

# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# **Oversight Committee Meeting**

May 21, 2014



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## Summary Overview of the May 21, 2014, Oversight Committee Meeting

Please find enclosed the meeting packet for the next meeting of the CPRIT Oversight Committee to be held on Wednesday, May 21, 2014, 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 new staff, office relocation plans, and the status of grant funds available for awards for the remainder of FY 2014.

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

Dr. Margaret Kripke will present the Program Integration Committee's recommendations for 14 scientific research awards and provide an update regarding the current review process and newly released requests for applications. Dr. Kripke will also report on the recent meeting of the University Advisory Committee.

## Chief Product Development Officer Program Overview, Grant Award Recommendations, and Proposed Contract Terms for Product Development Grants

Dr. Tom Goodman will present the Program Integration Committee's recommendations for two product development grant awards. These grant recommendations are the first product development grant applications to be considered under the review process set out by SB 149. Dr. Goodman will also discuss Product Development program principles and strategies. Following up on the Oversight Committee's direction at its last meeting, Dr. Goodman will present the proposed contract terms for the Product Development grant awards that were ratified at the February 19<sup>th</sup> Oversight Committee meeting.

Information related to the scientific 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.

### **Scientific Research and Prevention Programs Committee Appointments**

The Chief Executive Officer has appointed 58 new members to the CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires the appointments to be approved by the Oversight Committee. The Nominations Subcommittee recommends approval of the CEO's appointments. A biographical sketch for each appointee is included in the board packet.

**Program Priorities Project – Presentation by Robert Mittman** 

Dr. Becky Garcia (staff project lead) will introduce Robert Mittman, an experienced facilitator that has been retained pursuant to the Oversight Committee's direction to assist in setting program priorities. Mr. Mittman will give a brief presentation framing a process for the Oversight Committee to set annual priorities for CPRIT grant programs.

## Acceptance of Donation to the Cancer Prevention and Research Institute of Texas

A donation in the amount of \$29,877.00 has been given to CPRIT by the Texas Cancer Coalition Liquidating Trust, which has been designated to reimburse expenses by CPRIT peer reviewers. CPRIT is authorized pursuant to V.T.C.A. Health & Safety Code § 102.054 "to accept gifts and grants from any source for the purposes of this chapter." This authority, in conjunction with Article IX of the 2014-2015 General Appropriations Act, allows CPRIT to use funds received as a gift for the purposes designated by the grantor. Acceptance of these funds as a designated gift to the agency is the last issue to be resolved in the settlement agreement between CPRIT and the Texas Cancer Coalition, formerly known as the CPRIT Foundation. The total amount of the settlement agreement is \$473,677.81.

## Agency Strategic Plan/Legislative Appropriations Request

CPRIT staff has prepared drafts of required reports to be submitted in preparation for the upcoming legislative session. The Oversight Committee must authorize transmittal of final drafts of CPRIT's Strategic Plan and the Legislative Appropriations Request to the appropriate offices. The final submission must be signed by Presiding Officer Rice and CEO Roberts.

- The six-year strategic plan identifies an agency's current status, focus and orientation, as well as its planned future direction. The strategic plan must include a mission statement, identification of the agency's goals and the population it serves, and a description of the means by which the agency plans to achieve its goals. The structure of the plan is set by the Governor's Office of Budget, Planning and Policy (GOBPP) and the Legislative Budget Board (LBB). CPRIT"s strategic plan, signed by Oversight Committee Chair Rice, is due to the GOBPP and the LBB on June 23, 2014.
- Each state agency prepares a Legislative Appropriation Request (LAR) pursuant to instructions sent by the LBB and the Governor's Office. Performance measures are included in the agency's LAR. The LBB and GOBPP will hold hearings in late summer or early fall with each agency concerning requests prior to developing budget bills for introduction in the 84<sup>th</sup> Legislature in January 2015. The LAR must be submitted by the end of the summer to the LBB, GOBPP, the state auditor, the state comptroller.

## **Authorization of Request for Financing to the Texas Public Finance Authority and Bond Review Board**

The Texas Public Finance Authority (TPFA) is statutorily authorized to issue debt on behalf of CPRIT. The Oversight Committee will consider a resolution requesting financing for \$300 million in bond proceeds appropriated to CPRIT for its operations and prevention and research grant awards

## Proposed Amendments to Agency Administrative Rules, Bylaws, and Code of Conduct

- Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. The Board Governance Subcommittee has considered the proposed administrative rule changes and recommends that Oversight Committee approve the proposed rule changes for publication in the *Texas Register*.
- Pursuant to the Oversight Committee's direction at the February 19, 2014, meeting, the Board Governance Subcommittee has reviewed the Bylaws, including the Code of Conduct, for consistency with the statute. Proposed changes recommended by the subcommittee eliminate potential variations from statutory directives.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## **Oversight Committee Meeting**

## Texas State Capitol Extension 1400 N. Congress Avenue, Austin, Texas 78701 Room: E1.012

May 21, 2014 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		
1.	Call to Order	
2.	Roll Call/Excused Absences	
3.	Adoption of Minutes from February 19, 2014 meeting	TAB 1
Public Co	omment 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
Program	Activities	
8.	Chief Scientific Officer Report	TAB 5
	Grant Award Recommendations	
9.	Chief Product Development Officer Report	TAB 6
	<ul> <li>Contract Terms for Product Development Grants</li> </ul>	
	<ul> <li>Grant Award Recommendations</li> </ul>	
10.	Chief Prevention and Communications Officer Report	TAB 7
11.	Scientific Research and Prevention Program Committee Appointments	TAB 8
12	Program Priorities Project	$T\Delta RQ$

## **Agency Business**

13.	Acceptance of a Donation Pursuant to Texas Health & Safety Code § 102.054	TAB 10
14.	Agency Strategic Plan	TAB 11
15.	Legislative Appropriations Request for 2016-2017 biennium	TAB 12
16.	Authorization of Request for Financing to Texas Public Finance Authority and Bond	TAB 13
	Review Board	
17.	Internal Audit Report Status	TAB 14
18.	Proposed Amendments to 25 T.A.C. Chapters 701 - 703 and Authorization to Publish	TAB 15
	in the Texas Register	
19.	Proposed Amendments to Oversight Committee Bylaws, including Code of Conduct	TAB 16
20.	Subcommittee Business	
21.	Consultation with General Counsel	

## Closing

- 22. Future Meeting Dates and Agenda Items
- 23. 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.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## February 19, 2014 Minutes

## 1. Meeting Called to Order

Meeting called to order at 10:03 a.m.

## 2. Roll Call /Excused Absences

Secretary Mitchell called the roll.

Amy Mitchell:

Angelos Angelou

Gerry Geistweidt

Pete Geren

**Ned Holmes** 

Will Montgomery

Cynthia Mulrow

William Rice

Craig Rosenfeld

## 3. Adoption of Minutes from January 24, 2014 meeting

There being no discussion or corrections, a motion to approve the minutes of the January 24, 2014, Oversight Committee meeting was made by Dr. Rosenfeld and seconded by Dr. Mulrow.

### MOTION CARRIED UNANIMOUSLY

## 4. Chief Executive Officer Report

CEO Wayne Roberts reported on the following issues presented in the memorandum included in the Board Meeting Packet:

## University Advisory Committee

CEO Roberts advised that university officials, as designated by V.T.C.A. Health & Safety Code § 102.154, have been contacted to appoint (or re-appoint) members to the University Advisory Committee. He informed members that this committee is required by CPRIT's statute. Mr. Roberts stated that he believed it may be useful in establishing program priorities and that the Diversity subcommittee expressed an interest in having this advisory committee help them in gathering information. Two appointments remain open and Mr. Roberts stated that he expects them to be filled soon.

## Status and summary of CPRIT staff vacancy postings

CEO Roberts reported that the Chief Product Development position is critical for this agency and the necessary processes to finalize the selection are underway.

Mr. Roberts advised that in reviewing the agency processes for hiring that he found a conflict in language between the Oversight Committee by-laws and state law. CPRIT's by-laws Section 4.4 states that the CEO is to review and make recommendations to the Oversight Committee regarding senior staff officer hirings, dismissals and compensation. However V.T.C.A. Health and Safety Code §102.0511 specifically directs the CEO to hire the Chief Product Development Officer. Mr. Roberts advised that with any conflict, statute prevails. In the interest of not violating the spirit of the bylaws, CEO Roberts suggested the following as a possible resolution for member discussion.

The CEO will determine his choice for finalist and then meet with the Audit subcommittee to inform them concerning the choice and the rationale behind the choice. The Audit subcommittee will then report back to the Oversight Committee at the next meeting concerning that discussion. Mr. Roberts stated that he would then proceed based on that discussion.

Chair Rice entertained a motion to direct the CEO to advise the Audit Subcommittee of the CEO's selection of a Chief Product Development Officer before making an offer of employment. The Audit Subcommittee will provide advice to the CEO that may be considered in making the CEO's final decision.

Motion was made by Mr. Geistweidt and seconded by Mr. Angelou.

## MOTION CARRIED UNANIMOUSLY

The Chair entertained a motion to direct the Board Governance Subcommittee to review the Board Bylaws for consistency with the statute and CPRIT's new administrative rules and recommend any changes at the next meeting.

Motion was made by Mr. Angelou and seconded by Dr. Rosenfeld.

## MOTION CARRIED UNANIMOUSLY

#### **Dashboard Metrics**

CEO Roberts requested that Heidi McConnell, COO, address the Committee regarding the Dashboard Metrics.

Ms. McConnell reported that there were currently 36 metrics organized into three categories: accountability, mission and transparency. She informed the members that most of the information is available to CPRIT quarterly and some are related to performance measures that CPRIT is required to report to the Legislative Budget Board. She further stated that some of the metrics are shaded because the information is not readily available at this point but is reported annually to the LBB. Dr. Rice asked if that could be reported quarterly and Ms. McConnell replied yes.

Mr. Geren inquired about the record of published articles and asked if CPRIT kept a record of them. Ms. McConnell responded the agency does. Mr. Geren asked if that same process was followed for the Prevention program. Dr. Garcia answered that in addition to articles, the number of Prevention publications also includes educational materials produced.

Dr. Rosenfeld asked how many articles from our grantees have been published to date. Ms. McConnell responded that it would be in the hundreds and possibly close to 1,000 by the end of the year.

Dr. Rice asked if this information comes from SRA, CPRIT's grants management vendor, and how it is defined. Ms. McConnell stated that it is reported in CPRIT's grants management system and verified through PubMed. She further stated that the publication must be related to a grant that CPRIT is funding and must be in an academic publication such as a peer reviewed academic journal. Dr. Rosenfeld asked if the numbers included abstracts and Ms. McConnell replied no. CEO Roberts commented that this item is an LBB measure and has very specific requirements.

Dr. Mulrow commented that it is easy to use Google Scholar to find out how often work is cited. She stated that it could be automated and done very easily.

Dr. Mulrow asked if some of the items on the Dashboard could fit under more than one category. She asked if we could identify priority areas of grants so we can get some routine reporting regarding the number of grants relevant to those priority areas. She commented that some programs routinely use surveys at the end of the year, directed to the leaders of the institutions funded, to ask questions about their perception of the relative impact of these awards on their institutions, faculty and faculty development.

Ms. McConnell responded that both the survey and Google Scholar were options that she would look into. She further stated that the data could be placed where the Members would like. She stated that this was an ongoing process and data can be added or taken away as needed.

Chair Rice stated that the objective of the discussion on the Dashboard was to bring something forward to seek input of the Oversight Committee.

Mr. Montgomery asked if some of the categories could be something that CPRIT has cofunded. Ms. McConnell stated that anytime an article about a CPRIT-funded grant is published, it must be cited by the author and that it could be a co-funded project.

CEO Roberts commented that with respect to Chair Rice's comments, this tool will be useful to him. Mr. Roberts informed members that if they have something they would like to see added to email him or Ms. McConnell.

Mr. Montgomery asked if the data could be broken down into short term, mid-term and long term. Mr. Montgomery stated that patents are an example of something that will not happen for a number of years and that he is concerned about having too many blanks on the report.

Mr. Angelou asked if other investments from sources other than CPRIT can be captured from the grantee in addition to matching funds.

Ms. Doyle responded that follow-on funding information is requested in all three programs and is part of the Annual Report.

Dr. Rosenfeld asked if the number of Investigational New Drugs (IND) could be reported as a way to know how many have gone into clinical trials. He asked about the dramatic increase in the number of website hits. Ms. McConnell responded that some of that increase would be due to the number of recent job postings.

## 5. Honoraria Policy

This topic was not taken up.

### 6. Chief Scientific Officer Report and Grant Award Recommendations

Dr. Kripke provided the Chief Scientific Officer report.

Dr. Kripke pointed out the grant awards that will be recommended for funding during this meeting are the first to go through the new processes. Seven Training and four Multi Investigator awards went through the Program Integration Committee (PIC). She stated these are continuation grants that were initially approved for five years in 2010 but funded for three because of other statutory restrictions.

Dr. Kripke reported that the RFAs for new Individual Investigator Research (IIRA) Awards closed on February 3, 2014 and a total of 584 applications have now been distributed among the seven peer review panels for review. She pointed out that this is the first time this award has been offered in over a year, which would explain the large volume of applications received. Dr. Kripke stated that those applications recommended by the Scientific Review Panels will be presented for consideration at the August Oversight Committee Meeting.

Dr. Kripke advised that new members of the Scientific Review Panels will be presented for consideration at this meeting. She further stated that she still has fifteen to twenty expert and advocate reviewers that will be presented at the May meeting.

Dr. Kripke reported that the Recruitment of First-time Faculty, Rising Stars, and Established Investigators RFAs were released on January 17, 2013, and are expected to be reviewed by the SRC in time to be considered by the Oversight Committee at its May meeting.

Dr. Kripke reported that she will be releasing another round of RFAs for research grants in March. One is for IIRAs (untargeted). In order to stimulate research in a particular area, there will be two targeted for IIRAs for studies on prevention and early detection research and for studies on cancer of children and adolescents.

Dr. Rosenfeld asked if the primary investigator could apply for more than one Individual Investigator award at a time. Dr. Kripke replied no. He then asked if the primary investigator could ever submit more than one application in a review cycle. Dr. Kripke responded yes; for example some investigators have more than one individual investigator grant, but they are on different topics and were funded in different cycles.

CEO Roberts gave a brief overview of the Program Integration Committee process mandated by statute. The committee includes Wayne Roberts, Chair; Dr. Kripke, Chief Scientific Officer; Dr. Garcia, Chief Prevention and Communications Officer; the Product Development Officer and Dr. David Lakey, Commissioner of the Department of State Health Services. In addition, CPRIT's compliance officer must also attend and document that agency administrative rules were followed. Based on the statute, the PIC must approve, with a majority vote, a list of grant applications recommended for funding by the respective review councils. CEO Roberts advised that certain factors in this process must be documented, including an explanation of any decision to not recommend an application recommended by the respective review council. PIC decisions are final unless the PIC vote is not unanimous. If the vote is not unanimous, the PIC may present a list to the Oversight Committee and provide an alternative list along with an explanation of their decision. The Oversight Committee may consider all lists. CEO Roberts reported that the first PIC meeting was held on February 6<sup>th</sup> and he was pleased with the process.

CEO Roberts reported that after the PIC meeting on February 6<sup>th</sup>, CPRIT discovered an issue with the four MIRA grant applications recommended by the PIC. The MIRA application required applicants to be fiscally current in order to apply for the continuation grant. Although the four applicants recommended by the PIC are currently up to date with required financial documents, they were not at the time of their applications for continuation grants. CEO Roberts reconvened the PIC on February 12<sup>th</sup> to determine whether the information impacted the PIC's decision to recommend the MIRA grants. By the time of the PIC meeting, three applicants were up to date and were recommended for funding by the PIC. The fourth application was recommended contingent upon becoming fiscally up to date prior to the February 19, 2014 Oversight Committee meeting. CEO Roberts reported that by the end of the day on February 12<sup>th</sup> all four were up to date with fiscal filings.

CEO Roberts advised members that as CPRIT begins to hold training sessions around the state, some of these issues will be addressed and that CPRIT is refining schedules and processes. An additional step was added to the pedigree process used by the PIC and our compliance officer as a result of this issue.

Chair Rice paused the meeting to welcome Senator Jane Nelson, co-author of the original legislation which created CPRIT in 2007, to the meeting.

Senator Nelson first thanked the Oversight Committee for the work they are doing. She stated that when CPRIT was created, a ten year commitment was made that Texas would support the fight against cancer, invest in prevention and bring quality research projects to Texas along with the best and brightest to make our state a premier research corridor. She stated that had happened. Senator Nelson reaffirmed her belief that CPRIT's mission will lead to a cure for cancer – not just for Texans but for people around the world. Senator Nelson addressed the reorganizing bill, SB149, and stated that this legislation would help to rebuild complete public trust in what CPRIT is doing. She challenged the Oversight Committee to move forward with a commitment to transparency and fairness and to not only follow the letter of the law and rules but also the spirit of that legislative intent.

### **COMPLIANCE CERTIFICATION**

David Reisman, CPRIT's Chief Compliance Officer, provided the compliance certification for the award slates. Mr. Reisman stated that with regard to the Research Training Awards Continuation Grants, he has conferred with staff at CPRIT and SRA International (SRA) and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. He further stated that he is satisfied that the application review process that resulted in the seven RTA Continuation Grants, recommended by the PIC for these two grant slates, followed applicable laws and agency administrative rules. Mr. Reisman certified the award slate for the Oversight Committee's consideration.

Mr. Reisman stated that with regard to the four Multi Investigator Research Awards Continuation Grants, he has conferred with staff at CPRIT and SRA, CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. He informed the members that the applicable pedigrees and third-party observer reports support that the application review process was followed. However, Mr. Reisman advised that the Request for Applications prescribes that applicants must file programmatic and fiscal reports by the application deadline. However, his review shows that four MIRA Continuation grant applicants had not submitted one or more required financial status reports (FSRs) by the application deadline. He advised that since the four MIRA applicants did not provide the required FSRs by the application deadline, they do not qualify for compliance certification.

Chair Rice summarized for clarity, that the four applications in question had not filed the required reports or had filed and CPRIT didn't respond timely in order for the applicant to submit their FSRs prior to their application. Chair Rice stated that, as he understood it, certain other financial information should have been reviewed and returned to the applicant in order for them to submit the FSR.

Ms. Doyle stated that the reports in question were matching fund certification and financial forms and based on the RFA an applicant must be programmatically and fiscally up to date.

Mr. Reisman responded that the facts varied in each case, but in at least some of them the information was submitted but it crossed over into this application period.

Dr. Kripke pointed out that the grant monitoring system, CGMS, would not have allowed the applicants to submit their FSRs prior to receiving feedback from CPRIT on their previously submitted documents.

Chair Rice, stated for clarity that he understands that the applicants for the MIRA grants were in the conundrum of having to wait for CPRIT to approve the matching fund certifications prior to submitting the FSR and that that needs to be understood for clarity prior to the Oversight Committee voting on approving award.

Mr. Geren expressed confusion. He had understood Mr. Roberts to say that this was a minor but not fatal error. However, listening to Mr. Reisman, it sounded like the four applications in question would not be considered today.

Mr. Reisman stated that the RFA requirements are pretty rigid and that if an FSR is not on time, the application does not get considered for an award. He further stated that as CPRIT's compliance officer, he could not certify that they were in compliance; however, the Oversight Committee can grant an exception based on mitigating circumstances.

CEO Roberts referred to his report earlier where the discovery was made that four of the MIRA applications were not in compliance at the time of their application due to issues. He again stated that the issue was immediately returned to the PIC and that all four applications were in compliance within one day. He related to the Members that this was an unusual situation wherein the applicants had submitted required documentation that CPRIT staff had processed timely, however because they were not aware that the grantee had submitted another application, there was overlap in the time requirements for submitting their application for continued funding.

Mr. Roberts commented that the PIC was justified in granting an exception based on mitigating circumstances. He stated that staff evaluated what had happened rather than automatically deny the applications. He informed that experience reveals the massive requirements that CPRIT applicants must go through. Everything occurs in a large application review system and follows precise steps. The system will not let a grantee go to the next step until they have completed the previous one. He emphasized that this was an administrative issue and did not justify stopping funding for these MIRAs.

CEO Roberts stated that going forward, staff would identify these situations, and make sure desk reviews proceed expediciously. Roberts commented that this is educational for all levels. While warnings exist for grantees regarding timeframes, CPRIT will take a more proactive stance to help grantees in this area when needed

Chair Rice asked if an improvement to avoid this in the future would be an alert system. He further stated that he had the sense that there was some ability to move more quickly by CPRIT staff had they known that they had current applicants in their workload for review of financial reports.

Ms. Mitchell asked if CPRIT staff went beyond the thirty day requirement to process the matching funds report. Mr. Reisman responded that staff did process the information within their thirty day window, however, they had no knowledge that these applicants were applying for additional funding and their processing of the information crossed over the time frame for the institutions to submit their applications.

Mr. Geren asked Mr. Reisman if he was now satisfied that these applications met the requirements for funding. Mr. Reisman stated that he was not able to certify those applications for compliance under the CPRIT administrative rules. He stated however, that the Oversight Committee could consider mitigating circumstances.

Mr. Reisman stated that going forward CPRIT should work on policies to address these types of situations because it will happen again. He also advised that the Oversight Committee may want to grant staff the ability to determine an exception in predetermined situations such as an applicant not being able to submit an application because the applicant is in the hospital or technical difficulties. As Chief Compliance Officer, he stated he would then be able to take into consideration CEO Roberts' determination that the application meets the predetermined rules for granting of an exception. The CCO would then be able to say that it is accepted.

Mr. Geren stated that as the CCO, Mr. Reisman had determined that these four applications were not in compliance. He then asked Mr. Reisman if he felt that the necessary efforts were made to grant an exception based on mitigating circumstances and that substantively the Committee had all of the information needed to determine approval. Mr. Reisman stated that true transparency is served, as it was today, by bringing the issue to the Oversight Committee to determine mitigating circumstances. Mr. Reisman stated that part of his job was to investigate and that the facts presented to the Committee were correct.

Mr. Geren stated that he has confidence that no one on staff would ever feel any pressure to do anything other than what they are comfortable with doing. He commented that the conversation had been useful since it clarified concerns about what occurred. He stated that CPRIT must operate within the letter of the law and the spirit of the law. He further stated that the CCO needs to be comfortable with stopping any issue he sees as appropriate.

Mr. Geistweit asked Ms. Doyle if the Committee could waive their own rules. Ms. Doyle stated that there are rules to grant an exception for mitigating circumstances, such as technical issues with uploading the application or someone in the hospital. Ms. Doyle further advised that the current rules were not in effect at that time the applications in question were submitted, which makes this instance unusual. Ms. Doyle stated that the rulemaking process requires public comment and adoption by the Oversight Committee, so any process to waive application of adopted rules should be specified in the administrative rules.

Mr. Holmes commented that he believed the processes should be fine-tuned to avoid the Catch-22 encountered today. He stated that he thought CPRIT would be caught in it again if they didn't streamline their processes.

#### **CONFLICT OF INTEREST NOTIFICATIONS**

Chair Rice noted for the record that Oversight Committee member Amy Mitchell has reported a conflict of interest with application ID numbers 140020, 140021, 140022, 140024, 140102, 140103, 140105, 140106, 140108, 140110, and 140113.

He also noted that Oversight Committee member Gerry Geistweidt has reported a conflict of interest with application ID number 140024.

Chair Rice informed the Committee that in accordance with CPRIT's rules, Ms. Mitchell and Mr. Geistweidt are recused from the discussion or action on the applications where they have reported a conflict of interest.

Chair Rice asked the members if there were any conflict of interest declarations for Oversight Committee members that have not been reported.

It was noted for the record that Dr. Kripke reported a conflict of interest with application ID number RP140106.

### APPROVAL PROCESS

Chair Rice explained to the Members that these award recommendations are subject to the law in effect at the time that the applications were submitted. This means that the process to finalize the PIC's recommendations will follow the process put into place with the enactment of SB149.

The PIC's recommendation will be approved if two-thirds of the Oversight Committee present and able to do so approves the PIC's funding recommendations.

The Chair proposed that the Oversight Committee take action to approve the award recommendations by application type. This would mean that a vote would be taken for the training applications as one group.

The exception would be if an Oversight Committee member requests that the Oversight Committeee vote on an application individually or if an Oversight Committee member has reported a conflict of interest.

Motion was made by Mr. Geren and seconded by Mr. Angelou to follow the process laid out by the chair for voting on the grant awards by the application type.

## MOTION CARRIED UNANIMOUSLY

A motion was made by Mr. Holmes and seconded by Mr. Angelou to approve the PIC's recommendations for Research Training Grant Continuation Awards.

#### MOTION CARRIED UNANIMOUSLY

Chair Rice noted for the record that Ms. Mitchell abstained from voting.

A motion to approve the PIC's recommendations for continuation grants for the following Multi-Investigator Research Awards: RP140020, 140021, and 140022 was made by Dr. Mulrow and seconded by Mr. Geren.

The Chair noted that RP 140024 was not taken up with this group because of Mr. Geistweidt's conflict of interest.

### MOTION CARRIED UNANIMOUSLY

Chair Rice noted for the record that Ms. Mitchell abstained from voting.

A motion was made by Dr. Mulrow and seconded by Mr. Holmes to approve continuation grants for the following Multi-Investigator Research Awards: RP140024.

#### MOTION CARRIED UNANIMOUSLY

Chair Rice noted for the record that Ms. Mitchell and Mr. Geistweidt abstained from voting.

Having approved the PIC recommendations for the Training Grant awards and the Multi-Investigator awards, Chair Rice called for a motion to delegate contract negotiation authority to the Chief Executive Officer and the General Counsel and to authorize the Chief Executive Officer to sign the contracts on behalf of the Institute.

A motion to delegate contract negotiation authority to the Chief Executive Officer and the General Counsel and to authorize the Chief Executive Officer to sign the contracts on behalf of the Institute was made by Mr. Holmes and seconded by Mr. Angelou.

### MOTION CARRIED UNANIMOUSLY

The Oversight Committee was adjourned for a break at 11:35a.m.

Chair Rice called the Oversight Committee back to order at 11:54a.m.

## 7. Product Development Officer Report and Grant Award Recommendations

Kristen Doyle, Interim Product Development Officer, was recognized by the Chair to provide the Product Development Report and to introduce the Chief Executive Officer's Grant Award recommendations for product development grant awards.

Chair Rice introduced Dr. Jack Geltosky who is chair of CPRIT's Product Development Review Council and has been part of CPRIT's review program almost from its inception. He explained that Dr. Geltosky was here to answer Oversight Committee questions about CPRIT's product development portfolio and the Review Council's product development recommendations.

Ms. Doyle provided history of how the Product Development Program was first organized.

In June, 2009, the Economic Development and Commercialization Subcommittee, which was a subcommittee of the Oversight Committee, issued their report and recommendations on how the Commercialization Program should be set up.

Ms. Doyle and Dr. Geltosky provided an overview of the Product Development Program. Dr. Geltosky stated that when dealing with pharmaceuticals, disappointment can occur because even if you have a drug approved, there is no guarantee of success. The drug industry has been productive over time and progress has been made but there is still much to be done. He advised the Oversight Committee that the investments should continue even though the odds are daunting.

Dr. Geltosky stated that the time between research and clinical discoveries in the lab (commonly referred to as the valley of death) is when funding is most difficult. The venture community, which historically has been active in this early stage, has now become risk averse.

Dr. Mulrow asked where the (IND) process occurs. Dr. Geltosky stated that it is between pre-clinical and Phase 1.

Dr. Geltosky advised that companies must be Texas based to receive funding. Encouraging companies to relocate from other states serves the objective to build a more robust biotechnology infrastructure in Texas; however, no preference is given to those companies seeking to move to Texas over those company applicants already in Texas.

Ms. Doyle pointed out that award ratification in an open Oversight Committee meeting does not guarantee that the company receives funding. Disbursement of grant funds is dependant upon an executed contract. CPRIT staff and the company negotiate award contract terms. If the company does not agree to the award contract terms, then no award funds are provided to the company.

Dr. Mulrow asked if the creation of new jobs was considered. Dr. Geltosky responded that although many funded projects create jobs, the creation of new jobs is not a primary criterion. Dr. Mulrow then asked if methodologists or statisticians are routinely on review panels. Dr. Geltosky stated that this is part of the review process and also the due diligence process performed by ICON, CPRIT's due diligence experts.

### **COMPLIANCE CERTIFICATION**

David Reisman, CPRIT's Chief Compliance Officer provided the compliance certification for the award slates. Mr. Reisman stated that he had reviewed the compliance pedigrees for the grant applications for Product Development awards. He stated that he had conferred with staff at CPRIT and SRA, CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. He further stated that he is satisfied that the application review process that resulted in the three Product Development award slates recommended by the Chief Executive Officer, which included the Company Product Development Awards, the Company Formation Awards, and the Company Relocation Awards, all followed applicable laws and agency administrative rules. Mr. Reisman certified the award slates for the Oversight Committee's consideration.

#### CONFLICT OF INTEREST NOTIFICATIONS

Chair Rice noted for the record that Oversight Committee member Amy Mitchell reported a conflict of interest with application ID numbers CP130020 and CP130013. In accordance with CPRIT's rules, Ms. Mitchell was recused from the discussion or action on these applications.

Chair Rice asked if there were any other conflict of interest declarations for Oversight Committee members that have not reported. None reported.

#### **CONSIDERATION OF SLATES**

Chair Rice reminded members that the award recommendations were subject to the law in effect at the time that the applications were submitted. He further stated that the process to finalize the Chief Executive Officer's recommendations would follow the process in effect prior to the enactment of SB149. The Oversight Committee will follow the Chief Executive Officer's funding recommendations unless two-thirds of the Oversight Committee members vote to disregard the recommendations.

Chair Rice stated that the Chief Executive Officer presented three product development slates which would be taken up separately.

Chair Rice entertained a motion to disregard the Chief Executive Officer's funding recommendation for the Company Commercialization Award Slate.

NO MOTION OCCURRED

The companies in the Company Commercialization slate were:

DNAtrix (\$10,813,623) and ProPep Surgical (\$4,435,857)

Chair Rice entertained a motion to disregard the Chief Executive Officer's funding recommendation for the Company Formation Award Slate.

NO MOTION OCCURRED

The companies in the Company Formation Slate are:

## CerRX (\$10,725,000) and BetaCat (\$15,908,085)

Dr. Rosenfeld stated that, based on the discussion at the Product Development Subcommittee, he recommended funding for CerRX at an amount not to exceed \$6,000,000 to support a Phase 2a Proof of Concept trial in Peripheral T-Cell lymphoma. Accordingly, Dr. Rosenfeld moved to reject the Company Formation slate with the direction to the CEO to bring back a revised slate.

Motion seconded by Mr. Holmes.

### MOTION CARRIED UNANIMOUSLY

Chair Rice informed the Members that CPRIT's administrative rules permit the CEO to resubmit recommendations for consideration by the Oversight Committee pursuant to a process and time established by the Oversight Committee.

Mr. Angelou moved to direct the CEO to resubmit the slate today at 12:59 p.m. in accordance with the Board discussion today.

Motion was seconded by Mr. Geren.

#### MOTION CARRIED UNANIMOUSLY

At 12.59p.m. CEO Roberts presented the revised slate to the Oversight Committee.

CEO Roberts recommended two awards for the Company Formation Slate,

Beta Cat Pharmaceuticals not to exceed \$15,908,485.

CerRX, Inc. not to exceed \$6,000,000 to support Phase 2a Proof of Concept trial in Peripheral T-Cell lymphoma.

Chair Rice entertained a motion to disregard the CEO's revised funding recommendations for the Company Formation Slate.

Hearing none, the revised slate was accepted.

Chair Rice entertained a motion to disregard the Chief Executive Officer's funding recommendation for the Company Relocation Award Slate.

The companies in the Relocation Slate are:

Essa (\$12,000,000) and ProNAi (\$14,000,000)

Hearing no motion to disregard these slates, Chair Rice called for a motion to delegate contract negotiation authority to the Chief Executive Officer and the General Counsel pursuant to the process set forth by Ms. Doyle.

Motion was made by Dr. Rosenfeld and seconded by Mr. Holmes.

## MOTION CARRIED UNANIMOUSLY

## 8. Chief Prevention and Communications Officer Report

Chair Rice recognized Dr. Becky Garcia to provide the Chief Prevention and Communications Officer Report.

Dr. Garcia reported that RFAs for Competitive Continuation/Expansion Projects, Health Behavior Change through Public Education and Evidence Based Cancer Prevention Services will close on February 27, 2014. She stated that another round of RFAs for prevention will be released in March 2014.

Dr. Garcia stated that 110 people attended a webinar on January 29, 2014, regarding RFAs and changes due to the new administrative rules.

Dr. Rosenfeld asked about the recent Canadian National Breast Screening Study that cast doubt on the value of mammograms. He asked if that would have any effect on CPRIT. Dr. Garcia responded that screening guidelines may change as national organizations review new research available. CPRIT prevention projects are required to follow national screening guidelines.

She stated that the national guidelines have not changed but if and when they do, CPRIT's RFAs would incorporate changes to guidelines.

Dr. Mulrow commented that this study is actually a follow-up of the Candian National Breast Cancer Screening Study. She stated that the sixteen year follow-up was negative so it is no surprise that the twenty-five year study was negative. Dr. Mulrow stated that she did not believe that it is likely to have much influence on the national guidelines.

## 9. Strategic Communications Contract

Dr. Garcia presented the recommendation for the Strategic Communications Contract.

Chair Rice recognized Mr. Angelou, Chair of the Audit Subcommittee, to discuss the subcommittee's recommendation regarding the Strategic Communications Contract.

Mr. Angelou stated that the Audit subcommittee met February 12<sup>th</sup> and discussed the Strategic Communications Contract with CPRIT staff. He informed members that CPRIT Bylaws require the Audit Subcommittee to review any non-grant contract exceeding \$100,000 and recommend approval to the Oversight Committee.

Mr. Angelou reported that the Audit Subcommittee recommended awarding the Strategic Communications Contract to Hahn Public Communications as presented by Dr. Garcia.

A motion was made by Mr. Montgomery and seconded by Mr. Holmes to approve the Strategic Communications Contract as recommended by the Audit Subcommittee and presented by Dr. Garcia.

#### MOTION CARRIED UNANIMOUSLY

Chair Rice noted for the record that Mr. Montgomery would be leaving; however a quorum would still be intact.

The Oversight Committee adjourned for a break at 1:07p.m.

Chair Rice called the Oversight Committee back to order at 1:23 p.m.

## 10. Appointments to Scientific Research and Prevention Programs Committees

The Chair laid out the Nominations Subcommittee recommendations for the Chief Executive Officer's appointments to the Scientific Research and Prevention Programs Committees.

Chair Rice noted that Ned Holmes, the Nominations Subcommittee chair, was unable to attend the Nominations Subcommittee meeting on February 17<sup>th</sup> and that he had chaired the meeting in Mr. Holmes' absence. He related that the Nominations subcommittee discussed the Chief Executive Officer's new appointments to the Scientific Research and Prevention Programs Committee. The Nominations subcommittee recommended approval of the CEO's 58 appointments to CPRIT's Scientific Research and Prevention Programs Committees.

A motion to approve the Chief Executive Officer's appointments to the Scientific Research and Prevention Programs Committee was made by Dr. Rosenfeld and seconded by Mr. Geren.

#### MOTION CARRIED UNANIMOUSLY

## 11. Proposed Amendment to 25 T.A.C. 703.13

Agenda Item No. 11 was not taken up in this meeting.

## 12. <u>Presentation by SRA, International Inc.</u>

The Chair recognized Dr. Rajan Munshi and Dr. Steven Goldberg to present a summary of the professional services provided to support CPRIT's peer review and grants management activities. Dr. Munshi and Dr. Goldberg are with SRA International, Inc. SRA is CPRIT's third party grant administrator.

Dr. Goldberg gave an introduction to SRA, their mission and services they provide to CPRIT. He described their approach to ensure the integrity of the review process is maintained throughout.

Dr. Munshi gave an overview of the grant lifecycle and how SRA interacts in the process.

Dr. Rosenfeld asked if the Help Desk is housed at CPRIT or SRA. Dr.Munshi replied both. He explained that there is a Help Desk at SRA for technical issues but programmatic questions are forwarded to the program office for responses.

## 13. Program Priorities Project

Chair Rice turned the gavel over to Mr. Geren, Vice Chair.

Vice Chair Geren recognized Dr. Rice to present the program priorities project. Dr. Rice began with asking the question of how the committee should proceed to develop program priorities. He acknowledged that the Research Program and the Prevention Program already have begun the process of establishing program priorities.

After much discussion among members about the best way to move forward, Mr. Geren suggested that a professional facilitator be identified to work with members through this process.

It was agreed that CEO Roberts proceed to develop a plan that includes a planning retreat with a professional facilitator and that he update the Oversight Committee at the May meeting.

### 14. Subcommittee Business

Ms. Doyle reminded members that it had been suggested earlier in the meeting that the Board Governance Subcommittee be directed to look at CPRIT's administrative rules and statute and make appropriate recommendations to bring them into alignment.

A motion was made by Mr. Geistweidtt to direct the Board Governance Subcommittee to look at CPRIT's administrative rules and statute and make appropriate recommendations to bring them into alignment. Seconded by Mr. Geren.

#### MOTION CARRIED UNANAMOUSLY

### 15. Chief Operating Officer Report

The Chair recognized Heidi McConnell to present the Chief Operating Officer's Report.

Ms. McConnell stated recommendations in the 2013 State Auditor's management report and the 2013 *Information Technology Internal Audit Report* included audits of the security, availability, processing integrity, confidentiality and privacy controls used on the SRA-managed proprietary systems. She reported that the cost to perform all five trust principles would cost, at a minimum, \$80,000 and perhaps \$100,000. Internal audit staff recommended that we move forward on the two elements of processing integrity. The auditors have since reported that the American Institute of Certified Public Accountants has identified common criteria that reach across all principles. The recommendation now includes looking at all common criteria plus security and processing integrity.

The Chair recognized Mr. Angelou, Chair of the Audit Subcommittee, who stated that the subcommittee met on February 12<sup>th</sup> to discuss audit issues, including a proposed

amendment of CPRIT's contract with Grant Thornton for internal audit services. Mr. Angelou advised that the contract amendment adds an audit of SRA-managed, proprietary information technologies systems used by CPRIT to process and review grant applications and monitor grant awards. He reported that the additional audit is estimated to cost \$45,000, which would result in an overall internal audit contract of \$245,000. Mr. Angelou stated that the Audit Subcommittee recommends approval of an amendment to the Grant Thornton contract to add the audit of SRA-managed technology systems.

A motion was made by Mr. Angelou and seconded by Ms. Mitchell to approve an amendment to the Grant Thornton contract to include an audit of SRA-managed technology that will increase the total contract to an amount not to exceed \$245,000.

### MOTION CARRIED UNANIMOUSLY

## 16. <u>Compliance Officer Report</u>

Chair Rice recognized David Reisman to present the Chief Compliance Officer's Report.

Mr. Reisman reported that as of February 11, 2014, there were twenty active grant projects that had not filed the required quarterly financial status reports by the deadline and seven that had not filed the required progress reports by the deadline.

Mr. Reisman reported that CPRIT staff will follow up with the grant projects that have delinquent reports. He also reminded members that CPRIT's recently adopted administrative rules will provide new options to address delinquent reports, however, these options will not be implemented until after the staff has an opportunity to train grant recipients on the recently adopted rules.

Dr. Rosenfeld inquired if there was any particular institution stood out as more delinquent that others. Mr. Reisman responded that delinquencies were spread out among entities. Dr. Rice asked if they were corporate or academic. Mr. Reisman stated that it was a mix.

Mr. Reisman informed members that they should have ethics and compliance training every year. He stated that he hoped to be able to do that at the Oversight Committee meeting in May.

Mr. Reisman also informed the members that their Personal Financial Statements were due to the Ethics Commission by April 30<sup>th</sup>. He stated that they would receive a notice from the Ethics Commission.

## 17. Consultation with General Counsel

No consultation with General Counsel was required.

### 18. Future Meeting Dates and Agenda Items

The next Oversight Committee meeting will be held May 21. CPRIT staff will circulate a tentative agenda prior to the meeting.

## 19. Public Comment

There were no requests to make public comment.

## 20. Adjourn

The Chair moved to adjourn the meeting. Seconded by Mr. Angelou.

Motion carries. This meeting stands adjourned at 2:50p.m.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE ROBERTS, CHIEF EXCUTIVE OFFICER

**SUBJECT:** AGENDA ITEM 5: CHIEF EXECUTIVE OFFICER REPORT

**DATE:** MAY 15, 2014

Behind this memo are copies of the March 28 and May 5, 2014, CPRIT Activities Update reports. These updates began in March to provide an overview of significant or unique staff activities that occur in the months the Oversight Committee (OC) does not meet. I hope that these monthly updates will shorten the CEO report at the quarterly OC meetings and increase communication between the OC and staff. My intent is not to repeat information from the memos at the quarterly OC meetings but to reprint them in the meeting books for your convenience. Some topics will be repeated or updated as needed at the quarterly meetings.

As of this writing, the Chief Executive Officer Report for the May 21, 2014, Oversight Committee (OC) meeting includes the following.

## 1. New Employees, Title Changes and Status of CPRIT staff vacancy postings

- The following new employees will be introduced to the OC:
  - o Dr. Tom Goodman, Chief Product Development Officer
  - o Cameron Eckel, Attorney
  - o Dan Limas, Grant Accountant
  - o Mary Gerdes, Special Assistant to the CEO
- The following employees have title changes:
  - o Sandra Balderrama, Grant Specialist Manager
  - o Oralia Huggins, Grant Accountant
- The following positions are filled effective June 1
  - o Purchaser
  - o Three Grant Specialists
- *Manager of Internal Audit* The position description will be modified again and reposted. State Auditor John Keel told me that these positions are difficult to fill for a variety of reasons. Mr. Keel suggested the changes in the new job postings. At the November 1, 2013, meeting the OC decided that CPRIT staff will screen initial applicants and identify candidates to be interviewed by the Audit Subcommittee. The subcommittee will then recommend a finalist to the OC for final approval.

## 2. Facilities Update

A verbal update of the moves to temporary lease of facilities and state-owned space will be provided

## 3. Status of Grant Funds Available for Awards in August

A verbal update and spreadsheet estimating the amount of funds remaining for grant awards in August from FY 2014 appropriations will be presented.

## 4. Other topics will be added as warranted

\*\*\*\*

## CPRIT has awarded 528 grants totaling \$938.7 million

- 115 prevention awards totaling \$96.7 million
- 413 academic research and product development awards totaling \$842 million

## Of the \$842 million in academic research and product development awards

- 30.6% of the funding (\$250.3 million) supports clinical research projects
- 26.2% of the funding (\$214.2 million) supports translational research projects
- 21.7% of funding (\$177.6 million) supports recruitment awards
- 17.9% of the funding (\$146.5 million) supports discovery stage research projects
- 3.6% of funding (\$29.5 million) supports training programs.

## CPRIT has 11 open Requests for Applications (RFAs)

- 3 Product Development
- 6 Research
- 2 Prevention



## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

**FROM:** WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

**SUBJECT:** CPRIT ACTIVITIES UPDATE

**DATE:** MAY 5, 2014

Topics in this update include: office and staff developments, the Program Priority Project, Program updates, Operations (including contracts and RFPs), committee meetings, ongoing projects, and legislative meetings.

CPRIT will be communicating with you frequently this month as we prepare for the May 21 Oversight Committee meeting. A draft meeting agenda is attached to this update; the final meeting agenda will be posted by May 13. You will receive the board packet and access to the grants portal with information about the grants recommended by the PIC on or before May 16. If you have any questions about the upcoming meeting or any or the matters discussed in the update, feel to contact me at 412/305-8416.

## **New Hires and Personnel Changes**

Several new people joined the agency in April and May. In addition to Mary Gerdes (Special Assistant to the CEO) and Tom Goodman (Chief Product Development Officer), who I told you about in the March update, new hires and personnel actions include:

- Daniel Limas started work as a grant accountant on May 1. He is a member of our finance team and reports to Heidi McConnell, Chief Operating Officer.
- Charlotte Craig accepted the position of purchaser effective June 1. Charlotte is certified as a
  contract manager; filing this position with an individual with her certifications addresses a postpayment audit recommendation from the Comptroller of Public Accounts. Charlotte will be a
  member of our finance team and report to Heidi.
- Cameron Eckel will start work on May 7 as an entry-level attorney supporting legal and compliance. Cameron will be assigned to Kristen Doyle and David Reisman.
- Interviews to fill three grant specialist positions took place May 1 and 2. CPRIT expects to make job offers following the satisfactory reference checks, with a planned start in early June.
- CPRIT will hire two additional grant accountants in May; the job posting closes May 8.
- I elected not to put forward final candidates to be interviewed by the Audit Subcommittee for the Internal Auditor position. The position will be reposted with changes suggested by State Auditor

John Keel, who I contacted concerning my difficulty in finding qualified applicants. Final interviews of qualified candidates and the hiring decision will be made by the Audit Subcommittee because the Internal Auditor will report directly to the Oversight Committee.

## Office Relocation Now Off Schedule Necessitating Temporary Offices

CPRIT's move to state-owned space in the William B. Travis Building, originally planned for this August, is now projected to occur in February 2015. The additional time is necessary to complete construction and renovation on the state office space that CPRIT will occupy. Start of construction has been delayed because the current occupants have not yet relocated.

Unfortunately, CPRIT's current space has already been leased to new tenants that will take occupancy on September 1. This means that CPRIT must move offices twice, including a move that will take place during the legislative session. The Texas Facilities Commission has identified adequate space available for a short-term interim lease (August 2014-February 2015) in the Wells Fargo Building, 400 West 15<sup>th</sup> Street.

Two moves cost more than one. The projected cost for the two moves, including renovation of the state-owned space, is nearly \$1.5 million. Changes to our budget are being prepared and will be submitted to the Legislative Budget Board (LBB) for budget transfer approval as required in the General Appropriations Act. Authorization is expected since relocating state agencies from leased space to state-owned space is a high priority for the LBB. The state will realize lease savings over the life of the agency that exceeds the cost of the move and renovation.

## **Program Priority Project – Facilitator Retained and Planning**

Pursuant to the Oversight Committee's direction, CPRIT staff has retained an experienced facilitator to assist the Oversight Committee in setting program priorities. Robert Mittman has health care and medical expertise, the majority of which is in the oncology field. Robert practices "active content facilitation." Although he will not argue for a specific endpoint or have a substantive outcome in mind, he is sufficiently well-versed in the content of the meeting to engage actively with the participants on the topic and assess whether the group is thinking realistically and redirect them if they are not. He has worked with a wide range of cancer-related research, prevention, clinical, and policy organizations including non-profits, government, and corporate clients.

A proposed plan for Robert's involvement with the project includes meetings of the three program subcommittees, opportunity for public input, and a full Oversight Committee retreat. We are firming up dates for subcommittee meetings necessary for this project, as well as the retreat. We will present an update and overview of the proposed process and timeline at the May 21, 2014 meeting.

### **Academic Research Program Update**

- The Scientific Review Council reviewed 25 applications for Recruitment Awards on April 17, 2014, and will forward a recommendation to fund 14 recruitment grants to the Program Integration Committee and the Oversight Committee for consideration. The total amount requested for these 14 awards is \$37.3 million.
- CPRIT's seven Academic Research Peer Review Panels are finishing preliminary evaluation of 484 Individual Investigator Research Award applications. Applications that score favorably in

the preliminary evaluation stage will be reviewed during the May-June peer review meetings, along with 100 High Impact-High Risk grant applications.

- Three new Requests for Applications (RFAs) were released March 31, with applications accepted beginning May 15 through June 26. These RFAs seek projects undertaken by an individual investigator; two target specific research areas (cancer prevention/early detection and cancer in children and adolescents.) Awards for these RFAs are expected to be announced February 2015. In addition to the three new RFAs, three recruitment RFAs have been open since January. Grant recommendations for recruitment applications submitted by June 11, 2014 will be considered at either the August or November Oversight Committee meetings.
- Dr. Rice and CPRIT staff, including all three program officers and the CEO, convened the University Advisory Committee meeting on April 30 in Houston. A report on this meeting will be presented at the May 21 Oversight Committee meeting.

## **Product Development Program Update**

Tom Goodman started work as the Chief Product Development Officer on April 14 and has hit the ground running. He is overseeing activity in three open grant cycles (described below), in addition to progress monitoring for current CPRIT-funded companies and other product development outreach activities. Tom will present his preliminary overview and expectations for the Product Development program at the May 21 Oversight Committee meeting.

- FY 2013 Grant Cycles 1 and 2 (awards announced at the February 19<sup>th</sup> Oversight Committee meeting) Pursuant to the Oversight Committee's direction, CPRIT is negotiating award contract terms with the six companies recommended for grant awards announced in February. Tom and Kristen will present proposed contract terms for the Oversight Committee's consideration at the May 21<sup>st</sup> Oversight Committee meeting. The Oversight Committee may take action at the meeting to delegate contract execution authority to me if you are satisfied with the terms negotiated.
- FY 2014 Grant Cycle 1 (applications submitted January 31, 2014, Oversight Committee consideration expected May and August 2014) This review cycle is in the due diligence phase. Four product development grant applications were recommended for due diligence review following in-person presentations by company applicants in early April. The four applications total \$58 million. Due diligence reviews for two applicants were completed by May 2. The Product Development Review Council will meet May 8 to consider the due diligence reviews for these two companies. Following an evaluation of the due diligence, the Review Council may make grant award recommendations to be considered by the PIC for the May 21st Oversight Committee meeting. The diligence reviews for the other two companies will be finished in June. Consideration of recommendations made by the Review Council and the PIC, if any, for the remaining two FY2014 applications will be considered by the Oversight Committee in August.
- FY 2015 Grant Cycle 1 (applications due by May 29, 2014, Oversight Committee consideration expected November 2014) CPRIT's application portal opened April 28 to begin receiving Product Development grant applications for research projects at new companies, established companies, and companies that are willing to relocate to Texas.

A Product Development subcommittee meeting is scheduled for May 19, 2014. The Program Priorities Project, grant recommendations, and new appointments to the Product Development review panels will be discussed.

## **Prevention Program Update**

- For the current review cycle, FY 14 Cycle 1, reviewers were recruited to the two prevention panels, applications were assigned and staff held an orientation webinar for the reviewers on April 2, 2014. Two new prevention peer reviewers are being recommended to the Nominations Committee for appointment. Reviewer critiques and preliminary scores were due on April 29<sup>th</sup>. Panel meetings are scheduled for May 5-7<sup>th</sup> in Dallas.
- For the next review cycle, FY 15 Cycle, two RFAs, Evidence Based Cancer Prevention Services and Competitive Continuation/Expansion, were released March 31st and the CPRIT Application receipt system (CARS) opened on April 29<sup>th</sup> to begin accepting applications. The recommendations for awards from this cycle will go to the Oversight Committee in November.

## **Other Major Committee Meetings**

- The Nominations Subcommittee is scheduled to meet on May 13 to consider appointments to the Research, Prevention, and Product Development peer review committees.
- The Governance Subcommittee is scheduled to meet prior to the May Oversight Committee to consider changes to administrative rules and Oversight Committee bylaws, including the Code of Conduct.
- The Program Integration Committee is scheduled to meet on May 13 to consider recommendations from the Research, Product Development, and Prevention Review Councils.

## **Operations (Contracts, RFPs, Internal Audit)**

- CPRIT received four responses to our request for proposals for development of a compliance
  program design plan for the agency. The compliance plan will be used to structure a compliance
  program based on best practices in this area. CPRIT staff interviewed three companies that
  responded to a request for proposals and a finalist will be selected soon. This is a contract for
  consulting services, so CPRIT must request approval from the Governor to finalize it as required
  by state procurement law.
- CPRIT received notification on May 2 that the LBB approved our February 19 request for strategic communications services with Hahn Communications.
- As reported last month, SRA and CPRIT staff are working to address additional SRA contract
  costs associated with adding new grant cycles and other programming needs this fiscal year. The
  estimate is being refined, but it is likely to entail a sizable increase for the SRA contract. We will
  provide the Oversight Committee with more information as the options are finalized and discuss
  any contract amendments with the Audit Subcommittee.

• The internal auditor, Grant Thornton, LLP, is conducting field work for the audits on governance, expenditures, and the SRA-managed information technology systems (our third party vendor for pre- and post-award grant support services) according to the schedule in the 2014 Audit Plan. With input from CPRIT staff, the auditor has also completed a grantee risk assessment to identify the 10 grantees that will undergo audits this year. This risk assessment will be discussed with the Audit Subcommittee.

## **Ongoing Projects**

- Agency Strategic Plan: A first draft has been prepared and is currently being refined by appropriate CPRIT staff. The proposed plan will be discussed for approval at the May 21 Oversight Committee.
- Customer Satisfaction Survey: Ellen Read, Senior Communications Specialist, drafted a customer satisfaction survey for the required state agency strategic plan. It was released April 14 and responses to the survey are due by close of business May 9.

### **Legislative Outreach**

I met with Senators Kel Seliger (April 11) and Kirk Watson (May 2) and Representative Dan Flynn (March 28) to update them on the progress CPRIT has made since the 83<sup>rd</sup> Regular Session. I am scheduled to meet with Representatives Drew Darby (May 12), John Zerwas (May 13), and Senfronia Thompson (May 15). I will add more meetings as schedules permit and may ask you to participate, especially as the conversations shift to issues related to the 84<sup>th</sup> Session.

Representative Jim Keffer is organizing an informal briefing for selected legislators interested in advancing CPRIT. The target week for this event is July 14. The topic will be CPRIT's activities and progress made since the end of the 83<sup>rd</sup> Legislature. Likely participants include Representatives Sylvester Turner, Lois Kolkhorst, Geanie Morrison, Sarah Davis, Jim Otto and Senator Jane Nelson, among others.

