of Lung Metastasis in Triple Negative Breast Cancer	\$899,637	2.2
17	RP150485	IIRA	The University of Texas Southwestern Medical Center	Translating Online Adaptive Radiotherapy from Lab to Clinical Practice	\$858,356	2.2
18	RP150084	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of PTEN feedback mechanism in cancer	\$900,000	2.2
19	RP150403	IIRA	The University of Texas M. D. Anderson Cancer Center	On the role of DEAR1 in the regulation of cell polarity and progression from DCIS to invasive breast cancer	\$899,846	2.3
20	RP150232	IIRA	Baylor College of Medicine	The Role of Progesterone Receptor in Early Stage Breast Cancer.	\$864,661	2.3
21	RP150440	IIRA	Baylor College of Medicine	Effects of hormonal therapy on subclonal evolution of breast tumors with ESR1 mutations	\$899,805	2.3
22	RP150231	IIRA	The University of Texas M. D. Anderson Cancer Center	Function of Fibroblasts and Collagen I in Pancreas Cancer	\$898,811	2.4

23	RP150197	IIRA	Baylor College of Medicine	Understanding How NCOA6 Suppresses \$886,524 Endometrial Cancer by Inhibiting the Wnt/beta-Catenin Pathway		2.4
24	RP150094	IIRA	The University of Texas M. D. Anderson Cancer Center	Investigating the regulation of miRNA and lncRNAs by p63 in mammary tumor progression and metastasis	\$900,000	2.4
25	RP150386	IIRA	The University of Texas Southwestern Medical Center	A Phase I Trial of Stereotactic HYpofractionateD RadioAblative (HYDRA) Treatment of Advanced Laryngeal Cancer	\$860,540	2.4
26	RP150129	IIRACCA	Baylor College of Medicine	Drug Discovery and Mechanistic Studies of Protein Methylation Targeting Leukemia	\$1,733,813	2.6
27	RP150032	IIRACCA	Baylor College of Medicine	Developing New Combinatory Therapies for Pediatric High Grade Glioma	\$1,945,940	2.6
28	RP150408 ****	IIRA	The University of Texas Health Science Center at San Antonio	Cellular mechanisms of chemotherapy- induced peripheral neuropathy	\$844,746	2.6
29	RP150293	IIRA	The University of Texas M. D. Anderson Cancer Center	Identification of clinically relevant targets for radiosensitization	\$899,280	2.7
30	RP150316	IIRA	The University of Texas M. D. Anderson Cancer Center	T-cell activating immunotherapy for indolent B-cell malignancies	\$852,595	2.7
31	RP150356	IIRA	The University of Texas Southwestern Medical Center	Peripheral nerve tolerance to single- session stereotactic irradiation	\$897,779	2.8
32	RP150081	IIRACCA	Baylor College of Medicine	Genetic susceptibility to testicular germ cell tumors	\$1,406,791	2.8
33	RP150093	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting 17q23 amplicon in HER2- positive Breast Cancer	\$828,242	2.8
34	RP150292	IIRA	Baylor College of Medicine	Broad Shortening of 3' UTRs in Human Cancers: Methods, Target Genes and Functional Consequences	\$900,000	2.9
35	RP150102	IIRA	The University of Texas M. D. Anderson Cancer Center	Genome stability and immune diversity controlled by the POLQ pathway	\$900,000	2.9
36	RP150079	IIRA	The University of Texas M. D. Anderson Cancer Center	Elucidating the evolution of the premalignant airway genome in space and time	\$886,173	2.9
37	RP150301	IIRACCA	The University of Texas M. D. Anderson Cancer Center	Epigenetics in Medulloblastoma Development and Therapeutics	\$1,871,708	3.0
38	RP150179	IIRA	The University of Texas M. D. Anderson Cancer Center	Regulation of dormancy of metastatic prostate cancer cells by bone microenvironment	\$900,000	3.0
39	RP150449	IIRAP	The University of Texas Medical Branch at Galveston	Noninvasive multiscale imaging for optical biopsy in epithelial cancers	\$852,748	3.0
40	RP150346	IIRA	The University of Texas at Austin	Targeting Twist1 for Prevention and Treatment of Non-Melanoma Skin Cancer	\$900,000	3.0
41	RP150235	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of TBK1 in Regulating Dendritic Cell Function and Antitumor Immunity.	\$876,958	3.0
42	RP150454	IIRA	Texas A&M University	Tumor Suppression Through the cGAMP/STING Pathway	\$900,000	3.0
43	RP150421	IIRAP	Texas Engineering Experiment Station	High-throughput Screening and Detection of Circulating Tumor Cells	\$1,135,450	3.1
44	RP150166	IIRA	The University of Texas Health Science Center at San Antonio	Prostate Cancer Chemoprevention with Resveratrol	\$900,000	3.1
45	RP150405	IIRA	The University of Texas M. D. Anderson Cancer Center	Tumor Cell Epithelial-Mesenchymal Transition in Regulating Immunosuppression and Metastasis in Lung Cancer	\$900,000	3.1

				metastatic melanoma  Total Recommended Amount	\$56,922	004
				patients with high-risk resectable		
			Anderson Cancer Center	to combined BRAF/MEK inhibition in		
31	KF130030	IIRA	The University of Texas M. D. Anderson Cancer Center	Exploring molecular and immune mechanisms of response and resistance	\$900,000	3.2
51	RP150030	IID A	The University of Toyog M. D.	chemoprevention	000 0002	2.2
			Anderson Cancer Center	differential effects on colon cancer		
50	RP150195	IIRAP	The University of Texas M. D.	Mechanisms of DHA and EPA	\$920,926	3.2
				clinics in Houston, TX		
			Houston	vaccination in a network of pediatric		
17	13130014	man	Health Science Center at	patients and providers to increase HPV	Ψ2,170,700	5.2
49	RP150014	IIRAP	The University of Texas	Multi-component interventions for	\$2,498,986	3.2
				compound that arrests glioma stem cell growth with high activity and specificity		
			Southwestern Medical Center	characterization of a small chemical		
48	RP150242	IIRA	The University of Texas	Functional and structural	\$900,000	3.2
10	77150212			with bone cancer		
			Southwestern Medical Center	to improve risk stratification in children		
47	RP150164	IIRACCA	The University of Texas	Using imaging and computational tools	\$1,290,442 3.2	
				Cancer Use		
			Sciences Center	Fenretinide and Safingol For Pediatric		
46	RP150416	IIRACCA	Texas Tech University Health	Translational Investigations On	\$1,999,415	3.1

<sup>\*</sup> RP150053 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$900,000.

<sup>\*\*\*\*</sup>RP150408 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$844,746.

Success Rate by Panel				
Peer Review	Success	Score		
Panel	Rate	Cutoff		
BCR1	12.3%	3.2		
BCR2	10.3%	2.9		
CB	13.4%	3.0		
CPR	12.5%	3.2		
CTCR/TCR	15.0%	3.2		
ITI	13.1%	3.2		

Success Rate by Mechanism vs. Total Reviewed*			
Mechanism	Success Rate	# Recommended	
IIRA	13.3%	36/371	
IIRACCA	17.9%	10/56	
IIRAP	7.6%	5/66	
Overall	12.9%	51/393	

\*The overall success rate for FY2014 IIRAs was 13%

Percent of Applications Recommended by Mechanism vs. Total Recommended			
Mechanism	# Recommended	Percentage	
IIRA	36/51	70.6%	
IIRACCA	10/51	19.6%	
IIRAP	5/51	9.8%	

<sup>\*\*</sup>RP150445 - Budget will be adjusted down during contracting to accommodate a reduction in personnel and associated supplies and materials as recommended by the peer review panel. The total amount requested was \$2,000,000.

<sup>\*\*\*</sup>RP150451 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$900,000.



# **CEO Affidavit Supporting Information**

FY 2015—Cycle 1
Individual Investigator Research Awards for
Cancer in Children and Adolescents

### **Request for Applications**



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS RFA R-15-IIRACCA-1

## Individual Investigator Research Awards for Cancer in Children and Adolescents

Please also refer to the Instructions for Applicants document, which will be posted on May 15, 2014

**Application Receipt Opening Date: May 15, 2014 Application Receipt Closing Date: June 26, 2014** 

FY 2015

Fiscal Year Award Period September 1, 2014–August 31, 2015

#### **TABLE OF CONTENTS**

1.	ABOUT CPRIT	5
2.	RATIONALE	5
3.	RESEARCH OBJECTIVES	6
4.	FUNDING INFORMATION	7
5.	ELIGIBILITY	7
6.	RESUBMISSION POLICY	8
7.	RENEWAL POLICY	9
8.	RESPONDING TO THIS RFA	9
	8.1. APPLICATION SUBMISSION GUIDELINES	9
	8.1.1. Submission Deadline Extension	9
	8.2. APPLICATION COMPONENTS	9
	8.2.1. Abstract and Significance (5,000 characters)	10
	8.2.2. Layperson's Summary (2,000 characters)	10
	8.2.3. Goals and Objectives	10
	8.2.4. Timeline (One page)	11
	8.2.5. Renewal Summary (Two pages)	11
	8.2.6. Research Plan (Ten pages)	11
	8.2.7. Vertebrate Animals and/or Human Subjects (One page)	
	8.2.8. Publications/References	11
	8.2.9. Budget and Justification	12
	8.2.10. Biographical Sketches (Two pages each)	
	8.2.11. Current and Pending Support	
	8.2.12. Institutional/Collaborator Support and/or Other Certification (Four pages)	
	8.2.13. Clinical Trial Plan	
9.	APPLICATION REVIEW	14
	9.1. Preliminary Evaluation	14
	9.2. FULL PEER REVIEW	14
	9.3. CONFIDENTIALITY OF REVIEW	15
	9.4. REVIEW CRITERIA	16
	9.4.1. Primary Criteria	16
	9.4.2. Secondary Criteria	17
10	. KEY DATES	18

11.	AWARD ADMINISTRATION	18
12.	REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	19
13.	CONTACT INFORMATION	19
13.	.1. HelpDesk	19
13	2 SCIENTIFIC AND PROGRAMMATIC OUESTIONS	20

### **RFA VERSION HISTORY**

Rev 3/31/14 RFA release

Rev 5/13/14 Revised Section 8.2 Application Components

• Added Section 8.2.13 Clinical Trial Plan

### 1. ABOUT CPRIT

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

CPRIT is charged by the Texas Legislature to:

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

### 2. RATIONALE

In recent decades, great strides have been made in reducing mortality from childhood cancers. Most of these gains have been realized in childhood leukemia and lymphoma. However, improvements in survival have been less robust in other types of childhood cancers, which make up more than 40 percent of total cancer cases in children and adolescents aged 0 to 19 years. Furthermore, the overall incidence of pediatric cancer has increased at an annual rate of 0.6 percent since 1975, with most of the increases being seen in acute lymphocytic leukemia, brain and central nervous system tumors, non-Hodgkin's lymphoma, and testicular germ cell tumors. Reasons for increases in these tumor types are unknown, indicating that information on the etiology of these cancers is urgently needed. Because of the high rates of survival for certain childhood and adolescent cancers, there are increasing numbers of survivors of such cancers living today. These individuals have a high rate of late effects from the cancer or its treatment, including the occurrence of additional cancers. Clearly, more effective, less toxic treatments are needed for these diseases. However, few new therapies have been developed in recent years. Several reasons account for the paucity of new treatments, including the lack of interest on the part of pharmaceutical companies in developing treatments for cancers that account for only 1 percent of all cancer cases and the difficulty of collecting sufficient numbers of tumors for laboratory studies.

Because cancers in children and adolescents differ from those in adults with regard to genetic alterations and biological behavior, application of adult therapies to these cancers may not be successful. Therefore, this area of investigation represents an opportunity for CPRIT to deploy funding in an area of critical need that is not heavily represented in other funding portfolios.

### 3. RESEARCH OBJECTIVES

This Request for Applications (RFA) solicits applications from individual investigators for innovative research projects addressing questions that will advance our knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents.

Applications may address any topic related to these areas as well as projects dealing with the causes or amelioration of late effects of cancer treatment. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Applications that seek to apply or develop state-of-the-art approaches, technologies, tools, treatments, and/or resources are encouraged, particularly those with potential for commercialization. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies.

The subject of applications may include, but is not limited to, the following:

- 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;
- Improvements in quality of life for survivors of childhood and adolescent cancers.

The degree of relevance to reducing the burden of cancer in these populations will be an important criterion for evaluation of projects for funding by CPRIT.

### 4. FUNDING INFORMATION

Applicants may request a maximum of \$500,000 per year for a period of up to 4 years. Exceptions to these limits may be requested if extremely well justified. Applications funded in this cycle will be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5 percent of the <u>total</u> award amount.

### 5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism.
   A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Program.
- The Principal Investigator (PI) must have a doctoral degree, including M.D., Ph.D.,
   D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may submit only one new application under this RFA during this funding cycle. A
  PI may not submit applications to this RFA and to RFA-R-15-IIRA-1 or RFA R-15IIRAP. Only one IIRACCA, IIRA, or IIRAP application per cycle is allowed. Because
  this award mechanism is intended to support research directed by a single investigator,
  only one Co-PI may be included.
- Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.

- An applicant is eligible to receive a grant award only if the applicant certifies that the
  applicant institution or organization, including the PI, any senior member or key
  personnel listed on the grant application, and any officer or director of the grant
  applicant's institution or organization (or any person related to one or more of these
  individuals within the second degree of consanguinity or affinity), has not made and will
  not make a contribution to CPRIT or to any foundation specifically created to benefit
  CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in <a href="Section 11">Section 11</a> and <a href="Section 12">Section 12</a>. All statutory provisions and relevant administrative rules can be found at <a href="www.cprit.state.tx.us">www.cprit.state.tx.us</a>.

### 6. RESUBMISSION POLICY

Because Individual Investigator Research Awards for Cancer in Children and Adolescents is a new award mechanism, resubmission is not available under this RFA. If a previously unfunded IIRA application is responsive to the IIRACCA RFA, it may be submitted as a new application under the IIRACCA mechanism.

### 7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA that is appropriate for the IIRACCA mechanism may be submitted under this RFA for a competitive renewal. See <u>Section 8.2.5</u>. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See <u>Section 9.2</u>.

### 8. RESPONDING TO THIS RFA

### 8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<a href="https://CPRITGrants.org">https://CPRITGrants.org</a>). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 a.m. Central Time on May 15, 2014, and must be submitted by 3 p.m. Central Time on June 26, 2014. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

### **8.1.1.** Submission Deadline Extension

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

### **8.2.** Application Components

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

### 8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the Research Plan. Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (e.g., that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly). Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see Section 9.1).

### 8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (Section 9.2) in evaluating the significance and impact of the proposed work.

### 8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

### 8.2.4. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

### 8.2.5. Renewal Summary (Two pages)

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

### 8.2.6. Research Plan (Ten pages)

**Background:** Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

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

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

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

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

### 8.2.8. Publications/References

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

### 8.2.9. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Do not exceed \$500,000 per year over a maximum period of 4 years. Applicants are advised not to interpret the maximum allowable time and funding under this award as a suggestion that they should expand their anticipated work and budget to this level. Reasonable budgets clearly work in favor of the applicant.

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

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

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

### 8.2.10. Biographical Sketches (Two pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to two additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

### 8.2.11. Current and Pending Support

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

### 8.2.12. Institutional/Collaborator Support and/or Other Certification (Four pages)

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

### 8.2.13. Clinical Trial Plan

If you are planning to conduct clinical trials as part of your proposed project, please submit required documentation as a single PDF file via e-mail to the CPRIT HelpDesk at <a href="help@CPRITgrants.org">help@CPRITgrants.org</a>. In this document, please include the clinical trial protocol, informed consent document, and a letter of drug availability from the sponsor if the trial is using an investigational drug. CPRIT may require institutional review board (IRB) approval prior to the initiation of funding.

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

### 9. APPLICATION REVIEW

### 9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

### 9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a two-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC.

The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

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

### 9.3. Confidentiality of Review

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

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

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

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: An Oversight Committee Member, a Program Integration Committee Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee is comprised of the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services.

The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

### 9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

### 9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the 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 application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important 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? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

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

**Applicant Investigator:** Does the applicant investigator demonstrate the required creativity and

expertise to make a significant contribution to the research? Applicants' credentials will be

evaluated in a career stage-specific fashion. Have early career-stage investigators received

excellent training, and do their accomplishments to date offer great promise for a successful

career? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to

this project?

**Relevance:** Does the proposed research address cancer in children or adolescents? Is it likely to

make an impact on these diseases? This will be an important criterion for evaluation of projects

for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these

criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and

resources to accomplish all aspects of the proposed research? Are the levels of effort of the key

personnel appropriate? Is there evidence of institutional support of the research team and the

project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are

included in the proposed research, certification of approval by the institutional IACUC and/or

IRB, as appropriate, will be required before funding can occur.

**Budget:** Is the budget appropriate for the proposed work?

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

### 10. KEY DATES

### **RFA**

RFA release March 31, 2014

### **Application**

Online application opens May 15, 2014, 7 a.m. Central Time Application due June 26, 2014, 3 p.m. Central Time

Application review October - November 2014

### **Award**

Award notification January 2015
Anticipated start date March 2015

### 11. AWARD ADMINISTRATION

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

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

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

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

### 12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11, for specific requirements regarding demonstration of available funding.

### 13. CONTACT INFORMATION

### 13.1. HelpDesk

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

**Dates of operation:** March 31 - June 26, 2014 (excluding public holidays)

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

Wednesday, 8 a.m. to 4 p.m. Central Time

**Tel:** 866-941-7146

E-mail: Help@CPRITGrants.org

### 13.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

E-mail: <u>Help@CPRITGrants.org</u>

Web site: <u>www.cprit.state.tx.us</u>

### **Third Party Observer Report**

### CPRIT Basic Cancer Research Peer Review Panel Report

Report #2015-211

Panel Name: Basic Cancer Research-1

Panel Date: November 6, 2014 Report Date: November 17, 2014

### **Background**

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

#### Introduction

The subject of this report is the Basic Cancer Research-1 peer review panel finalization of recommended prevention program applications. The meeting was chaired by Tom Curran and held at the Hyatt Regency in Dallas TX, on November 6, 2014.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the peer review panel meeting held at the Hyatt Regency and chaired by Tom Curran on November 6, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 24 applications were discussed within the Prevention Review Council for their review and approval.
- Fifteen reviewers, two advocate reviewers, two CPRIT staff members and six SRA employee were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

## CPRIT Basic Cancer Research Review Council Report

Report #2015-209

Panel Name: Basic Cancer Research 2

Panel Date: October 30, 2014-October 31, 2014

Report Date: October 31, 2014

### **Background**

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

### Intro duction

The subject of this report is the Basic Cancer Research review of applications for FY15 funding. The meeting was chaired by Carol Prives and held at the Hyatt Regency in Dallas, TX on October 30 and October 31, 2014.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the in-person Basic Cancer Research Panel final scoring of applications held October 30, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 19 applications were discussed within the Basic Cancer Research Panel for their review and approval.
- Three CPRIT staff members and seven SRA employees were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.

• The Council members' discussions were limited to the application evaluation criteria.

#### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

# CPRIT Cancer Biology Review Council Report

Report #2015-210

Panel Name: Cancer Biology

Panel Date: November 3, 2014 Report Date: November 3, 2014

### **Background**

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

### Intro duction

The subject of this report is the Cancer Biology review of applications for FY15 funding. The meeting was chaired by Peter Jones and held at the Hyatt Regency in Dallas TX, on November 3, 2014.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the in-person Cancer Biology final scoring of applications held November 3, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 18 applications were discussed within the Basic Cancer Research Panel for their review and approval.
- Three CPRIT staff members and five SRA employees were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

## CPRIT Cancer Prevention Research Panel Review Report

Report #2015-208

Panel Name: Cancer Prevention Research

Panel Date: October 28, 2014 Report Date: November 17, 2014

### **Background**

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

#### Introduction

The subject of this report is the Cancer Prevention Research Panel finalization of recommended prevention program applications. The meeting was chaired by Tom Sellers and held at the Hyatt Regency in Dallas TX on October 28, 2014.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the Cancer Prevention Research Panel meeting held at the Hyatt Regency and chaired by Tom Sellers on October 28, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 20 applications were discussed within the Cancer Prevention Research Panel for their review and approval.
- Eighteen panel members, two advocate reviewers, five CPRIT staff members, and six SRA employees were
  present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

### CPRIT Imaging Technology and Informatics Review Council Report

Report #2015-207

Panel Name: Imaging Technology and Informatics

Panel Date: October 27, 2014 Report Date: October 27, 2014

### **Background**

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

### Intro duction

The subject of this report is the Imaging Technology and Informatics review of applications for FY15 funding. The meeting was chaired by Sam Gambhir and held at the Hyatt Regency in Dallas TX, on October 27, 2014.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the in-person Imaging Technology and Informatics Panel final scoring of applications held October 27, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 21 applications were discussed within the Imaging Technology and Informatics Panel for their review and approval.
- Two CPRIT staff members and six SRA employees were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

### CPRIT Peer Review Panel Report

### Report #2015-212

Panel Name: Translational Cancer Research & Clinical and

Translational Cancer Research

Panel Date: November 11, 2014 Report Date: November 17, 2014

### **Background**

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

### Introduction

The subject of this report is the Translational Cancer Research panel & Clinical and Translational Cancer Research panel review of applications for FY15 funding. The joint meeting was co-chaired by Richard O'Reilly and Margaret Tempero, and held on November 11, 2014 at the Hyatt Regency in Dallas, TX.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the in-person Translational Cancer Research & Clinical and Translational Cancer Research joint meeting held November 11, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- Over the course of the panel meeting, seventeen Translational Cancer Research applications and seven Clinical and Translational Cancer Research applications were discussed for their review and approval
- Twenty-one review panel members, three advocate reviewers, two CPRIT staff members, and five SRA
  employees were present for the in-person panel meeting. Seven panel members were on teleconference. A
  total of twenty-eight panelists participated in the meeting.

- Multiple conflicts of interests (COIs) were identified prior to the panel meeting. All COIs were noted and left the room.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

# CPRIT Scientific Review Council Observation Report

Report #2015-213

Panel Name: FY15 Scientific Review Council Meeting -

Recruitment Program Applications

Panel Date: January 6, 2015 Report Date: January 7, 2015

### **Background**

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

### Introduction

The subject of this report is the Scientific Review Council review of recruitment program applications. The meeting was chaired by Richard Kolodner and held over the phone on January 6, 2015.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on January 6, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- Five recruitment applications were discussed and evaluated by the Scientific Review Council to determine
  which grants would receive CPRIT funding.
- Six council members, two CPRIT staff members, and two SRA employees were present for the Council
  meeting over the phone.

- No conflicts of interest were identified prior to or during the call.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

### **Noted Conflicts of Interest**

# Conflicts of Interest for Scientific Research Cycle 15.1 Applications (Scientific Research Cycle 15.1 Awards Announced at February 18, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Scientific Research Cycle 15.1 include *Individual Investigator Research Awards for Cancer in Children and Adolescents*, and *Individual Investigator Research Awards for Prevention and Early Detection*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	<b>Conflict Noted</b>			
Applications Considered by the PIC and Oversight Committee						
RP150006	Konopleva, Marina	The University of Texas M.D. Anderson Cancer	Mullighan, Charles			
		Center				
RP150014	Vernon, Sally	The University of Texas Health Science Center at Houston	Kushi, Lawrence			
RP150032	Li, Xiao-Nan	Baylor College of Medicine	Baker, Suzanne			
RP150053	Chook, Yuh Min	The University of Texas Southwestern Medical Center	Houchens, David; Sonenberg, Nahum			
RP150079/ RP150079pe	Kadara, Humam	The University of Texas M.D. Anderson Cancer Center	Mucci, Lorelei			
RP150094	Flores, Elsa	The University of Texas M.D. Anderson Cancer Center	Pure, Ellen			
RP150166/ RP150166pe	Kumar, Addanki	The University of Texas Health Science Center at San Antonio	Kristal, Alan			
RP150224/ RP150224pe	Tyler, Jessica	The University of Texas M.D. Anderson Cancer Center	Edelmann, Winfried			
RP150228	Cinciripini, Paul	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas			

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150231	Kalluri, Raghu	The University of Texas M.D. Anderson Cancer Center	Kripke, Margaret <sup>1</sup>
RP150232/ RP150232pe	Edwards, Dean	Baylor College of Medicine	Greene, Geoffrey
RP150235	Sun, Shao-Cong	The University of Texas M.D. Anderson Cancer Center	Cooney, Kathleen
RP150334	Deneen, Benjamin	Baylor College of Medicine	Baker, Suzanne
RP150356/ RP150356pe	Medin, Paul	The University of Texas Southwestern Medical Center	Wu, Anna
RP150440	Fuqua, Suzanne	Baylor College of Medicine	Fearon, Eric; Greene, Geoffrey; Lawlor, Elizabeth; Roberts, Charles
RP150440pe	Fuqua, Suzanne	Baylor College of Medicine	Knudsen, Karen; Greene, Geoffrey; Lawlor, Elizabeth; Roberts, Charles
RP150451/ RP150451pe	Sreekumar, Arun	Baylor College of Medicine	Costello, Joseph
Applicat	ions Not Recommended fo	r PIC or Oversight Committee	e Consideration
RP150022*	Zhao, Hua	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150041*/ RP150041pe	Pati, Debananda	Baylor College of Medicine	Bhardwaj, Nina; Manfredi, James
RP150046pe	Kim, Jung-whan	The University of Texas at Dallas	Knudsen, Karen
RP150064pe	Davies, Michael	The University of Texas M.D. Anderson Cancer Center	McMahon, Martin
RP150069*/ RP150069pe	Bhattarai, Shanta	The University of Texas M.D. Anderson Cancer Center	Berbeco, Ross
RP150082*	Nyitray, Alan	The University of Texas Health Science Center at Houston	Brandon, Thomas

<sup>&</sup>lt;sup>1</sup> Dr. Kripke is not a peer reviewer, but attends peer review meetings as an observer in her capacity as Chief Scientific Officer, which is allowed in her FY2015 COI waiver. Because of the professional relationship between the applicant and Dr. Fidler, out of extreme caution Dr. Kripke chose not to be present when the application was discussed. She also abstained from voting on the application during the PIC meeting.

<sup>\* =</sup> Application not discussed

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150095pe	Kurie, Jonathan	The University of Texas M.D. Anderson Cancer Center	Belinsky, Steven
RP150128*/ RP150128pe	Wenzel, Pamela	The University of Texas Health Science Center at Houston	DeClerck, Yves
RP150150*	Wu, Xifeng	The University of Texas M.D. Anderson Cancer Center	Hunter, Kent
RP150154*/ RP150154pe	Paull, Tanya	The University of Texas at Austin	Tomkinson, Alan
RP150165*/ RP150165pe	Hassan, Manal	The University of Texas M.D. Anderson Cancer Center	Petersen, Gloria
RP150167pe	Gong, Zihua	The University of Texas M.D. Anderson Cancer Center	Bardeesy, Nabeel; Petrini, John
RP150173*	Bi, Xiaohong	The University of Texas Health Science Center at Houston	Mitchell, Duane
RP150175/ RP150175pe	Kundra, Vikas	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150186pe	Keyomarsi, Khandan	The University of Texas M.D. Anderson Cancer Center	Martinez, Maria
RP150188*	Rakheja, Dinesh	The University of Texas Southwestern Medical Center	Lawlor, Elizabeth
RP150201	Hamann, Heidi	The University of Texas Southwestern Medical Center	Barlow, William
RP150216*/ RP150216pe	Pinney, Kevin	Baylor University	Mitchell, Duane
RP150219*/ RP150219pe	Post, Sean	The University of Texas M.D. Anderson Cancer Center	Tomkinson, Alan
RP150222*/ RP150222pe	Han, Arum	Texas Engineering Experiment Station	Nie, Shuming
RP150225/ RP150225pe	Bondy, Melissa	Baylor College of Medicine	Martinez, Maria

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150234	Feng, Ziding	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kristal, Alan; Li, Christopher
RP150251pe	Gunaratne, Preethi	University of Houston	Costello, Joseph
RP150252pe	Cho, Sang	The University of Texas M.D. Anderson Cancer Center	Berbeco, Ross
RP150254*	McNeill, Lorna	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas
RP150259*/ RP150259pe	Zheng, Yanbin	The University of Texas Southwestern Medical Center	Greene, Geoffrey
RP150262*	Beretta, Laura	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kristal, Alan; Li, Christopher
RP150273*/ RP150273pe	Raj, Ganesh	The University of Texas Southwestern Medical Center	Greene, Geoffrey
RP150273pe	Raj, Ganesh	The University of Texas Southwestern Medical Center	Knudsen, Karen
RP150308pe	Nahleh, Zeina	Texas Tech University Health Sciences Center El Paso	Barlow, William
RP150335pe	Lizee, Gregory	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150344*/ RP150344pe	Mitsiades, Nicholas	Baylor College of Medicine	Roberts, Charles
RP150361	Maitra, Anirban	The University of Texas M.D. Anderson Cancer Center	Niedzwiecki, Donna
RP150379*	Li, Donghui	The University of Texas M.D. Anderson Cancer Center	Petersen, Gloria
RP150384*	Arun, Banu	The University of Texas M.D. Anderson Cancer Center	Li, Christopher
RP150394pe	Mancini, Michael	Baylor College of Medicine	Greene, Geoffrey
RP150399*	Patel, Darpan	The University of Texas Health Science Center at San Antonio	Kristal, Alan

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150404*/ RP150404pe	Glisson, Bonnie	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150418*/ RP150418pe	Wang, Wei	Texas Tech University Health Sciences Center	Chen, Xinbin
RP150422* RP150424/ RP150424pe	Jayaraman, Arul Aromougame, Asaithamby	Texas A&M University The University of Texas Southwestern Medical Center	Greene, Geoffrey Berbeco, Ross
RP150433	Taguchi, Ayumu	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Li, Christopher; Petersen, Gloria; Kristal, Alan
RP150471pe	Castrillon, Diego	The University of Texas Southwestern Medical Center	Bardeesy, Nabeel
RP150479*	Chan, Lawrence	Baylor College of Medicine	Williams, Bart
RP150499*	Decuzzi, Paolo	The Methodist Hospital Research Institute	Rutt, Brian
RP150500*	Vokes, Steven	The University of Texas at Austin	Chazin, Walter
RP150516/ RP150516pe	Liu, Mingyao	Texas A&M University System Health Science Center	Williams, Bart

### **De-Identified Overall Evaluation Scores**

## Individual Investigator Research Awards for Cancer in Children and Adolescents

Scientific Research Cycle 15.1

	Final Overall
Application ID	Score
RP150343*	1.2
RP150334*	1.9
RP150006*	1.9
RP150445*	2.0
RP150032*	2.6
RP150129*	2.6
RP150081*	2.8
RP150301*	3.0
RP150416*	3.1
RP150164*	3.2
В	3.4
С	3.6
D	3.7
Е	3.7
F	3.7
G	3.8
Н	3.9
I	4.0
J	4.0
K	4.0
L	4.0
M	4.2
N	4.3
0	4.3
Р	4.3
Q	4.3
R	4.3
S	4.3
Т	4.3
U	4.6
V	4.7
W	4.7
Х	4.8

<sup>\*=</sup>Recommended for Funding

Υ	5.0
Z	5.0
AA	5.0
AB	5.0
AC	5.0
AD	5.0
AE	5.3
AF	5.3
AG	5.3
AH	5.3
Al	5.3
AJ	5.7
AK	5.7
AL	5.7
AM	5.7
AN	6.0
AO	6.0
AP	6.0
AQ	6.0
AR	6.3
AS	6.7
AT	6.7
AU	7.0

## Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd January 8, 2015

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Senior Advisor on Academic Affairs

New York Office

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

rkolodner@ucsd.edu

#### San Diego Branch

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

**T** 858 534 7804 **F** 858 534 7750

#### **New York Office**

28<sup>th</sup> Floor 666 Third Avenue New York, NY 10017

**T** 212 450 1500 **F** 212 450 1555

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

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

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), and Individual Investigator Research Awards for Prevention and Early Detection (IIRAP). The SRC met on Tuesday, January 6, 2015 to consider the applications recommended by the peer review panels following their meetings that were held between October 27 and November 12, 2014. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to four grants applications. These adjustments are listed at the end of the list of recommended projects.

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

Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Award Mechanism	Organization	Application Title	Budget	Overall Score
1	RP150224	IIRA	The University of Texas M. D. Anderson Cancer Center	Discovering the molecular mechanisms that determine replicative lifespan	\$892,104	1.1
2	RP150343	IIRACCA	University of Houston	An ultra-sensitive nanomagnetic sensor for the early detection of anaplastic large cell lymphoma	\$1,929,710	1.2
3	RP150498	IIRA	The University of Texas Southwestern Medical Center	Harnessing the Cytosolic DNA Sensing Pathway for Cancer Immunotherapy	\$889,185	1.2
4	RP150228	IIRAP	The University of Texas M. D. Anderson Cancer Center	Varenicline and Combined NRT for Initial Smoking Cessation and Rescue Treatment in Smokers: A Randomized Pilot Trial	\$1,493,464	1.5
5	RP150456	IIRA	The University of Texas Southwestern Medical Center	TAMU–UT Southwestern Partnership for Breast Imaging and Spectroscopy at 7 Tesla	\$897,311	1.7
6	RP150245	IIRA	The University of Texas M. D. Anderson Cancer Center	EGFR Arginine Methylations: Biomarkers for Cetuximab Resistance in colon cancer	\$900,000	1.8
7	RP150334	IIRACCA	Baylor College of Medicine	Personalized Functionalization of Pediatric High Grade Glioma	\$1,820,319	1.9
8	RP150319	IIRA	The University of Texas M. D. Anderson Cancer Center	Leukemia inhibitory factor receptor signaling and function in cancer	\$900,000	1.9
9	RP150053	IIRA	The University of Texas Southwestern Medical Center	Mechanisms of nuclear import and export in cancer	\$900,000	1.9
10	RP150230	IIRA	The University of Texas Health Science Center at Houston	Counteracting tumor evasion of antibody immunity by a novel therapeutic strategy	\$900,000	1.9
11	RP150006	IIRACCA	The University of Texas M. D. Anderson Cancer Center	Defining and Treating Targetable Lesions in AYA Acute Lymphoblastic Leukemia	\$1,989,950	1.9
12	RP150445 **	IIRACCA	The University of Texas Health Science Center at San Antonio	Ewing's sarcoma, a homologous recombination defective disease	\$2,000,000	2.0
13	RP150277	IIRA	The University of Texas Health Science Center at San Antonio	Vertical targeting of the B cell receptor in leukemia and lymphoma	\$899,879	2.0
14	RP150451 ***	IIRA	Baylor College of Medicine	SRC-2 driven "Metabolic Switch" in metastatic prostate cancer- Prognostic and Therapeutic implications	\$900,000	2.1
15	RP150282	IIRA	The University of Texas M. D. Anderson Cancer Center	Mechanisms of de novo and acquired resistance to therapeutic treatment of bone-metastatic prostate cancer	\$900,000	2.1
16	RP150148	IIRA	The University of Texas M. D. Anderson Cancer Center	Identifying Drivers of Lung Metastasis in Triple Negative Breast Cancer	\$899,637	2.2
17	RP150485	IIRA	The University of Texas Southwestern Medical Center	Translating Online Adaptive Radiotherapy from Lab to Clinical Practice	\$858,356	2.2
18	RP150084	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of PTEN feedback mechanism in cancer	\$900,000	2.2
19	RP150403	IIRA	The University of Texas M. D. Anderson Cancer Center	On the role of DEAR1 in the regulation of cell polarity and progression from DCIS to invasive breast cancer	\$899,846	2.3
20	RP150232	IIRA	Baylor College of Medicine	The Role of Progesterone Receptor in Early Stage Breast Cancer.	\$864,661	2.3
21	RP150440	IIRA	Baylor College of Medicine	Effects of hormonal therapy on subclonal evolution of breast tumors with ESR1 mutations	\$899,805	2.3
22	RP150231	IIRA	The University of Texas M. D. Anderson Cancer Center	Function of Fibroblasts and Collagen I in Pancreas Cancer	\$898,811	2.4

23	RP150197	IIRA	Baylor College of Medicine	Understanding How NCOA6 Suppresses Endometrial Cancer by Inhibiting the Wnt/beta-Catenin Pathway	\$886,524	2.4
24	RP150094	IIRA	The University of Texas M. D. Anderson Cancer Center	Investigating the regulation of miRNA and lncRNAs by p63 in mammary tumor progression and metastasis	\$900,000	2.4
25	RP150386	IIRA	The University of Texas Southwestern Medical Center	A Phase I Trial of Stereotactic HYpofractionateD RadioAblative (HYDRA) Treatment of Advanced Laryngeal Cancer	\$860,540	2.4
26	RP150129	IIRACCA	Baylor College of Medicine	Drug Discovery and Mechanistic Studies of Protein Methylation Targeting Leukemia	\$1,733,813	2.6
27	RP150032	IIRACCA	Baylor College of Medicine	Developing New Combinatory Therapies for Pediatric High Grade Glioma	\$1,945,940	2.6
28	RP150408 ****	IIRA	The University of Texas Health Science Center at San Antonio	Cellular mechanisms of chemotherapy- induced peripheral neuropathy	\$844,746	2.6
29	RP150293	IIRA	The University of Texas M. D. Anderson Cancer Center	Identification of clinically relevant targets for radiosensitization	\$899,280	2.7
30	RP150316	IIRA	The University of Texas M. D. Anderson Cancer Center	T-cell activating immunotherapy for indolent B-cell malignancies	\$852,595	2.7
31	RP150356	IIRA	The University of Texas Southwestern Medical Center	Peripheral nerve tolerance to single- session stereotactic irradiation	\$897,779	2.8
32	RP150081	IIRACCA	Baylor College of Medicine	Genetic susceptibility to testicular germ cell tumors	\$1,406,791	2.8
33	RP150093	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting 17q23 amplicon in HER2- positive Breast Cancer	\$828,242	2.8
34	RP150292	IIRA	Baylor College of Medicine	Broad Shortening of 3' UTRs in Human Cancers: Methods, Target Genes and Functional Consequences	\$900,000	2.9
35	RP150102	IIRA	The University of Texas M. D. Anderson Cancer Center	Genome stability and immune diversity controlled by the POLQ pathway	\$900,000	2.9
36	RP150079	IIRA	The University of Texas M. D. Anderson Cancer Center	Elucidating the evolution of the premalignant airway genome in space and time	\$886,173	2.9
37	RP150301	IIRACCA	The University of Texas M. D. Anderson Cancer Center	Epigenetics in Medulloblastoma Development and Therapeutics	\$1,871,708	3.0
38	RP150179	IIRA	The University of Texas M. D. Anderson Cancer Center	Regulation of dormancy of metastatic prostate cancer cells by bone microenvironment	\$900,000	3.0
39	RP150449	IIRAP	The University of Texas Medical Branch at Galveston	Noninvasive multiscale imaging for optical biopsy in epithelial cancers	\$852,748	3.0
40	RP150346	IIRA	The University of Texas at Austin	Targeting Twist1 for Prevention and Treatment of Non-Melanoma Skin Cancer	\$900,000	3.0
41	RP150235	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of TBK1 in Regulating Dendritic Cell Function and Antitumor Immunity.	\$876,958	3.0
42	RP150454	IIRA	Texas A&M University	Tumor Suppression Through the cGAMP/STING Pathway	\$900,000	3.0
43	RP150421	IIRAP	Texas Engineering Experiment Station	High-throughput Screening and Detection of Circulating Tumor Cells	\$1,135,450	3.1
44	RP150166	IIRA	The University of Texas Health Science Center at San Antonio	Prostate Cancer Chemoprevention with Resveratrol	\$900,000	3.1
45	RP150405	IIRA	The University of Texas M. D. Anderson Cancer Center	Tumor Cell Epithelial-Mesenchymal Transition in Regulating Immunosuppression and Metastasis in Lung Cancer	\$900,000	3.1

				metastatic melanoma  Total Recommended Amount	\$56,922	004
				patients with high-risk resectable		
			Anderson Cancer Center	to combined BRAF/MEK inhibition in		
31	KF130030	IIKA	Anderson Cancer Center	mechanisms of response and resistance	\$900,000	3.2
51	RP150030	IIRA	The University of Texas M. D.	chemoprevention Exploring molecular and immune	\$900,000	3.2
			Anderson Cancer Center	differential effects on colon cancer		
50	RP150195	IIRAP	The University of Texas M. D.	Mechanisms of DHA and EPA	\$920,926	3.2
				clinics in Houston, TX		
			Houston	vaccination in a network of pediatric		
.,	13 150011	111011	Health Science Center at	patients and providers to increase HPV	\$2,170,700	5.2
49	RP150014	IIRAP	The University of Texas	Multi-component interventions for	\$2,498,986	3.2
				compound that arrests glioma stem cell growth with high activity and specificity		
			Southwestern Medical Center	characterization of a small chemical		
48	RP150242	IIRA	The University of Texas	Functional and structural	\$900,000	3.2
40	DD150242	TID 1		with bone cancer	Ф000 000	
			Southwestern Medical Center	to improve risk stratification in children		
47	RP150164	IIRACCA	The University of Texas	Using imaging and computational tools	\$1,290,442	3.2
				Cancer Use		
			Sciences Center	Fenretinide and Safingol For Pediatric		
46	RP150416	IIRACCA	Texas Tech University Health	Translational Investigations On	\$1,999,415	3.1

<sup>\*</sup> RP150053 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$900,000.

<sup>\*\*\*\*</sup>RP150408 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$844,746.

Success Rate by Panel				
Peer Review	Success	Score		
Panel	Rate	Cutoff		
BCR1	12.3%	3.2		
BCR2	10.3%	2.9		
CB	13.4%	3.0		
CPR	12.5%	3.2		
CTCR/TCR	15.0%	3.2		
ITI	13.1%	3.2		

Success Rate by Mechanism vs. Total Reviewed*				
Mechanism	Success Rate	# Recommended		
IIRA	13.3%	36/371		
IIRACCA	17.9%	10/56		
IIRAP	7.6%	5/66		
Overall	12.9%	51/393		

\*The overall success rate for FY2014 IIRAs was 13%

Percent of Applications Recommended by Mechanism vs. Total Recommended				
Mechanism # Recommended Percentage				
IIRA	36/51	70.6%		
IIRACCA	10/51	19.6%		
IIRAP	5/51	9.8%		

<sup>\*\*</sup>RP150445 - Budget will be adjusted down during contracting to accommodate a reduction in personnel and associated supplies and materials as recommended by the peer review panel. The total amount requested was \$2,000,000.

<sup>\*\*\*</sup>RP150451 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$900,000.



## **CEO Affidavit Supporting Information**

FY 2015—Cycle 1
Individual Investigator Research Awards for
Prevention and Early Detection

### **Request for Applications**



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS RFA R-15-IIRAP-1

## Individual Investigator Research Awards for Prevention and Early Detection

Please also refer to the Instructions for Applicants document, which will be posted on May 15, 2014

**Application Receipt Opening Date: May 15, 2014 Application Receipt Closing Date: June 26, 2014** 

FY 2015

Fiscal Year Award Period
September 1, 2014–August 31, 2015

#### **TABLE OF CONTENTS**

1.	ABOUT CPRIT	5
2.	RATIONALE	5
3.	RESEARCH OBJECTIVES	6
4.	FUNDING INFORMATION	7
5.	ELIGIBILITY	7
6.	RESUBMISSION POLICY	8
7.	RENEWAL POLICY	9
8.	RESPONDING TO THIS RFA	9
	8.1. APPLICATION SUBMISSION GUIDELINES	9
	8.1.1. Submission Deadline Extension	9
	8.2. APPLICATION COMPONENTS	9
	8.2.1. Abstract and Significance (5,000 characters)	10
	8.2.2. Layperson's Summary (2,000 characters)	10
	8.2.3. Goals and Objectives	10
	8.2.4. Timeline (One page)	11
	8.2.5. Renewal Summary (Two pages)	11
	8.2.6. Research Plan (Ten pages)	11
	8.2.7. Vertebrate Animals and/or Human Subjects (One page)	
	8.2.8. Publications/References	11
	8.2.9. Budget and Justification	12
	8.2.10. Biographical Sketches (Two pages each)	
	8.2.11. Current and Pending Support	
	8.2.12. Institutional/Collaborator Support and/or Other Certification (Four pages)	
	8.2.13. Clinical Trial Plan	
9.	APPLICATION REVIEW	14
	9.1. Preliminary Evaluation	14
	9.2. FULL PEER REVIEW	14
	9.3. Confidentiality of Review	15
	9.4. REVIEW CRITERIA	16
	9.4.1. Primary Criteria	16
	9.4.2. Secondary Criteria	17
10	KEY DATES	18

11.	AWARD ADMINISTRATION	18
12.	REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	19
13.	CONTACT INFORMATION	19
13.	.1. HelpDesk	19
13	2 SCIENTIFIC AND PROGRAMMATIC OLIESTIONS	20

#### **RFA VERSION HISTORY**

Rev 3/31/14 RFA release

Rev 5/13/14 Revised Section 8.2 Application Components

• Added Section 8.2.13 Clinical Trial Plan

#### 1. ABOUT CPRIT

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

CPRIT is charged by the Texas Legislature to:

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

#### 2. RATIONALE

A major opportunity for investment in cancer research is in the area of cancer prevention. Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence. This has the added advantage of sparing people and families from the psychological and emotional trauma of a cancer diagnosis, the often devastating physical consequences of cancer therapies, and the financial burdens associated with cancer treatment. Identification of causes of cancer, including environmental chemicals, microbial agents, and genetic susceptibilities, is essential for reducing cancer incidence. In addition, intervening in the process at early stages of cancer development, before genetic instability becomes widespread, holds promise of successfully eliminating cells destined to become cancer cells. Basic research on the identification and control of premalignant cells, the role of the tumor cell microenvironment in tumor development, environmental drivers, and predictive markers of cancer progression may provide new avenues for intervening early in the process of cancer development. Early detection of cancer using biomarkers and early screening methods also can reduce morbidity and mortality from cancer. Although CPRIT is required to spend 10 percent of its budget on cancer prevention, CPRIT's Cancer Prevention Program focuses exclusively on the delivery of evidence-based interventions to underserved populations and does not fund prevention research.

Thus, there is a unique opportunity for CPRIT's Research Program to fund research on adoption of cancer-preventing behaviors, effectiveness of various interventions, and how best to deliver prevention services that could eventually result in implementation through the Prevention Program.

#### 3. RESEARCH OBJECTIVES

This Request for Applications (RFA) solicits applications for innovative research projects addressing questions that will advance our knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. Applications may address any topic or issue related to cancer causation, prevention, early progression, or early detection. Research may be laboratory-, clinical-, or population-based and may include behavioral/intervention, dissemination, or health services/outcomes research to reduce cancer incidence or promote early detection. CPRIT expects the outcomes of activities supported by this mechanism to reduce the burden of cancer in the near or long term. CPRIT encourages applications that seek to apply or develop state-of-the-art technologies, tools, and/or resources for prevention or early detection of cancer, including those with potential commercialization opportunities. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies.

The subject of applications may include, but is not limited to, the following:

- Environmental carcinogenesis, including high-throughput methods for carcinogen detection and identification of carcinogens and their mechanisms of action
- 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

• Development and adaptation of novel interventions for effective and efficient delivery of cancer prevention and screening services

The *degree of relevance* to reducing the burden of cancer will be an important criterion for evaluation of projects for funding by CPRIT.

#### 4. FUNDING INFORMATION

Applicants may request a maximum of \$500,000 in total costs per year for up to 3 years for laboratory and clinical research and up to \$1,000,000 in total costs per year for up to 3 years for population-based research. Exceptions to these limits may be requested if extremely well justified (see Section 8.2.9). Applications funded in this cycle will be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5 percent of the total award amount.

#### 5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Program.
- The Principal Investigator (PI) must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may submit only one new application under this RFA during this funding cycle. A PI may not submit applications to this RFA and to RFA-R-15-IIRA-1 or RFA R-15-IIRACCA-1. Only one IIRAP, IIRA, or IIRACCA application per cycle is allowed. Because this award mechanism is intended to support research directed by a single investigator, only one Co-PI may be included. Collaborators should have specific and well-defined roles.

- Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 11 and Section 12. All statutory provisions and relevant administrative rules can be found at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>.

#### 6. RESUBMISSION POLICY

Because Individual Investigator Research Awards for Prevention and Early Detection is a new award mechanism resubmission in not available under this RFA. If a previously unfunded IIRA application is responsive to the IIRAP RFA, it may be submitted as a new applications under the IIRAP mechanism.

#### 7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA that is appropriate for the IIRAP mechanism may be submitted under this RFA for a competitive renewal. See <u>Section 8.2.5</u>. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See <u>Section 9.2</u>.