#### **Staff Presentations**

CPRIT program chiefs and I have been invited by Walter Ulrich, President and Chief Executive Officer of the Houston Technology Center, to address a meeting of Houston community leaders on July 10. This event should provide allow us to promote CPRIT activities and to enhance professional networks.

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CPRIT has 8 open Requests for Applications (RFAs). Three RFAs will be open on May 15.



### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS

**FROM:** WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

**SUBJECT:** CPRIT ACTIVITIES UPDATE

**DATE:** MARCH 28, 2014

Now that the Oversight Committee has settled into its regular meeting schedule, I plan to provide an overview of significant or unique staff activities that occur in the months that we do not meet. As always, please contact me or anyone on the staff if you have questions or needs with which we can assist.

Topics in this update include: office and staff developments, the latest on the Program Priority Project, Program updates, Operations (including contracts and RFPs), distribution of the proceeds from the Foundation settlement, ongoing projects, and legislative meetings.

## **New Hires and Personnel Changes**

CPRIT has several new people joining the agency in April, as well as some changes with office staffing.

- Tom Goodman, Ph.D., accepted the position of Chief Product Development Officer. Although he will officially begin his duties on April 14, Tom will attend the Product Development review panel meetings next week in Dallas.
- Effective April 1, CPRIT will no longer maintain a receptionist position because the volume of calls and walk-in visitor traffic does not justify dedicated staff to perform these activities. The front office will be reconfigured for two administrative support staff (Sandra Reyes and Yvette Jimenez) that will be able to assist visitors and answer calls coming in via the general line, in addition to their other duties.
- A new position, "Special Assistant to the Chief Executive Officer," will be filled on April 7 by Mary Gerdes, who is joining CPRIT from Teachers Retirement System. Mary will assist both Kristen Doyle and me, and will assume the duties of the Senior Advisor to the Executive Director (this work is currently done by Sandra Balderrama, who is transitioning to a new position). All administrative support staff will report directly to Mary.
- Sandra Balderrama will fill the newly-created Grant Specialist Director position, coordinating the work of three grant specialists that we expect to bring on staff in April May. The grant specialist positions are posted until April 4. The grant specialist team will assist both the legal and compliance programs and will report directly to Kristen.

- Offers are being extended this week to two Grant Accountants.
- Interviews are underway for two positions: an entry-level attorney to be assigned to Kristen and David, and a Purchaser who will work with the finance team. Offers are expected to be made in April.
- CPRIT staff is interviewing applicants for the Internal Auditor position. Final interviews and the
  hiring decision will be made by the Audit Subcommittee because the Internal Auditor will report
  directly to the Oversight Committee. Internal Auditor interviews with the Audit Subcommittee
  should take place in April.

## Office Relocation on Schedule for August, 2014

CPRIT's move from the current leased space to state-owned space in the William B. Travis Building, located at Congress Avenue and 17<sup>th</sup> Street, is scheduled for August. The required space renovation and moving costs are estimated to be \$985,000. This expense was not built into our FY2014 Operating Budget so a request has been filed with the Legislative Budget Board (LBB) to transfer funds from CPRIT's Research Grants line item to Indirect Administration to cover the expected costs. Since relocating state agencies from leased space to state-owned space is a high priority for the LBB, approval is expected.

## Program Priority Project – Seeking a Professional Facilitator

Pursuant to the Oversight Committee's direction, CPRIT staff is investigating options for a facilitator that will assist the Oversight Committee in setting program priorities. Currently the plan is to have an experienced facilitator meet individually with the three program subcommittees prior to a full Oversight Committee retreat in June. We are firming up dates for the meetings; however the expected cost of the facilitator may be high enough to require a bid for services. We will release a request for bids for a facilitator with health care and medical expertise (with an emphasis on cancer expertise) by early next week. Although the bid process may cause a delay of one to two weeks, it is the prudent course.

## **Academic Research Program Update**

- Academic Research applications have been assigned to review panels and initial review is beginning. The review panels will meet in Dallas in late May and early June to discuss and score the grant applications.
- New requests for applications (RFAs) for Recruitment Awards and Individual Investigator
  Awards will be released early in April. For the first time, CPRIT will release RFAs specifically
  seeking Prevention and Early Detection research applications and Cancer in Children and
  Adolescents research applications.
- The Research Subcommittee met March 21. Topics discussed included the Oversight Committee's advisory committees, nominations to the Scientific Peer Review Panels to be recommended for Oversight Committee approval, and program priorities.

## **Product Development Program Update**

- The Product Development review panels will meet in Dallas on Monday and Tuesday to conduct the second stage of peer reviews in-person presentations by grant applicants. Of the 42 applications submitted for this cycle of product development awards, 18 companies have been invited to make presentations. Following the in-person presentations, the panels will decide which applicants will move forward to due diligence review.
- The Product Development program will release new RFAs by early next week. The RFAs will seek applications for research projects at new companies, established companies, and companies that are willing to relocate to Texas. Applications submitted for the new RFAs are expected to be considered by the Oversight Committee in November.
- A Product Development subcommittee meeting will be scheduled once Tom starts work in April.
   The Program Priorities Project and new appointments to the Product Development review panels will be discussed.

## **Prevention Program Update**

- The Prevention program received 50 applications by the February 27 deadline. The applications have undergone an initial compliance review and been assigned to review panels. The panels will meet to discuss the application in Dallas in early May.
- The Prevention program will release two RFAs, Evidence Based Cancer Prevention Services and Competitive Continuation/Expansion, within the next two weeks. Applications submitted in response to the new RFAs are expected to be considered by the Oversight Committee in November.
- Dr. Garcia attended the *Prevent Cancer Conference: Dialogue for Action* in Baltimore, Maryland, March 20-21, to network, promote CPRIT activities, and identify prevention partnership opportunities.
- The Prevention Subcommittee met on March 5. The Program Priority Project was the main topic of discussion.

## **Operations (Contracts and RFPs)**

- CPRIT released a request for proposals on March 14 for development of a compliance plan for the agency. The compliance plan will be used to structure a best practices compliance program. Responses are due April 14.
- The LBB approved CPRIT's request to increase the internal audit services contract by an additional \$45,000. The increase, originally approved by the Oversight Committee on February 19, will be used to pay for auditing the information technology systems managed by SRA. The audit will fulfill a requirement of the State Auditor's Office.

- Pursuant to a state budget rider requirement specific to CPRIT, the agency's quarterly budget report was provided to the LBB on March 18.
- As of this writing, the LBB has not yet approved CPRIT's February 19 request for strategic communications services with Hahn Communications. CPRIT is operating without these services until we receive LBB approval. I expect approval to be given soon and have reached out to legislative offices to answer any questions and provide additional information.
- SRA and CPRIT staff are working to address additional SRA contract costs associated with adding new grant cycles and other programming needs this fiscal year. The estimate is being refined, but it is likely to entail a sizable increase for the SRA contract. We will provide the Oversight Committee with more information as the options are finalized and discuss any contract amendments with the Audit Subcommittee.

#### **CPRIT Foundation Settlement**

As you were previously notified by Kristen, the settlement with the former CPRIT Foundation was finalized. The settlement terms were agreed to last May, but formal resolution of all issues required Oversight Committee approval and a fix for a technical issue related to distribution of \$29,877 in funds that were designated for a certain purpose. Dr. Rice was authorized to finalize the settlement by the Oversight Committee at the November 1, 2013, meeting. The Office of the Attorney General and CPRIT worked with the Comptroller to develop an appropriate plan for the designated funds.

No further action is necessary from the Oversight Committee related to the distribution agreement. However, as explained previously, \$29,877 of the settlement must be provided to CPRIT as a gift from the Foundation. This is necessary so that the money that was originally designated for peer review services when it was donated to the CPRIT Foundation can be used by CPRIT for the purpose intended by the donor. Consistent with CPRIT's statute and rules, the Oversight Committee will need to take action to accept the gift at its next open meeting.

#### **Ongoing Projects**

<u>CPRIT's Data Mining Project</u>: CPRIT began a major effort this month, which we are referring to internally as the "Data Mining Project." The project relates to the Dashboard you will see on a regular basis; it is designed to aggregate and analyze data concerning CPRIT grants for management and legislative reports that will also be of interest to the general public. A staff team led by Ramona Magid, Senior Program Manager for Prevention, is charged with keeping the project on task with routine reports to me concerning progress.

An example of what the Data Mining effort is designed to address is the "Company and Academic Awards" spreadsheet prepared at the request of the Office of Lt. Governor Dewhurst. A previous iteration of this report was provided in October 2012; however, the recent version is expanded and significantly refined. You and the Lt. Governor's Office were provided this report on March 19.

<u>Client Satisfaction Surveys and the State Strategic Plan</u>: Ellen Read, Senior Communications Specialist, is evaluating options for conducting a client/customer satisfaction survey. The survey results will be

included in CPRIT's strategic plan. The required strategic plan document officially kicks off the 2016-17 budget process. You will hear more about this in the weeks ahead.

#### **Legislative Outreach**

I met with Representatives Otto (March 13) and Kolkhorst (March 18) to update them on the progress CPRIT has made since the 83<sup>rd</sup> Regular Session. I am scheduled to meet with Representative Flynn, co-Chair of the House Transparency Committee, today (March 28) and with Senator Seliger on April 11. I will add more meetings as schedules permit and may ask you to participate, especially as the conversations shift to issues related to the 84<sup>th</sup> Session.

As noted above, on March 19 CPRIT provided a comprehensive report to the Lt. Governor, at his request, with detailed information about the academic research, prevention, and product development awards made to date by CPRIT.

#### **Staff Presentations**

CPRIT staff members delivered four significant presentations this month. Dr. Becky Garcia discussed CPRIT prevention activities and agency progress at The University of Texas Health Sciences Center at Houston on March 28.

I spoke on February 20 to the Texas Life Science Forum in Houston concerning the events related to CPRIT over the last 18 months and what to expect from CPRIT in the future.

In addition, I addressed the Texas Fiscal Officers' Academy twice. The academy is a biennial series of week-long training events for state agency fiscal staff that have been identified as potential chief fiscal officer candidates. It is sponsored by the LBB, the Governor's Office, the State Auditor's Office, and the Comptroller's Office. I have presented frequently for the academy over the years; my topics this time included "Communicating Your Agency's Budget" and "Effectively Managing Organizational Change".

\*\*\*\*

#### CPRIT has awarded 528 grants totaling \$938.7 million

- 115 prevention awards totaling \$96.7 million
- 413 academic research and product development awards totaling \$842 million

Of the \$842 million in academic research and product development awards

- 30.6% of the funding (\$250.3 million) supports clinical research projects
- 26.2% of the funding (\$214.2 million) supports translational research projects
- 21.7% of funding (\$177.6 million) supports recruitment awards
- 17.9% of the funding (\$146.5 million) supports discovery stage research projects
- 3.6% of funding (\$29.5 million) supports training programs.

CPRIT has no open Requests for Applications (RFAs) at this time; 9 new RFAs are expected to be released in early April.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

**FROM:** DAVID A. REISMAN, CHIEF COMPLIANCE OFFICER

**SUBJECT:** COMPLIANCE OFFICER REPORT

**DATE:** MAY 16, 2014

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. One of CPRIT's administrative rules, 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 May 9, 2014, the date the report was run, information regarding delinquent grant recipient reports was as follows:

- 42 grant projects, either active or in close out, at 15 separate entities, have not filed required quarterly financial status (FSR) reports by the deadline. At the last Oversight Committee meeting, on February 19, 2014, I reported that 20 grant projects had not filed required FSRs by the deadline. An FSR is due to CPRIT within 90 days following the close of the fiscal quarter. Of the 42 delinquent reports, 11 are less than 30 days overdue. 13 are more than 30 days but less than 90 days overdue. 18 FSRs are currently 90+ days overdue.
- 10 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 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. Of the 10 delinquent progress reports, 2 are less than 30 days overdue and 8 are currently 90+ days overdue.

On March 7, 2014, a report indicated 76 overdue FSR's and 18 overdue progress reports. I asked the research and prevention programs, and the CPRIT finance division, to address the issue of late FSRs and progress reports by researching these delinquencies and by making contact with the grantees to identify where and what issues might be preventing them from submitting those outstanding reports. The research and prevention program staff contacted the grantees and has made progress identifying issues and facilitating the filing of many late reports. However, from information gathered in consultation with program staff and review of the CPRIT Grants Management System (CGMS) records, the issue of overdue FSR and progress reports continues and is estimated to continue for at least the next several months while CPRIT staff addresses the processing of late report filings.

Additionally, CPRIT program staff identified that the report identifying delinquencies run from CGMS identifies if an FSR is overdue. However, additional quarterly FSRs', that may have become due from a grantee while that FSR is waiting to be either submitted and/or approved, are not identified by the report. In some instances several FSRs are "backed up" waiting in line for the initial FSR to be filed and approved, and then each subsequent FSR must be individually processed and approved before each succeeding FSR may be submitted. As a result, the actual number of delinquent FSRs' is difficult to quantify due to the daily changes in filings, but is estimated to be significantly greater than the number identified in the report on delinquencies run from CGMS.

The causes for the number of reports on delinquent report may be attributed to several factors including grants that are coming off the grant moratorium, resulting in past reports being immediately due, delinquencies in filing by the grantees, and the ability of CPRIT staff to process the incoming reports. While these are separate factors, due to the timing of grants coming off the moratorium, and limitations of staff, the factors do affect each other, and can compound the overall delinquency issue.

CPRIT staff is working to resolve these issues. Program staff contacting grantees on submitting delinquent reports has resulted in a significant reduction in the number of delinquent reports, as well as serving as an opportunity to educate grantees. Also, in April, CPRIT sent a memo to all grantees with one or more outstanding FSRs. The memo noted the issue of the backlog of FSRs and requested the grantees' assistance by submitting their next FSR within ten days after the approval of one FSR to diminish the time between FSR approvals. Another communication was sent to all grantees to educate the grantees on the consequences of new administrative rules, with respect to late FSR deadlines, as well as other requirements going into effect June 1, 2014. Additionally, CPRIT has hired an additional staff member for the finance division and three grant specialists to work with grantees on grant monitoring, including upcoming reporting deadlines and overdue reports. A third grant accountant is expected to be hired in late May or early June.

The above actions should help to address the issue of delinquent reports. However, CPRIT should continue to examine current procedures and possible causes, and continue to identify and implement solutions to resolve this issue. Agency management is committed to attaining full reporting compliance for CPRIT grantees.



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL

**SUBJECT:** CPRIT FINANCIAL OVERVIEW FOR FISCAL YEAR 2014, QUARTER 1

**DATE:** MAY 16, 2014

#### FY 2014, Quarter 2 Operating Budget

CPRIT expended or obligated approximately \$2.2 million in Indirect Administration in the second quarter. The expenditures of almost \$1 million in the Professional Fees and Services category are pay for outsourced legal, audit and communications services to the agency.

The agency has also expended almost \$4.9 million in Grant Review and Award Operations. The expenditures reflected in the Professional Fees and Services category are primarily for the pre- and post-award grant management support services provided by SRA International.

#### **Debt Issuance History**

Through the Texas Public Finance Authority (TPFA), CPRIT has issued \$102.2 million in commercial paper notes this fiscal year, bringing the total debt issued to date to almost \$488.5 million. The \$47 million debt issuance in March provides \$7.3 million for agency administration—approximately half a year of the agency's total operations including grant review—and \$1.5 million for the transfer to the Department of State Health Services for Texas Cancer Registry operations. The remaining \$38.2 million allows CPRIT to make reimbursement payments due to grant recipients for award expenses.

## Cancer Prevention and Research Institute of Texas LBB Summary As of April 30, 2014

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Indirect A	nh/	าเทเต	tration	R 1 1 1

		2014		% of Total	Actual Expenditures & Grant Encumbrances	Remaining	Percent	Estimated Expenditures	
		Appropriated	2014 Budgeted	Budget	(FYTD)	Budget	Expended	(YTD)	Lapse/Overspent
1001	Salaries and Wages	\$ 1,559,830	\$ 1,386,196		\$ 664,346	721,850	48%	\$ 1,138,880	\$ 247,316
1002	Other Personnel Costs	21,400	50,000		29,351	20,649	59%	50,317	(317)
2001	<b>Professional Fees and Services</b>	350,500	928,321		983,411	(55,090)	106%	1,685,848	(757,527)
2003	Consumable Supplies	25,332	22,500		12,262	10,238	54%	21,020	1,480
2004	Utilities	32,600	63,648		46,904	16,745	74%	80,406	(16,758)
2005	Travel	24,176	34,874		12,826	22,048	37%	21,987	12,887
2006	Rent - Building	427,450	415,450		254,014	161,436	61%	435,453	(20,003)
2007	Rent-Machine and Other	16,763	24,150		10,532	13,618	44%	18,055	6,095
2009	Other Operating Expenses	348,824	342,551		227,116	115,435	66%	389,342	(46,791)
	Subtotal - Indirect Administration (B.1.1.)	\$ 2.806.875	\$ 3,267,690	1.10%	\$ 2,240,763	\$ 1.026.927	69%	\$ 3.841.308	\$ (573,618)

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

							Ac	tual Expenditures &				E	Estimated		
			2014			% of Total	Total Grant Encumbrances Remaining		Remaining	Percent	Ex	penditures			
		Ар	propriated	2	2014 Budgeted	Budget		(FYTD)		Budget	Expended		(YTD)	Lapse	/Overspent
1001	Salaries and Wages	\$	1,026,701	\$	2,627,082		\$	1,067,103	\$	1,559,979	41%	\$	1,829,320	\$	797,762
1002	Other Personnel Costs		3,600		100,000			14,168		85,832	0%		24,289		75,711
2001	Professional Fees and Services		4,285,471		8,608,808			3,753,088		4,855,720	44%		6,433,864		2,174,944
2003	Consumable Supplies		27,324		-			-		-	0%		-		-
2005	Travel		24,400		35,430			7,603		27,827	21%		13,034		22,396
2006	Rent - Building		4,867		32,400			29,517		2,883	91%		50,601		(18,201)
2007	Rent-Machine and Other		-		7,500			2,327		5,173	31%		3,990		3,510
2009	Other Operating Expenses		1,551,996		-			-		-	0%		-		
	Subtotal - Grant Operations (A.1.3.)	\$	6,924,359	\$	11,411,220	3.84%	\$	4,873,807	\$	6,537,413	43%	\$	8,355,097	\$	3,056,123

#### Grant

		Al	2014 ppropriated	2	2014 Budgeted	% of Total Budget	tual Expenditures & ant Encumbrances (FYTD)	Remaining Budget	Percent Expended	E	Estimated Expenditures (YTD)	Lap	ose/Overspent
	Grants - Prevention (A.1.2)	\$	29,022,567	\$	29,022,567		\$ 10,778,222	\$ 18,244,345	37%	\$	18,476,952	\$	10,545,615
4000	Grants - Research (A.1.1.)		261,262,199		253,344,969		92,055,545	\$ 161,289,424	36%		157,809,506		95,535,463
	Subtotal - Grants	\$	290,284,766	\$	282,367,536	95.06%	\$ 102,833,767	\$ 179,533,769	36%	\$	176,286,458	\$	106,081,078
	<b>Grand Totals</b>	\$	300,016,000	\$	297,046,446	100.00%	\$ 109,948,337	\$ 187,098,109	37%	\$	188,482,863	\$	108,563,583

<sup>\* 2014</sup> 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 Cancer Prevention and Research Institute Fund Account - 5136 As of April 30, 2014

	2014 thru 30/2014	AY 14 Year to Date as of 4/30/2014		
Beginning Balance : 09/01/2013			499,412	
Increases:				
(1) License Plate Revenue Received	\$ 1,324	\$	9,712	
(2) Revenue Sharing / Royalties	7,203		334,569	
(3) Settlement Contribution	-		274,000	
Total Increases	\$ 8,526	\$	618,280	
Reductions:				
Expenditures - Appropriated	\$ 0.00	\$	0.00	
Estimated Transfers for Employee Benefits	-		-	
Benefit Replacement Pay	-		-	
Total Reductions	\$ 0.00	\$	0.00	
Ending Balance, 4/30/2014		\$	1,117,693	

Note:

<sup>(1)</sup> The beginning balance includes \$473,135 in revenue sharing/royalties received from grant recipients from CPRIT's inception through 8/31/2013. Those amounts were deposited into the State Treasury but not appropriated to CPRIT. Additionally, the beginning balance includes \$26,277 in license plate revenue that was not appropriated to CPRIT in the current biennium.

<sup>(2)</sup> The Institute received a settlement amount from the CPRIT Foundation. This amount represents the final distribution and transfer of all funds from the CPRIT Foundation which ceased operations. Theses funds have been deposited into the State Treasury but are not appropriated to CPRIT.

## Cancer Prevention and Research Institute of Texas Appropriated Receipts - 666 As of April 30, 2014

		4/1/2014 thru 4/30/2014		_	ar to Date as of 30/2014
Beginning B	alance : 09/01/2013				0
Increases: (1)	Product Development Application Fees Received	\$	0.00	\$	41,000
(2)	Appropriated Receipts applied to payments	·	-	·	-
Total Increas	ses	\$	0.00	\$	41,000
Reductions:					
	Expenditures - Appropriated Estimated Transfers for Employee Benefits Benefit Replacement Pay	\$	0.00 - -	\$	0.00
Total Reduc	tions	\$	0.00	\$	0.00
Ending Bala	nce, 4/30/2014			\$	41,000

#### **Cancer Prevention and Research Institute of Texas**

Actual Performance for Output/Efficiency Measures
Fiscal Year 2014

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	88,282	74803	N/A	N/A	163,085	40.77%
Number of Entities Relocating to TX for Cancer Research Related Projects	7.00	0.00	N/A	N/A	N/A	0.00	
Percentage of Texas Regions w/ Cancer Prevention Services and Activities Initiated	100%	N/A	N/A	N/A	N/A	N/A	N/A
Annual Age-adjusted Cancer Mortality Rate*	176.5	N/A	N/A	N/A	N/A	N/A	N/A
Number of Published Articles on CPRIT- Funded Research Projects	300	N/A	N/A	N/A	N/A	N/A	N/A
Number of New Jobs Created and Maintained	140	N/A	N/A	N/A	N/A	N/A	N/A

#### **Variance Explanations**

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

There are fewer active grants than anticipated when these measures were established due to the grant moratorium. In addition, the number of people served varies significantly depending on where each grantee is in their funding cycle.

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

CPRIT did not make any relocation awards to companies commercializing cancer research in fiscal year 2013 due to the state leadership imposed moratorium. This output 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. Because the measure reflects awards made about one year previously, there is a delay from when a relocation award is made and when it can impact this measure.

#### **CPRIT Commercial Paper and G.O. Bond Issuance**

Fiscal Year	Amount Appropriated	Dated Issued	Aı	mount Issued	ount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	\$ 225,000,000	September 9, 2009	\$	9,100,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2010		September 9, 2009	\$	3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	Footnote 1
2010		March 12, 2010	\$	63,800,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2010		August 26, 2010	\$	148,500,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
					\$ 225,000,000				
2011	\$ 225,000,000	September 7, 2010	\$	11,800,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2011		August 10, 2011	\$	50,775,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	\$	232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded \$233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
					\$ 62,575,000				
2012	\$ 300,000,000	September 7, 2011	¢	3,200,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2012	\$ 500,000,000	December 8, 2011		3,200,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		March 2, 2012		12,300,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		June 21, 2012		15,000,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		August 16, 2012		42,000,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
			-	,,	\$ 75,700,000				
2013	\$ 300,000,000	September 5, 2012	\$	9,600,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2013		May 16,2013	\$	13,400,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
					\$ 23,000,000				
2014	\$300,000,000	November 22, 2013	\$	55,200,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
		March 12, 2014	\$	47,000,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
					\$ 102,200,000				
TOTAL ISSU	JED TO DATE				\$ 488,475,000				

<sup>&</sup>lt;sup>1</sup>The weighted average interest rates for Commercial Paper Notes maturing in each year is as follows: FY 2010 = 0.30%; FY 2011 = 0.32%; FY 2012 = 0.23%; FY 2013 = 0.19%; FY 2014 = ?.



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL

**SUBJECT:** FY 2014 AMENDMENT TO SRA INTERNATIONAL PRE- AND POST-

AWARD GRANTS MANAGEMENT SUPPORT CONTRACT

**DATE:** MAY 15, 2014

#### **Summary and Recommendation:**

CPRIT has a contract with SRA International, Inc. to provide support services for CPRIT's pre- and post-award grant operations. The amount contracted for these services in fiscal year 2014 is \$7,784,209 for labor to augment CPRIT staff resources for grant applications processing, peer review meeting support, and programmatic review of grant award progress reports. The contracted amount also includes other direct costs for peer review travel, honoraria, and meetings costs. SRA has submitted a contract amendment for \$1,267,377 to the agency to continue to provide these services and pay other direct costs from sometime in June through August 31, 2014 as it estimates that the current contract budget will be fully expended during the month of June. The Oversight Committee must approve the contract amendment for CPRIT to proceed with utilizing SRA's services through the end of the fiscal year. With approval to move forward with the contract amendment, CPRIT will have to seek authority from the Legislative Budget Board to transfer money from the Research Grant Award appropriations strategy to the Grant Review and Award Operations appropriations strategy to support this cost.

#### **Discussion**

The contract budget is being expended more quickly than anticipated because SRA has provided services to CPRIT that were not included in the original assumptions for the fiscal year 2014 contract renewal. CPRIT had assumed that only one complete grant application and award cycle would occur for all three programs this year with almost no changes to the request for application (RFA) requirements as it has ramped its operations back up after the grant moratorium ended October 31, 2013. However, CPRIT has ramped up its operations more quickly than the staff could project during the summer of 2013 when this contract renewal was negotiated.

In addition to completing one grant application and award cycle in fiscal year 2014, all three programs have started the first grant application and award cycle for fiscal year 2015. They have

published RFAs and are preparing for the corresponding peer review meetings to occur in August 2014 for product development and in September 2014 for prevention and research. The additional cost for this activity is \$584,209. The largest portion of this cost is for the payment of partial honorarium to the peer reviewers for the work they complete through August 31, 2014 when the contract with SRA ends and the August 2014 meeting costs for product development peer reviewers.

CPRIT has made a greater number of changes to RFAs and created new RFAs than were originally envisioned to meet statutory requirements and demand from the potential grant applicants. This activity in combination with the additional application and award cycle has required more revisions to the electronic application receipt system than were planned and budgeted. The additional cost for this activity is \$198,681.

CPRIT has also requested additional enhancements to the post-award grants management system to accommodate changes to grant management processes as CPRIT has been implementing the recommendations for the January 2013 State Auditor's management report and the statutory changes in Senate Bill 149, 83<sup>rd</sup> Legislature, R.S. The additional cost for these enhancements is \$484,487.



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS

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

**SUBJECT:** UPDATE OF RESEARCH ACTIVITIES

**DATE:** MAY 21, 2014

#### **Research Grants**

The Scientific Review Council (SRC) evaluated responses to RFAs for the Recruitment of Established Investigators, Rising Stars, and First-Time, Tenure-Track Faculty (REC 14.1) on April 17, 2014, and its recommendation was forwarded to the Program Integration Committee and the Oversight Committee for approval. Twenty-five applications were reviewed by the SRC, and 14 were recommended for funding. The unusually high number of applications was most likely due to the funding gap created by last year's moratorium. The Oversight Committee will vote on these recommendations later in this meeting.

The 583 responses to our RFAs for Individual Investigator and High Impact/High Risk grants (RP14.1) are currently under peer review. Meetings of the 7 peer review panels will be held in Dallas between May 28 and June 10, 2014, after which the awards recommended by each panel will be forwarded to the Scientific Review Council for prioritization. The Oversight Committee will act on these awards at its August 2014 meeting.

RFAs for Individual Investigator Research Awards (RP15.1) are now open for submission. These include one untargeted RFA, one targeted toward Prevention and Early Detection Research, and one targeted to Cancers of Children and Adolescents. The closing date is June 26, 2014.

RFAs for new recruitment awards are also open and will be open continuously.

In July, 2014, we anticipate releasing RFAs for Multi-Investigator Research Awards, Core Facility Support Awards, and another round of High Impact/High Risk Awards (RP15.2).

#### **Research Subcommittee**

The Oversight Committee's Research Subcommittee has met twice since the last Oversight Committee Meeting. On March 21, the OCRS discussed the committees that are advisory to the OC, new nominations to peer review panels, and the program priorities project. On May 12, the OCRS received an update on the pending recruitment awards that are up for approval today, reviewed additional nominations to the peer review panels, and discussed the outcome of the meeting with the University Advisory Committee.

#### **Nominations for Peer Review Panels**

The Scientific Research office presented an additional 42 peer review panelists to the Nominations Subcommittee for recommendation on May 14, 2014. Oversight Committee members have these recommendations before you today for approval. With the addition of these review panelists, we now have a total of 129 peer reviewers across 7 peer review panels. The large number of review panelists is due to the large number of grant applications being reviewed in the current cycle. These individuals have stellar records of achievement in their areas of expertise and will enhance our already illustrious review panels.

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

CPRIT convened a meeting of the University Advisory Committee on April 30, 2014 in Houston. This is a statutorily mandated committee whose charge is to "advise the Oversight Committee and a research and prevention programs committee regarding the role of institutions of higher education in cancer research". The nine members of the committee are appointed by the chancellor or president of the various institutions. The minutes of this meeting are appended.



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **CPRIT University Advisory Committee Meeting**

Wednesday, April 30, 2014, 11:00 AM to 3:00 PM Rice University Bioscience Research Collaborative Building

Meeting Notes

#### **Members Present**

David Cistola Stacy Kalovidouris C. Kent Osborne Mary Ann Ottinger Ian Thompson (via phone) Cheryl Walker James Willson

#### **Members Absent**

P. Michael Conn Bill Covington

#### **Oversight Committee Present**

William Rice

#### **CPRIT Staff Present**

Wayne Roberts Becky Garcia Margaret Kripke Kristen Doyle David Reisman Michael Brown

#### Welcome and Introductions

Mr. Wayne Roberts, CPRIT CEO opened the meeting and welcomed the members. He gave a brief account of CPRIT's activities in the past year and indicated that the agency was now poised to move ahead aggressively with its programs in research, prevention, and product development. Dr. Bill Rice, Chair of CPRIT's Oversight Committee added his welcome and thanks for the UAC members' participation. He also apprised the UAC of the new mandate for the Oversight Committee to establish priorities within and among CPRIT programs and noted that the Committee would welcome guidance from UAC in this effort. Participants then introduced themselves.

#### **Discussion on the Election of Committee Chair**

Dr. Margaret Kripke outlined the statutory requirement for the UAC and suggested that the UAC members elect a Chair sometime during the day, so that there could be a regular point of contact between CPRIT and the UAC. Dr. Cheryl Walker of the Texas A&M University Institute of Biosciences and Technology was elected as Chair at the end of the meeting. Ms. Kristen Doyle indicated that the responsibilities of the UAC were enumerated in the Bylaws of the Oversight Committee. This document was forwarded to members of the UAC.

Overview of the CPRIT Scientific Research Grant Program Portfolio and Disccusion An overview of CPRIT's current research grants portfolio was presented by Dr. Kripke. She noted that grant awards approved, but delayed by the moratorium on funding had now been released. Questions and comments generated by this presentation included the following:

- a) Does the Individual Investigator Research Award (IIRA) mechanism fund clinical trials? If so, this is not completely clear from the RFA. Dr. Kripke indicated that CPRIT would take steps to clarify this and would consider developing a specific RFA for clinical trials.
- b) One member expressed concern that his institution had received only 1 CPRIT award out of 63 applications to date, in spite of the faculty having a strong record of success in competing for NIH grants. He suggested that we might look at CPRIT grant success rates by institution to see if this is an anomaly or if there is systematic bias somewhere in the review system.
- c) A question was asked regarding the boundaries between the research and product development portfolios. Dr. Kripke responded that her view was that the Early Translational Research Awards were more closely aligned with the product development portfolio and, consequently, these have been transferred from research to product development. The product development program now has considerable expertise among its reviewers in both business development and academic research, so they are in a better position to review these translational awards.

#### **Discussion of Responses to Pre-Meeting Questions**

The group then turned their attention to the questions circulated in advance of the meeting. (Written comments provided by members not in attendance were included in the discussion.)

a) Which CPRIT research grant mechanism is most valuable to your institution? Recruitment grants were mentioned as being the most visible indicator of success of CPRITs research program and extremely important for the various institutions' recruiting efforts. The recruitment awards for first-time faculty were viewed as being the most valuable in the long term, and there was a sentiment that they would have a significant impact on cancer research in Texas in the future. Some caution was expressed that the established investigator awards should not be used to recruit candidates who had passed the peak of their productivity. Another concern, supported by the distribution of the previous awards, was that most of the awards have gone to institutions that already have strong programs and a critical mass of researchers. Enabling some of the other institutions to compete for these awards in order to build up a critical mass of cancer researchers might be a goal to consider. Another critically important award mechanism is the IIRA, which is where most dollars have been spent to date. MIRAs were cited as contributing greatly to improved collaborations and interactions among the various Texas institutions. In general, all award mechanisms were viewed as making valuable contributions.

- b) Are there other research grant mechanisms that CPRIT should consider? Suggestions included sabbatical support for investigators; RFAs targeted to research on cancers disproportionately affecting Texans and on populations within the "catchment area" of cancer research institutions; a career development type research grant for junior faculty; and a mechanism that would enable participation of faculty members outside the major cancer centers; infrastructure awards to bolster cancer research efforts in more rural areas of the state, such as West and South Texas. Specific areas suggested to consider for future, more focused research solicitations were 1) prevention research associated with health disparities; 2) rare cancers where focused resources will be needed to achieve a critical mass of both researchers and patients for clinical trials that can have an impact on these diseases; 3) Community outreach and "pipelining' into STEM fields to invest in future cancer researchers; 4) training grants in computational biology that will provide 2-year fellowships for computational biologists to work with cancer researchers.
- c) Are the 3 types of recruitment grants currently offered equally valuable? The consensus was that they were. The timing of the review of these awards was discussed, and a strong plea was to continue to review them monthly instead of quarterly, so that the recruitment process would not be delayed. CPRIT staff agreed to reconsider this request. One idea was that there should be recruitment awards targeted to areas of the State in which no recruitment awards had been given previously to help build the critical mass of investigators needed to attract others.
- d) CPRIT is considering handling the Multi-Investigator Research Awards as a single contract, with projects at other institutions handled as subcontracts. Would this negatively affect their desirability?
  The MIRAs were considered to be extremely valuable for fostering collaborations and enabling interdisciplinary research. Members were divided as to the best mechanism for administering them, however, because there are advantages and disadvantages to both mechanisms. The principle upon which everyone agreed was that the best mechanism would be one that created the fewest barriers to inter-institutional collaborations.
- e) CPRIT is interested in increasing the diversity of researchers and trainees supported by its awards. How might this be achieved? Suggestions included ensuring that the review committees understand that this is a high priority for CPRIT, targeting research applications on cancers prevalent in minority populations, and awarding supplements to research grants for support of underserved students and postdoctoral trainees.
- f) What other topics would you like to discuss with CPRIT staff in the future?" Interest was expressed in having input into the priority-setting process of the Oversight Committee. Also, an opportunity to hear from the product development and prevention programs would be welcome. Dr. Walker was charged with developing an agenda for a subsequent meeting. In addition, the UAC will be working with CPRIT to develop processes within its charter for how the UAC can provide input into the Oversight Committee, assist in the identification of CPRIT success metrics, and provide advice into development of programs that will have a lasting impact on cancer research and the lives of Texans across the state.

<u>Prioritization of Program Funding for Research and Product Development</u>
Dr. Tom Goodman, Chief Product Development Officer, briefly described his vision for the product development program, which he believes should focus on early stage projects, where other funding sources are scarce. He also supported the concept that peer review should drive funding decisions.

The meeting was adjourned at 2:45 PM.

### Conflicts of Interest for Research Cycle 14.1 Recruitment Applications (Research Cycle 14.1 Recruitment Awards Announced at May 2014 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. 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.

Grant ID	Applicant	Institution	<b>Conflict Noted</b>				
Applications considered by the PIC and Oversight Committee							
RR140008	Berk, Steven	Texas Tech University Health Sciences Center	Mitchell, Amy				
RR140012	Dmitrovsky, Ethan	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy				
RR140013	Roysam, Badrinath	University of Houston	Mitchell, Amy; Montgomery, Will				
RR140023	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy; Montgomery, Will				
RR140025	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy; Montgomery, Will				
RR140027	Dmitrovsky, Ethan	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy				
RR140033	Kuspa, Adam	Baylor College of Medicine	Mitchell, Amy				
RR140035	Thomas, Edwin	Rice University	Mitchell, Amy; Montgomery, Will				
RR140036	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy; Montgomery, Will				
RR140038	Kuspa, Adam	Baylor College of Medicine	Mitchell, Amy				
RR140042	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy; Montgomery, Will				
RR140049	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy; Montgomery, Will				
RR140052	Dmitrovsky, Ethan	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy				

<b>Grant ID</b>	Applicant	Institution	<b>Conflict Noted</b>	
RR140053	Giroir, Brett	Texas A&M University	Mitchell, Amy;	
		Health Science Center	Montgomery, Will	
		Institute of Biosciences		
		and Technology		
Applications Not Recommended for PIC or Oversight Committee Consideration				
RR140031	Fitz, John	The University of Texas	Gambhir, Sanjiv Sam	
		Southwestern Medical		
		Center		



### CEO Affidavit Supporting Information

FY 2014 – Cycle 1 Recruitment of Established Investigator Research Award

### **Request for Applications**



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS RFA R-14-REI-1

## Recruitment of Established Investigators

Please also refer to the Instructions for Applicants document, which will be posted on March 3, 2014.

Application Receipt Opening Date: March 3, 2014

FY 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

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#### **RFA VERSION HISTORY**

Rev 1/15/14	RFA release		
Rev 2/21/14	Application Receipt opening date March 3, 2014		
Rev 2/21/14	Revised Section 6.1 Application Submission Guidelines		
	<ul> <li>Added application receipt opening and closing dates</li> </ul>		
Rev 2/21/14	Revised Section 6.2.4 Goals and Objectives		
	• "Goals and Objectives" changed to "Summary of Goals and Objectives"		
Rev 2/21/14	Revised Section 6.2.7 Timeline		
	Added page limit: one page		
Rev 2/21/14	Revised Section 8. Key Dates		
	Added Application Receipt and Review Timeline		
Rev 2/23/14	Revised Section 7.1 Review Process		
	• Revised sentence: "Applications may be submitted continuously in response		

Scientific Review Council."

to this RFA, but will generally be reviewed on a quarterly basis by the CPRIT

#### 1. ABOUT CPRIT

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

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

- Create and expedite innovation in the area of cancer research and product or service
  development, thereby enhancing the potential for a medical or scientific breakthrough in
  the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development
  and coordination of effective and efficient statewide public and private policies, programs,
  and services related to cancer and by encouraging cooperative, comprehensive, and
  complementary planning among the public, private, and volunteer sectors involved in
  cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

#### 2. RATIONALE

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

Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment.

#### 3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. This award honors outstanding senior investigators with proven track records of research accomplishments combined with excellence in leadership and teaching. All candidates should be recognized research or clinical investigators, held in the highest esteem by professional colleagues nationally and internationally, whose contributions have had a significant influence on their discipline and, likely, beyond. They must have clearly established themselves as exemplary faculty members with exceptional accomplishments in teaching and advising and/or basic, translational, population-based, or clinical cancer research activities. It is expected that the candidate will contribute significantly to and have a major impact on the institution's overall cancer research initiative. Candidates will be leaders capable of initiating and developing creative ideas leading to novel solutions related to cancer detection, diagnosis, and/or treatment. They are also expected to maintain and lead a strong research group and have a stellar, high-impact publication portfolio, as well as continue securing external funding. Furthermore, recipients will lead and inspire undergraduate and graduate students interested in pursuing research careers and will engage in collegial and collaborative relationships with others within and beyond their traditional discipline in an effort to expand the boundaries of cancer research.

Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework. Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates should be at the career level of a full professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience as vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution.

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

#### 4. FUNDING INFORMATION

This is a 5-year award and is not renewable. Grant support will be awarded based upon the breadth and nature of the research program proposed. Grant funds of up to \$6 million (total costs) for the 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. The award request may include indirect costs of up to 5 percent of the total award amount (5.263 percent 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 percent 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, or appropriate dean of a Texasbased 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 one institution. If more than one 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 M.D., Ph.D., D.D.S., D.M.D.,
  Dr.P.H., D.O., D.V.M., or equivalent, and reside in Texas for the duration of the
  appointment. The candidate must devote at least 70 percent time to research activities.
  Candidates whose major responsibilities are clinical care, teaching or administration are not
  eligible.
- At the time of the application, the candidate should hold an appointment at the rank of professor (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. The candidate must not reside in Texas at the time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. 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, and 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 <a href="Section 9">Section 9</a> and <a href="Section 10">Section 10</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. RESPONDING TO THIS RFA

#### **6.1.** Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, 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 quarterly. To manage the timely review of nominations for each evaluation period, the application receipt system will open and close sequentially. For the most immediate submission period, nominations will be accepted beginning at 7 a.m. Central Time on March 3, 2014 and must be submitted by 3 p.m. Central Time on March 31, 2014. The next submission period will open on April 1, 2014. A complete timeline of review for this fiscal year is provided in <u>Section 8</u>. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

#### **6.2.** 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.

#### 6.2.1. 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.

#### 6.2.2. Recruitment Activities/Institutional Commitment (two pages)

Describe the recruitment activities, strategies, and priorities that have led to nomination of this candidate. 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. While scholars may engage in direct patient care activities and/or have some administrative, or teaching duties, at least 70 percent of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding.

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 (i.e., "rent") is not a permitted institutional commitment item.
- Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of nomination of the candidate by the institution.
- **Description of Candidate Duties and Certification** that 70 percent time will be spent on research must be included.

#### 6.2.3. Curriculum Vitae (CV)

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

#### 6.2.4. 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.

#### 6.2.5. Research (four 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 one 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."

#### 6.2.6. Publications

Provide the five 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.

#### 6.2.7. Timeline (one 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.

#### 6.2.8. 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.

#### **6.2.9.** Research Environment (one page)

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

#### 6.2.10. Descriptive Biography (Up to two 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 Web site. Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing one 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.

#### 7. APPLICATION REVIEW

#### 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 quarterly 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.

#### 7.2. Confidentiality of Review

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

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

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee 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. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

#### 7.3. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from 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/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research.

Questions to be considered by the reviewers are as follows:

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

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

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

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

#### 8. KEY DATES

#### **RFA**

RFA Release

January 15, 2014

#### **Application Receipt and Review Timeline**

Application Receipt System opens, 7 am CT	Application Receipt System closes, 3 pm CT	Anticipated Application Review	Anticipated Award Notification	Anticipated Award Start Date
March 3, 2014	March 31, 2014	Mid-April 2014	May 21, 2014	June 1, 2014
April 1, 2014	TBD	TBD	TBD	TBD

#### 9. 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 <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>.

#### 10. 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.

#### 11. CONTACT INFORMATION

#### 11.1. 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:** January 15, 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:** 866-941-714

E-mail: Help@CPRITGrants.org

#### 11.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

E-mail: Help@CPRITGrants.org

Web site: <a href="www.cprit.state.tx.us">www.cprit.state.tx.us</a>

### **Third Party Observer Report**

# CPRIT Scientific Review Council Observation Report

Report #2014-09

Panel Name: Scientific Review Council Meeting - Recruitment Review

Panel - 2

Panel Date: April 17, 2014 Report Date: April 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 Scientific Review Council Recruitment Review Panel – 2 chaired by Richard Kolodner and held over the phone on April 17, 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 Recruitment Review Panel meeting held telephonically on April 17, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twenty-one recruitment applications were presented, discussed, and evaluated by the Scientific Review Council to determine which grants would receive CPRIT funding.
- Seven council members, four CPRIT staff members, and three SRA employees were present for the Council meeting over the phone

- One conflict of interest was identified prior to the call. The council member with the conflict of interest left the teleconference and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The council members' discussions were limited to the application evaluation criteria.

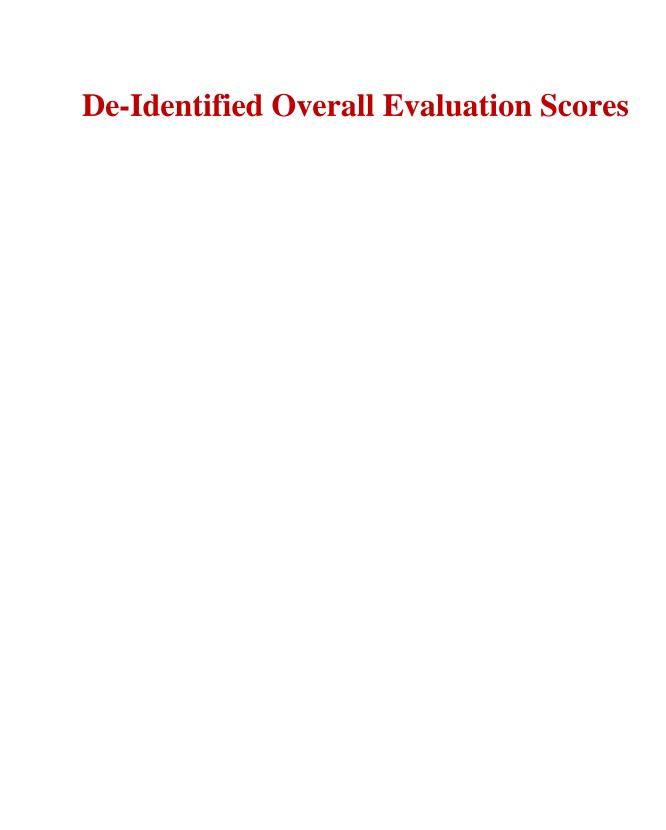
#### **Disclaimer**

The third-party observation did not include the following:

 An evaluation of the appropriateness or rigor of the 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.



## Recruitment of Established Investigator Awards

### FY2014-Cycle 2 De-Identified Scores

SRC Rank	Application ID	Score
3	RR140052*	1.0
10	RR140033*	2.2
11	RR140049*	2.2
18	K	3.0

<sup>\*</sup> Recommended for funding

## Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd

May 6, 2014

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Senior Advisor on Academic Affairs

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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 Thursday, April 17 to consider the applications submitted to CPRIT under the **Recruitment for First-Time**, **Tenure Track Faculty Members**, **Recruitment of Established Investigators**, 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

Rank	Application ID	Institution	Candidate	Requested Budget	Overall Score
1	RR140023	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Gary Hon	\$2,000,000	1.0
2	RR140027	The University of Texas M.D. Anderson Cancer Center	Recruitment of First-Time, Tenure- Track Nomination of Priscilla Brastianos	\$2,000,000	1.0
3	RR140052	The University of Texas M.D. Anderson Cancer Center	Recruitment of Established Investigator Nomination of John Tanier	\$6,000,000	1.0
4	RR140025	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Jian Xu	\$2,000,000	1.2
5	RR140042	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Laura Banaszynski	\$2,000,000	1.2
6	RR140012	The University of Texas M.D. Anderson Cancer Center	Recruitment of First-Time, Tenure- Track Nomination of Cullen Taniguchi	\$2,000,000	1.7
7	RR140035	Rice University	Recruitment of First-Time, Tenure- Track Nomination of Samira Azarin	\$2,000,000	2.0
8	RR140036	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Weibo Luo	\$2,000,000	2.0
9	RR140038	Baylor College of Medicine	Recruitment of First-Time, Tenure- Track Nomination of Andre Catic	\$2,000,000	2.0
10	RR140033	Baylor College of Medicine	Recruitment of Established Investigator Nomination of Matthew Ellis	\$6,000,000	2.2
11	RR140049	The University of Texas Southwestern Medical Center	Recruitment of Established Investigator Nomination of Marco Durante	\$3,000,000	2.2
12	RR140053	Texas A&M University Health Science Center Institute of Biosciences and Technology	Recruitment of First-Time, Tenure- Track Nomination of Yun Huang	\$1,800,000	2.8
13	RR140013	The University of Houston	Recruitment of First-Time, Tenure- Track Nomination of David Mayerich	\$2,000,000	2.8
14	RR140008	Texas Tech University Health Sciences Center	Recruitment of Rising Stars Nomination of Kevin Pruitt	\$2,539,259	2.8



## CEO Affidavit Supporting Information

FY 2014 – Cycle 1
Recruitment of First-Time Tenure-Track Faculty
Members Research Award

### **Request for Applications**



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## REQUEST FOR APPLICATIONS RFA R-14-RFT-1

## Recruitment of First-Time Tenure-Track Faculty Members

Please also refer to the Instructions for Applicants document, which will be posted on March 3, 2014.

Application Receipt Opening Date: March 3, 2014

Fiscal Year Award Period

September 1, 2013-August 31, 2014

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#### **RFA VERSION HISTORY**

- Rev 1/15/14 RFA release
- Rev 2/21/14 Application Receipt opening date March 3, 2014
- Rev 2/21/14 Revised Section 6.1 Application Submission Guidelines
  - Added application receipt opening and closing dates
- Rev 2/21/14 Revised Section 6.2.4 Goals and Objectives
  - "Goals and Objectives" changed to "Summary of Goals and Objectives"
- Rev 2/21/14 Revised Section 6.2.7 Timeline
  - Added page limit: one page
- Rev 2/21/14 Revised Section 8. Key Dates
  - Added Application Receipt and Review Timeline
- Rev 2/23/14 Revised Section 7.1 Review Process
  - Revised sentence: "Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a quarterly basis by the CPRIT Scientific Review Council."

#### 1. ABOUT CPRIT

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

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

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the
  development and coordination of effective and efficient statewide public and private
  policies, programs, and services related to cancer and by encouraging cooperative,
  comprehensive, and complementary planning among the public, private, and volunteer
  sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

#### 2. RATIONALE

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 encouraged strongly 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 percent of the total award amount (5.263 percent 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 percent 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, 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 one institution. If more than one 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 M.D., Ph.D., D.D.S., D.M.D.,
  Dr.P.H., D.O., D.V.M., or equivalent, and reside in Texas for the duration of the
  appointment. The candidate must devote at least 70 percent 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, and any officer or director of the grant applicant's institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. 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, and 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 <a href="Section 9">Section 9</a> and <a href="Section 10">Section 10</a>. 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. RESPONDING TO THIS RFA

#### 6.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, 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 quarterly. To manage the timely review of nominations for each evaluation period, the application receipt system will open and close sequentially. For the most immediate submission period, nominations will be accepted beginning at 7 a.m. Central Time on March 3, 2014 and must be submitted by 3 p.m. Central Time on March 31, 2014. The next submission period will open on April 1, 2014. A complete timeline of review for this fiscal year is provided in <u>Section 8</u>. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

#### **6.2.** 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 <a href="Section 5">Section 5</a> will be administratively withdrawn without review.

#### 6.2.1. 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.

#### **6.2.2.** Recruitment Activities/Institutional Commitment (three pages)

Describe the recruitment activities, strategies, and priorities that have led to nomination of this candidate. 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. While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70 percent of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding.

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 (i.e., "rent") is not a permitted institutional commitment item
- Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification for nomination of the candidate by the institution.
- **Description of Candidate Duties and Certification** that 70 percent time will be spent on research must be included.

The letter of institutional commitment must also:

- 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.

#### **6.2.3.** Curriculum Vitae (CV)

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

#### 6.2.4. 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.

#### 6.2.5. Research (four 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 one 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."

#### 6.2.6. Publications

Provide the three 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.

#### **6.2.7.** Timeline (one 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.

#### **6.2.8.** 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.

#### 6.2.9. Letters of Recommendation

Provide three 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.

#### **6.2.10.** Research Environment (one page)

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

#### 6.2.11. Descriptive Biography (Up to two 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 Web site. Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing one 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.

#### 7. APPLICATION REVIEW

#### 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 quarterly 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.

#### 7.1.1. 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 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. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

#### 7.2. 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 of 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?

#### 8. KEY DATES

#### **RFA**

RFA Release

January 15, 2014

#### **Application Receipt and Review Timeline**

Application Receipt System opens, 7 am CT	Application Receipt System closes, 3 pm CT	Anticipated Application Review	Anticipated Award Notification	Anticipated Award Start Date
March 3, 2014	March 31, 2014	Mid-April 2014	May 21, 2014	June 1, 2014
April 1, 2014	TBD	TBD	TBD	TBD

#### 9. 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.

#### 10. 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.

#### 11. CONTACT INFORMATION

#### 11.1. 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:** January 15, 2014 onward (excluding public holidays)

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

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

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

#### 11.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

**E-mail:** Help@CPRITGrants.org

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

### **Third Party Observer Report**

# CPRIT Scientific Review Council Observation Report

Report #2014-09

Panel Name: Scientific Review Council Meeting - Recruitment Review

Panel - 2

Panel Date: April 17, 2014 Report Date: April 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 Scientific Review Council Recruitment Review Panel – 2 chaired by Richard Kolodner and held over the phone on April 17, 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 Recruitment Review Panel meeting held telephonically on April 17, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twenty-one recruitment applications were presented, discussed, and evaluated by the Scientific Review Council to determine which grants would receive CPRIT funding.
- Seven council members, four CPRIT staff members, and three SRA employees were present for the Council meeting over the phone

- One conflict of interest was identified prior to the call. The council member with the conflict of interest left the teleconference and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The council members' discussions were limited to the application evaluation criteria.