#### 8. RESPONDING TO THIS RFA

#### 8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<a href="https://CPRITGrants.org">https://CPRITGrants.org</a>). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 a.m. Central Time on May 15, 2014, and must be submitted by 3 p.m. Central Time on June 26, 2014. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

#### **8.1.1.** Submission Deadline Extension

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

#### **8.2.** Application Components

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

#### 8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the Research Plan. Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (e.g., that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; that the type of cancer of interest to the PI is important, vexing, or deadly). Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see Section 9.1).

#### 8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (Section 9.2) in evaluating the significance and impact of the proposed work.

#### 8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

#### 8.2.4. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

#### 8.2.5. Renewal Summary (Two pages)

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

#### 8.2.6. Research Plan (Ten pages)

**Background:** Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

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

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

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

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

#### 8.2.8. Publications/References

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

#### 8.2.9. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Do not exceed \$500,000 per year for laboratory and clinical studies, and \$1,000,000 for population-based studies. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. Reasonable budgets clearly work in favor of the applicant.

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

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

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

#### 8.2.10. Biographical Sketches (Two pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to two additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

#### 8.2.11. Current and Pending Support

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

#### 8.2.12. Institutional/Collaborator Support and/or Other Certification (Four pages)

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

#### 8.2.13. Clinical Trial Plan

If you are planning to conduct clinical trials as part of your proposed project, please submit required documentation as a single PDF file via e-mail to the CPRIT HelpDesk at <a href="help@CPRITgrants.org">help@CPRITgrants.org</a>. In this document, please include the clinical trial protocol, informed consent document, and a letter of drug availability from the sponsor if the trial is using an investigational drug. CPRIT may require institutional review board (IRB) approval prior to the initiation of funding.

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

#### 9. APPLICATION REVIEW

#### 9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

#### 9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a two-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an

open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

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

#### 9.3. Confidentiality of Review

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

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

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

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a Program Integration Committee Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee is comprised of the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant

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

#### 9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

#### 9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the 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 application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important 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? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

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

**Applicant Investigator:** Does the applicant investigator demonstrate the required creativity and

expertise to make a significant contribution to the research? Applicants' credentials will be

evaluated in a career stage-specific fashion. Have early career-stage investigators received

excellent training, and do their accomplishments to date offer great promise for a successful

career? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to

this project?

**Relevance:** Does the proposed research have a high degree of relevance to cancer prevention

research or early detection? This will be an important criterion for evaluation of projects for

CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these

criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and

resources to accomplish all aspects of the proposed research? Are the levels of effort of the key

personnel appropriate? Is there evidence of institutional support of the research team and the

project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are

included in the proposed research, certification of approval by the institutional IACUC and/or

IRB, as appropriate, will be required before funding can occur.

**Budget:** Is the budget appropriate for the proposed work?

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

#### 10. KEY DATES

#### **RFA**

RFA release March 31, 2014

#### **Application**

Online application opens May 15, 2014, 7 a.m. Central Time Application due June 26, 2014, 3 p.m. Central Time

Application review October - November 2014

#### **Award**

Award notification January 2015
Anticipated start date March 2015

#### 11. AWARD ADMINISTRATION

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

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

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

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11, for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. HelpDesk

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

**Dates of operation:** March 31 – June 26, 2014 (excluding public holidays)

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

Wednesday, 8 a.m. to 4 p.m. Central Time

**Tel:** 866-941-7146

E-mail: Help@CPRITGrants.org

#### 13.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

E-mail: <u>Help@CPRITGrants.org</u>

Web site: <u>www.cprit.state.tx.us</u>

### **Third Party Observer Report**

## CPRIT Basic Cancer Research Peer Review Panel Report

Report #2015-211

Panel Name: Basic Cancer Research-1

Panel Date: November 6, 2014 Report Date: November 17, 2014

#### **Background**

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

#### Introduction

The subject of this report is the Basic Cancer Research-1 peer review panel finalization of recommended prevention program applications. The meeting was chaired by Tom Curran and held at the Hyatt Regency in Dallas TX, on November 6, 2014.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the peer review panel meeting held at the Hyatt Regency and chaired by Tom Curran on November 6, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- 24 applications were discussed within the Prevention Review Council for their review and approval.
- Fifteen reviewers, two advocate reviewers, two CPRIT staff members and six SRA employee were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

#### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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

# CPRIT Basic Cancer Research Review Council Report

Report #2015-209

Panel Name: Basic Cancer Research 2

Panel Date: October 30, 2014-October 31, 2014

Report Date: October 31, 2014

### **Background**

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

### Intro duction

The subject of this report is the Basic Cancer Research review of applications for FY15 funding. The meeting was chaired by Carol Prives and held at the Hyatt Regency in Dallas, TX on October 30 and October 31, 2014.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the in-person Basic Cancer Research Panel final scoring of applications held October 30, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 19 applications were discussed within the Basic Cancer Research Panel for their review and approval.
- Three CPRIT staff members and seven SRA employees were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.

• The Council members' discussions were limited to the application evaluation criteria.

### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

# CPRIT Cancer Biology Review Council Report

Report #2015-210

Panel Name: Cancer Biology

Panel Date: November 3, 2014 Report Date: November 3, 2014

### **Background**

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

### Intro duction

The subject of this report is the Cancer Biology review of applications for FY15 funding. The meeting was chaired by Peter Jones and held at the Hyatt Regency in Dallas TX, on November 3, 2014.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the in-person Cancer Biology final scoring of applications held November 3, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 18 applications were discussed within the Basic Cancer Research Panel for their review and approval.
- Three CPRIT staff members and five SRA employees were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

# CPRIT Cancer Prevention Research Panel Review Report

Report #2015-208

Panel Name: Cancer Prevention Research

Panel Date: October 28, 2014 Report Date: November 17, 2014

### **Background**

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

### Introduction

The subject of this report is the Cancer Prevention Research Panel finalization of recommended prevention program applications. The meeting was chaired by Tom Sellers and held at the Hyatt Regency in Dallas TX on October 28, 2014.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the Cancer Prevention Research Panel meeting held at the Hyatt Regency and chaired by Tom Sellers on October 28, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 20 applications were discussed within the Cancer Prevention Research Panel for their review and approval.
- Eighteen panel members, two advocate reviewers, five CPRIT staff members, and six SRA employees were
  present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

## CPRIT Imaging Technology and Informatics Review Council Report

Report #2015-207

Panel Name: Imaging Technology and Informatics

Panel Date: October 27, 2014 Report Date: October 27, 2014

### **Background**

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

### Intro duction

The subject of this report is the Imaging Technology and Informatics review of applications for FY15 funding. The meeting was chaired by Sam Gambhir and held at the Hyatt Regency in Dallas TX, on October 27, 2014.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the in-person Imaging Technology and Informatics Panel final scoring of applications held October 27, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- 21 applications were discussed within the Imaging Technology and Informatics Panel for their review and approval.
- Two CPRIT staff members and six SRA employees were present for the meetings.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

## CPRIT Peer Review Panel Report

## Report #2015-212

Panel Name: Translational Cancer Research & Clinical and

Translational Cancer Research

Panel Date: November 11, 2014 Report Date: November 17, 2014

### **Background**

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

### Introduction

The subject of this report is the Translational Cancer Research panel & Clinical and Translational Cancer Research panel review of applications for FY15 funding. The joint meeting was co-chaired by Richard O'Reilly and Margaret Tempero, and held on November 11, 2014 at the Hyatt Regency in Dallas, TX.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the in-person Translational Cancer Research & Clinical and Translational Cancer Research joint meeting held November 11, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- Over the course of the panel meeting, seventeen Translational Cancer Research applications and seven Clinical and Translational Cancer Research applications were discussed for their review and approval
- Twenty-one review panel members, three advocate reviewers, two CPRIT staff members, and five SRA
  employees were present for the in-person panel meeting. Seven panel members were on teleconference. A
  total of twenty-eight panelists participated in the meeting.

- Multiple conflicts of interests (COIs) were identified prior to the panel meeting. All COIs were noted and left the room.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

# CPRIT Scientific Review Council Observation Report

Report #2015-213

Panel Name: FY15 Scientific Review Council Meeting -

Recruitment Program Applications

Panel Date: January 6, 2015 Report Date: January 7, 2015

### **Background**

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

### Introduction

The subject of this report is the Scientific Review Council review of recruitment program applications. The meeting was chaired by Richard Kolodner and held over the phone on January 6, 2015.

### Panel Observation Objectives and Scope

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

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

### **Observation Results Summary**

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on January 6, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

- Five recruitment applications were discussed and evaluated by the Scientific Review Council to determine
  which grants would receive CPRIT funding.
- Six council members, two CPRIT staff members, and two SRA employees were present for the Council
  meeting over the phone.

- No conflicts of interest were identified prior to or during the call.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

## **Noted Conflicts of Interest**

# Conflicts of Interest for Scientific Research Cycle 15.1 Applications (Scientific Research Cycle 15.1 Awards Announced at February 18, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Scientific Research Cycle 15.1 include *Individual Investigator Research Awards for Cancer in Children and Adolescents*, and *Individual Investigator Research Awards for Prevention and Early Detection*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	<b>Conflict Noted</b>
	<b>Applications Considered </b>	by the PIC and Oversight Com	mittee
RP150006	Konopleva, Marina	The University of Texas M.D. Anderson Cancer	Mullighan, Charles
		Center	
RP150014	Vernon, Sally	The University of Texas Health Science Center at Houston	Kushi, Lawrence
RP150032	Li, Xiao-Nan	Baylor College of Medicine	Baker, Suzanne
RP150053	Chook, Yuh Min	The University of Texas Southwestern Medical Center	Houchens, David; Sonenberg, Nahum
RP150079/ RP150079pe	Kadara, Humam	The University of Texas M.D. Anderson Cancer Center	Mucci, Lorelei
RP150094	Flores, Elsa	The University of Texas M.D. Anderson Cancer Center	Pure, Ellen
RP150166/ RP150166pe	Kumar, Addanki	The University of Texas Health Science Center at San Antonio	Kristal, Alan
RP150224/ RP150224pe	Tyler, Jessica	The University of Texas M.D. Anderson Cancer Center	Edelmann, Winfried
RP150228	Cinciripini, Paul	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas

Application	Applicant	Institution	Conflict Noted
ID RP150231	Kalluri, Raghu	The University of Texas M.D. Anderson Cancer Center	Kripke, Margaret <sup>1</sup>
RP150232/ RP150232pe	Edwards, Dean	Baylor College of Medicine	Greene, Geoffrey
RP150235	Sun, Shao-Cong	The University of Texas M.D. Anderson Cancer Center	Cooney, Kathleen
RP150334	Deneen, Benjamin	Baylor College of Medicine	Baker, Suzanne
RP150356/ RP150356pe	Medin, Paul	The University of Texas Southwestern Medical Center	Wu, Anna
RP150440	Fuqua, Suzanne	Baylor College of Medicine	Fearon, Eric; Greene, Geoffrey; Lawlor, Elizabeth; Roberts, Charles
RP150440pe	Fuqua, Suzanne	Baylor College of Medicine	Knudsen, Karen; Greene, Geoffrey; Lawlor, Elizabeth; Roberts, Charles
RP150451/ RP150451pe	Sreekumar, Arun	Baylor College of Medicine	Costello, Joseph
Applicat	ions Not Recommended fo	r PIC or Oversight Committee	e Consideration
RP150022*	Zhao, Hua	The University of Texas M.D. Anderson Cancer Center	Barlow, William
RP150041*/ RP150041pe	Pati, Debananda	Baylor College of Medicine	Bhardwaj, Nina; Manfredi, James
RP150046pe	Kim, Jung-whan	The University of Texas at Dallas Knudsen, Karen	
RP150064pe	Davies, Michael	The University of Texas McMahon, Martin M.D. Anderson Cancer Center	
RP150069*/ RP150069pe	Bhattarai, Shanta	The University of Texas M.D. Anderson Cancer Center	Berbeco, Ross
RP150082*	Nyitray, Alan	The University of Texas Health Science Center at Houston	Brandon, Thomas

¹ Dr. Kripke is not a peer reviewer, but attends peer review meetings as an observer in her capacity as Chief Scientific Officer, which is allowed in her FY2015 COI waiver. Because of the professional relationship between the applicant and Dr. Fidler, out of extreme caution Dr. Kripke chose not to be present when the application was discussed. She also abstained from voting on the application during the PIC meeting.

<sup>\* =</sup> Application not discussed

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150095pe	Kurie, Jonathan	The University of Texas M.D. Anderson Cancer Center	Belinsky, Steven
RP150128*/ RP150128pe	Wenzel, Pamela	The University of Texas Health Science Center at Houston	DeClerck, Yves
RP150150*	Wu, Xifeng	The University of Texas M.D. Anderson Cancer Center	Hunter, Kent
RP150154*/ RP150154pe	Paull, Tanya	The University of Texas at Austin	Tomkinson, Alan
RP150165*/ RP150165pe	Hassan, Manal	The University of Texas M.D. Anderson Cancer Center	Petersen, Gloria
RP150167pe	Gong, Zihua	The University of Texas M.D. Anderson Cancer Center	Bardeesy, Nabeel; Petrini, John
RP150173*	P150173* Bi, Xiaohong The University of Texas Health Science Center at Houston		Mitchell, Duane
RP150175/ RP150175pe	Kundra, Vikas	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150186pe	Keyomarsi, Khandan	The University of Texas M.D. Anderson Cancer Center	Martinez, Maria
RP150188*	Rakheja, Dinesh	The University of Texas Southwestern Medical Center	Lawlor, Elizabeth
Southwestern		The University of Texas Southwestern Medical Center	Barlow, William
RP150216*/ RP150216pe	Pinney, Kevin	Baylor University	Mitchell, Duane
RP150219*/ RP150219pe	Post, Sean	The University of Texas M.D. Anderson Cancer Center	Tomkinson, Alan
RP150222*/ Han, Arum Texas Engineering Nie, S RP150222pe Experiment Station		Nie, Shuming	
RP150225/ RP150225pe	Bondy, Melissa	Baylor College of Medicine	Martinez, Maria

Application ID	Applicant	Institution	<b>Conflict Noted</b>	
RP150234	Feng, Ziding	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kristal, Alan; Li, Christopher	
RP150251pe	Gunaratne, Preethi	University of Houston	Costello, Joseph	
RP150252pe	Cho, Sang	The University of Texas M.D. Anderson Cancer Center	Berbeco, Ross	
RP150254*	McNeill, Lorna	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas	
RP150259*/ RP150259pe	Zheng, Yanbin	The University of Texas Southwestern Medical Center	Greene, Geoffrey	
RP150262*	Beretta, Laura	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Kristal, Alan; Li, Christopher	
RP150273*/ RP150273pe	Raj, Ganesh	The University of Texas Southwestern Medical Center	Greene, Geoffrey	
Son		The University of Texas Southwestern Medical Center	Knudsen, Karen	
RP150308pe	Nahleh, Zeina	Texas Tech University Health Sciences Center El Paso	Barlow, William	
RP150335pe	Lizee, Gregory	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan	
RP150344*/ RP150344pe	Mitsiades, Nicholas	Baylor College of Medicine	Roberts, Charles	
RP150361	Maitra, Anirban	The University of Texas Niedzwiecki M.D. Anderson Cancer Center		
RP150379*	Li, Donghui	ghui The University of Texas Petersen, Gloria M.D. Anderson Cancer Center		
RP150384*	Arun, Banu	The University of Texas M.D. Anderson Cancer Center  Li, Christopher		
RP150394pe	Mancini, Michael	Baylor College of Medicine	Greene, Geoffrey	
RP150399*	Patel, Darpan	The University of Texas Health Science Center at San Antonio  Kristal, Alan		

Application ID	Applicant	Institution	<b>Conflict Noted</b>
RP150404*/ RP150404pe	Glisson, Bonnie	The University of Texas M.D. Anderson Cancer Center	Riddell, Stan
RP150418*/ RP150418pe	Wang, Wei	Texas Tech University Health Sciences Center	Chen, Xinbin
RP150422*	Jayaraman, Arul	Texas A&M University	Greene, Geoffrey
RP150424/ RP150424pe	Aromougame, Asaithamby	The University of Texas Southwestern Medical Center	Berbeco, Ross
RP150433	Taguchi, Ayumu	The University of Texas M.D. Anderson Cancer Center	Barlow, William; Li, Christopher; Petersen, Gloria; Kristal, Alan
RP150471pe	Castrillon, Diego	The University of Texas Southwestern Medical Center	Bardeesy, Nabeel
RP150479*	Chan, Lawrence	Baylor College of Medicine	Williams, Bart
RP150499*	Decuzzi, Paolo	The Methodist Hospital Rutt, Brian Research Institute	
RP150500*	Vokes, Steven	The University of Texas at Austin Chazin, Walter	
RP150516/ RP150516pe	Liu, Mingyao	Texas A&M University System Health Science Center	Williams, Bart

## **De-Identified Overall Evaluation Scores**

# Individual Investigator Research Awards for Prevention and Early Detection

Scientific Research Cycle 15.1

Application ID	Final Overall
	Score
RP150228*	1.5
RP150449*	3.0
RP150421*	3.1
RP150014*	3.2
RP150195*	3.2
BA	3.4
ВВ	3.4
ВС	3.5
BD	3.7
BE	3.8
BF	4.0
BG	4.0
ВН	4.0
BI	4.0
BJ	4.0
BK	4.1
BL	4.3
BM	4.3
BN	4.3
ВО	4.3
BP	4.3
BQ	4.3
BR	4.3
BS	4.4
BT	4.5
BU	4.7
BV	4.7
BW	4.7
BX	4.7
BY	4.7
BZ	4.7
CA	4.7
СВ	4.8

<sup>\*=</sup>Recommended for Funding

CC	4.8
CD	4.9
CE	5.0
CF	5.0
CG	5.0
СН	5.0
CI	5.0
CJ	5.0
CK	5.0
CL	5.0
CM	5.0
CN	5.1
СО	5.3
СР	5.3
CQ	5.4
CR	5.4
CS	5.7
СТ	5.7
CU	5.7
CV	5.7
CW	5.8
CX	5.9
CY	6.0
CZ	6.0
DA	6.0
DB	6.3
DC	6.3
DD	6.3
DE	6.4
DF	6.7
DG	7.3
DH	7.3
DI	7.3

# Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd January 8, 2015

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Senior Advisor on Academic Affairs

New York Office

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

rkolodner@ucsd.edu

#### San Diego Branch

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

**T** 858 534 7804 **F** 858 534 7750

#### **New York Office**

28<sup>th</sup> Floor 666 Third Avenue New York, NY 10017

**T** 212 450 1500 **F** 212 450 1555

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

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

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), and Individual Investigator Research Awards for Prevention and Early Detection (IIRAP). The SRC met on Tuesday, January 6, 2015 to consider the applications recommended by the peer review panels following their meetings that were held between October 27 and November 12, 2014. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to four grants applications. These adjustments are listed at the end of the list of recommended projects.

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

Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Award Mechanism	Organization	Application Title	Budget	Overall Score
1	RP150224	IIRA	The University of Texas M. D. Anderson Cancer Center	Discovering the molecular mechanisms that determine replicative lifespan	\$892,104	1.1
2	RP150343	IIRACCA	University of Houston	An ultra-sensitive nanomagnetic sensor for the early detection of anaplastic large cell lymphoma		1.2
3	RP150498	IIRA	The University of Texas Southwestern Medical Center	Harnessing the Cytosolic DNA Sensing Pathway for Cancer Immunotherapy	\$889,185	1.2
4	RP150228	IIRAP	The University of Texas M. D. Anderson Cancer Center	Varenicline and Combined NRT for Initial Smoking Cessation and Rescue Treatment in Smokers: A Randomized Pilot Trial	\$1,493,464	1.5
5	RP150456	IIRA	The University of Texas Southwestern Medical Center	TAMU–UT Southwestern Partnership for Breast Imaging and Spectroscopy at 7 Tesla	\$897,311	1.7
6	RP150245	IIRA	The University of Texas M. D. Anderson Cancer Center	EGFR Arginine Methylations: Biomarkers for Cetuximab Resistance in colon cancer	\$900,000	1.8
7	RP150334	IIRACCA	Baylor College of Medicine	Personalized Functionalization of Pediatric High Grade Glioma	\$1,820,319	1.9
8	RP150319	IIRA	The University of Texas M. D. Anderson Cancer Center	Leukemia inhibitory factor receptor signaling and function in cancer	\$900,000	1.9
9	RP150053	IIRA	The University of Texas Southwestern Medical Center	Mechanisms of nuclear import and export in cancer	\$900,000	1.9
10	RP150230	IIRA	The University of Texas Health Science Center at Houston	Counteracting tumor evasion of antibody immunity by a novel therapeutic strategy	\$900,000	1.9
11	RP150006	IIRACCA	The University of Texas M. D. Anderson Cancer Center	Defining and Treating Targetable Lesions in AYA Acute Lymphoblastic Leukemia	\$1,989,950	1.9
12	RP150445 **	IIRACCA	The University of Texas Health Science Center at San Antonio	Ewing's sarcoma, a homologous recombination defective disease	\$2,000,000	2.0
13	RP150277	IIRA	The University of Texas Health Science Center at San Antonio	Vertical targeting of the B cell receptor in leukemia and lymphoma	\$899,879	2.0
14	RP150451 ***	IIRA	Baylor College of Medicine	SRC-2 driven "Metabolic Switch" in metastatic prostate cancer- Prognostic and Therapeutic implications	\$900,000	2.1
15	RP150282	IIRA	The University of Texas M. D. Anderson Cancer Center	Mechanisms of de novo and acquired resistance to therapeutic treatment of bone-metastatic prostate cancer	\$900,000	2.1
16	RP150148	IIRA	The University of Texas M. D. Anderson Cancer Center	Identifying Drivers of Lung Metastasis in Triple Negative Breast Cancer	\$899,637	2.2
17	RP150485	IIRA	The University of Texas Southwestern Medical Center	Translating Online Adaptive Radiotherapy from Lab to Clinical Practice	\$858,356	2.2
18	RP150084	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of PTEN feedback mechanism in cancer	\$900,000	2.2
19	RP150403	IIRA	The University of Texas M. D. Anderson Cancer Center	On the role of DEAR1 in the regulation of cell polarity and progression from DCIS to invasive breast cancer	\$899,846	2.3
20	RP150232	IIRA	Baylor College of Medicine	The Role of Progesterone Receptor in Early Stage Breast Cancer.	\$864,661	2.3
21	RP150440	IIRA	Baylor College of Medicine	Effects of hormonal therapy on subclonal evolution of breast tumors with ESR1 mutations	\$899,805	2.3
22	RP150231	IIRA	The University of Texas M. D. Anderson Cancer Center	Function of Fibroblasts and Collagen I in Pancreas Cancer	\$898,811	2.4

23	RP150197	IIRA	Baylor College of Medicine	Understanding How NCOA6 Suppresses Endometrial Cancer by Inhibiting the Wnt/beta-Catenin Pathway	\$886,524	2.4
24	RP150094	IIRA	The University of Texas M. D. Anderson Cancer Center	Investigating the regulation of miRNA and lncRNAs by p63 in mammary tumor progression and metastasis	\$900,000	2.4
25	RP150386	IIRA	The University of Texas Southwestern Medical Center	A Phase I Trial of Stereotactic HYpofractionateD RadioAblative (HYDRA) Treatment of Advanced Laryngeal Cancer	\$860,540	2.4
26	RP150129	IIRACCA	Baylor College of Medicine	Drug Discovery and Mechanistic Studies of Protein Methylation Targeting Leukemia	\$1,733,813	2.6
27	RP150032	IIRACCA	Baylor College of Medicine	Developing New Combinatory Therapies for Pediatric High Grade Glioma	\$1,945,940	2.6
28	RP150408 ****	IIRA	The University of Texas Health Science Center at San Antonio	Cellular mechanisms of chemotherapy- induced peripheral neuropathy	\$844,746	2.6
29	RP150293	IIRA	The University of Texas M. D. Anderson Cancer Center	Identification of clinically relevant targets for radiosensitization	\$899,280	2.7
30	RP150316	IIRA	The University of Texas M. D. Anderson Cancer Center	T-cell activating immunotherapy for indolent B-cell malignancies	\$852,595	2.7
31	RP150356	IIRA	The University of Texas Southwestern Medical Center	Peripheral nerve tolerance to single- session stereotactic irradiation	\$897,779	2.8
32	RP150081	IIRACCA	Baylor College of Medicine	Genetic susceptibility to testicular germ cell tumors	\$1,406,791	2.8
33	RP150093	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting 17q23 amplicon in HER2- positive Breast Cancer	\$828,242	2.8
34	RP150292	IIRA	Baylor College of Medicine	Broad Shortening of 3' UTRs in Human Cancers: Methods, Target Genes and Functional Consequences	\$900,000	2.9
35	RP150102	IIRA	The University of Texas M. D. Anderson Cancer Center	Genome stability and immune diversity controlled by the POLQ pathway	\$900,000	2.9
36	RP150079	IIRA	The University of Texas M. D. Anderson Cancer Center	Elucidating the evolution of the premalignant airway genome in space and time	\$886,173	2.9
37	RP150301	IIRACCA	The University of Texas M. D. Anderson Cancer Center	Epigenetics in Medulloblastoma Development and Therapeutics	\$1,871,708	3.0
38	RP150179	IIRA	The University of Texas M. D. Anderson Cancer Center	1		3.0
39	RP150449	IIRAP	The University of Texas Medical Branch at Galveston	Noninvasive multiscale imaging for optical biopsy in epithelial cancers	\$852,748	3.0
40	RP150346	IIRA	The University of Texas at Austin	Targeting Twist1 for Prevention and Treatment of Non-Melanoma Skin Cancer  \$900,000		3.0
41	RP150235	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of TBK1 in Regulating Dendritic Cell Function and Antitumor Immunity.	\$876,958	3.0
42	RP150454	IIRA	Texas A&M University	Tumor Suppression Through the cGAMP/STING Pathway	\$900,000	3.0
43	RP150421	IIRAP	Texas Engineering Experiment Station	High-throughput Screening and Detection of Circulating Tumor Cells	\$1,135,450	3.1
44	RP150166	IIRA	The University of Texas Health Science Center at San Antonio	Prostate Cancer Chemoprevention with Resveratrol	\$900,000	3.1
45	RP150405	IIRA	The University of Texas M. D. Anderson Cancer Center	Tumor Cell Epithelial-Mesenchymal Transition in Regulating Immunosuppression and Metastasis in Lung Cancer	\$900,000	3.1

46	RP150416	IIRACCA	Texas Tech University Health Sciences Center	Translational Investigations On Fenretinide and Safingol For Pediatric Cancer Use	\$1,999,415	3.1
47	RP150164	IIRACCA	The University of Texas Southwestern Medical Center	Using imaging and computational tools to improve risk stratification in children with bone cancer	\$1,290,442	3.2
48	RP150242	IIRA	The University of Texas Southwestern Medical Center	Functional and structural characterization of a small chemical compound that arrests glioma stem cell growth with high activity and specificity	\$900,000	3.2
49	RP150014	IIRAP	The University of Texas Health Science Center at Houston	Multi-component interventions for patients and providers to increase HPV vaccination in a network of pediatric clinics in Houston, TX	\$2,498,986	3.2
50	RP150195	IIRAP	The University of Texas M. D. Anderson Cancer Center	Mechanisms of DHA and EPA differential effects on colon cancer chemoprevention	\$920,926	3.2
51	RP150030	IIRA	The University of Texas M. D. Anderson Cancer Center	Exploring molecular and immune mechanisms of response and resistance to combined BRAF/MEK inhibition in patients with high-risk resectable metastatic melanoma	\$900,000	3.2
	Total Recommended Amount \$56,922,094					

<sup>\*</sup> RP150053 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$900,000.

<sup>\*\*\*\*</sup>RP150408 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$844,746.

Success Rate by Panel					
Peer Review	Success	Score			
Panel	Rate	Cutoff			
BCR1	12.3%	3.2			
BCR2	10.3%	2.9			
СВ	13.4%	3.0			
CPR	12.5%	3.2			
CTCR/TCR	15.0%	3.2			
ITI	13.1%	3.2			

Success Rate by Mechanism vs. Total Reviewed*						
Mechanism	Success Rate	# Recommended				
IIRA	13.3%	36/371				
IIRACCA	17.9%	10/56				
IIRAP	7.6%	5/66				
Overall	12.9%	51/393				

\*The overall success rate for FY2014 IIRAs was 13%

Percent of Applications Recommended by Mechanism vs. Total Recommended				
Mechanism	# Recommended	Percentage		
IIRA	36/51	70.6%		
IIRACCA	10/51	19.6%		
IIRAP	5/51	9.8%		

<sup>\*\*</sup>RP150445 - Budget will be adjusted down during contracting to accommodate a reduction in personnel and associated supplies and materials as recommended by the peer review panel. The total amount requested was \$2,000,000.

<sup>\*\*\*</sup>RP150451 - Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 3) as recommended by the peer review panel. The total amount requested was \$900,000.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# CEO AFFIDAVIT Application RP150030 Individual Investigator Research Awards

### THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R/Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the understhe day of February by WAYNE R. ROBERTS.	signed authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas  My Commission Expires  SEPTEMBER 30, 2017
	Notary without Bond

L

### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

**FY** 2015 **CYCLE** 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150030

Exploring Molecular and Immune Mechanisms of Response and Resistance to Combined BRAF/MEK

APPLICATION TITLE

Response and Resistance to Combined BRAF/MEK
Inhibition in Patients with High-Risk Resectable Metastatic

Melanoma

APPLICANT NAME Wargo, Jennifer

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Translational Cancer Research (TCR )

Category	Compliance Requirement	information	Attestation Date
	RFA published in Texas Register	05/16/14	12/12/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
	Date application submitted	06/24/14	12/12/14
	Method of submission	CARS	12/12/14
	Within receipt period	YES	12/12/14
	Appeal to submit application after CARS closed	N/A	12/12/14
	Appeal for late application submission accepted	N/A	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
2. Receipt, Referral, and Assignment	Assigned to primary reviewers	08/18/14	12/12/14
	Applicant notified of review panel assignment	08/11/14	12/12/14
	Primary Reviewer 1 COI signed	10/02/14	12/12/14
	Primary Reviewer 2 COI signed	09/04/14	12/12/14
	Primary Reviewer 3 COI signed	07/25/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/12/14
	Primary Reviewer 1 critique submitted	N/A	12/12/14
	Primary Reviewer 2 critique submitted	09/05/14	12/12/14
	Primary Reviewer 3 critique submitted	09/06/14	12/12/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
valuation	COI indicated by non-primary reviewer	NONE	12/12/14
	Preliminary Evaluation score summary sent to Chair	09/22/14	12/12/14
	Recommended for full review	YES	12/12/14
	Applicant notified of outcome	10/17/14	12/12/14
	Assigned to primary reviewers	10/03/14	12/12/14
	Primary Reviewer 1 COI signed	10/02/14	12/12/14
	Primary Reviewer 2 COI signed	10/23/14	12/12/14
	Primary Reviewer 3 COI signed	10/28/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/29/14	12/12/14
	Primary Reviewer 1 critique submitted	11/01/14	12/12/14
	Primary Reviewer 2 critique submitted	10/29/14	12/12/14
	Primary Reviewer 3 critique submitted	10/28/14	12/12/14
. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	11/09/14	12/12/14
/leeting	COI indicated by non-primary reviewer	NONE	12/12/14
	COI recused from participation	N/A	12/12/14
	Discussed at On-Site Meeting	YES	12/12/14
	Peer Review Meeting	11/11/14	12/12/14
	Post review statements signed	11/18/14	12/12/14
	Third Party Observer Report	11/17/14	12/12/14
	Score report delivered to CSO	11/25/14	12/12/14
	Recommended for SRC Review	YES	12/12/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
. Final SRC	SRC Meeting	01/06/15	01/13/15
ecommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	M. Kripke*	02/03/15
. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES YES	02/03/15
	CEO Notification to Oversight Committee	DATE	02/03/13
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	-
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications. The identity of the attesting party is retained by CPRIT.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# CEO AFFIDAVIT Application RP150053 Individual Investigator Research Awards

THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-2 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the the 4th day of tebnuary by WAYNE R. ROBERTS.	undersigned authority, on2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Taxas  My Commission Expires  SEPTEMBER 30, 2017  Notary without Bond

### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150053

APPLICATION TITLE Mechanisms of Nuclear Import and Export in Cancer

APPLICANT NAME Chook, Yuh Min

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/26/14	12/24/14
	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
3. Prenminary Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	07/26/14	12/24/14
		07/23/14	12/24/14
	Primary Reviewer 2 COI signed	07/31/14	
	Primary Reviewer 3 COI signed	09/11/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	10/21/14	12/24/14
	Primary Reviewer 1 critique submitted		12/24/14
	Primary Reviewer 2 critique submitted	10/17/14	12/24/14
	Primary Reviewer 3 critique submitted	10/28/14	12/24/14
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/27/14 Houchens, David	12/24/14
Meeting	COI indicated by non-primary reviewer	_	12/24/14
	COI recused from participation	YES	12/24/14
	COI indicated by non-primary reviewer	Sonenberg, Nahum	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/30/14-10/31/14	12/24/14
	Post review statements signed	10/31/14	12/24/14
	Third Party Observer Report	10/31/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
i. PIC Review	COI recused from participation	N/A	02/03/15
o. Fic neview	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	L
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
Committee Approval			
Committee Approval	Award approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# CEO AFFIDAVIT Application RP150079 Individual Investigator Research Awards

### THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the 4th day of February by WAYNE R. ROBERTS.	signed authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

2015 CYCLE PROGRAM

Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150079

Elucidating the Evolution of the Premalignant Airway APPLICATION TITLE

Genome in Space and Time Kadara, Humam

APPLICANT NAME ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	information	Attestation Date
	RFA published in Texas Register	05/16/14	12/23/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/23/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/23/14
	Date application submitted	06/23/14	12/23/14
l. Pre-Receipt	Method of submission	CARS	12/23/14
	Within receipt period	YES	12/23/14
	Appeal to submit application after CARS closed	N/A	12/23/14
	Appeal for late application submission accepted	N/A	12/23/14
	Administrative review notification	N/A	12/23/14
	Donation(s) made to CPRIT/foundation	NO	12/23/14
	Assigned to primary reviewers	08/05/14	12/23/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/23/14
and Assignment	Primary Reviewer 1 COI signed	07/30/14	12/23/14
	Primary Reviewer 2 COI signed	07/25/14	12/23/14
	Primary Reviewer 3 COI signed	07/30/14	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/23/14
	Primary Reviewer 1 critique submitted	08/12/14	12/23/14
	Primary Reviewer 2 critique submitted	08/13/14	12/23/14
	Primary Reviewer 3 critique submitted	08/17/14	12/23/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/23/14
valuation	COI indicated by non-primary reviewer	Mucci, Lorelei	12/23/14
	Preliminary Evaluation score summary sent to Chair	08/28/14	12/23/14
	Recommended for full review	YES	12/23/14
	Applicant notified of outcome	10/17/14	12/23/14
	Assigned to primary reviewers	08/29/14	12/23/14
	Primary Reviewer 1 COI signed	07/30/14	12/23/14
	Primary Reviewer 1 COI signed Primary Reviewer 2 COI signed	07/25/14	12/23/14
		07/30/14	12/23/14
	Primary Reviewer 3 COI signed	08/31/14	
	Primary (Advocate) Reviewer 4 COI signed		12/23/14
	Primary Reviewer 1 critique submitted	10/13/14 09/23/14	12/23/14
	Primary Reviewer 2 critique submitted		12/23/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/03/14	12/23/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/25/14	12/23/14
	COI indicated by non-primary reviewer	Mucci, Lorelei	12/23/14
	COI recused from participation	YES	12/23/14
	Discussed at On-Site Meeting	YES	12/23/14
	Peer Review Meeting	10/28/14	12/23/14
	Post review statements signed	10/28/14	12/23/14
	Third Party Observer Report	11/17/14	12/23/14
	Score report delivered to CSO	11/25/14	12/23/14
	Recommended for SRC Review	YES	12/23/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
i. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
. PIC Review	COI recused from participation	M. Kripke*	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	il
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150084 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-1 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the	signed authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	BANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Trotaly I dolle, State of Texas	Notary without Bond

FY 2015 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150084

APPLICATION TITLE Role of PTEN Feedback Mechanism in Cancer

APPLICANT NAME Song, Min Sup

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/24/14	12/24/14
l. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/05/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	07/23/14	12/24/14
g	Primary Reviewer 2 COI signed	08/06/14	12/24/14
	Primary Reviewer 3 COI signed	07/25/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted Primary Reviewer 2 critique submitted	08/22/14	12/24/14
	Primary Reviewer 2 critique submitted	08/22/14	12/24/14
. Parlimina		_	
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 critique submitted	N/A NONE	12/24/14
valuation	COI indicated by non-primary reviewer		12/24/14
	Preliminary Evaluation score summary sent to Chair	09/02/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/08/14	12/24/14
	Primary Reviewer 1 COI signed	08/11/14	12/24/14
	Primary Reviewer 2 COI signed	08/06/14	12/24/14
	Primary Reviewer 3 COI signed	07/25/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/05/14	12/24/14
	Primary Reviewer 1 critique submitted	10/12/14	12/24/14
	Primary Reviewer 2 critique submitted	10/16/14	12/24/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/13/14	12/24/14
Vieeting	Primary (Advocate) Reviewer 4 critique submitted	10/23/14	12/24/14
	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/06/14	12/24/14
	Post review statements signed	11/19/14	12/24/14
	Third Party Observer Report	11/17/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/31/15
	COI recused from participation	N/A	01/31/15
5. Final SRC	SRC Meeting	01/06/15	01/31/15
Recommendation	Third Party Observer Report	01/07/15	01/31/15
	Recommended for grant award	YES	01/31/15
	SRC Chair Notification to PIC and OC	01/08/15	01/31/15
	COI Indicated by PIC member	NONE	02/03/15
	COI recused from participation	M. Kripke*	02/03/15
6. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO OF N/A	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
.cmittee Approval	Award approved by Oversight Committee		
	Authority to advance funds requested	YES/NO	
	Partitioned to advance ratios requested	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications.
The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150093 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-2 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED be the day of by WAYNE R. ROBERTS.	fore me, the undersigned authority, on £2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

**FY** 2015 **CYCLE** 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150093

APPLICATION TITLE Targeting 17q23 Amplicon in HER2-Positive Breast Cancer

APPLICANT NAME Zhang, Xinna

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
1. Pre-Receipt	Date application submitted	06/23/14	12/24/14
t. rie-keceipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/11/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	08/05/14	12/24/14
	Primary Reviewer 2 COI signed	07/24/14	12/24/14
	Primary Reviewer 3 COI signed	08/02/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/29/14	12/24/14
	Primary Reviewer 2 critique submitted	08/11/14	12/24/14
	Primary Reviewer 3 critique submitted	09/01/14	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	NONE	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/04/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	08/05/14	12/24/14
	Primary Reviewer 2 COI signed	07/24/14	12/24/14
	Primary Reviewer 3 COI signed	07/26/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	10/15/14	12/24/14
	Primary Reviewer 1 critique submitted	10/19/14	12/24/14
	Primary Reviewer 2 critique submitted	10/07/14	12/24/14
	Primary Reviewer 3 critique submitted	10/21/14	12/24/14
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/19/14	12/24/14
Meeting	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/30/14-10/31/14	12/24/14
	Post review statements signed	10/31/14	12/24/14
		10/31/14	12/24/14
	Third Party Observer Report	11/25/14	1
	Score report delivered to CSO	YES YES	12/24/14
	Recommended for SRC Review		01/13/15
	COI Indicated by SRC member	NONE	-
. m lana	COI recused from participation	N/A 01/06/15	01/13/15
5. Final SRC Recommendation	SRC Meeting		01/13/15
recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
5. PIC Review	COI recused from participation	M. Kripke*	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150094 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-2 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the the day of February WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas  My Commission Expires  SEPTEMBER 30, 2017
	Notary without Bond

FY 2015 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150094

APPLICATION TITLE Investigating the Regulation of miRNA and IncRNAs by p63

in Mammary Tumor Progression and Metastasis

APPLICANT NAME Flores, Elsa

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
B B	Date application submitted	06/23/14	12/24/14
l. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	07/30/14	12/24/14
	Primary Reviewer 2 COI signed	07/24/14	12/24/14
	Primary Reviewer 3 COI signed	08/02/14	12/24/14
		09/11/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed		-
	Primary Reviewer 1 critique submitted	10/27/14	12/24/14
	Primary Reviewer 2 critique submitted		12/24/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/19/14	12/24/14
Vieeting	Primary (Advocate) Reviewer 4 critique submitted	10/27/14	12/24/14
	COI indicated by non-primary reviewer	Pure, Ellen	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/30/14-10/31/14	12/24/14
	Post review statements signed	10/31/14	12/24/14
	Third Party Observer Report	10/31/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
. Final SRC	SRC Meeting	01/06/15	01/13/15
tecommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
i. PIC Review	COI recused from participation	M. Kripke*	02/03/15
. TIC NEVICW	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications.

The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



#### Cancer Prevention & Research Institute of Texas

# CEO AFFIDAVIT Application RP150102 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-2 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis SWORN to and SUBSCRIBED before me, the under	rsigned authority, on
SWORN to and SUBSCRIBED before me, the under the	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150102

APPLICATION TITLE Genome Stability and Immune Diversity Controlled by the

APPLICANT NAME POLQ Pathway

McBride, Kevin

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/19/14	12/24/14
. Pre-Recelpt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/11/14	12/24/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
nd Assignment	Primary Reviewer 1 COI signed	07/27/14	12/24/14
	Primary Reviewer 2 COI signed	07/28/14	12/24/14
	Primary Reviewer 3 COI signed	07/24/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/31/14	12/24/14
	Primary Reviewer 2 critique submitted	08/20/14	12/24/14
	Primary Reviewer 3 critique submitted	09/02/14	12/24/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	NONE	12/24/14
valuation	Preliminary Evaluation score summary sent to Chair	09/04/14	12/24/14
	Recommended for full review	YES YES	12/24/14
		10/17/14	12/24/14
	Applicant notified of outcome	09/12/14	12/24/14
	Assigned to primary reviewers	07/27/14	12/24/14
	Primary Reviewer 1 COI signed	07/24/14	12/24/14
	Primary Reviewer 2 COI signed		12/24/14
	Primary Reviewer 3 COI signed	07/25/14	-
	Primary (Advocate) Reviewer 4 COI signed	10/15/14	12/24/14
	Primary Reviewer 1 critique submitted	10/17/14	12/24/14
	Primary Reviewer 2 critique submitted	10/17/14	12/24/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/17/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/20/14	12/24/14
	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/30/14-10/31/14	12/24/14
	Post review statements signed	10/31/14	12/24/14
	Third Party Observer Report	10/31/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
. PIC Review	COI recused from participation	M. Kripke*	02/03/15
. FIC NEVICW	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150148 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the unc	lersigned authority, on
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150148

APPLICATION TITLE Identifying Drivers of Lung Metastasis in Triple Negative

Breast Cancer

APPLICANT NAME Piwnica-Worms, Helen

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Biology (CB)

Catagory	Compilance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/19/14	12/24/14
Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/12/14	12/24/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	07/23/14	12/24/14
ma Assignment	Primary Reviewer 2 COI signed	08/25/14	12/24/14
	Primary Reviewer 3 COI signed	07/28/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
		08/28/14	12/24/14
	Primary Reviewer 1 critique submitted Primary Reviewer 2 critique submitted	08/26/14	12/24/14
			12/24/14
	Primary Reviewer 3 critique submitted	08/15/14	
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	NONE	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/03/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/10/14	12/24/14
	Primary Reviewer 1 COI signed	07/23/14	12/24/14
	Primary Reviewer 2 COI signed	08/25/14	12/24/14
	Primary Reviewer 3 COI signed	07/28/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/15/14	12/24/14
	Primary Reviewer 1 critique submitted	10/15/14	12/24/14
	Primary Reviewer 2 critique submitted	10/15/14	12/24/14
. Peer Review	Primary Reviewer 3 critique submitted	10/14/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/23/14	12/24/14
•	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	M. Kripke*	02/03/15
i. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	- 1
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
on,microc Approval	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	7
	Industrial to advance rangs requested	123/110	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150166 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the unde the 4th day of February by WAYNE R. ROBERTS.	rsigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

FY 2015 CYCLE 1 PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150166

APPLICATION TITLE
APPLICANT NAME
ORGANIZATION
The University of Texas Health Science Center at San

ANNEL NAME
Cancer Prevention Research (CPR) The University of Texas Health Science Center at San Antonio

Cancer Prevention Research (CPR) PANEL NAME

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/23/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	05/15/14	12/23/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/23/14
	Date application submitted	06/24/14	12/23/14
	Method of submission	CARS	12/23/14
	Within receipt period	YES	12/23/14
	Appeal to submit application after CARS closed	N/A	12/23/14
	Appeal for late application submission accepted	N/A	12/23/14
	Administrative review notification	N/A	12/23/14
	Donation(s) made to CPRIT/foundation	NO	12/23/14
	Assigned to primary reviewers	08/05/14	12/23/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/23/14
and Assignment	Primary Reviewer 1 COI signed	07/30/14	12/23/14
	Primary Reviewer 2 COI signed	08/15/14	12/23/14
	Primary Reviewer 3 COI signed	08/11/14	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/23/14
	Primary Reviewer 1 critique submitted	08/20/14	12/23/14
	Primary Reviewer 2 critique submitted	08/20/14	12/23/14
	Primary Reviewer 3 critique submitted	08/11/14	12/23/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/23/14
Evaluation	COI indicated by non-primary reviewer	Kristal, Alan	12/23/14
	Preliminary Evaluation score summary sent to Chair	08/28/14	12/23/14
	Recommended for full review	YES	12/23/14
	Applicant notified of outcome	10/17/14	12/23/14
	Assigned to primary reviewers	08/29/14	12/23/14
	Primary Reviewer 1 COI signed	07/30/14	12/23/14
	Primary Reviewer 2 COI signed	08/15/14	12/23/14
	Primary Reviewer 3 COI signed	08/11/14	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	08/29/14	12/23/14
	Primary Reviewer 1 critique submitted	10/26/14	12/23/14
	Primary Reviewer 2 critique submitted	10/02/14	12/23/14
	Primary Reviewer 3 critique submitted	09/30/14	12/23/14
4. Peer Review Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/26/14	12/23/14
Meering	COI indicated by non-primary reviewer	Kristal, Alan	12/23/14
	COI recused from participation	YES	12/23/14
	Discussed at On-Site Meeting	YES	12/23/14
	Peer Review Meeting	10/28/14	12/23/14
	Post review statements signed	10/28/14	12/23/14
	Third Party Observer Report	11/17/14	12/23/14
	Score report delivered to CSO	11/25/14	12/23/14
	Recommended for SRC Review	YES	12/23/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
6. PIC Review	COI recused from participation	N/A	02/03/15
b. FIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
7. Oversight	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150179 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R/Roberts,

State of Texas County of Travis	J
SWORN to and SUBSCRIBED before me, the under the day of Fibruary by WAYNE R. ROBERTS.	ersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150179

APPLICATION TITLE Regulation of Dormancy of Metastatic Prostate Cancer Cells

by Bone Microenvironment

APPLICANT NAME Lin, Sue-Hwa

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Biology (CB)

Category	Compliance Regulrement	information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/23/14	12/24/14
	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/12/14	12/24/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
nd Assignment		07/27/14	12/24/14
na Assignment	Primary Reviewer 1 COI signed	08/29/14	12/24/14
	Primary Reviewer 2 COI signed	07/28/14	12/24/14
	Primary Reviewer 3 COI signed		
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/24/14	12/24/14
	Primary Reviewer 2 critique submitted	08/29/14	12/24/14
	Primary Reviewer 3 critique submitted	08/25/14	12/24/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	NONE	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/03/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/10/14	12/24/14
	Primary Reviewer 1 COI signed	08/01/14	12/24/14
	Primary Reviewer 2 COI signed	08/29/14	12/24/14
	Primary Reviewer 3 COI signed	07/28/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/11/14	12/24/14
	Primary Reviewer 1 critique submitted	10/20/14	12/24/14
	Primary Reviewer 2 critique submitted	10/16/14	12/24/14
	Primary Reviewer 3 critique submitted	10/13/14	12/24/14
J. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/29/14	12/24/14
Vieeting	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
i. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
recommendation	Recommended for grant award	YES	01/13/15
		01/08/15	01/13/15
	SRC Chair Notification to PIC and OC	NONE	02/03/15
	COI indicated by PIC member	M. Kripke*	02/03/15
. PIC Review	COI recused from participation		02/03/15
	PIC review meeting	02/03/15	_
7. Oversight	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE NONE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150197 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-1 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R/Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the day of February by WAYNE R. ROBERTS.	signed authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150197