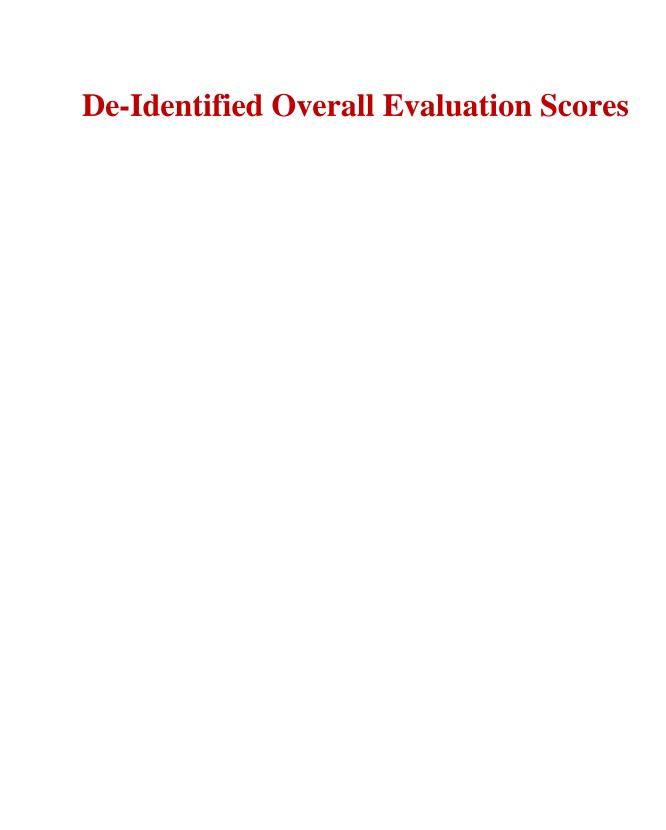
#### **Disclaimer**

The third-party observation did not include the following:

 An evaluation of the appropriateness or rigor of the 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.



## Recruitment of First Time, Tenure-Track Faculty Member Awards

FY2014-Cycle 2 De-Identified Scores

SRC Rank	Application ID	Score
1	RR140023*	1.0
2	RR140027*	1.0
4	RR140025*	1.2
5	RR140042*	1.2
6	RR140012*	1.7
7	RR140035*	2.0
8	RR140036*	2.0
9	RR140038*	2.0
12	RR140053*	2.8
13	RR140013*	2.8
15	A	3.0
17	В	3.0
20	С	3.7
25	D	4.0

<sup>\*</sup> Recommended for funding

# Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd

May 6, 2014

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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 Thursday, April 17 to consider the applications submitted to CPRIT under the **Recruitment for First-Time**, **Tenure Track Faculty Members**, **Recruitment of Established Investigators**, 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

Rank	Application ID	Institution	Candidate	Requested Budget	Overall Score
1	RR140023	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Gary Hon	\$2,000,000	1.0
2	RR140027	The University of Texas M.D. Anderson Cancer Center	Recruitment of First-Time, Tenure- Track Nomination of Priscilla Brastianos	\$2,000,000	1.0
3	RR140052	The University of Texas M.D. Anderson Cancer Center	Recruitment of Established Investigator Nomination of John Tanier	\$6,000,000	1.0
4	RR140025	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Jian Xu	\$2,000,000	1.2
5	RR140042	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Laura Banaszynski	\$2,000,000	1.2
6	RR140012	The University of Texas M.D. Anderson Cancer Center	Recruitment of First-Time, Tenure- Track Nomination of Cullen Taniguchi	\$2,000,000	1.7
7	RR140035	Rice University	Recruitment of First-Time, Tenure- Track Nomination of Samira Azarin	\$2,000,000	2.0
8	RR140036	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Weibo Luo	\$2,000,000	2.0
9	RR140038	Baylor College of Medicine	Recruitment of First-Time, Tenure- Track Nomination of Andre Catic	\$2,000,000	2.0
10	RR140033	Baylor College of Medicine	Recruitment of Established Investigator Nomination of Matthew Ellis	\$6,000,000	2.2
11	RR140049	The University of Texas Southwestern Medical Center	Recruitment of Established Investigator Nomination of Marco Durante	\$3,000,000	2.2
12	RR140053	Texas A&M University Health Science Center Institute of Biosciences and Technology	Recruitment of First-Time, Tenure- Track Nomination of Yun Huang	\$1,800,000	2.8
13	RR140013	The University of Houston	Recruitment of First-Time, Tenure- Track Nomination of David Mayerich	\$2,000,000	2.8
14	RR140008	Texas Tech University Health Sciences Center	Recruitment of Rising Stars Nomination of Kevin Pruitt	\$2,539,259	2.8



## CEO Affidavit Supporting Information

FY 2014 – Cycle 1 Recruitment of Rising Stars Research Award

## **Request for Applications**



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# REQUEST FOR APPLICATIONS RFA R-14-RRS-1

### **Recruitment of Rising Stars**

Please also refer to the Instructions for Applicants document, which will be posted on March 3, 2014.

Application Receipt Opening Date: March 3, 2014

Fiscal Year Award Period

September 1, 2013-August 31, 2014

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#### **RFA VERSION HISTORY**

Rev 1/15/14	RFA release
Rev 2/21/14	Application Receipt opening date March 3, 2014
Rev 2/21/14	Revised Section 6.1 Application Submission Guidelines
	<ul> <li>Added application receipt opening and closing dates</li> </ul>
Rev 2/21/14	Revised Section 6.2.4 Goals and Objectives
	• "Goals and Objectives" changed to "Summary of Goals and Objectives"
Rev 2/21/14	Revised Section 6.2.7 Timeline
	Added page limit: one page
Rev 2/21/14	Revised Section 8. Key Dates
	Added Application Receipt and Review Timeline
Rev 2/23/14	Revised Section 7.1 Review Process

Scientific Review Council."

Revised sentence: "Applications may be submitted continuously in response

to this RFA, but will generally be reviewed on a quarterly basis by the CPRIT

#### 1. ABOUT CPRIT

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

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

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher
  education and other public or private entities that will promote a substantial increase in
  cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development
  and coordination of effective and efficient statewide public and private policies, programs,
  and services related to cancer and by encouraging cooperative, comprehensive, and
  complementary planning among the public, private, and volunteer sectors involved in
  cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

#### 2. RATIONALE

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 encouraged strongly 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 percent of the total award amount (5.263 percent 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 percent 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, or appropriate dean of a Texasbased 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 one institution. If more than one 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 M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70 percent 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, and any officer or director of the grant applicant's institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. 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, and 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 <a href="Section 9">Section 9</a> and <a href="Section 10">Section 10</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. RESPONDING TO THIS RFA

#### 6.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be **considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, 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 quarterly. To manage the timely review of nominations for each evaluation period, the application receipt system will open and close sequentially. For the most immediate submission period, nominations will be accepted beginning at 7 a.m. Central Time on March 3, 2014 and must be submitted by 3 p.m. Central Time on March 31, 2014. The next submission period will open on April 1, 2014. A complete timeline of review for this fiscal year is provided in <u>Section 8</u>. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

#### **6.2.** 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.

#### 6.2.1. 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.

#### 6.2.2. Recruitment Activities/Institutional Commitment (two pages)

Describe the recruitment activities, strategies, and priorities that have led to nomination of this candidate. 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. While scholars may engage in direct patient care activities and/or have some administrative, or teaching duties, at least 70 percent of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding.

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 (i.e., "rent") is not a permitted institutional commitment item.
- Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of nomination of the candidate by the institution.
- **Description of Candidate Duties and Certification** that 70 percent time will be spent on research must be included.

#### 6.2.3. Curriculum Vitae (CV)

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

#### 6.2.4. 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.

#### 6.2.5. Research (four 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 one 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."

#### 6.2.6. Publications

Provide the five 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.

#### 6.2.7. Timeline (one 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.

#### **6.2.8.** 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.

#### **6.2.9.** Research Environment (one page)

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

#### 6.2.10. Descriptive Biography (Up to two 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 Web site.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing one 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.

#### 7. APPLICATION REVIEW

#### 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 quarterly 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

#### 7.1.1. 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 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. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

#### 7.2. 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/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?

#### 8. KEY DATES

#### RFA

**RFA Release** 

January 15, 2014

#### **Application Receipt and Review Timeline**

Application Receipt System opens, 7 am CT	Application Receipt System closes, 3 pm CT	Anticipated Application Review	Anticipated Award Notification	Anticipated Award Start Date
March 3, 2014	March 31, 2014	Mid-April 2014	May 21, 2014	June 1, 2014
April 1, 2014	TBD	TBD	TBD	TBD

#### 9. 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.

#### 10. 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.

#### 11. CONTACT INFORMATION

#### 11.1. 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:** January 15, 2014 onward (excluding public holidays)

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

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

**Tel:** 866-941-7146

E-mail: Help@CPRITGrants.org

#### 11.2. Scientific and Programmatic Questions

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

**Tel:** 512-305-8491

**E-mail:** Help@CPRITGrants.org

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

## **Third Party Observer Report**

# CPRIT Scientific Review Council Observation Report

Report #2014-09

Panel Name: Scientific Review Council Meeting - Recruitment Review

Panel - 2

Panel Date: April 17, 2014 Report Date: April 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 Scientific Review Council Recruitment Review Panel – 2 chaired by Richard Kolodner and held over the phone on April 17, 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 Recruitment Review Panel meeting held telephonically on April 17, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twenty-one recruitment applications were presented, discussed, and evaluated by the Scientific Review Council to determine which grants would receive CPRIT funding.
- Seven council members, four CPRIT staff members, and three SRA employees were present for the Council meeting over the phone

- One conflict of interest was identified prior to the call. The council member with the conflict of interest left the teleconference and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The council members' discussions were limited to the application evaluation criteria.

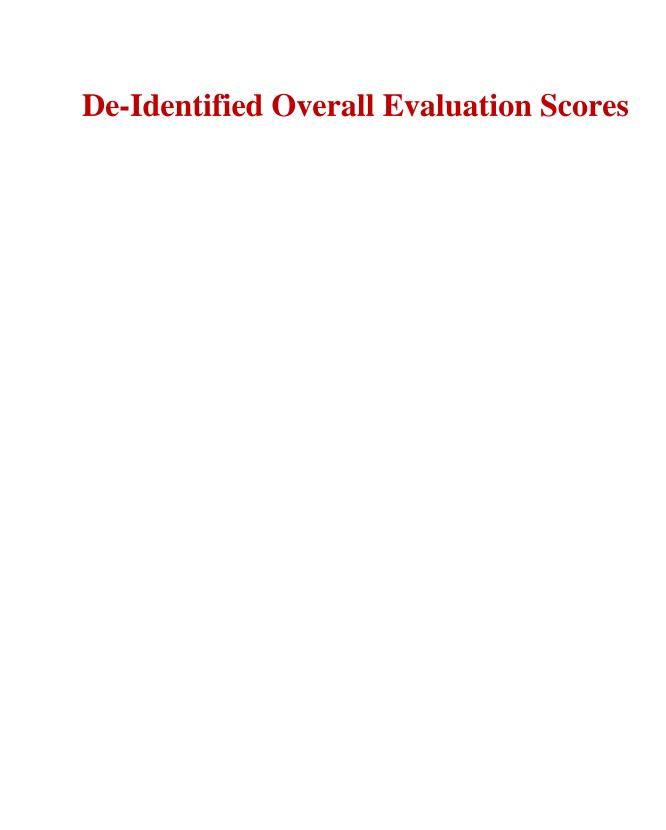
#### **Disclaimer**

The third-party observation did not include the following:

 An evaluation of the appropriateness or rigor of the 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.



## Recruitment of Rising Star Awards

FY2014-Cycle 2 De-Identified Scores

SRC Rank	Application ID	Score
14	RR140008*	2.8
16	Е	3.0
19	F	3.5
21	G	4.3
22	Н	3.5
23	I	4.0
24	J	4.0

<sup>\*</sup> Recommended for funding

# Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd

May 6, 2014

Richard D. Kolodner Ph.D.

Head, Laboratory of Cancer Genetics San Diego Branch

Senior Advisor on Academic Affairs

New York Office

Distinguished Professor of Medicine, University of California San Diego

rkolodner@ucsd.edu

San Diego Branch

Univ of California San Diego 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 Thursday, April 17 to consider the applications submitted to CPRIT under the **Recruitment for First-Time**, **Tenure Track Faculty Members**, **Recruitment of Established Investigators**, 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

Rank	Application ID	Institution	Candidate	Requested Budget	Overall Score
1	RR140023	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Gary Hon	\$2,000,000	1.0
2	RR140027	The University of Texas M.D. Anderson Cancer Center	Recruitment of First-Time, Tenure- Track Nomination of Priscilla Brastianos	\$2,000,000	1.0
3	RR140052	The University of Texas M.D. Anderson Cancer Center	Recruitment of Established Investigator Nomination of John Tanier	\$6,000,000	1.0
4	RR140025	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Jian Xu	\$2,000,000	1.2
5	RR140042	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Laura Banaszynski	\$2,000,000	1.2
6	RR140012	The University of Texas M.D. Anderson Cancer Center	Recruitment of First-Time, Tenure- Track Nomination of Cullen Taniguchi	\$2,000,000	1.7
7	RR140035	Rice University	Recruitment of First-Time, Tenure- Track Nomination of Samira Azarin	\$2,000,000	2.0
8	RR140036	The University of Texas Southwestern Medical Center	Recruitment of First-Time, Tenure- Track Nomination of Weibo Luo	\$2,000,000	2.0
9	RR140038	Baylor College of Medicine	Recruitment of First-Time, Tenure- Track Nomination of Andre Catic	\$2,000,000	2.0
10	RR140033	Baylor College of Medicine	Recruitment of Established Investigator Nomination of Matthew Ellis	\$6,000,000	2.2
11	RR140049	The University of Texas Southwestern Medical Center	Recruitment of Established Investigator Nomination of Marco Durante	\$3,000,000	2.2
12	RR140053	Texas A&M University Health Science Center Institute of Biosciences and Technology	Recruitment of First-Time, Tenure- Track Nomination of Yun Huang	\$1,800,000	2.8
13	RR140013	The University of Houston	Recruitment of First-Time, Tenure- Track Nomination of David Mayerich	\$2,000,000	2.8
14	RR140008	Texas Tech University Health Sciences Center	Recruitment of Rising Stars Nomination of Kevin Pruitt	\$2,539,259	2.8



#### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

## CEO AFFIDAVIT Application RR140008 Recruitment of Rising Stars Nomination of Kevin Pruitt

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of Rising Stars Nomination of Kevin Pruitt Request for Applications (RFA). CPRIT received 7 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. Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

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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 by WAYNE R. ROBERTS.	lersigned authority, on, 2014,
Sandra Reyes Notary Public, State of Texas	PANDRA J. REYES  Notary Public, State of Texas  My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CEO Affidavit Page 2

### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research

AWARD MECHANISM Recruitment of Rising Stars (RRS)

APPLICATION ID RR140008

**APPLICATION TITLE** Recruitment of Rising Stars - Pruitt

APPLICANT NAME Berk, Steven

ORGANIZATION Texas Tech University Health Sciences Center

PANEL NAME Recruitment Review Panel – 2 (RRP-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
1 Due Dennius	Date application submitted	03/12/14	05/09/14
1. Pre-Receipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
•	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	4/3/2014	05/09/14
	Primary Reviewer 2 COI signed	4/2/2014	05/09/14
	Primary Reviewer 1 critique submitted	04/07/14	05/09/14
	Primary Reviewer 2 critique submitted	04/14/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference	Peer Review: Teleconference Meeting	04/17/14	05/09/14
Meeting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
4. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
- non-1	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	and the
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



#### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

## CEO AFFIDAVIT Application RR140012

#### Recruitment of First-Time, Tenure-Track Nomination of Cullen Taniguchi

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of Cullen Taniguchi Request for Applications (RFA). CPRIT received 14 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

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 13th day of May by WAYNE R. ROBERTS.	undersigned authority, on, 2014,
ZX6/W_	_
Sandra Reyes	SANDRA J. REYES
Notary Public, State of Texas	Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

FY 2014 CYCLE 1

PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR140012

APPLICATION TITLE Recruitment of First-Time, Tenure-Track Faculty - Dr. Cullen

Taniguchi

APPLICANT NAME Dmitrovsky, Ethan

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
1 Due Deseint	Date application submitted	03/03/14	05/09/14
1. Pre-Receipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	4/3/2014	05/09/14
	Primary Reviewer 2 COI signed	4/3/2014	05/09/14
17.00	Primary Reviewer 1 critique submitted	04/07/14	05/09/14
	Primary Reviewer 2 critique submitted	04/16/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference	Peer Review: Teleconference Meeting	04/17/14	05/09/14
Meeting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
4. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	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	



## CEO AFFIDAVIT Application RR140013

#### Recruitment of First-Time, Tenure-Track Nomination of David Mayerich

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of David Mayerich Request for Applications (RFA). CPRIT received 14 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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.

K	ay RND
Wayne R.	Roberts,
CEO, Cano	er Prevention and Research Institute of Texas

This statement is true."

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the under	ersigned authority, on
the 13th day of May	, 2014,
by WAYNE R. ROBERTS. $0$	
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 2014 CYCLE 1

PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR140013

APPLICATION TITLE

NOMINATION of David Mayerich for the CPRIT Scholar in

Cancer Research Program

APPLICANT NAME Roysam, Badrinath
ORGANIZATION University of Houston

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
1 Due Dessint	Date application submitted	03/05/14	05/09/14
1. Pre-Receipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/15/14	05/09/14
	Primary Reviewer 2 COI signed	04/02/14	05/09/14
	Primary Reviewer 1 critique submitted	04/15/14	05/09/14
	Primary Reviewer 2 critique submitted	04/14/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
Meering	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
4. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
F DIC D1	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
6. 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	
	Advance authority approved by Oversight Committee	YES/NO	



# CEO AFFIDAVIT Application RR140023 Recruitment of First-Time, Tenure-Track Nomination of Gary Hon

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of Gary Hon Request for Applications (RFA). CPRIT received 14 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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

FY 2014 CYCLE 1

PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR140023

APPLICATION TITLE Genomic Interrogation and Computational Modeling of

**Enhancer Dysregulation in Cancer** 

APPLICANT NAME Fitz, John

ORGANIZATION The University of Texas Southwestern Medical Center

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
1 Due Dessint	Date application submitted	03/05/14	05/09/14
1. Pre-Receipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/02/14	05/09/14
	Primary Reviewer 2 COI signed	04/03/14	05/09/14
	Primary Reviewer 1 critique submitted	04/14/14	05/09/14
	Primary Reviewer 2 critique submitted	04/10/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
Meeting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
4. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
F 010 D	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. 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 RR140025 Recruitment of First-Time, Tenure-Track Nomination of Jian Xu

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of Jian Xu Request for Applications (RFA). CPRIT received 14 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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."
namen 13
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 13th day of May	, 2014,
by WAYNE R. ROBERTS. $O$	
Λ Λ	
, 201	SANDRA L REYES
Sandra Reyes	Notary Public, State of Texas
Notary Public, State of Texas	SEPTEMBER \$0, 2017
Notary I ublic, State of Texas	Notary without Bond

**FY** 2014 **CYCLE** 1

PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR140025

APPLICATION TITLE Context-Specific Functions of PRC2 in Hematopoietic

**Development and Oncogenesis** 

APPLICANT NAME Fitz, John

**ORGANIZATION** The University of Texas Southwestern Medical Center

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
d Due Dessint	Date application submitted	03/12/14	05/09/14
1. Pre-Receipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
No.	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
•	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/03/14	05/09/14
	Primary Reviewer 2 COI signed	04/03/14	05/09/14
View View China	Primary Reviewer 1 critique submitted	04/15/14	05/09/14
	Primary Reviewer 2 critique submitted	04/09/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
Meeting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
4. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
A COMPANY OF THE PARTY OF THE P	COI indicated by PIC member	NONE	05/14/14
4	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
V/3////	CEO Notification to Oversight Committee	DATE	and the second second
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. 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	70.000000000000000000000000000000000000



## CEO AFFIDAVIT Application RR140027

#### Recruitment of First-Time, Tenure-Track Nomination of Priscilla Brastianos

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of Pricilla Brastianos Request for Applications (RFA). CPRIT received 14 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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.

Kurkent	
Wayne R. Roberts.	

This statement is true."

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 by WAYNE R. ROBERTS.	ersigned authority, on, 2014,
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 2014

CYCLE 1

PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR140027

APPLICATION TITLE Recruitment of First-time, Tenure Track- Dr. Brastianos

APPLICANT NAME Dmitrovsky, Ethan

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
	Date application submitted	03/28/14	05/09/14
1. Pre-Receipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/03/14	05/09/14
	Primary Reviewer 2 COI signed	04/03/14	05/09/14
	Primary Reviewer 1 critique submitted	04/13/14	05/09/14
	Primary Reviewer 2 critique submitted	04/15/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
B. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
viceting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
I. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
	COI recused from participation	N/A	05/14/14
. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	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 RR140033 Recruitment of Established Investigator Nomination of Matthew Ellis

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of Established Investigator Nomination of Matthew Ellis Request for Applications (RFA). CPRIT received 4 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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 13th day of May	
by WAYNE R. ROBERTS. $oldsymbol{\delta}$	
M	Notary Public, State of Texas My Commission Expires
Sandra Reyes	SEPTEMBER 30, 2017
Notary Public, State of Texas	Notary without Bond

**FY** 2014 **CYCLE** 1

PROGRAM Research

AWARD MECHANISM Recruitment of Established Investigators (REI)

APPLICATION ID RR140033

APPLICATION TITLE Dr. Matt Ellis: Established Investigator Recruit

APPLICANT NAME Kuspa, Adam

ORGANIZATION Baylor College of Medicine

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
1. Pre-Receipt	Date application submitted	03/31/14	05/09/14
1. Fre-Neceipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/03/14	05/09/14
	Primary Reviewer 2 COI signed	04/03/14	05/09/14
9	Primary Reviewer 1 critique submitted	04/10/14	05/09/14
	Primary Reviewer 2 critique submitted	04/13/14	05/09/14
	CO! indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
Meeting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
NASANDA - INC.	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
4. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
5. 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	11.00
	Advance authority approved by Oversight Committee	YES/NO	



## CEO AFFIDAVIT Application RR140035

#### Recruitment of First-Time, Tenure-Track Nomination of Samira Azarin

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of Samira Azarin Request for Applications (RFA). CPRIT received 14 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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.

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$\perp 1  \mathrm{ms}$	statem	eni	18	irue.	

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 13th day of 1014,
by WAYNE R. ROBERTS.
Sandra Reyes SANDRA J. REYES
Notary Public, State of Texas  SEPTEMBER 30, 2017
Notary without Bond

**FY** 2014 **CYCLE** 1

PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR140035

APPLICATION TITLE Elucidating mechanisms of cellular dormancy for cancer

therapeutics

APPLICANT NAME Thomas, Edwin ORGANIZATION Rice University

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
	Date application submitted	03/31/14	05/09/14
1. Pre-Receipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/15/14	05/09/14
	Primary Reviewer 2 COI signed	04/03/14	05/09/14
	Primary Reviewer 1 critique submitted	04/15/14	05/09/14
	Primary Reviewer 2 critique submitted	04/13/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
Meering	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
4. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
r nich-d-	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. 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	- Patter



# CEO AFFIDAVIT Application RR140036 Recruitment of First-Time, Tenure-Track Nomination of Weibo Lu

#### THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of Weibo Luo Request for Applications (RFA). CPRIT received 14 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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.

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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	undersigned authority, on, 2014,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Taxas  My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

FY 2014 CYCLE 1

PROGRAM Research

**AWARD MECHANISM** Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR140036

APPLICATION TITLE The Role of Hypoxia-Inducible Factor 1 in Breast Cancer

APPLICANT NAME Fitz, John

**ORGANIZATION** The University of Texas Southwestern Medical Center

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
	Date application submitted	03/19/14	05/09/14
1. Pre-Receipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/03/14	05/09/14
	Primary Reviewer 2 COI signed	04/02/14	05/09/14
Successful Control	Primary Reviewer 1 critique submitted	04/13/14	05/09/14
	Primary Reviewer 2 critique submitted	04/14/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
Wieeting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
50/8 (III - 910) S - 10 - 10 - 10 - 10 - 10 - 10 - 10 -	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
4. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
1	COI indicated by PIC member	NONE	05/14/14
	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	The silentine
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 RR140038

#### Recruitment of First-Time, Tenure-Track Nomination of Andre Catic

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of Andre Catic Request for Applications (RFA). CPRIT received 14 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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	rsigned authority, on
the 13th day of Mry	, 2014,
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

2014

CYCLE

1

**PROGRAM** 

Research

AWARD MECHANISM

Recruitment of First-Time Faculty Members (RFTFM)

**APPLICATION ID** 

RR140038

APPLICATION TITLE

Dr. Andre Catic, First-time Tenure Track Recruit

APPLICANT NAME

Kuspa, Adam

ORGANIZATION

**Baylor College of Medicine** 

PANEL NAME

Recruitment Review Panel - 2 (RRP-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
l Duo Dosoint	Date application submitted	03/31/14	05/09/14
1. Pre-Receipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
ind Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/02/14	05/09/14
	Primary Reviewer 2 COI signed	04/03/14	05/09/14
CONTRACTOR OF THE PARTY OF THE	Primary Reviewer 1 critique submitted	04/14/14	05/09/14
	Primary Reviewer 2 critique submitted	04/16/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
B. Peer Review:	COI recused from participation	N/A	05/09/14
eleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
AICECITIE	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
20	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
non I	COI recused from participation	N/A	05/14/14
i. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	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	



## CEO AFFIDAVIT Application RR140042

#### Recruitment of First-Time, Tenure-Track Nomination of Laura Banaszynski

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of Laura Banaszynski Request for Applications (RFA). CPRIT received 14 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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.

May 2 M
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

This statement is true."

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the the 13th day of May by WAYNE R. ROBERTS.	undersigned authority, on, 2014,
Sandra Reyes Notary Public, State of Texas	Notary Public, State of Taxase My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

FY 2014 CYCLE 1

PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR140042

**APPLICATION TITLE** The Role of Histone Variants in Pediatric Gliomas

APPLICANT NAME Fitz, John

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Recruitment Review Panel – 2 (RRP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
	Date application submitted	03/25/14	05/09/14
	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
12775.	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/02/14	05/09/14
	Primary Reviewer 2 COI signed	04/03/14	05/09/14
N-E-VII	Primary Reviewer 1 critique submitted	04/14/14	05/09/14
	Primary Reviewer 2 critique submitted	04/16/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
eleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
weeting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
. Final SRC	SRC Meeting	04/17/14	05/09/14
tecommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
	COI recused from participation	N/A	05/14/14
. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
6. Oversight	COI recused from participation	YES/NO or N/A	-
	Donation(s) made to CPRIT/foundation	YES/NO OF IN/I	
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	(

The identity of the attesting party is retained by CPRIT



# CEO AFFIDAVIT Application RR140049 Recruitment of Established Investigator Nomination of Marco Durante

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of Established Investigator Nomination of Marco Durante Request for Applications (RFA). CPRIT received 4 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I 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.

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

This statement is true."

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the	-
	, 2014,
by WAYNE R. ROBERTS.	
M	SAMDRA J. REYES  Notary Public, State of Texas  My Commission Expires SEPTEMBER 30, 2017
Sandra Reyes	Notary without Bond
Notary Public, State of Texas	

FY 2014
CYCLE 1
PROGRAM Research

AWARD MECHANISM Recruitment of Established Investigators (REI)

APPLICATION ID RR140049

APPLICATION TITLE Biophysical Effects of Charged Particles and Their

**Application to Cancer Therapy** 

APPLICANT NAME Fitz, John

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME Recruitment Review Panel – 2 (RRP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
	Date application submitted	03/27/14	05/09/14
	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/15/14	05/09/14
	Primary Reviewer 2 COI signed	04/03/14	05/09/14
	Primary Reviewer 1 critique submitted	04/15/14	05/09/14
	Primary Reviewer 2 critique submitted	04/10/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
3. Peer Review:	COI recused from participation	N/A	05/09/14
Teleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
viceting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
I. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
DIC Davidson	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	CEO Notification to Oversight Committee	DATE	
6. Oversight Committee Approval	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	W. O. William
	Advance authority approved by Oversight Committee	YES/NO	dan markatan da ka

The identity of the attesting party is retained by CPRIT



# CEO AFFIDAVIT Application RR140052 Recruitment of Established Investigator Nomination of John Tanier

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of Established Investigator Nomination of John Tanier Request for Applications (RFA). CPRIT received 4 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.

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

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

This statement is true "

undersigned authority, on, 2014,
SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Notary without Bond

FY 2014 CYCLE 1

PROGRAM Research

AWARD MECHANISM Recruitment of Established Investigators (REI)

APPLICATION ID RR140052

APPLICATION TITLE Recruitment of Established Investigator - Dr. John Tainer

APPLICANT NAME Dmitrovsky, Ethan

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	03/14/14	05/09/14
	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
	Date application submitted	03/31/14	05/09/14
	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral,	Assigned to primary reviewers	04/06/14	05/09/14
and Assignment	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/03/14	05/09/14
	Primary Reviewer 2 COI signed	04/02/14	05/09/14
	Primary Reviewer 1 critique submitted	04/15/14	05/09/14
	Primary Reviewer 2 critique submitted	04/14/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
. Peer Review:	COI recused from participation	N/A	05/09/14
eleconference Meeting	Peer Review: Teleconference Meeting	04/17/14	05/09/14
viceting	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
l. Final SRC	SRC Meeting	04/17/14	05/09/14
Recommendation	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
	COI recused from participation	N/A	05/14/14
. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	CEO Notification to Oversight Committee	DATE	
6. Oversight Committee Approval	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	(d.1100)
	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 RR140053 Recruitment of First-Time, Tenure-Track Nomination of Yun Huang

THE STATE OF TEXAS

#### **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the Recruitment of First-Time, Tenure-Track Nomination of Yun Huang Request for Applications (RFA). CPRIT received 14 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.

- 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. Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

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Wayne R. Roberts,

This statement is true."

CEO, Cancer Prevention and Research Institute of Texas

County of Travis	
•	
SWORN to and SUBSCRIBED before me, the day of day by WAYNE R. ROBERTS.	ne undersigned authority, on, 2014,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES  Notary Public, State of Texas  My Commission Expires SEPTEMBER 30, 2017  Notary without Bond

**CEO Affidavit** 

### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2014 CYCLE 1

PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR140053

APPLICATION TITLE Recruitment of Dr. Yun (Nancy) Huang

APPLICANT NAME Giroir, Brett

ORGANIZATION Texas A&M University Health Science Center Institute of Biosciences and Technology

PANEL NAME Recruitment Review Panel – 2 (RRP-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	03/14/14	05/09/14
1. Pre-Receipt  2. Receipt, Referral, and Assignment  3. Peer Review: Teleconference Meeting  4. Final SRC Recommendation  5. PIC Review  6. Oversight	CPRIT Application Receipt System (CARS) opened	03/03/14	05/09/14
	CPRIT Application Receipt System (CARS) closed	03/31/14	05/09/14
1 Dro Bossint	Date application submitted	03/28/14	05/09/14
1. Pre-keceipt	Method of submission	CARS	05/09/14
	Within receipt period	YES	05/09/14
	Appeal to submit application after CARS closed	N/A	05/09/14
	Appeal for late application submission accepted	N/A	05/09/14
	Administrative review notification	N/A	05/09/14
	Donation(s) made to CPRIT/foundation	NO	05/09/14
2. Receipt, Referral, and Assignment  3. Peer Review: Teleconference Meeting  4. Final SRC Recommendation  5. PIC Review  6. Oversight	Assigned to primary reviewers	04/06/14	05/09/14
	Applicant notified of review panel assignment	N/A	05/09/14
	Primary Reviewer 1 COI signed	04/02/14	05/09/14
	Primary Reviewer 2 COI signed	04/03/14	05/09/14
	Primary Reviewer 1 critique submitted	04/14/14	05/09/14
	Primary Reviewer 2 critique submitted	04/16/14	05/09/14
	COI indicated by non-primary reviewer	NONE	05/09/14
Teleconference	COI recused from participation	N/A	05/09/14
	Peer Review: Teleconference Meeting	04/17/14	05/09/14
Meering	Post review statements signed	04/22/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Score report delivered to CSO	04/22/14	05/09/14
	COI indicated by SRC member	NONE	05/09/14
	COI recused from participation	N/A	05/09/14
2. Receipt, Referral, and Assignment  3. Peer Review: Teleconference Meeting  4. Final SRC Recommendation	SRC Meeting	04/17/14	05/09/14
	Third Party Observer Report	04/17/14	05/09/14
	Recommended for grant award	YES	05/09/14
	SRC Chair Notification to PIC and OC	05/06/14	05/09/14
	COI indicated by PIC member	NONE	05/14/14
	COI recused from participation	N/A	05/14/14
5. PIC Review	PIC review meeting	05/13/14	05/09/14
	Recommended for grant award	YES	05/14/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight	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	



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# CPRIT Product Development Activities: Program Principles and Strategies

## **CPRIT** should identify commercial entities to develop products that will benefit cancer patients.

Gaps exist in the market's ability to translate research insights and product visions into FDA approved, commercially available products. Some of these gaps are well known, *e.g.*, the difficulty that many early-stage cancer companies have in securing their first rounds of funding. Other gaps may be specific to certain products or types of cancer.

These gaps may delay, or even deny, cancer patient access to important scientific advances. CPRIT should work to bridge these gaps, leveraging its funds with matching funds from other sources.

## CPRIT should selectively deploy its resources where they are most needed and can do the most good.

More scientifically and commercially sound product development opportunities exist than CPRIT is capable of funding. Thus, CPRIT should:

- <u>not</u> act in competition with existing support programs, private funding sources, or other state funding sources such as the Texas Emerging Technology Fund;
- balance the desire to do "the greatest good for the greatest number" with opportunities to impact commercially neglected cancers and cancer-related conditions;
- use its funds to attract matching funds from other sources; and
- take risks in its investments, funding projects that might be "game changing" or disruptive.

## Texans should be fairly compensated for the capital they provide to commercial enterprises through CPRIT.

Unlike most academic research awards, product development grants are made to for-profit ventures. While CPRIT does not provide the management services to a new business that venture investors typically do, its grant monies and diligence are high value-added contributions for which there should be fair compensation.

CPRIT's return from any product development grant awarded should be:

- "success based," that is, based on revenues received by the grantee from the sale of something developed or approved through the use of CPRIT funding;
- proportional to the amount of the grant; and
- larger when the grant is made to a more established company that is closer to market and might alternatively have access to venture funding.

## The rate of compensation required from commercial grant recipients should be uniform for similarly sized grants and for companies at similar stages in their development.

Venture investors operate privately and are responsible only to their partners for the terms they dictate to companies. CPRIT, in contrast, operates publicly and is responsible for its activities to its Oversight Committee, the legislature and the taxpayers. This calls for established terms and conditions of revenue sharing known by all – both applicants and investors - ahead of time. Such terms may be modified for good cause, but only when a clear rationale is stated in the agreement. This policy promotes consistency and transparency.

## CPRIT's revenue sharing requirements should not weaken the recipient company or discourage future investments from private sources of capital.

Cash is a critical resource for companies without revenues from products already in the market. Payments analogous to upfront license issue fees, license maintenance fees, diligence, minimum royalty, and milestone payments by a company, prior to product launch, weaken the cash position of the company and discourage later-stage investors. CPRIT should not require these types of payments.

#### CPRIT should be able to:

- take equity in the companies it funds under terms and conditions validated by a third-party investor;
- allow its obligations for revenue sharing to be bought out by the grantee in order to unencumber the company; and
- cap its total return from revenue sharing at reasonable multiples of the grant award.

## CPRIT should structure its compensation requirements to achieve its program priority goals and humanitarian objectives ahead of considerations of maximizing economic return.

Time is critical to cancer patients. CPRIT's support of product development in commercial ventures should encourage speed to market by:

- simplifying finalizing award contracts;
- not requiring pre-revenue fees or payments that could discourage later stage investors; and
- setting its royalty buyout fee to increase over time after the conclusion of the award contract in order to incentivize follow-on investors to conclude a buyout deal.

CPRIT should not seek any return on its investment from products used only in clinical trials or from commercial products or commercial services provided on a compassionate basis, that is, where the providing company does not profit.

#### How should these principles be worked out in CPRIT's award contracts?

Revenue sharing provisions are required in all CPRIT grant award contracts. Specifically, Section 102.256 of the Health and Safety Code states:

- (a) The oversight committee shall establish standards that require all grant awards to be subject to an intellectual property agreement that allows the state to collect royalties, income, and other benefits, including interest or proceeds resulting from securities and equity owner-ship, realized as a result of projects undertaken with money awarded under Subchapter E.
- (b) In determining the state's interest in any intellectual property rights, the oversight committee shall balance the opportunity of the state to benefit from the patents, royalties, licenses, and other benefits that result from basic research, therapy development, and clinical trials with the need to ensure that essential medical research is not unreasonably hindered by the intellectual property agreement and that the agreement does not unreasonably remove the incentive on the part of the individual researcher, research team, or institution."

CPRIT's proposal to satisfy the requirements of the statute is included below. This proposal incorporates the following features:

- Revenue sharing terms are consistent, transparent, and commercially reasonable. We believe they balance the interests required in § 102.256(b) above.
- Revenue return is dependent on the size of the grant award and the commercial maturity of the recipient company.
- Revenue buyout terms are provided to allow a company to unencumber itself for late stage investment, if necessary.
- CPRIT may accept equity, at its discretion, for the buyout fee. It would do so only when there is a third-party valuation of the company, as in a later investment round.
- The revenue buyout fee increases with time after the completion of the CPRIT grant so as to encourage speed to market and return of money to the state.
- Any *required* return of revenue to the state is dependent on sales. Note that the revenue buyout is optional and at the sole discretion of the company. There are no requirements for milestones or other pre-revenue payments that might weaken a company's cash position prior to getting a product in the marketplace.

Proposed language for revenue sharing found in Attachment D, Section 4 for the standard CPRIT Contract Attachment D:

### PART 4 REVENUE SHARING

**Section D4.01 Revenue Sharing Payments; Revenue Sharing Buyout.** In consideration for the monies paid to RECIPIENT by INSTITUTE under the Contract:

- a. RECIPIENT shall pay to INSTITUTE:
- (i) A% of all Revenues until the aggregate amount of payments made to INSTITUTE pursuant to this Section D4.01a(i) equals 200% of Grant Award Proceeds; and
  - (ii) B% of all Revenues thereafter.
- b. RECIPIENT shall have the option at any time after the termination of the Contract to discontinue any payments to INSTITUTE under Section D4.01a above after payment to the INSTITUTE of a one time, non-refundable revenue sharing buyout fee ("Buyout Fee"). The Buyout Fee shall be calculated as follows:

Buyout Fee = 
$$(1 + (Months/12)) \times C \times Grant Award Proceeds$$

where, "Months" shall equal the sum of the number of full months following the termination date of the Contract up until and including the month in which the Buyout Fee is actually paid to INSTITUTE. The value of "Months" shall not be greater than 60.

For clarity, the month in which the Buyout Fee is paid shall count as a full month, any monies paid under D4.01a shall <u>not</u> be creditable against the Buyout Fee, the factor " $(1 + (Months/12)) \times C$ " shall in no case be less than 1.10, and after payment in full to INSTITUTE of the Buyout Fee, RECIPIENT shall have no further obligations under this Section D4.01.

c. The values of "A", "B", and "C" in this Section D4.01 shall be guided by the commercial maturity of the RECIPIENT and the amount of the Grant according to the following matrix:

	Grant is eight million dollars (\$8,000,000) or less.	Grant is greater than eight million dollars (\$8,000,000).
RECIPIENT has received aggregate professional investment of twelve million	A = 4.0	A = 5.0
dollars (\$12,000,000) or more,	B = 2.0	B = 3.0
exclusive of any matching funds required for the Grant.	C = 1.3	C = 1.6
RECIPIENT has <u>not</u> received aggregate professional investment of twelve million	A = 3.0	A = 4.0
dollars (\$12,000,000) or more, exclusive of any matching funds required for the Grant.	B = 1.5	B = 2.0
	C = 0.7	C = 0.9

For the purposes of the Contract, including this Attachment D, the RECIPIENT and INSTITUTE agree that the values of "A" and "B" in Section D4.01a above shall be \_\_\_\_ and \_\_\_\_, respectively, and that the value of "C" in Section D4.01b above shall be \_\_\_\_ .

d. In its sole discretion, INSTITUTE may accept a mutually agreed upon amount of equity in satisfaction of the Buyout Fee described in Section D4.01b above.

**Section D4.02 Adjustments.** If any funding source other than the INSTITUTE (but excluding RECIPIENT and any investors in RECIPIENT who receive equity, debt obligation or other consideration for their funding) contributes funds, directly or indirectly, to the RECIPIENT's research yielding or contributing to any particular Commercial Product or Commercial Service and such funding source is legally or contractually entitled to receive sales-based royalty compensation with respect to such Commercial Product or Commercial Service (hereinafter a "Participating Funding Source"), then the percentages in Section D4.01a(i) and (ii) in effect at any time shall be reduced by multiplying them by the Adjustment Factor. The Adjustment Factor shall be calculated as follows:

Adjustment Factor = X/(X + Y)

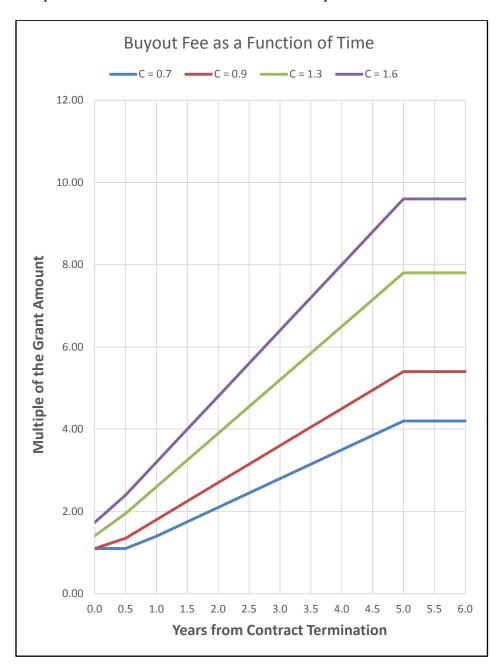
where,

X = the Grant Award Proceeds, and

Y = the sum of all monies paid to RECIPIENT by all Participating Funding Sources.

The above notwithstanding, the Adjustment Factor shall not be less than 0.5. For the sake of clarity, Participating Funding Sources do not include equity or quasi-equity financing funding sources or debt arrangements. In calculating the Adjustment Factor, funds from Participating Funding Sources used for Indirect Costs or for any costs of product development, manufacturing, marketing, sales, regulatory approval or similar commercialization activities shall not be included. In addition, for clarity, the percentages in Section D4.01a(i) and (ii) shall not be reduced as a result of any funds received from funding sources where such funding sources are not legally or contractually entitled to receive sales-based royalty compensation with respect to such Commercial Product or Commercial Service.

Graphically, the operation of the Buyout Fee can be described as a function of time after completion of the Contract for each of the four quadrants of the matrix above as:





## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: THOMAS GOODMAN, PhD, CHIEF PRODUCT DEVELOPMENT OFFICER

KRISTEN DOYLE. GENERAL COUNSEL

**SUBJECT:** PROPOSED CONTRACT TERMS FOR PRODUCT DEVELOPMENT

AWARDS RATIFIED FEBRUARY 19, 2014

**DATE:** MAY 16, 2014

#### **Summary and Recommendation**

We recommend that the Oversight Committee delegate contract execution authority to CPRIT's CEO to execute grant award contracts consistent with the terms and conditions outlined in the Attachment below. Delegation of contract execution authority for six companies with awards ratified at the February 2014 meeting was contingent on the Oversight Committee's consideration of negotiated milestones, tranching, revenue sharing terms, and satisfaction of issues raised by the Product Development Review Council during the due diligence process.

It is Dr. Goodman's opinion that the deal terms and tranching presented in the Attachment are consistent with the proposals, appropriately mitigate risks, and provide an opportunity for return to the state of Texas while not unreasonably impacting the companies' ability to raise future funding. Dr. Goodman is not yet ready to propose final deal terms for the Oversight Committee's consideration with one company, ProNAi. We will continue to work with ProNAi and hope to bring proposed deal terms forward for consideration at a future Oversight Committee meeting.

#### **Contract Process Overview**

State law requires grant funding recommendations to be ratified by the Oversight Committee as the final step in the application review process. However, approval of the grant recommendation does not entitle an applicant to receive grant funds. The statute is clear that a grant is <u>awarded</u> by signing a written grant contract. Disbursement of grant funds is contingent upon a final contract.

The statutory bifurcation of the grant recommendation approval and award contract is meaningful. The statute lays out several issues that must be included and agreed to in the award contract, including revenue sharing terms. Therefore, it is possible that a project may be approved by the Oversight Committee for CPRIT grant funding, but the grant is never awarded (and grant funds are not disbursed) because the applicant cannot agree to CPRIT's contractual terms. If no agreement is reached, the contract is not executed, and grant funds set aside for the project are released.

The statute directs that, "the Oversight Committee shall negotiate on behalf of the state regarding awarding, by grant, money under this chapter." It has been the standard practice for the Committee to approve a motion delegating contract negotiation authority to CPRIT's CEO and General Counsel and authorizing the CEO to execute the award contract following the ratification of the grant recommendations by the Oversight Committee.

#### **Contract Process for Product Development**

For Product Development grant projects, CPRIT ties the disbursement of grant funds to the achievement of defined milestones that are specified in the grant contract. Each slice of funding, commonly known as a tranche, and its associated objectives or deliverables are negotiated and included in the award contract.

Tranching adds complexity, both to contract negotiation and to contract monitoring, but it is an effective way to limit CPRIT's risk exposure. Although the total award amount for the project must be ratified by the Oversight Committee, the grantee receives only enough grant funds to accomplish the specified milestones within the particular tranche. The company must demonstrate successful completion through a written report detailing how the company has achieved the milestones tied to a specific tranche in order to access the next amount of grant funding. Expert reviewers assess the work done by the company and recommend the release of the next tranche of funding or that funding be terminated.

Tranches for the grant project are developed using deal-specific documentation, including:

- <u>Information supplied by the applicant</u>. Applicants are asked to provide specific goals and associated timelines for the proposed project in the application. The aims and timeline are evaluated during the review process, and the reviewers may indicate a change to be included in the contract or an issue to be negotiated.
- <u>Information from the due diligence review</u>. Icon, the company that performs due diligence reviews of CPRIT's Product Development applications, provides guidance on appropriate milestones to be achieved during the course of the project.
- <u>Information from the intellectual property review</u>. IP counsel may provide recommendations regarding specific steps to be taken regarding protecting IP, ensuring freedom to operate, or cleaning up problematic licensing agreements.

Icon, IP counsel, or the Review Council may identify an issue that, if not corrected or adequately addressed prior to contract, could be a reason for CPRIT not executing the contract. Although this is not technically a tranche recommendation, this information impacts the contract negotiations. For example, the IP and licensing review may identify an issue with the license agreement for the underlying technology that, if not resolved, is a deal breaker. CPRIT will direct the company to fix the underlying licensing issue (usually through renegotiation of the underlying licensing agreement) before contract negotiation with CPRIT can begin.

Two other important points are the agreed revenue sharing payments and revenue sharing buyout amount payable to CPRIT. These are determined by the size of the grant and the commercial maturity of the company according to the following schematic.

In the schematic below, "A" is the percentage of sales paid to CPRIT by the grant recipient until the total amount paid is equal to 200% of the grant amount; "B" is the percentage of sales paid to CPRIT by the grant recipient thereafter; and "C" is a factor affecting the buyout fee. The buyout fee is the amount of money that the grant recipient must pay to CPRIT to eliminate all future payments based on sales. It is calculated as follows:

Buyout fee =  $(1 + \text{number of years after the grant}) \times C \times \text{amount of the grant award}$ 

	Grant is eight million dollars (\$8,000,000) or less.	Grant is greater than eight million dollars (\$8,000,000).
RECIPIENT has received aggregate professional investment of twelve million dollars (\$12,000,000) or more, exclusive of any matching funds required for the Grant.	A = 4.0 $B = 2.0$ $C = 1.3$	A = 5.0 $B = 3.0$ $C = 1.6$
RECIPIENT has <u>not</u> received aggregate professional investment of twelve million dollars (\$12,000,000) or more, exclusive of any matching funds required for the Grant.	A = 3.0 $B = 1.5$ $C = 0.7$	A = 4.0 $B = 2.0$ $C = 0.9$

The above revenue sharing terms are the only revenue sharing terms present in the CPRIT contract. This results in the following features:

- Revenue sharing terms are consistent, transparent, and commercially reasonable. We believe they balance the interests required in § 102.256(b).
- Revenue return is dependent on the size of the grant award and the commercial maturity of the recipient company.
- Revenue buyout terms are provided to allow a company to unencumber itself for late stage investment, if necessary.
- CPRIT may accept equity, at its discretion, for the buyout fee. It would do so only when there is a third-party valuation of the company, as in a later investment round.
- The revenue buyout fee increases with time after the completion of the CPRIT grant so as to encourage speed to market and return of money to the state.
- Any *required* return of revenue to the state is dependent on sales. Note that the revenue buyout is optional and at the sole discretion of the company. There are no requirements for milestones or other pre-revenue payments that might weaken a company's cash position prior to getting a product in the marketplace.

#### **Oversight Committee Contract Review and Approval Prior to Final Execution**

The Oversight Committee delegated contract negotiation authority to CPRIT staff to finalize deal terms for the six Product Development grant awards ratified at the February 19, 2014 meeting. Over the past month, Dr. Goodman has negotiated with representatives of the six companies. Terms that are believed to be satisfactory have been reached with five of the six. A recommendation with regard to ProNAi (see below) may be brought forward at a future meeting of the Oversight Committee.

It is Dr. Goodman's opinion that the deal terms presented in the Attachment below are consistent with the applications, appropriately mitigate risks, and provide an opportunity for return to the state of Texas while not unreasonably impacting the companies' ability to raise future funding.

We recommend that the Oversight Committee delegate contract execution authority to CPRIT's CEO to execute a final award contract consistent with the terms and conditions outlined in the Attachment.

#### **ATTACHMENT**

#### 1. Beta Cat - Company Formation

Company and Project Summary (written by the company): Beta Cat Pharmaceuticals specializes in developing novel cancer drugs that attack molecular targets never before addressed clinically. Our first drug, BC2059, inhibits the beta catenin pathway and represents a major breakthrough. Many cancers have abnormal activation of this pathway, but despite much industry effort, no drugs have been developed previously that address it. Beta Cat has succeeded by attacking a novel target in the pathway. BC2059 has very low toxicity but is highly effective at killing tumor cells. We first will test the drug in colorectal carcinoma and in myelodysplastic syndrome, an orphan drug indication. We also have a promising second generation program that we hope to move from intravenous to oral administration and further enhance the pharmacokinetics of attacking the target, broadening the potential applications for our therapies. In addition, we will continue to work to develop sustained release formulations for our lead molecule for patient convenience. We plan to locate in Texas to develop our innovative drug, our second generation compounds, as well as add and discover drugs targeting additional pathways. In addition to our internal research programs, we also plan to collaborate with Texas academic centers to identify compounds that broaden and extend our pipeline, in order to develop into a pharmaceutical company that could have a large economic impact in Texas. Beta Cat seeks to transition from a virtual to a "bricks and mortar" company.

<u>Proposed Milestones and Tranching</u>: The total award requested from CPRIT is \$15,908,085. The grants funds would be distributed in three tranches, contingent upon successful achievement of the milestones set forth below.

**Tranche 1**: \$5 Mil CPRIT (matched with \$2.5 Mil private) Beta Cat requests initial funding to achieve the following milestones in the first year:

- 1. move and establish itself in Texas in rented facilities
- 2. incorporate
- 3. match an initial round of financing
- 4. purchase equipment and reagents for discovery efforts
- 5. hire and move an initial team of at least 5 individuals

According to Beta Cat, the company has already been raising money with a select group of venture capitalists and high net worth individuals.

**Tranche 2**: \$5 Mil CPRIT (matched with \$2.5 Mil private) Beta Cat requests a second tranche of funding to achieve the following milestones in the second year of the project:

- 1. complete all preclinical studies for BC2059 prodrug or tween
- 2. complete drug substance and drug product for GLP and clinical studies
- 3. complete cGLP toxicology studies
- 4. file an IND for clinical studies
- 5. hire another 5 individuals

Beta Cat expects to submit for our second tranche of funding, having completed all Milestone 1 activities, shown good progress in advancing BC2059 tween or prodrug, and in advancing its second generation program toward an oral agent, as of mid or late 2015, or perhaps somewhat sooner.

**Tranche 3:** \$5.908085 Mil CPRIT (matched with \$2.969365.5 Mil private) Beta Cat requests a third tranche of funding to achieve the following milestones in the third year of the project:

- 1. begin and complete a phase 1 study in AML
- 2. begin and complete a second study, likely in colon cancer
- 3. do biomarker studies on nuclear beta catenin levels in the two phase 1's
- 4. hire another 5 individuals
- 5. complete preclinical studies to determine good combinations with BC2059 in key diseases for phase 1b.

<u>Proposed Revenue Sharing Terms</u>: The revenue sharing terms in the contract shall read, "For the purposes of the Contract, including this Attachment D, the RECIPIENT and INSTITUTE agree that the values of "A" and "B" in Section D4.01a above shall be 4.0 and 2.0, respectively, and that the value of "C" in Section D4.01b above shall be 0.9."

Since Beta Cat is requesting more than \$8 million but has not received more than \$12 million of aggregate professional investment, they fall into the lower right hand quadrant of the revenue sharing matrix described in the memorandum. As an example of the operation of the buyout fee in this case, where "C" equals 0.9, if Beta Cat (possibly through a late-stage investor or acquirer) wishes to buy out the continuing revenue sharing at a point two years after the conclusion of the contract, they could do so for:

Buyout fee = 
$$(1 + 2) \times (0.9) \times (\$15,908,085) = \$42,951,830$$

Each additional year that they wait after contract completion costs them (their subsequent investors) an additional  $0.9 \times (\$15,908,085) = \$14,317,276$ . Thus, they are incentivized to move quickly. If the third party investor independently values their stock at \$8/share, and CPRIT wishes to take equity at that point, it could do so at the end of the second year after contract completion as \$42,951,830/(\$8/share) = 5,368,978.7 shares.

**Remaining Diligence Provisions**: Beta Cat has satisfactorily responded to all diligence concerns raised by the Product Development Review Council and due diligence process.

**Recommendation:** I recommend that the Oversight Committee delegate contract execution authority to the CEO of CPRIT for this grant, subject to the Company's agreement to appropriate tranches and milestones and to CPRIT's standard revenue sharing terms for a grant of this size to a company of this commercial maturity.

#### 2. CerRx - Company Formation

Company and Project Summary (written by the company): CerRx is developing drugs to trick cancer cells into overproducing toxic waxes, called ceramides. When the ceramides increase to a certain level, cancer cells die. CerRx has a pipeline of such drugs, including fenretinide and safingol, which work synergistically against many cancer types in laboratory testing. Human testing already shows fenretinide eliminates the cancers of some patients with relapsed lymphomas. CerRx needs funding to advance these drugs to market, specifically for the following clinical trials to be conducted in Texas-based consortia: 1) a larger trial of fenretinide in advanced Peripheral T-cell lymphoma, 2) a larger trial in advanced Cutaneous T-cell lymphoma, and 3) a trial combining fenretinide and safingol in advanced solid tumors like colon and small cell lung cancer. If patient responses in these trials confirm the activity observed in early testing, CerRx will have sufficient data to justify expanding these trials, ideally including CTNet, for accelerated FDA product approval for T-cell lymphoma patients in need. If fenretinide + safingol is as tolerable and active as expected, CerRx drugs will lead a revolutionary new treatment approach based on ceramides that is likely effective against many types of cancer resistant to current therapies. These goals are consistent with the CPRIT mission to improve the lives of cancer patients in Texas by supporting innovative, potentially breakthrough therapies, and to create high-quality new jobs in Texas.

<u>Proposed Milestones and Tranching</u>: The total award approved by CPRIT is \$6,000,000. The grant funds would be distributed in three tranches, contingent upon successful achievement of the milestones set forth below.

**Tranche 1:** \$2.2 Mil CPRIT (matched with \$1.1 Mil private) CerRx request initial funding to achieve the following milestone in the first year:

- 1. Initiate contracts with Ockham Oncology CRO for the conduct of the confirmatory Phase 2a Proof-of-Concept (POC) trial of IV fenretinide in relapsed/refractory Peripheral T-cell lymphoma (PTCL)
- 2. Complete re-certification of Active Pharmaceutical Ingredient (API) and Reference Standards
- 3. Initiate contracts with Coldstream Labs for the manufacture of clinical trial product and produce first batches of clinical trial product
- 4. Order microfluidizer and ancillary peripherals for the scale-up of cGMP manufacture of clinical trial product
- 5. Initiate the confirmatory Phase 2a POC trial of IV fenretinide in relapsed/refractory PTCL
- 6. Secure General, Director and Officers, Employment Practices, and Fiduciary Liability Insurances

**Tranche 2:** \$2.408 Mil CPRIT (matched with \$1.204 Mil private) CerRx requests funding to achieve the following milestones in the second year of the project:

- 7. Conduct the confirmatory Phase 2a POC trial of IV fenretinide in relapsed/refractory PTCL.
- 8. Install the microfluidizer and complete manufacturing of clinical trial product

**Tranche 3:** \$1.392 Mil CPRIT (matched with \$841K Mil private) CerRx requests advanced funding to achieve the following milestones in the final six months of the project:

- Complete the confirmatory Phase 2a POC trial of IV fenretinide in relapsed/refractory PTCL
- 10. Make the go/no go decision to complete the registration Phase 2 trial for registration in PTCL

<u>Proposed Revenue Sharing Terms</u>: The revenue sharing terms in the contract shall read, "For the purposes of the Contract, including this Attachment D, the RECIPIENT and INSTITUTE agree that the values of "A" and "B" in Section D4.01a above shall be 3.0 and 1.5, respectively, and that the value of "C" in Section D4.01b above shall be 0.7."

Since CerRx is requesting less than \$8 million and has not received more than \$12 million of aggregate professional investment, they fall into the lower left hand quadrant of the revenue sharing matrix above. As an example of the operation of the buyout fee in this case, where "C" equals 0.7, if CerRx (possibly through a late-stage investor or acquirer) wishes to buy out the continuing revenue sharing at a point two years after the conclusion of the contract, they could do so for:

Buyout fee = 
$$(1 + 2) \times (0.7) \times (\$6,000,000) = \$12,600,000$$

Each additional year that they wait after contract completion costs them (their subsequent investors) an additional  $0.7 \times (\$6,000,000) = \$4,200,000$ . If the third party investor independently values their stock at \$2/share, and CPRIT wishes to take equity at that point, it could do so at the end of the second year after contract completion as \$12,600,000/(\$2/share) = 6,300,000 shares.

**Remaining Diligence Provisions**: At the direction of the Oversight Committee, CerRx reduced the number of clinical trials from three (as outlined in the Abstract above) to one. The amount of the grant was correspondingly reduced from the initially requested \$10.5 million to the present amount of \$6 million.

CerRx has satisfactorily responded to all diligence concerns raised by the Product Development Review Council (PRDC) and due diligence process with the exception of one item. The PDRC review identified an issue regarding CerRx's agreement with Children's Hospital Los Angeles (CHLA). CerRx and CHLA attempted to resolve the issue, with certain concessions made by CHLA. However, the PDRC reports that the concessions are inadequate to address the concern that later stage investors would be put off by the high total royalty burden on the product. To resolve the issue, the PDRC mandates two changes. To avoid revealing CPRIT's negotiation position to other parties in the ongoing the negoation, the two provisios will be reported to the Oversight Committee in closed session.

**Recommendation:** I recommend that the Oversight Committee delegate contract execution authority to the CEO of CPRIT for this grant, subject to the satisfactory resolution of the above remaining diligence item, the Company's agreement to appropriate tranches and milestones, and to CPRIT's standard revenue sharing terms for a grant of this size to a company of this commercial maturity.

#### 3. DNAtrix - Established Company

Company and Project Summary (written by the company): DNAtrix, Inc. is a Texas-based company developing modified viruses for the treatment of the most aggressive type of brain cancer, called glioblastoma (GB). Scientists have modified the common cold virus called adenovirus in 2 specific ways so that it can recognize and kill cancer cells very effectively without harming normal brain. The first product of its kind, called Delta-24-RGD, has just completed its first big test in more than 35 patients with GB at the MD Anderson Cancer Center in Houston. Many patients with GB who participated had a remarkable response to the therapy, with evidence of tumor killing and improved survival. Perhaps equally important, there were no safety concerns or side-effects such as those that can arise from chemotherapy. If Delta-24-RGD continues to produce benefits for patients in additional clinical trials, the FDA will support its use for treating this devastating disease. This therapy could have a major impact for patient care in Texas and around the world as there are currently very few therapeutic option for patients if the tumor recurs.

**Proposed Milestones and Tranching**: The total award requested from CPRIT is \$10,813,623. The grants funds would be distributed in three tranches, contingent upon successful achievement of the milestones set forth below.

DNAtrix is initiating a small lead-in study (TARGET I) prior to initiating the Phase II (TARGET II) clinical study. The milestones are directly linked to the tranches as shown below. The company's goal is to seek accelerated FDA approval upon completion of the Phase 2 (TARGET II) study.

**Tranche 1:** \$2.889 Mil CPRIT (matched with \$1.038 Mil private) DNAtrix requests funding to achieve the following milestones in the first year of the project:

- 1. Complete and close-out Phase I clinical trial at MDACC
- 2. Complete cGMP Prep, Manufacturing & Testing of clinical supplies
- 3. Initiate Phase 1b "lead in" study (TARGET I) in US

**Tranche 2:** \$5.065 Mil CPRIT (matched with \$2.533 Mil private) DNAtrix requests funding to achieve the following milestones in the second year of the project:

- 1. Initiate Phase 2 study (TARGET II) in US
- 2. Develop CMC validation criteria and initiate process validation
- 3. Complete patient enrollment in Phase 1b (TARGET I) study

**Tranche 3:** \$2.859 Mil CPRIT (matched with \$1.430 Mil private) DNAtrix requests funding to achieve the following milestones in the final year of the project:

- 1. Complete enrollment Phase 2 study (TARGET II)
- 2. Complete process validation runs
- 3. Initiate BLA preparations

<u>Proposed Revenue Sharing Terms</u>: The revenue sharing terms in the contract shall read, "For the purposes of the Contract, including this Attachment D, the RECIPIENT and INSTITUTE agree that the values of "A" and "B" in Section D4.01a above shall be 4.0 and 2.0, respectively, and that the value of "C" in Section D4.01b above shall be 0.9."

Since DNAtrix is requesting more than \$8 million but has not received more than \$12 million of aggregate professional investment, they fall into the lower right hand quadrant of the revenue sharing matrix above (as did Beta Cat, above). As a further example of the operation of the buyout fee in this case, where "C" equals 0.9, if DNAtrix (possibly through a late-stage investor or acquirer) wishes to buy out the continuing revenue sharing at a point one year after the conclusion of the contract, they could do so for:

Buyout fee = 
$$(1 + 1) \times (0.9) \times (\$10,813,623) = \$19,464,521$$

Each additional year that they wait after contract completion costs them (their subsequent investors) an additional  $0.9 \times (\$10,813,623) = \$9,732,261$  (as compared with Beta Cat's \$14,317,276, owing to the lesser amount of the grant).

**Remaining Diligence Provisions**: DNAtrix has satisfactorily responded to all diligence concerns raised by the Product Development Review Council and due diligence process.

**Recommendation:** I recommend that the Oversight Committee delegate contract execution authority to the CEO of CPRIT for this grant, subject to the Company's agreement to appropriate tranches and milestones and to CPRIT's standard revenue sharing terms for a grant of this size to a company of this commercial maturity.

#### 4. ESSA Pharmaceuticals - Relocation Company

Company and Project Summary (written by the company): ESSA Pharma Inc. (ESSA) intends to treat castrate-resistant prostate cancer (or CRPC). Growth of prostate cancer cells is driven by male hormones. ESSA's drugs block the hormone-fueled growth of prostate cancer tumors by an entirely novel mechanism. Specifically, our drugs covalently block the N-terminus of the androgen receptor, preventing activation of the receptor by any means. Thus, our drugs may overcome all of the known mechanisms for hormone-therapy resistance. Our goal is that all men with recurrent prostate cancer will enjoy more months or even years of progression-free lifespan than current therapy offers. ESSA is currently in the clinical candidate selection stage and expects to commence clinical trials in 2013.

<u>Proposed Milestones and Tranching</u>: The total award requested from CPRIT is \$12,000,000. The grant funds would be distributed in three tranches, contingent upon successful achievement of the milestones set forth below.

**Tranche 1:** \$2.791 Mil CPRIT (matched with \$1.396 Mil private) ESSA requests funding to achieve the first milestone – filing of a successful IND with the FDA - in the first year of the project. The work here relates to completing the pre-clinical development of EPI-506 and then filing an IND based on that work. Also included is the required preparatory work for commencing clinical studies.

**Tranche 2:** \$3.787 Mil CPRIT (matched with \$1.893 Mil private) ESSA requests funding to achieve the second milestone – completion of Phase 1 Clinical Safety Study - in the second year of the project. Following successful IND filing (first milestone), ESSA must undertake clinical development of the drug candidate, EPI-506. The first stage is the Phase 1 dose-escalation safety study in approximately 20 patients. Successful completion of the milestone entails identifying the highest non-toxic dose in humans to take into the next stage of clinical testing (must be higher than expected therapeutic dose which is 3 mg/kg).

**Tranche 3:** \$5.422 Mil CPRIT (matched with \$4.698 Mil private) ESSA requests funding to achieve the following milestone – completion of the Phase 2 portion of the Phase 1/2 clinical trial in approximately 100 patients - in the third year of the project.

**Proposed Revenue Sharing Terms**: The revenue sharing terms in the contract shall read, "For the purposes of the Contract, including this Attachment D, the RECIPIENT and INSTITUTE agree that the values of "A" and "B" in Section D4.01a above shall be 4.0 and 2.0, respectively, and that the value of "C" in Section D4.01b above shall be 0.9."

Since ESSA is requesting more than \$8 million but has not received more than \$12 million of aggregate professional investment, they fall into the lower right hand quadrant of the revenue sharing matrix above (as did DNAtrix, above). As a different example of the operation of the buyout fee in this case, where "C" equals 0.9, if ESSA (possibly through a late-stage investor or acquirer) wishes to buy out the continuing revenue sharing at a point three years after the conclusion of the contract, they could do so for:

Buyout fee = 
$$(1 + 3) \times (0.9) \times (\$12,000,000) = \$43,200,000$$

Each additional year that they wait after contract completion costs them (their subsequent investors) an additional  $0.9 \times (\$12,000,000) = \$10,800,000$ .

Remaining Diligence Provisions: ESSA has satisfactorily responded to all diligence concerns raised by the Product Development Review Council (PRDC) and due diligence process with the exception of one item. CPRIT has requested a signed agreement showing that ESSA has the right to, 'acquire ownership of all IP (Licensor patents plus Licensor Improvements) related to this program' to address the remaining concern of the Product Development Review Council ("PDRC"). To avoid revealing CPRIT's negotiation position on this matter to other parties in the ongoing negotiation, the proviso will be reported to the Oversight Committee in closed session.

**Recommendation:** I recommend that the Oversight Committee delegate contract execution authority to the CEO of CPRIT for this grant, subject to satisfactory completion of the above remaining diligence item, the Company's agreement to appropriate tranches and milestones, and to CPRIT's standard revenue sharing terms for a grant of this size to a company of this commercial maturity.

#### 5. ProNAi - Company Relocation

Company and Project Summary (written by the company): ProNAi Therapeutics, Inc., a venture-backed clinical-stage cancer company funded with \$20M, is developing a first-in-class cancer drug, PNT2258. The drug consists of a piece of DNA surrounded by a protective "shell" that silences a cancer-causing gene from making a protein called BCL2. PNT2258 represents a technology called DNA interference (DNAi). We need to conduct several clinical trials for the FDA to make the drug available to patients. We have successfully treated over 20 patients in Texas and learned that PNT2258 is safe without side effects of traditional cancer therapy. The next step is to test if PNT2258 will help patients with lymphoma and leukemia, which are driven by BCL2. These trials will be conducted at hospitals throughout Texas. We will also advance new DNAi drugs in our portfolio against other cancer-causing genes. We are currently in Michigan but worked for years with clinics and laboratories in Texas. The management team is experienced doctors, scientists, and businessmen with a proven record of successful drug development. We plan to relocate corporate offices to Texas to combine our scientific operations already there and use the State's commitment to funding, infrastructure, and talent to advance novel treatments for cancer.

<u>Proposed Milestones and Tranching</u>: The total award request ratified by the Oversight Committee is \$14,000,000.

<u>Proposed Revenue Sharing Terms</u>: The revenue sharing terms in the contract shall read, "For the purposes of the Contract, including this Attachment D, the RECIPIENT and INSTITUTE agree that the values of "A" and "B" in Section D4.01a above shall be 5.0 and 3.0, respectively, and that the value of "C" in Section D4.01b above shall be 1.6."

Since ProNAi is requesting more than \$8 million and has received more than \$12 million of aggregate professional investment, they fall into the upper right hand quadrant of the revenue sharing matrix above. As an extreme example of the operation of the buyout fee in this case, where "C" equals 1.6, if ProNAi (possibly through a late-stage investor or acquirer) wishes to buy out the continuing revenue sharing at a point five or more years after the conclusion of the contract, they could do so for:

Buyout fee = 
$$(1 + 5) \times (1.6) \times (\$14,000,000) = \$134,400,000$$

Each additional year that they wait after contract completion costs them (their subsequent investors) nothing more, as they have reached the five year plateau on return to CPRIT.

**Remaining Diligence Provisions**: At the time of this writing, a number of outstanding diligence provisions are being discussed.

**Recommendation:** No recommendation is made to the Oversight Committee at this time in regard to this Company. Any negotiated terms will be brought to the Oversight Committee for consideration at the August 2014 meeting.

#### 6. ProPep Surgical - Established Company

Company's Summary: ProPep Surgical is an Austin, TX based medical device company developing a system of products to aid surgeons in identifying otherwise invisible nerves during robotic-assisted laparoscopic pelvic surgery for prostate, cervical and colorectal cancer. Currently, surgeons rely on anatomic landmarks to identify these nerves during surgery. Unfortunately, these landmarks are not always reliable and these nerves are often damaged during surgery which is a major contributor to the urinary dysfunction, fecal incontinence, and sexual dysfunction side effects that are common with these surgeries. The Company intends to conduct two multi-center clinic studies to assess the clinical utility of the ProPep Nerve Monitoring System and determine if use of the System results in improved urinary continence outcomes following robotic-assisted, laparoscopic prostatectomy surgery and improved urinary and fecal continence outcomes following robotic-assisted, laparoscopic hysterectomy surgery.

**Proposed Milestones and Tranching**: The total award requested from CPRIT is \$4,435,857. The grants funds would be distributed in three tranches, contingent upon successful achievement of the milestones set forth below.

**Tranche 1:** \$1.279 Mil CPRIT (matched with \$639,500 private) ProPep requests funding to achieve the following milestones in the first year of the project:

- 1. Prostatectomy Study Design/Finalize
- 2. Prostatectomy Study start up activities
- 3. Prostatectomy Study IRB approval
- 4. Prostatectomy Study First Site Initiation Visit
- 5. Prostatectomy Study First Subject Enrolled

**Tranche 2:** \$2.075 Mil CPRIT (matched with \$1.038 Mil private) ProPep requests funding to achieve the following milestones in the second year of the project:

- 1. Prostatectomy Study Last Subject Enrolled
- 2. Prostatectomy Study Last Subject Follow-up
- 3. Prostatectomy Study Closeout Visits
- 4. Prostatectomy Study-Clinical Study Reports
- 5. Hysterectomy Study Design/Finalize (starting approximately June 2015)
- 6. Hysterectomy Study start up activities
- 7. Hysterectomy Study IRB approval
- 8. Hysterectomy Study First Site Initiation Visit
- 9. Hysterectomy Study First Subject Enrolled

**Tranche 3:** \$1.081 Mil (matched with \$540,500 private) ProPep requests funding to achieve the following milestones in the third year of the project:

- 1. Hysterectomy Study Last Subject Enrolled
- 2. Hysterectomy Study Last Subject Follow-up
- 3. Hysterectomy Study Closeout Visits

#### 4. Hysterectomy Study-Clinical Study Reports

<u>Proposed Revenue Sharing Terms</u>: The revenue sharing terms in the contract shall read, "For the purposes of the Contract, including this Attachment D, the RECIPIENT and INSTITUTE agree that the values of "A" and "B" in Section D4.01a above shall be 3.0 and 1.5, respectively, and that the value of "C" in Section D4.01b above shall be 0.7."

Since ProPep is requesting less than \$8 million and has not received more than \$12 million of aggregate professional investment, they fall into the lower left hand quadrant of the revenue sharing matrix above (as did CerRx, above). As a further example of the operation of the buyout fee in this case, where "C" equals 0.7, if ProPep (possibly through a late-stage investor or acquirer) wishes to buy out the continuing revenue sharing at a point four years after the conclusion of the contract, they could do so for:

Buyout fee = 
$$(1 + 4) \times (0.7) \times (\$4,435,857) = \$15,525,500$$

Each additional year that they wait after contract completion costs them (their subsequent investors) an additional  $0.7 \times (\$4,435,857) = \$3,105,100$ .

**Remaining Diligence Provisions**: ProPep has satisfactorily responded to all diligence concerns raised by the Product Development Review Council and due diligence process.

**Recommendation:** I recommend that the Oversight Committee delegate contract execution authority to the CEO of CPRIT for this grant, subject to the Company's agreement to appropriate tranches and milestones and to CPRIT's standard revenue sharing terms for a grant of this size to a company of this commercial maturity.



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

May 15, 2014,

Oversight Committee Members:

Pursuant to 25 T.A.C. II § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of a grant contract for the following Product Development grant recipients announced at the February 19, 2014, Oversight Committee meeting:

- Beta Cat Pharmaceuticals
- CerRx
- DNAtrix
- ESSA Pharmaceuticals
- ProNAi
- ProPep Surgical

In addition to the six companies listed above, I also seek approval for authority to advance grant funds upon execution of grant contracts for the two companies that will be considered for Product Development grant awards at the May 21, 2014, 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, Section 4.03(a). Typically, the amount of grant funds 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.

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 companies listed above: 1.) a larger amount of start-up funds is needed than can be advanced from cash on hand; 2.) 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 R. Roberts

**CPRIT Chief Executive Officer** 

## Conflicts of Interest for Product Development Cycle 14.1 Applications (Product Development Cycle 14.1 Awards Announced at May 2014 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. 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.

Grant ID	Applicant	Company	<b>Conflict Noted</b>	
Applications considered by the PIC and Oversight Committee				
DP140031	Lowe, David	AERase, Inc.	Jones, Elaine	
DP140067	Bader, Andreas	Mirna Therapeautics,	Dhingra, Kapil;	
		Inc.	Mitchell, Amy	
Applications N	ot Recommended for PIC	or Oversight Committee C	Consideration	
DP140018*	Palleiko, Ben	Cielo Therapeutics, Inc.	Saxberg, Bo	
DP140021	Lenox, Mark	CVUS Clinical Trials,	Cosan, Roy	
		LLC		
DP140023	Andruss, Bernard	Asuragen, Inc.	Jones, Elaine	
DP140028	Klemp, Walter	Moleculin, LLC	Jones, Elaine	
DP140033*	Bearss, David	Tolero Pharmaceuticals,	Saxberg, Bo	
		Inc.		
DP140035	Burns, Lindsay	Pain Therapeutics, Inc.	Jones, Elaine	
DP140039	Carney, Darrell	Chrysalis	Jones, Elaine	
		BioTherapeutics, Inc.		
DP140041*	Osborne, Nick	Avicin Therapeutics, Inc.	Clendeninn, Neil	
DP140089	Paradiso, DVM, Linda	Boston Strategics	Saxberg, Bo	
		Therapeutics		
		Corporation		
DP140011	Asaithambi, Arunkumar	Lantern Pharma, Inc.	Jones, Elaine	
DP140036*	Szabo, Csaba	CBS Therapeutics, Inc.	DuBois, Ray	
DP140086**	Lopez-Berestein,	BINAFOR	DuBois, Ray	
	Gabriel			

<sup>\* =</sup> Not Discussed

<sup>\*\*=</sup> Administratively Withdrawn



## CEO Affidavit Supporting Information

FY 2014 – Cycle 1
Established Company Product Development Awards

## **Request for Applications**



# REQUEST FOR APPLICATIONS RFA C-14-ESTCO-1

# **Established Company Product Development Awards**

Please also refer to the Instructions for Applicants document, which will be posted December 23, 2013

**Application Receipt Opening Date:** December 23, 2013 **Application Receipt Closing Date:** January 31, 2014

FY 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

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#### **RFA VERSION HISTORY**

Rev 12/9/13 RFA release

#### 1. KEY POINTS

This Established Company Product Development Award mechanism is governed by the following restrictions:

- Company applicants must be Texas-based companies that have already received at
  least one round of professional institutional investment (i.e., Series A financing or a
  substantive equivalent). Applicants that have not yet received a round of
  professional institutional investment should apply under the New Company Product
  Development Awards mechanism.
- Recipient companies must currently have or must commit to the following:
   Headquarters in Texas, the majority of staff residing in or relocated to Texas, and
   use of Texas-based subcontractors and suppliers unless adequate justification is
   provided for the use of out-of-State entities.
- Of the total program budget, the Cancer Prevention and Research Institute of Texas (CPRIT) will contribute \$2.00 for every \$1.00 contributed in matching funds by the company. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be designated for the CPRIT-funded project but may be spent outside of Texas.
- Funding may be 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
  www.cprit.state.tx.us.
- Renewal applications will be accepted (see Section 9.3 and Section 11.4.5).

#### 2. ABOUT CPRIT

The State of Texas established CPRIT, which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the
  development and coordination of effective and efficient statewide public and
  private policies, programs, and services related to cancer and by encouraging
  cooperative, comprehensive, and complementary planning among the public,
  private, and volunteer sectors involved in cancer prevention, detection, treatment,
  and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

#### 3. APPLICATION 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 January 13, 2014. Company representatives should provide the following information: applicant name, name of company, telephone number, email address, estimated award amount, and award mechanism. Please select only one award mechanism as only one application can be submitted per funding cycle. This information will be used for planning purposes only, and will not be used for evaluation of the application. The survey is available here.

#### 4. EXECUTIVE SUMMARY

CPRIT will foster cancer research as well as product and service development in Texas by providing financial support for a wide variety of projects relevant to cancer. This Request for Applications (RFA) solicits applications for the research and development of innovative products addressing critically important needs related to diagnosis, prevention, and/or treatment of cancer and the product development infrastructure needed to support these efforts. CPRIT encourages applicants who seek to apply or develop state-of-the-art products, services (e.g., contract research organization services), technologies, tools, and/or resources for cancer research, prevention, or treatment. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure.

#### 5. MECHANISM OF SUPPORT

The goal of the Established Company Product Development Award is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will provide companies or limited partnerships located and headquartered in Texas with the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award is intended to support companies that will be staffed with a majority of Texas-based employees, including C-level executives.

#### 6. OBJECTIVES

The long-term objective of this award is to support commercially oriented therapeutic and medical technology products, diagnostic- or treatment-oriented information technology products, diagnostics, tools, services, and infrastructure projects. Common to all applications under this RFA (with the exception of infrastructure applications) should be

the intent to further the research and development of products that would eventually be approved for marketing for the diagnosis, prevention, and/or treatment of cancer. Eligible products or services include—but are not limited to—therapeutics (e.g., small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques. Eligible stages of research and development include translational research, proof-of-concept studies, preclinical studies, and Phase I or Phase II clinical trials. By exception, Phase III clinical trials and later stage product development projects will be considered where circumstances warrant CPRIT investment.

#### 7. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development program proposed. While requested funds must be well justified, there is no limit on the amount that may be requested. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property protection, external consultants and service providers, and other appropriate research and development costs, subject to certain limitations set forth by Texas State law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the State of Texas. Texas State law limits the amount of awarded funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs).

Consistent with statutory mandate, of the total program budget, CPRIT will contribute \$2.00 for every \$1.00 contributed in matching funds by the company. The demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be made on a year-by-year basis.

# 8. KEY DATES

**RFA release** December 9, 2013

**Online application opens** December 23, 2013, 7 a.m. Central Time

**Applications due** January 31, 2014, 3 p.m. Central Time

**Invitations to present sent** March 2014

**Notifications sent if not invited** March 2014

Presentations to CPRIT\* April 2014

\*All applicants who wish to be considered are requested to reserve these presentation dates until notified. Information on the timing of subsequent steps will be provided to applicants later in the process.

# 9. ELIGIBILITY

# 9.1. New Applications

- Company applicants must be Texas-based companies that have already received at
  least one round of professional institutional investment (i.e., Series A financing or a
  substantive equivalent). Applicants that have not yet received a round of
  professional institutional investment should apply under the New Company Product
  Development Award mechanism.
- Recipient companies must currently have or must commit to the following: Headquarters in Texas, the majority of staff residing in or relocated to Texas, and Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-State entities. To the extent that Texas-based subcontractors or collaborators are not available, non-Texas-based collaborators and subcontractors may be used. However, non-Texas-based collaborators and subcontractors are not eligible to receive funds from CPRIT unless exceptional circumstances are demonstrated and approved by CPRIT.

- An applicant may submit only one application under this RFA during this funding cycle.
- Only one co-applicant may be included on the application. Co-applicants should have specific and well-defined roles.
- A company applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, any company officer or director (or any person related to one or more of these individual within the second degree of consanguinity or affinity) have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- A company applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, and 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="https://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). More than one resubmission is not permitted. Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A one-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

# 9.3. Renewal Policy

A grant recipient that has previously been awarded grant funding from CPRIT may submit an application under this mechanism to be considered for a competitive renewal. The eligibility criteria described in <u>Section 9</u>.1 also apply to renewal applications. In addition:

- Applicants must have received a CPRIT award, either a Company
   Commercialization Award (this mechanism was called Company Investment in
   FY 2010), a Company Formation Award, a Company Relocation Award, an
   Individual Investigator Award with a commercialization component, or a High
   Impact/High Risk Award with a commercialization component.
- Before submitting a renewal application, applicants must consult with the Product
  Development Programmatic Office (see <u>Section 14.2</u>) to determine whether it is
  appropriate for their company to seek renewal funding at this time.

# 10. APPLICATION REVIEW

# 10.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. CPRIT requires the submission of a comprehensive scientific plan (see Section 11.4.8) and a detailed business plan (see Section 11.4.9). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and scientific plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made by the review process described below.

# 10.2. Review Process

- 1. Product Development and Scientific Review: Applications that pass initial administrative compliance review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of company applicants may be invited to deliver in-person presentations to the review panel.
- 2. Due Diligence Review: Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—intellectual property, management, regulatory, manufacturing, and market assessments. Following the due diligence review, applications will be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and intellectual property reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.

- 3. Program Integration Committee Review: Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.
- **4. Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

# 10.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Panel members, Product Development Review Council members, 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 Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's Web site. By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict

of Interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

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

# 10.3. Review Criteria

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

# 10.3.1. Primary Criteria

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

Primary criteria include:

**Significance and Impact:** Will the outcomes of this CPRIT-funded work result in the development of innovative products with significant product development potential? Will

the outcome substantially impact the diagnosis, treatment, prevention of cancer, or supportive care for patients with cancer? How would competing products or services affect the value of the proposed offering?

**Product:** Is there demonstrated proof of relevance, and does the product fulfill a clear, unmet medical or infrastructure need? Has work been conducted that supports the advancement of the proposed product, service, or technology? Can the product be produced or manufactured in a commercially viable fashion? Is there an appropriate basis for a reimbursement strategy?

**Market Plan:** Is there a realistic assessment of the market size and expected penetration? Has management adequately assessed potential competitors and described how the company's offering will successfully compete with them?

**Development Plan and/or Regulatory Path:** Is the development plan and/or regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both a positive and a negative outcome? Does the budget appropriately support the plan?

**Scientific Plan:** Is the proposed product, service, and/or infrastructure based on a feasible research framework, hypothesis, and/or goal? Are the methods appropriate, and are potential research and developmental obstacles and unexpected outcomes discussed?

**Management and Staffing:** Does the applicant have the appropriate level of management experience to execute the stated strategy? Does the team have the needed experience or access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan?

# 10.3.2. Secondary Criteria

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

Secondary criteria include:

**Budget and Duration of Support:** Are the budget and duration appropriate for the proposed work? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is it clear how funds will be used? Does the proposed investment fund the research and development of the proposed product, service, or technology to a point where, if the results are positive, it is likely that the project will be able to attract further financial support outside of CPRIT?

# 11. SUBMISSION GUIDELINES

Applicants are advised to carefully review all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Applications that are missing one or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

11.1. Online Application Receipt System and Application Submission Deadline
Applications must be submitted via the CPRIT Application Receipt System (CARS)
(https://CPRITGrants.org). Only applications submitted through this portal will be
considered eligible for evaluation. The applicant is eligible solely for the grant
mechanism specified by the RFA under which the grant application was submitted. The
company applicant must create a user account in the system to start and submit an
application. The co-applicant, if applicable, must also create a user account to participate
in the application. Furthermore, the Authorized Signing Official (ASO) (an individual
authorized to sign and submit an application on behalf of the company applicant) must
also create a user account in CARS. An application may not be submitted without ASO
approval. Only the ASO is authorized to officially submit the application to CPRIT.
Applications will be accepted beginning at 7 a.m. Central Time on December 23, 2013
and must be submitted by 3 p.m. Central Time on January 31, 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. All payments must be postmarked by the application submission deadline and mailed to:

Cancer Prevention and Research Institute of Texas P.O. Box 12097 Austin, TX 78711

# 11.4. Application Components

# 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

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

# 11.4.3. Timeline (One page)

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

# 11.4.4. Resubmission Summary (One page)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

**Note:** An application is a resubmission only if the previous application was finalized and submitted to CPRIT. However, an application that was submitted to CPRIT to be considered for FY2013 Cycle 3 awards and was returned by CPRIT due to the moratorium is not considered to be a resubmission.

# 11.4.5. Renewal Justification Summary (One page)

If this is a renewal, upload a summary that briefly outlines the progress made with the initial CPRIT award and outlines the proposed use of renewal funding and the resulting value for Texas. Clearly indicate whether (1) the technological/scientific underpinning is the same as that evaluated during review of the company's originally funded CPRIT application, or (2) whether funding is sought for the research and development of a new product or service not previously reviewed by CPRIT, or represents a significant

modification of the original product or service reviewed by CPRIT. (Either option is acceptable.) If this is not a renewal, no summary is required.

# 11.4.6. Executive Summary (One page)

Provide an executive summary that clearly explains the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

# 11.4.7. Slide Presentation (Ten pages)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with one slide filling each landscape-orientation page. The slides should succinctly capture all essential elements of the application and should stand alone.

# 11.4.8. Scientific Plan (Ten pages)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims. Outline the steps to be taken during the proposed period of the award, including the design of the translational or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The scientific plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by the highly qualified group of reviewers. To the extent possible, the scientific plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred.

# 11.4.9. Business Plan (Fifteen pages)

Provide a business plan covering all of the topics below in the order shown. Successful applicants will make thoughtful, careful, and economical use of the limited space. Note that if the company is selected to undergo due diligence, information to support a full intellectual property review will be requested at that time. Established Company Product Development Award applicants will be evaluated based not only on the current status of the components of the business plan, but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

- A. Introduction: Describe the label claims that the company ultimately hopes to make, and briefly describe the plan to gather evidence to support these claims. Include the minimum level of detail required to provide a context for the rest of the business plan. Cross-reference sections in the scientific plan where further details may be found.
- **B. 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.
- **C. 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.
- **D. Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated.
- **E.** 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.
- **F. Financial Projections:** Provide a detailed source and use analysis of the development plan, focusing on the achievement of specific milestones.

- **G. Resources Requested:** Include resources needed for research and product development and for any relocation expenses. The matching funds amount should be included in this section; however, this is the only section of the business plan that does not deal exclusively with CPRIT-requested funds.
- **H. 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.
- I. Key Personnel: For each member of the senior management and scientific team, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications.
- **J. Organizational Commitment to Texas:** Describe how CPRIT funding of the applicant's company would benefit the State of Texas. For example, describe how the company would create high-quality new jobs in the State and/or recruit out-of-State talent, and mention any Texas-based subcontractors and suppliers that would be used and any other unique, Texas-based resources that would be leveraged.

# 11.4.10. Biographical Sketches of Key Scientific Personnel (Eight pages)

Provide a biographical sketch for up to four key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed two pages and must use the "Product Development Programs: Biographical Sketch" template. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see Section 11.4.9]).

# 11.4.11. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. The budget must be aligned with the proposed milestones.

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

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas State law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.
- The annual salary that an individual may receive under a CPRIT award for
  FY 2014 is \$200,000. In other words, an individual may request salary proportional
  to the percentage effort up to a maximum of \$200,000. Salary does not include
  fringe benefits. CPRIT FY 2014 is from September 1, 2013, through
  August 31, 2014.

# 12. AWARD ADMINISTRATION

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

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property

rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10 - 703.12.

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

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

**Project Economics Sharing:** Recipients should also be aware that the funding award contract will include a revenue-sharing agreement and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>.

# 13. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas State law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has \$1.00 in matching funds for every \$2.00 from CPRIT. Matching funds need not be in hand when the application is submitted. However, matching funds must be obtained before CPRIT funds will be released for use. CPRIT

funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements associated with the requirement to demonstrate available funds

# 14. CONTACT INFORMATION

# 14.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific and product development aspects of applications. Before contacting the HelpDesk, please refer to the "Instructions for Applicants" document, which provides a step-by-step guide on using the Application Receipt System.

**Dates of operation:** December 23, 2013 to January 31, 2014 (excluding public

holidays)

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

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

**Tel:** 866-941-7146

E-mail: Help@CPRITGrants.org

# 14.2. Programmatic Questions

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

**Tel:** 512-305-8486

E-mail: Help@CPRITGrants.org

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

# **Third Party Observer Report**

# CPRIT Product Development Panel Screening Review Report

Report #2014-05

Panel Name: Product Development Screening Review Meeting for

Product Development – Part 1

Panel Date: February 27, 2014 Report Date: February 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.

# Introduction

The subject of this report is the Product Development Panel screening review chaired by David Shoemaker and held over the phone on February 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 Product Development Panel screening review meeting held telephonically on February 27, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Seventeen out of the twenty-two product development applications were discussed and evaluated by the
  Product Development Review Panel to determine which grants would be brought forth for further review. A
  cut-off was determined by the chair, and the applications discussed were based on their initial scores. However,
  the panel had the ability to champion an application, if requested.
- Twelve panel members, two advocate reviewers, four CPRIT staff members, and four SRA employees were present for the panel meeting over the phone.

- Ten conflict of interests were identified prior to or during the call. The panel members with the conflict of
  interests left the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies. SRA
  program staff did not participate in the discussions around the merits of the applications. The panel members'
  discussions were limited to the application evaluation criteria.

# Disclaimer

The third-party observation did not include 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 #2014-06

Panel Name: Product Development Panel Screening Review Meeting for Product Development Part 2

Panel Date: February 28, 2014 Report Date: February 28, 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 Product Development Panel screening review chaired by Jack Geltosky and held over the phone on February 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 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 on February 28, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

• Fourteen out of twenty product development applications were discussed and evaluated by the Product Development Review Panel to determine which grants would be brought forth for further review. A cut-off is determined by the chair, and the applications discussed were based on their initial scores. However, the panel had the ability to champion an application, if requested.

- Eleven members, two CPRIT staff members, and four SRA employees were present for the panel meeting over the phone.
- One conflict of interest were identified prior to or during the call. The panel member with the conflict of
  interest left the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The 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 #2014-07

Panel Name: Product Development Screening Review Panel - 1

Panel Date: March 31, 2014 - April 1, 2014

Report Date: April 1, 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 March 31, 2014 – April 1, 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 March 31, 2014 – April 1, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Eleven product development applications were discussed and evaluated by the Product Development Review
  Panel to determine which grants would be brought forth for further review over the course of two days. A
  cut-off is determined by the panel as to which applications will move on further for due diligence.
- Twelve review panel members, four CPRIT staff members, and two SRA employees were present for the inperson panel meeting.

- Eight conflicts of interest were identified prior to or during the in-person review. Seven of the eight conflicts of interest panel members left the room and did not participate in the review of the conflicted applications. One panel member identified that they had a conflict of interest during the in-person presentation and notified a CPRIT staff member to confirm. The panel member participated in the review by asking a question to the applicants; however, the panel member's participation did not have an effect on the results of the scoring. Once the CPRIT staff confirmed the conflict of interest, the panel member 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.

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 #2014-08

Panel Name: Product Development Review Panel - 2

Panel Date: March 31, 2014 - April 1, 2014

Report Date: April 1, 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 March 31, 2014 – April 1, 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 March 31, 2014 – April 1, 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, seven 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.
- Eleven review panel members, two advocate reviewers, four CPRIT staff members, and three SRA employees
  were present for the in-person panel meeting.

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

# **Disclaimer**

The third-party observation did not include the following:

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

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

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

# CPRIT Product Development Review Panel Report

Report #2014-12

Panel Name: Product Development Review Council Meeting

Panel Date: May 8, 2014 Report Date: May 8, 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 Product Development Review Council discussion for two expedited Product Development applications. The meeting was chaired by Jack Geltosky and held over the phone on May 8, 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 Review Council meeting held telephonically and chaired by Jack Geltosky on May 8, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Two product development applications were discussed and evaluated by the Product Development Review Council to determine which grants would be recommended to receive CPRIT funding.
- Five council members, five CPRIT staff members, and one SRA employees were present for the Council meeting over the phone.

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

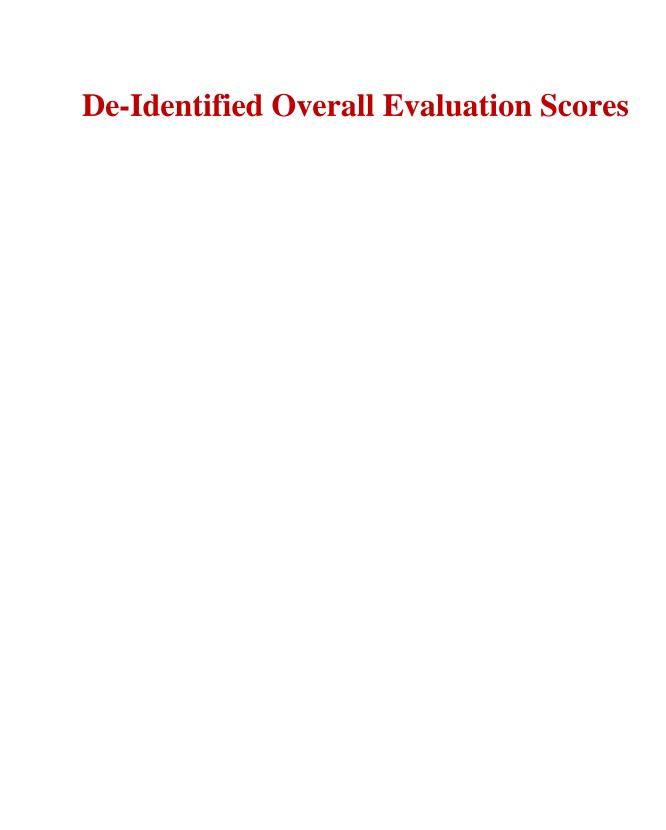
# **Disclaimer**

The third-party observation did not include the following:

 An evaluation of the appropriateness or rigor of the 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.



# Established Company Product Development Awards

FY2014, Cycle 1 – De-identified Scores

Company ID	Score
DP140031*	1.8
DP140067*	1.8
A	3.2
В	3.4
С	3.6
D	3.7
Е	5.0
F	6.0
G	7.5

<sup>\*</sup> Recommended for funding by PIC

# Final Overall Evaluation Scores and Rank Order Scores

# Product Development Review Council Award Recommendations FY 2014, Cycle 1, Part 1\*

	Application	Company		Requested	Overall
Rank	ID	Name	Project	Budget	Score
1	DP140031	AERase, Inc.	Pre-IND Development, Phase I	\$19,806,145	1.8
			Clinical Trials, & Predictive		
			Evaluation, for Engineered		
			Human Arginase Targeting the		
			Metabolic Vulnerability of Tumors		
2	DP140067	Mirna	Preclinical and Clinical	\$25,147,614	1.8
		Therapeutics,	Development of Synergistic		
		Inc.	MicroRNA + Targeted Drug		
			Combinations		

<sup>\*</sup> Two product development proposals submitted in response to FY2014 Cycle 1 RFAs are currently undergoing due diligence review. The due diligence reviews were not complete when the PDRC met on May 8, 2014. Should one or both of these companies satisfactorily complete due diligence reviews and be recommended by the PDRC, consideration of the PDRC recommendations will be at the August 2014 Oversight Committee meeting.



# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

# CEO AFFIDAVIT Application DP140031 Established Company Product Development Award

THE STATE OF TEXAS

# **COUNTY OF TRAVIS**

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Established Company Product Development Award* Request for Applications (RFA). CPRIT received nine applications for this RFA. The application was assigned to the Product Development Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

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 FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This	staten	ent	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 13th day of May by WAYNE R. ROBERTS.	ersigned authority, on, 2014,
Sandra Reyes	SANDRA J. REYES
Notary Public, State of Texas	My Commission Expires
1.0000, 2.0000, 2.0000	SEPTEMBER 30, 2017
	Notary without Bond

# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2014 CYCLE 1

PROGRAM Product Development

AWARD MECHANISM Established Company Product Development Awards (ESTCO)

APPLICATION ID DP140031

Pre-IND Development, Phase I Clinical Trials, & Predictive

APPLICATION TITLE Biomarker Evaluation, for Engineered Human Arginase

Targeting
APPLICANT NAME Lowe, David
ORGANIZATION AERase, Inc.

PANEL NAME Product Development Panel - 1 (PDP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	12/20/13	05/12/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	05/12/14
	CPRIT Application Receipt System (CARS) closed	01/31/14	05/12/14
	Date application submitted	01/31/14	05/12/14
1. Pre-Receipt	Method of submission	CARS	05/12/14
	Within receipt period	YES	05/12/14
	Appeal to submit application after CARS closed	N/A	05/12/14
	Appeal for late application submission accepted	N/A	05/12/14
	Submission of application fee	YES	05/12/14
	Administrative review notification	N/A	05/12/14
	Donation(s) made to CPRIT/foundation	NO	05/12/14
	Assigned to primary reviewers	02/14/14	05/12/14
	Applicant notified of review panel assignment	02/26/14	05/12/14
2. Receipt, Referral,	Primary Reviewer 1 COI signed	02/17/14	05/12/14
and Assignment	Primary Reviewer 2 COI signed	02/12/14	05/12/14
	Primary Reviewer 3 COI signed	02/13/14	05/12/14
	Primary (Advocate) Reviewer 4 COI signed	02/12/14	05/12/14
	Primary (Advocate) Reviewer 5 COI signed	02/12/14	05/12/14
	Primary Reviewer 1 critique submitted	02/26/14	05/12/14
	Primary Reviewer 2 critique submitted	02/24/14	05/12/14
	Primary Reviewer 3 critique submitted		
		02/28/14	05/12/14
3. Peer Review:	COI indicated by non-primary reviewer	JONES, ELAINE	05/12/14
Screening	COI recused from participation	YES	05/12/14
Teleconference	Peer Review: Screening Teleconference	02/27/14	05/12/14
	Post-Screening Teleconference score report	03/04/14	05/12/14
	Post review statements signed	03/19/14	05/12/14
	Third Party Observer Report	02/27/14	05/12/14
	Recommended for On-Site Meeting	YES	05/12/14
	Primary (Advocate) Reviewer 4 critique submitted	03/25/14	05/12/14
	Primary (Advocate) Reviewer 5 critique submitted	03/25/14	05/12/14
	COI indicated by non-primary reviewer	JONES, ELAINE	05/12/14
. Peer Review: On-	COI recused from participation	YES	05/12/14
ite Meeting	Peer Review: On-Site Meeting	03/31/14 - 04/01/14	05/12/14
	Post review statements signed	04/03/14	05/12/14
	Third Party Observer Report	04/01/14	05/12/14
	Score report delivered to CPDO	04/08/14	05/12/14
	Recommended for due diligence and IP review	YES	05/12/14
. Due Diligence and IP	Final due diligence review submitted to PDRC	04/30/14	05/12/14
5. Due Diligence and IP Review	Intellectual Property conflict check	04/08/14	05/12/14
	Final intellectual property review submitted	05/02/14	05/12/14
	COI indicated by PDRC member	NONE	05/12/14
	COI recused from participation	N/A	05/12/14
. Final PDRC	Due Diligence Evaluation Meeting / PDRC Meeting	05/08/14	05/12/14
tecommendation	Third Party Observer Report	05/08/14	05/13/14
	Recommended for grant award	YES	05/12/14
	PDRC Chair Notification to PIC and OC	05/09/14	05/12/14
	COI indicated by PIC member	NONE	05/14/14
	COI recused from participation	N/A	05/14/14
. PIC Review	PIC review meeting	05/13/14	05/12/14
	Recommended for grant award	YES	05/14/14
-	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	<del></del>
. Oversight	Donation(s) made to CPRIT/foundation		
ommittee Approval		YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	-
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



# **CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS**

# CEO AFFIDAVIT Application DP140067 Established Company Product Development Award

THE STATE OF TEXAS

**COUNTY OF TRAVIS** 

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to the *Established Company Product Development Award* Request for Applications (RFA). CPRIT received nine applications for this RFA. The application was assigned to the Product Development Panel-2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

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 FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

Wayne R. Roberts

This statement is true."

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the use the\3\frac{1}{h} day of \mathcal{M} \mathcal{M} \mathcal{M} \mathcal{M} \mathcal{M} \mathcal{M} by WAYNE R. ROBERTS.	undersigned authority, on, 2014,
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 2014 CYCLE 1

PROGRAM Product Development

AWARD MECHANISM Established Company Product Development Awards (ESTCO)

APPLICATION ID DP140067

APPLICATION TITLE Preclinical and Clinical Development of Synergistic

MicroRNA + Targeted Drug Combinations

APPLICANT NAME Bader, Andreas
ORGANIZATION Mirna Therapeutics, Inc.

PANEL NAME Product Development Panel - 2 (PDP-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	12/20/13	05/12/14
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	12/23/13	05/12/14
	CPRIT Application Receipt System (CARS) closed	01/31/14	05/12/14
	Date application submitted	01/31/14	05/12/14
	Method of submission	CARS	05/12/14
	Within receipt period	YES	05/12/14
	Appeal to submit application after CARS closed	N/A	05/12/14
	Appeal for late application submission accepted	N/A	05/12/14
	Submission of application fee	YES	05/12/14
	Administrative review notification	N/A	05/12/14
	Donation(s) made to CPRIT/foundation	YES	05/12/14
	Assigned to primary reviewers	02/14/14	05/12/14
	Applicant notified of review panel assignment	02/26/14	05/12/14
2. Receipt, Referral,	Primary Reviewer 1 COI signed	02/11/14	05/12/14
and Assignment	Primary Reviewer 2 COI signed	02/11/14	05/12/14
	Primary Reviewer 3 COI signed	02/13/14	05/12/14
	Primary (Advocate) Reviewer 4 COI signed	02/11/14	05/12/14
	Primary (Advocate) Reviewer 5 COI signed	02/11/14	05/12/14
	Primary Reviewer 1 critique submitted	02/21/14	05/12/14
	Primary Reviewer 2 critique submitted	02/23/14	05/12/14
	Primary Reviewer 3 critique submitted	02/26/14	05/12/14
	COI indicated by non-primary reviewer	DHINGRA, KAPIL	05/12/14
3. Peer Review:	COI recused from participation	YES YES	+
Screening			05/12/14
Teleconference	Peer Review: Screening Teleconference	02/28/14	05/12/14
	Post-Screening Teleconference score report	03/04/14	05/12/14
	Post review statements signed	04/06/14	05/12/14
	Third Party Observer Report	02/28/14	05/12/14
	Recommended for On-Site Meeting	YES OR 194 14 4	05/12/14
	Primary (Advocate) Reviewer 4 critique submitted	03/24/14	05/12/14
	Primary (Advocate) Reviewer 5 critique submitted	03/25/14	05/12/14
	COI indicated by non-primary reviewer COI recused from participation	DHINGRA, KAPIL YES	05/12/14
4. Peer Review: On-			05/12/14
Site Meeting	Peer Review: On-Site Meeting	03/31/14 - 04/01/14	05/12/14
	Post review statements signed  Third Party Observer Paper	04/01/14	05/12/14
	Third Party Observer Report	04/01/14	05/12/14
	Score report delivered to CPDO	04/08/14	05/12/14
	Recommended for due diligence and IP review	YES	05/12/14
. Due Diligence and IP	Final due diligence review submitted to PDRC	04/30/14	05/12/14
Review	Intellectual Property conflict check	04/08/14	05/12/14
	Final intellectual property review submitted	04/30/14	05/12/14
	COI indicated by PDRC member	DHINGRA, KAPIL	05/12/14
	COI recused from participation	YES	05/12/14
5. Final PDRC	Due Diligence Evaluation Meeting / PDRC Meeting	05/08/14	05/12/14
Recommendation	Third Party Observer Report	05/08/14	05/13/14
	Recommended for grant award	YES	05/12/14
	PDRC Chair Notification to PIC and OC	05/09/14	05/12/14
	COI indicated by PIC member	NONE	05/14/14
. PIC Review	COI recused from participation	N/A	05/14/14
	PIC review meeting	05/13/14	05/12/14
	Recommended for grant award	YES	05/14/14
	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	1
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	122110



### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATION!

**OFFICER** 

**SUBJECT:** PREVENTION PROGRAM AND COMMUNICATIONS UPDATE

**DATE:** MAY 9, 2014

Prevention and Communications activities since the last Oversight Committee meeting include:

### **Prevention Program**

- For the current review cycle, FY 14 Cycle 1, reviewers were recruited to the two prevention panels with two new prevention peer reviewers being recommended to the Nominations Committee for appointment. Staff held an orientation webinar for the reviewers on April 2, 2014. Panel meetings were held May 5-7<sup>th</sup> in Dallas. The next step is for the Prevention Review Council to meet and consider the recommendations from the two panels. This meeting is scheduled for June 27<sup>th</sup> in Dallas.
- For the next review cycle, FY 15 Cycle, two RFAs, Evidence Based Cancer Prevention Services and Competitive Continuation/Expansion, were released March 31st and the CPRIT Application receipt system (CARS) opened on April 29<sup>th</sup> to begin accepting applications. The recommendations for awards from this cycle will go to the Oversight Committee in November 2014.

#### **Communications**

- CPRIT received notification on May 2 that the LBB approved the February 19 request for strategic communications services with Hahn Communications. Priority items that they are addressing include developing CPRIT talking points, new grant award announcement, plans to share and promote CPRIT successes, a slidecast for grantee training, and layout/design for the Strategic Plan.
- New content that was required by statute has been posted to the website.
- Ellen Read, Senior Communications Specialist, drafted a customer satisfaction survey for the required state agency strategic plan. It was released April 14 and responses to the survey are due by close of business May 9.