APPLICATION TITLE Understanding How NCOA6 Suppresses Endometrial Cancer by Inhibiting the Wnt/beta-Catenin Pathway

APPLICANT NAME Xu, Jianming

ORGANIZATION Baylor College of Medicine
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	information	Attestation Dat
	RFA published in Texas Register	05/16/14	12/24/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/25/14	12/24/14
	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/05/14	12/24/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	08/11/14	12/24/14
	Primary Reviewer 2 COI signed	07/31/14	12/24/14
	Primary Reviewer 3 COI signed	08/14/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/23/14	12/24/14
	Primary Reviewer 2 critique submitted	08/27/14	12/24/14
	Primary Reviewer 3 critique submitted	08/24/14	12/24/14
J. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	NONE	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/02/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/08/14	12/24/14
	Primary Reviewer 1 COI signed	08/11/14	12/24/14
	Primary Reviewer 2 COI signed	07/31/14	12/24/14
	Primary Reviewer 3 COI signed	08/14/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	10/12/14	12/24/14
	Primary Reviewer 2 critique submitted	10/13/14	12/24/14
	Primary Reviewer 3 critique submitted	10/15/14	12/24/14
I. Peer Review Meeting	Primary (Advocate) Reviewer 4 critique submitted	11/01/14	12/24/14
viceting	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/06/14	12/24/14
	Post review statements signed	11/19/14	12/24/14
	Third Party Observer Report	11/17/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
7. Oversight	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	1
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150224 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-2 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R/Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the und the day of February by WAYNE R. ROBERTS.	lersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150224

APPLICATION TITLE Discovering the Molecular Mechanisms that Determine

Replicative Lifespan
APPLICANT NAME Tyler, Jessica

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestution Dat
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/20/14	12/24/14
. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/11/14	12/24/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
nd Assignment	Primary Reviewer 1 COI signed	07/31/14	12/24/14
	Primary Reviewer 2 COI signed	07/28/14	12/24/14
	Primary Reviewer 3 COI signed	07/30/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	09/03/14	12/24/14
	Primary Reviewer 2 critique submitted	09/02/14	12/24/14
	Primary Reviewer 3 critique submitted	09/02/14	12/24/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	Edelmann, Winifried	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/04/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	07/31/14	12/24/14
	Primary Reviewer 2 COI signed	07/28/14	12/24/14
	Primary Reviewer 3 COI signed	07/30/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	10/15/14	12/24/14
	Primary (Advocate) Reviewer 4 Col signed  Primary Reviewer 1 critique submitted	10/28/14	12/24/14
	Primary Reviewer 2 critique submitted	10/13/14	12/24/14
	Primary Reviewer 3 critique submitted	10/27/14	12/24/14
I. Peer Review		10/21/14	12/24/14
Vieeting	Primary (Advocate) Reviewer 4 critique submitted	Edelmann, Winifried	12/24/14
	COI indicated by non-primary reviewer	YES YES	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting		12/24/14
	Peer Review Meeting	10/30/14-10/31/14	-
	Post review statements signed	10/31/14	12/24/14
	Third Party Observer Report	10/31/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
i. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
i. PIC Review	COI recused from participation	M. Kripke*	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notlfication to Oversight Committee	DATE	4
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150230 Individual Investigator Research Awards

#### THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the withe	andersigned authority, on 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150230

APPLICATION TITLE

Counteracting Turnor Evasion of Antibody Immunity by a

Novel Therapeutic Strategy

APPLICANT NAME An, Zhiqiang

ORGANIZATION The University of Texas Health Science Center at Houston

PANEL NAME Translational Cancer Research (TCR )

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/12/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
D. D. State	Date application submitted	06/24/14	12/12/14
l. Pre-Receipt	Method of submission	CARS	12/12/14
	Within receipt period	YES	12/12/14
	Appeal to submit application after CARS closed	N/A	12/12/14
	Appeal for late application submission accepted	N/A	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
	Assigned to primary reviewers	08/18/14	12/12/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/12/14
and Assignment	Primary Reviewer 1 COI signed	07/31/14	12/12/14
	Primary Reviewer 2 COI signed	09/04/14	12/12/14
	Primary Reviewer 3 COI signed	07/25/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/12/14
	Primary Reviewer 1 critique submitted	08/26/14	12/12/14
	Primary Reviewer 2 critique submitted	09/05/14	12/12/14
	Primary Reviewer 3 critique submitted	09/18/14	12/12/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
valuation	COI indicated by non-primary reviewer	NONE	12/12/14
	Preliminary Evaluation score summary sent to Chair	09/22/14	12/12/14
	Recommended for full review	YES	12/12/14
	Applicant notified of outcome	10/17/14	12/12/14
	Assigned to primary reviewers	10/03/14	12/12/14
	Primary Reviewer 1 COI signed	11/07/14	12/12/14
	Primary Reviewer 2 COI signed	10/26/14	12/12/14
	Primary Reviewer 3 COI signed	10/26/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/28/14	12/12/14
	Primary Reviewer 1 critique submitted	10/23/14	12/12/14
	Primary Reviewer 2 critique submitted	10/27/14	12/12/14
	Primary Reviewer 3 critique submitted	10/26/14	12/12/14
1. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	11/08/14	12/12/14
Meeting	COI indicated by non-primary reviewer	NONE	12/12/14
	COI recused from participation	N/A	12/12/14
	Discussed at On-Site Meeting	YES	12/12/14
	Peer Review Meeting	11/11/14	12/12/14
	Post review statements signed	11/18/14	12/12/14
	Third Party Observer Report	11/17/14	12/12/14
	Score report delivered to CSO	11/25/14	12/12/14
	Recommended for SRC Review	YES	12/12/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
recommendation	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
5. PIC Review		02/03/15	02/03/15
	PIC review meeting Recommended for grant award	YES YES	02/03/15
		DATE	02/03/13
	CEO Notification to Oversight Committee	NAME or NONE	
	COI Indicated by Oversight Committee member		
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO YES/NO	-1



# CEO AFFIDAVIT Application RP150231 Individual Investigator Research Awards

THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the unders	cioned authority on
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	<del>-</del>
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150231

APPLICATION TITLE Function of Fibroblasts and Collagen I in Pancreas Cancer

APPLICANT NAME Kalluri, Raghu

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/26/14	12/24/14
. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/12/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	08/29/14	12/24/14
	Primary Reviewer 2 COI signed	07/23/14	12/24/14
	Primary Reviewer 3 COI signed	07/28/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/29/14	12/24/14
	Primary Reviewer 2 critique submitted	08/22/14	12/24/14
	Primary Reviewer 3 critique submitted	08/25/14	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	NONE	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/03/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/10/14	12/24/14
	Primary Reviewer 1 COI signed	08/29/14	12/24/14
	Primary Reviewer 2 COI signed	07/23/14	12/24/14
	Primary Reviewer 3 COI signed	07/28/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/11/14	12/24/14
	Primary (Advocate) Reviewer 4 Col signed  Primary Reviewer 1 critique submitted	10/16/14	12/24/14
	Primary Reviewer 2 critique submitted	10/13/14	12/24/14
		10/13/14	12/24/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/27/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	Kripke, Margaret*	12/24/14
	COI indicated by non-primary reviewer	YES YES	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting		
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	_
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES OF 100 10 E	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
5. PIC Review	COI recused from participation	M. Kripke**	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	+
	COI indicated by Oversight Committee member	NAME or NONE	
7. Oversight	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	

<sup>\*</sup> Dr. Kripke is not a peer reviewer, but attends peer review meetings as an observer in her capacity as Chief Scientific Officer, as allowed in her COI waiver. Because of the professional relationship between the applicant and Dr. Fidler, out of extreme caution Dr. Kripke chose not to be present when the application was discussed.

<sup>\*\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150232 Individual Investigator Research Awards

### THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the und the	ersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150232

APPLICATION TITLE
The Role of Progesterone Receptor in Early Stage Breast

Cancer.

APPLICANT NAME Edwards, Dean

ORGANIZATION Baylor College of Medicine
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/24/14	12/24/14
1. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/12/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	10/09/14	12/24/14
	Primary Reviewer 2 COI signed	07/28/14	12/24/14
	Primary Reviewer 3 COI signed	07/28/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	09/03/14	12/24/14
	Primary Reviewer 2 critique submitted	09/02/14	12/24/14
	Primary Reviewer 3 critique submitted	08/15/14	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	Greene, Geoffrey	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/03/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/10/14	12/24/14
	Primary Reviewer 1 COI signed	10/09/14	12/24/14
	Primary Reviewer 2 COI signed	07/28/14	12/24/14
	Primary Reviewer 3 COI signed	07/23/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/15/14	12/24/14
	Primary Reviewer 1 critique submitted	10/19/14	12/24/14
	Primary Reviewer 2 critique submitted	10/14/14	12/24/14
	Primary Reviewer 3 critique submitted	10/15/14	12/24/14
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/24/14	12/24/14
Meeting	COI indicated by non-primary reviewer	Greene, Geoffrey	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
Committee Approval	Award approved by Oversight Committee	YES/NO	7
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	_



# CEO AFFIDAVIT Application RP150235 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under	•
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond
5	

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150235

APPLICATION TITLE

Role of TBK1 in Regulating Dendritic Cell Function and

Antitumor Immunity.

APPLICANT NAME Sun, Shao-Cong

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Translational Cancer Research (TCR )

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/12/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
	Date application submitted	06/23/14	12/12/14
. Pre-Receipt	Method of submission	CARS	12/12/14
	Within receipt period	YES	12/12/14
	Appeal to submit application after CARS closed	N/A	12/12/14
	Appeal for late application submission accepted	N/A	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
	Assigned to primary reviewers	08/18/14	12/12/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/12/14
and Assignment	Primary Reviewer 1 COI signed	07/25/14	12/12/14
ing Assignment	Primary Reviewer 2 COI signed	08/05/14	12/12/14
		08/01/14	12/12/14
	Primary Reviewer 3 COI signed	N/A	12/12/14
	Primary (Advocate) Reviewer 4 COI signed		12/12/14
	Primary Reviewer 1 critique submitted	08/28/14	
	Primary Reviewer 2 critique submitted	09/08/14	12/12/14
	Primary Reviewer 3 critique submitted	08/30/14	12/12/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
Evaluation	COI indicated by non-primary reviewer	NONE	12/12/14
	Preliminary Evaluation score summary sent to Chair	09/22/14	12/12/14
	Recommended for full review	YES	12/12/14
	Applicant notified of outcome	10/17/14	12/12/14
	Assigned to primary reviewers	10/03/14	12/12/14
	Primary Reviewer 1 COI signed	10/23/14	12/12/14
	Primary Reviewer 2 COI signed	10/28/14	12/12/14
	Primary Reviewer 3 COI signed	10/25/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/29/14	12/12/14
	Primary Reviewer 1 critique submitted	10/23/14	12/12/14
	Primary Reviewer 2 critique submitted	10/28/14	12/12/14
	Primary Reviewer 3 critique submitted	10/28/14	12/12/14
l. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	11/09/14	12/12/14
Meeting	COI indicated by non-primary reviewer	Cooney, Kathleen	12/12/14
	COI recused from participation	YES	12/12/14
	Discussed at On-Site Meeting	YES	12/12/14
	Peer Review Meeting	11/11/14	12/12/14
	Post review statements signed	11/18/14	12/12/14
		11/17/14	12/12/14
	Third Party Observer Report	11/25/14	12/12/14
	Score report delivered to CSO		
	Recommended for SRC Review	YES	12/12/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI Indicated by PIC member	NONE	02/03/15
i. PIC Review	COI recused from participation	M. Kripke*	02/03/15
. I IC REVIEW	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	the second
	COI recused from participation	YES/NO dr N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	4
Committee Approval	Presented to CPRIT Oversight Committee	DATE	1
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Tastierité co autaine laines le dansee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150242 Individual Investigator Research Awards

#### THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-1 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R/Roberts,

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the un	dersigned authority, on
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	
by William R. Roberts.	
Λ α Λ	
Sandra Reyes	SANDRA J. REYES
	Notary Public, State of Taxas
Notary Public, State of Texas	My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150242

Functional and Structural Characterization of a Small

APPLICATION TITLE Chemical Compound that Arrests Glioma Stem Cell Growth

with High Activity and Specificity

APPLICANT NAME Parada, Luis

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
D. D. D. L. L.	Date application submitted	06/26/14	12/24/14
L. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
_	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation		N/A	
Lydidation	COI indicated by non-primary reviewer  Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	_	
		N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/08/14	12/24/14
	Primary Reviewer 1 COI signed		12/24/14
	Primary Reviewer 2 COI signed	07/24/14	12/24/14
	Primary Reviewer 3 COI signed	07/25/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	10/14/14	12/24/14
	Primary Reviewer 2 critique submitted	10/13/14	12/24/14
4. Peer Review	Primary Reviewer 3 critique submitted	10/13/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	11/01/14	12/24/14
	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/06/14	12/24/14
	Post review statements signed	11/19/14	12/24/14
	Third Party Observer Report	11/17/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
5. PIC Review	COI recused from participation	N/A	02/03/15
o. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	1
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150245 Individual Investigator Research Awards

### THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R/Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the u the day of February by WAYNE R. ROBERTS.	ndersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas  My Commission Expires  SEPTEMBER 30, 2017  Notary without Bond

**FY** 2015 **CYCLE** 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150245

APPLICATION TITLE EGFR Arginine Methylations: Biomarkers for Cetuximab

Resistance in colon cancer

APPLICANT NAME Hung, Mien-Chie

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/19/14	12/24/14
	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
2. Recelpt, Referral, and Assignment	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/12/14	12/24/14
	Applicant notified of review panel assignment	08/11/14	12/24/14
	Primary Reviewer 1 COI signed	08/25/14	12/24/14
	Primary Reviewer 2 COI signed	07/23/14	12/24/14
	Primary Reviewer 3 COI signed	08/29/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/26/14	12/24/14
	Primary Reviewer 2 critique submitted	08/29/14	12/24/14
	Primary Reviewer 3 critique submitted	08/29/14	12/24/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	NONE	12/24/14
valuation	Preliminary Evaluation score summary sent to Chair	09/03/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
		09/10/14	12/24/14
	Assigned to primary reviewers	08/25/14	12/24/14
	Primary Reviewer 1 COI signed	07/23/14	12/24/14
	Primary Reviewer 2 COI signed	08/29/14	12/24/14
	Primary Reviewer 3 COI signed		
	Primary (Advocate) Reviewer 4 COI signed	09/11/14	12/24/14
	Primary Reviewer 1 critique submitted	10/15/14	12/24/14
	Primary Reviewer 2 critique submitted	10/13/14	12/24/14
. Peer Review	Primary Reviewer 3 critique submitted	10/16/14	12/24/14
/leeting	Primary (Advocate) Reviewer 4 critique submitted	10/27/14	12/24/14
	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
DIC Berden	COI recused from participation	M. Kripke*	02/03/15
. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150277 Individual Investigator Research Awards

### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R/Roberts,

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150277

APPLICATION TITLE Vertical Vargeting of the B Cell Receptor in Leukemia and

APPLICANT NAME Aguiar, Ricardo

ORGANIZATION The University of Texas Health Science Center at San Antonio

PANEL NAME Translational Cancer Research (TCR)

Compliance Requirement	information	Attestation Dat
RFA published in Texas Register	05/16/14	12/12/14
CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
Date application submitted	06/24/14	12/12/14
Method of submission	CARS	12/12/14
Within receipt period	YES	12/12/14
Appeal to submit application after CARS closed	N/A	12/12/14
Appeal for late application submission accepted	N/A	12/12/14
Administrative review notification	N/A	12/12/14
Donation(s) made to CPRIT/foundation	NO	12/12/14
Assigned to primary reviewers	N/A	12/12/14
Applicant notified of review panel assignment	08/11/14	12/12/14
	N/A	12/12/14
	N/A	12/12/14
	N/A	12/12/14
		12/12/14
		12/12/14
		12/12/14
		12/12/14
		12/12/14
		12/12/14
		12/12/14
		_
		12/12/14
		12/12/14
		12/12/14
		12/12/14
		12/12/14
		12/12/14
Primary (Advocate) Reviewer 4 COI signed		12/12/14
Primary Reviewer 1 critique submitted	10/26/14	12/12/14
Primary Reviewer 2 critique submitted	11/03/14	12/12/14
Primary Reviewer 3 critique submitted	10/28/14	12/12/14
Primary (Advocate) Reviewer 4 critique submitted	11/09/14	12/12/14
COI indicated by non-primary reviewer	NONE	12/12/14
COI recused from participation	N/A	12/12/14
Discussed at On-Site Meeting	YES	12/12/14
Peer Review Meeting	11/11/14	12/12/14
Post review statements signed	11/18/14	12/12/14
Third Party Observer Report	11/17/14	12/12/14
Score report delivered to CSO	11/25/14	12/12/14
Recommended for SRC Review	YES	12/12/14
	NONE	01/13/15
		01/13/15
		01/13/15
-		01/13/15
		01/13/15
-		01/13/15
		02/03/15
		02/03/15
		02/03/15
		02/03/15
		02/03/13
		-
	_	
Award approved by Oversight Committee	YES/NO	
Authority to advance funds requested	YES/NO	
	RFA published in Texas Register CPRIT Application Receipt System (CARS) opened CPRIT Application Receipt System (CARS) closed Date application submitted Method of submission Within receipt period Appeal to submit application after CARS closed Appeal for late application submission accepted Administrative review notification Donation(s) made to CPRIT/foundation Assigned to primary reviewers Applicant notified of review panel assignment Primary Reviewer 1 COI signed Primary Reviewer 2 COI signed Primary Reviewer 2 COI signed Primary Reviewer 1 critique submitted Primary Reviewer 1 critique submitted Primary Reviewer 2 critique submitted Primary Reviewer 3 critique submitted Primary Reviewer 3 critique submitted COI indicated by non-primary reviewer Preliminary Evaluation score summary sent to Chair Recommended for full review Applicant notified of outcome Assigned to primary reviewers Primary Reviewer 1 COI signed Primary Reviewer 1 COI signed Primary Reviewer 2 COI signed Primary Reviewer 3 COI signed Primary Reviewer 3 coli signed Primary Reviewer 3 coli signed Primary Reviewer 3 critique submitted Primary Reviewer 3 critique submitted Primary Reviewer 1 critique submitted Primary Reviewer 3 critique submitted Primary Reviewer 4 critique submitted Primary Reviewer 5 critique submitted Primary Reviewer 6 critique submitted Primary Reviewer 7 critique submitted Primary Reviewer 8 critique submitted Primary Reviewer 9 critique submitted Primary Reviewer 9 critique submitted Primary Reviewer 1 critique submitted Primary Reviewer 5 critique submitted Primary Reviewer 6 critique submitted Primary Reviewer 7 critique submitted Primary Reviewer 8 critique submitted Primary Reviewer 9 critique 9 critique 9 critique 9 crit	RFA published in Texas Register  O5/16/14  CPRIT Application Receipt System (CARS) opened  O5/15/14  Date application submitted  O6/24/14  Method of submission  CARS  Within receipt period  Appeal to submit application after CARS closed  Appeal for late application submission accepted  N/A  Donation(s) made to CPRIT/foundation  NO  Assigned to primary reviewers  Applicant notified of review panel assignment  Primary Reviewer 1 COI signed  N/A  Primary Reviewer 2 COI signed  N/A  Primary Reviewer 3 COI signed  N/A  Primary Reviewer 2 critique submitted  N/A  Primary Reviewer 3 critique submitted  N/A  Recommended for full review  N/A  Assigned to primary reviewers  10/03/14  Primary Reviewer 2 COI signed  10/26/14  Primary Reviewer 2 COI signed  10/26/14  Primary Reviewer 3 COI signed  10/26/14  Primary Reviewer 4 COI signed  10/26/14  Primary Reviewer 5 COI signed  10/26/14  Primary Reviewer 6 COI signed  10/26/14  Primary Reviewer 7 COI signed  10/26/14  Primary Reviewer 1



# CEO AFFIDAVIT Application RP150282 Individual Investigator Research Awards

### THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the u	undersigned authority, on
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Trotaly Lable, State of Lenas	Notary without Bond

m

.

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150282

APPLICATION TITLE Mechanisms of De Novo and Acquired Resistance to Therapeutic Treatment of Bone-Metastatic Prostate Cancer

APPLICANT NAME Gallick, Gary

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/19/14	12/24/14
1. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/12/14	12/24/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
nd Assignment	Primary Reviewer 1 COI signed	08/22/14	12/24/14
ing wasignment		07/31/14	12/24/14
	Primary Reviewer 2 COI signed	07/25/14	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed		12/24/14
	Primary Reviewer 1 critique submitted	08/22/14	-
	Primary Reviewer 2 critique submitted	08/26/14	12/24/14
	Primary Reviewer 3 critique submitted	08/28/14	12/24/14
J. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	NONE	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/03/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/10/14	12/24/14
	Primary Reviewer 1 COI signed	08/22/14	12/24/14
	Primary Reviewer 2 COI signed	07/31/14	12/24/14
	Primary Reviewer 3 COI signed	07/25/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/15/14	12/24/14
	Primary Reviewer 1 critique submitted	10/15/14	12/24/14
	Primary Reviewer 2 critique submitted	10/16/14	12/24/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/15/14	12/24/14
Vieeting	Primary (Advocate) Reviewer 4 critique submitted	10/24/14	12/24/14
viccing	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
4	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	M. Kripke*	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight Committee Approval		YES/NO OF N/A	
	Donation(s) made to CPRIT/foundation		
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150292 Individual Investigator Research Awards

#### THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-2 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

·	
State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the under	•
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes	SANDRA J. REYES  Notary Public, State of Texas  My Commission Expires
Notary Public, State of Texas	My Commission Expires SEPTEMBER 30, 2017
Trotaly 1 dolle, but of Texas	
	Notary without Bond

Ē

CYCLE 1 PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

RP150292 APPLICATION ID

Broad Shortening of 3' UTRs in Human Cancers: Methods, APPLICATION TITLE

Target Genes and Functional Consequences

APPLICANT NAME Li, Wei

ORGANIZATION Baylor College of Medicine Basic Cancer Research-2 (BCR-2) PANEL NAME

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/24/14	12/24/14
l. Pre-Recelpt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/11/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	07/30/14	12/24/14
ina rosigiimon	Primary Reviewer 2 COI signed	07/23/14	12/24/14
	Primary Reviewer 3 COI signed	08/05/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary (Advocate) Neviewer 4 Consigned  Primary Reviewer 1 critique submitted	09/01/14	12/24/14
	Primary Reviewer 2 critique submitted	08/31/14	12/24/14
		08/29/14	12/24/14
	Primary Reviewer 3 critique submitted		12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A NONE	12/24/14
Evaluation	COI indicated by non-primary reviewer		12/24/14
	Preliminary Evaluation score summary sent to Chair	09/04/14	
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	07/30/14	12/24/14
	Primary Reviewer 2 COI signed	07/23/14	12/24/14
	Primary Reviewer 3 COI signed	08/05/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/11/14	12/24/14
	Primary Reviewer 1 critique submitted	10/18/14	12/24/14
	Primary Reviewer 2 critique submitted	10/17/14	12/24/14
4. Peer Review	Primary Reviewer 3 critique submitted	10/20/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/27/14	12/24/14
	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/30/14-10/31/14	12/24/14
	Post review statements signed	10/31/14	12/24/14
	Third Party Observer Report	10/31/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
committee Approvat	Award approved by Oversight Committee	YES/NO	
		YES/NO	
	Authority to advance funds requested	TES/NO	



## CEO AFFIDAVIT Application RP150293 Individual Investigator Research Awards

## THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under	-
the 4th day of February by WAYNE R. ROBERTS.	, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
1 10 111 1 10 110 110 110 110 110 110 1	Notary without Bond
E	

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150293

APPLICATION TITLE Identification of Clinically Relevant Targets for

Radiosensitization

APPLICANT NAME Skinner, Heath

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compilance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
., Pre-Receipt	Date application submitted	06/23/14	12/24/14
1. Fre-Neceipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/07/14	12/24/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
ind Assignment	Primary Reviewer 1 COI signed	07/24/14	12/24/14
	Primary Reviewer 2 COI signed	07/27/14	12/24/14
	Primary Reviewer 3 COI signed	07/30/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/29/14	12/24/14
	Primary Reviewer 2 critique submitted	08/24/14	12/24/14
	Primary Reviewer 3 critique submitted	08/25/14	12/24/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	NONE	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/04/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	07/24/14	12/24/14
	Primary Reviewer 2 COI signed	07/27/14	12/24/14
	Primary Reviewer 3 COI signed	07/30/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	09/29/14	12/24/14
	Primary Reviewer 2 critique submitted	10/16/14	12/24/14
	Primary Reviewer 3 critique submitted	10/16/14	12/24/14
I. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/25/14	12/24/14
Vieeting	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/27/14	12/24/14
	Post review statements signed	10/27/14	12/24/14
	Third Party Observer Report	10/27/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
i. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	M. Kripke*	02/03/15
. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	The state of the s
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	The state of the s	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150316 Individual Investigator Research Awards

THE STATE OF TEXAS

### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

2015 FΥ CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

T-Cell Activating Immunotherapy for Indolent B-cell

APPLICATION ID RP150316

APPLICATION TITLE Malignancies

APPLICANT NAME Neelapu, Sattva

The University of Texas M. D. Anderson Cancer Center ORGANIZATION

PANEL NAME Translational Cancer Research (TCR )

Entegory	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/12/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
Due Descript	Date application submitted	06/23/14	12/12/14
L. Pre-Receipt	Method of submission	CARS	12/12/14
	Within receipt period	YES	12/12/14
	Appeal to submit application after CARS closed	N/A	12/12/14
	Appeal for late application submission accepted	N/A	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
	Assigned to primary reviewers	08/18/14	12/12/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/12/14
and Assignment	Primary Reviewer 1 COI signed	08/08/14	12/12/14
	Primary Reviewer 2 COI signed	08/26/14	12/12/14
	Primary Reviewer 3 COI signed	08/03/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/12/14
_	Primary Reviewer 1 critique submitted	09/17/14	12/12/14
	Primary Reviewer 2 critique submitted	09/06/14	12/12/14
	Primary Reviewer 3 critique submitted	09/22/14	12/12/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
Evaluation	COI Indicated by non-primary reviewer	NONE	12/12/14
	Preliminary Evaluation score summary sent to Chair	09/22/14	12/12/14
	Recommended for full review	YES	12/12/14
	Applicant notified of outcome	10/17/14	12/12/14
	Assigned to primary reviewers	10/03/14	12/12/14
		11/09/14	12/12/14
	Primary Reviewer 1 COI signed	10/25/14	12/12/14
	Primary Reviewer 2 COI signed	11/02/14	12/12/14
	Primary Reviewer 3 COI signed		12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/28/14	_
	Primary Reviewer 1 critique submitted	11/09/14	12/12/14
	Primary Reviewer 2 critique submitted	10/28/14	12/12/14
1. Peer Review	Primary Reviewer 3 critique submitted	11/03/14	12/12/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	11/08/14	12/12/14
	COI indicated by non-primary reviewer	NONE	12/12/14
	COI recused from participation	N/A	12/12/14
	Discussed at On-Site Meeting	YES	12/12/14
	Peer Review Meeting	11/11/14	12/12/14
	Post review statements signed	11/18/14	12/12/14
	Third Party Observer Report	11/17/14	12/12/14
	Score report delivered to CSO	11/25/14	12/12/14
	Recommended for SRC Review	YES	12/12/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
e proposition	COI recused from participation	M. Kripke*	02/03/15
6. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
		YES/NO or N/A	
	COI recused from participation		
7. Oversight		YES/NO	
7. Oversight Committee Approval	Donation(s) made to CPRIT/foundation	YES/NO DATE	
7. Oversight Committee Approval	Donation(s) made to CPRIT/foundation Presented to CPRIT Oversight Committee	DATE	
	Donation(s) made to CPRIT/foundation	_	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting, Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



## Cancer Prevention & Research Institute of Texas

# CEO AFFIDAVIT Application RP150319 Individual Investigator Research Awards

### THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-1 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the under the day of	rsigned authority, on, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150319

APPLICATION TITLE Leukemia Inhibitory Factor Receptor Signaling and Function in Cancer

APPLICANT NAME Ma, Li

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/19/14	12/24/14
. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/05/14	12/24/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
nd Assignment	Primary Reviewer 1 COI signed	07/26/14	12/24/14
ŭ	Primary Reviewer 2 COI signed	07/25/14	12/24/14
	Primary Reviewer 3 COI signed	08/05/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/29/14	12/24/14
	Primary Reviewer 2 critique submitted	08/22/14	12/24/14
	Primary Reviewer 3 critique submitted	08/23/14	12/24/14
I. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	NONE	12/24/14
valuation	Preliminary Evaluation score summary sent to Chair	09/02/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
		09/08/14	12/24/14
	Assigned to primary reviewers	07/26/14	12/24/14
	Primary Reviewer 1 COI signed		
	Primary Reviewer 2 COI signed	07/25/14	12/24/14
	Primary Reviewer 3 COI signed	08/05/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	10/15/14	12/24/14
	Primary Reviewer 2 critique submitted	10/13/14	12/24/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/13/14	12/24/14
Vieeting	Primary (Advocate) Reviewer 4 critique submitted	11/01/14	12/24/14
	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/06/14	12/24/14
	Post review statements signed	11/19/14	12/24/14
	Third Party Observer Report	11/17/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
i. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
DIC Davidson	COI recused from participation	M. Kripke*	02/03/15
. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications.
The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



## Cancer Prevention & Research Institute of Texas

# CEO AFFIDAVIT Application RP150346 Individual Investigator Research Awards

### THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

ersigned authority, on, 2015,
SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150346

APPLICATION TITLE Targeting Twist1 for Prevention and Treatment of Non-

Melanoma Skin Cancer
APPLICANT NAME
DiGiovanni, John

ORGANIZATION The University of Texas at Austin
PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/23/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/23/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/23/14
	Date application submitted	06/25/14	12/23/14
L. Pre-Receipt	Method of submission	CARS	12/23/14
	Within receipt period	YES	12/23/14
	Appeal to submit application after CARS closed	N/A	12/23/14
	Appeal for late application submission accepted	N/A	12/23/14
	Administrative review notification	N/A	12/23/14
	Donation(s) made to CPRIT/foundation	NO	12/23/14
	Assigned to primary reviewers	08/05/14	12/23/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/23/14
and Assignment	Primary Reviewer 1 COI signed	08/15/14	12/23/14
Ü	Primary Reviewer 2 COI signed	07/23/14	12/23/14
	Primary Reviewer 3 COI signed	07/30/14	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/23/14
	Primary Reviewer 1 critique submitted	08/20/14	12/23/14
	Primary Reviewer 2 critique submitted	08/13/14	12/23/14
	Primary Reviewer 3 critique submitted	08/20/14	12/23/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/23/14
S. Preliminary Evaluation	COI indicated by non-primary reviewer	NONE	12/23/14
- valuation	Preliminary Evaluation score summary sent to Chair	08/28/14	12/23/14
		YES	12/23/14
	Recommended for full review  Applicant notified of outcome	10/17/14	12/23/14
		08/29/14	12/23/14
	Assigned to primary reviewers	08/15/14	12/23/14
	Primary Reviewer 1 COI signed	07/23/14	12/23/14
	Primary Reviewer 2 COI signed		12/23/14
	Primary Reviewer 3 COI signed	07/30/14	
	Primary (Advocate) Reviewer 4 COI signed	08/31/14	12/23/14
	Primary Reviewer 1 critique submitted	10/05/14	12/23/14
	Primary Reviewer 2 critique submitted	10/01/14	12/23/14
1. Peer Review	Primary Reviewer 3 critique submitted	10/10/14	12/23/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/22/14	12/23/14
	COI indicated by non-primary reviewer	NONE	12/23/14
	COI recused from participation	N/A	12/23/14
	Discussed at On-Site Meeting	YES	12/23/14
	Peer Review Meeting	10/28/14	12/23/14
	Post review statements signed	10/28/14	12/23/14
	Third Party Observer Report	11/17/14	12/23/14
	Score report delivered to CSO	11/25/14	12/23/14
	Recommended for SRC Review	YES	12/23/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
6. PIC Review	COI recused from participation	N/A	02/03/15
o. FIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150356 Individual Investigator Research Awards

#### THE STATE OF TEXAS

## COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas	
County of Travis	
County of Travis	
SWORN to and SUBSCRIBED before me, the under	ersigned authority, on
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	
Α	
	SANDRA J. REYES
Sandra Reyes	Notary Public, State of Taxes
Notary Public, State of Texas	My Commission Expires SEPTEMBER 30, 2017
•	
	Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150356

APPLICATION TITLE Peripheral Nerve Tolerance to Single-Session Stereotactic

Irradiation

APPLICANT NAME Medin, Paul

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Reguliement	Information	Attestation Dat
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/27/14	12/24/14
1. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	NO	12/24/14
	Appeal to submit application after CARS closed	06/26/14	12/24/14
	Appeal for late application submission accepted	YES	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/07/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	07/24/14	12/24/14
_	Primary Reviewer 2 COI signed	07/25/14	12/24/14
	Primary Reviewer 3 COI signed	09/02/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/29/14	12/24/14
	Primary Reviewer 2 critique submitted	08/21/14	12/24/14
	Primary Reviewer 3 critique submitted	09/02/14	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	Wu, Anna	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/04/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	07/24/14	12/24/14
	Primary Reviewer 2 COI signed	07/25/14	12/24/14
	Primary Reviewer 3 COI signed	09/02/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	10/03/14	12/24/14
	Primary Reviewer 2 critique submitted	10/09/14	12/24/14
	Primary Reviewer 3 critique submitted	10/17/14	12/24/14
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/24/14	12/24/14
Meeting	COI indicated by non-primary reviewer	Wu, Anna	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/27/14	12/24/14
	Post review statements signed	10/27/14	12/24/14
	Third Party Observer Report	10/27/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
6. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7 Overelah	Donation(s) made to CPRIT/foundation	YES/NO	
7. Oversight Committee Approval	Presented to CPRIT Oversight Committee	DATE	
Committee Approval	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Authority to advance fullus requested	YES/NO	



# CEO AFFIDAVIT Application RP150386 Individual Investigator Research Awards

## THE STATE OF TEXAS

## **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Clinical and Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the unthe day of	dersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150386

A Phase I Trial of Stereotactic HYpofractionateD RadioAblative (HYDRA) Treatment of Advanced Laryngeal

APPLICATION TITLE RadioAblative (HYDRA) Treatment of Advanced Cancer

APPLICANT NAME Schwartz, David

ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Clinical and Translational Cancer Research (CTCR)

Entegory	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	05/16/14	12/12/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
	Date application submitted	06/27/14	12/12/14
	Method of submission	CARS	12/12/14
	Within receipt period	NO	12/12/14
	Appeal to submit application after CARS closed	06/26/14	12/12/14
	Appeal for late application submission accepted	YES	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
	Assigned to primary reviewers	08/18/14	12/12/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/12/14
nd Assignment	Primary Reviewer 1 COI signed	09/04/14	12/12/14
	Primary Reviewer 2 COI signed	08/19/14	12/12/14
	Primary Reviewer 3 COI signed	08/02/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/12/14
	Primary Reviewer 1 critique submitted	09/05/14	12/12/14
	Primary Reviewer 2 critique submitted	08/30/14	12/12/14
	Primary Reviewer 3 critique submitted	08/27/14	12/12/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
valuation	COI indicated by non-primary reviewer	NONE	12/12/14
	Preliminary Evaluation score summary sent to Chair	09/08/14	12/12/14
	Recommended for full review	YES	12/12/14
	Applicant notified of outcome	10/17/14	12/12/14
	Assigned to primary reviewers	09/24/14	12/12/14
	Primary Reviewer 1 COI signed	11/08/14	12/12/14
	Primary Reviewer 2 COI signed	11/07/14	12/12/14
	Primary Reviewer 3 COI signed	11/07/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/30/14	12/12/14
	Primary Reviewer 1 critique submitted	10/20/14	12/12/14
	Primary Reviewer 2 critique submitted	10/12/14	12/12/14
	Primary Reviewer 3 critique submitted	10/21/14	12/12/14
I. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	11/07/14	12/12/14
Vieeting	COI indicated by non-primary reviewer	NONE	12/12/14
	COI recused from participation	N/A	12/12/14
	Discussed at On-Site Meeting	YES	12/12/14
	Peer Review Meeting	11/11/14	12/12/14
	Post review statements signed	11/18/14	12/12/14
	Third Party Observer Report	11/17/14	12/12/14
	Score report delivered to CSO	11/25/14	12/12/14
	Recommended for SRC Review	YES	12/12/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation		01/07/15	01/13/15
tecommendation	Third Party Observer Report Recommended for grant award	YES	01/13/15
	SRC Chaîr Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
		YES	02/03/15
	Recommended for grant award	DATE	02/03/13
	CEO Notification to Oversight Committee		
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	4
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	-
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested  Advance authority approved by Oversight Committee	YES/NO YES/NO	



# CEO AFFIDAVIT Application RP150403 Individual Investigator Research Awards

## THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the under	ersigned authority, on
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	
by WATRE R. ROBERTS.	
\ (X) \\	SANDRA J. REYES
Sandra Reyes	Notary Public, State of Texas My Cornmission Expires SEPTEMBER 30, 2017
I v	SEPTEMBER 30, 2017
Notary Public, State of Texas	Aleksanish and Donald
	Notary without Bond

.

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150403

APPLICATION TITLE
On the Role of DEAR1 in the Regulation of Cell Polarity and

Progression from DCIS to Invasive Breast Cancer

APPLICANT NAME Killary, Ann

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Biology (CB)

Catagory	Compliance Regulrement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/25/14	12/24/14
	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/12/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	07/23/14	12/24/14
· ·	Primary Reviewer 2 COI signed	07/25/14	12/24/14
	Primary Reviewer 3 COI signed	07/23/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/28/14	12/24/14
	Primary Reviewer 2 critique submitted	08/29/14	12/24/14
	Primary Reviewer 3 critique submitted	08/29/14	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	NONE	12/24/14
-varaution	Preliminary Evaluation score summary sent to Chair	09/03/14	12/24/14
	Recommended for full review	YES YES	12/24/14
			12/24/14
	Applicant notified of outcome	10/17/14 09/10/14	12/24/14
	Assigned to primary reviewers	07/23/14	12/24/14
	Primary Reviewer 1 COI signed		12/24/14
	Primary Reviewer 2 COI signed	07/25/14	
	Primary Reviewer 3 COI signed	07/23/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/11/14	12/24/14
	Primary Reviewer 1 critique submitted	10/15/14	12/24/14
	Primary Reviewer 2 critique submitted	10/15/14	12/24/14
4. Peer Review	Primary Reviewer 3 critique submitted	10/15/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/29/14	12/24/14
	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI Indicated by PIC member	NONE	02/03/15
DIC Davidavi	COI recused from participation	M. Kripke*	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
Committee Approval	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	The state of the s		

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150405 Individual Investigator Research Awards

### THE STATE OF TEXAS

## **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

dersigned authority, on
, 2015,
SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150405

APPLICATION TITLE Tumor Cell Epithelial-Mesenchymal Transition in Regulating Immunosuppression and Metastasis in Lung Cancer

APPLICANT NAME Gibbons, Don

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Translational Cancer Research (TCR )

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/12/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
1. Pre-Receipt	Date application submitted	06/26/14	12/12/14
	Method of submission	CARS	12/12/14
	Within receipt period	YES	12/12/14
	Appeal to submit application after CARS closed	N/A	12/12/14
	Appeal for late application submission accepted	N/A	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
	Assigned to primary reviewers	08/18/14	12/12/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/12/14
and Assignment	Primary Reviewer 1 COI signed	07/25/14	12/12/14
	Primary Reviewer 2 COI signed	08/05/14	12/12/14
	Primary Reviewer 3 COI signed	09/04/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/12/14
	Primary Reviewer 1 critique submitted	09/06/14	12/12/14
	Primary Reviewer 2 critique submitted	09/08/14	12/12/14
	Primary Reviewer 3 critique submitted	09/06/14	12/12/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
valuation	COI indicated by non-primary reviewer	NONE	12/12/14
	Preliminary Evaluation score summary sent to Chair	09/22/14	12/12/14
	Recommended for full review	YES	12/12/14
	Applicant notified of outcome	10/17/14	12/12/14
	Assigned to primary reviewers	10/03/14	12/12/14
	Primary Reviewer 1 COI signed	10/28/14	12/12/14
	Primary Reviewer 2 COI signed	10/28/14	12/12/14
	Primary Reviewer 3 COI signed	10/26/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/28/14	12/12/14
	Primary Reviewer 1 critique submitted	10/28/14	12/12/14
	Primary Reviewer 2 critique submitted	10/28/14	12/12/14
	Primary Reviewer 3 critique submitted	10/26/14	12/12/14
. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	11/08/14	12/12/14
/leeting	COI indicated by non-primary reviewer	NONE	12/12/14
	COI recused from participation	N/A	12/12/14
	Discussed at On-Site Meeting	YES	12/12/14
	Peer Review Meeting	11/11/14	12/12/14
	Post review statements signed	11/18/14	12/12/14
	Third Party Observer Report	11/17/14	12/12/14
	Score report delivered to CSO	11/25/14	12/12/14
	Recommended for SRC Review	YES	12/12/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
. Final SRC	SRC Meeting	01/06/15	01/13/15
ecommendation	Third Party Observer Report	01/07/15	01/13/15
ccommendation	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	
	COI recused from participation		02/03/15
. PIC Review		M. Kripke*	02/03/15
	PIC review meeting	02/03/15	
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
ommittee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150408 Individual Investigator Research Awards

## THE STATE OF TEXAS

### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Basic Cancer Research-1 panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the understhe	signed authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REVES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150408

APPLICATION TITLE Cellular Mechanisms of Chemotherapy-Induced Peripheral

APPLICATION TITLE
Neuropathy
APPLICANT NAME
Stockand, James

ORGANIZATION The University of Texas Health Science Center at San Antonio

PANEL NAME Basic Cancer Research-1 (BCR-1)

Cutegory	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
1 Due Decelot	Date application submitted	06/26/14	12/24/14
1. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/05/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	08/14/14	12/24/14
	Primary Reviewer 2 COI signed	07/23/14	12/24/14
	Primary Reviewer 3 COI signed	08/06/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/23/14	12/24/14
	Primary Reviewer 2 critique submitted	08/05/14	12/24/14
	Primary Reviewer 3 critique submitted	08/06/14	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	NONE	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/02/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/08/14	12/24/14
	Primary Reviewer 1 COI signed	08/14/14	12/24/14
	Primary Reviewer 2 COI signed	08/11/14	12/24/14
	Primary Reviewer 3 COI signed	08/06/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	10/15/14	12/24/14
	Primary Reviewer 2 critique submitted	10/12/14	12/24/14
4. Peer Review	Primary Reviewer 3 critique submitted	10/19/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	11/02/14	12/24/14
weeting	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/06/14	12/24/14
	Post review statements signed	11/19/14	12/24/14
	Third Party Observer Report	11/17/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
6. PIC Review	COI recused from participation	N/A	02/03/15
or i remember	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150440 Individual Investigator Research Awards

## THE STATE OF TEXAS

## **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the undersigned authority, on the	015,
Sandra Reyes  Notary Public, State of Texas  Sandra Public, State of Texas	1
Notary Public, State of Texas  Notary Public, State of Texas  My Commission Expires SEPTEMBER 30, 2017	
Notary without Bond	-4

#### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2015 CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150440

Effects of Hormonal Therapy on SubclonalEevolution of Breast Tumors with ESR1 Mutations APPLICATION TITLE

APPLICANT NAME Fuqua, Suzanne ORGANIZATION Baylor College of Medicine PANEL NAME Cancer Biology (CB)

Caregory	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
L. Pre-Receipt	Date application submitted	06/23/14	12/24/14
	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted  Administrative review notification	N/A N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/12/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	07/31/14	12/24/14
	Primary Reviewer 2 COI signed	10/09/14	12/24/14
	Primary Reviewer 3 COI signed	07/30/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/29/14	12/24/14
	Primary Reviewer 2 critique submitted	08/31/14	12/24/14
	Primary Reviewer 3 critique submitted	09/01/14	12/24/14
	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
	COI indicated by non-primary reviewer	Fearon, Eric	12/24/14
3. Preliminary	COI indicated by non-primary reviewer	Greene, Geoffrey	12/24/14
Evaluation	COI indicated by non-primary reviewer	Knudsen, Karen	12/24/14
	COI indicated by non-primary reviewer	Lawlor, Elizabeth	12/24/14
	COI indicated by non-primary reviewer	Roberts, Charles	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/03/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/10/14	12/24/14
	Primary Reviewer 1 COI signed	07/31/14	12/24/14
	Primary Reviewer 2 COI signed	10/09/14	12/24/14
	Primary Reviewer 3 COI signed	07/30/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/15/14 10/16/14	12/24/14
	Primary Reviewer 1 critique submitted	10/19/14	12/24/14
	Primary Reviewer 2 critique submitted Primary Reviewer 3 critique submitted	10/15/14	12/24/14
	Primary (Advocate) Reviewer 4 critique submitted	10/29/14	12/24/14
	COI indicated by non-primary reviewer	Fearon, Eric	12/24/14
	COI recused from participation	YES	12/24/14
4. Peer Review	COI indicated by non-primary reviewer	Greene, Geoffrey	12/24/14
Meeting	COI recused from participation	YES	12/24/14
	COI indicated by non-primary reviewer	Lawlor, Elizabeth	12/24/14
	COI recused from participation	YES	12/24/14
	COI indicated by non-primary reviewer	Roberts, Charles	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member COI recused from participation	NONE N/A	02/03/15
6. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	VES YES	02/03/15
	CEO Notification to Oversight Committee	DATE	02,03113
	COI Indicated by Oversight Committee	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	VES/NO	



# CEO AFFIDAVIT Application RP150451 Individual Investigator Research Awards

#### THE STATE OF TEXAS

## **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

SWORN to and SUBSCRIB		•
the day of by WAYNE R. ROBERTS.	February	, 2015,
Sandra Reyes Notary Public, State of Texas		SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

#### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2015

CYCLE

1

PROGRAM

Research AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID

RP150451

APPLICATION TITLE

SRC-2 driven "Metabolic Switch" in Metastatic Prostate Cancer- Prognostic and Therapeutic Implications

APPLICANT NAME

Sreekumar, Arun

Baylor College of Medicine

ORGANIZATION PANEL NAME

Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/25/14	12/24/14
I. Pre-neceipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/12/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	07/25/14	12/24/14
	Primary Reviewer 2 COI signed	07/28/14	12/24/14
	Primary Reviewer 3 COI signed	07/30/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/28/14	12/24/14
	Primary Reviewer 2 critique submitted	08/25/14	12/24/14
	Primary Reviewer 3 critique submitted	08/31/14	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	Costello, Joseph	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/03/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/10/14	12/24/14
	Primary Reviewer 1 COI signed	07/25/14	12/24/14
	Primary Reviewer 2 COI signed	07/28/14	12/24/14
	Primary Reviewer 3 COI signed	07/30/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/15/14	12/24/14
	Primary Reviewer 1 critique submitted	10/15/14	12/24/14
	Primary Reviewer 2 critique submitted	10/13/14	12/24/14
	Primary Reviewer 3 critique submitted	10/20/14	12/24/14
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/30/14	12/24/14
Meeting	COI indicated by non-primary reviewer	Costello, Joseph	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
ACCOMMICTION OF	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
6. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	02/00/15
	COI Indicated by Oversight Committee	NAME or NONE	
	COI recused from participation		_
7 Ourselah		YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE VEC (NO	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150454 Individual Investigator Research Awards

## THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Noberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the understhe	signed authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Taxas My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150454

APPLICATION TITLE Tumor Suppression Through the cGAMP/STING Pathway

APPLICANT NAME Li, Pingwei

ORGANIZATION Texas A&M University

PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/12/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
	Date application submitted	06/24/14	12/12/14
L. Pre-Receipt	Method of submission	CARS	12/12/14
	Within receipt period	YES	12/12/14
	Appeal to submit application after CARS closed	N/A	12/12/14
	Appeal for late application submission accepted	N/A	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
	Assigned to primary reviewers	08/18/14	12/12/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/12/14
and Assignment	Primary Reviewer 1 COI signed	08/05/14	12/12/14
	Primary Reviewer 2 COI signed	07/25/14	12/12/14
	Primary Reviewer 3 COI signed	09/08/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/12/14
	Primary Reviewer 1 critique submitted	09/12/14	12/12/14
	Primary Reviewer 2 critique submitted	09/18/14	12/12/14
	Primary Reviewer 3 critique submitted	09/09/14	12/12/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
Evaluation	COI indicated by non-primary reviewer	NONE	12/12/14
- Variation	Preliminary Evaluation score summary sent to Chair	09/22/14	12/12/14
	Recommended for full review	YES	12/12/14
	Applicant notified of outcome	10/17/14	12/12/14
		10/03/14	12/12/14
	Assigned to primary reviewers	10/23/14	12/12/14
	Primary Reviewer 1 COI signed	10/25/14	12/12/14
	Primary Reviewer 2 COI signed		_
	Primary Reviewer 3 COI signed	10/25/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/29/14	12/12/14
	Primary Reviewer 1 critique submitted	11/02/14	12/12/14
	Primary Reviewer 2 critique submitted	10/28/14	12/12/14
1. Peer Review	Primary Reviewer 3 critique submitted	10/28/14	12/12/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	11/09/14	12/12/14
	COI indicated by non-primary reviewer	NONE	12/12/14
	COI recused from participation	N/A	12/12/14
	Discussed at On-Site Meeting	YES	12/12/14
	Peer Review Meeting	11/11/14	12/12/14
	Post review statements signed	11/18/14	12/12/14
	Third Party Observer Report	11/17/14	12/12/14
	Score report delivered to CSO	11/25/14	12/12/14
	Recommended for SRC Review	YES	12/12/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
5. PIC Review	COI recused from participation	N/A	02/03/15
A I IC NEVICW	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150456 Individual Investigator Research Awards

## THE STATE OF TEXAS

## **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the und	•
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond
	Tremity Tribute Bolton

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150456

APPLICATION TITLE

TAMU-UT Southwestern Partnership for Breast Imaging

and Spectroscopy at 7 Tesla

APPLICANT NAME Malloy, Craig

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/27/14	12/24/14
	Method of submission	CARS	12/24/14
	Within receipt period	NO	12/24/14
	Appeal to submit application after CARS closed	06/26/14	12/24/14
	Appeal for late application submission accepted	YES	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	08/26/14	12/24/14
	Primary Reviewer 2 COI signed	10/12/14	12/24/14
	Primary Reviewer 3 COI signed	08/07/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	10/14/14	12/24/14
	Primary Reviewer 2 critique submitted	10/17/14	12/24/14
	Primary Reviewer 3 critique submitted	10/13/14	12/24/14
l. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/24/14	12/24/14
Meeting	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/27/14	12/24/14
	Post review statements signed	10/27/14	12/24/14
	Third Party Observer Report	10/27/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
Clast CDC	SRC Meeting	01/06/15	01/13/15
lecommendation		01/07/15	01/13/15
ecommendation	Third Party Observer Report Recommended for grant award	YES	
	SRC Chair Notification to PIC and OC		01/13/15
	COI indicated by PIC member	01/08/15	01/13/15
		NONE	02/03/15
. PIC Review	COI recused from participation	N/A	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	



## CEO AFFIDAVIT Application RP150485 Individual Investigator Research Awards

#### THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

State of Texas County of Travis		
sworn to and subscribed the _4 th _ day of _ by WAYNE R. ROBERTS.	before me, the under February	rsigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas		SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

×

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150485

APPLICANT NAME

APPLICATION TITLE

Translating Online Adaptive Radiotherapy from Lab to

Clinical Practice Jiang, Steve

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Imaging Technology and Informatics (ITI)

Catagory	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
1. Pre-Recelpt	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/27/14	12/24/14
i. Fre-Neceipt	Method of submission	CARS	12/24/14
	Within receipt period	NO	12/24/14
	Appeal to submit application after CARS closed	06/26/14	12/24/14
	Appeal for late application submission accepted	YES	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	08/07/14	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	07/25/14	12/24/14
	Primary Reviewer 2 COI signed	07/24/14	12/24/14
	Primary Reviewer 3 COI signed	09/02/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	08/21/14	12/24/14
	Primary Reviewer 2 critique submitted	08/29/14	12/24/14
	Primary Reviewer 3 critique submitted	09/02/14	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
valuation	COI indicated by non-primary reviewer	NONE	12/24/14
	Preliminary Evaluation score summary sent to Chair	09/04/14	12/24/14
	Recommended for full review	YES	12/24/14
	Applicant notified of outcome	10/17/14	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	07/25/14	12/24/14
	Primary Reviewer 2 COI signed	07/24/14	12/24/14
	Primary Reviewer 3 COI signed	09/02/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	10/09/14	12/24/14
	Primary Reviewer 2 critique submitted	10/05/14	12/24/14
	Primary Reviewer 3 critique submitted	10/17/14	12/24/14
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/24/14	12/24/14
Meeting	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/27/14	12/24/14
	Post review statements signed	10/27/14	12/24/14
	Third Party Observer Report	10/27/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
		NONE	01/13/15
	COI indicated by SRC member	N/A	01/13/15
rilene	COI recused from participation	01/06/15	01/13/15
6. Final SRC Recommendation	SRC Meeting		01/13/15
Recommendation	Third Party Observer Report	01/07/15 YES	01/13/15
	Recommended for grant award		
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
. PIC Review	COI recused from participation	N/A	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	No.
	COI recused from participation	YES/NO or N/A	-
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	4
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	



# CEO AFFIDAVIT Application RP150498 Individual Investigator Research Awards

#### THE STATE OF TEXAS

## **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 285 applications for this RFA. The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the uthe day of	indersigned authority, on, 2015,
Sandra Reyes	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Notary Public, State of Texas	Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP150498

APPLICATION TITLE Harnessing the Cytosolic DNA Sensing Pathway for Cancer

APPLICATION TITLE Immunotherapy
APPLICANT NAME Chen, Zhijian

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Translational Cancer Research (TCR )

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/12/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
	Date application submitted	06/27/14	12/12/14
	Method of submission	CARS	12/12/14
	Within receipt period	NO	12/12/14
	Appeal to submit application after CARS closed	06/26/14	12/12/14
	Appeal for late application submission accepted	YES	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
	Assigned to primary reviewers	08/18/14	12/12/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/12/14
and Assignment	Primary Reviewer 1 COI signed	08/04/14	12/12/14
	Primary Reviewer 2 COI signed	08/05/14	12/12/14
	Primary Reviewer 3 COI signed	07/25/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/12/14
	Primary Reviewer 1 critique submitted	09/22/14	12/12/14
	Primary Reviewer 2 critique submitted	09/12/14	12/12/14
	Primary Reviewer 3 critique submitted	09/18/14	12/12/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
Evaluation	COI indicated by non-primary reviewer	NONE	12/12/14
	Preliminary Evaluation score summary sent to Chair	09/22/14	12/12/14
	Recommended for full review	YES	12/12/14
	Applicant notified of outcome	10/17/14	12/12/14
	Assigned to primary reviewers	10/03/14	12/12/14
	Primary Reviewer 1 COI signed	11/04/14	12/12/14
	Primary Reviewer 2 COI signed	10/23/14	12/12/14
	Primary Reviewer 3 COI signed	10/26/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/29/14	12/12/14
	Primary Reviewer 1 critique submitted	11/04/14	12/12/14
	Primary Reviewer 2 critique submitted	11/02/14	12/12/14
	Primary Reviewer 3 critique submitted	10/28/14	12/12/14
1. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	11/09/14	12/12/14
Meeting	COI indicated by non-primary reviewer	NONE	12/12/14
	COI recused from participation	N/A	12/12/14
		YES	12/12/14
	Discussed at On-Site Meeting	11/11/14	12/12/14
	Peer Review Meeting	11/11/14	12/12/14
	Post review statements signed	11/18/14	12/12/14
	Third Party Observer Report	11/25/14	12/12/14
	Score report delivered to CSO	YES YES	12/12/14
	Recommended for SRC Review	NONE	01/13/15
	COI indicated by SRC member		01/13/15
Long	COI recused from participation	N/A 01/06/15	01/13/15
Recommendation	SRC Meeting		01/13/15
recommendation	Third Party Observer Report	01/07/15 YES	
	Recommended for grant award		01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
5. PIC Review	COI recused from participation	N/A	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	_
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150006 Individual Investigator Research Awards for Cancer in Children and Adolescents

#### THE STATE OF TEXAS

## COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Clinical and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

 A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the unde the 4th day of February by WAYNE R. ROBERTS.	rsigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

#### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS **APPLICATION PEDIGREE**

FY 2015 CYCLE 1 PROGRAM

Individual Investigator Research Awards for Cancer in AWARD MECHANISM

Children and Adolescents (IIRACCA)

APPLICATION ID RP150006

Defining and Treating Targetable Lesions in AYA Acute APPLICATION TITLE

Lymphoblastic Leukemia

APPLICANT NAME Konopleva, Marina

ORGANIZATION The University of Texas M. D. Anderson Cancer Center PANEL NAME Clinical and Translational Cancer Research (CTCR)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/12/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
	Date application submitted	06/25/14	12/12/14
	Method of submission	CARS	12/12/14
	Within receipt period	YES	12/12/14
	Appeal to submit application after CARS closed	N/A	12/12/14
	Appeal for late application submission accepted	N/A	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
	Assigned to primary reviewers	N/A	12/12/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/12/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/12/14
	Primary Reviewer 2 COI signed	N/A	12/12/14
	Primary Reviewer 3 COI signed	N/A	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/12/14
	Primary Reviewer 1 critique submitted	N/A	12/12/14
	Primary Reviewer 2 critique submitted	N/A	12/12/14
	Primary Reviewer 3 critique submitted	N/A	12/12/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/12/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/12/14
	Recommended for full review	N/A	12/12/14
	A STATE OF THE STA		-
	Applicant notified of outcome	N/A	12/12/14
	Assigned to primary reviewers	09/24/14 10/24/14	12/12/14
	Primary Reviewer 1 COI signed	_	12/12/14
	Primary Reviewer 2 COI signed	11/03/14	12/12/14
	Primary Reviewer 3 COI signed	07/27/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/30/14	12/12/14
	Primary Reviewer 1 critique submitted	10/19/14	12/12/14
	Primary Reviewer 2 critique submitted	10/12/14	12/12/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/17/14	12/12/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	11/04/14	12/12/14
	COI indicated by non-primary reviewer	Mullighan, Charles	12/12/14
	COI recused from participation	YES	12/12/14
	Discussed at On-Site Meeting	YES	12/12/14
	Peer Review Meeting	11/11/14	12/12/14
	Post review statements signed	11/18/14	12/12/14
	Third Party Observer Report	11/17/14	12/12/14
	Score report delivered to CSO	11/25/14	12/12/14
	Recommended for SRC Review	YES	12/12/14
	COI Indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
i. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
DIC Baylay	COI recused from participation	M. Kripke*	02/03/15
. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
ommittee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	_

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150032 Individual Investigator Research Awards for Cancer in Children and Adolescents

## THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Basic Caner Research-1panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the day of februar by WAYNE R. ROBERTS.	- · · · · · · · · · · · · · · · · · · ·
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

#### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FΥ 2015 CYCLE 1 PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Cancer in

Children and Adolescents (IIRACCA)

APPLICATION ID RP150032

Developing New Combinatory Therapies for Pediatric High APPLICATION TITLE

Grade Glioma APPLICANT NAME Li, Xiao-Nan

ORGANIZATION Baylor College of Medicine PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Regulrement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/26/14	12/24/14
	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/08/14	12/24/14
	Primary Reviewer 1 COI signed	08/11/14	12/24/14
	Primary Reviewer 2 COI signed	07/27/14	12/24/14
		07/24/14	12/24/14
	Primary Reviewer 3 COI signed	09/10/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed		
	Primary Reviewer 1 critique submitted	10/12/14	12/24/14
	Primary Reviewer 2 critique submitted	10/14/14	12/24/14
4. Peer Review	Primary Reviewer 3 critique submitted	10/05/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/29/14	12/24/14
	COI indicated by non-primary reviewer	Baker, Suzanne	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/06/14	12/24/14
	Post review statements signed	11/19/14	12/24/14
	Third Party Observer Report	11/17/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
6. PIC Review	COI recused from participation	N/A	02/03/15
o. I ic neview	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	William
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150081 Individual Investigator Research Awards for Cancer in Children and Adolescents

THE STATE OF TEXAS

## **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Basic Caner Research-1 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

May 2MD

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the day of february by WAYNE R. ROBERTS.	rsigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

#### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2015 FY CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Cancer in Children and Adolescents (IRACCA)

APPLICATION ID RP150081

APPLICATION TITLE Genetic Susceptibility to Testicular Germ Cell Tumors

APPLICANT NAME Heaney, Jason

Baylor College of Medicine ORGANIZATION PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/24/14	12/24/14
	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral.	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
_	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
			12/24/14
	Applicant notified of outcome	N/A 09/08/14	12/24/14
	Assigned to primary reviewers	07/26/14	12/24/14
	Primary Reviewer 1 COI signed	_	
	Primary Reviewer 2 COI signed	08/04/14	12/24/14
	Primary Reviewer 3 COI signed	08/07/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/05/14	12/24/14
	Primary Reviewer 1 critique submitted	10/15/14	12/24/14
	Primary Reviewer 2 critique submitted	10/14/14	12/24/14
. Peer Review	Primary Reviewer 3 critique submitted	09/30/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/22/14	12/24/14
	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/06/14	12/24/14
	Post review statements signed	11/19/14	12/24/14
	Third Party Observer Report	11/17/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
i. PIC Review	COI recused from participation	N/A	02/03/15
. PIC Keview	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
, , , , , , , , , , , , , , , , , , ,	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	nationly to advance rands requested	ILD/140	



# CEO AFFIDAVIT Application RP150129 Individual Investigator Research Awards for Cancer in Children and Adolescents

#### THE STATE OF TEXAS

## **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

May R. N.

CEO. Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
CWODN to and CUDCCDIDED before me, the under	raigned authority on
SWORN to and SUBSCRIBED before me, the under	•
the 4th day of February	, 2015,
by WAYNE R. ROBERTS.	
A W	SANDRA J. REYES
Sandra Reyes	Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Notary Public, State of Texas	SEPTEMBER 30, 2017
	Notary without Bond
	, total y the control of the control

2015 CYCLE PROGRAM Research

AWARD MECHANISM Children Technology (Children Technology)

Children and Adolescents (IIRACCA)

APPLICATION ID RP150129

Drug Discovery and Mechanistic Studies of Protein APPLICATION TITLE

Methylation Targeting Leukemia

APPLICANT NAME Song, Yongcheng ORGANIZATION Baylor College of Medicine Cancer Biology (CB) PANEL NAME

Category	Compliance Requirement	information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
1. Pre-Receipt	Date application submitted	06/19/14	12/24/14
1. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/10/14	12/24/14
	Primary Reviewer 1 COI signed	07/30/14	12/24/14
		07/27/14	12/24/14
	Primary Reviewer 2 COI signed	07/28/14	12/24/14
	Primary Reviewer 3 COI signed	09/11/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed		+
	Primary Reviewer 1 critique submitted	10/15/14	12/24/14
	Primary Reviewer 2 critique submitted	10/08/14	12/24/14
1. Peer Review	Primary Reviewer 3 critique submitted	10/14/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/27/14 NONE	12/24/14
	COI indicated by non-primary reviewer		12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
5. PIC Review	COI recused from participation	N/A	02/03/15
. I IC NEVIEW	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
7. Oversight	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



## CEO AFFIDAVIT Application RP150164 Individual Investigator Research Awards for Cancer in Children and Adolescents

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the 4th day of February by WAYNE R. ROBERTS.	signed authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

2015 FY CYCLE PROGRAM Research

Individual Investigator Research Awards for Cancer in AWARD MECHANISM

Children and Adolescents (IIRACCA)

APPLICATION ID RP150164

Using Imaging and Computational Tools to Improve Risk APPLICATION TITLE

Stratification in Children with Bone Cancer

APPLICANT NAME Leavey, Patrick

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Imaging Technology and Informatics (ITI)

Cotegary	Compliance Regularment	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
Duo Bossint	Date application submitted	06/27/14	12/24/14
L. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	NO	12/24/14
	Appeal to submit application after CARS closed	06/26/14	12/24/14
	Appeal for late application submission accepted	YES	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	07/24/14	12/24/14
	Primary Reviewer 2 COI signed	07/24/14	12/24/14
	Primary Reviewer 2 COI signed	08/31/14	12/24/14
		09/10/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	10/13/14	12/24/14
	Primary Reviewer 1 critique submitted	10/14/14	12/24/14
	Primary Reviewer 2 critique submitted	10/18/14	12/24/14
4. Peer Review	Primary Reviewer 3 critique submitted	10/24/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	NONE	12/24/14
	COI indicated by non-primary reviewer	_	12/24/14
	COI recused from participation	N/A	-
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/27/14	12/24/14
	Post review statements signed	10/27/14	12/24/14
	Third Party Observer Report	10/27/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
5. PIC Review	COI recused from participation	N/A	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



## CEO AFFIDAVIT Application RP150301 Individual Investigator Research Awards for Cancer in Children and Adolescents

#### THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO. Cancer Prevention and Research Institute of Texas

County of Travis	
SWORN to and SUBSCRIBED before me, the undersigned aut the	hority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

FY 2015 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Cancer in

Children and Adolescents (IIRACCA)

APPLICATION ID RP150301

APPLICANT NAME

APPLICATION TITLE Epigenetics in Medulloblastoma Development and

Therapeutics Gopalakrishnan, Vidya

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Biology (CB)

Estegory	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
Dec Berelet	Date application submitted	06/24/14	12/24/14
L. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
, and the second	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted		
N. Pro-Houter-	Sec.	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/10/14	12/24/14
	Primary Reviewer 1 COI signed	07/28/14	12/24/14
	Primary Reviewer 2 COI signed	08/22/14	12/24/14
	Primary Reviewer 3 COI signed	07/28/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/11/14	12/24/14
	Primary Reviewer 1 critique submitted	10/14/14	12/24/14
	Primary Reviewer 2 critique submitted	10/15/14	12/24/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/13/14	12/24/14
Viceting	Primary (Advocate) Reviewer 4 critique submitted	10/27/14	12/24/14
viceting.	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/03/14	12/24/14
	Post review statements signed	11/21/14	12/24/14
	Third Party Observer Report	11/03/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI Indicated by PIC member	NONE	02/03/15
	COI recused from participation	M, Kripke*	02/03/15
. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	02/03/13
		NAME or NONE	
	COI indicated by Oversight Committee member	YES/NO or N/A	-
7. Oversight Committee Approval	COI recused from participation		
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M<sub>b</sub>D. Anderson applications.



## CEO AFFIDAVIT Application RP150334 Individual Investigator Research Awards for Cancer in Children and Adolescents

#### THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Basic Caner Research-1 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. R. berts,

May 2 pt

CEO. Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the day of February by WAYNE R. ROBERTS.	ersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notery Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notery without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM

Individual Investigator Research Awards for Cancer in

Children and Adolescents (IIRACCA)

APPLICATION ID RP150334

APPLICATION TITLE Personalized Functionalization of Pediatric High Grade

Glioma

APPLICANT NAME Deneen, Benjamin
ORGANIZATION Baylor College of Medicine
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/20/14	12/24/14
L. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
). Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
S. Preliminary Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
valuation	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
		N/A	12/24/14
	Applicant notified of outcome	09/08/14	12/24/14
	Assigned to primary reviewers		
	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	07/27/14	12/24/14
	Primary Reviewer 3 COI signed	07/26/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/05/14	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	10/14/14	12/24/14
I. Peer Review	Primary Reviewer 3 critique submitted	10/15/14	12/24/14
Vieeting	Primary (Advocate) Reviewer 4 critique submitted	10/22/14	12/24/14
_	COI indicated by non-primary reviewer	Baker, Suzanne	12/24/14
	COI recused from participation	YES	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	11/06/14	12/24/14
	Post review statements signed	11/19/14	12/24/14
	Third Party Observer Report	11/17/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
i. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
i. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
7. Oversight Committee Approval	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
.cmittee Approval	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	1
	Additiontly to advance funds requested	123/140	



## CEO AFFIDAVIT Application RP150343 Individual Investigator Research Awards for Cancer in Children and Adolescents

#### THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the understhe	signed authority, on, 2015,
Sandra Reyel Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Taxas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

2015 CYCLE 1 PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)

APPLICATION ID RP150343

An Ultra-Sensitive Nanomagnetic Sensor for the Early APPLICATION TITLE

Detection of Anaplastic Large Cell Lymphoma

APPLICANT NAME Willson, Richard ORGANIZATION University of Houston

PANEL NAME Imaging Technology and Informatics (ITI)

Entegory	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
f Dec Decelet	Date application submitted	06/26/14	12/24/14
1. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	10/12/14	12/24/14
	Primary Reviewer 2 COI signed	09/08/14	12/24/14
	Primary Reviewer 3 COI signed	07/27/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	10/17/14	12/24/14
	Primary Reviewer 2 critique submitted	10/17/14	12/24/14
	Primary Reviewer 3 critique submitted	10/18/14	12/24/14
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/25/14	12/24/14
Meeting	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/27/14	12/24/14
	Post review statements signed	10/27/14	12/24/14
	Third Party Observer Report	10/27/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	02,00,10
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
Overclaht	Donation(s) made to CPRIT/foundation		
7. Oversight		YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE VES/NO	
	Award approved by Oversight Committee  Authority to advance funds requested	YES/NO	
	nutrionity to advance runus requested	YES/NO	



## CEO AFFIDAVIT Application RP150416 Individual Investigator Research Awards for Cancer in Children and Adolescents

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Clinical and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the undersite the day of February by WAYNE R. ROBERTS.	igned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

2015 CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Cancer in

Children and Adolescents (IIRACCA)

APPLICATION ID RP150416

Translational Investigations On Fenretinide and Safingol For APPLICATION TITLE

Pediatric Cancer Use APPLICANT NAME Maurer, Barry

Texas Tech University Health Sciences Center ORGANIZATION Clinical and Translational Cancer Research (CTCR) PANEL NAME

Catagory	Campliance Requirement	information	Attestation Date
	RFA published in Texas Register	05/16/14	12/12/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/12/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/12/14
	Date application submitted	06/24/14	12/12/14
1. Pre-Receipt	Method of submission	CARS	12/12/14
	Within receipt period	YES	12/12/14
	Appeal to submit application after CARS closed	N/A	12/12/14
	Appeal for late application submission accepted	N/A	12/12/14
	Administrative review notification	N/A	12/12/14
	Donation(s) made to CPRIT/foundation	NO	12/12/14
	Assigned to primary reviewers	N/A	12/12/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/12/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/12/14
	Primary Reviewer 2 COI signed	N/A	12/12/14
	Primary Reviewer 3 COI signed	N/A	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/12/14
	Primary Reviewer 1 critique submitted	N/A	12/12/14
	Primary Reviewer 2 critique submitted	N/A	12/12/14
	Primary Reviewer 3 critique submitted	N/A	12/12/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/12/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/12/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/12/14
	Recommended for full review	N/A	12/12/14
	Applicant notified of outcome	N/A	12/12/14
	Assigned to primary reviewers	09/24/14	12/12/14
	Primary Reviewer 1 COI signed	11/07/14	12/12/14
	Primary Reviewer 2 COI signed	11/08/14	12/12/14
	Primary Reviewer 3 COI signed	10/26/14	12/12/14
	Primary (Advocate) Reviewer 4 COI signed	10/30/14	12/12/14
	Primary Reviewer 1 critique submitted	10/12/14	12/12/14
	Primary Reviewer 2 critique submitted	10/12/14	12/12/14
		10/26/14	12/12/14
4. Peer Review	Primary Reviewer 3 critique submitted Primary (Advocate) Reviewer 4 critique submitted	11/07/14	12/12/14
Meeting	COI indicated by non-primary reviewer	NONE	12/12/14
	COI recused from participation	N/A	12/12/14
	Discussed at On-Site Meeting	YES	12/12/14
		11/11/14	12/12/14
	Peer Review Meeting		
	Post review statements signed	11/18/14	12/12/14
	Third Party Observer Report	11/17/14	12/12/14
	Score report delivered to CSO	11/25/14	12/12/14
	Recommended for SRC Review	YES NONE	12/12/14
	COI indicated by SRC member		01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
6. PIC Review	COI recused from participation	N/A	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



## CEO AFFIDAVIT Application RP150445 Individual Investigator Research Awards for Cancer in Children and Adolescents

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 57 applications for this RFA. The application was assigned to the Basic Caner Research-1 panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancel Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the	rsigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

2015 CYCLE

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Cancer in

Children and Adolescents (IIRACCA)

APPLICATION ID RP150445

Ewing's Sarcoma, a Homologous Recombination Defective APPLICATION TITLE

Disease

APPLICANT NAME Bishop, Alexander

ORGANIZATION The University of Texas Health Science Center at San Antonio

PANEL NAME Basic Cancer Research-1 (BCR-1)

shed in Texas Register plication Receipt System (CARS) opened plication Receipt System (CARS) closed ication submitted if submission ceipt period submit application after CARS closed r late application submission accepted ative review notification	05/16/14 05/15/14 06/26/14 06/26/14 CARS YES N/A	12/24/14 12/24/14 12/24/14 12/24/14 12/24/14 12/24/14
olication Receipt System (CARS) closed ication submitted of submission ceipt period submit application after CARS closed or late application submission accepted ative review notification	06/26/14 06/26/14 CARS YES N/A	12/24/14 12/24/14 12/24/14
ication submitted  of submission ceipt period submit application after CARS closed r late application submission accepted ative review notification	06/26/14 CARS YES N/A	12/24/14 12/24/14
of submission ceipt period submit application after CARS closed r late application submission accepted ative review notification	CARS YES N/A	12/24/14
ceipt period submit application after CARS closed r late application submission accepted ative review notification	YES N/A	-
submit application after CARS closed r late application submission accepted ative review notification	N/A	12/24/14
r late application submission accepted ative review notification		
ative review notification	11/4	12/24/14
	N/A	12/24/14
A d. t. CRRITIF 1 .:	N/A	12/24/14
s) made to CPRIT/foundation	NO	12/24/14
to primary reviewers	N/A	12/24/14
notified of review panel assignment	08/11/14	12/24/14
eviewer 1 COI signed	N/A	12/24/14
eviewer 2 COI signed	N/A	12/24/14
eviewer 3 COI signed	N/A	12/24/14
Advocate) Reviewer 4 COI signed	N/A	12/24/14
eviewer 1 critique submitted	N/A	12/24/14
eviewer 2 critique submitted	N/A	12/24/14
eviewer 3 critique submitted	N/A	12/24/14
		-
Advocate) Reviewer 4 critique submitted	N/A	12/24/14
ited by non-primary reviewer	N/A	12/24/14
ry Evaluation score summary sent to Chair	N/A	12/24/14
ended for full review	N/A	12/24/14
notified of outcome	N/A	12/24/14
to primary reviewers	09/08/14	12/24/14
eviewer 1 COI signed	08/06/14	12/24/14
eviewer 2 COI signed	07/24/14	12/24/14
eviewer 3 COI signed	08/14/14	12/24/14
Advocate) Reviewer 4 COI signed	09/05/14	12/24/14
eviewer 1 critique submitted	10/17/14	12/24/14
eviewer 2 critique submitted	10/11/14	12/24/14
eviewer 3 critique submitted	10/15/14	12/24/14
Advocate) Reviewer 4 critique submitted	10/22/14	12/24/14
ted by non-primary reviewer	NONE	12/24/14
ed from participation	N/A	12/24/14
at On-Site Meeting	YES	12/24/14
ew Meeting	11/06/14	12/24/14
w statements signed	11/19/14	12/24/14
y Observer Report	11/17/14	12/24/14
ort delivered to CSO	11/25/14	12/24/14
ended for SRC Review	YES	12/24/14
ted by SRC member	NONE	01/13/15
ed from participation	N/A	01/13/15
ing	01/06/15	01/13/15
	01/07/15	01/13/15
y Observer Report ended for grant award	YES	01/13/15
Notification to PIC and OC	01/08/15	01/13/15
ited by PIC member	NONE	02/03/15
ed from participation	N/A	02/03/15
v meeting	02/03/15	02/03/15
		02/03/15
	NAME or NONE	
ed from participation	YES/NO or N/A	
s) made to CPRIT/foundation	YES/NO	
to CPRIT Oversight Committee	DATE	
proved by Oversight Committee	YES/NO	
	YES/NO	
	inded for grant award ication to Oversight Committee  sted by Oversight Committee member ed from participation (s) made to CPRIT/foundation d to CPRIT Oversight Committee proved by Oversight Committee to advance funds requested	DATE



# CEO AFFIDAVIT Application RP150014 Individual Investigator Research Awards for Prevention and Early Detection

#### THE STATE OF TEXAS

#### COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 66 applications for this RFA. The application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the day of February by WAYNE R. ROBERTS.	rsigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

 FY
 2015

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards for Prevention and

Early Detection (IIRAP)

APPLICATION ID RP150014

Multi-Component Interventions for Patients and Providers

APPLICATION TITLE to Increase HPV Vaccination in a Network of Pediatric

Clinics in Houston, TX

APPLICANT NAME Vernon, Sally

ORGANIZATION The University of Texas Health Science Center at Houston

PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/23/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/23/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/23/14
1. Pre-Receipt	Date application submitted	06/26/14	12/23/14
1. Fie-Receipt	Method of submission	CARS	12/23/14
	Within receipt period	YES	12/23/14
	Appeal to submit application after CARS closed	N/A	12/23/14
	Appeal for late application submission accepted	N/A	12/23/14
	Administrative review notification	N/A	12/23/14
	Donation(s) made to CPRIT/foundation	NO	12/23/14
	Assigned to primary reviewers	N/A	12/23/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/23/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/23/14
	Primary Reviewer 2 COI signed	N/A	12/23/14
	Primary Reviewer 3 COI signed	N/A	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/23/14
	Primary Reviewer 1 critique submitted	N/A	12/23/14
	Primary Reviewer 2 critique submitted	N/A	12/23/14
	Primary Reviewer 3 critique submitted	N/A	12/23/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/23/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/23/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/23/14
	Recommended for full review	N/A	12/23/14
	Applicant notified of outcome	N/A	12/23/14
	Assigned to primary reviewers	08/29/14	12/23/14
	Primary Reviewer 1 COI signed	07/30/14	12/23/14
	Primary Reviewer 2 COI signed	07/24/14	12/23/14
	Primary Reviewer 3 COI signed	07/30/14	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	08/31/14	12/23/14
	Primary Reviewer 1 critique submitted	10/05/14	12/23/14
	Primary Reviewer 2 critique submitted	10/05/14	12/23/14
4. Peer Review	Primary Reviewer 3 critique submitted	10/14/14	12/23/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/25/14	12/23/14
	COI indicated by non-primary reviewer	Kushi, Lawrence	12/23/14
	COI recused from participation	YES	12/23/14
	Discussed at On-Site Meeting	YES	12/23/14
	Peer Review Meeting	10/28/14	12/23/14
	Post review statements signed	10/28/14	12/23/14
	Third Party Observer Report	11/17/14	12/23/14
	Score report delivered to CSO	11/25/14	12/23/14
	Recommended for SRC Review	YES	12/23/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
5. PIC Review	COI recused from participation	N/A	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	4
	Advance authority approved by Oversight Committee	YES/NO	J



# CEO AFFIDAVIT Application RP150195 Individual Investigator Research Awards for Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 66 applications for this RFA. The application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the unthe 4th day of February by WAYNE R. ROBERTS.	dersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

**FY** 2015 **CYCLE** 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Prevention and

Early Detection (IIRAP)

APPLICATION ID RP150195

APPLICATION TITLE Mechanisms of DHA and EPA Differential Effects on Colon

Cancer Chemoprevention

APPLICANT NAME Shureiqi, Irnad

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
-	RFA published in Texas Register	05/16/14	12/23/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/23/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/23/14
Des Deseites	Date application submitted	06/23/14	12/23/14
. Pre-Receipt	Method of submission	CARS	12/23/14
	Within receipt period	YES	12/23/14
	Appeal to submit application after CARS closed	N/A	12/23/14
	Appeal for late application submission accepted	N/A	12/23/14
	Administrative review notification	N/A	12/23/14
	Donation(s) made to CPRIT/foundation	NO	12/23/14
	Assigned to primary reviewers	N/A	12/23/14
. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/23/14
nd Assignment	Primary Reviewer 1 COI signed	N/A	12/23/14
	Primary Reviewer 2 COI signed	N/A	12/23/14
	Primary Reviewer 3 COI signed	N/A	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/23/14
	Primary Reviewer 1 critique submitted	N/A	12/23/14
	Primary Reviewer 2 critique submitted	N/A	12/23/14
	Primary Reviewer 3 critique submitted	N/A	12/23/14
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/23/14
valuation	COI indicated by non-primary reviewer	N/A	12/23/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/23/14
	Recommended for full review	N/A	12/23/14
	Applicant notified of outcome	N/A	12/23/14
	Assigned to primary reviewers	08/29/14	12/23/14
	Primary Reviewer 1 COI signed	07/30/14	12/23/14
	Primary Reviewer 2 COI signed	07/25/14	12/23/14
	Primary Reviewer 3 COI signed	08/15/14	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	08/31/14	12/23/14
	Primary Reviewer 1 critique submitted	10/26/14	12/23/14
	Primary Reviewer 2 critique submitted	10/13/14	12/23/14
	Primary Reviewer 3 critique submitted	10/02/14	12/23/14
. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/23/14	12/23/14
Vieeting	COI indicated by non-primary reviewer	NONE	12/23/14
	COI recused from participation	N/A	12/23/14
	Discussed at On-Site Meeting	YES	12/23/14
		10/28/14	12/23/14
	Peer Review Meeting	10/28/14	12/23/14
	Post review statements signed	11/17/14	12/23/14
	Third Party Observer Report		12/23/14
	Score report delivered to CSO	11/25/14	
	Recommended for SRC Review	YES	12/23/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	
i. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
. PIC Review	COI recused from participation	M. Kripke*	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications.

The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150228 Individual Investigator Research Awards for Prevention and Early Detection

THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 66 applications for this RFA. The application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

May 2. No

CEO. Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the understate day of <u>February</u> by WAYNE R. ROBERTS.	igned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Toxas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

CYCLE PROGRAM Research

Individual Investigator Research Awards for Prevention AWARD MECHANISM

and Early Detection (IIRAP)

APPLICATION ID RP150228

Varenicline and Combined NRT for Initial Smoking Cessation and Rescue Treatment in Smokers: A

APPLICATION TITLE Randomized Pilot Trial

APPLICANT NAME Cinciripini, Paul

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Regulrement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/23/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/23/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/23/14
	Date application submitted	06/26/14	12/23/14
1. Pre-Receipt	Method of submission	CARS	12/23/14
	Within receipt period	YES	12/23/14
	Appeal to submit application after CARS closed	N/A	12/23/14
	Appeal for late application submission accepted	N/A	12/23/14
	Administrative review notification	N/A	12/23/14
	Donation(s) made to CPRIT/foundation	NO	12/23/14
	Assigned to primary reviewers	N/A	12/23/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/23/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/23/14
	Primary Reviewer 2 COI signed	N/A	12/23/14
	Primary Reviewer 3 COI signed	N/A	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/23/14
	Primary Reviewer 1 critique submitted	N/A	12/23/14
	Primary Reviewer 2 critique submitted	N/A	12/23/14
	Primary Reviewer 3 critique submitted	N/A	12/23/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/23/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/23/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/23/14
	Recommended for full review	N/A	12/23/14
	Applicant notified of outcome	N/A	12/23/14
	Assigned to primary reviewers	08/29/14	12/23/14
	Primary Reviewer 1 COI signed	07/30/14	12/23/14
	Primary Reviewer 2 COI signed	08/14/14	12/23/14
	Primary Reviewer 3 COI signed	07/30/14	12/23/14
	Primary (Advocate) Reviewer 4 COI signed	08/29/14	12/23/14
	Primary Reviewer 1 critique submitted	10/07/14	12/23/14
	Primary Reviewer 2 critique submitted	10/07/14	12/23/14
	Primary Reviewer 3 critique submitted	10/09/14	12/23/14
I. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	10/24/14	12/23/14
Meeting	COI indicated by non-primary reviewer	Brandon, Thomas	12/23/14
	COI recused from participation	YES	12/23/14
	Discussed at On-Site Meeting	YES	12/23/14
	Peer Review Meeting	10/28/14	12/23/14
	Post review statements signed	10/28/14	12/23/14
	Third Party Observer Report	11/17/14	12/23/14
	Score report delivered to CSO	11/25/14	12/23/14
	Recommended for SRC Review	YES	12/23/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	M. Kripke*	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	indicated to destrained rando requested	100/110	-

<sup>\*</sup>Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.



# CEO AFFIDAVIT Application RP150421 Individual Investigator Research Awards for Prevention and Early Detection

THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 66 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts.

CEO. Cancer Prevention and Research Institute of Texas

FΥ 2015 CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)

APPLICATION ID RP150421

High-throughput Screening and Detection of Circulating APPLICATION TITLE

Tumor Cells APPLICANT NAME Ugaz, Victor

ORGANIZATION Texas Engineering Experiment Station PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
	Date application submitted	06/26/14	12/24/14
1. Pre-Receipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
		09/12/14	12/24/14
	Assigned to primary reviewers  Primary Reviewer 1 COI signed	09/08/14	12/24/14
	Primary Reviewer 2 COI signed	07/24/14	12/24/14
	Primary Reviewer 3 COI signed	09/02/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
	Primary Reviewer 1 critique submitted	10/13/14	12/24/14
	Primary Reviewer 2 critique submitted	10/14/14	12/24/14
1. Peer Review	Primary Reviewer 3 critique submitted	10/17/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/25/14	12/24/14
	COI indicated by non-primary reviewer	NONE	12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/27/14	12/24/14
	Post review statements signed	10/27/14	12/24/14
	Third Party Observer Report	10/27/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
i. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
i. PIC Review	COI recused from participation	N/A	02/03/15
. I IC NEVIEW	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
7	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RP150449 Individual Investigator Research Awards for Prevention and Early Detection

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 66 applications for this RFA. The application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Røberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the u the 4th day of February by WAYNE R. ROBERTS.	ndersigned authority, on, 2015,
Sandra Reyes	SANDRA J. REYES  Motary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Notary Public, State of Texas	Notary without Bond

2015 FΥ CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Prevention and

Early Detection (IIRAP)

APPLICATION ID RP150449

Noninvasive Multiscale Imaging for Optical Biopsy in APPLICATION TITLE

**Epithelial Cancers** APPLICANT NAME Vargas, Gracie

The University of Texas Medical Branch at Galveston ORGANIZATION

PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Regulrement	Information	Attestation Date
	RFA published in Texas Register	05/16/14	12/24/14
	CPRIT Application Receipt System (CARS) opened	05/15/14	12/24/14
	CPRIT Application Receipt System (CARS) closed	06/26/14	12/24/14
l. Pre-Receipt	Date application submitted	06/26/14	12/24/14
L. Fre-Neceipt	Method of submission	CARS	12/24/14
	Within receipt period	YES	12/24/14
	Appeal to submit application after CARS closed	N/A	12/24/14
	Appeal for late application submission accepted	N/A	12/24/14
	Administrative review notification	N/A	12/24/14
	Donation(s) made to CPRIT/foundation	NO	12/24/14
	Assigned to primary reviewers	N/A	12/24/14
2. Receipt, Referral,	Applicant notified of review panel assignment	08/11/14	12/24/14
and Assignment	Primary Reviewer 1 COI signed	N/A	12/24/14
	Primary Reviewer 2 COI signed	N/A	12/24/14
	Primary Reviewer 3 COI signed	N/A	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	N/A	12/24/14
	Primary Reviewer 1 critique submitted	N/A	12/24/14
	Primary Reviewer 2 critique submitted	N/A	12/24/14
	Primary Reviewer 3 critique submitted	N/A	12/24/14
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	12/24/14
Evaluation	COI indicated by non-primary reviewer	N/A	12/24/14
	Preliminary Evaluation score summary sent to Chair	N/A	12/24/14
	Recommended for full review	N/A	12/24/14
	Applicant notified of outcome	N/A	12/24/14
	Assigned to primary reviewers	09/12/14	12/24/14
	Primary Reviewer 1 COI signed	07/24/14	12/24/14
	Primary Reviewer 2 COI signed	07/23/14	12/24/14
	Primary Reviewer 3 COI signed	07/24/14	12/24/14
	Primary (Advocate) Reviewer 4 COI signed	09/10/14	12/24/14
		10/14/14	12/24/14
	Primary Reviewer 1 critique submitted	10/10/14	12/24/14
	Primary Reviewer 2 critique submitted	10/13/14	12/24/14
4. Peer Review	Primary Reviewer 3 critique submitted	10/24/14	12/24/14
Meeting	Primary (Advocate) Reviewer 4 critique submitted	NONE	
	COI indicated by non-primary reviewer		12/24/14
	COI recused from participation	N/A	12/24/14
	Discussed at On-Site Meeting	YES	12/24/14
	Peer Review Meeting	10/27/14	12/24/14
	Post review statements signed	10/27/14	12/24/14
	Third Party Observer Report	10/27/14	12/24/14
	Score report delivered to CSO	11/25/14	12/24/14
	Recommended for SRC Review	YES	12/24/14
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
5. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
5. PIC Review	COI recused from participation	N/A	02/03/15
J. FIC NEVIEW	PIC review meeting	02/03/15	02/03/15
-	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	_



#### **MEMORANDUM**

To: MEMBERS OF THE OVERSIGHT COMMITTEE

From: THOMAS C. GOODMAN, PH.D., CHIEF PRODUCT DEVELOPMENT

**OFFICER** 

Subject: PRODUCT DEVELOPMENT PROGRAM UPDATE

**Date: FEBRUARY 10, 2015** 

- <u>Follow-on Funding for CPRIT Product Development Research Grantees</u>: In late 2014, Cell Medica received a private B-round investment of approximately \$75 million; Bellicum completed an initial public offering that raised approximately \$140 million; and DNAtrix raised \$20 million of private capital to advance its therapy to Phase III clinical testing.
- <u>FY2015 Cycle 1 Product Development Research Grants</u>: CPRIT is reviewing applications for Cycle 1 FY2015 product development awards. Of 30 applications received, the reviewers advanced eight into due diligence. The first four of these were completed and subsequently approved by the Program Integration Committee on February 3, 2015. They are now the subject of the memo to follow this introduction. The remaining four applications will be taken up by the Product Development Review Council on March 13, 2015; and potentially presented to the Oversight Committee on May 20, 2015.
- <u>FY2015 Cycle 4 Product Development Research Grant Applications</u>: CPRIT opened the application process for three RFAs for Company Relocation, Established Company, and New Company product development awards on January 5, 2015. RFAs for this cycle specifically targeted established product development program priorities. The application period closed on February 9, 2015. Sixteen applications were received. The first screening of these by the review panels will begin on March 26-7, 2015.
- Standard Revenue Sharing Terms and Conditions: The new Oversight Subcommittee on Economic Terms, working with CPRIT staff and the new Product Development Advisory Committee, recommended revised revenue sharing terms that provided for continuing State participation in revenues from blockbuster products. These terms were approved at the Oversight Committee of January 20, 2015. External counsel is preparing a revised CPRIT contract that incorporates these terms. There are currently six companies awaiting this contract.

# Conflicts of Interest for Academic Research Recruitment Cycle 15.2 Applications (Academic Research Recruitment Cycle 15.2 Awards Announced at February 18, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycle 15.2 include *Recruitment of Rising Stars* and *Recruitment of First-time, Tenure-track Faculty Members*. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Nominator	Institution	Conflict Noted
Applica	tions considered by the	e PIC and Oversight Co	mmittee
RR150025 <sup>1</sup>	Fitz, John	The University of	Mitchell, Amy
		Texas Southwestern	
		Medical Center	
RR150032	Fitz, John	The University of	Mitchell, Amy
		Texas Southwestern	
		Medical Center	
RR150033	Fitz, John	The University of	Mitchell, Amy
		Texas Southwestern	
		Medical Center	
RR150038	Newton, Howard	Texas A&M	Mitchell, Amy
		University	

\_

<sup>&</sup>lt;sup>1</sup> RR150025 was withdrawn by the applicant after the PIC meeting but before the Oversight Committee meeting.



# **CEO Affidavit Supporting Information**

FY 2015—Cycle 2
Recruitment of First-Time, Tenure-Track Faculty
Members

# **Request for Applications**



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# **REQUEST FOR APPLICATIONS**

# **RFA R-15-RFT-2**

# Recruitment of First-Time Tenure-Track Faculty Members

Please also refer to the Instructions for Applicants document, which will be posted on September 2, 2014

**Application Receipt Dates:** 

September 2, 2014-Aug 31, 2015

**Fiscal Year Award Period** 

September 1, 2014-August 31, 2015 (FY 2015)

# **TABLE OF CONTENTS**

1. ABOUT CPRIT	4
2. RATIONALE	4
3. RECRUITMENT OBJECTIVES	5
4. FUNDING INFORMATION	5
5. ELIGIBILITY	6
6. RESUBMISSION POLICY	8
7. RESPONDING TO THIS RFA	8
7.1. APPLICATION SUBMISSION GUIDELINES	
7.2. APPLICATION COMPONENTS	9
7.2.1. Summary of Nomination (2,000 characters)	9
7.2.2. Institutional Commitment (3 pages)	9
7.2.3. Letter of Support from Department Chair (1 page)	10
7.2.4. Curriculum Vitae (CV)	10
7.2.5. Summary of Goals and Objectives	
7.2.6. Research (4 pages)	
7.2.7. Publications	
7.2.8. Timeline (1 page)	
7.2.9. Current and Pending Support	
7.2.10. Letters of Recommendation	
7.2.11. Research Environment (1 page)	
7.2.12. Descriptive Biography (Up to 2 pages)	
8. APPLICATION REVIEW	
8.1. REVIEW PROCESS	
8.1.1. Confidentiality of Review	
8.2. REVIEW CRITERIA	
9. KEY DATES	
10. AWARD ADMINISTRATION	
11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	
12. CONTACT INFORMATION	
12.1. HelpDesk	
12.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	17

# **RFA VERSION HISTORY**

Rev 9/2/14 RFA release

## 1. ABOUT CPRIT

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

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

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

## 2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract very promising investigators who are pursuing their first faculty appointment at the level of assistant professor (first-time, tenure-track faculty members). These individuals must have demonstrated academic excellence, innovation during predoctoral and/or postdoctoral research training, commitment to pursuing cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the state of Texas.

The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment.

## 3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the state of Texas. All candidates are expected to have completed their doctoral and fellowship training and to have clearly demonstrated truly superior ability as evidenced by their accomplishments during training, proposed research plan, publication record, and letters of recommendation. This CPRIT-supported initiative is designed to enhance innovative programs of excellence by providing research support for promising, early-stage investigators seeking their first tenure-track position. CPRIT will provide start-up funding for newly independent investigators, with the goal of augmenting and expanding the institution's efforts in cancer research. Candidates will be expected to develop research projects within the sponsoring institution. Projects should be appropriate for a newly independent investigator and should foster the development of preliminary data that can be used to prepare applications for future independent research project grants to further both the investigator's research career and the CPRIT mission. The institution will be expected to work with each newly recruited research faculty member to design and execute a faculty career development plan consistent with his or her research emphasis. Relevance to cancer research is an important evaluation criterion for CPRIT funding.

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

## 4. FUNDING INFORMATION

This is a 4-year award and is not renewable, although individuals may apply for other future CPRIT funding as appropriate. Grant funds of up to \$2,000,000 (total costs) for the 4-year period may be requested. Funding is to be used by the candidate to support his or her research program. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the

year. Funds may not be carried over beyond 4 years. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified.

Grant funds may not be used for salary support of this candidate or to construct or renovate laboratory space. Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50% of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support for the individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

## 5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is
  interested in a given candidate, negotiations as to which institution will nominate him or
  her must be concluded before the nomination is made.
- Candidates who have already accepted a position as assistant professor tenure track at the
  recruiting institution are <u>not</u> eligible for a recruitment award as an investment by CPRIT
  is obviously not necessary. Such individuals may, however, apply for other CPRIT grant
  awards, as appropriate.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The

- candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate **must not** hold an appointment at the rank of assistant professor or above (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. Candidates holding non–tenure-track appointments at the rank of assistant professor are <u>not</u> eligible for this award. Examples of such appointments include Research Assistant Professor, Adjunct Research Assistant Professor, Assistant Professor (Non-Tenure Track), etc. The candidate <u>may or may not</u> reside in Texas at the time the application is submitted and may be nominated for a faculty position at the Texas institution where they are completing postdoctoral training.
- Successful candidates will be offered tenure-track academic positions at the rank of assistant professor.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. Prior to final approval of an award, the candidate must provide the same certification.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member. Prior to final approval of an award, the candidate must provide the same certification.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date

of the grant application. Prior to final approval of an award, the candidate must provide the same certification.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 10 and Section 11. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

## 6. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of First-Time, Tenure-Track Faculty Members award mechanism. Any nomination for the Recruitment of First-Time, Tenure-Track Faculty Members that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

# 7. RESPONDING TO THIS RFA

# 7.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<a href="https://CPRITGrants.org">https://CPRITGrants.org</a>). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (nominator) must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO), who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Applications will be accepted on a continuous basis and reviewed monthly. To manage the timely review of nominations for each evaluation period, the application submitted by the 20<sup>th</sup> day of each month will be reviewed by the 15<sup>th</sup> day of the following month. For the most immediate submission period, nominations will be accepted beginning at 7 AM central time on September 2, 2014, and must be submitted by 3 PM central time on September 20, 2014, to be reviewed by October 15, 2014. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

#### 7.2. **Application Components**

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in Section 5 will be administratively withdrawn without review.