### **Priorities Project**

 Robert Mittman has been retained as the facilitator for the program priority setting project.

•	As the lead staff for this project, I continue to work with Mr. Mittman on the proposed project plan and timeline. He will present an overview of the project for the Oversight Committee on May 21, 2014.



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: NED HOLMES, NOMINATIONS SUBCOMMITTEE CHAIR

**SUBJECT:** AGENDA ITEM 11 - INTENTION TO RECOMMEND APPROVAL OF THE

CHIEF EXECUTIVE OFFICER'S APPOINTMENTS TO THE SCIENTIFIC

RESEARCH AND PREVENTION PROGRAMS COMMITTEE

**DATE:** MAY 14, 2014

### **Summary and Recommendation:**

The Chief Executive Officer has appointed 58 people to the CPRIT's Scientific Research and Prevention Programs Committee. The Nominations Subcommittee discussed these appointments at its meeting on May 14, 2014. CPRIT's statute requires the appointments to be approved by the Oversight Committee. The Nominations subcommittee recommends that the Oversight Committee vote to approve the Chief Executive Officer's appointments at the May 21, 2014, meeting. The subcommittee's recommendations for product development reviewers are subject to the Product Development Subcommittee's approval. The Product Development Subcommittee is scheduled to meet on May 19, 2014.

#### **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) in Texas. 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. Therefore, the 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, 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 has considered the pending appointments and recommends Oversight Committee approval. It is noted that the Product Development Subcommittee will meet on May 19<sup>th</sup> to consider, among other items, Scientific Research and Prevention Programs committee members that will review product development applications. The Nominations Subcommittee's recommendations related to product development reviewers are subject Product Development Subcommittee's approval of the proposed reviewers. In the event that the Product Development Subcommittee declines to recommend approval for one or more proposed reviewers, the Product Development Subcommittee chair will notify the Oversight Committee at the May 21, 2014, meeting.



### **CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS**

# **Oversight Committee Nominations Subcommittee**

**Peer Review Panel Nominations** 

# Basic Cancer Research Panel 1 Tom Curran, Ph.D./FRS, Chair

- 1. Allan Balmain, Ph.D.
- 2. Steve Fiering, Ph.D.
- 3. Jacquelyn Hank, Ph.D.
- 4. Frank Rauscher, Ph.D.
- 5. Heide Schatten, Ph.D.
- 6. Joshua Schiffman, M.D.
- 7. Bart Williams, Ph.D.
- 8. Yu-Ching Yang, Ph.D.

# Basic Cancer Research Panel 2 Carol Prives, Ph.D., Chair

- 1. Nabeel Bardeesy, Ph.D.
- 2. Xinbin Chen, Ph.D., D.V.M.
- 3. James Manfredi, Ph.D.
- 4. Jeffrey Wrana, Ph.D.

# Cancer Biology Peter Jones, Ph.D., Chair

- 1. John Carpten, Ph.D.
- 2. Yves De Clerck, M.D.
- 3. Napoleone Ferrara, M.D.
- 4. Geoffrey Wahl, Ph.D.

# Cancer Prevention Research Thomas Sellers, Ph.D./M.P.H., Chair

- 1. Fazlul Sarkar, Ph.D.
- 2. Chinthalapally Rao, Ph.D.

# Clinical and Translational Cancer Research Margaret Tempero, M.D., Chair

- 1. Kathleen Cooney, M.D.
- 2. Fred Hirsch, M.D., Ph.D.
- 3. Albert Koong, M.D., Ph.D.
- 4. Ying Lu, Ph.D.
- 5. Pamela Munster, M.D.
- 6. Oliver Press, M.D., Ph.D.
- 7. Neil Shah, M.D., Ph.D.
- 8. Sarah Thayer, M.D., Ph.D.

# Imaging Technology and Informatics Sanjiv "Sam" Gambhir, M.D./Ph.D., Chair

- 1. James Basilion, Ph.D.
- 2. Kattesh Katti, Ph.D., D.Sc.
- 3. Jonathan Liu, Ph.D.
- 4. Robert Mattrey, M.D., Ph.D.
- 5. Duane Mitchell, M.D., Ph.D.
- 6. Shimon Weiss, D.Sc.
- 7. Anna Wu, Ph.D.
- 8. Kurt Zinn, Ph.D., D.V.M

# Translational Cancer Research Richard O'Reilly, M.D., Chair

- 1. Stephen Baylin, M.D.
- 2. Riccardo Dalla-Favera, M.D.
- 3. John DiPersio, M.D., Ph.D.
- 4. Stephan Grupp, Ph.D.
- 5. Robertson Parkman, M.D.
- 6. Simon Powell, Ph.D.
- 7. Jerome Ritz, M.D.
- 8. Alessandro Sette, D.Sc.

# Prevention Peer Review Panel Members for Approval

Michael Holtz, APR
 Marcus Plescia, MD, MPH

# Product Development Review Panel Members for Approval

- 1. Foley, Michael, PhD; Sanders Director, Tri-Institutional Therapeutics Discovery Institute and the Sanders Innovation and Education Initiative
- 2. Fox, Judy, PhD; R&D Consultant, FoxBiopharma, LLC
- 3. Fu, Darrick, MBA; President and Principal Consultant, Pralin Management, LLC
- 4. Greenberger, Lee, PhD; Chief Scientific Officer, Leukemia & Lymphoma Society
- 5. Jaffe, Charles, PhD; Chief Executive Officer, Health Level Seven, Inc.
- 6. Jones, Elaine, PhD; Executive Director, Pfizer Venture Investments
- 7. Kurman, Michael, MD; Adjunct Professor of Epidemiology and Health Promotion, Master of Clinical Trials Program, New York University
- 8. Lloyd, Ramona, PhD, RAC; President and Principal Consultant, Cymreg Consulting
- 9. Nicaise, Claude, MD; Senior Vice President Regulatory and Strategic Management, Alexion Pharmaceuticals
- 10. Rallis, Chris, Esq.; Executive in Residence, A.M. Pappas & Associates, LLC
- 11. Sternberg, Cora, MD, FACP; Adjunct Professor, College of Science & Technology, Temple University
- 12. Turnbull, Colin, PhD; Independent Consultant
- 13. Weng, David, MD, PhD; Anne Arundel Medical Center, Oncology and Hematology
- 14. Williams, Grant, MD; President, Williams Cancer Drug Consulting, LLC

# Robert Mittman, B.S., M.S., M.P.P. Facilitator and Project Lead



As founder of Facilitation, Foresight, Strategy, Robert Mittman works with groups of organizations to discover and implement shared approaches to complex and intractable problems. He engages audiences in a lively exchange of perspectives to turn simple meetings into forums that allow diverse individuals to work productively together.

Robert is Professor of Practice in the Ira A. Fulton Schools of Engineering and Director of Biomedical Strategy and Knowledge Development in the

Complex Adaptive Systems group at Arizona State University.

Robert specializes as a health care and scientific strategist. He helps large groups of academics, clinicians, and scientists from diverse disciplines articulate shared areas of interest, frame significant and innovative research questions, and identify opportunities for new partnerships and collaborations to advance the development of new fields of science and clinical care.

Robert facilitates strategic thinking with non-profit health organizations, government agencies, and the for-profit health care industry, including the National Cancer Institute; the Centers for Disease Control and Prevention, the American Association for Cancer Research; the University of California, San Francisco's Schools of Medicine and Pharmacy; the Methodist Hospital Houston's Institute for Academic Medicine; Health Level 7; the Leukemia and Lymphoma Society; the Angiogenesis Foundation; the California HealthCare Foundation; Johnson and Johnson; Ascension Health; and Kaiser-Permanente. Recent work has included developing an academic strategic plan for a major medical center; developing a multi-disciplinary, multi-institutional, university-based alliance to develop standards for the development of biomarkers; integrating the disciplines of biophysics, physical chemistry, and mathematics into biological research; developing a vision of how information technology can improve quality and safety in a range of health care settings from research to the clinic to the home; and crafting a vision for personalized health care.

Robert's health care strategic analysis combines both quantitative and qualitative methodologies to examine how the health system will evolve. His forecasts include work on the role of the Internet in health care, an analysis of the diffusion of innovation in health care, an investigation of the future of cost and utilization controls across health care practice settings, the development of cancer care quality measurements, and an analysis of the impact of managed care on the practice of oncology. He is a co-author of *The Internet in Health Care: A Five-Year Forecast* and *The Diffusion of Innovation in Health Care*.

For nearly two decades, Robert provided strategic advice to health care organizations as director at Institute for the Future. Robert holds graduate degrees in computer science and public policy analysis, and a Bachelor of Science degree in electrical engineering, all from the University of California at Berkeley.

### Selected Experience:

 National Biomarker Development Alliance; workshops convened by Arizona State University, December 2012 – August 2013

- Strategic Workshops; convened by the Institute for Academic Medicine, The Methodist Hospital, Houston, December 2012 August 2013
- Wet Age-Related Macular Degeneration, International Summit 2.0: Critical Pathways Forward; convened by the Angiogenesis Foundation, June 2013
- Forum on Healthy Behavior Change: Connecting Health Care to Healthy Choices; convened by Kaiser Permanente, the National Business Group on Health, and the American Heart Association, May 2013
- HPV Vaccination as a Model for Cancer Prevention; workshop series convened by the President's Cancer Panel, July 2012 April 2013
- Director's Consumer Liaison Group; periodic meetings convened by the Director, National Cancer Institute, October 2009 March 2013
- Expert Summit: Advancing Outcomes for Treatment of Metastatic Colorectal Carcinoma, convened by the Angiogenesis Foundation, Marc h 2013
- Asia-Pacific Summit on Age-Related Wet Macular Degeneration; convened by the Angiogenesis Foundation and the Singapore Eye Research Institute, February 2013
- Patient-Centered Outcomes Advocacy Forum, Annual Anti-Angiogenesis Conference; convened by the Angiogenesis Foundation, September 2012
- Strategic Retreat; convened by the Center for Science, Technology, and Society; Santa Clara University, September 2012
- Patient Outcomes Summit; convened by the American College for Wound Healing and Tissue Repair, July 2012
- Australian Summit on Age-Related Wet Macular Degeneration; convened by the Angiogenesis Foundation and the Australian Macular Degeneration Foundation, July 2012
- Roundtable on Patient Engagement in Cancer Care: Using Technology to Improve Communication and Care Coordination; convened by the Office of the National Coordinator for Health Information Technology, the National Cancer Institute, and the eHealth Initiative. June 2012
- Roundtable on Philanthropy and Government Working Together; convened by the Center on Philanthropy and Public Policy, University of Southern California, April 2012
- Scientific Retreat; convened by Karmanos Cancer Institute, Detroit, Ml, February 2012
- Physical Sciences Oncology Centers Retreat and Think Tank; convened by the Office of Physical Sciences Oncology, National Cancer Institute, December 2011 and February 2012
- Strategic Retreat; convened by the American Society for Pharmacology and Experimental Therapeutics, October 2011
- Scientific Strategy Retreat; convened by a global pharmaceutical company, September 2011
- Vision Expert Summit; convened by a cancer patient advocacy organization, June 2011
- Biobehavioral Perspectives on the Complex Patient-Cancer and Cardiovascular Disease; convened by the Behavioral Research Program, National Cancer Institute, June 2011

- Rethinking Primary Care; convened by an integrated delivery system and an insurance company, May 2011
- Primary Care Transformation; convened by Allina Hospitals & Clinics, April 2011
- Strategic Review of National Cancer Program; convened by National Cancer Advisory Board, May – August 2010
- Strategic Planning Retreat; convened by Karmanos Cancer Institute, Detroit, MI, May 2010
- Executive Committee Scientific Retreat; convened by Director, National Cancer Institute, February 2010
- Minding the Gap: Translating Promising Academic Discoveries into Breakthrough Therapeutics; convened by Leukemia and Lymphoma Society, January 2010
- Chief Nursing Officers Advisory Committee; convened by a major national hospital chain, January 2010
- Strategies to Increase the Supply of Health Professionals and Locally-Relevant Health Research in Tanzania; convened by Global Health Sciences, University of California, San Francisco, January 2009
- The Physical Sciences and New Frontiers in Oncology; series of three scientific conferences; convened by Deputy Director, National Cancer Institute, February 2008 – November 2008
- Strategic Summits; convened by Ascension Health, August 2008 March 2008
- Strategies for Maximizing the Nation's Investment in Cancer; convened by the President's Cancer Panel, July 2007 January 2008
- Genetic Age Symposium; convened by Northwestern University, Center for Genetic Medicine and Affymetrix, December 2006
- Workshop on Seniors Living at Home; convened by Blue Shield Foundation of California, November 2006
- Strategic Process; convened by HealthLevel 7, August 2005 August 2006
- Strategic Retreat; convened by UCSF Global Health Sciences, March 2006
- A Collaborative to Improve Access to Health Services in Los Angeles County; convened by the California Endowment, June 2003 to April 2005 (LA Health Collaborative is ongoing)
- Faculty Retreat; convened by the School of Pharmacy, University of California, San Francisco, January 2004
- Obesity and Cancer: Aligning Science, Policy, and Practice to Combat the Epidemics; convened by the National Dialogue on Cancer, September 2003
- Board Retreat; convened by the National Cancer Advisory Board, National Cancer Institute, June 2003
- Board Retreat; convened by the Pacific Business Group on Health, June 2003
- Clinical Vision Project; convened by Kaiser Permanente, February to April 2003
- Faculty Retreat; convened by School of Medicine, University of California, San Francisco, January 2003



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS **FROM:** KRISTEN DOYLE, GENERAL COUNSEL

**SUBJECT:** ACCEPTANCE OF A DESIGNATED GIFT FROM THE TEXAS CANCER

COALTION LIQUIDATING TRUST IN THE AMOUNT OF \$29,877.00

**DATE:** MAY 16, 2014

### **Summary and Recommendation**

I recommend that the Oversight Committee accept a gift from the Texas Cancer Coalition Liquidating Trust in the amount of \$29,877.00, which has been designated to reimburse expenses by CPRIT peer reviewers. Acceptance of these funds as a designated gift to the agency is the last issue to be resolved in the settlement agreement between CPRIT and the Texas Cancer Coalition, formerly known as the CPRIT Foundation. The total amount of the settlement agreement is \$473,677.81, including the salary supplement paid to the Chief Scientific Officer through August 31, 2013. The agreement resolved all issues related to the dissolution of the CPRIT Foundation, including disposition of funds collected by the Foundation on behalf of CPRIT.

### **Background**

In March 2013 the CPRIT Foundation notified CPRIT that the Foundation had renamed and repurposed itself in what the Foundation characterized as a rebranding effort. However, two changes in the Foundation's revised Articles of Incorporation caused concern: 1.) the Foundation ceased operating exclusively for the benefit of CPRIT, and 2.) the unilateral removal of CPRIT as the sole corporate member with altered direction of funds upon dissolution of the Foundation. Working with the OAG to ensure that CPRIT's interests were preserved, particularly with regard to the money raised in the name of and for the benefit of CPRIT, CPRIT and the Foundation reached an agreement in principle in May 2013 resolving all issues and claims relating to the Foundation.

The terms of the agreement in principle called for CPRIT to receive \$473,667.81 in funds raised by the Foundation on behalf of CPRIT, less \$33,124.14 in donations that CPRIT identified as associated with CPRIT grant applicants or grant recipients. The Foundation returned those donations to the donors in May 2013. The Foundation also continued monthly payments for the Chief Scientific

Officer's salary supplement through August 31, 2013, for a total of \$136,666.67. After the return of donations and payment of the salary supplement, \$303,877 in funds remained to be distributed to CPRIT.

The agreement in principle specified that the settlement of all issues must be approved by the Oversight Committee. Following discussion in closed session during the November 1, 2013, Oversight Committee meeting the board voted to authorize the Chair and the Executive Director (now CEO) to negotiate a final agreement to resolve all issues with the Foundation and to authorize the Chair to execute the agreement.

### **Distribution Agreement**

Since the November 1, 2013, meeting, CPRIT and the Foundation have worked to finalize the settlement terms and resolve all remaining issues related to the distribution of funds. The resulting agreement, *Distribution Agreement between the Oversight Committee of the Cancer Prevention and Research Institute of Texas and the Texas Cancer Coalition, formerly known as the CPRIT Foundation* (Distribution Agreement), sets forth the process for transferring funds to CPRIT and incorporates the terms from the agreement in principle, including the understanding that the Foundation will not operate under the names of "CPRIT Foundation," "Texas Cancer Coalition," or any other iteration that may imply an association with CPRIT. Both parties acknowledge that the deposit of the distribution checks represents the settlement of all issues that could have arisen between CPRIT and the Foundation. The Distribution Agreement (attached) was finalized on March 5, 2014, when signed by Oversight Committee Chair Rice.

### Special Treatment for Certain Funds Designated for a Dedicated Purpose

The Distribution Agreement acknowledges that a distribution check of \$29,877 represents a gift to CPRIT for which the grantor has specified the purpose "to reimburse expenses by Peer Reviewers." Receiving these funds as a gift is necessary in order to ensure that the remaining amount of a donation from the O'Donnell Foundation to the CPRIT Foundation can be used by CPRIT for the purpose intended at the time of the donation.

Generally, an agency can only spend money deposited in an agency's general account in the State Treasury if the agency has specific appropriations authority. CPRIT does not have this authority with regard to settlement funds, which means that the agency is unable to commit that the \$29,877 in dedicated funds will be spent as designated by the donor. However, CPRIT is authorized pursuant to V.T.C.A. Health & Safety Code § 102.054 "to accept gifts and grants from any source for the purposes of this chapter." This authority, in conjunction with Article IX of the 2014-2015 General Appropriations Act, allows CPRIT to use funds received as a gift for the purposes designated by the

donor. CPRIT and the OAG consulted with the Comptroller's Office when developing the plan for the proposed distribution of these funds to CPRIT.

CPRIT's administrative rules (<u>T.A.C.</u> § 702.7) provide a process for acceptance of gifts that is based upon the amount of the gift. For gifts exceeding \$10,000 but less than one million dollars, the rule permits the Executive Committee to accept the gift on behalf of the Oversight Committee. Since the Executive Committee has not yet been reconstituted, acceptance of the gift must be accepted by a majority vote of the Oversight Committee. Once accepted, the dedicated funds will be deposited in the State Treasury and used for the purpose specified by the donor.

### Distribution Agreement between

the Oversight Committee of the Cancer Prevention and Research Institute of Texas and the Texas Cancer Coalition, formerly known as the CPRIT Foundation

The Texas Cancer Coalition (TCC), formerly known as the CPRIT Foundation (Foundation), has ceased operations, transferred all funds to a Liquidating Trust, and designated Craig Enoch as the Trustee. This memorializes the agreement between the Cancer Prevention and Research Institute of Texas (CPRIT) and the Foundation/TCC. The Foundation/TCC and CPRIT agree to the following Settlement Terms:

- 1. To the extent CPRIT and the Foundation/TCC could assert any claims against the other or assert the rights or obligations against the other's governing board, staff, or contractors, CPRIT's deposit of Trust Check 1203 in the amount of \$29,877.00 and Trust Check 1204 in the amount of \$274,000.00 represents settlement of all issues that have or could have arisen between them.
- 2. The \$29,877.00 represents a gift pursuant to the statutory authority given to CPRIT in Health & Safety Code Sec. 102.054 for which the grantors specified the purpose was to reimburse expenses by Peer Reviewers. Pursuant to Section 8.01(e) of Article IX of the 2014-2015 General Appropriations Act, found at page IX-37 of Senate Bill 1, 83rd Legislature, R.S. 2013, this amount will be used by CPRIT for the purposes specified by the grantor.
- 3. The Trustee represents there were no outstanding liabilities or debts owed by the Foundation/TCC at the time of making these payments.
- 4. The Foundation/TCC agrees that it will not operate under the names "CPRIT Foundation," "Cancer Prevention and Research Institute of Texas Foundation," "Texas Cancer Coalition," or any other iteration that may imply to a reasonable person an association with CPRIT.
- 5. The Foundation/TCC will discontinue its direct support of CPRIT, and CPRIT will assert no further claim to, or control over, Foundation or TCC assets.
- 6. The Foundation/TCC agrees that it will not raise funds in the name of or for the benefit of CPRIT unless a majority of the CPRIT Oversight Committee votes to allow such activity.
- 7. On payment of the final accounting and legal services incurred by the Trust, the Trust will terminate. To the extent funds remain, they will be donated to CPRIT.

By their signatures, CPRIT and the Foundation/TCC approve these Settlement Terms.

1. Cancer Prevention and Research Institute of Texas

Dr. William Rice

Chair, CPRIT Oversight Committee

Date: 3-5-19

Date: Feb 21, 2014

On behalf of CPRIT Foundation/TCC

By: Craig Enoch

Trustee, Texas Cancer Coalition Liquidating Trust



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL

**SUBJECT:** 2015-2019 STRATEGIC PLAN

**DATE:** MAY 14, 2014

### **Summary and Recommendation:**

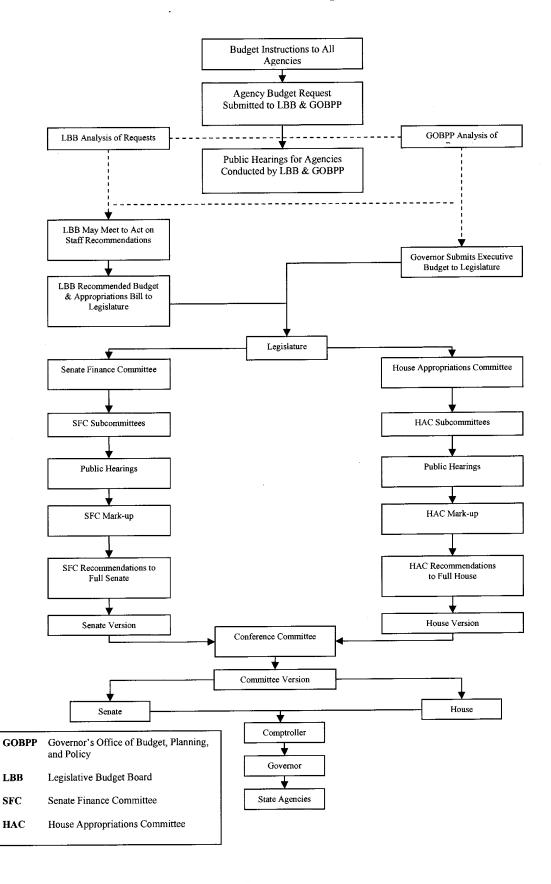
The strategic plan is a long-term plan that identifies an agency's current status, focus and orientation, as well as its planned future direction. The strategic plan must include a mission statement, identification of the agency's goals and the population it serves, and a description of the means by which the agency plans to achieve its goals. The Oversight Committee should vote to approve the agency transmitting a final draft of the document contained in the meeting book to the appropriate offices. The final submission must be signed by Presiding Officer Rice.

#### **Discussion:**

The structure of the strategic plan is defined by the Governor's Office of Budget, Planning and Policy (GOBPP) and the Legislative Budget Board (LBB). When the strategic plan is complete, the agency submits its plan to the GOBPP and the LBB for approval. CPRIT's strategic plan is due to those offices on June 23, 2014.

Additional information about how the strategic plan fits into the state budgeting process is outlined in the two attachments to this memo. These documents are in your orientation briefing books from last October as well.

# Texas Biennial Budget Cycle



### **The Budget Process**

Planning for the new budget begins in the spring of the year preceding the biennial legislative session, which begins in January of odd-numbered years.

**Instructions for agency strategic plans-**-The Governor's Office of Budget, Planning, and Policy (GOBPP) and the Legislative Budget Board (LBB) issue instructions for developing strategic plans in the spring preceding a legislative session. These instructions provide both a broad mission statement identifying the core principles of state government, as well as specific goals and benchmarks for individual state services and programs.

Strategic plans for each agency--Shortly after receiving these instructions the departments and agencies begin developing their strategic plans. A strategic plan is a long-term plan that identifies an agency's current status, focus and orientation, as well as its planned future direction. Strategic plans include a mission statement, identification of its goals and the population it serves, and a description of the means by which the agency plans to achieve its goals. After developing a strategic plan, the agency submits its plan to the GOBPP and the LBB for approval.

Legislative Appropriation Request (LAR)--Around the same time that strategic plans are being developed the LBB sends out instructions for Legislative Appropriation Requests (LARs). These instructions are used by agencies to develop their budget requests. Included in each agency's LAR are the performance measures on which budgeting is based. During the summer months, the LBB and GOBPP hold hearings with each agency to review its strategic plan and draft LAR. From these hearings the LBB and GOBPP determine the items to be included in the agency's final appropriation request. The finalized LARs must be submitted by the end of the summer and copies must be provided to the LBB, GOBPP, the state auditor, the state comptroller. These LARs form the basis for the appropriations bill prepared by the LBB.

**Draft of the general appropriations bill-**-During the fall LBB staff prepares the draft of the general appropriations bill. This draft contains performance measures, the maximum number of full-time equivalent employment positions (FTEs) allowed, specific enumerated instructions, the amount of funding recommended by the LBB, and the method of financing each agency's appropriation.

**Review & Approval: January-May of Odd-Numbered Years-**-Legislative action involves a lot of work in a very compressed time period (remember, the legislature meets for only 140 days), during which it must attend to numerous important legislative matters.

**Filing Appropriations Bill**--biennial revenue estimate--The draft of the appropriations bill is filed in both houses of the legislature, allowing each house to work on the bill simultaneously. The state comptroller is required to provide the legislature with a biennial revenue estimate (BRE) shortly after the regular session begins in January to ensure that the legislature does not

violate the constitutional prohibition on appropriating more money than is expected to be collected.

**Hearings-**-The Senate Committee on Finance and the House Committee on Appropriations, working separately, begin by hearing testimony from state agencies and others on the budget. Each committee makes changes to the budget document, a process known as "markup." After the bill passes out of these committees, it comes to the floor of each chamber for debate and ultimately approval.

Conference Committee and Final Vote--The bill is then referred to a conference committee composed of members of both houses to resolve differences between the senate and house versions of the bill. After the conference committee has agreed on a version of the appropriations bill, it sends the bill back to both houses for a final up-or-down vote (no amendment allowed).

Implementation & Monitoring: Takes Effect on September 1 of Odd-Numbered Years
Final review and approval of the appropriations bill and subsequent implementation of the
budget are primarily the responsibilities of executive branch officials. Nevertheless, the
legislative leadership plays an important role in ongoing monitoring of the implementation of the
budget through the LBB.

Review and Approval (May-June)—If the appropriations bill is passed by both houses, it is sent to the comptroller for certification. The Texas Constitution requires the comptroller to certify that there will be sufficient revenue to cover the appropriations made by the legislature. If not, then cuts need to be made. If the appropriations bill is certified by the comptroller, it goes to the governor for signing. The Texas Constitution gives the governor line-item veto authority—the authority to veto individual items in the appropriations bill. If the legislature is still in session when that authority is exercised (theoretically possible, but unlikely), it may override any vetoed line-items by a two-thirds majority vote in each house.

Implementation and Monitoring--After the appropriations bill is certified by the comptroller and signed by the governor, the bill guides spending over the next two years, beginning on September 1 of odd-numbered years. Although the budget is not recorded in Texas statutes or codes, it has the force of law. Agencies are bound by it, and their compliance is monitored by the LBB and the SAO. But there is wiggle room--the governor and the LBB acting together are empowered with "budget execution authority," allowing them to shift funds between agency programs, or even between agencies, if the need arises during the long period when the legislature is not in session.



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# Strategic Plan for Fiscal Years 2015-2019

### AGENCY STRATEGIC PLAN

### FOR FISCAL YEARS 2015 - 2019

BY

### CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

BOARD MEMBER	Dates of Term	Hometown
William Rice, M.D., Chair	2013-2017	Austin
Angelos Angelou	2013-2019	Austin
Gerald Geistweidt	2013-2015	Mason
Pete Geren	2013-2019	Fort Worth
Ned Holmes	2013-2019	Houston
Amy Mitchell	2013-2015	Austin
Will Montgomery	2013-2017	Dallas
Cynthia D. Mulrow, M.D., MSc., MACP	2013-2015	San Antonio
Craig Rosenfeld, M.D.	2013-2017	Dallas

June \_\_\_\_, 2014

Signed & Approved:

Board Chairman



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## Statewide Vision, Mission, and Philosophy

In March 2014, Governor Rick Perry issued the following in his *Strengthening our Prosperity: The Statewide Strategic Planning Elements for Texas State Government* statement.

## **Priority Goals**

As we begin this next round in our strategic planning process, we must continue to critically examine the role of state government by identifying the core programs and activities necessary for the long-term economic health of our state, while eliminating outdated and inefficient functions. We must continue to adhere to the priorities that have made Texas a national economic leader:

- ensuring the economic competitiveness of our state by adhering to principles of fiscal discipline, setting clear budget priorities, living within our means, and limiting the growth of government;
- investing in critical water, energy, and transportation infrastructure needs to meet the demands of our rapidly growing state;
- ensuring excellence and accountability in public schools and institutions of higher education as we invest in the future of this state and ensure Texans are prepared to compete in the global marketplace;
- defending Texans by safeguarding our neighbors and neighborhoods and protecting our international border; and
- increasing transparency and efficiency at all levels of government to guard against waste, fraud, and abuse, ensuring that Texas taxpayers keep more of their hard-earned money to keep our economy and our families strong.

#### The Mission of Texas State Government

Texas state government must be limited, efficient, and completely accountable. It should foster opportunity and economic prosperity, focus on critical priorities, and support the creation of strong family environments for our children. The stewards of the public trust must be men and women who administer state government in a fair, just, and responsible manner. To honor the public trust, state officials must seek new and innovative ways to meet state government priorities in a fiscally responsible manner.

Aim high...we are not here to achieve inconsequential things!

## The Philosophy of Texas State Government

The task before all state public servants is to govern in a manner worthy of this great state. We are a great enterprise, and as an enterprise, we will promote the following core principles:

- First and foremost, Texas matters most. This is the overarching, guiding principle by which we will make decisions. Our state, and its future, is more important than party, politics, or individual recognition.
- Government should be limited in size and mission, but it must be highly effective in performing the tasks it undertakes.
- Decisions affecting individual Texans, in most instances, are best made by those individuals, their families, and the local government closest to their communities.
- Competition is the greatest incentive for achievement and excellence. It
  inspires ingenuity and requires individuals to set their sights high. Just as
  competition inspires excellence, a sense of personal responsibility drives
  individual citizens to do more for their future and the future of those they love.
- Public administration must be open and honest, pursuing the high road rather than the expedient course. We must be accountable to taxpayers for our actions.
- State government has a responsibility to safeguard taxpayer dollars by eliminating waste and abuse and providing efficient and honest government.
- Finally, state government should be humble, recognizing that all its power and authority is granted to it by the people of Texas, and those who make decisions wielding the power of the state should exercise their authority cautiously and fairly.

## Relevant Statewide Goals and Benchmarking

**Higher Education:** To prepare individuals for a changing economy and workforce by:

 Furthering the development and application of knowledge through teaching, research, and commercialization.

#### Statewide Benchmarks

- Number of patents obtained in emerging technologies.
- Number of private sector companies created as a result of activities at public institutions of higher education.

**Health and Human Services:** To promote the health, responsibility and self-sufficiency of individuals and families by:

- Continuing to create partnerships with local communities, advocacy groups, and the private and not-for-profit sectors; and
- Investing state funds in Texas research initiatives which develop cures for cancer.

#### Statewide Benchmarks

- Number of state funded cancer research grant projects.
- Amount of leveraged dollars invested in state funded research grants projects.

**Economic Development:** To provide an attractive economic climate for current and emerging industries and market Texas as a premire business expansion and tourist destination that fosters that fosters economic opportunity, job creation, capital investment, and infrastructure development by:

promoting a favorable business climate.

#### Statewide Benchmarks

- Number of emerging technology research commercialization investments awarded.
- Number of nationally recognized researchers recruited to Texas public institutions of higher education as a result of emerging technology research superiority grants.

**General Government:** To provide citizens with greater access to government services while reducing service delivery costs and protecting the fiscal resources for current and future taxpayers by:

• supporting effective, efficient, and accountable state government operations.

#### Statewide Benchmark

• Issuance cost per \$1,000 in general obligation debt.

# Cancer Prevention and Research Institute of Texas Mission and Philosophy

## **Agency Mission**

Pursuant to V.T.C.A., Health and Safety Code, Section 102.002, the Cancer Prevention and Research Institute of Texas is to create and expedite innovation in the area of cancer research and to enhance the potential for a medical or scientific breakthrough in the prevention of cancer and 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 this state; and develop and implement the *Texas Cancer Plan*.

## Agency Philosophy

The Cancer Prevention and Research Institute of Texas will act in accordance with the highest standards of ethics, accountability, efficiency, and transparency. We affirm that our constitutional responsibility to distribute public funds to cure and mitigate cancer is a sacred covenant with the citizens of Texas. We approach our responsibilities with purpose to honor that trust.

## **External and Internal Assessment**

## **Overview**

The six year period covered by this strategic plan is affected by events that occurred during the 2012-13 fiscal biennium.

For CPRIT, fiscal year 2013 was defined by profound reflection and re-examination of why CPRIT was created by the Texas Legislature and authorized by the citizens of Texas in the first place, and of how the Institute had operated between 2008 and 2012.

During those years, the CPRIT Oversight Committee organized and retained the key leaders who quickly built the new agency into a major force in the fight against cancer. The Institute developed and implemented a complex peer review process, using out-of state blue-ribbon scientific, prevention, and product development professionals, to identify and guide funding for the cutting-edge programs envisioned by the Legislature and the Texas medical, public health and bioscience community.

In 2012, questions arose about several CPRIT awards as well as concerns about possible conflicts of interest that may have interfered in the evaluation processes. In December of that year, state leadership asked the Institute to suspend its operations until the Legislature could review if CPRIT had been operating as envisioned and what mid-course adjustments might be needed when it restarted. Also, during the latter part of 2012 a national search was conducted to identify a successor to the first chief scientific officer who had announced his resignation in May effective in mid-October. The successful search concluded with the nationally recognized recruit arriving at CPRIT in early January of 2013.

The first half of 2013 focused almost exclusively on the legislative reassessment and CPRIT's self-examination. The work began with the arrival of two administrators with some 72 years of state agency and legislative experience between them. These two worked closely with lawmakers to provide the information needed by the Legislature to decide if and how CPRIT should move forward. In addition, an exhaustive review of all grants awarded by CPRIT verified that all appropriate processes and procedures had been used and that no conflicts of interest affected the outcome of any grant making decision.

The outcome, Senate Bill 149, modified CPRIT's enabling legislation to restore trust in the Institute and improve transparency of agency operations and to incorporate recommendations made in a January 2013 state management audit. The legislation codified prior CPRIT administrative code provisions and established strict conflict of interest and process compliance procedures, enforced through numerous checks, balances and certifications that all requirements are met prior to any grant awards being made.

Senate Bill 149 also reconstituted the Oversight Committee of the Institute. As part of the legislative "reset," three members of the Oversight Committee are now physicians or scientists with extensive experience in the field of oncology or public health; others include cancer survivors or family members of cancer patients. To accommodate these requirements, the Legislature removed all Oversight Committee members serving prior to the effective date of the Act (June 14, 2013). New Oversight Committee members were appointed in the fall of 2013.

In October 2013 state leadership lifted the suspension of CPRIT's grant awarding and review process. In November, the agency began finalizing contracts for previously approved awards that had been affected by this moratorium and carefully resumed its grant solicitation, review and awarding processes.

CPRIT became fully operational by the end of November 2013 and is expected to make full use of its FY2014 appropriations. However, many measures related to this strategic plan are impacted as a result of the 2013 "moratorium" and related statutory and audit implementation.

One new requirement is relevant to this and future iterations of CPRIT's strategic plan. The Oversight Committee must establish annual priorities within and between the research, prevention, and product development grant programs. This endeavor, which is only just beginning, will make it possible for future CPRIT strategic plans and annual reports to provide additional information to evaluate its performance and progress in meeting its goals.

As CPRIT resumes its work, the Oversight Committee and staff are committed to new levels of transparency, accountability, integrity and adherence to its intricate processes in the conduct of Texans' business.

#### External Assessment

## <u>Groups of people served by CPRIT and of priority and other service</u> populations under current law.

CPRIT was constitutionally created to benefit all Texans. Every Texan is affected by cancer since each person either has or will have cancer <u>or</u> has or will know someone with cancer. CPRIT's programs are designed to find the causes, cures and to mitigate all types of cancer in humans.

Despite advances, cancer remains the second leading cause of death in Texas, accounting for nearly one of every four deaths (Figure I).<sup>1</sup> It is estimated that in the early part of the 21st century, cancer will overtake heart disease as the leading cause of death in the United States. In 2014, an estimated 44,150 Texans will die from cancer, which equates to more than 120 Texans dying each day. The number of patients with a newly diagnosed cancer is expected to exceed 119,000 in 2014.<sup>2</sup> A cancer diagnosis

often means lengthy, costly treatments, many of which are debilitating, painful, and exhausting. And the financial costs in medical care and lost productivity are staggering, bankrupting families and burdening health care systems. In Texas, a conservative estimate of the annual cost of cancer is \$30.4 billion, which includes a total cost to the Texas economy of some \$150.9 billion in reduced annual spending, \$74.4 billion in output losses per year, and 747,850 lost jobs. These totals represent about 5% of the total Texas economy. As the population increases, new treatments are discovered, and survival rates continue to increase, it is expected that costs will continue to rise.

#### **Cost of Cancer**

- Annual cost of cancer is \$30.4 billion
  - \$150.9 billion in reduced annual spending
  - o \$74.4 billion in output losses per year
  - o 747,850 lost jobs

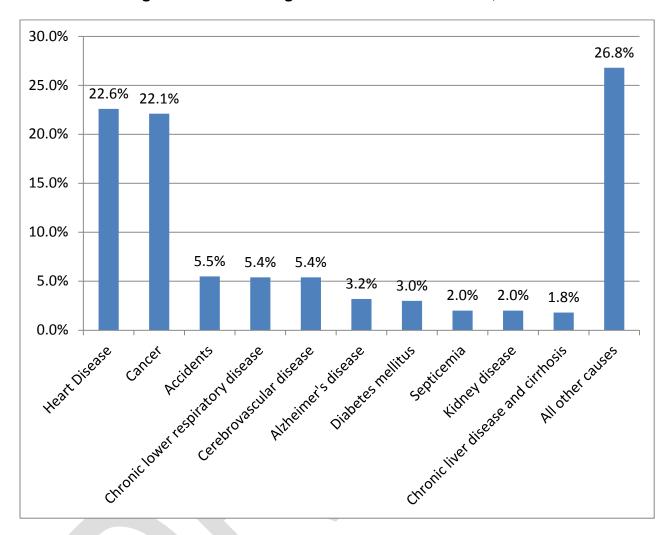


Figure I - Ten Leading Causes of Death in Texas, 2011

Source: Texas Department of State Health Services, Center for Health Statistics, ICD-10 Death Statistics for the State of Texas, 2011.

Cancer represents more than 100 distinct diseases, all characterized by uncontrolled reproduction of abnormal cells in the body. Each type of cancer possesses distinct risk factors and manifestations that necessitate different prevention measures and treatments. Some cancers are preventable, while others are successfully treated—even cured—if detected early enough. Survival rates vary greatly, depending on cancer site, stage at diagnosis, access to care, and a host of individual factors. There is no single cause or cure for cancer.

In 2013, the American Cancer Society, the Centers for Disease Control and Prevention, the National Cancer Institute, and the North American Association of Central Cancer Registries issued the Annual Report to the Nation on the Status of Cancer, 1975 – 2010. According to the report, cancer death rates in the United States decreased 1.8%

per year among men and an average 1.4% per year among women, and by 2.1% per year among children ages 0 to 19 for the time period, 2001-2010.<sup>5</sup> This decrease was observed in Texas as well.<sup>2</sup> The decline is credited to wider use of screening and early detection methods and better treatments that have extended life expectancy after diagnosis. To accelerate this trend, CPRIT invests in research and prevention efforts to help Texans reduce their risk of developing cancer, or detect it early, when treatments are more successful and less costly. One of CPRIT's goals is to enhance public access to evidence-based prevention programs and services throughout the State.

**Incidence:** Although cancer incidence rates in Texas are decreasing (Figure II), the number of new cancer cases is rising as the population of the State continues to age and grow.<sup>2</sup>

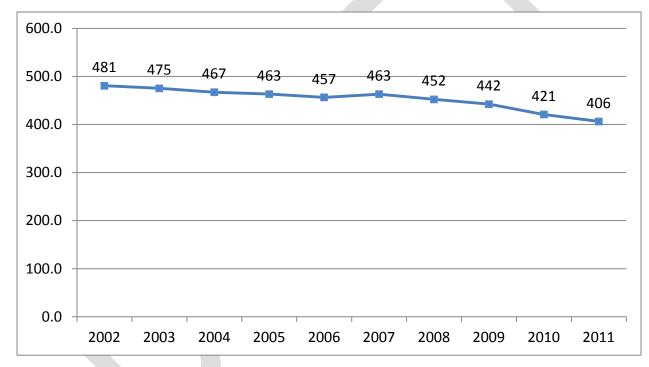


Figure II - Trends in Cancer Incidence Rates, Texas, 2002-2011

Source: Texas Department of State Health Services, Texas Cancer Registry, Incidence – Texas, 1995-2011, Cutoff 11-30-13, SEER\*Prep 2.5.2 (Confidential – Linked to County Attributes – Texas, 1969-2005.

In 2014, an estimated 119,115 Texans will be diagnosed with cancer. Among those:

- 17,348 Texas women will be diagnosed with breast cancer;
- 17,991 Texas men will be diagnosed with prostate cancer;
- 15,520 Texans will be diagnosed with lung cancer;
- 10,944 Texans will be diagnosed with colorectal cancer;
- 5,081 Texans will be diagnosed with melanoma, a form of skin cancer,

- 1,253 Texas women will be diagnosed with cervical cancer; and,
- 1,097 Texas children ages 0-14 were diagnosed with cancer in 2011.

Cancer is manifested differently in children, the most common cancer sites being blood and bone marrow, brain, lymph nodes, nervous system, kidneys, and soft tissues. An average of 1,423 children and adolescents younger than 20 are diagnosed with cancer each year in Texas.

**Mortality:** As previously noted, the overall cancer mortality rate in Texas decreased by an average of 1.9 percent a year from 2002-2011 (Figure IV). <sup>2</sup> Similar to cancer incidence, as the population ages and grows, the number of deaths will continue to increase even as the rate decreases. It is estimated that just over 44,000 Texans will die from cancer in 2014. Among the leading causes (based on projections):

- 11,257 Texans will die from lung cancer;
- 4,142 Texans will die from colorectal cancer;
- 3,178 Texas women will die from breast cancer;
- 2,745 Texans will die from pancreatic cancer; and
- 2,113 Texas men will die from prostate cancer.

•

Figure III - Cancer Mortality in Texas by Sex, 2011

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	Total Deaths	Male	Female
All Deaths	167,997	85,728	82,269
Deaths attributable to cancer	37,121	19,862	17,259
Percent Cancer	22.1%	23.2%	21.0%

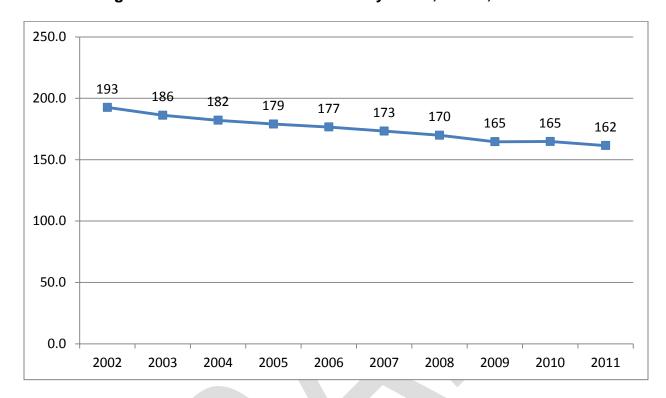


Figure IV - Trends in Cancer Mortality Rates, Texas, 2002-2011

Source: Texas Department of State Health Services, Texas Cancer Registry, Mortality – Texas, 1990-2011, SEER\*Prep 2.5.2 (created 02/26/14) - Linked to County Attributes – Texas, 1969-2005.

Cancer is the leading cause of death from disease among children in Texas and the United States. Approximately 13 percent of all deaths in children between the ages of 1 to 14 were attributable to cancer in 2011.

**Survivors:** In 2010, 488,114 Texans who were diagnosed with cancer in the last ten years are alive today.<sup>2</sup> Survival differs greatly by the type of cancer and the stage at which the cancer was diagnosed. As Figure V below indicates, five-year survival rates for lung, breast, prostate, colon and rectum, and cervical cancers drop substantially once the cancer spreads beyond the local tumor. Early detection and effective treatments for these cancers greatly improve five-year survival rates.

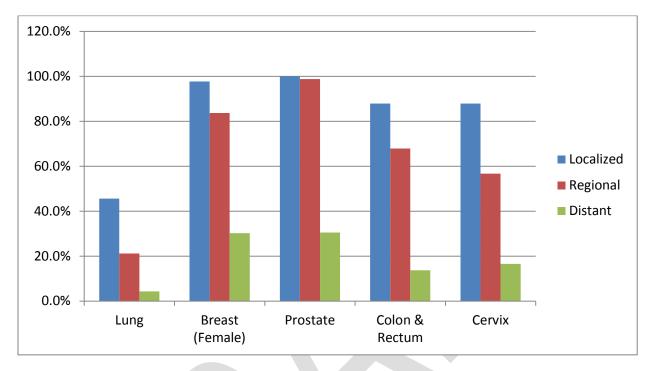


Figure V - Five-Year Relative Survival Rates by Stage at Diagnosis, 2002-2011, Texas

Source: Texas Department of State Health Services, Texas Cancer Registry, Incidence – Texas, 1995-2011, Cutoff 11-30-13, SEER\*Prep 2.5.2 (Confidential – Linked to County Attributes – Texas, 1969-2005.

Due to advances in diagnosis and treatment, children with acute lymphoblastic leukemia now have at least an 80 percent 5-year survival rate.<sup>2</sup> The recent phenomenon of children surviving cancer is causing a host of new questions and policy issues related to their long-term development, education, and insurance coverage needs, as well as research into relative risks for developing new cancers later in life.

**Cost:** In addition to improving survival chances, detection of cancer at an early stage can significantly reduce the cost of treatment, suffering and lost productivity. Cancer costs may contribute up to six percent of total health care expenditures in the United States.<sup>3</sup> The estimated annual cost of cancer in Texas is \$30.4 billion, and costs vary substantially across regions of the state and by cancer sites.<sup>4</sup>

**Cancer Disparities:** Underserved segments of the Texas population are affected by cancer to a greater degree. Some racial and ethnic groups are more likely than others to have cancer discovered at a later stage, leading to higher mortality rates. Rural and low-income populations have geographic and financial barriers to accessing cancer prevention and treatment resources. Barriers are compounded by insufficient numbers of health professionals and facilities in many sparsely populated counties.

**Race and Ethnicity:** Cancer incidence and mortality rates vary by race and ethnicity (Figure VI). Differences in incidence and mortality rates in some populations result from differences in risk factors, access to screening and treatment, and need for culturally sensitive preventive healthcare.

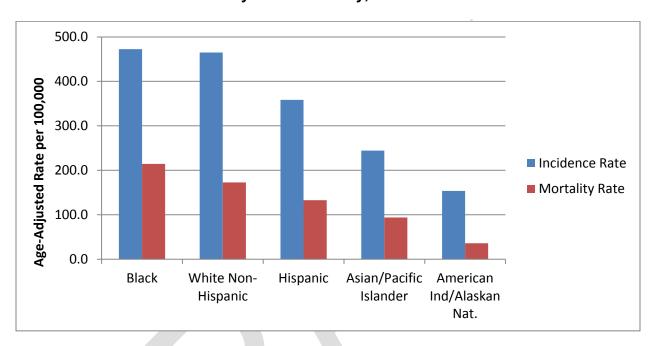


Figure VI - Overall Cancer Incidence and Mortality Rates, 2007-2011 by Race/Ethnicity, Texas<sup>2</sup>

Source: Texas Department of State Health Services, Texas Cancer Registry, Incidence – Texas, 1995-2011, Cut-off 11-30-13, SEER\*Prep 2.5.2 (Confidential – Linked to County Attributes – Texas, 1969-2005. Texas Department of State Health Services, Texas Cancer Registry, Mortality – Texas, 1990-2011, SEER\*Prep 2.5.2 (created 02/26/14) - Linked to County Attributes – Texas, 1969-2005.

Blacks bear an excess burden of cancer overall with cancer incidence and mortality rates that exceed those of whites and other racial/ethnic groups. Both black men and women were diagnosed with colorectal cancer at a rate almost 1.4 times greater than that of non-Hispanic white men and women; colorectal cancer mortality rates were about 1.7 times higher than those of non-Hispanic whites. Prostate cancer incidence and mortality rates were also greater than those of non-Hispanic whites; incidence rates were 1.4 times greater and mortality rates were 2.2 times greater.

Disparities in incidence and mortality among racial and ethnic groups differ by cancer site as well. For example, Hispanic women have the highest incidence rates of cervical cancer compared with other racial/ethnic groups, followed closely by black women, while black women suffer slightly higher mortality rates for cervical cancer, than other racial/ethnic groups.

**Income:** Low-income populations face financial barriers to accessing cancer prevention and treatment resources. At least 17 percent of the people in Texas live below poverty level, compared to the national rate of 15 percent<sup>8</sup>. The median household income in Texas in 2011 was \$51,563. In addition, Texas has the highest percentage of uninsured population of any state, estimated at 24 percent in 2012, or approximately 6.25 million people.

**Age:** The risk of developing cancer increases with age; adults in mid-life or older are most affected. In Texas, as in the nation, the growing number of older adults will increases the number of people affected by cancer, thereby making present-day prevention efforts imperative.

Over 95 percent of cancer deaths occur among Texans who are age 45 years or older.<sup>2</sup> With the maturing of the Baby Boom generation, cancer deaths will increase unless the trend is reversed by breakthroughs in cancer knowledge and treatment, and significant improvements in prevention and early detection occur for those most at risk.

**Geographic Areas:** Texas is unique, with more than 260,000 square miles and a vastly diverse population. Rural patients often must travel hundreds of miles to access prevention, detection, or treatment services. Cancer incidence and mortality rates vary by geographic area. The reason for these differences is likely due to varying cancer risk factors, tobacco use and population demographics of an area, including age, racial/ethnic makeup, income, and insurance coverage.<sup>7</sup>

Disparities exist in the 38-county area of South Texas, where 81% of the population is of Hispanic ethnicity. Cancer incidence is higher (compared to the rest of Texas) for such cancers as stomach, liver, and cervix. An estimated 33 percent of adults from South Texas are uninsured, more than double the national average. Two critical care issues facing this region are lack of health insurance and a shortage of health care providers.

Rural Texans are also medically underserved. Rural Texans tend to be older, have less income, and are less likely to have insurance than their urban counterparts. Residents of rural areas often have less contact and fewer visits with physicians and, in general, lower levels of available preventative care.

## Analysis of current agency resources for meeting current needs and expected needs.

CPRIT receives annual funding from the Legislature in the General Appropriations Act. Appropriated amounts are affected by two legal provisions. Article III, Section 67(c) of the Texas Constitution limits the sale of general obligation bonds in amounts not to exceed \$300 million per year. V.T.C.A., Health and Safety Code Section 102.253 limits the Oversight Committee from awarding more than \$300 million per year. The Legislature historically has authorized and appropriated the maximum \$300 million in

bond proceeds per year. This appropriation meets current funding needs and if continued, should meet future funding needs.

However, from the annual appropriation of \$300 million, CPRIT is required by rider provision to transfer \$2,969,554 to the Department of State Health Services to fund the Texas Cancer Registry. This transfer reduces the amounts available to CPRIT for curing and mitigating cancer in humans. If deleted and other funds made available to fund the registry, CPRIT could increase by nearly \$3 million per year its amount of awards for tangible prevention and research activities.

At this writing, the currently authorized 32 full-time equivalent positions are projected to be sufficient for at least the first two years of the period covered by this strategic plan. However, staffing needs may be affected by changes in informational technology requirements (see discussion on capital needs below).

## <u>Analysis of expected changes in services provided by CPRIT due to changes in state or federal law.</u>

Legislation from the 83<sup>rd</sup> Texas Legislature, Regular Session, made significant changes to CPRIT's governance, grant approval processes, conflicts of interest and ethics requirements, and creation of a compliance program. These changes impact administrative activities of the agency and substantially increase programming for major in-house and contracted grant management systems. Major administrative and other cost elements include:

- Hiring a chief compliance officer and developing a compliance program to ensure that all applicable laws, rules and procedures are followed in the grant award process and post-award administration.
- Requiring the Oversight Committee to establish priorities within and between grant programs.
- Changing the authority of the Oversight Committee from allowing two-thirds of the members to override award recommendations to a two-thirds vote to affirmatively approve award recommendations.
- Requiring scoring and documentation of factors considered in making each award and adding trained patient advocates on peer review committees.
- Reducing the authority of the Chief Executive Officer (CEO) by establishing a
  five-member Program Integration Committee (PIC) to review all grants after initial
  reviews by the various peer review committees and prepare a list of
  recommendations to the Oversight Committee.