#### 7.2.1. **Summary of Nomination (2,000 characters)**

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

#### 7.2.2. **Institutional Commitment (3 pages)**

Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. The institutional commitment must state the total award amount requested. Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean. The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

**Start-up Package:** Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.

**Rent:** Amount for recovery of occupying facility space (ie, "rent") is not a permitted institutional commitment item.

# 7.2.3. Letter of Support from Department Chair (1 page)

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

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

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

# Description of Candidate Duties and Certification of 70% Time Commitment to Research.

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

The letter of support from the department chair <u>must</u> also do the following:

- 1. Describe how the candidate will be independent and autonomous in developing his or her research program at the institution;
- 2. Present a plan for mentoring that includes the design and execution of a faculty career development plan for the candidate.

# 7.2.4. Curriculum Vitae (CV)

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

# 7.2.5. Summary of Goals and Objectives

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

# 7.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.

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

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

### 7.2.7. Publications

Provide the 3 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

# **7.2.8. Timeline (1 page)**

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

# 7.2.9. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted.

#### 7.2.10. **Letters of Recommendation**

Provide 3 letters of recommendation from individuals who are in a position to detail the candidate's academic and scientific research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research.

#### 7.2.11. **Research Environment (1 page)**

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

#### 7.2.12. **Descriptive Biography (Up to 2 pages)**

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

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

#### 8. APPLICATION REVIEW

#### 8.1. **Review Process**

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications approved by Council will be forwarded to the CPRIT Program Integration

Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

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

# 8.1.1. Confidentiality of Review

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

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

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional,

serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

## 8.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution.

It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have some reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

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

Quality of the Candidate: Has the candidate demonstrated academic excellence? Has the candidate received excellent predoctoral and postdoctoral training? Does the candidate show exceptional potential for achieving future impact on basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated a commitment to cancer research? Has the candidate demonstrated independence or the potential for independence?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will the proposed research generate preliminary data that can be used for the preparation of applications for future independent research project grants?

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

**Letters of Recommendation:** Do the letters of recommendation detail the candidate's academic and clinical research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research?

**Research Environment:** Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on growing his or her research? Has the institution identified a mentor who will design and execute a faculty career development plan for the candidate?

#### 9. **KEY DATES**

## **RFA**

RFA Release

September 2, 2014

# **Application Receipt and Review Timeline**

Application Receipt System opens, 7 AM CT	Application Receipt	Anticipated Application Review
September 2, 2014	Continuous	Monthly by the 15 <sup>th</sup> day of the month

#### 10. AWARD ADMINISTRATION

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

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

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

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

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

#### 11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

#### 12. **CONTACT INFORMATION**

# 12.1. HelpDesk

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

**Dates of operation:** September 2, 2014 onward (excluding public holidays)

**Hours of operation:** Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. central time

Wednesday, 8 a.m. to 4 p.m. central time

**Tel:** 866-941-7146

E-mail: <u>Help@CPRITGrants.org</u>

# 12.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

E-mail: <u>Help@CPRITGrants.org</u>

Website: www.cprit.state.tx.us

# **Third Party Observer Report**

# CPRIT Scientific Review Council Observation Report

Report #2015-213

Panel Name: FY15 Scientific Review Council Meeting -

Recruitment Program Applications

Panel Date: January 6, 2015 Report Date: January 7, 2015

### **Background**

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

### Introduction

The subject of this report is the Scientific Review Council review of recruitment program applications. The meeting was chaired by Richard Kolodner and held over the phone on January 6, 2015.

## Panel Observation Objectives and Scope

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

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

# **Observation Results Summary**

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on January 6, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Five recruitment applications were discussed and evaluated by the Scientific Review Council to determine
  which grants would receive CPRIT funding.
- Six council members, two CPRIT staff members, and two SRA employees were present for the Council
  meeting over the phone.

- No conflicts of interest were identified prior to or during the call.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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

# **De-Identified Overall Evaluation Scores**

# Recruitment of First-Time, Tenure-Track Faculty Members

Recruitment Cycle 15.2

Application ID	Final Overall Score
RR150032*	1.0
RR150038*	1.4
RR150033*	1.6
A	2.8

<sup>\*=</sup>Recommended for Funding

# Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd January 8, 2015

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Senior Advisor on Academic Affairs

New York Office

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

rkolodner@ucsd.edu

San Diego Branch

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

**T** 858 534 7804 **F** 858 534 7750

**New York Office** 

28<sup>th</sup> Floor 666 Third Avenue New York, NY 10017

**T** 212 450 1500 **F** 212 450 1555

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

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

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its final list of research grant recommendations. The SRC met on Tuesday, January 6<sup>th</sup> to consider the applications submitted to CPRIT under the **Recruitment for First-Time**, **Tenure Track Faculty Members and Recruitment of Rising Stars** Request for Applications. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC did not make changes to the funding amount, goals, timelines, or project objectives requested by the applicant.

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

Chair, CPRIT Scientific Review Council

Attachment

					Budget	Overall
Rank	App ID	Organization/Company	Candidate	Mechanism	Requested	Score
		The University of Texas				
1	RR150032	Southwestern Medical Center	Dr. Jenna L. Jewell	RFT	\$2,000,000	1.0
2	RR150038	Texas A&M University	Dr. Jonathan T. Sczepanski	RFT	\$2,000,000	1.4
3	RR150033	The University of Texas Southwestern Medical Center	Dr. Vincent S. Tagliabracci	RFT	\$2,000,000	1.6
4	RR150025	The University of Texas Southwestern Medical Center	Dr. H. Charles Manning	RRS	\$4,000,000	2.0

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

RRS = Recruitment of Rising Stars



# **CEO Affidavit Supporting Information**

FY 2015—Cycle 2
Recruitment of Rising Stars

# **Request for Applications**



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS

# **RFA R-15-RRS-2**

# **Recruitment of Rising Stars**

Please also refer to the Instructions for Applicants document, which will be posted on September 2, 2014

**Application Receipt Dates:** 

September 2, 2014-August 31, 2015

Fiscal Year Award Period

September 1, 2014-August 31, 2015 (FY 2015)

# **TABLE OF CONTENTS**

1.	AB(	OUT CPRIT	4
2.	RA	ΓΙΟΝΑLE	4
3.	REC	CRUITMENT OBJECTIVES	4
4.		NDING INFORMATION	
5.	ELI	GIBILITY	6
6.	RES	SUBMISSION POLICY	8
7.		SPONDING TO THIS RFA	
	7.1.	APPLICATION SUBMISSION GUIDELINES	8
	7.2.	APPLICATION COMPONENTS	
	7.2.1		
	7.2.2		
	7.2.3		
	7.2.4	Curriculum Vitae (CV)	10
	7.2.5	. Summary of Goals and Objectives	10
	7.2.6	6. Research (4 pages)	10
	7.2.7	'. Publications	11
	7.2.8	Timeline (1 page)	11
	7.2.9	8 11	
	7.2.1	0. Research Environment (1 page)	11
	7.2.1	1. Descriptive Biography (Up to 2 pages)	11
8.	APF	PLICATION REVIEW	. 12
	8.1.	7.1. Review Process	. 12
	8.1.1	. Confidentiality of Review	12
	8.2.	Review Criteria	. 13
9.	KEY	Y DATES	. 14
10	. AW	ARD ADMINISTRATION	. 14
11		QUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	
12		NTACT INFORMATION	
	12.1.	HELPDESK	
	12.2.	SCIENTIFIC AND PROGRAMMATIC QUESTIONS	

# **RFA VERSION HISTORY**

Rev 9/2/14 RFA release

## 1. ABOUT CPRIT

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

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

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

# 2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract individuals whose work has outstanding merit, who show a marked capacity for self-direction, and who demonstrate the promise for continued and enhanced contributions to the field of cancer research ("Rising Stars"). Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the state of Texas. The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment.

## 3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the state of Texas. Having already demonstrated extraordinary accomplishments during their initial years of independent research, Rising Stars represent a

unique blend of scholastic aptitude, scientific rigor, and commitment to exploring transformational research through the development of creative ideas with high potential.

Candidates who have not historically worked in cancer research but are proposing creative hypotheses and research plans for this field are encouraged to apply. Similarly, candidates pursuing original and potentially high-impact basic science programs that have the potential to be translated toward clinical investigations or provide "proof of principle" are also encouraged to apply. It is expected that the candidate will contribute significantly to and have a major impact on the institution's overall cancer research initiative. Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.

Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates are expected to be approximately at the career level of a late assistant/early associate professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution.

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

## 4. FUNDING INFORMATION

This is a 5-year award and is not renewable. Grant funds of up to \$4,000,000 (total costs) over a 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. Annual allocations of this award are at the discretion of the awardee, as long as the total award does not exceed \$4,000,000. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried

over beyond 5 years. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified.

Grant funds may be used for salary support of this candidate but may not be used to construct or renovate laboratory space. Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50% of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support and endowment for the individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

#### 5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is
  interested in a given candidate, negotiations as to which institution will nominate him or
  her must be concluded before the nomination is made.
- Candidates who have already accepted a position at the recruiting institution are <u>not</u>
  eligible for a recruitment award as an investment by CPRIT is obviously not necessary.
  Such individuals may, however, apply for other CPRIT grant awards, as appropriate.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The

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

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before

submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 10 and Section 11. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

#### 6. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Rising Stars award mechanism. Any nomination for the Recruitment of Rising Stars that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

#### 7. RESPONDING TO THIS RFA

#### 7.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<a href="https://CPRITGrants.org">https://CPRITGrants.org</a>). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (nominator) must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO), who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Applications will be accepted on a continuous basis and reviewed monthly. To manage the timely review of nominations for each evaluation period, the application submitted by 20<sup>th</sup> day of each month will be reviewed by 15<sup>th</sup> day of the following month. For the most immediate submission period, nominations will be accepted beginning at 7 AM central time on September 2, 2014 and must be submitted by 3 PM central time on September 20, 2014 to be reviewed by October 15, 2014. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

#### 7.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens.

Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>Section 5</u> will be administratively withdrawn without review.

#### 7.2.1. Summary of Nomination (2,000 characters)

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

#### 7.2.2. Institutional Commitment (2 pages)

Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. **The institutional commitment must state the total award amount requested.** Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean.

The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

**Start-up Package:** Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.

**Endowment Equivalents:** The principal of an endowment may not be included as part of the institutional match, but endowment income over the lifetime of the award may be included.

**Rent:** Amount for recovery of occupying facility space (ie, "rent") is not a permitted institutional commitment item.

#### 7.2.3. Letter of Support from Department Chair (1 page)

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

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

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

Description of Candidate Duties and Certification of 70% Time Commitment to Research.

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

#### 7.2.4. Curriculum Vitae (CV)

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

#### 7.2.5. Summary of Goals and Objectives

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

#### 7.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort, and place it into context with regard to what pressing problem in cancer will be addressed. This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.** "I understand that I do not need to have made a commitment to <*nominating* 

*institution*> before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. Requests to change the recruiting institution during the recruitment process are inappropriate."

#### 7.2.7. Publications

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

#### **7.2.8. Timeline (1 page)**

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

#### 7.2.9. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted.

#### 7.2.10. Research Environment (1 page)

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

#### 7.2.11. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award.

This section of the application must be prepared by the candidate. If the application is approved for funding, this section will be made publicly available on CPRIT's website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

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

#### 8. APPLICATION REVIEW

#### 8.1. 7.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment.

Applications approved by Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

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

#### 8.1.1. Confidentiality of Review

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

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

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

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

#### 8.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have some reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research.

Questions to be considered by the reviewers are as follows:

**Quality of the Candidate:** Has the candidate 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?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will it expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques?

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

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

#### 9. KEY DATES

#### **RFA**

**RFA** Release

September 2, 2014

#### **Application Receipt and Review Timeline**

Application Receipt System opens, 7 AM CT	Application Receipt System closes, 3 PM CT	Anticipated Application Review
September 2, 2014	Continuous	Monthly by the 15 <sup>th</sup> day of the month

#### 10. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant

recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

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

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. **Continuation of funding is contingent upon the timely receipt of these reports.** Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

#### 11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

#### 12. CONTACT INFORMATION

#### 12.1. HelpDesk

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

**Dates of operation:** September 2, 2014 onward (excluding public holidays)

**Hours of operation:** Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

**Tel:** 866-941-7146

E-mail: <u>Help@CPRITGrants.org</u>

#### 12.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

## **Third Party Observer Report**

# CPRIT Scientific Review Council Observation Report

Report #2015-213

Panel Name: FY15 Scientific Review Council Meeting -

Recruitment Program Applications

Panel Date: January 6, 2015 Report Date: January 7, 2015

#### **Background**

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

#### Introduction

The subject of this report is the Scientific Review Council review of recruitment program applications. The meeting was chaired by Richard Kolodner and held over the phone on January 6, 2015.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on January 6, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Five recruitment applications were discussed and evaluated by the Scientific Review Council to determine
  which grants would receive CPRIT funding.
- Six council members, two CPRIT staff members, and two SRA employees were present for the Council
  meeting over the phone.

- No conflicts of interest were identified prior to or during the call.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

#### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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

## **De-Identified Overall Evaluation Scores**

## Recruitment of Rising Stars

Recruitment Cycle 15.2

Application ID	Final Overall Score
RR150025*	2.0

<sup>\*=</sup>Recommended for Funding

## Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd January 8, 2015

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Senior Advisor on Academic Affairs

New York Office

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

rkolodner@ucsd.edu

San Diego Branch

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

**T** 858 534 7804 **F** 858 534 7750

**New York Office** 

28<sup>th</sup> Floor 666 Third Avenue New York, NY 10017

**T** 212 450 1500 **F** 212 450 1555

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

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

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its final list of research grant recommendations. The SRC met on Tuesday, January 6<sup>th</sup> to consider the applications submitted to CPRIT under the **Recruitment for First-Time**, **Tenure Track Faculty Members and Recruitment of Rising Stars** Request for Applications. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC did not make changes to the funding amount, goals, timelines, or project objectives requested by the applicant.

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

Chair, CPRIT Scientific Review Council

Attachment

					Budget	Overall
Rank	App ID	Organization/Company	Candidate	Mechanism	Requested	Score
		The University of Texas				
1	RR150032	Southwestern Medical Center	Dr. Jenna L. Jewell	RFT	\$2,000,000	1.0
2	RR150038	Texas A&M University	Dr. Jonathan T. Sczepanski	RFT	\$2,000,000	1.4
3	RR150033	The University of Texas Southwestern Medical Center	Dr. Vincent S. Tagliabracci	RFT	\$2,000,000	1.6
4	RR150025	The University of Texas Southwestern Medical Center	Dr. H. Charles Manning	RRS	\$4,000,000	2.0

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

RRS = Recruitment of Rising Stars



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## CEO AFFIDAVIT Application RR150025 Recruitment of Rising Stars Nomination of Dr. H. Charles Manning

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., IIealth & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Rising Stars* Request for Applications (RFA). CPRIT received one application for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the until the	dersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Taxas My Commission Expires
	My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

**FY** 2015 **CYCLE** 2

PROGRAM Research - Recruitment

AWARD MECHANISM Recruitment of Rising Stars (RRS)

APPLICATION ID RR150025

**APPLICATION TITLE** Rising Star Application for H. Charles Manning, Ph.D.

NOMINATOR NAME Fitz, John

CANDIDATE NAME Manning, H. Charles

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Recruitment Review Panel 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	09/19/14	01/13/15
	CPRIT Application Receipt Cycle opened	09/21/14	01/13/15
4 Bu Buutu	CPRIT Application Receipt Cycle closed	11/20/14	01/13/15
1. Pre-Receipt	Date application submitted	10/20/14	01/13/15
	Method of submission	CARS	01/13/15
	Within receipt period	YES	01/13/15
	Administrative review notification	N/A	01/13/15
	Donation(s) made to CPRIT/foundation	NO	01/13/15
2. Receipt, Referral,	Assigned to primary reviewers	12/17/14	01/13/15
and Assignment	Applicant notified of review panel assignment	N/A	01/13/15
	Primary Reviewer 1 COI signed	12/24/14	01/13/15
	Primary Reviewer 2 COI signed	12/24/14	01/13/15
	Primary Reviewer 1 critique submitted	12/24/14	01/13/15
	Primary Reviewer 2 critique submitted	01/02/15	01/13/15
	COI indicated by non-primary reviewer	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
3. Peer Review	Discussed at Peer Review Meeting	YES	01/13/15
Meeting	Peer Review Meeting	01/06/15	01/13/15
	Post review statements signed	01/14/15	01/19/15
	Third Party Observer Report	01/07/15	01/13/15
	Score report delivered to CSO	01/13/15	01/13/15
	Recommended for SRC Review	YES	01/13/15
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
4. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
6. Oversight	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	-

The identity of the attesting party is retained by CPRIT.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## CEO AFFIDAVIT Application RR150032 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Dr. Jenna L. Jewell

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Fist-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received four applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the 4th day of February by WAYNE R. ROBERTS.	signed authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SIEPTEMBER 30, 2017 Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

**FY** 2015 **CYCLE** 2

PROGRAM Research - Recruitment

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR150032

APPLICATION TITLE

Recruitment of First-Time, Tenure-Track Faculty Member -

Jenna Lee Jewell, Ph.D.

NOMINATOR NAME Fitz, John CANDIDATE NAME Jewell, Jenna

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Recruitment Review Panel 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	09/19/14	01/13/15
	CPRIT Application Receipt Cycle opened	09/21/14	01/13/15
4. Dec Deceint	CPRIT Application Receipt Cycle closed	11/20/14	01/13/15
1. Pre-Receipt	Date application submitted	11/20/14	01/13/15
	Method of submission	CARS	01/13/15
	Within receipt period	YES	01/13/15
	Administrative review notification	N/A	01/13/15
	Donation(s) made to CPRIT/foundation	NO	01/13/15
2. Receipt, Referral,	Assigned to primary reviewers	12/17/14	01/13/15
and Assignment	Applicant notified of review panel assignment	N/A	01/13/15
	Primary Reviewer 1 COI signed	12/24/14	01/13/15
	Primary Reviewer 2 COI signed	12/24/14	01/13/15
	Primary Reviewer 1 critique submitted	12/24/14	01/13/15
	Primary Reviewer 2 critique submitted	01/02/15	01/13/15
	COI indicated by non-primary reviewer	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
3. Peer Review	Discussed at Peer Review Meeting	YES	01/13/15
Meeting	Peer Review Meeting	01/06/15	01/13/15
	Post review statements signed	01/14/15	01/19/15
	Third Party Observer Report	01/07/15	01/13/15
	Score report delivered to CSO	01/13/15	01/13/15
	Recommended for SRC Review	YES	01/13/15
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
4. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
6. Oversight	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## CEO AFFIDAVIT Application RR150033 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Dr. Vincent S. Tagliabracci

THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Fist-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received four applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts.

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the unders the	igned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Taxas My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

**FY** 2015 **CYCLE** 2

PROGRAM Research - Recruitment

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR150033

APPLICATION TITLE

Recruitment of First-Time, Tenure-Track Faculty Member -

Vincent S. Tagliabracci, Ph.D.

NOMINATOR NAME Fitz, John

CANDIDATE NAME Tagliabracci, Vincent

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Recruitment Review Panel 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	09/19/14	01/13/15
	CPRIT Application Receipt Cycle opened	09/21/14	01/13/15
4 Don Donains	CPRIT Application Receipt Cycle closed	11/20/14	01/13/15
1. Pre-Receipt	Date application submitted	11/20/14	01/13/15
	Method of submission	CARS	01/13/15
	Within receipt period	YES	01/13/15
	Administrative review notification	N/A	01/13/15
	Donation(s) made to CPRIT/foundation	NO	01/13/15
2. Receipt, Referral,	Assigned to primary reviewers	12/17/14	01/13/15
and Assignment	Applicant notified of review panel assignment	N/A	01/13/15
	Primary Reviewer 1 COI signed	12/24/14	01/13/15
	Primary Reviewer 2 COI signed	12/24/14	01/13/15
	Primary Reviewer 1 critique submitted	12/24/14	01/13/15
	Primary Reviewer 2 critique submitted	12/31/14	01/13/15
	COI indicated by non-primary reviewer	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
3. Peer Review	Discussed at Peer Review Meeting	YES	01/13/15
Meeting	Peer Review Meeting	01/06/15	01/13/15
	Post review statements signed	01/14/15	01/19/15
	Third Party Observer Report	01/07/15	01/13/15
	Score report delivered to CSO	01/13/15	01/13/15
	Recommended for SRC Review	YES	01/13/15
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
4. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
E DIG D. I.	COI recused from participation	N/A	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
6. Oversight	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## CEO AFFIDAVIT Application RR150038 Recruitment of First-Time, Tenure-Track Faculty Members Nomination of Dr. Jonathan T. Sczepanski

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Fist-Time, Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received four applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the under the day of by WAYNE R. ROBERTS.	ersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas  My Commission Expires  SEPTEMBER 30, 2017  Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY

2015

CYCLE

2

**PROGRAM** 

Research - Recruitment

AWARD MECHANISM

Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID

RR150038

**APPLICATION TITLE** 

Recruitment of First-Time Tenure-Track Faculty Member – Dr. Jonathan Sczepanski and Develop Novel Therapies

NOMINATOR NAME

Newton, Howard Sczepanski, Jonathan

CANDIDATE NAME ORGANIZATION

Texas A&M University

**PANEL NAME** 

Recruitment Review Panel 4 (RRP-4)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	09/19/14	01/13/15
	CPRIT Application Receipt Cycle opened	11/21/14	01/13/15
4 Per Preside	CPRIT Application Receipt Cycle closed	12/20/14	01/13/15
1. Pre-Receipt	Date application submitted	12/19/14	01/13/15
	Method of submission	CARS	01/13/15
	Within receipt period	YES	01/13/15
	Administrative review notification	N/A	01/13/15
	Donation(s) made to CPRIT/foundation	NO	01/13/15
2. Receipt, Referral,	Assigned to primary reviewers	12/30/14	01/13/15
and Assignment	Applicant notified of review panel assignment	N/A	01/13/15
	Primary Reviewer 1 COI signed	12/24/14	01/13/15
	Primary Reviewer 2 COI signed	12/24/14	01/13/15
	Primary Reviewer 1 critique submitted	01/02/15	01/13/15
	Primary Reviewer 2 critique submitted	01/05/15	01/13/15
	COI indicated by non-primary reviewer	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
3. Peer Review	Discussed at Peer Review Meeting	YES	01/13/15
Meeting	Peer Review Meeting	01/06/15	01/13/15
	Post review statements signed	01/14/15	01/19/15
	Third Party Observer Report	01/07/15	01/13/15
	Score report delivered to CSO	01/13/15	01/13/15
	Recommended for SRC Review	YES	01/13/15
	COI indicated by SRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
4. Final SRC	SRC Meeting	01/06/15	01/13/15
Recommendation	Third Party Observer Report	01/07/15	01/13/15
	Recommended for grant award	YES	01/13/15
	SRC Chair Notification to PIC and OC	01/08/15	01/13/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
5. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
6. Oversight	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
,,	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



#### **MEMORANDUM**

To: MEMBERS OF THE OVERSIGHT COMMITTEE

From: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER

Subject: ADMINISTRATION OF THE EARLY TRANSLATIONAL RESEARCH

**AWARDS (ETRA) PROGRAM** 

**Date: FEBRUARY 10, 2015** 

#### **Summary and Recommendation**

The "Bridging the Gap: Early Translational Research Awards" (ETRAs) were initially offered as grants under the Academic Research Program, but were transferred to the Product Development Research Program in 2014. At the Oversight Committee meeting in November, 2014, the Oversight Committee discussed whether it was appropriate to retain the ETRAs in the Product Development Research Program or to have the grants administered by the Academic Research Program. I recommend that the Academic Research Program evaluate and administer ETRAs. Doing so maintains consistency in the review process, contract terms, and data reporting between ETRA grants and all other research grants made to institutions of higher education.

#### **Background**

ETRA grants support applications for research projects addressing critically important needs related to the diagnosis, prevention, and/or treatment of cancer. The objective of this award is to "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development of those discoveries by funding advancement toward investigational new drug (IND) clearance or investigational device exemption (IDE) approval. Researchers at institutions of higher education in Texas are eligible to receive ETRAs grants, companies are not eligible.

The first cycle of ETRA grants, awarded in FY2012, were reviewed by the Academic Research Program. CPRIT staff has had considerable discussion concerning the proper location of these awards with differing opinions. CPRIT staff, including Dr. Kripke and Dr. Goodman, decided to reassign the evaluation and administration of these applications to the Product Development Research Program. The rationale for this change was that the reviewers in the Product Development Research Program had more commercial and business experience, in addition to their scientific backgrounds. It was anticipated that they might be better able to evaluate the ability of these applications to "bridge the gap."

The Product Development Research Program released its first Request for Applications (RFAs) in 2014. Besides the move from Academic to Product Development Research, two additional changes were made to the ETRA application. First, the maximum grant award was increased to \$2 million to allow an increased amount of scientific work to be done. Second, a requirement was added for a business plan to be prepared during the first year of work to describe the

commercialization plan for the project's technology. Staff anticipated that the business plans would be reviewed by reviewers from the Product Development Research Program.

Forty six ETRA applications were reviewed by the Product Development Research Program reviewers. Of these, twenty were approved by the review panels and Product Development Review Council for a total of \$33,856,975 going to 10 academic institutions. The Oversight Committee approved the ETRA grants on November 19, 2014.

At the November, 2014 meeting, the Oversight Committee also discussed whether the Product Development Research Program is the appropriate program for ETRA and asked CPRIT staff to examine this issue before releasing a new RFA for ETRA grants.

If the ETRA grants remain with the Product Development Research Program, the next RFA for ETRAs is expected to open on March 16, 2015, with presentation of any applications selected to the Oversight Committee on November 18, 2015. Moving the ETRA grants to the Academic Research Program will likely cause some delay in order to accommodate reprogramming CPRIT's grant management system and to incorporate the ETRA applications into the Academic Research review schedule.

#### **Discussion and Recommendation**

Based upon discussion with staff, I recommend that the administration of the ETRA grants be returned to the Academic Research Program for the following reasons:

- The approval process for general Product Development Awards is significantly different from Academic Research Awards by virtue of due diligence reviews and in-person interviews with product development peer reviewers. Academic Research Awards do not undergo these two requirements. Since ETRAs are awarded to universities and not companies, keeping ETRAs in the Product Development Research Program requires university applicants to undergo two different processes or to have product development reviewers adapt to two different processes, either of which is unnecessarily confusing.
- Revenue sharing terms included in the ETRA grant contracts are the terms used for universities and not those used for product development companies.
- Concerns about lack of commercial and business experience among the Academic Research Program peer reviewers can be addressed by adding reviewers with that expertise to the existing panels for review of ETRA applications. Dr. Goodman and Dr. Kripke can work together to identify appropriate reviewers.
- For data consistency and reporting purposes, since ETRAs are awarded only to institutions of higher education and not to companies, it is preferable to consider the ETRA awards along with the others made by the Academic Research Program. This is congruent with many of the data requests we receive from state policy makers.

Administration of ETRAs Page 2



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

February 13, 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 four companies that will be considered for Product Development grant awards at the February 18, 2015, Oversight Committee meeting. The Oversight Committee will consider the PIC's recommendation at the February 18, 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 Dr. Tom Goodman, CPRIT's Chief Product Development Officer, one or more of the following reasons support advance payment of grant funds for the four companies to be considered at the February 18, 2015, meeting: 1.) a larger amount of start-up funds is needed than can be advanced from cash on hand; 2.) pre-clinical trial contracts will need to be entered into with substantial upfront payments; and/or 3.) significant equipment purchases will be needed for work to begin.

Sincerely,

Wayne K. Roberts,

**CPRIT Chief Executive Officer** 



#### **MEMORANDUM**

To: MEMBERS OF THE OVERSIGHT COMMITTEE

From: THOMAS C. GOODMAN, PH.D., CHIEF PRODUCT DEVELOPMENT

**OFFICER** 

**Subject:** PRODUCT DEVELOPMENT GRANT RECOMMENDATIONS

Date: FEBRUARY 4, 2015

#### **Summary:**

The CPRIT Program Integration Committee has reviewed and recommended four New Company Product Development grant awards totaling \$48,542,265. The recommended awards are described below.

#### **Mechanism of Support and Program Objectives:**

The goal of the New Company Product Development Awards is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on cancer patient care. These investments will assist early-stage startup companies by providing the opportunity: (1) to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; (2) to establish infrastructure that is critical to the development of a robust industry; and (3) to fill any treatment, industry, or research gaps.

The State of Texas seeks to attract industry partners in the field of cancer care to advance economic development in the state. This award mechanism supports companies that intend to undertake product research and development in Texas with Texas-based employees. In determining eligibility for this award, CPRIT evaluated whether applicants would have a significant presence in Texas.

The goal of this award mechanism is to support the formation and establishment of new startup companies that will develop products to significantly impact cancer care. Consistent with CPRIT's Product Development Program Priorities, the present mechanism seeks to fund projects at companies that are most likely to bring important products to the market.

Applications for these awards were submitted pursuant to the RFA released March 31, 2014. All applications were submitted by May 29, 2014. Peer review took place at meetings on July 15 & 16, 2014, and at in-person presentations held August 12 through 15, 2014.

# **Summary of the Product Development Slate**

Applications were submitted in response to the following CPRIT RFA:

# ❖ New Company Product Development Awards – RFA C15-NEWCO-1

This award mechanism seeks to support early-stage "start-up" companies in the research and development of new products for the diagnosis, treatment, or prevention of cancer. Companies must have a significant presence in Texas or be willing to relocate to Texas.

Applications Submitted: 30 In-Person Presentations: 17

Recommended Projects: 4 (Four other projects from this cycle remain in due diligence.)

Total Recommended: \$48,542,265

# **Proposed New Company Product Development Awards**

# **NanoTx Therapeutics**

# Introduction

Radiation therapy remains an essential component in the treatment of most cancers, including primary brain tumors. Theoretically, any tumor can be controlled if a sufficient dose of radiation is delivered. The main limiting factor is the potential for damage to the surrounding normal tissue. This is especially true with brain tumors, as damage to normal brain tissue can result in profound side effects.

NanoTx has developed a method of loading <sup>186</sup>Rhenium into lipid particles about one thousandth the size of a cell to create what they call <sup>186</sup>Rhenium Nanoliposomes or RNLs. These RNLs can be injected into a tumor where they are essentially ingested by the tumor cells, irradiating them from the inside out. Because of the limited range of the radioactivity, the surrounding normal brain tissue receives less radiation exposure than it would from the use of an external beam. This allows treatment with significantly higher amounts of radiation.

Experiments in rodents have shown that RNLs can safely deliver over 30X the amount of radiation that is delivered by standard techniques. Tumors in these animals were largely eliminated without evidence of significant collateral injury. Studies in dogs showed that no toxicity was observed at the highest levels tested.

Based on these findings, the FDA approved a human clinical trial, and patients will be treated soon. The \$2 million requested from CPRIT to support these trials is being matched with \$1 million in support from the Cancer Therapy and Research Center (CTRC) in San Antonio. It is hoped that the further development of these RNLs will have a significant impact on cancer.

# Funding Request and Risk Mitigation

NanoTx Therapeutics is requesting \$2,000,000 from CPRIT over a period of three years. This will be matched by \$1,000,000 from CTRC for a total project cost of \$3,000,000.

To mitigate risk, CPRIT proposes to provide the money requested in three tranches. These funds would be provided in advance to enable the studies described. In the event that the agreed upon milestones for each tranche are not achieved, CPRIT may elect either: (i) to postpone the following tranche until they are achieved, or (ii) terminate the contract, recovering any amount of unspent CPRIT funds. Milestones and timelines are described below.

### NanoTx Goals and Milestones 2014 2015 2016 2017 --> 2019 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 RNL K Release 188RNL Kit Product Development 60 Kits Development Development SAB Second Disease IND Mtg Site Tox (CRO) Service Agreements to Explore Additional Indications Phase 1 Clinical Trial Dose Escalation Phase 1 ansion Cohort Transition to Multi-Institution Study Break Through Designation Orphan Designation Path Fast Track & SPA First year of sales Sales \$13.5M \$1 Million \$2 Million CPRIT Pre-seed Financings \$150k \$7.0 Million Preseed Series B Triggered \$0.83 Million Cumulative \$1.85 Million Cash flow \$2.12 Million positive \$3.88 Million

*First Tranche – 12 months duration – \$1,125,227*A Phase I dose escalation trial will begin in the first year.

# Second Tranche – 12 months duration – \$500,000

Continuation of the Phase I trial with expansion to multiple institutions is expected during the second year of funding.

# Third Tranche – 12 months duration – \$374,773

Completion of the Phase I dose escalation trial is expected. Second disease site toxicology will be performed and a second IND filed.

# Summary of Independent Scientific Evaluation

The reviewers felt that the proposal was supported by strong, peer-reviewed data of efficacy in rats, as well as evidence of minimal toxicity in a dog study. They said that the "product meets an unmet medical need in the initial application to glioblastoma, and it has potential for applicability to a variety of other solid tumor types. <sup>186</sup>Re is readily available from nuclear reactor processing, more than other isotopes. It has a good beta emission for therapy and gamma for diagnostics. The applicant has apparently solved the problem of encapsulating it in nanoliposomes, thereby hopefully ensuring relatively localized delivery. All in all, this is a unique and interesting approach to solid cancers."

# Summary of CPRIT Diligence and Recommendation for Funding

NanoTx currently has an open IND for the treatment of glioblastoma following a pre-IND meeting with the FDA.

There is always a clinical risk with any new drug development. Given that this is a known treatment regimen using a benign and established delivery technology, the main risk would appear to come from liposome leakage, either before administration or in vivo. These concerns have been adequately addressed by the applicant, and the PDRC endorses funding for this application.

# Medicenna Therapeutics, Inc.

# Introduction

Medicenna is developing treatments for brain cancers that affect both adults and children, including glioblastoma multiforme (GBM). GBM is the most common form of adult brain cancer, with 11,000 new cases annually in the US. It is the second most common cause of brain cancer deaths.

Brain cancers make a protein on the cancer cells' surface called the IL-4 receptor (IL-4R). Most normal cells have no IL-4R. Medicenna has developed an anti-cancer agent, MDNA55, which is administered directly into tumors and targets IL-4R. MDNA55 targets and kills brain cancer cells, while not harming healthy cells. MDNA55 has the potential to save lives and

extend survival for brain cancer patients, especially among the 60% of patients whose tumors recur.

MDNA55 has shown promising clinical results among 72 adult GBM patients. The FDA has already granted MDNA55 Orphan Drug and Fast Track designations. Medicenna is requesting \$21.2 million from CPRIT to support two clinical trials for GBM patients testing MDNA55's safety, dosage, and effectiveness.

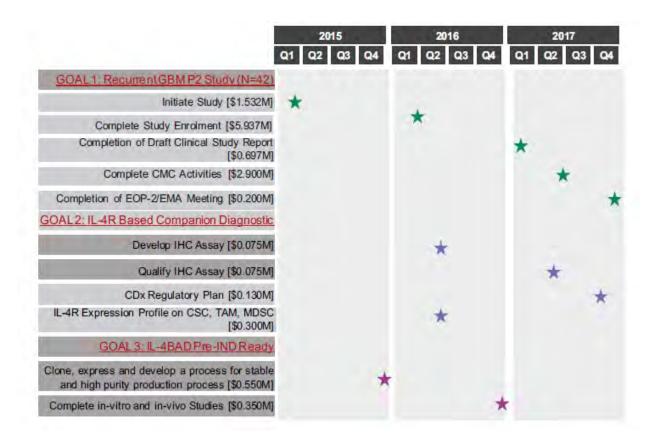
# Funding Request and Risk Mitigation

Medicenna Therapeutics, Inc. is requesting \$14,140,090 from CPRIT over a period of three years. This will be matched by \$7,070,046 from other sources for a total project cost of \$21,210,136.

To mitigate risk, CPRIT proposes to provide the money requested in three tranches. These funds would be provided in advance to enable the studies described. In the event that the agreed upon milestones for each tranche are not achieved, CPRIT may elect either: (i) to postpone the following tranche until they are achieved, or (ii) terminate the contract, recovering any amount of unspent CPRIT funds. Milestones and timelines are described below.

Key Milestones	Anticipated Date for
	<b>Achieving Milestones</b>
GOAL 1: Complete Phase 2 recurrent GBM study and be ready for the	
pivotal Phase 3 study	
Objective 1: Initiate recurrent GBM study	Q2 2015
Objective 2: Complete study enrollment	Q2 2016
Objective 3: Completion of Draft Clinical Study Report	Q2 2017
Objective 4: Complete CMC activities in preparation for readiness to start Phase 3 study	Q1 2015 - Q2 2017
Objective 5: Complete EOP-2/EMA meeting for design of Phase 3 trial	Q3 2017 - Q4 2017
GOAL 2: Develop, qualify and test an IL-4R based in-vitro companion	
diagnostic (CDx) for use alongside MDNA55 in order to select GBM patients	
most likely to respond to treatment	
	Q2 2015 - Q2 2016
analyzing expression of IL-4R in GBM patient biopsies	
	Q2 2016 - Q2 2017
use in the Phase 3 recurrent GBM study	
Objective 3: Develop a CDx plan to commercialization and submit to FDA at the	Q3 2017
EOP-2 meeting	
Objective 4: Evaluate IL-4R expression profile on Cancer Stem Cells (CSC),	Q3 2016 - Q3 2017
Tumor Associated Macrophages (TAM), and Myeloid Derived Suppressor Cells	
(MDSC) isolated from biopsy samples obtained from the Phase 2 recurrent GBM	

GOAL 3: Design a novel fusion protein with enhanced Type 2 IL-4R targeting with reduced off-target affinity, improved safety for multi-cycle	
systemic delivery and an effective anti-tumor immune response	
Objective 1: Develop process for production of a second generation IL-4R targeted	Q1 2015 - Q4 2015
fusion protein	
Objective 2: Complete in-vitro and in-vivo studies of second generation IL-4R	Q1 2016 - Q4 2016
targeted fusion protein to demonstrate proof-of-concept and establish therapeutic	
window	



# First Tranche – 12 months duration – \$6,740,660

Initiation of the recurrent glioblastoma study will take place. Development of the process for production of a second generation IL-4R targeted fusion protein will be completed.

# Second Tranche – 12 months duration – \$4,813,473

Completion of recurrent glioblastoma study enrollment is expected. Completion of the IHC assay will be accomplished.

# Third Tranche – 12 months duration – \$2,585,957

The recurrent glioblastoma draft clinical study report will be completed. CMC activities will be completed, and a CDx regulatory plan will be in place.

# Summary of Independent Scientific Evaluation

The reviewers remarked that, "the proposed research plan is clear, thorough, extremely well conceived and described, and reflects key lessons learned from a similar approach with IL13-PE administered with Convection Enhanced Delivery (CED) to patients with Glioblastoma Multiforme (GBM). If successful, with success defined as establishing a relationship between tumor IL4 receptor expression levels and efficacy outcomes, and results reaching a predefined efficacy threshold, the product has the potential to represent a significant improvement, initially in the treatment of recurrent GBM, and eventually in a first line GBM setting where it would likely be integrated into the standard of care."

It is also proposed to co-develop a diagnostic test to identify patients with IL 4R expressing tumors and to correlate outcomes with levels of IL-4R expression. The reviewers felt that, "these plans also are well conceived. The proposed development of a second generation non-immunogenic, IL4R-based product for multiple systemic administration for solid tumors is likewise very well conceived. Based on the widespread expression of IL4R in solid tumors, this product has the potential for broad spectrum anti-tumor activity."

# Summary of CPRIT Diligence and Recommendation for Funding

Medicenna has a strong regulatory plan. The company management is experienced, and it has a strong advisory board. Medicenna has identified a number of key risks that the development program faces, such as clinical study risks, and has taken appropriate actions to mitigate these. It also faces competition risks, as does any development program. Given the strong science and high unmet medical need and the inherent difficulties of treating GBM, these risks were judged to be acceptable.

The PDRC endorses funding for this application.

# Armada Pharmaceuticals, Inc.

# Introduction

Armada Pharmaceuticals, Inc. is developing antibody-drug conjugates (ADCs), which promise to provide greater efficacy relative to currently marketed unconjugated antibodies, as well as improved safety relative to traditional chemotherapies.

Armada's lead product, AVID100 (an EGFR targeting antibody-SMCC-DM1 ADC), has been evaluated in preclinical cancer models, and exhibited excellent efficacy against many common cancers expressing EGFR, including breast, ovarian, head and neck, glioma, pancreatic, gastric, and lung cancers. Compared to the FDA-approved anti-EGFR antibody, Erbitux®, which generates revenues of approximately \$2 billion a year, AVID100 showed significantly superior activity, including in models resistant to Erbitux®. This improved efficacy could help address significant unmet medical needs.

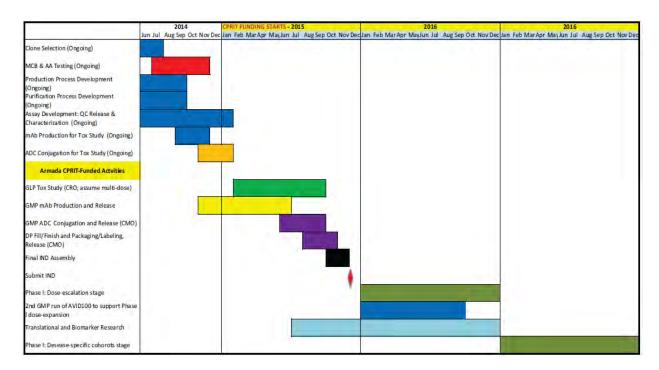
In addition to its superior efficacy, AVID100 has been shown to lack the increased on-target normal tissue toxicity expected from the toxin payload. *In vitro* tests on normal human keratinocyte cells expressing EGFR revealed that AVID100 was not more toxic than the naked antibody alone. This was unexpected. These *in vitro* safety observations were subsequently validated in monkey toxicology studies that demonstrated that the toxicity observed with AVID100 was similar to that seen with the naked antibody.

Over the 3 years of this funding cycle, Armada plans to establish a corporate presence in Texas, prepare an IND filing for AVID100, and initiate GMP manufacturing and conjugation.

# Funding Request and Risk Mitigation

Armada Pharmaceuticals, Inc. is requesting \$12,750,000 from CPRIT over a period of three years. This will be matched by \$6,375,000 from other sources for a total project cost of \$19,125,000.

To mitigate risk, CPRIT proposes to provide the money requested in three tranches. These funds would be provided in advance to enable the studies described. In the event that the agreed upon milestones for each tranche are not achieved, CPRIT may elect either: (i) to postpone the following tranche until they are achieved, or (ii) terminate the contract, recovering any amount of unspent CPRIT funds. Milestones and timelines are described below.



First Tranche – 12 months duration – \$4,710,000

Within the first twelve months, the company will complete GLP toxicology studies and submit an IND.

# Second Tranche – 12 months duration – \$4,010,000

A Phase I dose escalation study will be initiated, and a second, GMP production run of AVID100 prepared to support the Phase I dose-expansion.

# Third Tranche – 12 months duration – \$4,030,000

When a maximum tolerated dose of AVID100 has been established, at least two Phase I disease-specific, expansion cohorts of approx. 20 EGFR<sup>+</sup> patients each will be initiated with additional clinical trials centers being engaged.

# Summary of Independent Scientific Evaluation

A reviewer commented, "The applicant proposes an improved 'version' of anti-EGFR antibodies conjugated to DM-1, a toxin in the approved Kadcyla® product. The product has the potential, if shown effective in the clinic, to be an improvement over existing products, but of its own is not highly innovative. The concept of conjugation of the DM1 payload has established evidence. The product has demonstrated activity against tumor cell lines that are resistant to current anti-EGFR therapies, and as such, if demonstrated similar clinical activity, could represent an improvement and result in a greater number of indications achieved."

# Summary of CPRIT Diligence and Recommendation for Funding

Despite the promise they hold as effective anticancer agents, many challenges remain in the preclinical-to-clinical translation of ADCs. During the drug development stage, it becomes cumbersome to characterize and understand the disposition of each component of every ADC to help to design an optimal molecule with maximum therapeutic potential. This is a manageable problem.

AVID100 exhibited excellent efficacy in pre-clinical testing against many tumor models (including NSCLC, head & neck cancer, ovarian cancer, pancreatic cancer, and breast cancer) expressing or overexpressing EGFR. In addition, the safety profile of AVID100 *in vitro*, as well as in monkey toxicology studies, seems to be very similar to the original cetuximab antibody.

Taken as a whole, this project is very promising, and the PDRC endorses funding for this application.

# **Immatics Biotechnologies**

# Introduction

In 2013, the journal *Science* named cancer immunotherapy as the, "Breakthrough Discovery of the Year." Two emerging groups of observations are at the foundation of this success story. First, clinical trials applying checkpoint inhibitors such as anti-CTLA4 or anti-PD1 demonstrated long-term benefit for a proportion of metastatic cancer patients. Second,

durable, objective responses in advanced malignancies were demonstrated by clinical trials where patients were treated with adoptive cellular therapy (ACT). These types of responses are unprecedented and may allow the therapeutics tested to gain an accelerated approval for use in patients.

Despite these promising results, current immunotherapeutic approaches still have a number of limitations. First, only patients with pre-existing T cells, such as those with melanoma or lung cancer, benefit from treatment with checkpoint inhibitors. Many cancer indications such as gastrointestinal cancers unfortunately are not susceptible to this approach. Second, target specificities for T-cell engineering or soluble T-cell receptors are limited to a few antigens with limited tumor specificity such as MART-1, CEA, and CD19.

Immatics US, Inc. in Houston, Texas is a newly created subsidiary of the German company Immatics GmbH, a first-in-class biopharmaceutical company dedicated to the development and delivery of novel personalized cancer immunotherapies, including ACT and personalized vaccines. Both these types of immunotherapies activate the patient's own T-cells to battle the cancer, and both types are tailored to the specific characteristics of the individual tumor tissue in order to maximize the chances of successful therapy for the patient.

Immatics Biotechnologies is seeking CPRIT funding for two projects in the field of adoptive cellular therapy. These are "ACTolog in Glioblastoma" and "ACTengine in Pancreatic Cancer."

"ACTolog in Glioblastoma" is an adoptive cellular immunotherapy using antigen-specific endogenous autologous T-cells for the treatment of glioblastoma. Antigen specificities are determined for each individual patient based on tumor and blood biomarkers. Specific T-cells are enriched using a peptide and HLA-multimer library and expanded *ex vivo* before adoptive transfer. Personalization of the therapy is achieved through tailoring the choice of T-cells to be transferred based on patient-specific analysis of the heterogeneity of the cancer and the immune system. The current plan anticipates a multi-target approach by applying at least two different T-cell products, chosen from a library of 71 different targets, to each patient. Such antigen-specific T-cells would be expanded *ex vivo* and then infused into the patient after preconditioning.

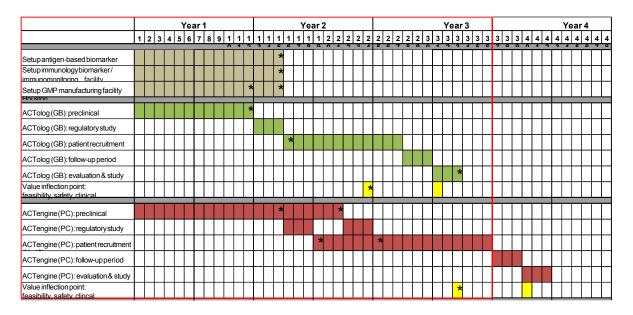
"ACTengine Pancreatic Cancer" is an adoptive cellular immunotherapy for the treatment of pancreatic cancer. It uses autologous T-cells for each individual patient that are genetically engineered to express exogenous (i.e. novel) T-cell receptors. Blood cells of the cancer patient are harvested by leukapheresis, and autologous T-cells are transfected with a vector system harboring a new T-cell receptor. Again, the current approach anticipates applying at least two different T-cell products, chosen from a library of initially six different targets, to each patient. Personalization of the therapy is achieved through tailoring the choice of T-cell receptors to the expression of antigens by the individual cancer.

# Funding Request and Risk Mitigation

Immatics Biotechnologies is requesting \$19,652,175 from CPRIT over a period of three years. This will be matched by at least \$9,826,088 from other sources for a total project cost of \$29,478,262.

To mitigate risk, CPRIT proposes to provide the money requested in three tranches. These funds would be provided in advance to enable the studies described. In the event that the agreed upon milestones for each tranche are not achieved, CPRIT may elect either: (i) to postpone the following tranche until they are achieved, or (ii) terminate the contract, recovering any amount of unspent CPRIT funds. Milestones and timelines are described below.

# Timelines: Goals and Milestones



# First Tranche – 12 months duration – \$6,206,662

Pre-clinical development and a GMP manufacturing suite in Houston for ACTolog in glioblastoma is expected to be completed in month 12.

# Second Tranche – 12 months duration – \$5,281,410

An antigen-based biomarker facility and GMP manufacturing suite for ACTengine pancreatic cancer should be completed at the Houston facility in month 15. Patient recruitment for the ACTolog glioblastoma trial should begin in month 16; recruitment of cohort 1 in the ACTengine pancreatic cancer trial in month 19.

Third Tranche – 12 months duration – \$8,164,103

By month 33 a clinical study report is expected in the ACTolog glioblastoma trial and headline results from the 24 patient ACTengine pancreatic cancer trial.

# Summary of Independent Scientific Evaluation

The reviewers commented:

"This is a highly innovative approach to immunotherapy using state of the art methods and collaborating with highly regarded MD Anderson immunotherapy experts. This creates strong synergy. The disease targets are important - advanced glioma and pancreatic cancer."

"The applicant has significant expertise in oncology and development currently and should be able to attract appropriately skilled talent upon establishment in Texas. Immatics US Inc. will establish an R&D infrastructure in Houston, including an experienced senior management team. Two management members of Immatics will relocate to Houston to set up operations. In addition, an estimated 50 FTEs will be based in Houston by the end of the third year of operations."

# Summary of CPRIT Diligence and Recommendation for Funding

# **Strengths:**

- (1) The application presents intriguing ideas that are clearly explained and justified. Basically, they will improve on ACT by: (i) selecting specific subsets of antigen-specific T-cells (ACTolog) and (ii) engineering T-cells to contain optimized T-cell receptors for specific cancer antigens (ACTengine).
- (2) The application presents an unabashed assessment of risks (scientific, regulatory, even recruiting talent) and mitigation strategies, demonstrating clear thinking and straightforwardness.
- (3) This is a strong team with established collaborations with ACT experts in Texas.
- (4) This is a refreshing approach a non-virtual company with plans to hire 50 people in three years.
- (5) There is a long-term business plan to grow a company with many products.
- (6) There is clear differentiation from the parent company, with the benefits of licensing technology and early financial support.

# Weaknesses:

- (1) While several aspects of the technologies have been validated, the risks are significant because the products/processes are early in development.
- (2) Given the complexity of patient enrollment and development of personalized product, the clinical plan timelines may be optimistic.

Taken as a whole, this project is quite promising, and the PDRC endorses funding for this application.

# Conflicts of Interest for Product Development Cycle 15.1 Applications (Product Development Cycle 15.1 Awards Announced at February 18, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Cycle 15.1 include *New Company Product Development Awards*, *Company Relocation Product Development Awards*, and *Established Company Product Development Awards*. Four applications were recommended to the PIC and Oversight Committee in February 2015 while other applications remain in due diligence and may be recommended in May 2015. Applications still in due diligence review are de-identified. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

<b>Application ID</b>	Applicant	Company	<b>Conflict Noted</b>			
Applications Considered by the PIC and Oversight Committee						
DP150031	Merchant, Fahar	Medicenna	Lloyd, Ramona			
		Therapeutics, Inc.				
Applications F	Applications Recommended For Due Diligence Review, which may be later					
Re	commended to the PIC	and Oversight Commit	ttee			
DP150***	***	***	Geltosky, Jack;			
			Spector, Neil			
Applications Not Recommended for PIC or Oversight Committee Consideration						
DP150010*	Carroll, Stephen	Synergys	Spector, Neil			
		Biotherapeutics, Inc.				
DP150023*	Burns, Lindsay	Pain Therapeutics,	Jones, Elaine;			
		Inc.	Saxberg, Bo			
DP150036	Schmid, Steven	Vivo Biosciences,	Craig, Adam			
		Inc.				
DP150038	Kim, Jason	Molecular Templates,	Craig, Adam			
		Inc.				
DP150048	Bearss, David	Tolero	Craig, Adam;			
		Pharmaceuticals, Inc.	Saxberg, Bo; Spector,			
			Neil			

<sup>\*=</sup>Application not discussed



# **CEO Affidavit Supporting Information**

FY 2015—Cycle 1
New Company Product Development Awards

# **Request for Applications**



# REQUEST FOR APPLICATIONS RFA C-15-NEWCO-1

# New Company Product Development Awards

Please also refer to the Instructions for Applicants document, which will be posted April 28, 2014

**Application Receipt Opening Date:** April 28, 2014 **Application Receipt Closing Date:** May 29, 2014

FY 2014

Fiscal Year Award Period

September 1, 2014–August 31, 2015

# **TABLE OF CONTENTS**

1.	KE	Y POINTS	5
2.	AB	OUT CPRIT	6
3.	API	PLICANT SURVEY	6
4.	EX	ECUTIVE SUMMARY	7
5.	ME	CHANISM OF SUPPORT	7
6.	OB.	JECTIVES	7
7.	FUI	NDING INFORMATION	8
8.	KE	Y DATES	9
9.	ELI	IGIBILITY	9
	9.1.	NEW APPLICATIONS	9
	9.2.	RESUBMISSION POLICY	11
	9.3.	RENEWAL POLICY	11
10	). A	PPLICATION REVIEW	12
	10.1.	Overview	12
	10.2.		
	10.2	1.1. Confidentiality of Review	
		REVIEW CRITERIA	
	10.3	.1. Primary Criteria	15
	10.3	.2. Secondary Criteria	16
11	. S	UBMISSION GUIDELINES	16
	11.1.	ONLINE APPLICATION RECEIPT SYSTEM AND APPLICATION SUBMISSION	
	Deadi	LINE	16
	11.2.	SUBMISSION DEADLINE EXTENSION	17
	11.3.	PRODUCT DEVELOPMENT REVIEW FEE	17
	11.4.	APPLICATION COMPONENTS	17
	11.4	.1. Layperson's Summary (1,500 characters)	18
	11.4	.2. Goals and Objectives (1,200 characters each)	18
	11.4	3. Timeline (One page)	18
	11.4	.4. Resubmission Summary (One page)	18
	11.4	5. Executive Summary (One page)	19

	11.4.6.	Slide Presentation (Ten pages)	19
	11.4.7.	Scientific Plan (Ten pages)	19
	11.4.8.	Business Plan (Fifteen pages)	20
	11.4.9.	Relocation Commitment to Texas (One page)	21
	11.4.10.	Biographical Sketches of Key Scientific Personnel (Eight pages)	22
	11.4.11.	Budget and Justification	22
12.	AWA	RD ADMINISTRATION	22
13.	REQ	UIREMENT TO DEMONSTRATE AVAILABLE FUNDS	24
14.	CON	TACT INFORMATION	24
1	4.1. HE	LPDESK	24
1	4.2. Pro	OGRAMMATIC OUESTIONS	25

# **RFA VERSION HISTORY**

Rev 03/31/14 RFA release

# 1. KEY POINTS

This New Company Product Development Award mechanism is governed by the following restrictions:

- Company applicants must be early-stage startup companies with no previous round
  of professional institutional investment (i.e., those that have not yet received Series
  A financing or a substantive equivalent). Companies at this early stage that are not
  currently located in Texas but intend to relocate to Texas should apply under this
  mechanism rather than the Company Relocation Awards mechanism.
- Recipient companies must currently have or must commit to the following:
   Headquarters or substantial business functions of the company in Texas; personnel
   sufficient to operate the Texas-based research and/or development activities of the
   company, along with appropriate management, relocated to or hired from within
   Texas.
- Of the total program budget, the Cancer Prevention and Research Institute of Texas
   (CPRIT) will contribute \$2.00 for every \$1.00 contributed, in matching funds, by
   the company. The demonstration of available matching funds must be made prior to
   the distribution of CPRIT grant funds, not at the time the application is submitted.
   CPRIT funds must, whenever possible, be spent in Texas. A company's matching
   funds must be targeted for the CPRIT-funded project but may be spent outside of
   Texas.
- Funding may be tranched and will be tied to the achievement of contract-specified milestones.
- Funding award contracts will include a revenue-sharing agreement or equity to be
  negotiated at contract execution and will require CPRIT to have input on any future
  patents, agreements, or other financial arrangements related to the products,
  services, or infrastructure supported by the CPRIT investment. These contract
  provisions are specified in CPRIT's Administrative Rules, which are available at
  <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>.

# 2. ABOUT CPRIT

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

CPRIT is charged by the Texas Legislature to:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the
  development and coordination of effective and efficient statewide public and
  private policies, programs, and services related to cancer and by encouraging
  cooperative, comprehensive, and complementary planning among the public,
  private, and volunteer sectors involved in cancer prevention, detection, treatment,
  and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

# 3. APPLICANT SURVEY

CPRIT will be administering a survey to determine the operational aspects of peer review. Company representatives that anticipate submitting an application are requested to complete the survey as soon as possible, but no later than May 8, 2014. Company representatives should provide the following information: Applicant name, name of company, telephone number, e-mail address, estimated award amount, and award mechanism. Please select only one award mechanism as only one application can be submitted per funding cycle. This information will be used for planning purposes only and will not be used for evaluation of the application. The survey is available here.

# 4. EXECUTIVE SUMMARY

CPRIT will foster the creation of high-quality new jobs in Texas by providing financial support for a wide variety of projects relevant to cancer. This Request for Applications (RFA) is designed to support the formation of oncology-focused companies in Texas. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any product development topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. The overall goal of this award program is to improve outcomes of patients with cancer by increasing the availability of Food and Drug Administration (FDA)—approved therapeutic interventions with a primary focus on Texas-centric programs.

# 5. MECHANISM OF SUPPORT

The goal of the New Company Product Development Awards is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will assist early-stage startup companies by providing the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award mechanism will support companies that intend to undertake product research and development in Texas with a strong presence of Texas-based employees. In determining eligibility for this award, CPRIT will evaluate whether applicants have a significant presence in Texas or are willing to relocate to Texas

# 6. OBJECTIVES

The State of Texas seeks to attract industry partners in the field of cancer care to advance economic development and cancer care efforts in the State. The goal of this award

mechanism is to support the formation and establishment of new startup companies in Texas that will develop products to significantly impact cancer care. These companies must be Texas based or have personnel sufficient to operate the Texas-based research and/or development activities of the company, along with appropriate management, who are willing to relocate to or be hired and remain in Texas for a specified period after funding. Eligible products or services include—but are not limited to—therapeutics (e.g., small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques. Eligible stages of research and development include translational research, proof-of-concept studies, preclinical studies, and Phase I or Phase II clinical trials. By exception, Phase III clinical trials and later stage product development projects will be considered where circumstances warrant CPRIT investment.

## 7. **FUNDING INFORMATION**

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development program proposed. While requested funds must be well justified, there is no limit on the amount that may be requested. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property protection, external consultants and service providers, and other appropriate research and development costs, subject to certain limitations set forth by Texas State law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the State of Texas. Texas State law limits the amount of awarded funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs).

Consistent with statutory mandate, of the total program budget, CPRIT will contribute \$2.00 for every \$1.00 contributed, in matching funds, by the company. The

demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be made on a year-by-year basis.

### 8. **KEY DATES**

RFA release March 31, 2014

Online application opens April 28, 2014, 7 a.m. Central Time

May 29, 2014, 3 p.m. Central Time **Applications due** 

July 2014 **Invitations to present sent** 

Notifications sent if not invited July 2014

Presentations to CPRIT\* August 2014

Award Notification November 2014

**Anticipated Start Date** December 2014

### 9. **ELIGIBILITY**

## 9.1. **New Applications**

- Early-stage startup companies are eligible. Such companies may have received seed funding from family, friends, and/or angel investors. However, only applicants with no previous round of professional institutional investment (i.e., those that have not yet received Series A financing or a substantive equivalent) are eligible. The inclusion of a complete and detailed capitalization table is required for assessment of eligibility.
- Recipient companies must commit to the following: Headquarters or substantial functions of the company in Texas; personnel sufficient to operate the Texas-based

<sup>\*</sup>All applicants who wish to be considered are requested to reserve these presentation dates until notified. Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

research and/or development activities of the company, along with appropriate management, relocated to or hired from within Texas who will remain in Texas for a specified period after funding; and use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-State entities. To the extent that Texas-based subcontractors or collaborators are not available, non-Texas-based collaborators and subcontractors may be used. However, non-Texas-based collaborators and subcontractors are not eligible to receive funds from CPRIT unless exceptional circumstances are demonstrated and approved by CPRIT.

- In general, a greater extent of commitment to establishing research and/or
  development functions in Texas will be viewed more favorably by CPRIT.
   However, it is left to the applicant's judgment to make a case for what they consider
  to be a sufficient extent of commitment to Texas.
- An applicant may submit only one application under this RFA during this funding cycle.
- A company applicant is eligible to receive a grant award only if the applicant
  certifies that the company, including the company representative, any senior
  member or key personnel listed on the application, or any company officer or
  director (or any person related to one or more of these individuals within the second
  degree of consanguinity or affinity) has not made and will not make a contribution
  to CPRIT or to any foundation specifically created to benefit CPRIT.
- A company applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The company applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful company applicants.
 Certain contractual requirements are mandated by Texas State law or by administrative rules. Although the company applicant need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in <a href="Section 12">Section 12</a> and <a href="Section 13">Section 13</a>. All statutory provisions and relevant administrative rules can be found at <a href="www.cprit.state.tx.us">www.cprit.state.tx.us</a>.

# 9.2. Resubmission Policy

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines (see Section 11.4.4). An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the Applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A one-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants** should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

# 9.3. Renewal Policy

Grant recipients that have previously received CPRIT grant funding may submit an application for competitive renewal under the Established Company Product

Development Award RFA. Before submitting a renewal application, applicants must consult with the Product Development Programmatic Office (see Section 14.2) to determine whether it is appropriate for their company to seek renewal funding at this time.

# 10. APPLICATION REVIEW

## 10.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. CPRIT requires the submission of a comprehensive scientific plan (see Section 11.4.7) and a detailed business plan (see Section 11.4.8). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and scientific plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made by the review process described below.

## 10.2. Review Process

- 1. Product Development and Scientific Review: Applications that pass initial administrative compliance review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of company applicants may be invited to deliver in-person presentations to the review panel.
- 2. Due Diligence Review: Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional indepth due diligence, including—but not limited to—intellectual property, management, regulatory, manufacturing, and market assessments. Following the due diligence review, applications will be

recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and intellectual property reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.

- 3. Program Integration Committee Review: Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.
- **4. Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

# **10.2.1.** Confidentiality of Review

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

Individuals directly involved with the review process operate under strict conflict-ofinterest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents. An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's Web site. By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

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

# 10.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

# 10.3.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study.

Primary criteria include the following:

**Significance and Impact:** Will the outcomes of this CPRIT-funded work result in the development of innovative products with significant product development potential? Will the outcome substantially impact the diagnosis, treatment, prevention of cancer, or supportive care for patients with cancer? How would competing products or services affect the value of the proposed offering?

**Product:** Is there demonstrated proof of relevance, and does the product fulfill a clear, unmet medical or infrastructure need? Has work been conducted that supports the advancement of the proposed product, service, or technology? Can the product be produced or manufactured in a commercially viable fashion? Is there an appropriate basis for a reimbursement strategy?

**Market Plan:** Is there a realistic assessment of the market size and expected penetration? Has management adequately assessed potential competitors and described how the company's offering will successfully compete with them?

**Development Plan and/or Regulatory Path:** Is the development plan and/or regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both a positive and a negative outcome? Does the budget appropriately support the plan?

**Scientific Plan:** Is the proposed product, service, and/or infrastructure based on a feasible research framework, hypothesis, and/or goal? Are the methods appropriate, and are potential research and developmental obstacles and unexpected outcomes discussed?

**Management and Staffing:** Does the applicant have the appropriate level of management experience to execute the stated strategy in Texas, especially if the headquarters of the company are not in Texas? Would the proposed team have the needed

experience or access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan?

# 10.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include the following:

Budget and Duration of Support: Are the budget and duration appropriate for the proposed work? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is it clear how funds will be used (Does the use of funds indicate a commitment to conducting the project work in Texas? Is it clear that no CPRIT funds will be sent to the corporate headquarters if those headquarters remain outside of Texas)? Does the proposed investment fund the research and development of the proposed product, service, or technology to a point where, if the results are positive, it is likely that the project will be able to attract further financial support outside of CPRIT?

# 11. SUBMISSION GUIDELINES

Applicants are advised to carefully review all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Applications that are missing one or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

11.1. Online Application Receipt System and Application Submission Deadline Applications must be submitted via the CPRIT Application Receipt System (CARS) (<a href="https://CPRITGrants.org">https://CPRITGrants.org</a>). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The

company applicant must create a user account in the system to start and submit an application. The co-applicant, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the company applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. Applications will be accepted beginning at 7 a.m. Central Time on April 28, 2014, and must be submitted by 3 p.m. Central Time on May 29, 2014. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

#### 11.2. **Submission Deadline Extension**

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

# 11.3. Product Development Review Fee

All applicants must submit a fee of \$1,000 for product development review. Payment should be made by check or money order payable to CPRIT; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. Unless a request to submit a late fee has been approved by CPRIT, all payments must be postmarked by the application submission deadline and mailed to the following address:

Cancer Prevention and Research Institute of Texas P.O. Box 12097 Austin, TX 78711

# 11.4. Application Components

Applicants are advised to minimize repetition between application components to the extent possible. In addition, Applicants should use discretion in cross-referencing sections in order to maximize the amount of information presented within the page limits.

# 11.4.1. Layperson's Summary (1,500 characters)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see Section 2). Would it fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The Layperson's Summary will be also used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

# 11.4.2. Goals and Objectives (1,200 characters each)

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

# 11.4.3. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

# 11.4.4. Resubmission Summary (One page)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in

question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

**Note:** An application is a resubmission only if the previous application was finalized and submitted to CPRIT. However, an application that was submitted to CPRIT to be considered for FY2013 Cycle 3 awards and was returned by CPRIT due to the moratorium is not considered to be a resubmission.

# 11.4.5. Executive Summary (One page)

Provide an executive summary that clearly explains the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs.

Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

# 11.4.6. Slide Presentation (Ten pages)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with one slide filling each landscape-orientation page. The slides should succinctly capture all essential elements of the application and should stand alone.

# 11.4.7. Scientific Plan (Ten pages)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims. Outline the steps to be taken during the proposed period of the award, including the design of the translational or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The scientific plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by the highly qualified group of reviewers. To the extent possible, the scientific plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred.

# 11.4.8. Business Plan (Fifteen pages)

Provide a business plan covering all of the topics below in the order shown. Successful applicants will make thoughtful, careful, and economical use of the limited space. Note that if the company is selected to undergo due diligence, information to support a full intellectual property review will be requested at that time. New Company Product Development Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

- **A. Products and Markets:** Provide a brief description of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care.
- **B.** Regulatory Plans: Provide a detailed regulatory plan, including preclinical and clinical activities, driven by interactions with the FDA, if possible. Summarize all interactions to date with the FDA.
- C. Risk Analysis: Describe the specific risks inherent to the product plan and how they would be mitigated.
- **D.** Current and Pending Support: Describe all funding sources. Provide a complete and detailed capitalization table, which should include all parties who have investments, stock, or rights in the company. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.
- **E. Financial Projections:** Provide a detailed source and use analysis of the development plan, focusing on the achievement of specific milestones.

- **F. Resources Requested:** Include resources needed for research and product development and for any relocation expenses. The matching funds should be included in this section; however, this is the only section of the business plan that does not deal exclusively with CPRIT-requested funds.
- **G. Scope of Work and Milestones:** Outline the specific goals of the project. Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract.
- **H. Intellectual Property:** Provide a concise discussion of the intellectual property related to your project. List any issued patents and patent applications along with their titles and dates they were filed/published/issued. In addition, list any licensing agreements that your company has signed that are relevant to this application.
- I. Key Personnel Located in Texas and Any Key Management Located Outside of Texas: Present a plan for recruiting a senior management and scientific team, describing the types of expertise and skillsets that the project will require. For each key person currently on board, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications.
- **J. Organizational Commitment to Texas:** Describe how CPRIT funding of the applicant's company would benefit the State of Texas. For example, describe how the company would create high-quality new jobs in the State and/or recruit out-of-State talent, and mention any Texas-based subcontractors and suppliers that would be used and any other unique, Texas-based resources that would be leveraged.

# 11.4.9. Relocation Commitment to Texas (One page)

If your company will be relocating to Texas, provide a timetable with key dates indicating the Applicant's plan and commitment to relocate to Texas. In addition, describe which personnel and management will be headquartered in Texas.

# 11.4.10. Biographical Sketches of Key Scientific Personnel (Eight pages)

Provide a biographical sketch for up to four key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed two pages and must use the "Product Development Programs: Biographical Sketch" template. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see Section 11.4.8]).

# 11.4.11. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. The budget must be aligned with the proposed milestones. In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas State law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.
- The annual salary that an individual may receive under a CPRIT award for FY 2014 is \$200,000. In other words, an individual may request salary proportional to the percentage effort up to a maximum of \$200,000. Salary does not include fringe benefits. CPRIT FY 2014 is from September 1, 2014, through August 31, 2015.

# 12. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has

approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at <a href="www.cprit.state.tx.us">www.cprit.state.tx.us</a>. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10–703.12.

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

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>.

**Project Economics Sharing:** Recipients should also be aware that the funding award contract will include a revenue-sharing agreement and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions

are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.

#### 13. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas State law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has \$1.00 in matching funds for every \$2.00 from CPRIT. Matching funds need not be in hand when the application is submitted. However, matching funds must be obtained before CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be designated for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11, for specific requirements associated with demonstration of available funds.

#### 14. CONTACT INFORMATION

#### 14.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific and commercialization aspects of applications. Before contacting the HelpDesk, please refer to the "Instructions for Applicants" document, which provides a step-by-step guide on using the Application Receipt System.

**Dates of operation:** April 28, 2014, to May 29, 2014 (excluding public holidays)

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

Wednesday, 8 a.m. to 4 p.m. Central Time

**Tel:** 866-941-7146

E-mail: Help@CPRITGrants.org

#### 14.2. Programmatic Questions

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

**Tel:** 512-305-8486

E-mail: Help@CPRITGrants.org

Web site: <u>www.cprit.state.tx.us</u>

# **Third Party Observer Report**

# CPRIT Product Development Panel Screening Review Report

Report #2014-24

Panel Name: Product Development Screening Review Panel - 1

Panel Date: July 15, 2014 Report Date: July 16, 2014

#### **Background**

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

#### Introduction

The subject of this report is the first Product Development Panel screening chaired by Jack Geltosky and held over the phone on July 15, 2014.

#### **Panel Observation Objectives and Scope**

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

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

#### **Observation Results Summary**

Internal Audit participated in the Product Development Panel screening review meeting held telephonically and chaired by Jack Geltosky on July 15, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twelve product development applications were discussed and evaluated by the first Product Development Review Panel to determine which grants would be brought forth to present.
- Twelve review panel members, five CPRIT staff members, and one SRA employee were present for the teleconference.

- Six conflicts of interest were identified prior to or during the in-person review. All panel members with
  conflicts of interest panel members dropped off the teleconference and did not participate in the review of
  the conflicted applications. The reviewers with conflicts of interest did not come back to the teleconference
  until receipt of an email from an SRA employee allowing them to participate in the teleconference.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

#### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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

# CPRIT Product Development Panel Screening Review Report

Report #2014-25

Panel Name: Product Development Screening Review Panel - 2

Panel Date: July 16, 2014 Report Date: July 16, 2014

#### **Background**

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

#### Introduction

The subject of this report is the second Product Development Panel screening chaired by David Shoemaker and held over the phone on July 16, 2014.

#### **Panel Observation Objectives and Scope**

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

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

#### **Observation Results Summary**

Internal Audit participated in the Product Development Panel screening review meeting held telephonically and chaired by David Shoemaker on July 16, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Thirteen product development applications were discussed and evaluated by the first Product Development Review Panel to determine which grants would be invited to present.
- Twelve review panel members, two CPRIT staff members, and one SRA employee were present for the teleconference.

- One conflict of interest was identified prior to or during the in-person review. The panel member with a
  conflict of interest dropped off the teleconference and did not participate in the review of the conflicted
  application. The reviewer with a conflict of interest did not come back to the teleconference until receipt of
  an email from an SRA employee allowing them to participate in the teleconference.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

#### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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

# CPRIT Product Development Review Panel Report

Report #2014-26

Panel Name: Product Development Review Panel - 1

Panel Date: August 12, 2014 – August 13, 2014

Report Date: August 13, 2014

#### **Background**

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

#### Introduction

The subject of this report is the in-person Product Development Panel chaired by Jack Geltosky and held August 12, 2014 – August 13, 2014.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the in-person Product Development Panel screening review meeting held August 12, 2014 – August 13, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Over the course of two days, nine product development applications were presented, discussed, and evaluated
  by the Product Development Review Panel to determine which grants would be recommended for due
  diligence review. A score cut-off is determined by the panel as to which applications will move on further for
  due diligence.
- Ten review panel members, two advocate reviewers, four CPRIT staff members, and three SRA employees were present for the in-person panel meeting.

- Five conflicts of interest was identified prior to the meeting; however, only two out of the five applications
  with conflicts of interest were discussed. The panel members with the conflicts of interest left the meeting
  room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

#### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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

# CPRIT Product Development Review Panel Report

Report #2014-27

Panel Name: Product Development Review Panel - 2

Panel Date: August 14, 2014 – August 15, 2014

Report Date: August 15, 2014

#### **Background**

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

#### Introduction

The subject of this report is the in-person Product Development Panel chaired by David Shoemaker and held August 14, 2014 – August 15, 2014.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the in-person Product Development Panel screening review meeting held August 14, 2014 – August 15, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Over the course of two days, eight product development applications were presented, discussed, and
  evaluated by the Product Development Review Panel to determine which grants would be recommended for
  due diligence review. A score cut-off is determined by the panel as to which applications will move on further
  for due diligence.
- Ten review panel members, two advocate reviewers, two CPRIT staff members, and three SRA employees were present for the in-person panel meeting.

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

#### **Disclaimer**

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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

# CPRIT Due Diligence Evaluation

## Report #2015-214

Panel Name: FY15 Product Development Review Council

Panel Date: January 8, 2015 Report Date: January 8, 2015

#### **Background**

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

#### Introduction

The subject of this report is the Due Diligence Evaluation review of product development. The meeting was chaired by David Shoemaker and Jack Geltosky and held over the phone on January 8, 2015.

#### Panel Observation Objectives and Scope

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

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

#### **Observation Results Summary**

Internal Audit participated in the Product Development Review Council meeting held telephonically and chaired by David Shoemaker and Jack Geltosky on January 8, 2015. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Four product development applications were discussed and evaluated by the Product Development Review Council to determine which grants would receive CPRIT funding.
- Seven council members, five CPRIT staff members, and one SRA employee was present for the Council
  meeting over the phone.
- One conflict of interest was identified prior to the call. The individual with the conflict left before the discussion of the conflicted application and then returned to the call when prompted.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.

- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

#### Disclaimer

The third-party observation did not include the following:

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

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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

## **Noted Conflicts of Interest**

#### Conflicts of Interest for Product Development Cycle 15.1 Applications (Product Development Cycle 15.1 Awards Announced at February 18, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Cycle 15.1 include *New Company Product Development Awards*, *Company Relocation Product Development Awards*, and *Established Company Product Development Awards*. Four applications were recommended to the PIC and Oversight Committee in February 2015 while other applications remain in due diligence and may be recommended in May 2015. Applications still in due diligence review are de-identified. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

<b>Application ID</b>	<b>Applicant</b>	Company	<b>Conflict Noted</b>	
Applications Considered by the PIC and Oversight Committee				
DP150031	Merchant, Fahar	Medicenna	Lloyd, Ramona	
		Therapeutics, Inc.		
Applications F	Recommended For Due	Diligence Review, which	ch may be later	
Recommended to the PIC and Oversight Committee				
DP150***	***	***	Geltosky, Jack;	
			Spector, Neil	
Applications Not Recommended for PIC or Oversight Committee Consideration				
DP150010*	Carroll, Stephen	Synergys	Spector, Neil	
		Biotherapeutics, Inc.		
DP150023*	Burns, Lindsay	Pain Therapeutics,	Jones, Elaine;	
		Inc.	Saxberg, Bo	
DP150036	Schmid, Steven	Vivo Biosciences,	Craig, Adam	
		Inc.		
DP150038	Kim, Jason	Molecular Templates,	Craig, Adam	
		Inc.		
DP150048	Bearss, David	Tolero	Craig, Adam;	
		Pharmaceuticals, Inc.	Saxberg, Bo; Spector,	
			Neil	

# **High Level Summary of Due Diligence**

#### NanoTx Therapeutics

#### Summary of CPRIT Diligence and Recommendation for Funding

NanoTx currently has an open IND for the treatment of glioblastoma following a pre-IND meeting with the FDA.

There is always a clinical risk with any new drug development. Given that this is a known treatment regimen using a benign and established delivery technology, the main risk would appear to come from liposome leakage, either before administration or *in vivo*. These concerns have been adequately addressed by the applicant, and the Product Development Review Council endorses funding for this application.

#### Medicenna Therapeutics, Inc.

#### Summary of CPRIT Diligence and Recommendation for Funding

Medicenna has a strong regulatory plan. The company management is experienced, and it has a strong advisory board. Medicenna has identified a number of key risks that the development program faces, such as clinical study risks, and has taken appropriate actions to mitigate these. It also faces competition risks, as does any development program. Given the strong science and high unmet medical need and the inherent difficulties of treating GBM, these risks were judged to be acceptable.

The Product Development Review Council endorses funding for this application.

#### Armada Pharmaceuticals, Inc.

#### Summary of CPRIT Diligence and Recommendation for Funding

Despite the promise they hold as effective anticancer agents, many challenges remain in the preclinical-to-clinical translation of antibody-drug conjugates (ADCs). During the drug development stage, it becomes cumbersome to characterize and understand the disposition of each component of every ADC to help to design an optimal molecule with maximum therapeutic potential. This is a manageable problem.

AVID100 exhibited excellent efficacy in pre-clinical testing against many tumor models (including NSCLC, head & neck cancer, ovarian cancer, pancreatic cancer, and breast cancer) expressing or overexpressing EGFR. In addition, the safety profile of AVID100 *in vitro*, as well as in monkey toxicology studies, seems to be very similar to the original cetuximab antibody.

Taken as a whole, this project is very promising, and the Product Development Review Council endorses funding for this application.

#### **Immatics Biotechnologies**

#### Summary of CPRIT Diligence and Recommendation for Funding

#### **Strengths:**

- (1) The application presents intriguing ideas that are clearly explained and justified. Basically, they will improve on adoptive cell therapy (ACT) by: (i) selecting specific subsets of antigen-specific T-cells (ACTolog) and (ii) engineering T-cells to contain optimized T-cell receptors for specific cancer antigens (ACTengine).
- (2) The application presents an unabashed assessment of risks (scientific, regulatory, even recruiting talent) and mitigation strategies, demonstrating clear thinking and straightforwardness.
- (3) This is a strong team with established collaborations with ACT experts in Texas.
- (4) This is a refreshing approach a non-virtual company with plans to hire 50 people in three years.
- (5) There is a long-term business plan to grow a company with many products.
- (6) There is clear differentiation from the parent company, with the benefits of licensing technology and early financial support.

#### Weaknesses:

- (1) While several aspects of the technologies have been validated, the risks are significant because the products/processes are early in development.
- (2) Given the complexity of patient enrollment and development of personalized product, the clinical plan timelines may be optimistic.

Taken as a whole, this project is quite promising, and the Product Development Review Council endorses funding for this application.

## **De-Identified Overall Evaluation Scores**

### New Company Product Development Awards

Product Development Cycle 15.1

Application ID	Final Overall
	Score
DP150031*	2.0
DP150021*	2.0
DP150029*	2.3
DP150039*	2.4
cc1**	2.9
cc2**	3.0
aa1	3.9
aa2	4.2
aa3	4.4
aa4	4.5
aa5	4.8
aa6	5.5
aa7	5.8
aa8	6.3
aa9	6.5
bb1	6.7
bb2	7.0

<sup>\*=</sup>Recommended for funding

<sup>\*\*=</sup>Applications are in the due diligence stage of review and may be recommended for grant awards at the May 2015 Oversight Committee meeting

# Final Overall Evaluation Scores and Rank Order Scores

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to <a href="mailto:bill.Rice@stdavids.com">Bill.Rice@stdavids.com</a>

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

Dear Mr. Roberts and Dr. Rice:

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendations for CPRIT New Company Product Development grant awards. The companies on the attached list submitted proposals in response to CPRIT requests for applications (RFA) released for the first review cycle of FY2015. These are the first four of eight currently pending awards approved by the review panels. The final four are still in the due diligence process. Each recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports.

The projects are numerically ranked in the order the PDRC recommends the applications be funded. The PDRC's order ranks one application, Armada Pharmaceuticals, Inc., ahead of another application, Immatics Biotechnologies, which received a more favorable score. The ranking was approved by the PDRC due to results from the due diligence reviews that elevated Armada's application. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PDRC did not make changes to the funding amounts, goals, timelines, or project objectives requested by the applicants.

Our recommendations met the PDRC's standards for grant award funding. These standards include the companies' potential to: 1.) expedite innovation and product development in cancer research and treatments; 2.) create and expand the number of high-quality new jobs in Texas; and 3.) make a return on CPRIT's investment in cancer research.

Sincerely,

/JG/

Chair, CPRIT Product Development Review Council

#### Attachment

Product Development Review Council Award Recommendations FY2015, Cycle 1, Part 1

Rank	Application ID	Company Name	Project	Requested Budget	Overall Score
1	DP150021	NanoTx Therapeutics	Development of Rhenium Nanoliposomes for Cancer Therapy	\$ 2,000,000	2.0
2	DP150031	Medicenna Therapeutics, Inc.	A Multi-Targeted Approach for Recurrent Glioblastoma and Other Aggressive Cancers: Exploiting the Potential of IL-4 Fusion Proteins Treatment of Cancer	\$14,140,090	2.0
3	DP150039	Armada Pharmaceuticals, Inc.	New Company Formation for the Development of Anti-Cancer Antibody – Drug Conjugate Therapeutics	\$12,750,000	2.4
4	DP150029	Immatics Biotechnologies	Personalized Cellular Immunotherapy against Novel Cancer Targets	\$19,652,175	2.3



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# CEO AFFIDAVIT Application DP150021 New Company Product Development Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *New Company Product Development Awards* Request for Applications (RFA). CPRIT received 19 applications for this RFA. The application was assigned to Product Development Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO. Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the u the day of february by WAYNE R. ROBERTS.	ndersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas  My Commission Expires  SEPTEMBER 30, 2017  Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2015 CYCLE 1

PROGRAM Product Development

AWARD MECHANISM New Company Product Development Awards (NEWCO)

APPLICATION ID DP150021

APPLICATION TITLE Development of Rhenium Nanoliposomes for Cancer

Therapy

APPLICANT NAME Brenner, Andrew ORGANIZATION NanoTx Therapeutics

PANEL NAME Product Development Panel-1 (PDP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/09/14	11/07/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	04/28/14	11/07/14
	CPRIT Application Receipt System (CARS) closed	05/29/14	11/07/14
	Date application submitted	05/29/14	11/07/14
	Method of submission	CARS	11/07/14
	Within receipt period	YES	11/07/14
	Appeal to submit application after CARS closed	N/A	11/07/14
	Appeal for late application submission accepted	N/A	11/07/14
	Submission of application fee	YES	01/26/15
	Administrative review notification	N/A	11/07/14
	Donation(s) made to CPRIT/foundation	NO	11/07/14
	Assigned to primary reviewers	06/25/14	11/07/14
2. Receipt, Referral,	Applicant notified of review panel assignment	07/11/14	11/07/14
and Assignment	Primary Reviewer 1 COI signed	06/19/14	11/07/14
	Primary (Advocate) Reviewer 2 COI signed	06/13/14	11/07/14
	Primary Reviewer 3 COI signed	06/18/14	11/07/14
	Primary Reviewer 4 COI signed	06/17/14	11/07/14
	Primary Reviewer 1 critique submitted	07/18/14	11/07/14
	Primary (Advocate) Reviewer 2 critique submitted	07/18/14	11/07/14
	Primary Reviewer 3 critique submitted	07/18/14	11/07/14
	Primary Reviewer 4 critique submitted	07/18/14	11/07/14
3. Peer Review:	COI indicated by non-primary reviewer	NONE	11/07/14
Screening	COI recused from participation	N/A	11/07/14
Teleconference	Peer Review: Screening Teleconference	07/15/14	11/07/14
	Post-Screening Teleconference score report	07/15/14	11/07/14
	Post review statements signed	08/12/14	11/07/14
	Third Party Observer Report	07/16/14	11/07/14
	Recommended for On-Site Meeting	YES	11/07/14
	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
	Peer Review: On-Site Meeting	08/12/14-08/13/14	11/07/14
4. Peer Review: On-	Post review statements signed	08/26/14	11/07/14
Site Meeting	Third Party Observer Report	08/13/14	11/07/14
	Score report delivered to CPDO	08/30/14	11/07/14
	Recommended for due diligence and IP review	YES	11/07/14
	Final due diligence review submitted to PDRC	12/26/14	01/26/15
5. Due Diligence and IP	Intellectual Property conflict check	11/17/14	01/30/15
Review	Final Intellectual property review submitted	12/21/14	01/30/15
	COI indicated by PDRC member	NONE	01/13/15
	COI recused from participation	N/A	01/13/15
6. Final PDRC	Due Diligence Evaluation Meeting / PDRC Meeting	01/08/15	01/13/15
Recommendation	Third Party Observer Report	01/08/15	01/27/15
	Recommended for grant award	YES	01/13/15
	PDRC Chair Notification to PIC and OC	01/21/15	01/27/15
	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
7. PIC Review	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
8. Oversight	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	The second secon	0/0	

The identity of the attesting party is retained by CPRIT.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# CEO AFFIDAVIT Application DP150029 New Company Product Development Awards

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *New Company Product Development Awards* Request for Applications (RFA). CPRIT received 19 applications for this RFA. The application was assigned to Product Development Panel-2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the undersign the day of	ned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Taxes  My Commission Expires  SEPTEMBER 30, 2017
	Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2015 CYCLE 1

PROGRAM Product Development

AWARD MECHANISM New Company Product Development Awards (NEWCO)

APPLICATION ID DP150029

APPLICATION TITLE Personalized Cellular Immunotherapy against Novel

APPLICATION ITTLE

APPLICANT NAME
ORGANIZATION

Cancer Targets
Kuttruff-Coqui, Sabrina
Immatics Biotechnologies

PANEL NAME Product Development Panel-2 (PDP-2)

Category	Compliance Requirement	triformation	Attestation Date
	RFA published in Texas Register	05/09/14	11/07/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	04/28/14	11/07/14
	CPRIT Application Receipt System (CARS) closed	05/29/14	11/07/14
	Date application submitted	05/28/14	11/07/14
	Method of submission	CARS	11/07/14
	Within receipt period	YES	11/07/14
	Appeal to submit application after CARS closed	N/A	11/07/14
	Appeal for late application submission accepted	N/A	11/07/14
	Submission of application fee	YES	01/26/15
	Administrative review notification	N/A	11/07/14
	Donation(s) made to CPRIT/foundation	NO	11/07/14
	Assigned to primary reviewers	06/25/14	11/07/14
2. Receipt, Referral,	Applicant notified of review panel assignment	07/11/14	11/07/14
and Assignment	Primary Reviewer 1 COI signed	06/18/14	11/07/14
	Primary (Advocate) Reviewer 2 COI signed	06/16/14	11/07/14
	Primary Reviewer 3 COI signed	06/16/14	11/07/14
	Primary Reviewer 4 COI signed	06/20/14	11/07/14
	Primary Reviewer 1 critique submitted	07/16/14	11/07/14
	Primary (Advocate) Reviewer 2 critique submitted	07/16/14	11/07/14
	Primary Reviewer 3 critique submitted	07/17/14	11/07/14
	Primary Reviewer 4 critique submitted	07/18/14	11/07/14
3. Peer Review:	COI indicated by non-primary reviewer	NONE	11/07/14
Screening	COI recused from participation	N/A	11/07/14
Teleconference	Peer Review: Screening Teleconference	07/16/14	11/07/14
}	Post-Screening Teleconference score report	07/16/14	11/07/14
	Post review statements signed	08/14/14	11/07/14
	Third Party Observer Report	07/16/14	11/07/14
	Recommended for On-Site Meeting	YES	11/07/14
	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
	Peer Review: On-Site Meeting	08/14/14-08/15/14	11/07/14
4. Peer Review: On-	Post review statements signed	08/15/14	11/07/14
Site Meeting	Third Party Observer Report	08/15/14	11/07/14
	Score report delivered to CPDO	08/30/14	11/07/14
		VES YES	11/07/14
	Recommended for due diligence and IP review	_	
5. Due Diligence and IP	Final due diligence review submitted to PDRC Intellectual Property conflict check	12/26/14	01/26/15
Review		12/21/14	01/30/15
	Final intellectual property review submitted  COI indicated by PDRC member		01/13/15
		NONE N/A	
C CII DDDC	COI recused from participation		01/13/15
5. Final PDRC	Due Diligence Evaluation Meeting / PDRC Meeting	01/08/15	+
Recommendation	Third Party Observer Report	01/08/15	01/27/15
	Recommended for grant award	YES OA (A.F.	01/13/15
	PDRC Chair Notification to PIC and OC	01/21/15	01/27/15
	COI indicated by PIC member	NONE	02/03/15
7. PIC Review	COI recused from participation	N/A	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
8. Oversight	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# CEO AFFIDAVIT Application DP150031 New Company Product Development Awards

THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *New Company Product Development Awards* Request for Applications (RFA). CPRIT received 19 applications for this RFA. The application was assigned to Product Development Panel-2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the und the day of February by WAYNE R. ROBERTS.	lersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2015 CYCLE 1

PROGRAM Product Development

AWARD MECHANISM New Company Product Development Awards (NEWCO)

APPLICATION ID DP150031

A Multi-Targeted Approach For Recurrent Glioblastoma

APPLICATION TITLE and Other Aggressive Cancers: Exploiting The Potential Of

IL-4 Fusion ProteinsTreatment of Cancer

APPLICANT NAME Merchant, Fahar

ORGANIZATION Medicenna Therapeutics, Inc.
PANEL NAME Product Development Panel-2 (PDP-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/09/14	11/07/14
	CPRIT Application Receipt System (CARS) opened	04/28/14	11/07/14
	CPRIT Application Receipt System (CARS) closed	05/29/14	11/07/14
	Date application submitted	05/28/14	11/07/14
1. Pre-Receipt	Method of submission	CARS	11/07/14
	Within receipt period	YES	11/07/14
	Appeal to submit application after CARS closed	N/A	11/07/14
	Appeal for late application submission accepted	N/A	11/07/14
	Submission of application fee	YES	01/26/15
	Administrative review notification	N/A	11/07/14
	Donation(s) made to CPRIT/foundation	NO	11/07/14
	Assigned to primary reviewers	06/25/14	11/07/14
2. Receipt, Referral,	Applicant notified of review panel assignment	07/11/14	11/07/14
and Assignment	Primary Reviewer 1 COI signed	06/18/14	11/07/14
	Primary (Advocate) Reviewer 2 COI signed	06/16/14	11/07/14
	Primary Reviewer 3 COI signed	06/20/14	11/07/14
	Primary Reviewer 4 COI signed	06/23/14	11/07/14
	Primary Reviewer 1 critique submitted	07/16/14	11/07/14
	Primary (Advocate) Reviewer 2 critique submitted	07/16/14	11/07/14
	Primary Reviewer 3 critique submitted	07/16/14	11/07/14
	Primary Reviewer 4 critique submitted	07/16/14	11/07/14
3. Peer Review:	COI indicated by non-primary reviewer	Lloyd, Ramona	11/07/14
Screening	COI recused from participation	YES	11/07/14
Teleconference	Peer Review: Screening Teleconference	07/16/14	11/07/14
	Post-Screening Teleconference score report	07/16/14	11/07/14
	Post review statements signed	08/14/14	11/07/14
	Third Party Observer Report	07/16/14	11/07/14
	Recommended for On-Site Meeting	YES YES	11/07/14
	COI indicated by non-primary reviewer	Lloyd, Ramona	11/07/14
	COI recused from participation	YES YES	11/07/14
	Peer Review: On-Site Meeting	08/14/14-08/15/14	
1. Peer Review: On-			11/07/14
Site Meeting	Post review statements signed	08/15/14	11/07/14
	Third Party Observer Report	08/15/14	11/07/14
	Score report delivered to CPDO	08/30/14	11/07/14
	Recommended for due diligence and IP review	YES	11/07/14
. Due Diligence and IP	Final due diligence review submitted to PDRC	12/26/14	01/26/15
Review	Intellectual Property conflict check	11/17/14	01/30/15
	Final intellectual property review submitted	12/21/14	01/30/15
	COI indicated by PDRC member	Geltosky, Jack	01/13/15
	COI recused from participation	YES	01/13/15
5. Final PDRC	Due Diligence Evaluation Meeting / PDRC Meeting	01/08/15	01/13/15
tecommendation	Third Party Observer Report	01/08/15	01/27/15
	Recommended for grant award	YES	01/13/15
	PDRC Chair Notification to PIC and OC	01/21/15	01/27/15
7. PIC Review	COI indicated by PIC member	NONE	02/03/15
	COI recused from participation	N/A	02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
B. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
4	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# CEO AFFIDAVIT Application DP150039 New Company Product Development Awards

THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., IIealth & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *New Company Product Development Awards* Request for Applications (RFA). CPRIT received 19 applications for this RFA. The application was assigned to Product Development Panel-2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

On January 30, 2015, Dr. David Lakey stepped down as Commissioner of the Texas Department of State Health Services. At the time of the meeting of the PIC, the new Interim Commissioner Kirk Cole, who had just been named, was unable to attend; therefore, the PIC consisted of all statutorily required members except for the Commissioner of the Texas Department of State Health Services.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis
SWORN to and SUBSCRIBED before me, the undersigned authority, on the
Sandra Reyes Notary Public, State of Texas  Notary Public, State of Texas  Notary Public, State of Texas  September 30, 2017
Notary Public, State of Texas  Notary without Bond

## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2015 CYCLE 1

PROGRAM Product Development

AWARD MECHANISM New Company Product Development Awards (NEWCO)

APPLICATION ID DP150039

Armada Pharmaceuticals Inc. New Company Formation

APPLICATION TITLE For Development of Anti-Cancer Antibody-Drug Conjugate

Therapeutics
APPLICANT NAME Tikhomirov, Ilia

ORGANIZATION Armada Pharmaceuticals, Inc

PANEL NAME Product Development Panel-2 (PDP-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/09/14	11/07/14
	CPRIT Application Receipt System (CARS) opened	04/28/14	11/07/14
1. Pre-Receipt  2. Receipt, Referral, and Assignment  3. Peer Review: Screening Teleconference  4. Peer Review: On-Site Meeting  5. Due Diligence and P Review  6. Final PDRC Recommendation  7. PIC Review	CPRIT Application Receipt System (CARS) closed	05/29/14	11/07/14
	Date application submitted	05/29/14	11/07/14
1. Pre-Receipt	Method of submission	CARS	11/07/14
	Within receipt period	YES	11/07/14
	Appeal to submit application after CARS closed	N/A	11/07/14
	Appeal for late application submission accepted	N/A	11/07/14
	Submission of application fee	YES	01/26/15
	Administrative review notification	06/16/14	11/07/14
	Donation(s) made to CPRIT/foundation	NO	11/07/14
	Assigned to primary reviewers	06/25/14	11/07/14
. Receipt, Referral,	Applicant notified of review panel assignment	07/11/14	11/07/14
and Assignment	Primary Reviewer 1 COI signed	06/23/14	11/07/14
	Primary (Advocate) Reviewer 2 COI signed	06/12/14	11/07/14
	Primary Reviewer 3 COI signed	06/16/14	11/07/14
	Primary Reviewer 4 COI signed	06/20/14	11/07/14
	Primary Reviewer 1 critique submitted	07/16/14	11/07/14
	Primary (Advocate) Reviewer 2 critique submitted	07/17/14	11/07/14
	Primary Reviewer 3 critique submitted	07/17/14	11/07/14
	Primary Reviewer 4 critique submitted	07/18/14	11/07/14
Screening	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
Teleconference	Peer Review: Screening Teleconference	07/16/14	11/07/14
	Post-Screening Teleconference score report	07/16/14	11/07/14
	Post review statements signed	08/14/14	11/07/14
	Third Party Observer Report	07/16/14	11/07/14
	Recommended for On-Site Meeting	YES	11/07/14
	COI indicated by non-primary reviewer	NONE	11/07/14
	COI recused from participation	N/A	11/07/14
	Peer Review: On-Site Meeting	08/14/14-08/15/14	11/07/14
	Post review statements signed	08/15/14	11/07/14
ite Meeting	Third Party Observer Report	08/15/14	11/07/14
	Score report delivered to CPDO	08/30/14	11/07/14
	Recommended for due diligence and IP review	YES	11/07/14
	Final due diligence review submitted to PDRC	12/26/14	01/26/15
	Intellectual Property conflict check	11/17/14	01/30/15
P Review	Final intellectual property review submitted	12/21/14	01/30/15
	COI indicated by PDRC member	NONE NONE	01/30/15
	COI recused from participation	N/A	01/13/15
Final PDPC	Due Diligence Evaluation Meeting / PDRC Meeting	01/08/15	01/13/15
	Third Party Observer Report	01/08/15	01/13/15
		YES	01/27/13
	Recommended for grant award PDRC Chair Notification to PIC and OC	01/21/15	
	COI indicated by PIC member	NONE	01/27/15
	COI recused from participation	N/A	02/03/15
. PIC Review			02/03/15
	PIC review meeting	02/03/15	02/03/15
	Recommended for grant award	YES	02/03/15
	CEO Notification to Oversight Committee	DATE NONE	
	COI indicated by Oversight Committee member	NAME or NONE	
0	COI recused from participation	YES/NO or N/A	
Chiorciolok	Donation(s) made to CPRIT/foundation	YES/NO	
		DATE	Maria Caracteria Control
	Presented to CPRIT Oversight Committee		
Oversight Committee Approval	Award approved by Oversight Committee Authority to advance funds requested	YES/NO YES/NO	

The identity of the attesting party is retained by CPRIT.