- Requiring the CEO to submit to the Oversight Committee a written affidavit for each grant award recommendation containing information about the peer review process, score, and any applicable due diligence or intellectual property reviews.
- Requiring grant recipients to dedicate an amount of matching funds equal to onehalf of the amount of the grant awarded and specify the amount of matching funds to be dedicated to a project. Contracts must also specify the period of the award and deliverables of the research.
- Establishing a system to document and justify increases in peer reviewer honorarium and implement a policy on in-state or out-of-state residency requirements for peer reviewers.
- Establishing conflict of interest policies requiring recusal from the consideration of a grant award and standards of conduct policies for Oversight Committee members, PIC members, peer reviewers and CPRIT employees.
- Establishing a process to investigate unreported conflicts of interest by the general counsel and outlines the disposition of an investigation by the CEO or presiding officer of the Oversight Committee, as appropriate.
- Requiring the Oversight Committee to adopt a code of conduct to apply to the Oversight Committee, CPRIT employees, and PIC members.
- Strengthening rules prohibiting business relationships among grantees and CPRIT employees, Oversight Committee members, and peer reviewers.
- Prohibiting CPRIT employees from having offices located at facilities owned by entities receiving or applying to receive funding from CPRIT.
- Requiring the Compliance Officer to track and monitor grant recipient reporting, and to verify grant recipients' matching funds annually.
- Providing for procedures to confidentially report and investigate compliance violations.

CPRIT's administrative code provisions increased from 40 to 103 pages to implement changes in state law and the recommendations of a January 2013 State Auditor's Management Report. In the expansion CPRIT adopted or revised 37 administrative rules.

None of the federal changes to health care pursuant to the Affordable Care Act impact CPRIT.

Description of means and strategies for meeting CPRIT's needs and achieving the applicable statewide goals identified by Governor Perry. Clarify in location TBD. Contained in the grant making process.

## Broad summary of the capital improvement needs of CPRIT between 2015 and 2019.

Pursuant to a provision attached to CPRIT's 2014-15 appropriations the agency was required to move from its current leased space to state-owned facilities by the end of December 2013. Delays related to construction of state-owned space elsewhere changed the date to August 2014. As of this writing it appears the move may now be postponed until February 2015. However, due to the end of the current lease that cannot be extended this second delay will require CPRIT to relocate its offices twice, first to short-term leased space and then to the state-owned facility.

Although the original relocation plan is fiscally prudent it alone would have been extremely disruptive to CPRIT's operations and could have resulted in extended periods without full or satisfactory access to information technology and other resources. Two moves within a six month period should be doubly disruptive.

These moves could negatively impact CPRIT's schedule for issuing FY2015 Requests for Applications, peer review, and other agency timelines thereby threatening the August and November 2014 Oversight Committee meetings as well as the February 2015 meeting. As a result, CPRIT may be hindered in its ability to use prudently all of its 2015 appropriations available for grant awards and thereby further delaying accomplishment of the agency's mission. Ability to meet legislative performance targets might be reduced as well. Although CPRIT will do everything within its power to minimize the negative effects of multiple relocations, some detrimental impact to its operations and schedule should be expected.

CPRIT currently uses an outside contractor for much of its intricate grant award peer review process. This \$7.7 million annual contract includes major systems development and operation for release of requests for applications, application submission, application peer review, Program Integration Committee review, Oversight Committee review and approval, contracting, and post-grant policy review and compliance monitoring. Many of the software applications for this process are proprietary to the specific contractor and built upon legacy platforms that were about 10 years old when the contract began in 2009. The initial contact period is ending. To separate what belongs to CPRIT and what belongs to the contractor to competitively procure individual components or the entire system currently requires substantial CPRIT staff time and additional contractor vendor costs. The time frame and the specifications of a new request for proposals are not currently known. However, one approach that will be considered is outsourcing the design and construction of a completely new system that will then be operated by CPRIT state employees. The impact on staffing levels and administrative costs may not be known until well into FY 2015 at the earliest.



## <u>Identification of each geographic region of Texas served by CPRIT,</u> including the Texas-Louisiana and the Trans-Mexico border regions.

CPRIT's programs serve all 254 Texas counties and therefore all geographic regions. Prevention programs are largely responsible for this widespread geographic inclusion. Research grants are highly clustered in counties in which major health-related institutions and general academic teaching institutions with major health-related research activities exist, such as Harris, Bexar, Dallas, Tarrant, Lubbock, Brazos, Travis, and El Paso.

Targeting specific geographic regions and demographic groups will be discussed in the aforementioned Oversight Committee program prioritization activity mandate in state law.

## Strengths, Weaknesses, Opportunities, Obstacles

CPRIT has a multitude of strengths upon which to draw. First is its rigorous, detailed, multi-step, accountable, documented peer review process led by teams of national and world renowned basic scientists, physician-scientists, clinical researchers, product development entrepreneurs, public health professionals, health care providers, and patient advocates. To qualify for a CPRIT peer review panel one must be nominated by peers and have attained a regional and national reputation in one's chosen field. In addition, those selected must be willing to commit to the hours of laborious intensive review of applications and the intellectually challenging debate with peers concerning the academic, healthcare, and translational research potential of hundreds of proposals received by CPRIT each year. It is considered an honor to sit on a CPRIT review panel, and a recommendation for funding by these experts is coveted and considered highly prestigious.

CPRIT has a small but highly qualified full-time staff. Each program is led by a career professional leader with a terminal degree who through decades of substantive related experience has achieved national recognition in his or her own right. These individuals lead teams fiercely dedicated to the agency's mission. Many of these team members are cancer survivors and know first-hand what the battle against cancer entails.

Thanks to the foresight of the citizens of Texas and their legislature, CPRIT has a secure, dedicated funding stream that is relatively insulated from the vagaries of national or state economic cycles.

CPRIT is blessed by having numerous prestigious Texas universities from which originate the hundreds of applications for CPRIT support. These institutions form a broad and deep health-care and product development intellectual base from which innovative and considered research emerges. Within these institutions every known type of cancer and field within the life sciences are represented, recognized, and studied.

Perhaps the greatest strength is the pioneer spirit that is uniquely Texan. This spirit led to the foresight and compassion to establish a world class enterprise to study one of the great problems of humankind—mitigating and ending human cancers.

CPRIT identifies no weaknesses in either its external or internal environment preventing it from achieving its mission. CPRIT recognizes only opportunities in the human intellectual capital within its peer review panels, the state and national product development community, health care providers, and the academic institutions of Texas. In addition, opportunity abounds due to the generosity and trust in the renewal of CPRIT's mission by the Texas Legislature in 2013.

Obstacles to the CPRIT enterprise are miniscule compared to the opportunities, but they do exist. Paramount are several budgetary restrictions affecting approval of fiscal operations, including the use of unexpended balances from prior years and transferability of agency funding between line items of appropriation. In addition, secondary approval of agency contracts by the Legislative Budget Board beyond that required by its fiscally responsible governing board is unnecessarily redundant and time consuming. Delays resulting from this approval have affected the ability of the agency to move quickly in addressing the goals set out for it by the citizens of Texans and the full Legislature. CPRIT recognizes why these restrictions were placed on its 2014-15 appropriations but hopes that the agency's rapid responsiveness not only in action but spirit in implementing the recommendations of the State Auditor in his January 2013 management report and the provisions of Senate Bill 149 indicate an ability and trustworthiness as responsible stewards of public funds that obviates the need for such restrictions in 2016 and beyond.

Other obstacles include the aforementioned relocation of the agency's offices and information technology reevaluation and re-procurement. The former will be resolved with time; the latter will require serious deliberation and reevaluation of resources, needs, and expertise available within and without the agency in the months ahead.

## **Customer Service Satisfaction Survey**

Survey results are being summarized and will be inserted later.

## Promotion of Customer Competitiveness

CPRIT is innervated by a can-do competitive entrepreneurial spirit. CPRIT's grant making is 100 percent merit-based competitively driven. CPRIT promotes healthy competition between and within academic institutions and companies and between and among researchers and entrepreneurs. CPRIT's administrative code provisions promulgate competitiveness through the peer review process. That said, CPRIT also

encourages constructive collaboration among researchers, universities, health-care providers, and private sector enterprises in seeking its merit-based awards.

CPRIT is confident that no other Texas state agency is as driven by the spirit of intellectual and entrepreneurial competition as is CPRIT.

#### Internal Assessment

An understanding of CPRIT's internal processes is necessary to understand the emphasis on CPRIT's merit-based competitive orientation. In many respects CPRIT's peer review process is modeled on best practices of the National Institutes of Health (NIH), but with a few significant differences. The chairs of CPRIT's peer review panels are recruited by CPRIT's Chief Program Officers and are senior, highly respected members of their respective fields. Panel members are recommended by these chairs and represent outstanding members of the scientific, prevention, and product development communities.

CPRIT uses only reviewers who are well established in their professions and have achieved recognition in their areas of expertise, whereas NIH uses a spectrum of reviewers at various stages of their careers. As such, CPRIT reviewers are well positioned to recognize new talent and innovation. Unlike NIH peer reviewers, CPRIT reviewers are ineligible for CPRIT awards, adding an element of objective detachment unavailable in the NIH process.

Thus, CPRIT's review panels have a higher level of expertise than others and consequently, the review process is more stringent.

#### **CPRIT Peer Review Process**

Rigorous, independent, merit-based peer review is the foundation of all of CPRIT's grant programs and the primary means for ensuring that the Institute wisely invests public funds in research, product development, and prevention programs with the greatest potential impact on cancer. From the Institute's initiation, the peer review process has included multiple safeguards to address potential conflicts of interest and ensure both fairness and accountability. Further enhancements were made to the process in fiscal year 2013 pursuant to the recommendations of the State Auditor and the provisions of Senate Bill 149.

The table below shows the major steps in the review process currently in effect for all programs.

Step One: Request For Applications

The initial step in the CPRIT funding cycle is the release of a request for applications. The request includes important information about submitting the proposal to CPRIT, including applicable deadlines, requirements, evaluation criteria, and special considerations related to the grant award. CPRIT publishes all open requests on its website and in the *Texas Register* and sends an announcement about any new releases to subscribers of CPRIT's email newsletter. Only proposals submitted by Texas-based academic institutions, organizations, or companies, or those entities that demonstrate they will relocate to Texas if they receive a CPRIT grant award are eligible for CPRIT grant awards.

## **Step Two: Applying Online**

All applicants must use CPRIT's <u>online application system</u> to electronically submit proposals to CPRIT. Only applications submitted via the designated electronic portal are eligible for consideration of a grant award, and applications are eligible only for the grant mechanism under which the grant application was submitted. An applicant creates a user account and designates an individual at their institution or organization with the authority to approve the submission of the proposal. Applications that are submitted by the deadline are checked for compliance against the application's administrative requirements. Applications may be rejected at this step if they are not in compliance.

## **Step Three: Grant Proposal Review**

Experts and advocates in the field of cancer research, product development and cancer prevention are provisionally appointed to the peer review committees by CPRIT's Chief Executive Officer and approved by the Oversight Committee. To minimize the potential for conflicts of interest in the review process, all research and prevention peer reviewers live and work outside of the state. Peer review members are assigned to panels in their area of expertise. At least one advocate reviewer is assigned to each panel. A list of members by panel is on <a href="CPRIT's website">CPRIT uses a two stage peer review process to evaluate grant applications. These stages include A) evaluation of grant applications by peer review panels and B) prioritization of applications by the Prevention, Product Development or Scientific Review Council.

A. An eligible application undergoes a rigorous peer review where all aspects of the proposal are assessed by (usually three) primary reviewers on the same panel who provide an individual overall score. After all proposals are individually reviewed, the full peer review panel (usually 12-15 reviewers) meets to discuss the applications. If there is insufficient time to discuss all

- grant applications, the Peer Review Panel chair determines which applications are to be discussed by the panel. After discussion, each panel member provides individual overall scores that are averaged to provide a final overall score. Based upon the discussion and scores, the peer review panel develops a rank ordered list of applications it recommends for grant awards.
- B. At the second stage of review, each program's Review Council considers and prioritizes the recommendations of each of the peer review panels by assigning a numerical ranking score to each application discussed by the review panel. The Council specifies and explains changes, if any, to the grant applications' goals, objectives, budget, or timeline recommended for a grant award. The numerical ranking score takes into account the final overall score, how well the grant application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications. Proposals for prevention awards undergo a programmatic review process during this stage. The Review Council determines which proposals will be recommended to the Program Integration Committee and Oversight Committee for funding.

If CPRIT receives a significant number of proposals for a particular grant award mechanism, the peer reviewers may narrow the application pool by conducting a preliminary evaluation process prior to the initial review process described above in A). In the preliminary review, assigned Peer Review Panel members (usually three) conduct the preliminary evaluation for a grant application based on a review of the abstract, budget, and PI biosketch; they then provide a preliminary score based on the criteria stated in the Request for Applications. The Peer Panel Review chair determines grant applications that move forward to initial review based upon preliminary evaluation scores. A grant application that does not move forward to initial review is removed from further consideration.

The review process for recruitment of researchers and clinicians is described in the <u>Research Review Process</u>. The additional process steps for Product Development grant applications are described in the <u>Product Development Review Process</u>.

#### **Peer Review Processes**

- Research Review Process
- Product Development Review Process
- Prevention Review Process

#### **Step Four: Program Integration Committee**

The Program Integration Committee (PIC) is composed of the Chief Executive Officer, the Chief Scientific Officer, the Chief Product Development Officer, the Chief Prevention Officer and the Commissioner of State Health Services. The PIC considers the prioritized list of grant applications submitted by the Program Review Councils and approves by a majority vote a final list of grant applications to be recommended to the Oversight Committee for funding.

In composing the final list of grant applications recommended for funding, the PIC must consider the items specified in the statute.

The Program Integration Committee's decision to not include a grant application on the prioritized list of grant applications submitted to the Oversight Committee is final.

### **Step Five: Oversight Committee Action**

Two-thirds of the Oversight Committee Members present and voting must approve each grant award recommendation submitted by the Program Integration Committee. The total amount of money approved to fund a multiyear project must be specified and the CEO's recommendation, if any, regarding an advance of grant award funds must be approved by a majority vote of the Oversight Committee.

If the Oversight Committee does not approve a grant award recommendation made by the PIC, the explanation must be recorded in the minutes of the meeting. The Oversight Committee may not award more than \$300 million in Grant Awards in a fiscal year.

### **Step Six: Funded Grant Awards**

All CPRIT grants are awarded through a contract that specifies the responsibilities and obligations of the award recipient and reflects certain reporting and legal requirements. Research grant recipients, including those receiving product development awards, must demonstrate that they have other funds dedicated to the project totaling at least half of the amount of the CPRIT award. All award contracts include an intellectual property agreement and terms related to revenue sharing with the state.

#### Review Councils

The Institute's three review councils — the Scientific Review Council, Prevention Review Council, and Product Development Review Council — oversee the peer review of all applications submitted to CPRIT. Members of the review councils chair the peer review committees within each program area. The councils assess the evaluations completed by the peer review committees and create a final prioritized list of proposals recommended for CPRIT grant awards, substantially based on the scores provided by the peer review panels.

Pursuant to Senate Bill 149, the review councils submit their lists of recommendations simultaneously to the CPRIT Program Integration Committee and the Oversight Committee. The Program Integration Committee then forwards its final recommendations to the Oversight Committee, which will approve individual awards.

## **Research Program**

#### **Action Plan**

The action plan of the CPRIT research program seeks to:

- 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; and
- Increase the prominence and stature of Texas in the fight against cancer.

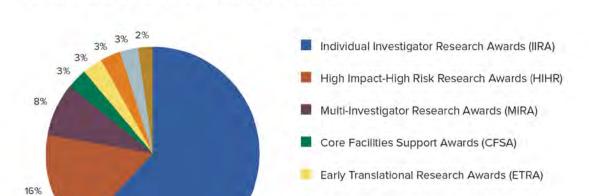
The Institute has sought to support the most creative ideas and the most meritorious projects, without regard to cancer type or geographic distribution. This strategy has been implemented by assembling seven independent peer review panels that evaluate all proposals. The peer reviewers are selected from among the most prominent cancer researchers in the country, outside of Texas. They are charged to assess research proposals on the basis of scientific merit and potential impact on cancer. Each of the seven panels is chaired by a distinguished cancer researcher; together, these chairs make up the Scientific Review Council, chaired by a world-renowned scientist.

The Institute uses a variety of grant award mechanisms to achieve the goals of the research program:

- The Institute supports discovery by funding the research of independent investigators that has the potential to reduce the burden of cancer, and by funding innovative projects that are high risk, but with high potential impact on cancer;
- Translation of research findings to bring new advances in cancer prevention, diagnosis, and treatment is achieved through the support of individual investigator awards and early translational research awards;
- Multi-investigator research grants stimulate collaboration and bring together researchers and clinicians to work on a common problem in cancer;
- The Institute also funds infrastructure to support cancer research in the form of core facility and specialized instrumentation awards, as well as multi-investigator awards to create research resources; and
- Building a critical mass of cancer researchers in Texas is addressed by supporting recruitment of cancer scientists and clinicians at all levels to academic institutions in Texas and through training programs in which pre- and postdoctoral fellows are educated to become cancer researchers.

#### **CPRIT's Research Portfolio**

As of this writing, since its inception, CPRIT has awarded 327 research grants, totaling more than \$481 million in research program funding, along with recruitment grants totaling more than \$169 million to bring 56 outstanding researchers and their teams to Texas. All grants in the portfolio were active as of August 31, 2013. Real-time award counts and funding totals may always be found at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>.



Shared Instrumentation Awards (SIA)

Research Training Awards (RTA)

Multi-Investigator Research Awards (Planning)

RESEARCH GRANT DISTRIBUTION BY MECHANISM

62%

As shown in the chart above, the majority (62 percent) of research grants funded by CPRIT support Individual Investigator Research Awards (IIRA). These 195 awards fund individual investigators who propose innovative research projects that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. These awards are highly competitive; only 10 percent of the applications received to date by CPRIT have been funded. Approximately \$193 million has been awarded to 15 institutions in Texas for the IIRA grant program.

High Impact-High Risk (HIHR) grants (16 percent of the portfolio) fund two-year projects to explore new avenues in cancer research. Only a limited number of applications are accepted from academic institutions and only 13 percent of the applications submitted to date have been funded. Fifty-two HIHR awards have been made to 20 institutions, totaling more than \$10 million.

The remaining 22 percent of the portfolio includes:

 Twenty-nine (including 4 continuation grants funded for two additional years of support for existing projects) Multi-Investigator Research Awards (MIRA) that fund large-scale, cross-disciplinary research programs requiring both innovation and collaboration. CPRIT has awarded almost \$194 million to these MIRAs, which in turn include 158 individual projects;

As well as the following smaller grant mechanisms that account for \$72 million of CPRIT's research portfolio:

- Eight small MIRA Planning grants to facilitate coordination among institutions submitting comprehensive applications;
- Eight Shared Instrumentation Awards and 11 Core Support Facilities Awards that provide infrastructure to support the cancer research of many investigators;
- Nine Early Translational Research Awards that support projects leading to the development of cancer therapeutic agents, devices, or diagnostics; and
- Seven Research Training Awards that support the training of the next generation of cancer researchers. Continuation funding for these seven grants was approved in February 2014 to provide an additional 2 years of support.

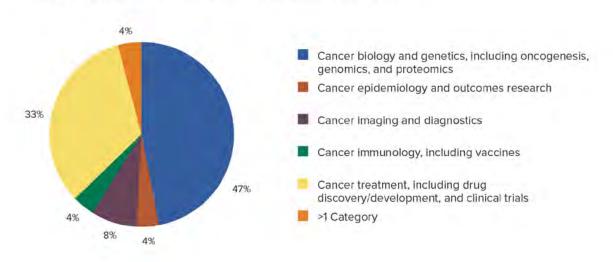


Active Research Grant Projects in Fiscal Year 2013 by Award Mechanism				
Award Mechanism	Award Maximum/ Project Duration	Award Mechanism Description	Number of Projects Active FY 2013	Total Award Amounts
High Impact-High Risk Research Awards (HIHR)	- Up to \$200,000 - 2 years	Supports relatively short- term high-impact/high risk projects that are innovative, developmental, and/or exploratory in nature targeting new avenues of cancer research.	52	\$10,342,469
Individual Investigator Research Awards (IIRA)	- Up to \$500,000 - 3 years	Supports innovative research projects directed by one scientist that address critically important questions that will significantly advance knowledge of the causes, prevention, diagnosis, and/or treatment of cancer.	195	\$193,744,261
Multi-Investigator Research Awards (MIRA)	- No maximum with appropriate justification  - 5 years	Supports integrated programs of collaborative and cross-disciplinary cancer research among multiple investigators for projects that cannot be effectively addressed by individual researchers or a group or researchers within the same discipline.	25	\$193,859,465
Multi-Investigator Research Awards- Planning	- Up to \$25,000 - 8 months	Support to assist applicants for the Multi-Investigational activities among several institutions submitting comprehensive applications.	8	\$133,845
Research Training Awards (RTA)	- Up to \$750,000/ year - 5 years	Supports training programs for predoctoral (PhD or MD/ PhD) and postdoctoral trainees committed to pursuing a  Also supports undergraduate summer research internships and Master's degree-level trainees.	7	\$29,465,885

Award Mechanism	Award Maximum/ Project Duration	Award Mechanism Description	Number of Projects Active FY 2013	Total Award Amounts
Shared Instrumentation Awards (SIA)	- Up to \$3M for 1st Year, up to \$300,000 subsequent years - 5 years	Supports the acquisition of major research instrumentation that cannot be requested through other CPRIT programs and whose purchase can be justified on a shared-use basis to support the goals of scientifically meritorious cancer research projects.	8	\$12,436,069
Core Facilities Support Awards (CFSA)	- Up to \$2M for 1st year, up to \$1M subsequent years - 5 years	Supports centralized laboratories performing widely used technologies that serve the needs of multiple researchers.	11	\$33,062,583
Early Translational Research Awards (ETRA)	- Up to \$1M - 1-3 years	Supports projects that "bridge the gap" between the research laboratory and potential clinical applications, such as proof-of-principle research to guide the development of therapeutics, devices or diagnostic assays.	O	\$8,283,557
TOTAL			315	\$458,430,154

The subject matter of research grants is broad and encompasses nearly all areas of cancer research. Roughly 47 percent of the funded grants address problems in basic science, 33 percent involve translating research findings into clinical use or products for treating cancer, and the remaining 20 percent address cancer epidemiology and outcomes research, cancer imaging and diagnostics, and cancer immunology including vaccine development.





### **Recruitment Grants**

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 and through training programs in which pre- and post-doctoral fellows are educated to become cancer researchers. Since its inception, CPRIT has supported the recruitment of 56 outstanding cancer researchers to 10 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.

Active Research Recruitment Grant Projects in Fiscal Year 2013 by Award Mechanism				
Award Mechanism	Award Maximum/ Duration	Award Mechanism Description	Number of Recruits	Total Award Amounts
Recruitment of Established Investigators	- Up to \$10M - 5 years	Support to recruit senior research faculty with distinguished professional careers and established cancer research programs.	14	\$78,715,750
Recruitment of First-Time, Tenure-Track Faculty	- Up to \$2M - 4 years	Support to recruit emerging investigators pursuing their first faculty appointment who have the ability to make outstanding contributions to the field of cancer research.	33	\$64,792,505
Recruitment of Missing Links	- Up to \$2M - 5 years	Support to recruit investigators who can fill special and specific needs as critically important members of collaborative research teams.	3	\$5,881,402
Recruitment of Rising Stars	- Up to \$4.5M - 5 years	Support to recruit early- stage investigators who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.	6	\$19,731,000
TOTAL			56	\$169,120,657

## Focus of Activities in Fiscal Year 2013

Although no new grant applications were solicited or reviewed during fiscal year 2013, several changes in the review process were implemented during this period. Most notably, six new chairs of peer review committees were recruited and one was reinstated; this enabled reconstitution of the Scientific Review Council (SRC), under the direction of one of the former panel chairs. Members of the review panels have also been recruited, in spite of concerns that this might be difficult, considering the upheavals at CPRIT during the past year. Thus, the research program is moving forward with its grant activities in the coming year. Information regarding the panels and chairs can be found on CPRIT's website at http://www.cprit.state.tx.us/grants-process/peer-review-committees/research-appointees/.

Another change implemented during the past year was the development by the three program officers of a formal honorarium policy for all members of the peer review committees. This policy is also available on CPRIT's website. In addition, the process for peer review of recruitment applications has been modified. Criteria for scoring these applications have been developed, and the Requests for Applications have been modified to include these criteria. These applications will now be scored by the SRC members. Based on the newly adopted rules, all Requests for Applications have been revised to incorporate the new requirements.

Finally, in response to a recommendation by the State Auditor, CPRIT has implemented a new process for the review of grantees' annual progress reports. These are now reviewed by a third-party, independent reviewer, based on specific aims and milestones established by the grant's principal investigator.



#### PREVENTION GRANT PROGRAM

### Action Plan

Since its inception, the CPRIT prevention program has been guided by the following principles:

- Funding Evidence-Based Interventions. CPRIT funds prevention programs and services, for any cancer type, that are culturally appropriate for the target population and that are validated by documented research or applied evidence.
- Funding across the Prevention Continuum. CPRIT funds quality proposals focused on:
  - Primary prevention: reducing risk or preventing cancer from occurring (e.g. vaccine-conferred immunity, tobacco cessation);
  - Secondary prevention: early detection of cancer to prevent it from spreading and treating diagnosed cases when the opportunity for greatest success exists (e.g., screening/early detection for breast, cervical, and/or colorectal cancer); and
  - Tertiary prevention: reducing risk of recurrence and improving quality of life for survivors and families (e.g., physical rehabilitation/therapy, psychosocial interventions, palliative care).
- Reaching Underserved Populations. CPRIT funds programs and services aimed to help those in most need, including:
  - Underinsured and uninsured individuals, especially those who have never been screened for colorectal, breast, and/or cervical cancer or who have not been screened within five years of the current guidelines;
  - Geographically or culturally isolated populations or those with low health literacy skills:
  - Medically unserved or underserved populations;
  - Racial, ethnic and cultural minority populations; and
  - Any other populations with low screening rates, high incidence rates and high mortality rates.
- Innovating and Evaluating. CPRIT's prevention portfolio aims to build understanding
  of and capacity to deliver effective programs by evaluating and disseminating
  innovations and best practices that address the needs of underserved populations.

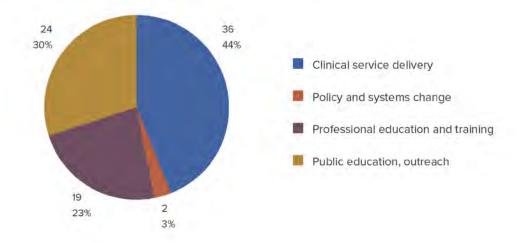
## **CPRIT's Prevention Portfolio**

As of this writing, CPRIT has funded 115 prevention grants for a total of \$96,730,804 in funding. Eighty-one of these grants were active during fiscal year 2013. Real-time award counts and funding totals may always be found at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a>. The active evidence-based projects have been awarded through the following mechanisms:

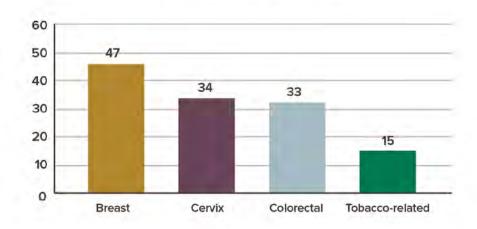
Active Prevention Grant Projects in Fiscal Year 2013 by Award Mechanism				
Award Mechanism	Award Maximum/ Project Duration	Award Mechanism Description	Number of Projects Active during FY 2013	Total Award Amounts
Cancer Prevention Microgrants (CPMG)	- Up to \$150,000 - 2 years	Supports programs focusing on improving systems and removing barriers that increase the delivery of primary and secondary preventive services.	3	\$596,441
Evidence- Based Cancer Prevention Services (EBP)	- Up to \$3M - 3 years	Supports evidence-based services in primary, secondary and/or tertiary cancer prevention.	40	\$65,672,199
Behavior Change Through Public and Professional Education and Training (PPE)	- Up to \$500,000 - 3 years	Supports health promotion, education and outreach of the public and/or training of professionals for primary, secondary and tertiary cancer prevention that will improve health behaviors related to cancer.	38	\$13,207,935
TOTAL ACTIVE FY 2013		81	\$79,476,575	

The following charts illustrate the distribution of these projects by type, cancer site and geographic location. Projects may address more than one focus area or cancer site.

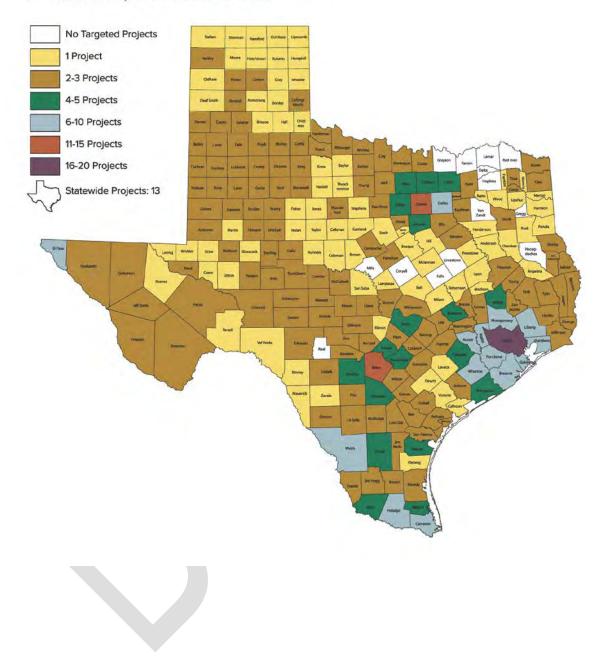
## NUMBER OF ACTIVE PROJECTS BY PRIMARY FOCUS AREA



## NUMBER OF ACTIVE PROJECTS BY CANCER SITE



# COUNTIES SERVED BY CPRIT PREVENTION PROJECTS (81 ACTIVE PROJECTS DURING FY 2013)



Prevention grantees report quarterly and annually on their progress. Based on grantee reports, since its inception through FY2013, the CPRIT funded prevention programs have served more than 1,365,000 Texans. Of these:

- 794,386 Texans have been served by education and training programs. According to grantee reports, these projects in the CPRIT prevention portfolio have led to:
- 1,251 Texans scheduling or receiving a preventive vaccination;
- 11,604 Texans taking steps to quit smoking;
- 30,385 Texans improving their behaviors related to healthy living and obesity control; and,
- 21,488 Texans scheduling or receiving screening and diagnostic services.
- 570,915 Texans have received clinical services. According to grantee reports, these projects in the CPRIT prevention portfolio have led to:
- 11,756 prevention vaccinations;
- 167,643 Texans receiving tobacco cessation services;
- 15,974 Texans receiving genetic testing and counseling;
- 9,994 Texans receiving survivor care; and
- 319,436 screenings and diagnostics for breast, cervical and colorectal cancer. Of these:
- 113,116 recipients had never before been screened;
- 23,241 abnormal results were identified;
- 1,897 cancer precursors were detected; and
- 811 cancers were detected.



#### PRODUCT DEVELOPMENT PROGRAM

## Action Plan

CPRIT's product development program is designed to accelerate the progression of new cancer drugs, diagnostics, and therapies from the laboratory into clinical practice. The objectives of CPRIT's product development program are:

- 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; and
- To provide a direct return, through intellectual property and revenue sharing, on the investments made by the people of Texas.

CPRIT funds scientifically meritorious product development projects based on the potential for translating research discoveries into products that can help cancer patients. In addition to the scientific peer review process used by all CPRIT initiatives, product development proposals are subjected to a thorough due-diligence analysis to evaluate the applicant's regulatory plan and business operations capacity.

CPRIT uses a variety of grant award mechanisms to fulfill its objectives. The three award types include:

- Company Awards supporting Texas-based companies that have undertaken at least one round of professional institutional investment in developing marketable oncology products or services;
- Company Formation Awards assisting new start-up companies, with no previous rounds of professional institutional investment, seeking to develop marketable oncology products or services (companies that are not already based in Texas must relocate to the state before receiving CPRIT funding); and
- Company Relocation Awards targeting companies based outside of the state that have conducted at least one round of professional institutional investment (these companies must relocate to Texas to develop commercially oriented oncology products or services with CPRIT funding).

## **CPRIT's Product Development Portfolio**

Information will be updated following OC meeting.

Eleven Texas-based companies have received CPRIT product development awards. Two more companies received research awards in January 2010 prior to the launch of CPRIT's commercialization program. The 13 CPRIT-funded company projects include promising drugs, diagnostics, and devices targeting a variety of cancers, including cancers of the blood (leukemia, lymphoma and myeloma), colon and rectum, esophagus, stomach, lung, and prostate. Some of the CPRIT-funded companies are developing approaches applicable to multiple cancer types.

CPRIT's product development portfolio totals \$98 million. Together with the companies' required matching funds, total investment in research and development for the 13 CPRIT-funded company projects exceeds \$150 million. In addition to creating new and improved tools and treatments for fighting cancer, CPRIT's investments are helping to build Texas' life-science industry. While bringing a product to market can take time, jobs and economic activity are generated throughout the process. Projects funded by CPRIT are expected to create approximately 140 direct jobs — highly skilled, high-wage positions in life sciences — in Texas over the three-year term of CPRIT's grant awards.

Every CPRIT award includes an intellectual property agreement that specifies a revenue return to the State of Texas from the successful development of CPRIT-funded drugs, devices, diagnostics or services. These revenue-sharing standards provide a fair return on Texas' grant funds without impeding the ability of the company to attract future investment. Like any interested investor, CPRIT is an engaged partner and holds award recipients accountable for their efforts to bring products to market.

As of August 31, 2013, 10 CPRIT-funded company projects were active, out of 13 grants that had been awarded since CPRIT's inception. One company – Apollo Endosurgery – completed work on its CPRIT- funded project prior to fiscal year 2013. Two other companies' grants were frozen during fiscal year 2013 – Kalon Biotherapeutics due to the CPRIT grant moratorium, and Peloton Therapeutics awaiting review of its application.

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Acti	Active Product Development Grant Projects in Fiscal Year 2013 by Award Mechanism							
Award Mechanism	Title	Entity	Cancer Type	Amount				
	Biobetter Cancer Monoclonal Antibody Program	Caliber Biotherapeutics	Leukemia, Lymphoma	\$12,808,151				
	Novel targeted biologics, Engineered Toxin Bodies (ETB), as cancer therapeutics	Molecular Templates, Inc.	Lymphoma	\$10,600,000				
Company	Clinically Actionable Mutation Profiling for Cancer Personalized Medicine using Scalable, Ultra-deep Next Generation Sequencing	Asuragen, Inc.	All Sites	\$6,837,265				
Award  Cancer Treatment Including Drug Discovery/Development and Clinical Trials		Mirna Therapeutics, Inc.	Basic Science, Multiple Sites	\$10,297,454				
	Cancer Biology and Genetics Including Oncogenesis Genomics and Proteomics	Rules-Based Medicine	Multiple Sites	\$3,024,432				

Award Mechanism	Title Entity		Cancer Type	Amount
	Clinical Development of CaspaCIDe, a Cell Therapy Safety Switch	Bellicum Pharmaceuticals, Inc.	Leukemia, Lymphoma, Myeloma	\$5,680,310
Company	MRI-Guided Laser Therapy for Targeted Treatment of Localized Prostate Cancer	Visualase, Inc.*	Prostate	\$2,151,776
Award	Enrichment Filter and Point- of- use Assay Platform for Detection of Circulating Tumor Cells  Ingeneron, Inc.*		Multiple Sites	\$198,111
Subtotal: Active	e Company Awards			\$51,597,499
Company Formation	Expanding the Market and Success Rates for Myeloablative Cancer Treatments Using PUL-042, an Innate Immune Stimulant	Pulmotect, Inc.	Breast, Leukemia, Lymphoma, Ovary	\$7,126,398
Company Relocation	TexCITE (Texas Cancer ImmunoTherapy Enterprise): Focused development of innovative cell therapies for cancer	Cell Medica	Lymphoma, Other	\$15,571,303
TOTAL ACTIVE	FY 2013	10	\$74,295,200	
Inactive/Close	Inactive/Closed			\$23,704,800
Total Grants to	Date	13	\$98,000,000	

Companies that received research awards in January 2010 prior to the launch of CPRIT's commercialization program.

# **Projected Programmatic Changes**

In some respect, CPRIT can be characterized as a passive strategic fund in contrast to other state investment programs such as the Texas Enterprise Fund and the Texas Emerging Technology Fund housed in the Office of the Governor. Those funds can be used proactively at the direction of state leadership to affect specific goals, targets, or purposes. CPRIT, on the other hand, can only respond to the applications it receives through its issuance of Requests for Applications (RFA). CPRIT can call for certain types of projects in its RFAs but it can only fund those that are recommended after going through the established competitive and rigorous peer review process. If no applications are made in response to an RFA, CPRIT cannot proactively solicit them.

Changes to CPRIT's enabling legislation in 2013 require for the first time that the Oversight Committee publicly develop priorities within and between the three programs. This will provide transparency in how the Oversight Committee plans to orient the agency's investment portfolio between and within the programs. It will also guide the staff in developing RFAs for each fiscal year. Once developed, the Oversight Committee priorities are to be reviewed and adjusted annually as circumstances change and new information is found concerning cancer-related advances in prevention, scientific research, and product development.

As a result of these factors, changes to each program should be expected.

Fiscal, staffing, and capital resource needs to accommodate programmatic changes will occur to some degree over time. These items have already been addressed in the External Assessment.

# <u>Use of Historically Underutilized Businesses (HUBs) in Agency Purchasing</u> and Public Works

CPRIT is committed to assisting the state to improve business opportunities for HUBs and details of the agency's progress are contained in the section "Historically Underutilized Businesses".

CPRIT's ability to improve its HUB goals is limited by the types of vendors available for the service needs of the Institute. In particular, CPRIT's professional services are dominated by the \$7.7 million per year contract with SRA International, Inc. which provides pre-and post-award grant management support services. In 2014 CPRIT was able to procure professional services to perform the independent audit of the agency's fiscal year 2013 financial statements from a HUB vendor, McConnell & Jones LLP, a Houston area accounting firm. CPRIT requires HUB preference in its contracts with grantees. Grantees must use reasonable efforts to purchase materials, supplies or services from HUB vendors. Additionally, grantees are required to report annually details concerning the types of good or services and actual dollars expended with HUB vendors. Presently, those data are not in a format that allows the Institute to extract and

compile it. However, CPRIT is working to improve its collection and analysis of these data.

CPRIT believes its most effective program for providing access to underrepresented individuals in cancer-related professions is through the use of its Training Awards RFAs. These awards sustain specialized cancer research training programs to promote the next generation of investigators and leaders in cancer research. Individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds are especially encouraged to participate in these programs. To date, CPRIT has made \_\_\_\_\_ of these awards totaling \$\_\_\_\_\_ (Margaret to update awards info.)

## Lisa to update gender/ethnic/cultural data.

CPRIT is also committed to diversity in its own offices. \_\_\_\_\_ of its 10 highest paid employees are women. Four out of seven members of the senior staff are women. In a related note, due to CPRIT's current Chief Scientific Officer's esteemed position within the scientific community, particularly as a champion of diversity in the workplace, the Margaret L. Kripke Award was established at MD Anderson Cancer Center to honor individuals who have enhanced the careers of women in cancer medicine and cancer science.

# Steps Taken to Ensure Fiduciary Responsibility and Accountability

In addition to having what it believes to be the strictest ethics policy for its board and staff among all state agencies, CPRIT has developed a rigorous compliance program for agency and board operations and the grant making and post award monitoring processes. As of this writing, CPRIT is evaluating proposals to develop further enhancements to its compliance plan which are expected to be implemented during this 2015-2019 Strategic Plan period. Also as of this writing, CPRIT is recruiting a full-time staff director of internal audit to conduct on-site audit activities and to manage CPRIT's on-going outsourced internal audit contract.

#### CPRIT COMPLIANCE PROGRAM

In December 2012, the CPRIT Oversight Committee established the agency's compliance program, which was later codified by statutory changes included in Senate Bill 149 as passed by the 83rd Texas Legislature, mandating a program "to assess and ensure compliance by the Institute's committee members and employees with applicable laws, rules and policies." Changes enacted by the 83rd Legislature also require the Institute to continuously monitor and ensure that each grant recipient complies with the terms and conditions of its grant contract: As such CPRIT has initiated a comprehensive overhaul of its compliance program. Steps already taken include:

- 1. Hiring a Chief Compliance Officer in December 2013.
- 2. Completion of "Grant Pedigree" Project: Beginning with the award slates ratified by the Oversight Committee in December 2012, the former compliance officer created a "grant pedigree" detailing the CPRIT processes each grant application must follow. This pedigree provides documentation and assurance to the Oversight Committee that each grant award has met statutory, rule and Institute procedures. The pedigree will continue for the life of each grant and document subsequent grant monitoring and compliance with contract terms and conditions. The grant pedigrees have undergone continued enhancement and improvement to ensure that each pedigree includes all the processes and procedures implemented by statute or CPRIT rules.
- 3. Hiring Additional Grant Monitors: To ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and to exercise proper stewardship over Grant Award funds, CPRIT has hired three Grant Specialists to work under the supervision of a grant manager, who reports to both the Chief Compliance Officer and the General Counsel. The Grant Specialists will be both communicating and conducting training on process and procedures, such as the importance of the timeliness of reports, with grant recipients, but also conducting monitoring responsibilities such as on-site desk reviews and inspections to ensure that each grant recipient complies with the terms and conditions of the grant contract, including verification of the amounts of matching funds dedicated to the research that is the subject of the grant award.
- 4. Hiring of a Legal/Compliance Attorney: To assist in the facilitation of the legal and compliance processes and procedures, as well as internal investigations among other duties, an attorney was hired in May 2014 to report to the Chief Compliance Officer and General Counsel.
- 5. Adoption for New Rules with Serious Consequences Imposed on Grantees who are Delinquent in Submitting Grant Monitoring Reports: The CPRIT Oversight Committee adopted new and enhanced rules providing consequences, such as the loss of grant funds, when required reporting obligations have not been met. These new rules in conjunction with the hiring of grant specialists to monitor

compliance and provide a better communication link with grantees, is intended to result in a more efficient and more thorough compliance program.

In addition to the actions above, the CPRIT is initiating a thorough review and design of a more comprehensive and robust compliance program. This includes CPRIT contracting with a qualified assurance firm to work with CPRIT staff to design and implement a comprehensive compliance program. The compliance design plan is estimated to be completed by July 2014.

The successful vendor will have experience in agency compliance, auditing, risk assessment, agency restructuring and reorganization, strategic planning, compliance training, and fraud investigation. The contracted services will provide, in a detailed written plan, strategic guidance and direction to CPRIT through the design and implementation phases of the compliance program that defines an optimal level and structure for staffing of outsourced and internal agency staff for the grant application and post award monitoring processes. The plan will include strategic guidance on how to develop of the comprehensive compliance program based on CPRIT's mission, goals and objectives including a program structure that incorporates the following specific compliance components and requirements.

#### Organizational Structure Design

Work with CPRIT to establish an accountability structure that ensures that a proper level of oversight and process ownership exists. The accountability structure should establish who maintains ownership of the design and operation of controls within the organization and provides mechanisms for regulating individuals to ensure they act ethically and in the Institute's best interest.

#### Risk Assessment

Identify and develop a strategy for ongoing risk assessment of the CPRIT grant award process including grant applicants, recipients, and contractors;

Identify any current information technologies to support CPRIT's risk assessment program that complements and/or utilizes existing compliance IT technologies.

#### Grant Compliance Monitoring

Develop a compliance monitoring model, including structure, budget and staffing needs, to implement an ongoing grant monitoring program that monitors compliance with grant awards and grant progress;

Recommend technological solutions for grant compliance monitoring while leveraging current software and technology.

#### Anonymous Compliance Reporting (Hotline Service)

Work with CPRIT staff to evaluate, recommend and implement an anonymous compliance communicating and reporting option, such as a hotline, that is cost effective and complements the comprehensive compliance program.

#### Investigation and Follow-up

Provide strategic consultation on internal and/or outsourced expertise and staffing required for a compliance investigations and follow-up to investigations.

#### **Enforcement**

Provide strategic consultation on developing and implementing compliance enforcement rules and policies, including staffing and budget changes necessary following a negative finding in a compliance investigation.

#### Internal Auditing

Work with CPRIT staff to develop an Internal Audit program, which complements the compliance program, to evaluate the effectiveness of internal controls, including automated controls for risk and compliance work flow; ensures that data flow is timely, accurate and comprehensive; and alerts senior management to best practices in compliance processes.

Provide recommendations on expertise and staffing requirements including outsourcing or co-sourcing the internal audit functions with respect to CPRIT's mission, goals and objectives.

#### Compliance Education and Training

Work with CPRIT to provide strategic direction to ongoing compliance training and education programs, including necessary staffing and budget changes, that complements CPRIT's comprehensive compliance program with education and training of CPRIT Oversight Committee members and staff as well as grant applicants and recipients.

# Agency Goals; Objectives and Outcomes Measures; Strategies and Output; Efficiency; and Explanatory Measures

GOAL: 1

Cancer Research and Prevention Services

**OBJECTIVE:** 1

To create and expedite innovation in the area of cancer research and prevention services

**STRATEGY: 1.1.1.** 

Award Cancer Research Grants

#### OUTCOME

- Non-State Funds Leveraged as Match for Research Grants (in millions)
- 2. Total Research Matching Fund Expenditures

#### OUTPUT

- Number of Researchers Recruited to Texas to Conduct Cancer Research
- 2. Number of Entities Relocating to Texas for Cancer-Research Related Projects

#### **EXPLANATORY**

- 1. Average Dollar Amount of Research Grants Awarded
- 2. Number of Research Grant Awards
- 3. Number of New Jobs Created and Maintained
- 4. Number of Published Articles on CPRIT-Funded Research Projects

#### STRATEGY: 1.1.2.

**Award Cancer Prevention Grants** 

#### OUTCOME

 Percent of Texas Regions with Cancer Prevention Services and Activities Initiated as addressed in the Texas Cancer Plan through Grant Awards

#### OUTPUT

 Number of People Served by Institute-funded Prevention and Control Activities

#### **EXPLANATORY**

Annual Age-adjusted Cancer Mortality Rate

**STRATEGY: 1.1.3.** 

**Grant Review and Award Operations** 

GOAL: 2

Indirect Administration

**OBJECTIVE: 2** Indirect Administration

STRATEGY: 2.1.1.
Indirect Administration

# **Historically Underutilized Businesses**

CPRIT makes a good faith effort to purchase and award contracts to historically underutilized businesses (HUB) in accordance with the Texas Government Code, Title 10, Subtitle D, Chapter 2161 and rules established by the Comptroller, Texas Procurement and Support Services Division (TPASS) in Texas Administrative Code, Title 34, Part 1, Chapter 20, Subchapter B.

A HUB expenditure is a payment made to a business that has been certified as a HUB by the Comptroller TPASS and classified under a Comptroller Object Code chosen for tracking HUB expenditures. The Comptroller TPASS tracks the Institute's HUB expenditures through the Uniform Statewide Accounting System.

State agencies are required to include in their strategic plans agency goals, objectives, performance measures, and strategies addressing their HUB expenditure plans located in the Internal Assessment. CPRIT's purchases consist of other services, professional services, and commodities. The operating budget for a small agency limits the dollars spent; however, the Institute continues to increase HUB purchases.

# Historically Underutilized Businesses Plan

CPRIT will continue to encourage increased participation of Historically Underutilized Businesses (HUB) in procurement and contracting. During fiscal years 2011-2015, CPRIT will make a good faith effort to purchase and contract with HUBs to achieve the target goals established for state agencies.

#### Figure XV HUB Plan

	The Institute will implement existing polices and procedures to ensure meaningful and substantial inclusion of HUB's in all possible agency purchases
Objective	To attain agency HUB targets for professional services, other services and commodities over the next year
Outcome Measure	Percentage of total dollar value of purchasing contracts awarded to HUB's
	Implement the agency plan for increasing HUB purchases
Measures	<ul> <li>Number of HUB contractors contacted for bid proposals</li> <li>Number of HUB contracts awarded</li> <li>Dollar value of HUB contracts awarded</li> <li>Percentage of HUB expenditures attained</li> </ul>

CPRIT grant award recipients are expected and required to make a good faith effort to use the services, products, or materials provided by a certified HUB. The CPRIT Project Guide require grant recipients to submit quarterly reports identifying efforts to procure goods and services through HUBs. Staff verifies submitted reports. The Institute proactively notifies eligible contractors about procedures for becoming certified as HUBs.

CPRIT will continue to analyze internal quarterly expenditures made with HUBs and seek opportunities to increase HUB procurements.

#### Figure XVI Annual Internal HUB Measures for FY 2013

Measures	<ul> <li>Number of HUB contractors contacted for bid proposals</li> <li>Number of HUB contracts awarded</li> </ul>				
	<ul> <li>Dollar value of HUB contracts awarded</li> </ul>		\$ 390,853		
Percentage of H	Percent Percentage of HUB Expenditures Attained Attained				
Other Services Commodities		4.01% 5.56%	24.6 % 21.0 %		

# **Technology Resource Planning**

# **Not Updated Yet**

# **Technology Assessment Summary**

## **Vision**

The vision for the CPRIT Information Technology (IT) division is to foster an environment that embraces the change that technology represents while leveraging technology to promote an accessible, collaborative, supportive and empowering culture internally within our agency and fostering a spirit of transparency in service to the people of Texas. As a supporting foundation of this vision, Information Technology is committed to the following core values and principles: accountability, integrity, teamwork, efficient and effective innovation, and responsiveness.

# Core Information Technology Processes

Information Technology acts as an operational foundation for CPRIT serving the needs of agency staff, partners and the general public. This foundation has three major components: infrastructure management (ensure daily operations, security, continuity), direct user/public support (troubleshooting, education), and agency/departmental level technology planning support (planning, business analysis, sustainability).

# Mission and Strategic Goals

The overall mission of Information Technology is to provide a reliable, consistent and secure information technology infrastructure that advances the core objectives of the Institute, enhances administrative operations, is driven by institutional priorities, incorporates stakeholder needs, and complies with statewide initiatives and goals set forth by the Department of Information Resources. IT's basic goals are access, collaboration and innovation, privacy and security, quality service, and "greener" IT. To this end, we have defined five broad strategic goals that encompass and support our department's mission.

### Goal 1: Anywhere/Anytime Access

Public and agency stakeholder access to information should not be limited or restricted because of physical location or time of day. IT will utilize redundant services and webbased tools to provide secure access to internal agency systems and hosted applications for agency personnel. Additionally, the agency website and other webbased services will be used to provide agency constituents and the general public with access to agency contact information, Institute mission objectives, grant request for applications, information on awarded grants, agency guidelines and policies.

#### Goal 2: Collaboration and Innovation

We accept the challenge of thinking outside of the box. By leveraging IT, staff knowledge and embracing new technologies, we will create efficient and cost-effective solutions to address agency issues and objectives. Focusing on the deployment and utilization of collaborative tools will enable staff to engage with each other and the public at large, working together to support and generate new ideas and processes to assist in the delivery of truly innovative and efficient services and solutions.

#### Goal 3: Privacy and Security

Protecting critical agency resources and sensitive information from service vulnerabilities, accidental disclosure, theft and cyber attacks are of paramount concern. IT will continue to ensure that infrastructure components are sufficiently robust and protected by developing processes in which periodic independent audits and internal policy reviews regularly occur.

#### **Goal 4: Quality of Service and Continuous Improvement**

Utilizing performance metrics and stakeholder feedback to determine IT effectiveness and to quantify performance will maintain a highly responsive and nimble enterprise environment which fosters a spirit of constant learning and comprehensive technical process examination to continue improving and evolving to meet agency initiatives and to efficiently and effectively serve the needs of our staff and constituents.

#### Goal 5: "Greener" IT

Information Technology will leverage software solutions and hardware platform selection as well as better defining internal processes to vigilantly reduce the agency's ecological footprint. By utilizing server and application virtualization, IT can remain highly responsive and innovative while maximizing the usage of current infrastructure components, realize cost savings from the reduction and centralization of infrastructure resources and support agreements, increase redundancy and reduce disaster recovery response timelines.

#### **Goal 6: Incorporate Cloud Services**

As internal systems age or initiative scopes increase, cloud services will be compared with the traditional costs of increasing infrastructure to meet those demands. Using stringent cost versus benefit guidelines, IT will evaluate and review security, privacy and data storage requirements of both new and existing initiatives so that cloud platforms and services can be incorporated where it improves operational efficiently and decreases the required maintenance footprint of the department.