#### **MEMORANDUM**

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS

FROM: NED HOLMES, NOMINATIONS SUBCOMMITTEE CHAIR

**SUBJECT:** INTENTION TO RECOMMEND APPROVAL OF APPOINTMENTS

TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS

**COMMITTEE** 

**DATE:** FEBRUARY 13, 2015

#### **Summary and Recommendation:**

The Chief Executive Officer has appointed three experts to the CPRIT's Scientific Research and Prevention Programs Committee; two appointments are to the Prevention Program review panels and one appointment is to an Academic Research Program review panel. CPRIT's statute requires the appointments be approved by the Oversight Committee. The Nominations Subcommittee discussed the appointments at its meeting on February 13, 2015, and recommends that the Oversight Committee vote to approve the appointments.

#### **Discussion:**

Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research, including product development research. Peer reviewers perform an important role for the state; all CPRIT grant awards must first be recommended by a Scientific Research and Prevention Programs committee. Individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members must be exceptionally qualified, highly respected, well-established members of the cancer research, product development research, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Nominations Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The Nominations Subcommittee considered the pending peer reviewer appointments and recommends Oversight Committee approval.

#### **BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.** 

NAME	POSITION TITLE
Pe'er Dana	Assistant Professor, Biological Sciences
eRA COMMONS USER NAME	
DanaPeer	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Hebrew University, Jerusalem Israel	B.Sc.	1995	Mathematics
Hebrew University, Jerusalem Israel	M.Sc.	1999	Computer Science
Hebrew University, Jerusalem Israel	Ph.D,	2003	Computational Biology
Harvard Medical School	Postdoc	2006	Systems Biology

#### A. Personal Statement

Our lab focuses on integration and analysis of high-throughput data towards understanding how molecular network process signals and manifest phenotype. With the advent of cost effective sequencing and genotyping, in the past 6 years our interest is focused on elucidating how genetic variation alters signal processing and subsequently propagating into more complex phenotype. My lab is interdisciplinary and cross-trains in both computer science and biology, with a systems biology and genomics focus. In addition to activity internal to my own lab, we work in a collaborative effort with leading cancer biologists studying melanoma, glioblastoma, ovarian cancer, breast cancer, colon cancer, lung cancer, acute myloid leukemia, chronic lymphocytic leukemia and acute lymphoblastic leukemia at Columbia University, Memorial Sloan-Kettering Cancer Center, Stanford University, Ontario Cancer Institute, Dana Farber Cancer Institute and Mass General Hospital.

## B. Positions and Honors. Positions and Employment

1996-2002	Teaching Assistant, Computer Science Dept., Hebrew University, Jerusalem Israel.
2003-2006	Postdoctoral Fellow, Church Lab, Genetics Dept, Harvard Medical School, Boston, MA.
2006-2012	Assistant Professor, Biological Sciences Dept., Columbia University, New York, NY.
2012 -	Associate Professor, Biological Sciences Dept., Columbia University, New York, NY.

#### **Editorial Boards and Advisory Committees (selected and recent)**

2015-present	External Consultants	Panel: for NIH Common	Fund Single Cell Analysis Progr	ram
<b>2</b> 010-0103011	EXICITIAL CONSULATION	i ancı. Idi ivili danınıdı	i i uliu oliluic ocii Aliaivala i ioul	ann

2014-present Board of Reviewing Editors, ELIFE

2009-present Editorial board, Cell

2009-present NIH External Consultants Panel: NIH Encyclopedia of DNA Elements (ENCODE) Project

2014 Review panel for NHGRI CEGS centers of excellence in genomic science

2013 Co-chair, CSHL Biology of Genomes, computational genomics

2013 Damon Runyon Fellowship selection committee

#### **Selected Honors (scholarships and prizes)**

2014 NIH Director's Pioneer Award

2014 SU2C Phil Sharp Award

2014 Overton Prize

2012 NSF CAREER Award

- 2012 RECOMB 2012 Test of Time Award2010 SU2C/AACR Innovator award.
- 2009 Packard Fellowship in Science and Engineering
- 2007 NIH Directors New Innovator Award
- 2005 Runner up for "Breakthough of the year", Science Magazine
- 2005 Career Award at the Interface of Science, Burroughs Welcome Fund
- 2003 Postdoctoral Fellowship in Biological Informatics, National Science Foundation
- 2001 Best Paper Award, International Conference in Intelligent Systems for Biology

#### **Reviewer for Journals:**

Nature, Nature Genetics; Molecular Cell; Proceedings of the National Academy of Science; Genome Research; PLOS Biology, PLOS Computational Biology; Nucleic Acid Research; Molecular Systems Biology; Bioinformatics; Genome Biology

#### **Invited Speaker (Selected List):**

#### **Invited Speaker (recent and selected):**

12/2014	NIH Common Fund High Risk High Reward Symposium, Bethesda, MD
12/2014	Seminar at Broad institute of MIT and Harvard, Cambridge, MA
11/2014	Keynote speaker, Recomb Regulatory Genomics, San Diego, CA
10/2014	Keynote speaker, SystemsX.ch Conference on Systems Biology, Lausanne, Switzerland
10/2014	Beyond the Genome: Cancer Genomics, Boston, MA
09/2014	Single-cell genomics 2014, Stockholm, Sweden
07/2014	Overton prize Keynote lecture at Intelligent Systems for Molecular Biology, Boston MA
05/2014	BioFrontiers Symposium on Big Data, Genomics and Molecular Networks, Boulder CO
05/2014	Co-chair computational genomics, CSHL Biology of Genomes, CSHL, NY
04/2014	ASBMB, 2014 Annual Meeting, San Diego, CA
04/2012	AACR Annual Meeting, "meet the experts" talk, San Diego, CA
03/2014	LabLinks symposium "Gene Circuits: molecular biology AND synthetic biology, Cambridge, MA
02/2014	Nature Webcast "Techniques for high-dimensional analysis of the human immune system"
11/2013	Seminar at UCSF, Integrative Program in Quantitative Biology, San Francisco, CA
10/2013	AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics, Boston, MA
10/2013	Nature CNIO Frontiers in Tumour Heterogeneity and Plasticity, Madrid, Spain
10/2013	Single Cell Genomics workshop, Weizmann Institute, Rehovot, Israel
09/2013	Third AACR International Conference on Frontiers in Basic Cancer Research, Maryland.
08/2013	Keynote Speaker, International Conference on Systems Biology, Copenhagen, Denmark
08/2013	FASEB meeting on hematologic malignancies, Saxtons River, VT
04/2013	Seminar at Cambridge Institute, Cambridge UK
01/2013	AACR Systems Biology "Think Tank", Philadelphia PA
11/2012	EMBO From Functional Genomics to Systems Biology, Heidelberg, Germany
05/2012	Integrative Network Biology 2012: Network Medicine, Denmark
04/2012	AACR Annual Meeting, "meet the experts" talk, Chicago, IL
02/2012	Keystone symposia, "Complex Traits", Breckenridge, CO
11/2011	CRI Symposium 2011 'Unanswered Questions in Transcription, Cambridge, England
04/2011	Dana Farber Systems Biology Distinguished lecture series, Boston, MA
04/2011	AACR Annual Meeting, Major Symposia, Orlando, FL
01/2011	MD Anderson Hematology Rounds, Houston, TX
09/2010	Stanford Center for Cancer Systems Biology, Palo Alto, CA
08/2010	Cancer Bioinformatics Workshop, Cambridge Research Institute, Cambridge, UK
08/2010	Cold Spring Harbor meeting on Systems Biology of Networks, Hixton, UK

#### C. Selected peer-reviewed publications

1. Oren Litvin, Sarit Swartz, Tanya Schild, Mark Rocco, Zhenmao Wan, Bo-Juen Chen, Noel Goddard, Christine Pratilas, Dana Pe'er, "Interferonα/β enhances the cytotoxic response of MEK inhibition in

- melanoma" Molecular Cell in press.
- 2. Felix Sanchez-Garcia\*, Patricia Villagrasa\*, Junji Matsui, Dylan Kotliar, Verónica Castro, Uri-David Akavia, Bo-Juen Chen, Laura Saucedo-Cuevas, Ruth Rodriguez Barrueco, David Llobet-Navas, Jose M. Silva<sup>&</sup>, Dana Pe'er<sup>&</sup>, "Helios identifies novel oncogenes in breast cancer by integrating genomic characterization of primary tumors and functional shRNA-screens on cell lines." Cell 2014 Dec 4;159(6):1461-75. Epub 2014 Nov 26.
- 3. Smita Krishnaswamy, Matthew H. Spitzer, Michael Mingueneau, Sean C Bendall, Oren Litvin, Erica Stone, Dana Pe'er\*#, Garry P Nolan\* (\* these authors contributed equally, # corresponding author), ("Conditional Density-based Analysis of Variability in T Cell Signaling in Single-cell Data" Science 2014 Nov 28;346(6213):1250689. Epub 2014 Oct 23. 1 citation
- 4. Sean C Bendall\*, Kara L Davis\*, El-ad David Amir\*, Michelle D Tadmor, Erin F Simonds, Tiffany J Chen, Daniel K Shenfeld, Garry P Nolan&, Dana Pe'er&, "Single-Cell Trajectory Detection Uncovers Progression and Regulatory Coordination in Human B cell Development", *Cell*. 2014 Apr 24;157(3).
- 5. Carl Danussi\*, Uri David Akavia\*, Fransesco Niola, Andreja Jovic, Anna Lasorella, Dana Pe'er<sup>&</sup>, Antonio Iavarone<sup>&</sup>, "RHPN2 Drives Mesenchymal Tranformation in Malignant Glioma by Triggering RhoA Activation". (\* these authors contributed equally, two co-first, two co-last authorships), Cancer Research, 2013 Aug 15;73(16):5140-50.
- 6. El-ad David Amir, Erin Simonds, Michelle Tadmor, Kara Davis, Jacob Levine, Sean Bendall, Daniel Shenfeld, Smita Krishnaswamy, Garry Nolan and Dana Pe'er. "viSNE enables visualization of high dimensional single-cell data and reveals phenotypic heterogeneity of leukemia". *Nature Biotechnology* 2013 Jun;31(6):545-52.
- 7. Bendall SC., Simonds EF., Qiu P., Amir ED., Krutzik PO., Finck R., Bruggner RV., Melamed R. Ornatsky OI., Balderas RS., Plevritis SK., Sachs K., Pe'er D., Tanner SD., Nolan GP., "Single-cell Mass Cytometry of Differential Immune and Drug Responses Across a Human Hematopoietic Continuum", *Science* 332(6030):687-96, May 2011.
- 8. Pe'er D., Hacohen N., Principles and Strategies for Developing Network Models in Cancer. *Cell.* 144(6):864-73, March 2011.
- **9.** Akavia UD., Litvin O., Kim J., Sanchez-Garcia F., Kotliar D., Causton, HC., Pochanard P., Mozes E., Garraway LA., Pe'er D. "An Integrated Approach to Uncover Drivers of Cancer", *Cell*, 10;143(6):1005-17, Dec 2010.
- 10. Sanchez-Garcia F., Akavia UD., Moses E., Pe'er D. "JISTIC: Identification of Significantly Aberrant Regions", BMC-*Bioinformatics*, 11(1):189, Apr 2010
- **11. Chen, BJ., Causton, HC.**, Goddard, NL., Perlstein, EO. and **Pe'er, D.** "Harnessing gene expression to identify the genetic basis of drug resistance", *Molecular Systems Biology*, 2009;5:310, Oct 2009
- **12.** Litvin, O., Chen, BJ., Causton, HC. and Pe'er, D. "Modularity and interactions in the genetics of gene expression.", *Proceedings of the National Academy of Science*, 106(16):6441-6, April 2009.
- **13.** Lee, S\*., Pe'er, D\*. Dudley, A., Church, G., and Koller, D. \* **these authors contributed equally**. "Identifying Regulatory Mechanisms and their Individual Variation Reveals Key Role of Chromatin Modification", *Proceedings of the National Academy of Science*, 19;103(38):14062-7, Sep 2006.
- 14. Sachs, K\*., Perez, O\*., Pe'er D\*., Lauffenburger, D., and Nolan, G., \* these authors contributed equally, "Causal protein-signaling networks derived from multiparameter single-cell data.", *Science* 308:523-529, April 2005.
- 15. Segal, E\*., Shapira, M., Regev, A\*., **Pe'er, D.\***, Botstein, D., Koller, D. and Friedman, N., , \* **these authors contributed equally**, "Module networks: identifying regulatory modules and their condition specific regulators from gene expression data". *Nature Genetics* 34:166-176, June 2003.

#### D. Research Support

NPI, NIH Pioneer 12/01/2014-11/30/2019 Single cell mapping of developmental trajectories underlying health and disease

NIH/NCI R01 CA164729 (Pe'er) 09/01/12-06/30/17 Integrative Cancer Genomics: Drivers, Pathways and Drugs

NSF/CAREER MCB-1149728 (Pe'er) 06/01/12-05/31/17 Characterizing a Landscape of Signal Processing in the Immune System

DOD W81XWH12-0591(Nolan, Stanford) 04/01/12-03/31/17 Organizing cellular & molecular heterogeneity in high-grade serous ovarian cancer

SU2C-AACR IRG0811(Pe'er) 06/01/11-05/31/13 A Systems Approach to Understanding Tumor Specific Drug Response

SU2C-AACR Phil-Sharp Award(Pe'er) 05/01/14-04/30/16
Analysis of High-Dimension Single-Cell Data from Cancer Immunotherapy Clinical Trials

Packard Fellowship for Science and Engineering 34714 (Pe'er) 10/09/09-10/08/14 Harnessing sequence diversity to elucidate the principles of cellular signal processing

NIH/NCI U54 CA121852 (Califano, CUMC) 09/26/10-07/31/15 National Center for the multi-scale study of cellular Networks

D Grants

**Active Grants** 

co-PI (PI Snyder, Stanford), NIH Center grant U01
"Genomics of Gene Regulation in Progenitor to Differentiated Keratinocytes"

PI, NIH Pioneer 12/01/2014-11/30/2019 Single cell mapping of developmental trajectories underlying health and disease

PI, NIH-RO1, 09/01/2012-08/31/2017 Integrative Cancer Genomics: Drivers, Pathways and Drugs.

PI, NSF-CAREER award, 06/01/2012-05/31/2017 Characterizing a Landscape of Signal Processing in the Immune System

Co-PI (PI Garry Nolan, Stanford), DOD Teal Innovator Team, 4/1/2012 - 3/31/2017 "Ovarian Cancer Dream Team, searching for tumor initiating cells"

PI, AACR/SU2C Phil Sharp Award, 05/01/2014-04/30/2016 "Analysis of High-Dimension Single-Cell Data from Cancer Immunotherapy Clinical Trials"

Packard fellowship for Science and Engineering, Packard Foundation, 11/01/09-10/31/14 "Harnessing sequence diversity to elucidate the principles of cellular signal processing"

Co-PI (PI Califano, CUMC), NIH/NCI center of excellence (U54), 09/26/2010 to 07/31/2015 "National Center for the multi-scale study of cellular Networks"

#### **Completed Grants**

PI, NIH-New Innovator award 09/30/07-08/31/12 "Genetic Variation and Regulatory Networks: Mechanisms and complexity"

PI, BWF-CASI 01/01/06-5/31/12

"A Systems Approach to Elucidate: Integration of Signal and Decision in Cells"

#### **Recommendations for Scientific Research and Prevention Programs Committee**

#### **Recommendations for Prevention Peer Review Panels:**



Jose Mendoza-Silveiras, M.D. is a colon cancer survivor and an advocate reviewer representing the Colon Cancer Alliance. He has served on national review panels of colon cancer research grant applications. In his professional life, Dr. Mendoza-Silveiras is the Vice President of Clinical Operations for the National Research Institute (NRI) in California, overseeing clinical operations in multiple therapeutic areas. Prior to this, Dr. Mendoza-Silveiras served as a Patient Representative Consultant for the Food and Drug Administration and worked with the United States Navy, National Institute of Allergies and Infectious Diseases and others with a focus on preventing infectious disease in underserved populations. He is the founder of the Naval Medical Research Center

clinical trials center. Dr. Mendoza-Silveiras received his medical degree with a specialty in general surgery and completed his residency in infectious diseases at the Central University of Venezuela.

Nominated as an advocate reviewer.



**Laura Seeff, M.D.** is the Chief, Comprehensive Cancer Control Branch, Division of Cancer Prevention and Control at the Centers for Disease Control and Prevention (CDC). Her research interests are colorectal cancer screening, economics of cancer screening, and outcomes of prevention programs. Dr. Seeff has authored over 40 publications and given numerous presentations. She received her medical degree from Georgetown University and completed residency training in internal medicine at Emory University.



#### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

Subject: SERVICE CONTRACTS OVERVIEW

**Date: FEBRUARY 10, 2015** 

#### **CPRIT Contract Management**

CPRIT has contracted with more than 25 vendors for services since FY 2009. The attached spreadsheet provides information about all of these service contracts. The contracts highlighted in light green are currently active. The services have been procured according to Government Code, Chapter 2155 and the guidance provided by the Comptroller's Texas Procurement and Support Services (TPASS) division through the Statewide Contract Management Guide and their online resources.

#### Senate Bill 353, 84th Texas Legislature

Senator Nelson has filed Senate Bill 353 which would establish new transparency requirements for agencies awarding contracts for goods or services. The new requirements include disclosure of conflicts of interest by and the prohibition of awarding contracts to vendors in which agency leadership or high level staff have financial interests. There are specific provisions for contracts for goods or services with a value of \$1 million or more and additional requirements for state contracts for goods or services with a value of \$5 million or more.

Conflict of interest provisions included in the proposed legislation require governing board members and specific agency employees (executive director, general counsel, chief procurement officer and procurement director) to disclose "any potential conflict of interest specified by state law or agency policy that is known by the employee or official with respect to any contract or bid for the purchase of goods or services by the agency." The agency is prohibited from contracting to receive goods or services from any entity that a governing board member or specified agency employees have a "financial interest." The proposed legislation finds that a financial interest exists if the employee or governing board member "owns or controls, directly or indirectly, an ownership interest in the person, including the right to share in profits, proceeds, or capital gains; or could reasonably foresee that a contract with the person could result in a financial benefit to the employee or [governing board member]." In addition to the employee or governing board official, the legislation includes family members within the second degree by consanguinity or affinity. In a financial benefit to the employee or governing board official, the legislation includes family members within the second degree by consanguinity or affinity.

<sup>&</sup>lt;sup>1</sup> Consanguinity includes relatives related by blood to the governing board member, affinity includes the governing board member's spouse and individuals related to the spouse. Taking the relationship to the second degree encompasses: grandparents, parents, children, grandchildren, and siblings, as well as any spouses of the individuals listed.

For contracts for goods or services with a value of \$1 million or more, agencies will be required to:

- Develop and implement contract reporting requirements;
- Have the governing board approve a contract of this value; and
- Have the presiding officer of the governing board sign the approved contract or delegate that signature authority to the agency head.

In addition, for contracts for goods or services with a value of \$5 million or more, agencies will be required to have the contract management office or procurement director verify in writing that the purchasing methods and selection process complied with state law and agency policy and submit to the governing body any information about any potential issue that may arise in the solicitation, purchase, or contractor selection process.

In a January 28, 2015, letter to all state agency heads, Governor Abbott asked that agencies implement the provision of Senator Nelson's bill to the extent possible. CPRIT already complies with many of these contracting requirements and will develop procedures to implement others, like the requirement for the procurement director to certify that the purchase methods comply with the law and document any issues in the contracting process.

#### Additional Historically Underutilized Business (HUB) Reporting Requirements

Proposed language in both the House and Senate versions of 2016-17 General Appropriations Act will require each agency to conduct an internal assessment of its efforts to increase participation in the HUB program for the previous two state fiscal years. The assessment will be due to the Comptroller and Legislative Budget Board (LBB) before December 1, 2015, and the Comptroller and LBB may evaluate the agency's good faith efforts to increase HUB participation. In addition, each agency will be required to submit a report demonstrating compliance with state HUB policies, including a plan for maintaining compliance and good faith efforts to increasing HUB participation in the future. This report must also be submitted to the Comptroller and LBB before December 1, 2015. These reports are subject to audit by the State Auditor's Office who will select entities for audit every biennium based on a risk assessment.

Attachment: CPRIT Service Contract History

## **CPRIT Service Contract History**

Entity	Contract Services	Contracted FY 2009	Contracted FY 2010	Contracted FY 2011	Contracted FY 2012	Contracted FY 2013	Contracted FY 2014	Contracted FY 2015
SRA International	Pre- and post-award grants management support services provided through scientific staff augmentation and information technology management	\$ 500,000	\$ 3,746,203	\$ 4,590,949	\$5,894,828	\$7,131,457	\$9,051,586	\$11,509,011
Texas BioAlliance	Virtual Management Company Support Services to assist entrepreneurs and researchers to take promising scientific discoveries from the laboratory to commercially viable products by providing them with product development guidance from national commercialization experts, recruiting experienced entrepreneurs in the life sciences industry to Texas to establish or relocate new oncology product companies in the state, and to introduce CPRIT through outreach opportunities at national and international scientific and investment conferences			\$1,068,140	\$2,967,449	\$1,902,732		
The Perryman Group	Economic analysis to estimate the annual cost of cancer to Texas and economic impact of CPRIT based on key performance indicators		\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	
ICON Clinical Research	Conduct business management and regulatory evaluation, or due diligence, of product development grant applications							\$350,000
Hahn Communications	Strategic communication services						\$112,250	\$250,000
Hahn Communications	Strategic communication services					\$149,000	\$90,000	
Hill & Knowlton	Strategic communication services				\$125,000	\$250,000		
Backstage Marketing	Strategic communication services			\$52,300	\$19,275			
Grant Thornton LLP	Internal audit services		\$25,000	\$80,649	\$141,000	\$293,750	\$250,000	
Grant Thornton LLP	Monitoring all product development, scientific and prevention peer review panel meetings as a third-party observer				\$11,000		\$38,500	\$90,000
Vinson & Elkins, LLP	Outside legal counsel services on intellectual property issues.		\$43,461	\$156,539	\$147,553	\$86,649	\$213,351	\$186,649

## **CPRIT Service Contract History**

Yudell Isidore	Outside legal counsel services on intellectual		\$26,100	\$73,900	\$65,925	\$39,750	\$149,000	\$100,000
[formerly Yudell	property issues.							
Isidore Ng Russell								
PLLC; and Dillon								
Yudell]								
Daffer McDaniel,	Outside legal counsel services on intellectual		\$82,119	\$17,881	\$100,000	\$100,000		
LLP	property issues.							
Yetter, Warden, &	Outside legal counsel services on		\$35,759	\$89,241				
Coleman	administrative law							
Ewell Bickham &	Outside legal counsel services for					\$54,343	\$100,000	
Brown	administrative law matters.							
Weaver and Tidwell	Compliance program design and planning						\$99,000	
McConnell and Jones	Annual financial audit of CPRIT						\$35,800	\$42,000
LLP								
Clifton Larson Allen	Annual financial audit of CPRIT		\$35,459	\$36,524	\$39,330	\$39,808		
[formerly Clifton								
Gunderson]								
Health and Human	Human resources and payroll support services	\$6,000	\$7,000	\$30,000	\$30,000	\$30,000	\$30,000	\$30,000
Services Commission								
Texas Medical	Physician Oncology Education and Awareness				\$347,699	\$347,699		
Association	Program for medical professionals in Texas							
Texas Nurses	Nurse Oncology Education and Awareness				\$313,850	\$264,741		
Association	Program for nursing professionals in Texas							
JHL Company	Planning and management of community and			\$32,061	\$141,615	\$99,000		
	stakeholder outreach events.							
Texas Tech	Research & Development of CPRIT Table					\$11,862	\$24,990	
University	Design for Mapping							
Billy Hamilton	Consulting Services- Independent Operational					\$15,000		
	Review							
Jennifer Redmond	Meeting facilitator for Texas Cancer Plan			\$13,351	\$5,149			
	revision							
Jennifer Redmond	Co-Facilitator/Coordinator Future Directions				\$9,512			
	meetings							
One World	Conference Abstract Services			\$3,222	\$5,949	\$4,972		
Presentation								
Synergy ET	Audiovisual services for 2012 Conference				\$113,549			
Freeman	Conference decorating services				\$33,800	\$29,204		

## **CPRIT Service Contract History**

Renaissance Hotel- Austin	Audiovisual services for 2013 Conference					\$101,232		
Austin Convention Center	Exhibit Space/Room Rental				\$25,991			
Robert Mittman Consulting	Meeting facilitation for program priorities project						\$50,000	
Spencer Stuart	Executive search services	\$206,333			\$100,000			
Total Service Contr	ract for FY 2012	\$712,333	\$4,151,101	\$6,394,757	\$10,788,474	\$11,167,948	\$10,394,477	\$12,557,660

Pursuant to Texas Administrative Code Section 701.13(7), the Advisory Committee on Childhood Cancers (ACCC) is required to report at least annually to the Oversight Committee regarding the activities of the Committee. The ACCC has elected to use its report that was submitted to the program priorities project as the ACCC annual report. Dr. Gail Tomlinson, Chair of the ACCC, will give the presentation today.

#### **Program Priorities for CPRIT: A Perspective on Childhood Cancer**

A Whitepaper submitted to the CPRIT Oversight Committee by the CPRIT Advisory Committee on Childhood Cancer

**I. Introduction** The CPRIT Advisory Committee on Childhood Cancer (ACCC) convened on September 2<sup>nd</sup>, with subsequent discussions by email and teleconferences to formulate recommendations to the CPRIT Oversight Committee on priority areas for funding of research, prevention/survivorship, and product development in childhood cancer.

The ACCC salutes CPRIT for its focus on research excellence as guided by the peer-review process. We specifically applaud the opportunities that have been provided for funding of research in childhood cancer by CPRIT, especially for the recently issued RFA specifically requesting grant applications focused on childhood and adolescent cancers. The ACCC appreciates the current opportunity to identify for the Oversight Committee what we believe are critical unmet needs in childhood cancer research and to identify opportunities for CPRIT to fund high-impact research, prevention, and product development efforts that will improve the lives of children with cancer in Texas and beyond.

## II. The ACCC recommends that current strengths in the CPRIT Research Portfolio remain a high priority:

#### 1) Investigator-Initiated Research

Support for clinical and translational research carried out by individual investigators or collaborative teams of investigators should remain a high-priority.

#### ACCC Recommendations

- a. The CPRIT RFA for individual investigator grants specific to childhood and adolescent cancer should be issued on a continuous basis.
- b. An RFA for multi-investigator grants focused on childhood and adolescent cancer (with an emphasis on inter-institutional collaboration) should be considered.
- c. CPRIT should consider increasing the number of pediatric oncologists and laboratory investigators who focus on childhood cancer in the grant review panels.

#### 2) Recruitment Awards

The recruitment award program has been successful in bringing high quality investigators to Texas. The presence of those investigators in the Texas institutions who successfully recruit them frequently benefits all in the institution, including those studying childhood cancer. However, a paucity of investigators trained in and studying childhood cancer have been brought to Texas by the recruitment grants. The number of clinical investigators receiving CPRIT recruitment grants is also very small.

#### ACCC Recommendations

- a. The RFA for recruiting clinical and translational investigators previously issued should be re-issued. Consideration should be given to recruitment of high-quality pediatric cancer laboratory, translational, and clinical investigators.
- b. Consideration should be given to setting aside a minimum number of recruitment grants to be identified in pediatric oncology (at each level). As review committees are currently constituted it is likely that the preponderance of adult oncology reviewers on these committees are likely to preferentially select for researchers in adult oncology, as these reviewers may not be sufficiently familiar with pediatric cancer research.
- c. Consideration should be given to prioritizing recruitment of suitable candidates to underserved areas of Texas as long as the appropriate research or clinical resources are available in those areas.

#### 3) Core facility Grants

The ACCC recommends that CPRIT develop additional initiatives for core facilities to support childhood cancer

- a. Pediatric Cancer Research Cores. The ACCC recommends that CPRIT allow institutions to apply for funds to support Pediatric Cancer Research Cores. Currently institutions in Texas are permitted to apply for one core facility in response to a core facility RFA. As the majority of investigators at our institutions are adult oncology oriented, under the current circumstances the likelihood of a pediatric cancer core resource being requested from any institution is very low. Enabling institutions to also apply for a Pediatric Cancer Research Core Facility will help improve the state's research infrastructure for childhood cancer.
- b. CPRIT Collaborative Grants in Childhood Cancer. Research in childhood cancer has benefited from the collaborative research, especially in clinical trials and tumor sample accrual that occurs via interactions among the many pediatric oncologists across North America. The ACCC recommends that CPRIT explore grant opportunities that will enable CPRIT funded research initiatives to partner with appropriate foundations or organizations (e.g. Children's Oncology Group) that fund research outside of Texas. This will stimulate collaborative research in pediatric oncology involving investigators within Texas and outside of Texas working together. It will also enable Texas researchers to leverage out-of-state funds to support pediatric cancer research in Texas.
- c. Multi-institutional core resource grants to support childhood cancer research. The ACCC recommends that CPRIT consider developing a grant funding mechanism that would support establishing high-impact, multi-institutional cores that support childhood cancer research in Texas. Examples of such cores include preclinical drug testing cores, CLIA-certified sequencing cores that define the genomic alterations in childhood cancers and support entry of children onto clinical trials with targeted agents, pediatric cancer biobanks, and childhood cancer epidemiology cores. Such cores could be able to process samples or analyze data and samples from pediatric cancer patients throughout the USA. Such cores could generate high-impact data by leveraging

pediatric oncology patient samples from across the USA that would be available by collaboration with the Children's Oncology Group (COG). Such an approach would advance national efforts in childhood cancer research and would result in Texas becoming a focal point for pediatric cancer research in the USA. Establishing national resource cores for pediatric oncology in Texas would also position Texas institutions to attract additional research funding from out of state.

#### **III. Prevention Portfolio**

#### Prevention initiatives in childhood and adolescent cancers

With the increased survival rates of childhood cancer, issues related to survivorship including long-term side effects of treatment, quality of life, fertility, employment and a host of other concerns have become increasingly prominent. The number of years of life saved by successfully treating a child with cancer is substantially greater than that of an adult, which magnifies the importance of survivorship issues. CPRIT should support initiatives aimed at providing needed services that may not otherwise be available to current childhood cancer survivors and also should encourage research in the area of childhood survivorship so that in the future survivors can enjoy a healthier lifespan.

#### IV. Product Development Portfolio

#### **Commercial Development of Diagnostics and Therapeutics for Childhood Cancer.**

The product development support for commercial entities and the early translational support both provide critically necessary support to aid moving diagnostics and therapeutics from research studies into products that can enter the marketplace and benefit large numbers of patients. In spite of CPRIT opportunities, and attempts by the Federal government at incentivizing pharmaceutical companies to develop drugs or childhood cancer, a paucity of pediatric cancer drug development programs exist in the pharmaceutical industry. None of the commercial entities currently funded by CPRIT have active clinical trials of diagnostics or therapeutics in childhood cancer.

#### The ACCC recommends:

CPRIT should explore innovative ways to facilitate and encourage commercial development of drugs and diagnostics for childhood cancer. A suggested first step would be to convene a working group of interested stakeholders (including pediatric oncologists, pediatric oncology patient advocates, CPRIT Product Development leadership/reviewers, and CPRIT-funded commercial entities). The working group should define the barriers facing commercial development of drugs and diagnostics for childhood cancer and also develop recommendations to CPRIT for approaches to overcome the identified barriers.

# Advisory Committee on Childhood Cancer (ACCC)

Gail E. Tomlinson, MD., Ph.D.

Committee Report for Oversight Committee February 18, 2015

- 7 Pediatric Oncologists
  - 6 academic, all with active research
  - 1 private practice

1 Laboratory Scientist

2 Patient/parent advocates

- Academic institutions represented
- Houston 3
  - Baylor 2
  - UT MD Anderson 1
- Dallas UTSW 2
- San Antonio UTHSCSA 1
- Lubbock 1

Current members:

Karen Albritton, MD

Susan Blaney, MD

Daniel Bowers, MD

Tim Culliver

Eugenia Kleinerman, MD

**Annette Leslie** 

David Poplack, MD

Patrick Reynolds, MD, PhD

Stephen Skapek, MD

Gail Tomlinson, MD,PhD

Currently evaluating membership guidelines

Research background

Advocacy

Membership turn-over Accepting nominations of new members

Geographic and institutional diversity

# **Committee Activities**

- Reconvened in summer 2014
- In-person meeting in Austin Sept 2014
- White paper recommendations presented to Oversight Committee fall 2014
- Meeting by conference call February 2, 2015

# Public Advocacy

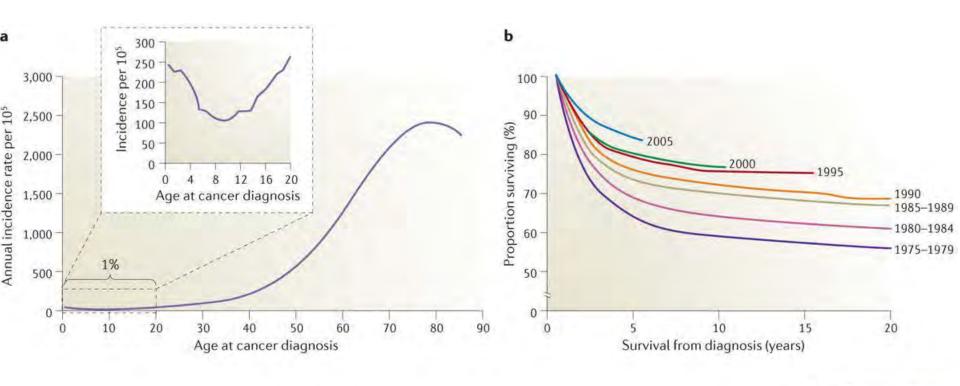


Childhood Cancer Awareness Month Washington, DC Sept 2015





## **Childhood Cancer: The Scope of the Problem**



Nature Reviews | Cancer

Hudson and Robison 2014

# Disease Priorities for Research

- Brain Tumors
- Metastatic Bone Tumors (Ewings)
- Acute Myeloid Leukemia
- Relapsed ALL
- High-risk Neuroblastoma
- Other relapsed solid tumor

## Investigator-initiated research

- Specialized RFA a success(!); continue
- Emphasis on multi-investigator / multiinstitutional projects
- Recruitments needed

## **Pediatric Cancer Research Cores**

Recognized that current limitations of one core application per institution may hinder opportunities for pediatric focus

Enable a second grant from institution if focus is pediatric

## **Clinical Trials Infrastructure**

Single-institution studies are rarely possible in pediatrics due to rarity of any tumor type

National cooperative group infrastructure available but often long time-line in developing

## **Annual Meeting**

Focused sessions on childhood cancer Childhood cancer tract?

Networking opportunities

## **Peer Review**

Observation that some grants deemed highly meritorious but limited by funds available

Alternatives for these grants, especially those of urgent translational nature

### Recommendations

#### **Peer Review**

Continue to insure that adequate expertise in pediatric cancer within all review teams

### Prevention and Childhood Cancer

 Historical thinking is that prevention not possible for most childhood cancers

Early detection may be possible for a minority

 Tertiary prevention – late effects, survivorship issues is a key issue

## Industry and Childhood Cancer

Childhood cancers are "orphan" diseases

 Paucity of pediatric drug development in industry

 CPRIT should include mechanisms for commercial development which would include drugs and diagnostics for pediatrics

# CPRIT Success Rate in Childhood Cancer Research

- Previous CPRIT funding
  - 2% indicated pediatric focus by self-report
  - May be higher
- Early MIRAs in disease specific areas
  - Three in childhood cancer
- Recent RFA- IIRACCA
  - 56 applications received
  - 10 to be funded (17.9%)
  - 10 of 51 overall awards in pediatric cancer (19.6%)

# Thank you CPRIT, for your support of childhood cancer research!



Pursuant to Texas Administrative Code Section 701.13(7), the University Advisory Committee (UAC) is required to report at least annually to the Oversight Committee regarding the activities of the Committee. The UAC has elected to use its whitepaper report, which was submitted to the program priorities project, as the UAC annual report. Dr. Mary Ann Ottinger, Vice-Chair of the UAC, will give the presentation today.

# Program Priorities for CPRIT: An Academic Perspective A Whitepaper submitted to the CPRIT Oversight Committee by the CPRIT University Advisory Committee

#### I. Introduction

The CPRIT University Advisory Committee (UAC) convened on April 30, 2014, with additional follow-up face-to-face (June 27) and phone (July 8) meetings, to formulate recommendations and provide input to the Oversight Committee on program funding prioritization. In these discussions, the UAC took a broad look at the type of awards within the research and prevention portfolios, including investigator initiated, early product development, and recruitment awards. In addition to considering existing mechanisms of support, the Committee also discussed new funding mechanisms that could be developed to achieve the objectives of the program, and identified new initiatives and programmatic focus areas to be considered for future funding.

#### II. The UAC recommends current strengths in the CPRIT portfolio remain a high priority

#### 1) Investigator-Initiated Research

Support for groundbreaking research, by individual researchers or collaborative teams, forms the basis for much of the success of CPRIT, and should remain a high priority for the program going forward. The availability of these types of grants allows investigators to successfully pursue research avenues aligned with their expertise, while providing the flexibility to capitalize on unexpected and impactful discoveries. As noted by the American Society for Biochemistry and Molecular Biology (ASBMB) in their recent whitepaper, "the investigator-initiated grant is the most vital force driving scientific research in this country".

#### **UAC Recommendation**

The UAC recommends that CPRIT continue to promote the best possible science by supporting investigator-initiated research.

#### 2) Recruitment Awards

These awards are arguably one of the most successful and impactful of all the CPRIT funding mechanisms. The caliber of scientists recruited to date has been extraordinary, and their presence in the state of Texas has raised the profile and impact of the state on the field of cancer research. These awards have infused the cancer research community across the state with both senior leaders and young rising stars, and allowed Texas institutions to compete effectively against other national research powerhouses to bring the "best and the brightest" to our state.

#### **UAC Recommendation**

The UAC recommends that CPRIT Recruitment Awards remain a high priority for the program.

#### III. The UAC recommends that CPRIT develop new initiatives

#### 1) Cancers that disproportionately affect Texans

Texans are at increased risk for many types of cancer due to co-morbidity associated with diseases such as obesity and diabetes, which are rising or at epidemic levels, and which disproportionately affect Texans. Cancer rates are also influenced by geographic and environmental factors, such as high hepatitis C and aflatoxin exposures and increased risk for hepatocellular carcinoma in the San Antonio region. Other examples include rates of cervical cancer, gastric cancer, and childhood leukemias in South Texas. Health disparities also impact

# Program Priorities for CPRIT: An Academic Perspective A Whitepaper submitted to the CPRIT Oversight Committee by the CPRIT University Advisory Committee

Texans such as the disproportionate impact of prostate cancer on African-American men and rates of hepatocellular and colorectal cancer in Hispanics. In some cases, increased risk is driven by environmental and geographic factors, in others racial and ethic factors, and because of the diversity of Texas and its citizens, often all of these combined. Seizing this opportunity would allow Texas to lead the country by advancing knowledge in these and other cancers that disproportionately affect Texans.

#### **UAC Recommendation**

The UAC recommends that CPRIT take into consideration during development of new scientific initiatives and in the review of submissions, new opportunities to address those cancers that disproportionately affect citizens of the State of Texas. Additional consideration should be taken for those cancers that disproportionately affect minority populations of the State of Texas such as Hispanics and African Americans. As a small group of tumors are found in both categories (e.g., hepatocellular cancers and Hispanics), these should be a high priority for CPRIT. This initiative could also include supplements tor existing grants (funded by CPRIT or other agencies such as NIH) to support the participation of underserved minority trainees, faculty collaborators and/or sabbaticals.

#### 2) Cooperative centers and regional and state-wide infrastructure networks

Access to research resources, which are often prohibitively expensive or may require too large an investment to duplicate, is nevertheless key to advancing cancer research. This type of infrastructure, as modeled by the Broad Institute and the New York Genome Center, can provide unparalleled access to cutting edge technology, advanced platforms for screening and research, and computational expertise needed to rapidly accelerate research. These centers and networks may be virtual, networked or contained within a single institution, but to be most impactful, should serve as a resource to the broader regional or statewide cancer research community. In addition, development of these centers and networks would provide opportunities for investments that build inter-institutional partnerships, and serve as a lasting legacy for CPRIT.

#### **UAC Recommendation**

The UAC recommends that CPRIT develop mechanism(s) to specifically foster the development of centers and networks ("Cooperative Centers of Excellence"), which will provide regional and state-wide access to innovative technologies and instrumentation that accelerates cancer research. These centers and networks would be expected to operate under a cost-recovery system that is subsidized by CPRIT to provide cost-effective resources, and should be required to have objective metrics for success and accessibility.

#### 3) Increased investment in disciplines aligned with computational biology

Computational biology, broadly encompassing modeling, bioinformatics and other *in silico* and predictive methodologies, is at the forefront of advancing research and identifying new cancer targets and therapies. The demand for expertise in these areas far exceeds supply, and lack of expertise in these disciplines is now one of the greatest bottle-necks in translating cancer research from the bench to the bedside (forward translation e.g. high-content and high-throughput screening assays for novel therapeutics) and back (reverse translation e.g. mining The Cancer Genome Atlas (TCGA) databases). Increased training in these disciplines, expansion of the available pool of researchers with this expertise, and providing access to researchers and resources in this field is key to the success of cancer research in Texas and the nation.

## Program Priorities for CPRIT: An Academic Perspective A Whitepaper submitted to the CPRIT Oversight Committee by the CPRIT University Advisory Committee

#### **UAC Recommendation**

The UAC recommends that there be additional programmatic focus on supporting computational biology and approaches that broadly encompass modeling, bioinformatics and other *in silico* and predictive methodologies. Examples of mechanisms that may be considered for expanding research and cross-training in these areas are training grants, interdisciplinary research awards that support collaborative research, for example between modelers, bioinformaticians and biologists, and research sabbaticals to acquire expertise in computational biology.

#### 4) Preclinical and clinical trials research

Researchers face many obstacles in translating research advances to the clinic, including access to preclinical models, toxicology resources, formulation of GMP materials and expertise in trial design. In addition, clinical trials of treatments for rare forms of cancer are challenging, due to relatively small profit margins and patient populations. Finally, the limited success of most single agent targeted therapies has opened the way for trials evaluating combination therapy. However, conducting trials on the best possible combinations is often difficult (or impossible) if the drugs to be combined belong to two different drug companies.

#### **UAC Recommendation**

UAC recommends that CPRIT consider repositioning or broadening the scope of existing award mechanisms including the Early Translational Research Awards (ETRA), Multi-investigator Research Awards (MIRA) and Product Development Awards, and create new mechanisms as needed, to support seed funding to acquire "proof-of-concept" preclinical data, early phase clinical trials with laboratory correlates, and trials designed to develop combination therapies, including trials with combination therapies using drugs from two different companies. Funding mechanisms similar to SBIR/STTR-type awards to support industry-academic partnerships conducting preclinical and early clinical trials should also be considered.

#### 5) Focus product development on new instrumentation and technologies

While commercialization to move drugs and devices into the clinic is the traditional path for resource investment in product development, it does little to reinforce the academic research community from whence a large (and growing) proportion of discoveries arise. In contrast, investments to advance technology may improve patient care, such as 3D digital mammography, but also have the potential to advance research. An example of this is the development of Polymerase Chain Reaction (PCR) technology, which revolutionized molecular biology research, and ultimately resulted in a Noble Prize. By increasing the emphasis of commercialization activities toward development of new technologies (as opposed to drugs), both the academic research community and the commercial sector can share the benefits of CPRIT investments in product development. Research awards in the area of technology development would also have the ability to attract new investigators to the cancer research community from engineering, biomedical engineering and related disciplines where Texas has great academic strengths.

#### **UAC Recommendation**

Product development investments in technology have the potential to equally impact the economy and academic institutions of Texas. The UAC recommends that CPRIT consider giving greater emphasis in the Product Development awards to technology development, to expand the impact of these awards on both the commercial and academic research sectors.



To: OVERSIGHT COMMITTEE MEMBERS

From: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER

**Subject:** FY2014 REPORT ON MERIT AND PROGRESS OF PROGRAMS

PURSUANT TO TEXAS HEALTH & SAFETY CODE § 102.260(C)

**Date: FEBRUARY 11, 2015** 

This report outlines my assessment of the progress and merit of CPRIT's Academic Research Program, Prevention Program and Product Development Research Program for fiscal year 2014. Senate Bill 149 amended Texas Health and Safety Code §102.260(c) to require the Chief Executive Officer to report at least annually to the Oversight Committee on the progress and continued merit of each research program. FY2014 is the first, complete fiscal year since the statutory change became effective; therefore, this report serves as the first iteration fulfilling the statutory requirement.

As described in this report, I believe that CPRIT's programs showed progress and merit in FY2014. This was a year of new beginnings for CPRIT, with the resumption of CPRIT's three programs in November 2013 following a one year hiatus. CPRIT restarted to unprecedented demand for its programs and funding opportunities; awarding 142 grants in FY2014 (108 academic research grants, nine product development research grants, and 25 prevention grants).

In addition to the information provided in CPRIT's 2014 Annual Report, I provide an overview below that lists some of the accomplishments that help illustrate program progress for each program. With regard to progress made by individual grant projects within each of CPRIT's three programs, I note that Texas Administrative Code § 703.21 requires all CPRIT grantees to submit progress reports at least annually. These progress reports are evaluated by experts to ensure that the grantee has made sufficient progress and should continue work under the grant. To the extent that an expert reviewer determines that a grant project is not making sufficient progress, CPRIT may take a number of actions including contract termination, which will be communicated to the Oversight Committee at the time the issue arises.

#### **Academic Research Program**

CPRIT's Academic Research Program supports innovative and meritorious projects that are discovering new information about cancer that can lead to prevention, early detection and cures; translating new and existing discoveries into practical advances in cancer diagnosis and treatment; and increasing the prominence and stature of Texas in the fight against cancer. In FY2014, CPRIT's Academic Research Program awarded 61 Individual Investigator Research Awards, 15 High Impact-High Risk research grants, seven continuation grants for Research Training Awards, and four continuation grants for Multi-Investigator Research Awards, for a total of \$77,175,515.

Building a critical mass of cancer researchers in Texas is addressed by supporting recruitment of cancer scientists and clinicians, at all career levels, to academic institutions in Texas. CPRIT approved 25 recruitment awards in FY2014, and 21 recruits accepted positions, for a total amount of \$52,339,259 in grant awards. Since its inception through August 31, 2014, CPRIT has supported the recruitment of 77 outstanding cancer researchers to 13 academic institutions in Texas. This program has been highly successful in enhancing Texas' cancer research efforts and increasing the external visibility of the state in this field.

During the past fiscal year, 87 new peer reviewers from outside the State were recruited to the Scientific Review Panels for Research, making a total of 145. These panel members reviewed a total of 595 academic research grant applications, 108 of which were recommended to the Program Integration Committee and the Oversight Committee for funding. In addition, 10 Requests For Applications (RFAs) for research projects were released, including newly developed ones for the high priority areas of prevention and early detection, and cancers of children and adolescents. Other activities during the past year included reconstitution of the University Advisory Committee and Advisory Committee on Childhood Cancer; both committees provided valuable input that was considered during CPRIT's program priorities project, development of priorities for the academic research program in conjunction with the Oversight Committee, and implementation of a new formal mechanism for reviewing progress reports.

#### **Prevention Program**

CPRIT's Prevention Program supports effective, evidence-based prevention programs to underserved populations in the state. Our efforts help Texans reduce the risk of getting cancer, identify cancers earlier and assist people in finding treatment when cancer is detected, thereby reducing the burden of cancer in Texas.

There were 81 active Prevention Program projects in FY2014, 25 of which were awarded during the fiscal year. The Prevention Program began the fiscal year with projects that provided targeted services in 64% of counties in Texas. The statewide coverage was comparatively low due to effects of the moratorium on grants that was lifted in late 2013; however, by the end of the fiscal year prevention projects were providing targeted services to 89% of counties across the state. Five additional statewide projects offer programs accessible to all counties.

To date the Prevention Program has provided 1.8 million prevention services to Texans. These services include education and training, vaccinations, tobacco cessation services, genetic testing and counseling, survivor care and cancer screenings. Of the more than 433,000 cancer screenings, 195,000 included people who had never before been screened. More than 2,600 cancer precursors were detected; potentially preventing the development of cancer in these individuals. In addition, 1,206 cancers were detected, the majority of which were early stage cancers. Early detection of cancers, at a stage when treatment is most effective, offers the best chance for survival and reduces the costs of treatment.

#### **Product Development Research Program**

CPRIT's Product Development Research Program funds innovative and scientifically meritorious product development projects with the potential of translating research discoveries into commercial products that can benefit cancer patients.

In early 2014, the Oversight Committee ratified grant awards to six companies with applications that had been pending approval during the moratorium. One company declined the relocation award, electing to stay in Michigan. In addition, the Product Development Research Program issued three Product Development RFAs during FY2014 and received 43 applications that underwent scientific review. Of those received, four applications totaling \$58,533,944 were approved by the Oversight Committee. The total amount of grants awarded to the nine companies in FY2014 is \$107,691,509.

A major policy initiative of the Product Development Research Program in FY2014 was to establish standard revenue sharing terms for all Product Development research grants. CPRIT Staff, members of the Oversight Committee and the newly formed Advisory Committee on Product Development, composed of nine members from the economic development, venture capital, and academic communities, worked together to develop standard revenue sharing terms. As a result of their hard work, CPRIT standard contract terms were approved by the Oversight Committee on January 20, 2015.

CPRIT has 12 active company grants in FY2014, with several more companies approved for grant awards and awaiting contract execution. CPRIT funded companies have raised \$865 million follow-on funding from other investors to continue development. These investments testify to the quality of CPRIT's original awards. CPRIT funded companies with notable follow on funding raised after receiving CPRIT grants include: Bellicum Pharmaceuticals, which raised \$129 million and went public in an IPO that raised an additional \$140 million; Cell Medica and DNAtrix, which raised \$75 million and \$20 million, respectively, in B-round financings; Visualase, which was acquired by Medtronic for about \$105 million; and Rules-Based Medicine, which was acquired by Myriad Genetics for \$80 million.

The continuing Texas presence of the companies whose projects were funded and the increasing number of jobs at those companies also demonstrate the impact of the Product Development Research Program. The Program benefits not only cancer patients, but also results in economic development in Texas.

#### **Conclusion**

It is my opinion that CPRIT's three programs show merit and progress and should continue operations. CPRIT's programs are part of an iterative cycle with observations emerging from the laboratory making their way to the patient's bedside and back again to the laboratory. Essential players in this cycle are basic scientists, physician scientists, clinical researchers, product development entrepreneurs, patients and health care providers in community organizations, early stage companies, and research institutions across Texas.



To: OVERSIGHT COMMITTEE MEMBERS

From: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

**Subject:** FY 2015 GRANT COMPLIANCE MONITORING PROCUREMENT

**Date: FEBRUARY 10, 2015** 

#### Recommendation

Based on the evaluation of the written proposals and an in-person presentation to CPRIT by each of the three vendors who submitted proposals to provide compliance monitoring services, I am presenting a staff recommendation that CPRIT contract with CohnReznick for a not to exceed amount of \$336,000 to provide grant compliance monitoring services for the remainder of FY 2015, or approximately the next six months.

CohnReznick presents the best value for this contract because:

- The company has extensive experience with compliance monitoring of grant programs in Texas and in other states, including scientific grants, with a strong customer service approach;
- The advisory team that would work on the CPRIT engagement includes a former Inspector General of the Department of Housing and Urban Development and former Auditor General of the U.S. Department of the Navy; and
- The company offered the lowest cost option among the three proposals with the certification that it would subcontract 24% of the monitoring work to a certified public accounting firm in Texas with a HUB designation.

If the Oversight Committee has no conflicts of interest with the recommended vendor and approves this recommendation, CPRIT will move forward with requesting approval of this contract from the Legislative Budget Board as required by CPRIT Rider 9, Limit on Expenditure for Contracts, in the General Appropriations Act for the 2014-15 Biennium.

#### **Background**

CPRIT received three proposals in response to a request for proposal (RFP) for Grant Compliance Monitoring Services published in the Electronic State Business Daily on December 9, 2014. The RFP was open for 38 days until January 16, 2015. Once CPRIT awards a contract to a vendor, the term of the contract will be for the remainder of FY 2015. The RFP provided options for three one-year renewals.



To: OVERSIGHT COMMITTEE MEMBERS

From: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

**Subject:** FY 2015 INTERNAL AUDIT SERVICES PROCUREMENT

**Date: FEBRUARY 10, 2015** 

#### Recommendation

Based on the evaluation of the written proposals and an in-person presentation to CPRIT by each of the three vendors who submitted proposals to provide internal audit services, I am presenting a staff recommendation that CPRIT contract with Weaver and Tidwell for a not to exceed amount of \$217,500 to provide internal audit services for FY 2015.

Weaver and Tidwell presents the best value because:

- It has extensive experience as an outsourced or co-sourced internal auditor for several Texas state agencies; and
- It provided a strategic recommendation to amend the Internal Audit Plan for FY 2015 by reducing the hours for or eliminating the 10 grantee audits and reallocating those hours to agency operational audits or reducing them altogether because the agency is moving forward with a grant compliance monitoring program and the grantee audits will be redundant.

I also note that Grant Thornton LLP, the incumbent internal auditor, submitted a proposal in response to the request for quote (RFQ). While Grant Thornton LLP is an experienced internal auditor, the firm has provided internal audit services to CPRIT for five years since FY 2010. Given the length of time this firm has provided these services to the agency, staff believes it is appropriate at this time to have a different firm perform these services and provide assurance that the agency is effectively monitoring and managing the financial, operational and compliance risks of the organization.

If the Oversight Committee has no conflicts of interest with the recommended vendor and approves this recommendation, CPRIT will move forward with requesting approval of this contract from the Legislative Budget Board as required by CPRIT Rider 9, Limit on Expenditure for Contracts, in the General Appropriations Act for the 2014-15 Biennium. CPRIT will also move forward with requesting audit delegation authority from the State Auditor's Office.

#### **Background**

CPRIT received three proposals in response to a RFQ issued to the pool of public accounting firms listed in the GSA-520 category on the Texas Multiple Award Schedule (TXMAS) on December 22, 2014. The RFQ closed on January 9, 2015.



To: OVERSIGHT COMMITTEE MEMBERS

From: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

Subject: FY 2016 CONTRACT RENEWAL FOR SRA INTERNATIONAL, INC.

**Date: FEBRUARY 10, 2015** 

#### Recommendation

CPRIT staff recommends that the agency prepare to move forward with exercising the 12-month renewal option for FY 2016 with SRA International for Pre- and Post-Award Grants Management Support Services. To prepare for the initial grant award cycles of FY 2016, the three CPRIT programs have to begin work 6-8 months prior to produce grant award recommendations for that time period. The initial steps, including issuing RFAs and scheduling peer review meetings, have to begin in March 2015. Exercising the renewal option will allow the agency to request pricing from SRA International for FY 2016 which will be submitted to the Oversight Committee for approval.

The new state contracting requirements will apply to this contract renewal because it will exceed the \$1 million and \$5 million contract thresholds explained in the bottom section below, so there will be a re-verification that the Oversight Committee has no conflicts of interest at the time the contract renewal is brought forward for approval.

#### **Background**

CPRIT issued a request for quote (RFQ) to SRA International, Inc. which is listed on the Texas Multiple Award Schedule (TXMAS) of existing competitively awarded government contracts with the State of Texas [contract no. TXMAS-14-874050]. The RFQ was open from July 3 through July 25, 2014. The RFQ was sole sourced to SRA International, Inc. as the incumbent vendor providing pre- and post-award grants management support services to CPRIT because CPRIT could not contend with an interruption in these support services as it was in the process of restarting the grant-making processes after the 11-month moratorium and implementing the provisions of Senate Bill 149, 83R through administrative rules, revisions of the business processes, and functional changes to the electronic grants management system (CGMS) to match the business process revisions.

Exercising the 12-month renewal for FY 2016 will allow the agency to maintain the momentum of re-establishing the grant-making processes and stabilize the electronic grants management system after making extensive changes to the system. The additional time will allow the agency to prepare a new Request for Proposal (RFP) for pre- and post-award grants management support services to vendors that provide these services, evaluate proposals received in response to the RFP, and allow ample time to transition services to a new vendor if the incumbent vendor is not selected to continue to provide these services. The agency will need approximately six months

to transition these services, including the transition of the data maintained in the electronic grants management system.

#### **New State Contracting Requirements**

Senator Nelson has filed Senate Bill 353 which would establish new transparency requirements for agencies awarding contracts for goods or services related to the disclosure of conflicts of interest and the prohibition of awarding contracts to vendors in which agency leadership or high level staff have financial interests. There are specific provisions for contracts for goods or services with a value of \$1 million or more and additional requirements for state contracts for goods or services with a value of \$5 million or more.

For contracts for goods or services with a value of \$1 million or more, agencies will be required to:

- Develop and implement contract reporting requirements
- Have the governing board approve a contract of this value
- Have the presiding officer of the governing board sign the approved contract or delegate that signature authority to the agency head

In addition, contracts for goods or services with a value of \$5 million or more, agencies will be required to have the contract management office or procurement director verify in writing that the purchasing methods and selection process complied with state law and agency policy and submit to the governing body any information about any potential issue that may arise in the solicitation, purchase, or contractor selection process.

In a January 28, 2015, letter to all state agency heads, Governor Abbott asked that agencies implement the provision of Senator Nelson's bill to the extent possible. CPRIT already complies with many of these contracting requirements and will develop procedures to implement others, like the requirement for the procurement director to certify that the purchase methods comply with the law and document any issues in the contracting process.



TO: CPRIT OVERSIGHT COMMITTEE MEMBERS

FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE

**CHAIR** 

**SUBJECT:** INTENTION TO RECOMMEND APPROVAL OF THE FINAL

ORDERS ADOPTING ADMINISTRATIVE RULE CHANGES

**DATE:** FEBRUARY 10, 2015

#### **Summary and Recommendation:**

The Board Governance subcommittee recommends that the Oversight Committee vote to adopt the final order approving changes to CPRIT administrative rules at its February 18, 2015 meeting. The Board Governance Subcommittee discussed the rule changes with CPRIT's General Counsel, Kristen Doyle, at its meeting on February 5, 2015.

#### **Discussion:**

Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. Pursuant to the Oversight Committee's Bylaws, the Board Governance Subcommittee is assigned the responsibility of considering changes to CPRIT's administrative rules. The Board Governance Subcommittee met with Ms. Doyle, on February 5, 2015, to discuss the administrative rule changes proposed for final adoption.

The changes made to CPRIT's administrative rules implement changes that (a) authorize the Chief Compliance Officer to attend peer review meetings and document compliance with CPRIT's statute and administrative rules; and (b) clarify matching fund requirements (see attached summary). The proposed administrative rule changes were provisionally approved by the Oversight Committee at the November 19, 2014, meeting. The proposed rules were published in the *Texas Register* in December and were posted on CPRIT's website. University of Texas MD Anderson Cancer Center submitted the only response to request for public comments. As described in the proposed final order, one comment was not germane to the rulemaking. The second comment, a request for clarification regarding the proposed change to § 703.11(c), was addressed without changing the text of the proposed rule amendment.

The Board Governance Subcommittee recommends that the Oversight Committee approve the final order formally adopting the changes in Chapter 703.

#### Summary of Administrative Rule Change to Chapters 703 Proposed for Final Adoption

§ 703.6(g) The change authorizes the Chief Compliance Officer to observe and report that the agency's grant review processes are consistently followed at peer review and review council meetings, including observance of CPRIT's established conflict of interest rules. Currently, a third party observes and reports whether the appropriate review processes are utilized. Among other checks, the third party confirms that CPRIT staff did not influence the discussion or vote on a grant award and confirms that reviewers with conflicts of interest leave the room or the telephone call when the designated application comes up for review. The proposed amendment permits the Chief Compliance Officer to fill this role if necessary. This is consistent with the Chief Compliance Officer's duties related to attending and observing all Program Integration Meetings to confirm compliance with Texas Health & Safety Code Chapter 102 and CPRIT's administrative rules, as required by § 703.7(g). The amendment, if adopted, does not preclude CPRIT from continuing to engage a third party to fill this role.

§ 703.11(b) Texas Health and Safety Code § 102.255(d)(1) allows public and private universities to use their federal indirect cost rate as a credit towards their match requirement. The proposed rule change clarifies how a grantee should calculate the federal indirect cost rate when the institution's indirect cost rate changes during project year. The proposed amendment allows a grantee to use the new rate if it changes within six months of the anniversary of the effective date of the contract; after six months the grantee must use the rate in place at the beginning of the project year for the entire project year.

§ 703.11(c) The proposed change also affects the matching requirement and concerns subcontractors and subawardees on grant awards. The amendment allows funds contributed by a subcontractor or subawardee to a grant project to count towards the grantee's required matching funds. However, the amount used as a credit to the match should not exceed the percentage of the total grant funds paid to the subcontractor or subawardee for the project year.

#### TITLE 25. HEALTH SERVICES

#### PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

#### **CHAPTER 703.** Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to §§ 703.6 and 703.11. The proposed amendments for Chapter 703 were published in the December 26, 2014, issue of the *Texas Register* (39 TexReg 10185).

#### **Reasoned Justification**

The proposed rule changes affect the grants review process and clarify both the calculation of federal indirect cost rate for institutions of higher education and the matching fund requirement. The proposed amendment to § 703.6(g) allows the Institute's Chief Compliance Officer, in place of a third-party observer, to attend and observe peer review meetings. The Chief Compliance Officer would then be required to report to the Oversight Committee any issues that may have occurred. The proposed changes to § 703.11 provide guidance for institutions of higher education in calculating their federal indirect cost rate, which is applicable to the matching funds credit, as well as address how funds spent by subcontractors or subawardees may be calculated as part of a grantee's matching requirement.

#### **Summary of Public Comments and Staff Recommendations**

The Institute accepted public comments in writing and by fax through January 26, 2015. Comments were received from The University of Texas M.D. Anderson Cancer Center ("M.D. Anderson") regarding proposed rule changes to §§ 703.6 and 703.11. These were the only comments received. M.D. Anderson's comment relating to § 703.6(e)(1) does not address the rule subsection that CPRIT proposes to amend and is not germane to the Institute's proposed rulemaking. M.D. Anderson's comment regarding the proposed change to § 703.11 seeks clarity on the proposed amendment, but does not require a change to the proposed text. The amendments to Chapter 703 rules will be adopted as published in the December 26, 2015, edition of the *Texas Register* and will not be republished.

#### § 703.6 Grants Review Process

M.D. Anderson submitted a proposed change to the grant application process set forth in §703.6(e)(1). The proposed change would incorporate a letter of intent process for grant mechanisms that are subject to the preliminary evaluation stage of review. M.D. Anderson did not offer comments or changes regarding the Institute's proposed rule changes to § 703.6(g) affecting the third party observer.

**Response:** The Institute declines to make the requested change to § 703.6(e). M.D. Anderson's proposed change to the grant application process is not responsive to the proposed rulemaking as published by the Institute in the *Texas Register*.

#### § 703.11 Requirement to Demonstrate Available Funds for Cancer Research Grants

M.D. Anderson requested clarity or alternate language for the proposed rule change to §703.11(c)(6) relating to the calculation of subcontractor or subawardee funds as part of the required match of the grantee. M.D. Anderson did not indicate opposition to the proposed rule change.

**Response:** The Institute declines to change the proposed rule. For clarity, the following example is provided for additional guidance regarding the allowable amount of matching funds a subcontractor or subawardee may contribute may contribute toward the total matching fund requirement for the CPRIT grant project.

For a grantee that receives a \$1,000,000 CPRIT grant and pays a subcontractor \$300,000 for work conducted in furtherance of the CPRIT funded grant project, the grantee may contribute up to 30% of the grantee's total matching funds requirement. In this example, the grantee's matching fund obligation is \$500,000. The subcontractor may contribute up to \$150,000 (30%) toward the grantee's \$500,000 matching fund requirement. As stated in the proposed rule change, the subcontractor's funds must be spent on the grant project.

The Oversight Committee approved the final order adopting the amendments to Chapter 703 rules on February 18, 2015.

#### **Statutory Authority**

The rules are proposed under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, which provides the Institute with broad rule-making authority to administer the chapter.

#### Certification

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on February 20, 2015.



TO: CPRIT OVERSIGHT COMMITTEE MEMBERS

FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE

**CHAIR** 

**SUBJECT:** INTENTION TO RECOMMEND APPROVAL OF PROPOSED

ADMINISTRATIVE RULE CHANGES

**DATE:** FEBRUARY 10, 2015

#### **Summary and Recommendation:**

The Board Governance subcommittee recommends that the Oversight Committee vote to approve publication of the proposed rule change to 25 T.A.C. Chapter 703 in the *Texas Register* to solicit public comment. The proposed change provides guidance regarding agency policies and grantee requirements related to the matching funds requirement for research grants. This recommendation was reviewed by the Board Governance subcommittee and discussed with CPRIT's General Counsel, Kristen Doyle, at its meeting on February 5, 2015.

#### **Discussion:**

Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. Pursuant to the Oversight Committee's Bylaws, the Board Governance Subcommittee is assigned the responsibility of considering changes to CPRIT's administrative rules. The Board Governance Subcommittee met with Ms. Doyle, on February 5, 2015, to discuss the proposed change to the CPRIT's administrative rule § 703.11(c).

Texas Health and Safety Code § 102.255(d) requires CPRIT research grant recipients to have encumbered funds equal to one-half of the amount of the grant award. Funds that may count towards the required match are listed in § 102.255(d) as well as Chapter 703 of the Institute's administrative rules. The proposed amendment to § 703.11(c) provides guidance on how grant funds awarded by other granting organizations or entities may be credited towards the Institute's matching fund requirement.

The Board Governance Subcommittee has considered the proposed change and recommends that the Oversight Committee approve publication of the proposed change in the *Texas Register*. Following public comment, the proposed rule will be brought back to the Oversight Committee in May for final adoption.

#### TITLE 25. HEALTH SERVICES

#### PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

#### CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas (Institute) proposes an amendment to § 703.11, regarding the matching fund requirements.

#### **Background and Justification**

Texas Health and Safety Code § 102.255(d) requires grant recipients to have encumbered funds equal to one-half of the amount of the grant award. A list of funds that may count towards the required match is contained in § 102.255(d) as well as Chapter 703 of the Institute's administrative rules. The proposed amendment to § 703.11(c) provides guidance on how grant funds awarded by other granting organizations or entities may be credited towards the Institute's matching fund requirement.

#### **Fiscal Note**

Kristen Pauling Doyle, General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule changes are in effect there will be no foreseeable implications relating to costs or revenues for state or local government as a result of enforcing or administering the rules.

#### **Public Benefit and Costs**

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated as a result of enforcing the rules will be clarification of policies and procedures the Institute will follow to implement its statutory duties.

#### **Small Business and Micro-business Impact Analysis**

Ms. Doyle has determined that the rule shall not have an effect on small businesses or on micro businesses.

Written comments on the proposed rule changes may be submitted to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711 no later than April 27, 2015. Parties filing comments are asked to indicate whether or not they support the rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to <a href="kdoyle@cprit.state.tx.us">kdoyle@cprit.state.tx.us</a>. Comments may be submitted by facsimile transmission to 512/475-2563.

#### **Statutory Authority**

The rule changes are proposed under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.255, which provides the Institute with broad rule-making authority to administer the chapter. Kristen Pauling Doyle, the Institute's General Counsel, has reviewed the proposed amendment and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article or code that is affected by these rules.

#### RULE §703.11 Requirement to Demonstrate Available Funds for Cancer Research Grants

- (a) Prior to the disbursement of Grant Award funds, the Grant Recipient of a Cancer Research Grant Award shall demonstrate that the Grant Recipient has an amount of Encumbered Funds equal to one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award. The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract. A Grant Recipient of a multiyear Grant Award may certify Matching Funds on a year-by-year basis for the amount of Award Funds to be distributed for the Project Year based upon the Approved Budget. A Grant Recipient receiving multiple Grant Awards may provide certification at the institutional level.
- (b) For purposes of the certification required by subsection (a) of this section, a Grant Recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the five percent (5%) Indirect Cost limit imposed by §102.203(c), Texas Health and Safety Code, subject to the following requirements:
- (1) The Grant Recipient shall file certification with the Institute documenting the federal indirect cost rate authorized for research grants awarded to the Grant Recipient;
- (2) To the extent that the Grant Recipient's Matching Funds credit does not equal or exceed one-half of the Grant Award funds to be distributed for the Project Year, then the Grant Recipient's Matching Funds certification shall demonstrate that a combination of the dollar amount equivalent credit and the funds to be dedicated to the Grant Award project as described in subsection (c) of this section is available and sufficient to meet or exceed the Matching Fund requirement;
  - (3) Calculation of the portion of federal indirect cost rate credit associated with subcontracted work performed for the Grant Recipient shall be in accordance with the Grant Recipient's established internal policy; and
  - (4) If the Grant Recipient's federal indirect cost rate changes less than six months following the anniversary of the Effective Date of the Grant Contract, then the Grant Recipient may use the new federal indirect cost rate for the purpose of calculating the Grant Recipient's Matching

Funds credit for the entirety of the Project Year.

- (c) For purposes of the certification required by subsection (a) of this section, Encumbered Funds must be spent directly on the Grant Project or spent on closely related work that supports, extends, or facilitates the Grant Project and may include:
- (1) Federal funds, including, but not limited to American Recovery and Reinvestment Act of 2009 funds, and the fair market value of drug development support provided to the recipient by the National Cancer Institute or other similar programs;
- (2) State of Texas funds;
- (3) funds of other states;
- (4) Non-governmental funds, (including private funds, foundation grants, gifts and donations;
- (5) Unrecovered Indirect Costs not to exceed ten percent (10%) of the Grant Award amount, subject to the following conditions:
- (A) These costs are not otherwise charged against the Grant Award as the five percent (5%) indirect funds amount allowed under §703.12(c) of this chapter (relating to Limitation on Use of Funds);
- (B) The Grant Recipient must have a documented federal indirect cost rate or an indirect cost rate certified by an independent accounting firm; and
- (C) The Grant Recipient is not a public or private institution of higher education as defined by §61.003 of the Texas Education Code.
- (6) Funds contributed by a subcontractor or subawardee and spent on the Grant Project, so long as the subcontractor's or subawardee's portion of otherwise allowable Matching Funds for a Project Year may not exceed the percentage of the total Grant Funds paid to the subcontractor or subawardee for the same Project Year.
- (d) For purposes of the certification required by subsection (a) of this section, the following items do not qualify as Encumbered Funds:
- (1) In-kind costs;
- (2) Volunteer services furnished to the Grant Recipient;
- (3) Noncash contributions;
- (4) Income earned by the Grant Recipient that is not available at the time of Grant Award;
- (5) Pre-existing real estate of the Grant Recipient including building, facilities and land;

- (6) Deferred giving such as a charitable remainder annuity trust, a charitable remainder unitrust, or a pooled income fund; or
- (7) Other items as may be determined by the Oversight Committee.
- (e) To the extent that a Grant Recipient of a multiyear Grant Award elects to certify Matching Funds on a yearly basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year shall serve as grounds for terminating the Grant Contract.
- (f) In no event shall Grant Award funds for a Project Year be advanced or reimbursed, as may be appropriate for the Grant Award and specified in the Grant Contract, until the certification required by subsection (a) of this section is filed and approved by the Institute.
- (g) No later than 60 days from the anniversary of the Effective Date of the Grant Contract, the Grant Recipient shall file a form with the Institute reporting the amount of Matching Funds spent for the preceding Project Year.
- (h) If the Grant Recipient failed to expend Matching Funds equal to one-half of the actual amount of Grant Award funds distributed to the Grant Recipient for the same period, the Institute shall:
- (1) Carry forward and add to the Matching Fund requirement for the next Project Year the dollar amount equal to the deficiency between the actual amount of Grant Award funds distributed and the actual Matching Funds expended, so long as the deficiency is equal to or less than twenty percent (20%) of the total Matching Funds required for the same period and the Grant Recipient has not previously had a Matching Funds deficiency for the project;
- (2) Suspend distributing Grant Award funds for the project to the Grant Recipient if the deficiency between the actual amount of Grant Funds distributed and the Matching Funds expended is greater than twenty percent (20%) but less than fifty percent (50%) of the total Matching Funds required for the period.
- (A) The Grant Recipient will have no less than eight months from the anniversary of the Grant Contract's effective date to demonstrate that it has expended Encumbered Funds sufficient to fulfill the Matching Funds deficiency for the project.
- (B) If the Grant Recipient fails to fulfill the Matching Funds deficiency within the specified period, then the Grant Contract shall be considered in default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract;
- (3) Declare the Grant Contract in default if the deficiency between the actual amount of Grant Award funds distributed and the Matching Funds expended is greater than fifty percent (50%) of the total Matching Funds required for the period. The Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract; or

- (4) Take appropriate action, including withholding reimbursement, requiring repayment of the deficiency, or terminating the Grant Contract if a deficiency exists between the actual amount of Grant Award funds distributed and the Matching Funds expended and it is the last year of the Grant Contract;
- (i) Nothing herein shall preclude the Institute from taking action other than described in subsection (h) of this section based upon the specific reasons for the deficiency. To the extent that other action not described herein is taken by the Institute, such action shall be documented in writing and included in Grant Contract records. The options described in subsection (h)(1) and (2) of this section may be used by the Grant Recipient only one time for the particular project. A second deficiency of any amount shall be considered an event of default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract.
- (j) The Grant Recipient shall maintain adequate documentation supporting the source and use of the Matching Funds reported in the certification required by subsection (a) of this section. The Institute shall conduct an annual review of the documentation supporting the source and use of Matching Funds reported in the required certification for a risk-identified sample of Grant Recipients. Based upon the results of the sample, the Institute may elect to expand the review of supporting documentation to other Grant Recipients. Nothing herein restricts the authority of the Institute to review supporting documentation for one or more Grant Recipients or to conduct a review of Matching Funds documentation more frequently.



TO: CPRIT OVERSIGHT COMMITTEE MEMBERS

FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE

**CHAIR** 

**SUBJECT:** INTENTION TO RECOMMEND APPROVAL OF THE CONTRACT

ISSUES SUBCOMMITTEE CHARTER

**DATE:** FEBRUARY 10, 2015

#### **Summary and Recommendation:**

The Board Governance subcommittee recommends that the Oversight Committee vote to approve the charter for the Contract Issues Subcommittee. Section 4.1 of the Oversight Committee Bylaws require that each subcommittee adopt a subcommittee charter to be approved by a simple majority of the Oversight Committee members. This recommendation was reviewed by the Board Governance Subcommittee and discussed with CPRIT's General Counsel, Kristen Doyle, at its meeting on February 5, 2015.

#### **Discussion:**

At the September 2, 2014, Oversight Committee meeting, the board voted to establish an Oversight Committee Subcommittee on Economic Terms. The ad hoc Subcommittee provided guidance to CPRIT staff and the Advisory Committee on Product Development regarding standard revenue sharing terms for product development grant contracts. Although the majority of the subcommittee's work concluded with the approval of the terms at the January 20, 2015 Oversight Committee meeting, CPRIT staff and the subcommittee members find a continuing need for the subcommittee to address other contract issues that may arise. Future issues include advising the Oversight Committee on contractual terms and actions related to the grant award contract as necessary and to review recommendations from the General Counsel and other agency staff regarding significant actions taken pursuant to a contract between the agency and a third party, including contract termination.

The Board Governance Subcommittee is assigned the responsibility of considering organizational documents, including subcommittee charters. The Board Governance Subcommittee met with Ms. Doyle, on February 5, 2015, to discuss the proposed charter for the Contract Issues Subcommittee, which has been renamed to reflect the subcommittee's broader objectives. The Board Governance Subcommittee has considered the proposed Contract Issues Subcommittee charter and recommends Oversight Committee approval.



### CHARTER OF THE CONTRACT ISSUES SUBCOMMITTEE FOR THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

#### BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas ("CPRIT" or "Institute") established a Contract Issues Subcommittee (the "Subcommittee") on September 3, 2014. This Charter, adopted by the Oversight Committee of the Cancer Prevention and Research Institute of Texas ("Oversight Committee") on \_\_\_\_\_\_\_\_, supersedes any other documents relating to the Contract Issues Subcommittee.

#### **PURPOSE**

The primary purpose of the Subcommittee is to advise the Oversight Committee on terms and issues related to CPRIT grantee award contracts.

#### COMPOSITION

The Subcommittee shall be composed of at least three members of the Oversight Committee; such members to be appointed from time to time by a majority vote of the Oversight Committee at a meeting at which a quorum is present and approved by the Oversight Committee. The Oversight Committee shall designate the Chairperson of the Subcommittee from among its members. A member of the Contract Issues Subcommittee will serve until his or her successor is duly appointed and qualified unless the member resigns or is removed from the Contract Issues Subcommittee. The Oversight Committee may replace any member of the Subcommittee by a majority vote of the Oversight Committee.

#### **MEETINGS AND QUORUM**

The Subcommittee shall meet as often as the Chairperson of the Subcommittee deems appropriate to perform its duties and responsibilities under the Bylaws and this charter. The Subcommittee shall keep regular minutes of its meetings and cause such minutes to be recorded in books kept for that purpose in the principal office of the Institute, and report the same to the Oversight Committee at its next regular meeting.

If a member of the Subcommittee is absent from any meeting, or disqualified from voting at that meeting, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of the Subcommittee, a majority of the then authorized members of the

Subcommittee will constitute a quorum, and the vote of a majority of the members of the Subcommittee present at any meeting at which there is a quorum will be the act of the Subcommittee.

Unless the Oversight Committee provides otherwise, the Subcommittee may make, alter, and repeal rules and procedures for the conduct of its business. In the absence of such rules and procedures, the Subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business, except that meetings of the Subcommittee are not required to be conducted pursuant to the Open Meetings Act.

#### **DUTIES AND RESPONSIBILITIES**

The Subcommittee has the following duties and responsibilities:

- Review and recommend proposed changes to the standard award contract template, including but not limited to revenue sharing terms, for consistency with the statute, CPRIT's agency rules, and best practices;
- Advise the Oversight Committee on contractual terms and actions related to grant award contracts and service contracts as necessary; and
- Review recommendations from the General Counsel and other agency staff regarding material actions taken pursuant to a contract between the agency and a third party, including but not limited to, contract termination;

#### **OTHER DUTIES**

The Subcommittee will submit this Charter to the Oversight Committee for its approval; evaluate the Subcommittee's performance on a periodic basis, periodically review the adequacy of this Charter and perform any other activities consistent with this Charter, the Bylaws, and applicable laws as the Subcommittee or the Oversight Committee deems necessary or appropriate.

In addition to its duties and responsibilities, the Subcommittee shall perform such additional special functions, duties or responsibilities related thereto as may from time to time be designated to it by the Oversight Committee Chair.



#### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: ANGELOS ANGELOU, AUDIT SUBCOMMITTEE CHARI

**Subject:** AUDIT SUBCOMMITTEE REPORT

**Date: FEBRUARY 10, 2015** 

The subcommittee met on December 18, 2014, and on February 9, 2015, and discussed the following items.

# **FY 2014 Independent Financial Audit**

On December 18, 2014, the financial auditors, McConnell and Jones, briefed the subcommittee about the results of the audit of the agency's FY 2014 financial statement. The auditors concluded that the agency's financial statements "present fairly, in all material respects, the respective financial position of the governmental activities and governmental funds" for FY 2014.

As part of the audit, the auditors also performed tests of CPRIT's internal financial controls for the purpose of expressing an opinion on the financial statements but do not express an opinion on the effectiveness of the internal controls. The auditors must report the results of this testing if any deficiencies in internal control exists according *Government Auditing Standards*. The auditors reported one control being deficient because the agency understated accounts payable and expenses by \$27.3 million associated with grant expense liabilities for the fourth quarter of FY 2014 because it reported this information on a fund accounting basis as required by the Comptroller's Office as part of completing the agency's FY 2014 Annual Financial Report. The auditors concluded that this information must also be adjusted and reported on a full accrual basis of accounting as required by U.S. GAAP. To address this control, the agency is seeking instruction from the Comptroller's Financial Reporting Section as to how ti should record differences between payables reported by state institutions of higher education in the state accounting system and actual reimbursements paid by CPRIT in the first quarter of the new fiscal year.

The other item identified is a significant deficiency that is not considered a material weakness. The auditors determined that CPRIT did not review adequate supporting documentation of grantees' reimbursement requests. The agency had already addressed this issue by hiring additional finance staff during the summer of 2014 and having that staff verify all supporting documentation for all expenses over \$750 reported on grantees' financial status reports.

#### **Internal Audit Services Contract**

At the February 9, 2015, meeting, Heidi McConnell brought forward a staff recommendations to approve a contract with Weaver and Tidwell for FY 2015 internal audit services at a not to exceed amount of \$217,500. While CPRIT's incumbent internal auditor, Grant Thornton LLP, also submitted a proposal and is highly qualified to provide these services, staff recommended that the agency rotate services to another audit firm for a fresh perspective on agency operational controls and compliance as Grant Thornton LLP has provided internal audit services to CPRIT for five years since FY 2010.

The subcommittee agrees with the staff recommendation and recommends that the Oversight Committee approve the contract with Weaver and Tidwell.

#### **Grant Compliance Monitoring Contract**

At the February 9, 2015, meeting, Heidi McConnell brought forward a staff recommendations to approve a contract with CohnReznick for grant compliance monitoring services at a not to exceed amount of \$336,000 for FY 2015. CohnReznick has extensive experience with compliance monitoring of grant programs both in Texas and in other states. It has specific experience monitoring scientific grants and understands how to work with scientists. CohnReznick is based in Maryland and will deliver its monitoring services by subcontracting with two firms in Texas, one a compliance-focused management consulting firm in the Dallas-Fort Worth area and the other a certified public accounting firm based in San Antonio. The public accounting firm in San Antonio is also a Historically Underutilized Business (HUB).

The subcommittee agrees with the staff recommendation and recommends that the Oversight Committee approve the contract with CohnReznick.

# FY 2016 Contract Renewal for Pre- and Post-Award Grants Management Support Services Contract with SRA International, Inc.

At the February 9, 2015, meeting, Heidi McConnell brought forward a staff recommendations to move forward to exercise the 12-month renewal option on the contract for pre- and post-award grants management support services that the agency sourced through the Texas Multiple Award Schedule (TXMAS) to allow the agency to get pricing from SRA International to continue moving forward with grant award processes for FY 2016 which have a 6-8 month lead time and finalize all functional changes to the electronic grants management system to match revised business processes.

Moving forward with the 12-month renewal will allow staff ample time to develop a request for proposal (RFP) for pre- and post-award grants management support services for future years and allow ample time to transition those services, estimated to be at least six month, to another vendor if necessary.

The subcommittee agrees with the staff recommendation and recommends that the Oversight Committee approve the exercise of the 12-month renewal.



#### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER

**Subject: SECTION 102.1062 WAIVER—DONALD BRANDY** 

**Date: FEBRUARY 18, 2015** 

#### **Waiver Request and Recommendation**

I request that the Oversight Committee approve a conflict of interest waiver for Mr. Donald Brandy, CPRIT's Purchaser and HUB Coordinator, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Mr. Brandy is not involved in the grant application or reporting process in his official capacity as purchaser of goods and services for the agency. However, the waiver ensures transparency regarding Mr. Brandy's relationship with some universities that receive CPRIT grants. Furthermore, CPRIT's Code of Conduct makes it clear that the agency's conflict of interest provisions apply to any expenditure of CPRIT funds. Although it is unlikely that CPRIT will procure goods and services from a university receiving grant funds from CPRIT, having the conflict of interest waiver in place ensures that Mr. Brandy can perform his duties. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for a conflict of interest to unduly influencing agency purchases.

## **Background**

CPRIT recently hired Donald Brandy to serve as the agency purchaser. Mr. Brandy is responsible for planning, organizing, coordinating, and preparing bid specifications and procurement documents to acquire goods and services from vendors and outside contractors used by the agency. The agency purchaser role requires little, if any, involvement with CPRIT's grant award process because CPRIT's grant award contracts are not considered vendor or outside service contracts.

Mr. Brandy requested approval to continue his outside employment as a referee for tennis tournaments held in and around Austin. In addition to refereeing for adult and junior-level tournaments, he occasionally serves as a referee for NCAA tennis matches held at area universities, including The University of Texas at Austin. Mr. Brandy is paid for his services as an independent contractor by the university athletic department when he referees collegiate matches.

CPRIT employees may engage in outside employment so long as the employment does not detract from the employee's ability to reasonably fulfill his or her responsibilities to CPRIT.

Employees must receive written approval from the CEO to engage in outside employment and I am required to notify the Audit Subcommittee regarding any approvals and to annually report all approved outside employment. I notified the Audit Subcommittee regarding my approval for Mr. Brandy's outside employment and it was discussed at the December 18, 2014, subcommittee meeting.

# **Exceptional Circumstances Requiring Mr. Brandy's Participation**

In order to approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process or other expenditure of CPRIT funds.<sup>1</sup>

This conflict of interest waiver is different than other waivers I have requested in that it is not seeking a waiver for actions related to CPRIT's grant review or grant monitoring process. As CPRIT's purchaser, I do not anticipate that Mr. Brandy will play any role in the review process for grant applications or grant reports. The purchaser deals only with agency procurement matters and has no influence over the grant award processes of the agency. To the extent that his outside employment necessitates involvement with university personnel, it is with collegiate athletic department staff that have no interaction with researchers working on or applying for grants. Nevertheless, if Mr. Brandy must be part of the review process or grant monitoring activities in the future, he will comply with CPRIT's conflict of interest notification and recusal requirements.

However, during the course of his official duties there may be circumstances requiring Mr. Brandy to procure goods or services on CPRIT's behalf from a university that has also employed him as a tennis referee. This is unlikely to occur; to date, CPRIT has only one services contract with an academic institution, Texas Tech University. However, as CPRIT's lead contact for agency purchases, Mr. Brandy should be allowed to perform his official duties to the fullest extent possible. Any involvement with university athletic department personnel resulting from his outside employment is unlikely to be the same individuals at the university responsible for contracting with CPRIT.

#### **Proposed Waiver and Limitations**

In granting the waiver of the conflict of interest set forth in Health & Safety Code Section 102.106(c)(3), I recommend that Mr. Brandy be permitted to perform all duties assigned as purchaser, subject to the limitations stated below:

1. Provide the Chief Operating Officer a list of universities that have used his services as referee during the past twelve months;

<sup>&</sup>lt;sup>1</sup> CPRIT's Code of Conduct Section III.B(2) states that, "The conflict of interest statutory and administrative rule provisions **apply to any decision to commit CPRIT funds**, whether or not the commitment is part of the grant award process or to a Grant Applicant." (emphasis added)

- 2. Notify the Chief Operating Officer prior to taking any action on a contract or other procurement document that would result in payment of CPRIT funds to a university on the list referenced above; and
- 3. The Chief Operating Officer, in conjunction with the CEO, Chief Compliance Officer and General Counsel, can review the circumstances and determine whether Mr. Brandy should be recused from involvement in the procurement.

# Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or review this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval of any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request. To the extent that Mr. Brandy has a conflict of interest not address in this waiver, then Mr. Brandy will follow the required notification and recusal process.



#### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: CYNTHIA MULROW, MD

Subject: DIVERSITY SUBCOMMITTEE REPORT

**Date: FEBRUARY 10, 2015** 

The subcommittee met on February 6 and discussed the following significant items. No action is requested of the Oversight Committee at this time.

# **Research Training Grants Update**

Dr. Kripke and Michael Brown reported on language to be included in the March 2015 RFA on Research Training Awards. These awards are to institutions to promote research and medical careers to expand interest in science and medicine as a career. Generally, these awards provide hands-on research and training experience for undergraduate and early graduate students by providing positions, stipends, and tuition assistance. To date, about five percent of students in these programs are Black and 15 percent are Hispanic. As reported to the Oversight Committee at the November 19, 2014, meeting, staff was considering adding extra "weights" or "points", which would be one of other factors for considering in evaluating these applications. In developing the new RFA, "weights" and "points" were not used. Instead, emphasis in the RFA on targeting and increasing participation of individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds and a plan for recruiting such people is a requirement for the award. These then become part of the criteria used to evaluate the award.

Chief Executive Officer Wayne Roberts is strongly supportive of such language and direction being given in the training grants program. This is a program that addresses the "pipeline" issue in higher education, particularly in graduate and medical programs that there are insufficient numbers of students from underrepresented groups advancing from K-12 through the baccalaureate level from which to draw graduate and medical students.

## National Institutes of Health (NIH) Interest in Diversity

Subsequent to the November 19, 2014, Oversight Committee meeting, NIH issued a notice to update NIH's diversity statement describing its interest in the diversity of the NIH-funded workforce. This notice affects NIH's Recruitment and Retention Plan to Enhance Diversity by adding women as part of the underrepresented classes the policy is intended to address. This a plan that institutional research training, institutional career development, and research education grant award applicants must include in their application. The plan describes their recruitment and

retention efforts to diversify the biomedical, behavioral, clinical, and social sciences workforce through increased participation of talented individuals from underrepresented racial and ethnic groups; individuals with disabilities; and individuals from economically, socially, culturally, or educationally disadvantaged backgrounds. Institutions are encouraged to identify candidates who will increase diversity on a national or institutional basis.

This was an informational item only. After the legislative session Wayne Roberts intends to contact NIH about this program and NIH's interest in increasing diversity in its funded programs to see if NIH's program could be applied to CPRIT's three programs of prevention, academic research, and product development research.

## **CPRIT Historically Underutilized Businesses (HUB) Activities**

Chief Operating Officer Heidi McConnell and new Purchaser Don Brandy discussed updated information concerning the agency's operational HUB activities and proposed language in the 2016-17 General Appropriations Act to strengthen state agencies HUB commitment and reporting. Don Brandy explained that as he receives notices from HUB vendors about commodities they sell, he adds them to the list of vendors that he sends requests for pricing on items the agency needs, often within in a few days of adding them to the list. In one recent instance, Don Brandy received a notice from a new HUB vendor and included them on a request for quote on some printer cartridges. Because the vendor provided the lowest price option among the group of vendors who provided pricing, he was able to purchase from that HUB vendor in a short period of time.

The proposed language for the 2016-17 General Appropriations Act will require each agency to conduct an internal assessment of its efforts to increase participation in the HUB program for the previous two state fiscal years. The assessment will be due to the Comptroller and Legislative Budget Board (LBB) before December 1, 2015, and the Comptroller and LBB may evaluate the agency's good faith efforts to increase HUB participation. In addition, each agency will be required to submit a report demonstrating compliance with state HUB policies, including a plan for maintaining compliance and good faith efforts to increasing HUB participation in the future. This report must also be submitted to the Comptroller and LBB before December 1, 2015. These reports are subject to audit by the State Auditor's Office who will select entities for audit every biennium based on a risk assessment.

The subcommittee requested information on CPRIT's HUB expenditures. Following are two charts which provide the HUB expenditure data for FY 2014 and FY 2013 for comparative purposes.

# **FY 2014 HUB Expenditures**

Procurement Category	Total Agency Expenditure	Total \$ Spent with HUBs	Total % Spent with HUBs	State Annual HUB Procurement Goal
Heavy Construction	\$0	\$0	0%	11.20%
Building	\$0	\$0	0%	21.10%
Special Trade	\$382	\$0	0%	32.70%
Professional	\$331,865	\$35,800	10.79%	23.60%
Other Services	\$9,656,472	\$184,536	1.91%	24.60%
Commodity	\$42,791	\$11,786	27.54%	21.00%
Purchasing				

# **FY 2013 HUB Expenditures**

Procurement Category	Total Agency Expenditure	Total \$ Spent with HUBs	Total % Spent with HUBs	State Annual HUB Procurement Goal
Heavy Construction	\$0	\$0	0%	11.20%
Building	\$145,856	\$0	0%	21.10%
Special Trade	\$4,494	\$0	0%	32.70%
Professional	\$187,652	\$0	0%	23.60%
Other Services	\$9,465,216	\$379,744	4.01%	24.60%
Commodity	\$199,933	\$11,109	5.56%	21.00%
Purchasing				

\*\*\*\*

The subcommittee has no recommendations for action by the Oversight Committee at this time. However, the subcommittee did express support and agreement with the proposed changes to the research training grants RFA. The subcommittee will monitor the above activities to identify meaningful ways to improve diversity in CPRIT agency operations and award programs.

# Oversight Committee Meetings and Standing Subcommittee Meetings

						May 2015
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
3	4	5 PIC Meeting CPRIT Staff Only	6 Portal Opens	7 Board Governance	8 Diversity	9
10	11 Audit	12 Prevention	13 Sci Research	14 Prod Dev	15 Nominations	16
17	18	19	20 Oversight Committee Meeting	21	22	23

					Αι	ugust 2015
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
2	3	4 PIC Meeting CPRIT Staff Only	5 Portal Opens	6 Board Governance	7 Diversity	8
9	10 Audit	11 Prevention	12 Sci Research	13 Prod Dev	14 Nominations	15
16	17	18	19 Oversight Committee Meeting	20	21	22

					Nove	mber 2015
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	PIC Meeting CPRIT Staff Only	4 Portal Opens	5 Board Governance	6 Diversity	7
8	9 Audit	10 Prevention	11 Sci Research	12 Prod Dev	13 Nominations	14
15	16	17	18 Oversight Committee Meeting	19	20	21

Note: Unless the subcommittee members agree to a different time, all subcommittee meetings will begin at 10:00 a.m. with the exception of Diversity and Nominations that will begin at 10:30 a.m. Members of the Audit and Program subcommittees should allocate 1.5 hours for a meeting. All others subcommittee meetings require one hour.



# Oversight Committee Meetings and Standing Subcommittee Meetings

					Febr	uary 2016
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1/31	1	2 PIC Meeting CPRIT Staff Only	3 Portal Opens	4 Board Governance	5 Diversity	6
7	8 Audit	9 Prevention	10 Sci Research	11 Prod Dev	12 Nominations	13
14	15	16	17 Oversight Committee Meeting	18	19	20

						May 2016
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3 PIC Meeting CPRIT Staff Only	4 Portal Opens	5 Board Governance	6 Diversity	7
8	9 Audit	10 Prevention	11 Sci Research	12 Prod Dev	13 Nominations	14
15	16	17	18 Oversight Committee Meeting	19	20	21

					Αι	ıgust 2016
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
7/31	1	2 PIC Meeting CPRIT Staff Only	3 Portal Opens	4 Board Governance	5 Diversity	6
7	8 Audit	9 Prevention	10 Sci Research	11 Prod Dev	12 Nominations	13
14	15	16	17 Oversight Committee Meeting	18	19	20

					Nover	mber 2016
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
10/30	10/31	1 PIC Meeting CPRIT Staff Only	2 Portal Opens	3 Board Governance	4 Diversity	5
6	7 Audit	8 Prevention	9 Sci Research	10 Prod Dev	11 Nominations	12
13	14	15	16 Oversight Committee Meeting	17	18	19

Note: Unless the subcommittee members agree to a different time, all subcommittee meetings will begin at 10:00 a.m. with the exception of Diversity and Nominations that will begin at 10:30 a.m. Members of the Audit and Program subcommittees should allocate 1.5 hours for a meeting. All others subcommittee meetings require one hour.