# Part II: Technology Initiative Alignment Why part 2 - where's 1? mg

The following table summarizes CPRIT Info objectives and strategies as they relate to a Additionally, each objective and/or strategy Statewide Technology Priorities (STPs), if p	departmental goals. is correlated to related possible.			Goal 1: Anywhere/Anytime Access	Goal 2: Collaboration and Innovation	Goal 3: Privacy and Security	Goal 4: Quality of Service and Continuous Improvement	Goal 5: "Greener" IT	Goal 6: Incorporate Cloud Services
Objectives	Strategies	STPs	Status			Goals			
Incorporate effective IT governance mechanisms that align technology priorities and policies with established agency goals and objectives	1.1: Develop an annual work plan detailing the prioritization of information technology efforts		Planned		<b>√</b>		✓		
	1.2: Clearly define key progress indicators and expected results for IT projects		Planned	•	<b>~</b>		<b>√</b>		
Clarify IT life-cycle policy and ensure that it continues to provide reliable, efficient and cost effective enterprise infrastructure services	2.1: Maintain existing enterprise infrastructure and services	P4	Current	<b>√</b>		✓	✓	✓	
	2.2: Continue agency current policy of responsible procurement	P1, P4	Current		✓	<b>√</b>	✓	<b>✓</b>	✓
	2.3: Implement a IT asset management and ticketing system	P4	Current		✓		✓		
Facilitate implementation of business continuity and disaster recovery planning and scheduled testing	3.1: Deploy agency-wide system, application level and service monitoring	P4	Planned		<b>√</b>		<b>√</b>		
	3.2: Create a virtualized, fully redundant hardware and software infrastructure on-site	P4	Current	<b>✓</b>	<b>√</b>		<b>√</b>	<b>√</b>	

The following table summarizes CPRIT Infobjectives and strategies as they relate to Additionally, each objective and/or strategy Statewide Technology Priorities (STPs), if	departmental goals.			Goal 1: Anywhere/Anytime Access	Goal 2: Collaboration and Innovation	Goal 3: Privacy and Security	Goal 4: Quality of Service and Continuous Improvement	Goal 5: "Greener" IT	Goal 6: Incorporate Cloud Services
Objectives	Strategies	STPs	Status			Goals			
	3.3: Clarify and update agency disaster recovery and emergency response plans	P1, P4	Planned	<b>✓</b>	*	*	✓		<b>√</b>
4. Develop a methodology to review, revise, and implement agency record, service and system security policies to ensure the privacy and integrity of information resources	4.1: Complete an annual analysis of information resources procedures and security policies	P9	Planned		<b>√</b>	<b>✓</b>	<b>√</b>		
	4.2: Development an Incident Response Plan	P9	Planned		<b>✓</b>	<b>✓</b>	✓		
	4.3: Regularly educate and inform agency staff on security policies, best practices, and incident reporting	P9	Planned		<b>√</b>	<b>~</b>	<b>√</b>		
	4.4: Define and require a consistent encryption policy to protect sensitive agency information	P9	Current			<b>✓</b>	✓		
	4.5: Engage DIR to perform an annual system/network vulnerability test	P9	Planned			<b>✓</b>	✓		
5. Support and enhance agency collaborative efforts	5.1: Implement an agency-wide, resource planning and project tracking system	P1	Planned		<b>~</b>		<b>√</b>		✓

The following table summarizes CPRIT Info objectives and strategies as they relate to a Additionally, each objective and/or strategy Statewide Technology Priorities (STPs), if pobjectives	departmental goals. is correlated to related	STPs	Status	Goal 1: Anywhere/Anytime Access	Goal 2: Collaboration and Innovation	Goal 3: Privacy and Security	Goal 4: Quality of Service and Continuous Improvement	Goal 5: "Greener" IT	Goal 6: Incorporate Cloud Services
2.0,200.00								T T	
	5.2: Deploy an enterprise collaboration suite and integrated storage system	P1	Planned	, The state of the	>		✓		<b>√</b>
	5.3: Maintain and expand agency adoption of audio/video technologies	P1, P4	Current		<b>√</b>		✓	<b>✓</b>	<b>√</b>
Provide access to agency information and services anywhere/anytime	6.1: Provide secure, web-based access to information, storage resources and critical services for agency staff and stakeholders	P1, P6	Current	<b>√</b>	<b>√</b>		<b>√</b>	<b>✓</b>	<b>√</b>
7. Redefine and enhance the agency's world wide web presence	7.1: Make existing agency public web resources easier to discover, navigate, and understand		Current	<b>✓</b>	✓		✓		
	7.2: Implement a web content management system		Current	✓	<b>√</b>		<b>√</b>		
8. Maintain and expand an environmentally responsible IT operational focus	8.1: Conduct an annual energy audit of agency servers and desktop system to determine and track footprint changes	P4	Planned				<b>√</b>	<b>✓</b>	
	8.2: Implement centralized storage and virtualization systems	P1, P4	Current				✓	<b>√</b>	✓

The following table summarizes CPRIT Info objectives and strategies as they relate to Additionally, each objective and/or strategy Statewide Technology Priorities (STPs), if	departmental goals.  is correlated to related possible.			Goal 1: Anywhere/Anytime Access	Goal 2: Collaboration and Innovation	Goal 3: Privacy and Security	Goal 4: Quality of Service and Continuous Improvement	Goal 5: "Greener" IT	Goal 6: Incorporate Cloud Services
Objectives	Strategies	STPs	Status			Goals	3		
Example 1. Services  9. Limit infrastructure procurement, deployment and maintenance costs while increasing efficiency by utilizing cloud services	9.1 Perform annual review of internal services and systems to determine if they are candidates for cloud hosted platforms or products	P1, P4	Planned						<b>√</b>
	9.2 Adopt cloud services for web-based public facing applications	P1	Planned						<b>√</b>

# Technology Initiative Alignment Details

**Objective 1:** Incorporate effective IT governance mechanisms that align technology priorities and policies with established Institute goals and objectives, and overall mission. Senior management and IT will work together to create an annual work plan defining agency-wide technology initiatives and establishing the prioritization of those efforts. IT will assist executive management in developing a policy framework that addresses stakeholder expectations, transparently defines infrastructure capabilities, and communicates risks in plain language inherent in new agency technology initiatives and requests. Working with agency senior management to establish a standard set of metrics and benchmarking measures for IT projects.

**Objective 2:** Clarify IT life-cycle policy and ensure that it continues to provide reliable, efficient and cost effective enterprise infrastructure services, maintenance services, and reviewing and updating maintenance contracts to ensure that core systems, equipment, and software platforms are fully covered and serviceable.

**Objective 3:** Facilitate implementation of business continuity and disaster recovery planning and scheduled testing to ensure that redundant systems exist to sufficiently

protect the integrity and security of agency data and maintain business continuity and accessibility to critical agency technical resources. This includes proactive monitoring of network, server and application level infrastructures; utilizing server virtualization technologies, redundant network infrastructure hardware along with centralized storage to ensure that physical and application-level redundancy exist on-site; and updating agency service/system criticality and service restoration guidelines and engaging with the Department of Information Resources, other state entities as well as commercial solution providers to determine what cloud-based or offsite resources exist for colocation or relocation of agency resources in the event of a facility, natural or manmade, disaster.

**Objective 4:** Develop a methodology to review, revise and implement agency record, service and system security policies to ensure the privacy and integrity of information resources. This includes reviewing agency security policies annually will assist in streamlining processes, in maintaining an effective service plan to address weaknesses and will ensure that major changes in technological trends are evaluated and prepared for; defining and developing an Incident Response Plan that will encompass the agency's process of identification of, response to, and notification of compromised or infected systems, determination of privacy impact, and target/victim notification; enhancing general security awareness among staff; defining and implementing an encryption policy for all agency data storage systems, mobile computing devices, email, electronic data transfers; and engaging the Department of Information Resources to perform an independent annual system, application, and external network vulnerability test.

**Objective 5:** Support and enhance agency collaborative efforts which includes implementing an agency-wide resource planning and project tracking system and enhancing teleconference bridges as well as both desktop and conference room videoconferencing systems and web-based meeting software to enhance collaboration between remote entities and CPRIT offices.

**Objective 6:** Provide access to agency information and services which includes a webbased, secure virtual private network for staff usage ensuring access to email, shared file storage locations and hosted productivity applications, providing access to collaborative resources and critical information from any location.

**Objective 7:** Redefine and enhance the agency's World Wide Web sites which provide accurate, up-to-date, and responsive information and a platform to assist the public in understanding the direct impact and relevance of CPRIT funded projects in their local neighborhoods, cities, counties and in the entire state of Texas.

**Objective 8:** Maintain and expand an environmentally responsible IT operational focus which includes purchasing infrastructure hardware designed for low energy consumption, limiting endpoint power usage by standardizing on small form factor PCs, and maintaining a limited infrastructure footprint by consolidating agency physical storage devices and server systems through the use of virtualization.

**Objective 9:** Limit infrastructure procurement, deployment and maintenance costs while increasing efficiency by utilizing cloud services. Instead of only performing traditional analysis when assessing business or customer requirements, IT will also research cloud platforms and products that could be leveraged instead. By employing mature services, response times should increase while support and maintenance costs decrease. Decoupling the agency, provided applications and services from physical hardware maintained by IT, providing a more agile disaster recovery response, increasing general availability of hosted services via the Internet and significantly reducing departmental investment in maintaining legacy systems while simultaneously limiting future hardware and software licensing purchases.



# **Appendices**

# This appendix needs updating

# Appendix A: Description of Agency's Planning Process

The following describes the key dates and activities undertaken by the Institute in its strategic planning process:

#### • June 2011

Began a series of facilitated meetings with Staff and Board Members to discuss strategic planning process, mission statement and future goals.

Priority areas for future program development were determined by the legislation creating the Institute and current ongoing prevention and education programs being funded.

#### March 2012

Institute strategic plan and information resources strategic plan instructions were received from the Governor's Office of Budget and Planning and the Legislative Budget Board. Staff will develop content and format of the FY 2013 – 2017 Strategic Plan (External/Internal Assessments, Mission, Goal, Objective, Strategies, Outcome, and Outputs).

Meeting with facilitator to to discuss priority areas and plans for implementation.

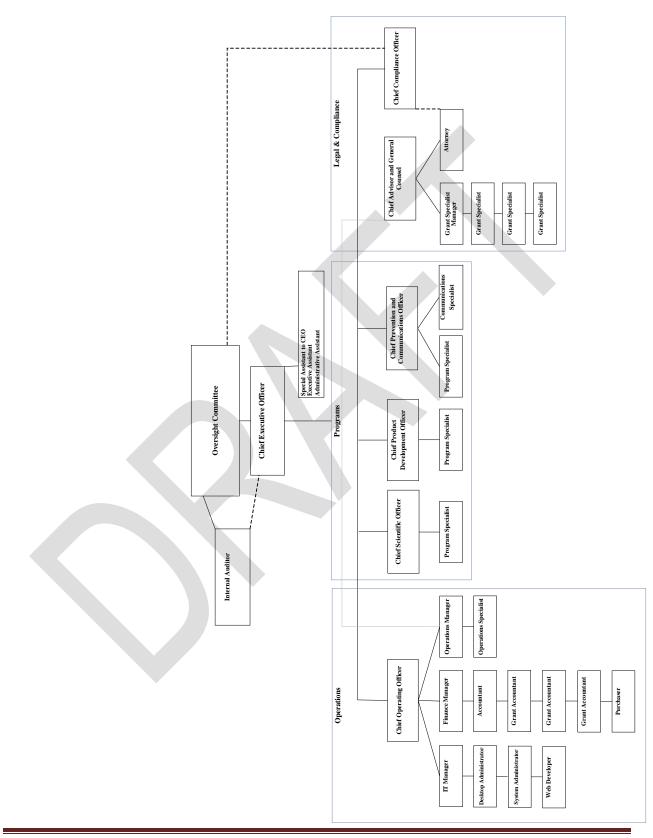
#### June 2012

Strategic plan contents reviewed, approved, and authorized for submission by Institute Oversight Committee.

#### June 2012

FY 2011 – 2015 Strategic Plan submitted.

Appendix B: Current Organizational Chart (as of 06-01-14)



# Appendix C: Five Year Projections for Outcomes 2011-2015

Not Updated Yet – Heidi and Alfonso

OUTCOME	2015	2016	2017	2018	2019
Non-State Funds					
Leveraged as Match for Research Grants (in					
millions)	\$29.4	\$35.9	\$34.4	\$35.2	\$41.4
Total Research Matching Fund Expenditures	\$88,121,008	\$107,889,465	\$103,214,692	\$105,639,831	\$124,206,531
Percent of Texas	. , ,	, ,			. , ,
Regions with Cancer					
Prevention Services and					
Activities Initiated	100%	100%	100%	100%	100%

#### Non-State Funds Leveraged as Match for Research Grants:

Total amount of non-state funds leveraged as match for Institute research grants. Non-state funds include any federal, non-profit, corporate, or philanthropic sources of money used as match.

## **Total Research Matching Fund Expenditures:**

The total expenditures for the conduct of research and development from all matching fund sources during the reporting period. The total may include indirect costs and fringe benefits.

# Percent of Texas Regions with Cancer Prevention Services and Activities Initiated as addressed in the *Texas Cancer Plan* through Grant Awards:

Total verified number of Texas regions (expressed as a percentage) receiving cancer prevention services through direct Institute intervention or Institute-funded contracts that address one or more of the following *Texas Cancer Plan* goals: Prevention Information and Services; Early Detection and Treatment; Professional Education and Practice; Cancer Data Acquisition and Utilization; and Survivorship. The measure reflects the Institute's ability to provide a comprehensive approach to cancer control planning and implementation. Inclusion of a Texas county in this measure calculation does not imply that all of the goals, objectives, and strategies related to the *Texas Cancer Plan* have been implemented.

# Appendix D: Performance Measures Definitions Not updated yet – Heidi and Alfonso

# **GOAL 1 – Cancer Research and Prevention Services**

# Objective A.1: Invest in Texas-Based Cancer Research Projects

Outcome Measure A.1.	Non-State Funds Leveraged as Match for Research Grants (in millions)
Short Definition:	Total amount of non-state funds leveraged as match for Institute research grants. Non-state funds include any federal, non-profit, corporate, or philanthropic sources of money used as match.
Purpose/Importance:	This measure indicates the amount of non-state appropriated dollars invested in cancer research in Texas.
Source/Collection of Data:	Data for all leverage funds announced is documented in the Institute agreements signed by grant recipients.
Method of Calculation:	Institute staff will total the amount of leverage investments identified in signed protect agreements for projects receiving Institute awards.
Data Limitations:	None
Calculations Type:	Cumulative
New Measure:	Yes
Desired Performance:	Higher than target

Outcome Measure A.2.	Total Research Matching Fund Expenditures
Short Definition:	The total expenditures for the conduct of research and development from all matching fund sources during the reporting period, including indirect costs. This would exclude amounts granted by the Cancer Prevention and Research Institute and would also exclude the Institute's fringe benefits.
Purpose/Importance:	This measure is an indicator of the level of matching research dollars expended for cancer research grant awards.
Source/Collection of Data:	Annual financial reports from grant recipients documenting actual expenditures of all funds related to the Institute's grant award.
Method of Calculation:	The total dollar amount of matching fund expenditures for the conduct of research and development from all funding sources documented in the Institute's award agreements signed by the grant recipients.
Data Limitations:	None
Calculations Type:	Cumulative
New Measure:	Yes
Desired Performance:	Higher than target

Outcome Measure A.3.	Percent TX Regions w/ Cancer Prevention Services and Activities Initiated					
Short Definition:	Total verified number of Texas regions, as described by the Texas Health and Human Services Commission, expressed as a percentage, receiving cancer prevention services through direct Institute intervention or Institute-funded contracts that address one or more of the Texas Cancer Plan goals.					
Purpose/Importance:	The Texas Cancer Plan goals are: Prevention Information and Services; Early Detection and Treatment; Professional Education and Practice; Cancer Data Acquisition and Utilization; and Survivorship. The measure reflects the Institute's ability to wage a multi-faceted attack on cancer.					
Source/Collection of Data:	Each initiative is required to apply for Institute funding annually. The applicant must report which Texas Cancer Plan goals are being addressed by their activities and must also indicate the geographic area(s) their program will serve. Each applicant must address at least one Cancer Plan goal and may address multiple goals.					
Method of Calculation:	Institute staff verifies the goals being addressed and creates a matrix documenting all initiatives and goals addressed. Geographic areas served will also be tracked. Agency records, and/or a current list of initiatives that are promoted by direct Institute intervention or funded initiatives will substantiate the percentage of Texas regions with services and activities addressed in the Texas Cancer Plan.					
Data Limitations:	Inclusion of a Texas region in this calculation does not imply that all of the goals, objectives, and strategies related to the Texas Cancer Plan have been implemented.					
Calculations Type:	Non-cumulative					
New Measure:	Yes					
Desired Performance:	Higher than target					
Output Measure A.1.1.2.	Measure: Number of People Served by Institute Funded Prevention and Control Activities					
Short Definition:	Total verified number of people in Texas receiving cancer related information or services provided by the Institute or Institute funded initiatives. This measure excludes professionals who are counted under separate measure. Duplicate counts may occur if people make multiple contacts with Institute initiatives.					
Purpose/Importance:	This measure is an indication of the prevention program's reach to Texans with effective science-based programs and/or services.					
Source/Collection of Data:	The number of persons in Texas receiving cancer related information and services is reported in <u>prevention grantees'</u> quarterly reports.					
Method of Calculation:	Institute staff verifies the number of people served <u>from grantees'</u> <u>quarterly reports</u> and creates a cumulative total that is substantiated by records retained at <del>contractors'</del> <u>grantees'</u> sites.					

Data Limitations:	The majority of data reported by the Institute involves work done by grantees and their subcontractors. This can create a lag time in reported data resulting in a need for updating previously reported numbers. Large variances in performance from quarter to quarter and year to year are likely to occur due to the wide variety of programs and services funded by the Institute including some grant projects ending and others beginning.					
Calculations Type:	Output					
New Measure:	No					
Desired Performance:	Higher than the target					
Output Measure A.1.1.1.	Number of Researchers Recruited to TX to Conduct Cancer Research					
Short Definition:	The total number of Scientific researchers who relocate to Texas for a faculty position at a Texas based academic institution.					
Purpose/Importance:	This measure indicates the number of scientific researchers in the area cancer research attracted to Texas because of the availability of CPRIT research grant funds.					
Source/Collection of Data:	CPRIT records of the number of academic institutions awarded a grant ratified by the Oversight Committee based on a grant application to recrua scientific researcher to their institution.					
Method of Calculation:	The total number of researchers recruited to Texas during the fiscal year documented by the ratified award slates and Oversight Committee meeting minutes which record these award decisions.					
Data Limitations:	None. All data is the result of the number of research recruitment grants awarded to academic institutions.					
Calculations Type:	Output					
New Measure:	No					
Desired Performance:	Higher than the target					
Output Measure A.1.1.1.	Number of Research Grant Awards					
Short Definition:	Number of research grants made by the Institute.					
Purpose/Importance:	This measure indicates the workload of the Institute in awarding grants and managing those grants through their award cycles.					
Source/Collection of Data:	Signed research grant awards with the Institute.					
Method of Calculation:	The total number of research grant awards issued to grant recipients through signed agreements.					

Data Limitations:	None.					
Calculations Type:	Explanatory					
New Measure:	No					
Desired Performance:	Higher than the target					
Output Measure A.1.1.1. Number of Entities Relocating to Texas for Cancer-Research						
Short Definition:	The total number of business or research entities which establish new business or research operations in Texas in order to participate in an Institute-funded grant award.					
Purpose/Importance:	This measure indicates the level of attraction of cancer research funding to draw new businesses and research entities to Texas.					
Source/Collection of Data:	Annual status or other reports from a grant recipient documenting the relocation of a business or research entity due to the research project funded by the Institute.					
Method of Calculation:  The total number of business or research entities relocating documented in status reports from grant award recipients.						
Data Limitations:	None.					
Calculations Type:	Explanatory					
New Measure:	No					
Desired Performance:	Higher than the target					

Explanatory Measure A.1.1.1.	Number of Published Articles on CPRIT-Funded Research Projects		
Short Definition:	Number of scientific publications that include articles that result from CPRIT funded research projects.		
Purpose/Importance:	This measure indicates the level of success recognized by external research and medical institutions of CPRIT funded projects in the quest to develop breakthroughs in cancer research and prevention services.		
Source/Collection of Data:	The number of publications is reported in awardees annual reports.		
Method of Calculation:	Institute staff will verify and total the number of publications reported by awardees in their report submissions. Publications are interpreted as articles that include references to actual scientific outcomes from awarded projects.		

Data Limitations:	The majority of data reported by the Institute involves work done by grantees and their subcontractors. This can create a lag time in reported data resulting in a need for updating previously reported numbers. Variances in performance from quarter to quarter and year to year are likely to occur due to the variety of work done by Institute funded initiatives.
Calculations Type:	Explanatory
New Measure:	No
Desired Performance:	Higher than the target

Explanatory Measure A.1.1.1.	Number of New Jobs Created and Maintained
Short Definition:	An unduplicated count of the number of jobs that were created and maintained (one year) using funds provided by the Institute.
Purpose/Importance:	This measure indicates the impact of Institute funding to preserve and create new jobs; to build human resources stability in the Cancer arena.
Source/Collection of Data:	The number of jobs created and maintained is annually reported in awardees reports.
Method of Calculation:	Institute staff will verify and total the number of jobs created and maintained that are reported by awardees in their report submissions.
Data Limitations:	The majority of data reported by the Institute involves work done by grantees and their subcontractors. This can create a lag time in reported data resulting in a need for updating previously reported numbers. Variances in performance from quarter to quarter and year to year are likely to occur due to the variety of work done by Institute funded initiatives.
Calculations Type:	Explanatory
New Measure:	No
Desired Performance:	Higher than the target

Explanatory Measure A.1.1.1.	Average Dollar Amount of Research Grants Awarded				
Short Definition:	The average dollar amount of research grant awards made by the Institute.				
Purpose/Importance:	This measure indicates the average size of grant awards issued by the Institute.				
Source/Collection of Data:	Signed research grant awards with the Institute.				
Method of Calculation:	The total dollar amount of research grants divided by the total number of research grants made as documented in signed agreements with the Institute.				
Data Limitations:	None.				
Calculations Type:	Explanatory				

New Measure:	No
Desired Performance:	Higher than the target

Explanatory Measure A.1.1.2.	Annual Age-adjusted Cancer Mortality Rate				
Short Definition:	Statewide annual age-adjusted cancer mortality rate, as determined by the Cancer Registry Division, Texas Department of State Health Services.				
Purpose/Importance:	All of the Institute's activities positively contribute to reducing cancer mortality, as do Texas physicians, hospitals, cancer treatment centers, volunteer organizations and other health care facilities. The Institute recognizes that cancer mortality rate is the ultimate outcome measure for cancer control.				
Source/Collection of Data:	The Cancer Registry Division of the Texas Department of State Health Services provides the data reported for this measure.				
Method of Calculation:	The calculation age-adjusts cancer death rates to the U.S. 2000 Standard Population, as used by the National Cancer Institute.				
Data Limitations:	Age-adjusted mortality rates are relative rates used nationally for comparison purposes. Age-adjusted rates fluctuate when population forecasts change and as the population ages. Cancer rates will be adjusted to the 2000 United States standard. Comparisons with previous mortality rates will require recalculations to the new standards. There is an 8-12 month delay in obtaining cancer mortality data from the Texas Department of State Health Services. A long-term, expensive study would be needed to correlate the impact of the Institute projects with the state mortality rate. Further, the impact of cancer prevention efforts on mortality rates cannot be measured in legislative budget cycles.				
Calculations Type:	Explanatory				
New Measure:	No				
Desired Performance:	Lower than the target				

# Appendix E: Workforce Plan Not updated yet – Heidi – Lisa- Wayne

## Overview of Statute, Mission, and Essential Functions

Texas voters overwhelmingly approved a constitutional amendment in 2007 establishing the Cancer Prevention and Research Institute of Texas (CPRIT) and authorizing the state to issue \$3 billion in general obligation bonds over ten years to fund groundbreaking cancer research and prevention programs and services throughout the state. House Bill 14, 80<sup>th</sup> Texas Legislature, is the authorizing statute that charges CPRIT 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 cancer and 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 this state; and
- Develop and implement the Texas Cancer Plan.

Under the guidance of the Oversight Committee, CPRIT's governing board, CPRIT accepts applications and awards grants for a wide variety of cancer-related research and for the delivery of cancer prevention programs and services by public and private entities located in Texas. All CPRIT-funded research will be conducted in state by Texas-based scientists and reflect CPRIT's mission to attract and expand the state's research capabilities and create high quality new jobs in Texas.

Since the first appropriation of \$225 million of cancer bond funds became available on September 1, 2009, CPRIT has awarded funds for individual investigator research projects; high-risk innovation research projects; evidence-based prevention programs and services; health promotion and public education prevention programs; company-based research; and professional education programs. CPRIT is awarding funds to academic institutions to recruit outstanding researchers to Texas as *CPRIT Scholars in Cancer Research* and to train exceptional predoctoral and postdoctoral candidates who are committed to pursuing a career in basic, translational, and clinical cancer research to cultivate the next generation of investigators and leaders in the cancer research field in Texas. CPRIT is also focusing a significant amount of funding on community collaborative prevention programs for breast, cervical, and colorectal cancers and on multi-institutional collaborations to enhance the capabilities and infrastructure in Texas to improve the research resources for the future growth of the state's biotechnology industry.

All of the proposals are reviewed by scientists or other experts who live and work outside the State of Texas to ensure the greatest objectivity in the review process. Their advice is used by the Executive Director to develop the cancer research and prevention award slates which are ratified by the Oversight Committee.

CPRIT has 24 budgeted FTEs headed by an Executive Director who oversees five functional areas—Research, Prevention, Commercialization, Operations, and Legal. These functional divisions are necessary to accomplish the essential business functions and duties of the agency.

# **Agency Workforce**

CPRIT is currently staffed by 19 employees, five of which are contract employees. 21 employees are centrally located in Austin, two are in the Dallas satellite office and one is in the Houston satellite office.

## Workforce Demographics

The following chart profiles CPRIT's total workforce as of May 2012. Seventy-three percent of CPRIT's employees are over the age of 40. CPRIT's workforce is comprised of 79 percent females and 21 percent males.

Five percent of employees have less than 2 years of service with the agency. 52 percent of the staff have over 10 years of state service. The majority of employees have the potential for continued service with the agency.



The following table compares the percentage of African American, Hispanic and Female CPRIT employees as of January 2012 to the statewide civilian workforce as reported by the Texas Commission on Human Rights.

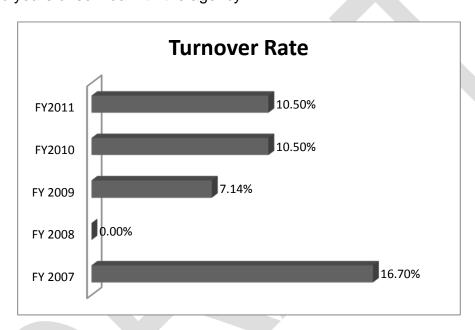
	African American		Hispanic American		Females	
Job Category	CPRIT %	State %	CPRIT %	State %	CPRIT %	State %
Officials, Administration	4.3.00%	6.00%	21.7%	9.00%	52.17%	29.00%
Professional	8.69.00%	8.00%	0.00%	9.00%	21.7%	47.00%

# Retirement Eligibility

CPRIT projects that 3 employees will be eligible to retire within the next four years. This represents 15.78 percent of the total workforce.

## Employee Turnover

The following chart shows the CPRIT turnover during fiscal years 2007 through 2011. During this period of time, the turnover rate varied from 16.7 percent to 10.5 percent. In general when turnover occurs, it is most commonly among employees who have less than two years of service with the agency.



# Essential Critical Workforce Skills Necessary for Institute Mission

CPRIT is fortunate to have a workforce with a broad range of experience. It is essential in a small agency to have staff diverse in skills and experience because it is likely that an employee will perform more than one job function. The agency has highly qualified, dependable employees with skills that allow CPRIT to operate efficiently and effectively. To maintain quality services for Texas and carry out essential functions, the agency will continue to make every effort to hire and retain employees with experience and skills in leadership, management, administration, information technology, financial administration and grant monitoring.

# Future Workforce Profile (Demand and Gap Analysis)

A continuing analysis of CPRIT demands will be reviewed to ensure that there is an adequate and effective agency workforce in place. It is estimated that the CPRIT workforce will remain at 24 FTEs.

# **Strategy Development**

CPRIT has determined that there are no anticipated gaps or surpluses in workforce numbers or skills for the next five years. CPRIT will continue to follow the established recruitment plan and will keep agency policies and procedures documented to ensure knowledge is retained. CPRIT is prepared to recruit and hire the staff necessary to continue to support the agency mission.



## References

#### Not updated yet – need to wait until the document is closer to final – Heidi – Lisa - Wayne

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#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL

**SUBJECT:** 2016-17 LEGISLATIVE APPROPRIATIONS REQUEST (LAR)

**DATE:** MAY 12, 2014

#### **Summary and Recommendation**

The LAR is the agency's budget request for September 1, 2015-August 31, 2017. The LAR structure is based on the budget structure approved in the agency's strategic plan, including goals, outcomes, strategies, and performance measures. The Oversight Committee must approve the 2016-17 LAR for submission to the Governor and Legislative Budget Board, and it must signed by Presiding Officer Rice. The agency cannot submit the LAR until the Strategic Plan is approved by the Legislative Budget Board and Governor's Office. CPRIT's Strategic Plan is not due until June 23, 2014. Generally, the LAR will be due in earl August, but the agency has not received the LAR instructions, which includes the submission schedule, yet.

CPRIT staff has prepared a draft of the 2016-17 LAR with the major budget schedules and rider revisions, additions, and deletions. The Oversight Committee should consider delegating approval of the final version of the 2016-17 LAR to the Audit Subcommittee given the timing of the LAR submission and the next Oversight Committee meeting.

#### Discussion

CPRIT's draft LAR reflects a request for \$600 million in general obligation bond proceeds for the 2016-17 biennium, \$300 million per year, as authorized in Article III, Sec. 67 of the Texas Constitution.

- Same amount of funding appropriated to CPRIT for the current 2014-15 biennium.
- Includes no additional budget, or "exceptional item," requests.

CPRIT does not request the debt service for the bond proceeds in its LAR. The request is made through the Texas Public Finance Authority's LAR.

The draft LAR also reflects a request for \$32,000 in General Revenue-Dedicated Funds estimated to be collected from the sale of the Texas Conquer Cancer license plates. This license plate revenue provides grants to community-based organizations that assist cancer patients with

personal care items or services, like wigs for patients undergoing chemotherapy or funeral costs for a deceased cancer patient.

Riders in the appropriations bill provide additional authority and direction for appropriated funds. CPRIT currently has 10 riders. In the LAR, CPRIT plans to requests to strike four riders which no longer pertain to the agency's circumstances. Two riders are being updated for date references, and a third rider revision would require notification of appropriations transfers, rather than the submission of requests for approval to follow the general authority given to other agencies. Three riders require no changes. The request also includes the addition of three new riders. These riders include two that restore unexpended balance authority of unexpended and unobligated bond proceeds between biennia and between the fiscal years of the 2016-17 biennium. The third new rider requests the appropriation of any premium generated from the sale of CPRIT's debt to pay the costs of issuing the bonds. Currently, premiums generated above the appropriated amount of general obligation bonds may not be used to pay for the costs associated with issuance and therefore reduce the maximum amount of bond proceeds that could go to projects.

### Cancer Prevention and Research Institute of Texas Summary of Budget by Strategy

	Expended	Estimated		Budgeted		Requested		Requested	
	2013	2014	%	2015	%	2016	%	2017	%
A. Goal: Cancer Research and Prevention Services									
Create and Expedite Innovation in Cancer Research and									
Prevention Services									
A.1.1. Strategy: Award Cancer Research Grants	91,580,447	255,489,448	85.2%	261,059,105	87.0%	256,833,659	85.6%	256,488,074	85.5%
A.1.2. Strategy: Award Cancer Prevention Grants	13,576,658	29,022,567	9.7%	29,022,567	9.7%	29,022,567	9.7%	29,022,567	9.7%
A.1.3. Strategy: Grant Review and Award Operations	9,115,330	11,161,220	3.7%	6,924,359	2.3%	11,177,289	3.7%	11,474,707	3.8%
TOTAL, GOAL 1	114,272,435	295,673,235		297,006,031		297,033,515		296,985,348	
B. Goal: Indirect Administration									
<b>B.1.1. Strategy:</b> Indirect Administration	4,012,676	4,342,766	1.4%	3,009,969	1.0%	2,982,485	1.0%	3,030,652	1.0%
GRAND TOTAL	118,285,111	300,016,000	100.0%	300,016,000	100.0%	300,016,000	100.0%	300,016,000	100.0%

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Rider #	Proposed Rider Revision for 2016-17	Justification  The wider has been undeted to reflect the dates of the new highlight
2	Texans Conquer Cancer Plates: Appropriation of License Plate Receipts. Included in the amounts appropriated above in Strategy A.1.2, Award Cancer Prevention Grants, is all license plate revenue collected on or after September 1, 20135 (estimated to be \$16,000 in fiscal year 20146 and \$16,000 in fiscal year 20157) from the sale of the Texans Conquer Cancer license plates as provided by Transportation Code, \$504.620 and deposited to the credit of the License Plate Trust Fund No. 0802.	The rider has been updated to reflect the dates of the new biennium.
	Any unexpended balances remaining as of August 31, 20146, in the appropriation made herein are appropriated to the Cancer Prevention and Research Institute of Texas for the fiscal year beginning September 1, 20146.	
3	Salary Supplements for Exempt Positions. The Executive Director and the Chief Scientific Officer of the Institute, because of the particular requirements of directing the administrative and scientific affairs of the Institute, may receive, in addition to salary amounts appropriated above out of state funds, a supplement from a foundation established to benefit the Cancer Prevention and Research Institute of Texas. The amounts identified above in the line item, "Schedule of Exempt-Positions", reflects the not-to-exceed salary amounts for the Executive Director and the Chief Scientific Officer which may be paid out of appropriated state funds. The Executive Director may not receive a total combined salary that exceeds \$250,000 out of state and foundation funds in any year of the biennium. Likewise, the Chief Scientific Officer may not receive a combined salary that exceeds \$340,000 out of state and foundation funds in any year of the biennium. Amounts paid from appropriated funds are reduced to the extent that foundation funds are used to increase-salaries above the respective limit established in this rider. The respective salaries paid out of appropriated state funds and foundation funds for each fiscal year of the biennium for the Executive Director and the Chief Scientific Officer of the Institute may not exceed the highest salary paid to a chancellor of a public university system.  The salary of the Executive Director and the Chief Scientific Officer as provided under this section are not limited by Article IX, Section 3.05 of this Act. In addition to reporting requirements-provided in Article IX, Section 3.02 of this Act, it is the intent of the legislature that contributions and expenditures of the foundation established to benefit the Cancer Prevention and Research Institute of Texas be annually reported to the Legislative Budget Board, the Senate Finance—Committee, and the House Appropriations Committee no later than December 31. An individual, an organization, or an employee, officer or director of an o	The rider should be struck from the General Appropriations Act because it contradicts Health and Safety Code, Sec. 102.056 which prohibits the salary supplementation from gifts or grants of any employee of the agency and provides specific prohibitions on supplementing the salaries of the Chief Executive Officer and Chief Scientific Officer.
5	Transfer Authority. Notwithstanding Article IX, Section 14.01, Appropriation Transfers, no- appropriations or unexpended balances may be transferred out of Strategy A.1.1, Award Cancer- Research Grants, or Strategy A.1.2, Award Cancer Prevention Grants, unless the Cancer Prevention and Research Institute of Texas submits a written request to the Legislative Budget Board, in a- format prescribed by the Legislative Budget Board, that provides information regarding the purposes for the transfer; and the Legislative Budget Board issues written approval. The Cancer Prevention and Research Institute of Texas shall notify the Legislative Budget Board and Governor of all appropriations transfers allowed under Article IX, Section 14.01.	The revision allows CPRIT's chief executive officer to transfer funds according to the same authority provided to the chief executive administrator at all other state agencies to maximize operational efficiency while providing transparency about any budget transfer actions to the legislature and governor.
6	Transfer to Department of State Health Services for the Cancer Registry. Contingent on the enactment of Senate Bill 149, House Bill 951, or similar legislation, by the Eighty third-Legislature, Regular Session, 2013, relating to the administration of the Cancer Prevention and Research Institute of Texas, i_Included in amounts appropriated above out of General Obligation Bond Proceeds, of this Act, to the Cancer Prevention and Research Institute of Texas is \$2,969,554 out of General Obligation Bond Proceeds each fiscal year of the 2014-15 biennium which shall be transferred to the Department of State Health Services in Strategy A.1.2, Health Registries, Information, and Vital Records, for administration of the Cancer Registry in accordance with the Texas Constitution, Article III, Section 67 and Health and Safety Code, Chapter 102.	The rider has been updated to eliminate the reference to the passage of legislation.
7	Limit on Expenditures. Contingent on the passage of Senate Bill 149, House Bill 951, or similar legislation, by the Eighty-third Legislature, Regular Session, 2013, relating to the administration of the Cancer Prevention and Research Institute of Texas, the agency may expend an amount not to exceed \$150,623 out of General Obligation Bond Proceeds appropriated above in Strategies A.1.3, Grant Review and Award Operations, and B.1.1, Indirect Administration, to close out lease expenses and costs related to moving the agency into state owned space. The Cancer Prevention and Research Institute of Texas shall work with the Texas Facilities Commission to relocate into state-owned space no later than December 31, 2013.  If the agency is unable to move into state owned space by this date, they must submit a letter to the Legislative Budget Board no later than 45 days prior to this date providing information regarding why the agency is unable to meet this deadline and any request for additional appropriation authority related to continuing lease payments. The agency may expend additional General Obligation Bond Proceeds out of Strategy B.1.1, Indirect Administration, if the agency is provided written approval by the Legislative Budget Board.	CPRIT will be out of a leased facility and occupying state office space by February 28, 2015.

Limitation on Expenditure for Contracts. Without the prior approval of the Legislative Budget The CPRIT Oversight Committee, composed of members appointed by the Board, the Cancer Prevention and Research Institute of Texas shall not use funds appropriated governor, lieutenant governor, and speaker of the house, must approve all above to enter into any contract, excluding grant awards under Health and Safety Code Chapterservice contracts in excess of \$100,000 at an open meeting before the agency 102, Subchapter F, in excess of \$100,000. Additional information requested by the Legislativemay enter into such a contract. This rider restriction is unnecessarily Budget Board related to this approval shall be provided in a timely manner and shall be prepared redundant. a format specified by the Legislative Budget Board. Contingency for Administration of the Cancer Prevention and Research Institute of Texas. The referenced legislation was enacted. Contingent on the enactment of Senate Bill 149, House Bill 951, or similar legislation, by the Eighty-third Legislature, Regular Session, 2013, relating to administration of the Cancer Preven and Research Institute of Texas, appropriations are included above to the Cancer Prevention and Research Institute of Texas as follows (1) \$261,262,199 for fiscal year 2014 and \$261,059,105 for fiscal year 2015 to the Cancer Prevention and Research Institute of Texas, out of General Obligation Bond Proceeds, in Strategy A.1.1. Award Cancer Research Grants, to make cancer research grants to award-(2) \$29,006,567 each fiscal year of the 2014-15 biennium to the Cancer Prevention and Research Institute of Texas, out of General Obligation Bond Proceeds, in Strategy A.1.2, Award Cancer-Prevention Grants, to make cancer prevention grants to award recipients; (3) \$6,924,359 and 7.0 FTEs each fiscal year of the 2014-15 biennium to the Cancer Prevention and Research Institute of Texas, out of General Obligation Bond Proceeds, in Strategy A.1.3, Gran Review and Award Operations, for the review of grant applications and to provide direct administration for awarding of research and prevention grants; (4) \$2,806,875 for fiscal year 2014 and \$3,009,969 for fiscal year 2015 to the Cancer Prevention and Research Institute of Texas, out of General Obligation Bond Proceeds, in Strategy B.1.1, Indirect Administration, for indirect administration at the agency; Included in amounts appropriated elsewhere in this Act to the Texas Public Finance Authority to make debt service payments for the bond proceeds appropriated herein are as follows: Method of Finance FY 2014 FY 2015 Permanent Fund for Health & Tobacco Education & Enforcement No. 5044 \$ 616,695 \$ 3,653,167 Permanent Fund for Children & Public Health No. 5045 \$ 308 347 \$ 1.826 584 Unexpended Balances of Bond Proceeds. Included in amounts appropriated above are CPRIT requests restoration of the unexpended balances of bond proceeds rider unexpended and unobligated balances of General Obligation Bond Proceeds remaining as of from the 2012-13 biennium to allow CPRIT to carry forward its unexpended August 31, 2015, (estimated to be \$0) for the Cancer Prevention and Research Institute for the appropriations authority from the 2014-15 biennium to the 2016-17 biennium to maximize available appropriations authority for grant awards in its 2016-17 biennium in Strategies A.1.1, Award Cancer Research Grants, A.1.2, Award Cancer Prevention Grants, A.1.3, Grant Review and Award Operations, and B.1.1, Indirect Administration prevention and research programs. The ability to carry forward unexpended and unobligated balances from one biennium to the next will allow CPRIT to for purposes authorized by Health and Safety Code Chapter 102. make the best use of its available funding for grant awards. Any unexpended balances in General Obligation Bond Proceeds described herein and remaining as As an example, when CPRIT makes an obligation for a grant award in the first of August 31, 2016, are hereby appropriated for the same purposes for the fiscal year beginning fiscal year of a biennium and the grant recipient declines it after that fiscal year September 1, 2016 has expired, CPRIT loses the ability to award that money to another potential grant recipient in the subsequent year without the authority requested in this rider. Another example is that CPRIT did not expend approximately \$31,000 from its operating budget in fiscal year 2014. Debt was issued for the total Nev agency administrative budget in that year. The bond proceeds now sit in the state treasury unable to be used to cover any expenditures at CPRIT. For similar reasons, the ability to carry forward unexpended balances in general obligation bond proceeds would provide CPRIT with the ability to manage and utilize the debt it has already issued and has available to it between its two operating strategies (A.1.3, Grant Review and Award, and B.1.1. Indirect Administration). These amounts are small and are restricted to use by CPRIT because of the nature of the funds as bond proceeds. The bond proceeds remain in the treasury if not used. Unexpended Balances Within the Biennium. Any unexpended balances remaining as of August | CPRIT requests restoration of the unexpended balances rider from the 2012-13 31, 2016, in the appropriations made above are hereby appropriated for the fiscal year beginning biennium to allow CPRIT to carry forward its unexpended appropriations September 1, 2016. authority from fiscal year 2016 to fiscal year 2017, maximizing the available appropriations authority for the award of grants across its prevention and research programs. The ability to carry forward unexpended balances from one biennium to the next will allow CPRIT to make the best use of its available funding for grant awards. As an example, when CPRIT makes an obligation for a grant award in the first New fiscal year of a biennium and the grant recipient declines it after that fiscal year has expired, CPRIT loses the ability to award that money to another potential grant recipient in the subsequent year without the rider. Another example is that CPRIT did not expend approximately \$31,000 from its operating budget in fiscal year 2014. Debt was issued for the total agency administrative budget in that year. The bond proceeds now sit in the state treasury unable to be used to cover any expenditures at CPRIT.

	Bond Proceeds. The bond proceeds listed above are estimated aggregate principal amounts of one	This rider maximizes the amount of funds available for cancer projects. CPRIT
	or more series of bonds and do not included or limit receipt of any premium generated in	requests the rider to clarify that any bond premiums earned above the bond
	connection with the issuance and sale of each series of bonds.	proceed amounts listed in the General Appropriations Act are appropriated to
		CPRIT to pay the costs of issuing the bonds. Otherwise, bond issuance costs
		must be paid from the bond proceeds which reduces the amount of proceeds
		available for cancer research and prevention grant awards.
New		
		A premium is the additional price a buyer will pay for the bond due to current
		prevailing interest rates being below those of the bond. This is in contrast to a
		discount which is a lower price the buyer will pay due to current prevailing
		interest rates being above those of the bond.



### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL

**SUBJECT:** FY 2015 REQUEST FOR FINANCING OF CPRIT DEBT SERVICE

**DATE:** MAY 12, 2014

#### **Summary and Recommendation:**

For the Texas Public Finance Authority (TPFA) to issue debt on behalf of CPRIT in fiscal year 2015, the Oversight Committee must approve a resolution that requests financing for \$300 million in bond proceeds appropriated to CPRIT for its operations and prevention and research grant awards. I estimate that CPRIT will request TPFA issue \$241.6 million in commercial paper notes four times during fiscal year 2015 to pay for CPRIT administrative operations and to pay for reimbursements or authorized advances on grant awards made in fiscal years 2011, 2012, 2013, and 2014.

#### **Discussion**

Through the Texas Public Finance Authority (TPFA), CPRIT has issued \$200.9 million in commercial paper notes from fiscal year 2012 through 2014 for agency operations and to pay expenses for grant awards. In addition, TPFA has issued \$282.9 million in long-term general obligation bonds for debt CPRIT incurred in fiscal years 2010 and 2011. These prior issued bonds will yield \$287.8 million in proceeds to cover CPRIT's actual expenditures and outstanding grant award obligations from fiscal year 2010 and part of fiscal year 2011.

In addition to the resolution and its supporting documents, I have provided a diagram of the debt authorization and issuance process and spreadsheet with the history of CPRIT's debt issuance since fiscal year 2010.

### Annual CPRIT Debt Authorization and Issuance Process (\$300 million annually)



August 31

September 1

Fiscal year requiring financing

Summer preceding the state fiscal year that financing is needed

**CPRIT** Oversight Committee authorizes request for financing by resolution

Texas Public Finance **Authority (TPFA)** Board approves requests for financing

TPFA structures debt issuance (commercial 🛑 paper notes)

**Texas Bond Review** Board approves debt issuance

**CPRIT** requests tranches of commercial paper notes be issued (multiple times during the year)



TPFA sells commercial paper as requested /proceeds are deposited into State Treasury (Fund 7639)

#### **CPRIT Commercial Paper and G.O. Bond Issuance**

Fiscal Year	Amount Appropriated	Dated Issued	Aı	mount Issued	Am	ount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	\$ 225,000,000	September 9, 2009	\$	9,100,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2010		September 9, 2009	\$	3,600,000			Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	Footnote 1
2010		March 12, 2010	\$	63,800,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2010		August 26, 2010	\$	148,500,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
					\$	225,000,000				
2011	\$ 225,000,000	September 7, 2010	\$	11,800,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2011		August 10, 2011	\$	50,775,000			G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	\$	232,045,000			G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded \$233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
					\$	62,575,000				
2012	\$ 300,000,000	September 7, 2011	Ś	3,200,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2012	+,,	December 8, 2011		3,200,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		March 2, 2012	_	12,300,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		June 21, 2012	\$	15,000,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		August 16, 2012	\$	42,000,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
					\$	75,700,000				
2013	\$ 300,000,000	September 5, 2012	Ś	9,600,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
2013	,,,	May 16,2013		13,400,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
					\$	23,000,000	·			
2014	\$ 300,000,000	November 22, 2013	\$	55,200,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
		March 12, 2014	\$	47,000,000			Commercial Paper Notes	Series A, Taxable		Footnote 1
					\$	102,200,000				
TOTAL ISSU	JED TO DATE				\$	488,475,000				

<sup>&</sup>lt;sup>1</sup>The weighted average interest rates for Commercial Paper Notes maturing in each year is as follows: FY 2010 = 0.30%; FY 2011 = 0.32%; FY 2012 = 0.23%; FY 2013 = 0.19%.



### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## A RESOLUTION AUTHORIZING A REQUEST FOR FINANCING AND THE EXECUTION AND DELIVERY OF DOCUMENTS REQUIRED TO EFFECT SUCH FINANCING

Whereas, the Texas Public Finance Authority (the "Authority") is authorized to issue bonds for the use and benefit of the Cancer Prevention & Research Institute of Texas (the "Institute"), to provide funds for grants for cancer research, prevention, and control and related purposes and for the operations of the Institute, (the "Program") pursuant to Article III, Section 67, Texas Constitution; Texas Health & Safety Code, Chapter 102, as amended; Texas Government Code, Chapter 1232, as amended; and provisions of the General Appropriations Act, 83<sup>rd</sup> Legislature, R.S. (2013), (collectively, the "Authorizing Law");

**Whereas,** the Institute desires and intends to request the Authority to finance its Program costs as permitted by the Authorizing Law;

Whereas, the Institute recognizes that in order to finance the cost of the Program, the Authority may issue public securities including short-term obligations, general obligation bonds, or other authorized obligations (collectively, "Obligations") in an aggregate principal amount not to exceed \$300,000,000 for authorized Program costs appropriated in the 2015 state fiscal year together with related costs of issuance and other ancillary costs to be determined at the time of issuance; provided that the total amount of Obligations issued in a year may never exceed \$300 million in accordance with the requirements of Authorizing Law;

**Whereas,** a Request for Financing, including a description of the Program and a proposed expenditure schedule is presently before the Cancer Prevention and Research Institute of Texas Oversight Committee ("Committee") and attached hereto as Exhibits A and B, respectively;

#### NOW THEREFORE BE IT RESOLVED by the Committee that:

Section 1. The Committee hereby ratifies and confirms that the purpose of the financing is to provide funds for the purposes in the Authorizing Law including grants for cancer research, prevention, and control and related purposes, and for the operations of the Institute and that financing thereof is appropriate at this time. Accordingly, the execution and delivery of the Request for Financing to the Authority pursuant to the Authorizing Law is hereby ratified, approved and confirmed.

Section 2. The Committee hereby empowers, authorizes and directs the Executive Director or designee of the Institute, for and on the behalf of the Board and the Institute, to negotiate, date, sign, and otherwise execute on behalf of the Institute (i) a Memorandum of Understanding (the "Memorandum of Understanding"), as necessary, between the Authority and the Institute and to deliver the Memorandum of Understanding; (ii) a financing Agreement (the "Agreement") between the Authority and the Institute and to deliver such Agreement; and (iii) such other documents (the "Other Documents") as are necessary or desirable to effect the issuance of the Obligations, to provide funds for the Program, and to deliver such Other Documents.

Upon execution by both parties thereto and delivery thereof, the Memorandum of Understanding, the Agreement, and the Other Documents shall be binding upon the Authority and the Institute in accordance with the terms and provisions thereof.

Section 3. The Committee recognizes that the Authority will proceed to issue the Obligations to provide the requested financing upon receipt of any necessary approvals from the Texas Bond Review Board ("BRB") and the Texas Attorney General of Public Finance Division ("OAG").

Section 4. The Executive Director or designee of the Institute is hereby authorized to cooperate with the Authority, and its consultants, to obtain approval from the BRB and OAG and to prepare an Official Statement or other offering documents in connection with the sale of the Obligations and to take any other action necessary to assist in such sale.

Section 5. All actions not inconsistent with provisions of this Resolution heretofore taken by the Institute and the Executive Director or designee thereof and the other officers of, or consultants to the Institute, directed toward the financing of the Program, and the issuance of the Obligations are hereby ratified, approved and confirmed.

Section 6. The officers of the Institute and the Executive Director or designee thereof shall take all action in conformity with the Authorizing Law to effect the issuance of the Obligations and complete the Program as provided in the Agreement and take all action necessary or desirable or in conformity with the Authorizing Law for carrying out, giving effect to, and consummating the transactions contemplated by the Memorandum of Understanding, the Agreement, the Obligations, and this Request for Financing, including without limitation, the execution and delivery of any closing documents in connection with the closing of the Obligations.

Section 7. If any section, paragraph, clause, or provision of this Resolution shall be held to be invalid or unenforceable, the invalidity or unenforceability of such section, paragraph, clause, or provision shall not affect any of the remaining portions of this Resolution.

Section 8. This Resolution was adopted at a meeting open to the public, and public notice of the time, place and purpose of said meeting was given, all as required by Ch. 551, Texas Government Code.

Texas Oversight Committee present and vot	ing on this day of, 2014.	e 01
Cancer Prevention and Research Institute of Texas Oversight Committee	Attested:	
Chairman	Secretary	



## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### Fiscal Year 2015 Request for Financing Program Description

#### **Purpose**

The Cancer Prevention and Research Institute of Texas (CPRIT) is the state agency mandated 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 cancer and
  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 this state; and
- 3) develop and implement the Texas Cancer Plan.

#### **Powers and Duties**

CPRIT will make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and make grants to institutions of learning and to advanced medical research facilities and collaborations in this state for:

- 1) research into the causes of and cures for all types of cancer in humans;
- 2) facilities for use in research into the causes of and cures for cancer:
- 3) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans; and
- 4) cancer prevention and control programs in this state to mitigate the incidence of all types of cancer in humans.

#### **Implementation Plan**

CPRIT estimates that \$241.6 million in bonds proceeds must be issued on an as-needed basis consistent with Texas Government Code, Chapter 1232 to cover grant award obligations from fiscal years 2011, 2012, 2013, and 2014; new grant award obligations made during fiscal year 2015; and operating costs for general agency administration and pre- and post-award grants management processes. During fiscal year 2015, CPRIT will use the bond proceeds to disburse grant funds for grants awarded by CPRIT during the last three months of fiscal year 2011 as well as during fiscal years 2012, 2013, and 2014. CPRIT is currently authorized to obligate approximately \$287 million for cancer prevention and research grant awards in fiscal year 2015.

CPRIT announces grant awards for cancer prevention education and service programs and academic and product development cancer research programs four times per year. Since CPRIT

has resumed its grant pre-award peer review and decision-making processes in November 2013 following the rescission of moratorium on its grant-making processes, CPRIT has published 26 new award opportunities and implements additional review steps and certifications required by the passage of Senate Bill 149, 83<sup>rd</sup> Regular Legislature which made significant changes to Health and Safety Code, Chapter 102, including the adoption of new rules by the Oversight Committee in February 2014. CPRIT anticipates that it will obligate all of the available \$287 million for cancer prevention, product development research, and academic research

Grant funds are generally disbursed quarterly on a reimbursement basis to grant recipients. For certain types of grant awards, historically limited to product development and scientific recruitment awards, CPRIT advances funds in order to provide those specific types of recipients with working capital to meet their research milestones or objectives.

CPRIT is authorized to use bond proceeds to fund its grant review and award operations and indirect administration costs. At this time, the total budgeted amount of these two categories is \$9.9 million in bond proceeds for fiscal year 2015 based on the authorized appropriations in Senate Bill 1, 83<sup>rd</sup> Legislature, R.S. (General Appropriation Act). CPRIT anticipates transferring funding from the strategy for research awards to the grant review and award operations strategy to support its pre- and post-award review and compliance processes. This transfer requires the approval of the Legislative Budget Board. CPRIT must also transfer \$2.9 million in bond proceeds to the Texas Department of State Health Services (DSHS) for the operating costs associated with the Texas Cancer Registry. From the total of all of the agency's operating costs, CPRIT requires half of the proceeds to be available at the beginning of the state fiscal year to be able to cover the operating expenses for six months. CPRIT also requires proceeds at the beginning of each state fiscal quarter to pay for award costs reimbursed to grant recipients for the previous state fiscal quarter.

The scientific research program provides awards in the following areas: cancer biology, cancer genetics, immunology, imaging, therapeutics, prevention/epidemiology, and informatics/computation. The product development research program focuses awards on the development of cancer drugs, diagnostics, and devices based on discoveries made in one of the seven areas described above. Prevention program grants are awarded for cancer prevention information and services, early detection and treatment, professional education and practice, cancer data acquisition and utilization, or survivorship (the areas of the Texas Cancer Plan). Awards for all programs are issued for multiple years, ranging from two years to five years.

CPRIT has established a grant process that allows grant proposals for cancer prevention, scientific research, and product development research to be submitted through requests for applications (RFA) issued throughout each fiscal year. All proposals are reviewed by multiple experts in the appropriate area. CPRIT has historically had approximately 200 national experts in cancer prevention, research and product development to review proposals and provide funding recommendations to CPRIT. While about 40% of the scientific reviewers resigned from the academic research peer committees during the fall of 2012, CPRIT has recruited reviewers of the same caliber to participate on the committees. In some cases, reviewers who resigned have returned to serve on committees.

The award recommendations developed by the peer review committees must now be forwarded to the Program Integration Committee (PIC) for consideration. The five members of the PIC are statutorily set as the Chief Executive Officer (CEO), Chief Scientific Officer, Chief Prevention Officer, Chief Product Development Officer, and the DSHS Commissioner. The PIC finalizes award recommendations across all programs prior to every Oversight Committee meeting. When those proposed awards are forwarded to the Oversight Committee, each recommended award is accompanied by an affidavit signed by the CEO to affirm that the award followed all required pre-award grant procedures. The Oversight Committee considers each recommended award separately, voting to approve it for funding or not.

#### Cancer Prevention and Research Institute of Texas

Estimated Expenditure Schedule, Fiscal Year 2015

Fiscal Year 2015	5	eptember		October	November	December		January	February	March		April		May		June		July		August		Total
Bond proceeds for Indirect Administration	\$	1,504,98	5 5	\$ -	\$	\$ -	\$	-	\$	\$ 1,504,984	\$	-	\$	-			\$		\$		\$	3,009,969
Bond proceeds for Grant Review and Award Operations	\$	3,462,18	0 5	\$ -	\$ -	\$ -	\$	-	\$ -	\$ 3,462,179	\$	-	\$	-	\$	-	\$	-	\$	-	\$	6,924,359
Bond proceeds for Texas Cancer Registry (GAA 2014-15,																						
Art. I, CPRIT Rider 6)	\$	1,484,77	7   5	\$ -	\$ -	\$ -	\$	-	\$ -	\$ 1,484,777	\$	-	\$	-	\$	-	\$	-	\$	-	\$	2,969,554
Bond proceeds for Prevention and Research Grants	\$	46,548,05	8 5	\$ -	\$ -	\$ 50,000,000	\$	-	\$ -	\$ 52,548,060	\$	-	\$	-	\$	79,600,000	\$	-	\$	-	\$ 2	228,696,118
Debt Issuance Subtotal, Fiscal Year 2015	\$	53,000,00	0 5	\$ -	\$ -	\$ 50,000,000	\$	-	\$ -	\$ 59,000,000	\$		\$	-	\$	79,600,000	\$	-	\$	-	\$ 2	241,600,000
Cumulative Debt Total, Fiscal Year 2015	\$	53,000,00	0 5	\$ 53,000,000	\$ 53,000,000	\$ 103,000,000	\$ 1	103,000,000	\$ 103,000,000	\$ 162,000,000	\$ 16	52,000,000	\$ 1	62,000,000	\$ :	241,600,000	\$ 2	41,600,000	\$ 2	41,600,000	\$ 2	241,600,000

Version 05/15/2014 Request for Financing 2015, Exhibit B

# Information for this item provided under separate cover.



### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE INTERIM

**CHAIR** 

SUBJECT: INTENTION TO RECOMMEND APPROVAL OF PROPOSED

ADMINISTRATIVE RULE CHANGES

**DATE:** MAY16, 2014

#### **Summary and Recommendation:**

The Board Governance subcommittee recommends that the Oversight Committee vote to approve proposed changes to CPRIT's administrative rules at its May 21, 2014 meeting. The Board Governance Subcommittee discussed the new rules and rule changes with CPRIT's General Counsel, Kristen Doyle, at its meeting on May 14, 2014.

#### **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 May 14, 2014, to discuss the proposed changes to the administrative rules.

The Board Governance Subcommittee has considered the proposed changes and recommends that the Oversight Committee approve publication of the proposed changes in the *Texas Register*. The proposed changes provide additional clarity regarding operations of the agency and expected performance.



### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS **FROM:** KRISTEN DOYLE, GENERAL COUNSEL

**SUBJECT:** APPROVAL OF PROPOSED ADMINISTRATIVE RULE CHANGES

**DATE:** MAY 15, 2014

#### **Summary and Recommendation:**

Some revisions to CPRIT's administrative rules are necessary to clarify agency policies and procedures. The Oversight Committee should approve the proposed amendments to the administrative rules found in Chapter 702 - *Institute Standards on Ethics and Conflicts, Including Acceptance of Gifts and Donations to the Institute* and Chapter 703 - *Grants for Cancer Research and Prevention*. Once approved, the proposed rule amendments will be published in the *Texas Register* for public comment. Final rules that incorporate changes recommended by the public should be ready for the Committee's consideration at an Oversight Committee meeting held August 20, 2014.

#### **Discussion:**

CPRIT completed an extensive revision to its administrative rules in January 2014, conforming agency practices to newly-enacted legislative requirements and implementing recommendations made by the State Auditor's Office in its January 2013 report, *Grant Management at the Cancer Prevention and Research Institute of Texas and Selected Grantees*. CPRIT is in the process of incorporating the new administrative rules into the agency's policies and practices. In the course of doing so, CPRIT staff identified some rule provisions that would benefit from additional clarity. A rule-by-rule explanation for the proposed changes is attached to this memorandum.

The Oversight Committee's consideration and approval for publishing the proposed rules in the next edition of the *Texas Register* (likely to be the June 6<sup>th</sup> edition) is the first step in the process to adopt final rules. Once the proposed rules are published, the public has 30 days to submit written comments to CPRIT before the rules may be brought back to the Oversight Committee for final approval. The rules, along with a summary of the input received from the public and any recommended changes, will be brought to the Oversight Committee for final approval and adoption at an open meeting held in August 2014.

In the rules proposed for your consi deletions are struck-through.	ideration, new text is denote	ed by underscoring while propo	osed

#### **Explanation of Proposed Administrative Rule Changes**

#### Chapter 702

§702.7(f)(4)(B)-(C) These subsections are part of a list of items that are not subject to CPRIT's gift reporting requirement as it applies to an Oversight Committee Member, Institute Employee, or Program Integration Committee Member. Changes are made to track language found in Chapter 36 of the Penal Code and Section 3.104 of the Business & Commerce Code.

§702.7(f)(5)(B) This subsection is part of a list of items that are that are not subject to CPRIT's gift reporting requirement if a Scientific Research and Prevention Programs Committee Member receives a gift by a Grant Applicant or Recipient. Changes are made to track language found in Chapter 36 of the Penal Code and Section 3.104 of the Business & Commerce Code.

§702.7(6)(A)-(C) While a member of an Advisory Committee participates in the Grant Review Process, he or she is required to report gifts, grants, or other consideration received from a Grant Applicant or Recipient. These subsections list out gifts that are not subject to CPRIT's reporting requirement. Changes are made to track Chapter 36 of the Penal Code and Section 3.104 of the Business & Commerce Code.

§702.9 Corrects a typographical error in the title of the section.

#### Chapter 703

§703.3(d) Clarifying language added to read an "otherwise qualified applicant" is only eligible for Grant Mechanism in RFA.

§703.3(j) Language added to require Grant Applicant to indicate if ineligible to receive state grant funds in addition to federal grant funds. Currently, only federal funds are listed.

§703.6(e)(1)(C) Corrects title to read Peer Review Panel chairperson.

§703.6(k) A new subsection that allows either a Peer Review Panel chairperson or Review Council chairperson who cannot carry out duties to designate a co-chairperson. This designation must be in writing and contain the specific time and extent of designation.

§703.8(1)(B) and (2) Allows the Chief Executive Officer, instead of the Chief Compliance Officer, to recommend "corrective actions" for variances that occurred in grant review process. The Oversight Committee must approve the actions by a simple majority of members present and voting.

- §703.11(c)(5)(C) Removes requirement that Chief Executive Officer must approve the allowance for unrecovered Indirect Costs because electronic grants management records make requirement superfluous.
- §703.11(i) When a Grant Recipient does not match funds, this subsection allows CPRIT to take action not specifically listed in §703.11(h). Language is added so that the Chief Executive Officer must approve such action.
- §703.13(a)(3) Clarifying change requiring Grant Recipients to submit independent audit within 30 days of receiving audit. This is consistent with Uniform Grant Management Standards. Instead of nine months as currently written, the Grant Recipient has 270 days following the end of their fiscal year to submit this audit. This change is due to the fact that CPRIT's Grant Management System counts time by days instead of months.
- §703.13(a)(3)(B) If Grant Recipients cannot meet audit deadline, they may ask CPRIT for more time. This subsection clarifies that period of time. The grantees must submit their request no later than the 270<sup>th</sup> day after the end of their fiscal year.
- §703.13(d) Language changed to achieve consistency within the statute. If a grantee is delinquent under §703.13 then the grantee is not eligible "to be awarded" a new grant or a "continuation Grant Award." If a grantee has been approved by CPRIT for more time, the grantee remains eligible "to be awarded" a new grant or "continuation Grant Award."
- §703.14(c)(5) This is a new subsection that allows CPRIT, before 180 days prior to termination date of a Grant Contract, to approve an amendment to the Grant Contract extending the termination date via something other than a no cost extension request. There must be a finding of good cause.
- §703.14(d) Clarifies that final Financial Status Report, final Grant Progress Report, and any other documents are collectively referred to as "close out documents."
- \$703.14(d)(1) New language that clarifies waiver of reimbursement costs as it relates to the final Financial Status Report and other close out documents. As it appears now, the grantee may submit a late Financial Status Report and still be reimbursed. The new language fixes this in two ways. First, if the Grant Recipient submits the final Financial Status Report but no other close out documents, then final reimbursement will not be paid until all close out documents are submitted. Second, if the Grant Recipient does not submit the final Financial Status Report within 30 days after the deadline, reimbursement of costs incurred during that reporting period will be waived.

§703.14(d)(2) New language that imposes a stricter penalty on a Grant Recipient that does not submit close out documents. If close out documents are not submitted within 180 days of termination, the Grant Recipient will be ineligible to receive new grants or continued grants. CPRIT may waive final submission of documents if requested by Grant Recipient.

§703.14(d)(2)(A)-(C) New subsections to lay out the process of granting a waiver of late close out document submission. The Chief Executive Officer must grant the approval. The Oversight Committee will be notified of both the waiver request by the Grant Recipient and the decision of the Chief Executive Officer. The decision of the Chief Executive Officer will be final unless overturned by a simple majority of Oversight Committee members present and voting.

§703.20(2) Requires a Grant Recipient to show good cause for not certifying adoption and enforcement of a Tobacco-free workplace policy.

§703.21(b)(2) New language added to clarify that this subsection also applies to Grant Recipients that received advanced funds. If a Grant Recipient does not timely submit Financial Status Reports within 30 days of due date, reimbursement of projects costs for that time period are waived.

§703.21(b)(2)(A)-(B) New language clarifying Financial Status Report due date of 90 days following the end of the state fiscal quarter. Language is also added to clarify when Grant Recipient must submit request to defer reimbursement request.

§703.21(b)(3)(G)-(H) Both are new subsections that implement penalty for not timely submitting the Grant Progress Report. If a Grant Recipient does not submit the Grant Progress Report within 60 days of anniversary of effective date of Grant Contract, CPRIT will not disperse funds until the report is filed. Additionally, Product Development Grant Recipients must submit "Tranche Grant Progress Reports," along with other reports required by CPRIT. If this is not timely done, funds for the next tranche as per the Grant Contract will not be disbursed until reports reviewed and approved.

Proposed Administrative Rule Changes
May, 2014

#### **RULE §702.7** Acceptance of Gifts and Donations by the Institute

- (a) As authorized by Texas Health and Safety Code §102.054, the Institute may solicit and accept gifts from any source to support the operations of the Institute and to further its purposes; except that the Institute may not supplement the salary of any Institute Employee with a gift or grant received by the Institute.
- (b) An Oversight Committee Member or an Institute Employee shall not authorize a donor to use the property of the Institute unless the property is used in accordance with a contract between the Institute and the donor, the contract is found by the Institute to serve a public purpose, the contract contains provisions to ensure the public purpose continues, and the Institute is reasonably compensated for the use of the property.
- (c) Procedure for acceptance of gifts.
- (1) Gifts to the Institute may be designated for one of the following categories:
- (A) Unrestricted General Support;
- (B) Restricted Programmatic Support;
- (C) Endowed and Restricted Funds; or
- (D) Other (includes gifts of real or personal property).
- (2) Gifts of ten thousand dollars (\$10,000) or less may be accepted on behalf of the Institute by the Chief Executive Officer.
- (3) The Executive Committee of the Oversight Committee may accept gifts of cash, stock, bonds, or personal property with a value in excess of ten thousand dollars (\$10,000) but less than one million dollars (\$1,000,000) on behalf of the Institute. If one or more Executive Committee members do not agree with the decision to accept the gift on behalf of the Institute, the decision to accept the gift will be made by a majority vote of the Oversight Committee.
- (4) Acceptance of gifts made to the Institute of cash, stock, bonds, or personal property with a value in excess of one million dollars, gifts of real property regardless of value, and all other gifts not herein described shall be approved by a majority vote of the Oversight Committee. To assist in its decision, a report shall be created by the Chief Executive Officer that includes the following information:
  - (A) Name and biographical data regarding the individual or organization making the gift;
  - (B) A description of the gift;
- (C) A list of conditions or requirements to be imposed on the Institute as a result of accepting the gift;

- (D) If one of the conditions is naming, then include a description of the object to be named and whether there is a time limit on continuing the name;
  - (E) If the gift is real property, an evaluation of the gift by the General Land Office;
- (F) If the gift is stock or other investments, a description of how they will be sold and the expected net proceeds; and
  - (G) A description of how the gift will be used.
- (5) All funds received from donations to the Institute will be deposited to the state treasury and used for the purpose specified by the donor or for general Institute programs when no purpose is specified.
- (d) The Institute encourages the offer of gifts of additional revenue and real and personal property through naming.
- (1) Naming can be given to both real objects and inanimate objects, such as Grant Awards.
- (2) The Oversight Committee will consider a request for naming in connection with a gift of real or personal property of substantial value to the Institute and its programs. In determining whether a gift has substantial value, the Oversight Committee will evaluate the following factors:
- (A) The size of the real or personal property in relation to other fund sources--including bonds--available at the same time and consideration of whether the donation will make a material contribution to the Institute's goals and programs that otherwise would not be made;
  - (B) Availability of the real or personal property; and
- (C) The degree of flexibility and discretion the Institute will have in the use of the real or personal property.
- (3) The Oversight Committee must approve the recommendation to name an object or program by a majority vote of its members.
- (e) The Oversight Committee may refuse a gift to the Institute for any reason, including:
- (1) The gift requires an initial and/or on-going expenditure that will likely equal or exceed the value of the gift.
- (2) The gift is from an institution, entity, or organization, or a director, officer, or an executive of an institution, entity or organization that has applied for funding from the Institute, or currently receives funding from the Institute, or the gift is from a Senior Member or Key Personnel of the research or prevention program team listed on a Grant Application or Grant Award.

- (3) The Institute may return a gift made by an institution, entity, organization, or individual that was otherwise eligible to make the donation at the time that the gift was accepted by the Institute in the event that the donor subsequently submits a Grant Application for funding from the Institute within the fiscal year of the donation.
- (4) For purposes of this section, the limitation on gifts does not apply to a donation made as the result of the final bequeathal.
- (f) The Institute shall report information pertaining to gifts, grants, or other consideration provided to the Institute, an Institute Employee, or a member of an Institute committee, subject to the requirements in this subsection.
- (1) The information shall be posted on the Institute's Internet website.
- (2) The information to be posted shall include the donor's name, the date of the donor's donation, and the amount of the donor's donation.
- (3) The reporting requirement applies to all gifts, grants, or other consideration provided to the Institute except that individual conference registration fees paid to CPRIT by conference attendees shall not be treated as consideration for purposes of the reporting requirement. The total amount received for conference registration fees may be reported.
- (4) The reporting requirement applies to all gifts, grants, or other consideration given to a Oversight Committee Member, Institute Employee, or Program Integration Committee Member except that the following items are not considered gifts, grants or consideration subject to the reporting requirement:
- (A) Books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of an Oversight Committee Member, Institute Employee, or Program Integration Committee Member and that are accepted by the individual on behalf of Institute for use in performing the individual's job duties;
- (B) Items or consideration of any value given to the Oversight Committee Member, Institute Employee, or Program Integration Committee Member by a Relative; A gift or other benefit conferred on account of kinship or a personal, professional, or business relationship independent of the official status of the recipient
- (C) Items or consideration of any value given to the Oversight Committee Member, Institute Employee, or Program Integration Committee Member by a personal friend so long as:
  - (i) The item or consideration is given based solely on an existing personal relationship;
- (ii) The personal friend or a Relative of the personal friend is not an employee of an entity receiving or applying to receive money from the Institute; and

- (iii) The individual subject to this provision has no reason to believe that the item or consideration is being offered through an intermediary in an attempt to evade reporting requirements.
- (<u>DC</u>) Items of nominal intrinsic with a value of less than \$50, excluding cash or a negotiable instrument described by Section 3.104, Business & Commerce Code such as modest items of food and refreshment on infrequent occasions, shared ground transportation in non-luxury vehicles, and unsolicited advertising or promotional material such as plaques, certificates, trophies, paperweights, calendars, note pads, and pencils, but excluding cash or negotiable instruments.
- (5) The reporting requirement applies only to the gifts, grants, or other consideration given to a Scientific Research and Prevention Programs Committee Member by a Grant Applicant or Grant Recipient during the period that the Member is appointed except that the following items are not considered gifts, grants or consideration subject to the reporting requirement:
- (A) Books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of the Scientific Research and Prevention Programs Committee Member and that are accepted by the individual for use in performing the individual's job duties;
- (B) Items of nominal intrinsic with a value of less than \$50, excluding cash or a negotiable instrument as described by Section 3.104, Business & Commerce Code-such as modest items of food and refreshment on infrequent occasions, shared ground transportation in non-luxury vehicles, and unsolicited advertising or promotional material such as plaques, certificates, trophies, paperweights, calendars, note pads, and pencils, but excluding cash or negotiable instruments.
- (6) The reporting requirement applies to a member of an Advisory Committee of the Institute only to the extent that the individual participates in the Grant Review Process.
- (A) If the individual participates in the Grant Review Process, then the individual must report gifts, grants, or other consideration given to the Advisory Committee member by a Grant Applicant or Grant Recipient during the period that the Advisory Committee member participates in the Grant Review Process except that the following items are not considered gifts, grants or consideration subject to the reporting requirement A gift or other benefit conferred on account of kinship or personal, professional, or business relationship independent of the official status of the recipient so long as:
- (i) The personal friend or a Relative of the personal friend is not an employee of an entity receiving or applying to receive money from the Institute; and

- (ii) The individual subject to this provision has no reason to believe that the item or consideration is being offered through an intermediary in an attempt to evade reporting requirements.
- (B) If the individual participates in the Grant Review Process, then the individual must report gifts, grants, or other consideration given to the Advisory Committee member by a Grant Applicant or Grant Recipient during the period that the Advisory Committee member participates in the Grant Review Process except that the following items are not considered gifts, grants or consideration subject to the reporting requirement:
- (i) Books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of the Advisory Committee member and that are accepted by the individual for use in performing the individual's job duties;
- (ii) Items of nominal intrinsic with a value of less than \$50, excluding cash or a negotiable instrument as described by Section 3.104, Business & Commerce Code such as modest items of food and refreshment on infrequent occasions, shared ground transportation in non-luxury vehicles, and unsolicited advertising or promotional material such as plaques, certificates, trophies, paperweights, calendars, note pads, and pencils, but excluding cash or negotiable instruments.
- (BC) For purposes of this subsection, participation in the Grant Review Process by an Advisory Committee member does not include submitting a Grant Application or receiving a Grant Award.

RULE §702.9 Code of Conduct and Ethics for Oversight Committee Members, Institute Employees, and Program Integration Committee Members



### **RULE §703.3 Grant Applications**

- (a) The Institute shall accept Grant Applications for Cancer Research and Cancer Prevention programs to be funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute in response to standard format Requests for Applications issued by the Institute.
- (b) Each Request for Applications shall be publicly announced in the *Texas Register* and available through the Institute's Internet website. The Institute reserves the right to modify the format and content requirements for the Requests for Applications from time to time. Notice of modifications will be announced and available through the Institute's Internet website. The Request for Applications shall:
- (1) Include guidelines for the proposed projects and may be accompanied by instructions provided by the Institute.
- (2) State the criteria to be used during the Grant Review Process to evaluate the merit of the Grant Application, including guidance regarding the range of possible scores.
- (A) The specific criteria and scoring guidance shall be developed by the Chief Program Officer in consultation with the Review Council.
- (B) When the Institute will use a preliminary evaluation process as described in §703.6 of this chapter (relating to Grants Review Process) for the Grant Applications submitted pursuant to a particular Grant Mechanism, the Request for Applications shall state the criteria and Grant Application components to be included in the preliminary evaluation.
- (c) Requests for Applications for Cancer Research and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:
- (1) Basic research;
- (2) Translational research, including proof of concept, preclinical, and Product Development activities;
- (3) Clinical research;
- (4) Population based research;
- (5) Training;
- (6) Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;
- (7) Infrastructure, including centers, core facilities, and shared instrumentation;

- (8) Implementation of the Texas Cancer Plan; and
- (9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.
- (d) An <u>otherwise qualified</u> applicant is eligible solely for the Grant Mechanism specified by the Request for Applications under which the Grant Application was submitted.
- (e) The request for Grant Applications for Cancer Research projects shall seek information from Grant Applicants regarding whether the proposed project has Product Development prospects, including, but not limited to anticipated regulatory filings, commercial abstracts or business plans.
- (f) Failure to comply with the material and substantive requirements set forth in the Request for Applications may serve as grounds for disqualification from further consideration of the Grant Application by the Institute. A Grant Application determined by the Institute to be incomplete or otherwise noncompliant with the terms or instructions set forth by the Request for Applications shall not be eligible for consideration of a Grant Award.
- (g) Only those Grant Applications submitted via the designated electronic portal designated by the Institute by the deadline, if any, stated in the Request for Applications shall be eligible for consideration of a Grant Award.
- (1) Nothing herein shall prohibit the Institute from extending the submission deadline for one or more Grant Applications upon a showing of good cause.
- (2) The Institute shall document any deadline extension granted, including the reason for extending the deadline and will cause the documentation to be maintained as part of the Grant Review Process records.
- (h) The Grant Applicant shall certify that it has not made and will not make a donation to the Institute or any foundation created to benefit the Institute.
- (1) Grant Applicants that make a donation to the Institute or any foundation created to benefit the Institute on or after June 14, 2013, are ineligible to be considered for a Grant Award.
- (2) For purposes of the required certification, the Grant Applicant includes the following individuals or the spouse or dependent child(ren) of the following individuals:
  - (A) the Principal Investigator, Program Director, or Company Representative;
  - (B) a Senior Member or Key Personnel listed on the Grant Application;
  - (C) an officer or director of the Grant Applicant.

- (3) Notwithstanding the foregoing, one or more donations exceeding \$500 by an employee of a Grant Applicant not described by paragraph (2) of this subsection shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.
- (4) The certification shall be made at the time the Grant Application is submitted.
- (5) The Chief Compliance Officer shall compare the list of Grant Applicants to a current list of donors to the Institute and any foundation created to benefit the Institute.
- (6) To the extent that the Chief Compliance Officer has reason to believe that a Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, the Chief Compliance Officer shall seek information from the Grant Applicant to resolve any issue. The Grant Application may continue in the Grant Review Process during the time the additional information is sought and under review by the Institute.
- (7) If the Chief Compliance Officer determines that the Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, then the Institute shall take appropriate action. Appropriate action may entail:
  - (A) Withdrawal of the Grant Application from further consideration;
- (B) Return of the donation, if the return of the donation is possible without impairing Institute operations.
- (8) If the donation is returned to the Applicant, then the Grant Application is eligible to be considered for a Grant Award.
- (i) Grant Applicants shall identify by name all sources of funding, including a capitalization table that reflects private investors, if any, contributing to the project proposed for a Grant Award. This information shall include those individuals or entities that have an investment, stock or rights in the project. The Institute shall make the information provided by the Grant Applicant available to Scientific Research and Prevention Programs Committee members, Institute employees, independent contractors participating in the Grant Review Process, Program Integration Committee Members and Oversight Committee Members for purposes of identifying potential Conflicts of Interest prior to reviewing or taking action on the Grant Application. The information shall be maintained in the Institute's Grant Review Process records.
- (j) A Grant Applicant shall indicate if the Grant Applicant is currently ineligible to receive Federal or State grant funds or if the Grant Applicant has had a grant terminated for cause within five years prior to the submission date of the Grant Application. For purposes of the provision, the term Grant Applicant includes the Senior Member and Key Personnel.
- (k) The Institute may require each Grant Applicant for a Cancer Research Grant Award for Product Development to submit an application fee.

- (1) The Chief Executive Officer shall adopt a policy regarding the application fee amount.
- (2) The Institute shall use the application fee amounts to defray the Institute's costs associated with the Product Development review processes, including due diligence and intellectual property reviews, as specified in the Request for Application.



### **RULE §703.6 Grants Review Process**

- (a) For all Grant Applications that are not administratively withdrawn by the Institute for noncompliance or otherwise withdrawn by the Grant Applicant, the Institute shall use a two-stage Peer Review process.
- (1) The Peer Review process, as described herein, is used to identify and recommend meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control projects for Grant Award consideration by the Program Integration Committee and the Oversight Committee.
- (2) Peer Review will be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Texas Health and Safety Code.
- (b) The two stages of the Peer Review Process used by the Institute are:
- (1) Evaluation of Grant Applications by Peer Review Panels; and
- (2) Prioritization of Grant Applications by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council, as may be appropriate for the Grant Program.
- (c) Except as described in subsection (e) of this section, the Peer Review Panel evaluation process encompasses the following actions, which will be consistently applied:
- (1) The Institute distributes all Grant Applications submitted for a particular Grant Mechanism to one or more Peer Review Panels.
- (2) The Peer Review Panel chairperson assigns each Grant Application to no less than two panel members that serve as the Primary Reviewers for the Grant Application. Assignments are made based upon the expertise and background of the Primary Reviewer in relation to the Grant Application.
- (3) The Primary Reviewer is responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the Primary Reviewer's general impression of the Grant Application's merit. The Primary Reviewers' individual Overall Evaluation Scores are averaged together to produce a single initial Overall Evaluation Score for the Grant Application.
- (4) The Peer Review Panel meets to discuss the Grant Applications assigned to the Peer Review Panel. If there is insufficient time to discuss all Grant Applications, the Peer Review Panel chairperson determines the Grant Applications to be discussed by the panel. The chairperson's decision is based largely on the Grant Application's initial Overall Evaluation Score; however a

Peer Review Panel member may request that a Grant Application be discussed by the Peer Review Panel.

- (A) If a Grant Application is not discussed by the Peer Review Panel, then the initial Overall Evaluation Score serves as the final Overall Evaluation Score for the Grant Application. The Grant Application is not considered further during the Grant Review Cycle.
- (B) If a Grant Application is discussed by the Peer Review Panel, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.
  - (i) The panel chairperson participates in the discussion but does not score Grant Applications.
- (ii) A Primary Reviewer has the option to revise his or her score for the Grant Application after panel discussion or to keep the same score submitted during the initial review.
- (C) If the Peer Review Panel recommends changes to the Grant Award funds amount requested by the Grant Applicant or to the goals and objectives or timeline for the proposed project, then the recommended changes and explanation shall be recorded at the time the final Overall Evaluation Score is set.
- (5) At the conclusion of the Peer Review Panel evaluation, the Peer Review Panel chairperson submits to the appropriate Review Council a list of Grant Applications discussed by the panel ranked in order by the final Overall Evaluation Score. Any changes to the Grant Award funding amount or to the project goals and objectives or timeline recommended by the Peer Review Panel shall be provided to the Review Council at that time.
- (d) The Review Council's prioritization process for Grant Award recommendations encompasses the following actions, which will be consistently applied:
- (1) The Review Council prioritizes the Grant Application recommendations across all the Peer Review Panels by assigning a Numerical Ranking Score to each Grant Application that was discussed by a Peer Review Panel. The Numerical Ranking Score is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.
- (2) The Review Council's recommendations are submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. The recommendations, listed in order by Numerical Ranking Score shall include:

- (A) An explanation describing how the Grant Application meets the Review Council's standards for Grant Award funding;
- (B) The final Overall Evaluation Score assigned to the Grant Application by the Peer Review Panel, including an explanation for ranking one or more Grant Applications ahead of another Grant Application with a more favorable final Overall Evaluation Score; and
- (C) The specified amount of the Grant Award funding for each Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline.
- (e) Circumstances relevant to a particular Grant Mechanism or to a Grant Review Cycle may justify changes to the dual-stage Peer Review process described in subsections (c) and (d) of this section. Peer Review process changes the Institute may implement are described below. The list is not intended to be exhaustive. Any material changes to the Peer Review process, including those listed below, shall be described in the Request for Applications or communicated to all Grant Applicants.
- (1) The Institute may use a preliminary evaluation process if the volume of Grant Applications submitted pursuant to a specific Request for Applications is such that timely review may be impeded. The preliminary evaluation will be conducted after Grant Applications are assigned to Peer Review Panels but prior to the initial review described in subsection (c) of this section. The preliminary evaluation encompasses the following actions:
- (A) The criteria and the specific Grant Application components used for the preliminary evaluation shall be stated in the Request for Applications;
- (B) No less than two Peer Review Panel members are assigned to conduct the preliminary evaluation for a Grant Application and provide a preliminary score that conveys the general impression of the Grant Application's merit pursuant to the specified criteria; and
- (C) The Peer Panel Review Panel chairperson is responsible for determining the Grant Applications that move forward to initial review as described in subsection (c) of this section. The decision will be based upon preliminary evaluation scores. A Grant Application that does not move forward to initial review will not be considered further and the average of the preliminary evaluation scores received becomes the final Overall Evaluation Score for the Grant Application.
- (2) The Institute shall assign all Grant Applications submitted for recruitment of researchers and clinicians to the Scientific Review Council.
- (A) The Scientific Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation

Score that conveys the Review Council member's recommendation related to the proposed recruitment.

- (B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.
- (C) If more than one recruitment Grant Application is reviewed by the Scientific Review Council during the Grant Review Cycle, then the Scientific Review Council shall assign a Numerical Ranking Score to each Grant Application to convey its prioritization ranking.
- (D) If the Scientific Review Council recommends a change to the Grant Award funds requested by the Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.
- (E) The Scientific Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.
- (3) The Institute may assign continuation Grant Applications to the appropriate Review Council.
- (A) The Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the progress and continued funding.
- (B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.
- (C) If more than one continuation Grant Application is reviewed by the Review Council during the Grant Review Cycle, then the Review Council shall assign a Numerical Ranking Score to each continuation Grant Application to convey its prioritization ranking.
- (D) If the Review Council recommends a change to the Grant Award funds or to the scope of work or timeline requested by the continuation Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.
- (E) The Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.
- (4) The Institute's Peer Review process described in subsections (c) and (d) of this section may include the following additional process steps for Product Development of Cancer Research Grant Applications:

- (A) A Grant Applicant may be invited to deliver an in-person presentation to the Peer Review Panel. The Product Development Review Council chairperson is responsible for deciding which Grant Applicants will make in-person presentations. The decision is based upon the initial Overall Evaluation Scores of the primary reviewers following a discussion with Peer Review Panel members, as well as explicit criteria published in the Request for Applications.
- (i) Peer Review Panel members may submit questions to be addressed by the Grant Applicant at the in-person presentation.
- (ii) A Grant Application that is not presented in-person will not be considered further. The average of the primary reviewers' initial Overall Evaluation Scores will be the final Overall Evaluation Score for the Grant Application.
- (iii) Following the in-person presentation, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.
- (B) A Grant Application may undergo business operations and management due diligence review and an intellectual property review conducted by third parties. The Peer Review Panel decides which Grant Applications will undergo business operations and management due diligence and intellectual property review. The decision is based upon the Grant Application's final Overall Evaluation Score, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications. A Grant Application that is not recommended for due diligence and intellectual property review will not be considered further.
- (C) After receipt of the business operations and management due diligence and intellectual property reviews for a Grant Application, the Product Development Review Council and the Primary Reviewers meet to determine whether to recommend the Grant Application for a Grant Award based upon the information set forth in the due diligence and intellectual property reviews. The Product Development Review Council may recommend changes to the Grant Award budget and goals and objectives or timeline.
- (D) The Product Development Review Council assigns a Numerical Ranking Score to each Grant Application recommended for a Grant Award.
- (f) Institute Employees may attend Peer Review Panel and Review Council meetings. If an Institute Employee attends a Peer Review Panel meeting or a Review Council meeting, the Institute Employee's attendance shall be recorded and the Institute Employee shall certify in writing that the Institute Employee complied with the Institute's Conflict of Interest rules. The

Institute Employee's attendance at the Peer Review Panel meeting or Review Council meeting is subject to the following restrictions:

- (1) Unless waived pursuant to the process described in Chapter 702, §702.17 of this title (relating to Exceptional Circumstances Requiring Participation), the Institute Employee shall not be present for any discussion, vote, or other action taken related to a Grant Applicant if the Institute Employee has a Conflict of Interest with that Grant Applicant; and
- (2) The Institute Employee shall not participate in a discussion of the merits, vote, or other action taken related to a Grant Application, except to answer technical or administrative questions unrelated to the merits of the Grant Application and to provide input on the Institute's Grant Review Process.
- (g) The Institute shall engage an independent third party to observe meetings of the Peer Review Panel and Review Council where Grant Applications are discussed.
- (1) The independent third party shall serve as a neutral observer to document that the Institute's Grant Review Process is consistently followed, including observance of the Institute's established Conflict of Interest rules and that participation by Institute employees, if any, is limited to providing input on the Institute's Grant Review Process and responding to committee questions unrelated to the merits of the Grant Application. Institute Program staff shall not participate in a discussion of the merits, vote, or any other action taken related to a Grant Application.
- (2) The independent third party reviewer shall issue a report to the Chief Compliance Officer specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.
- (h) Excepting a finding of an undisclosed Conflict of Interest as set forth in §703.9 of this chapter (relating to Limitation on Review of Grant Process), the Review Council's decision to not include a Grant Application on the prioritized list of Grant Applications submitted to the Program Integration Committee and the Oversight Committee is final. A Grant Application not included on the prioritized list created by the Review Council shall not be considered further during the Grant Review Cycle.
- (i) At the time that the Peer Review Panel or the Review Council concludes its tasks for the Grant Review Cycle, each member shall certify in writing that the member complied with the Institute's Conflict of Interest rules.
- (j) The Institute shall retain a review record for a Grant Application submitted to the Institute, even if the Grant Application did not receive a Grant Award. Such records will be retained by the Institute's electronic Grant Management System. The records retained by the Institute must include the following information:

- (1) The final Overall Evaluation Score and Numerical Ranking Score, if applicable, assigned to the Grant Application;
- (2) The specified amount of the Grant Award funding for the Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline;
- (3) The Scientific Research and Prevention Programs Committee that reviewed the Grant Application;
- (4) Conflicts of Interest, if any, with the Grant Application identified by a member of the Scientific Research and Prevention Programs Committee, the Review Council, the Program Integration Committee, or the Oversight Committee; and
- (5) Documentation of steps taken to recuse any member or members from the Grant Review Process because of disclosed Conflicts of Interest.
- (k) For purposes of this rule, a Peer Review Panel chairperson or a Review Council chairperson that is unable to carry out his or her assigned duties for any reason with regard to one or more Grant Applications may designate a co-chairperson from among the appointed Scientific Research and Prevention Programs committee members to fulfill the chairperson role. Such designation shall be recorded in writing and include the specific time and extent of the designation.

# **RULE §703.8** Oversight Committee Consideration of the Program Integration Committee's Funding Recommendation

The Oversight Committee must vote to approve each Grant Award recommendation submitted by the Program Integration Committee.

- (1) Prior to the Oversight Committee's consideration and approval of the Program Integration Committee's Grant Award recommendations, the Chief Compliance Officer must review the process documentation for each Grant Application recommended for a Grant Award by the Program Integration Committee and report the findings to the Chief Executive Officer and to the Oversight Committee. The Chief Compliance Officer's report shall:
- (A) Publicly certify that the Grant Review Process complied with the Institute's administrative rules and procedures, including those procedures stated in the Request for Applications.
- (B) Indicate variances, if any, in the Grant Review Process. The Chief Compliance Officer may recommend corrective actions to address variances, if any, and the Oversight Committee may consider and approve corrective actions at that time that the Grant Award recommendations are approved.
- (C) Compare the list of Grant Applicants recommended for a Grant Award to a list of donors from any nonprofit organization established to provide support to the Institute.
- (2) <u>The Chief Executive Officer may recommend corrective actions to address variances, if any, identified by the Chief Compliance Officer. The Oversight Committee shall consider and may approve proposed corrective actions at that time that the Grant Award recommendations are approved by a vote of a simple majority of Oversight Committee members present and voting.</u>
- (23)Two-thirds of the Oversight Committee Members present and voting must approve each Grant Award recommendation. At the time that the Oversight Committee approves the Grant Award recommendation:
  - (A) The total amount of money approved to fund a multiyear project must be specified.
- (B) The Chief Executive Officer's recommendation, if any, regarding an advance of Grant Award funds must be approved by a majority vote of the Oversight Committee.
- (34) If the Oversight Committee does not approve a Grant Award recommendation made by the Program Integration Committee, the minutes of the meeting shall record the explanation for the failure to follow the Grant Award recommendation.
- (45) The Oversight Committee may not award more than \$300 million in Grant Awards in a fiscal year.

# 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; and
- (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.
- (c) For purposes of the certification required by subsection (a) of this section, Encumbered Funds 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; and

- (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 allowance for unrecovered Indirect Costs must be specifically approved by the Chief Executive Officer: and
- (D) The Grant Recipient is not a public or private institution of higher education as defined by §61.003 of the Texas Education Code.
- (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, approved by the Chief Executive Officer, 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.



### **RULE §703.13** Audits and Investigations

- (a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the end of the Grant Recipient's fiscal year during which the Grant Contract was terminated.
- (b) Notwithstanding the foregoing, a Grant Recipient expending \$500,000 or more in state awards during its fiscal year shall obtain either an annual single independent audit or a program specific independent audit.
- (1) A single audit is required if funds from more than one state program are spent by the Grant Recipient.
- (2) The audited time period is the Grant Recipient's fiscal year.
- (3) The audit must be submitted to the Institute within 30 days of receipt by the Grant Recipient but no later than nine (9) months 270 days following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.
- (A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.
- (B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than the 270<sup>th</sup> day following the close of the Grant Recipient's fiscal year.
- (C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.
- (c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to apply for be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan is are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to apply for to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.



### **RULE §703.14** Termination, Extension, and Close Out of Grant Contracts

- (a) The termination date of a Grant Contract shall be the date stated in the Grant Contract, except:
- (1) The Chief Executive Officer may elect to terminate the Grant Contract earlier because the Grant Recipient has failed to fulfill contractual obligations, including timely submission of required reports or certifications;
- (2) The Institute terminates the Grant Contract because funds allocated to the Grant Award are reduced, depleted, or unavailable during the award period, and the Institute is unable to obtain additional funds for such purposes; or
- (3) The Institute and the Grant Recipient mutually agree to terminate the Grant Contract earlier.
- (b) If the Institute elects to terminate the Grant Contract pursuant to subsection (a)(1) or (2) of this section, then the Chief Executive Officer shall notify the Grant Recipient in writing of the intent to terminate funding at least 30 days before the intended termination date. The notice shall state the reasons for termination, and the procedure and time period for seeking reconsideration of the decision to terminate. Nothing herein restricts the Institute's ability to terminate the Grant Contract immediately or to seek additional remedies if justified by the circumstances of the event leading to early termination.
- (c) The Institute may approve the Grant Recipient's written request to extend the termination date of the Grant Contract to permit the Grant Recipient additional time to complete the work of the project.
- (1) A no cost extension may be granted only if the Grant Recipient is in good fiscal and programmatic standing.
- (2) The Grant Recipient may request a no cost extension no earlier than 180 days and no later than 30 days prior to the termination date of the Grant Contract.
- (3) The Institute may approve one no cost extension, the duration of which may be no longer than six months from the termination date of the Grant Contract, unless the Institute finds that special circumstances justify authorizing additional time to complete the work of the project.
- (4) If the Institute approves the request to extend the termination date of the Grant Contract, then the termination date shall be amended to reflect the change.
- (5) Nothing herein prohibits the Institute and the Grant Recipient from taking action more than 180 days prior to the termination date of the Grant contract to extend the termination date of the Grant Contract. Approval of an extension must be supported by a finding of good cause and the Grant Contract shall be amended to reflect the change.

- (d) Within ninety (90) days after the termination of the Grant Contract, the Grant Recipient must submit a final Financial Status Report and final Grant Progress Report as well as any other required reports as specified in the Grant Contract. For purposes of this rule, these reports shall be collectively referred to as "close out documents."
- (1) If the Grant Recipient has submitted the final Financial Status Report on or before the 30<sup>th</sup> day following the due date specified in § 703.21(b), but has not submitted other close out documents, then Tthe final reimbursement payment shall not be made until such other close out documents have been submitted and approved by the Institute. The Grant Recipient's failure to submit the Financial Status report within 30 days following the due date specified in 703.21(b) will waive reimbursement of project costs incurred during the reporting period.
- (2) Failure to submit <u>all other</u> close out documents within 180 days of the Grant Contract termination date <u>may shall</u> result in the Grant Recipient being ineligible <u>for other Institute to receive new</u> Grant Awards <u>or continuation Grant Awards</u> until such time that the close out documents are submitted-<u>unless the Institute waives the final submission of close out documents by the Grant Recipient.</u>
- (A) Approval of the Grant Recipient's request to waive the submission of close out documents is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.
- (B) The Oversight Committee shall be notified in writing of the Grant Recipient's waiver request and the Chief Executive Officer's decision to approve or reject the waiver request.
- (C) Unless the Oversight Committee votes by a simple majority of the members present and able to vote to overturn the Chief Executive Officer's decision regarding the waiver, the Chief Executive Officer's decision shall be considered final.
- (e) The Institute may make upward or downward adjustments to the Allowable Costs requested by the Grant Recipient within ninety (90) days following the receipt of the close out reports.
- (f) Nothing herein shall affect the Institute's right to disallow costs and recover Grant Award funds on the basis of a later audit or other review or the Grant Recipient's obligation to return Grant Award funds owed as a result of a later refund, correction, or other transaction.
- (g) Any Grant Award funds paid to the Grant Recipient in excess of the amount to which the Grant Recipient is finally determined to be entitled under the terms of the Grant Contract constitute a debt to the state. If not paid within a reasonable period after demand, the Institute may reduce the debt owed by:
- (1) Making an administrative offset against other requests for reimbursements;
- (2) Withholding advance payments otherwise due to the Grant Recipient; or

(3) Other action permitted by law.



## RULE §703.20 Certification of Tobacco-Free Policy for Grant Recipients

To be eligible to receive a Grant Award, a Grant Recipient shall certify that the entity has adopted and enforces a Tobacco-free workplace policy.

- (1) A Tobacco-free workplace policy will comply with the certification required by this section if the policy is adopted by the Grant Recipient's board of directors, governing body, or similar and, at a minimum, includes provisions:
- (A) Prohibiting the use of all Tobacco products by all employees and visitors to the property owned, operated, leased, occupied, or controlled by the Grant Recipient. For purposes of the Tobacco-free workplace policy, the Grant Recipient may designate the property to which the policy applies, so long as the workplace policy encompasses all buildings and structures where the Grant Award project is taking place as well as the sidewalks, parking lots, walkways, and attached parking structures immediately adjacent, but only to the extent the Grant Recipient owns, leases or controls the building, sidewalks, parking lots and parking structures.
  - (B) Providing for and/or referring to Tobacco use cessation services for employees.
- (2) Upon request by a Grant Recipient <u>and a showing of good cause</u>, the Chief Executive Officer may authorize a waiver of compliance with this section. If approved, the waiver is effective only for the State fiscal year during which it was approved.
- (3) The certification and waiver requests addressed herein shall be submitted by the Grant Recipient via the Institute's electronic Grant Management System.

## **RULE §703.21** Monitoring Grant Award Performance and Expenditures

- (a) The Institute, under the direction of the Chief Executive Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and exercise proper stewardship over Grant Award funds. Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.
- (b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:
- (1) Financial Status Reports Review Quarterly financial status reports shall be submitted to the Institute within 90 days of the end of the state fiscal quarter (based upon a September 1 August 31 fiscal year.) The Institute shall review expenditures and supporting documents to determine whether expenses charged to the Grant Award are:
- (A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and
- (B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.
- (2) Timely submission of Financial Status Reports The Grant Recipient waives the right to reimbursement of project costs incurred during the reporting period if the financial status report for that quarter is not submitted to the Institute within 30 days of the <a href="#FSR">FSR</a> due date. <a href="#Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.">FSR</a> due date. <a href="#Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.
  - (A) For purposes of this rule, the "FSR due date" is 90 days following the end of the state fiscal quarter.
  - (B) The Chief Executive Officer may approve an extension of the submission deadline a Grant Recipient's request to defer submission of the reimbursement request for the current fiscal quarter until the next fiscal quarter if, prior toon or before the original FSR due date, the gGrant FRecipient submits a written explanation for the gGrant FRecipient's inability to complete a timely submission of the FSR.
- (3) Grant Progress Reports The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the scope of work and timeline set forth in the Grant Contract.
- (A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

- (B) The annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:
- (i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;
- (ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;
- (iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;
- (iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;
- (v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;
  - (vi) A Historically Underutilized Businesses report;
- (vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;
- (viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;
- (ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;
- (x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report;
- (xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and
  - (xii) A single audit determination form.
- (C) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

- (D) The Grant Progress Report will be evaluated by a grant manager pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff.
- (E) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.
- (i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.
- (ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts).
- (F) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.
- (G) If a Grant Recipient's fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Awards funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is filed.
- (H) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific tranches of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a tranche of funding shall be known as "Tranche Grant Progress Report."
- (i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.
- (ii) Grant Funds for the next tranche of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.
- (4) Desk Reviews The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

- (5) Site Visits and Inspection Reviews The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.
- (6) Audit Reports The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).





# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE INTERIM

**CHAIR** 

**SUBJECT:** PROPOSED CHANGES TO BYLAWS

**DATE:** MAY16, 2014

### **Summary and Recommendation:**

The Board Governance subcommittee recommends that the Oversight Committee vote to approve proposed changes to the Oversight Committee Bylaws at its May 21, 2014 meeting. The Board Governance Subcommittee discussed the proposed changes to the Bylaws and Code of Conduct with CPRIT's General Counsel, Kristen Doyle, and CPRIT's Chief Compliance Officer, David Reisman, at its meeting on May 14, 2014.

#### Discussion:

At its February 19, 2014, meeting, the Oversight Committee directed the Board Governance subcommittee to review the Bylaws to ensure that the provisions are consistent with CPRIT's statute, V.T.C.A. Health & Safety Code. The Board Governance Subcommittee met with Ms. Doyle and Mr. Reisman on May 14, 2014, to discuss the proposed changes to the Bylaws and the Code of Conduct, which is incorporated by reference in the Bylaws. In addition to one clarifying change to Section 8.6(b), a change was made to the Bylaws at Section 4.4(a)(ii) to eliminate a potential conflict between the Bylaws and the statute. CPRIT staff also recommends changes to Section IV of the Code of Conduct so that the direction regarding acceptance of gifts is consistent with other statutory guidance.

The Board Governance Subcommittee has considered the proposed changes and recommends that the Oversight Committee votes to adopt the amended Bylaws and Code of Conduct.



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS **FROM:** KRISTEN DOYLE, GENERAL COUNSEL

**SUBJECT:** PROPOSED CHANGES TO OVERSIGHT COMMITTEE BYLAWS AND

CODE OF CONDUCT

**DATE:** MAY 15, 2014

### **Summary and Recommendation:**

Statutory changes enacted by the 2013 Texas Legislature impact some provisions of the Oversight Committee Bylaws ("Bylaws"). A revision to the Bylaws is required to ensure consistency with applicable Texas law. In addition, changes to the Code of Conduct are necessary to align Code of Conduct provisions with the text of applicable Texas Penal Code and Business and Commerce Code provisions. The Oversight Committee should vote to adopt the proposed Bylaw changes, including the changes to the Code of Conduct.

#### Discussion:

A change to Section 4.4(a) of the Bylaws is necessary to conform the Bylaws to a new statutory provision, V.T.C.A. Tex. Health & Safety Code § 102.0511(c). The statute specifically directs the CEO to hire various program officers. However, Section 4.4(a)(ii) requires that the Audit Subcommittee review and recommend the CEO's hiring and firing of senior staff. Removing Section 4.4(a)(ii) from the Bylaws eliminates a potential conflict between the Bylaws and the statute. In addition, a clarifying change has been made to the name of one of the Oversight Committee's ad hoc advisory committees. In Section 8.6(b), a change has been made to reflect that the committee is now referred to as the "Product Development Advisory Committee."

The Code of Conduct is incorporated by reference into the Bylaws. Proposed changes to the Code of Conduct, Section IV "Gifts and Entertainment," are necessary so that the guidance regarding exceptions to the gift prohibitions tracks the text of applicable Penal Code and Business & Commerce Code provisions.



# THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

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November 1, 2013
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# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS OVERSIGHT COMMITTEE BYLAWS

# ARTICLE 1 ESTABLISHMENT AND PURPOSES

Section 1.1 Establishment. The Cancer Prevention and Research Institute of Texas (the "<u>Institute</u>") was established by the Texas Legislature in 2007, as authorized by Article 3, Section 67 of the Constitution of the State of Texas. The statutory provisions establishing the Institute are set forth in Chapter 102 of the Health and Safety Code of the State of Texas (the "<u>Health and Safety Code</u>"). Administrative rules governing the Institute are set forth in Title 25, Chapters 701–704, of the Texas Administrative Code.

# Section 1.2 <u>Purposes</u>. The Institute is established to:

- (a) 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 cancer and cures for cancer;
- (b) 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 this state; and
  - (c) develop and implement the Texas Cancer Plan.

# ARTICLE 2 AUTHORITY, AMENDMENT, AND INTERPRETATION

- Section 2.1 <u>Rulemaking Authority</u>. These Bylaws ("<u>Bylaws</u>") have been adopted by the Oversight Committee (as defined herein) pursuant to the authority granted to the Oversight Committee in Section 102.108 of the Health and Safety Code.
- Section 2.2 <u>Amendment</u>. These Bylaws may be amended or modified only with the approval of a simple majority of the members of the Oversight Committee as set forth in Section 3.13; <u>provided</u>, that no amendment or modification to these Bylaws may be made if such amendment or modification would cause these Bylaws to conflict with applicable law. All approved amendments or modifications shall be noted in a "Statement of Revisions" at the end of these Bylaws.
- Section 2.3 <u>Interpretation</u>. These Bylaws are adopted subject to any applicable law, including, but not limited to, Chapter 102 of the Health and Safety Code and Title 25, Chapters 701–704, of the Texas Administrative Code. Whenever these Bylaws may conflict with applicable law, the conflict will be resolved in favor of the applicable law. If at any time the Oversight Committee determines that these Bylaws conflict with applicable law, then the Oversight Committee shall promptly act to amend these Bylaws to cause them to conform to applicable law.

# ARTICLE 3 THE OVERSIGHT COMMITTEE

- Section 3.1 <u>General Powers</u>. The Oversight Committee of the Institute (the "<u>Oversight Committee</u>") is the governing body of the Institute. The Oversight Committee may adopt such policies and practices, consistent with applicable law, as it may deem proper for the conduct of its meetings and the management of the Institute.
- Section 3.2 <u>Number</u>. The Oversight Committee is composed of the following nine (9) members:
  - (a) three members appointed by the Governor of the State of Texas;
- (b) three members appointed by the Lieutenant Governor of the State of Texas; and
- (c) three members appointed by the Speaker of the House of Representatives of the State of Texas
  - Section 3.3 .Composition; Disqualification.
- (a) The members of the Oversight Committee must represent the geographic and cultural diversity of the State of Texas. In making appointments to the Oversight Committee, the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas shall each appoint at least one person who is a physician or a scientist with extensive experience in the field of oncology or public health and should attempt to include cancer survivors and family members of cancer patients if possible.
- (b) A person may not be a member of the Oversight Committee if the person or the person's spouse: (i) is employed by or participates in the management of a business entity or other organization receiving money from the Institute; (ii) owns or controls, directly or indirectly, an interest in a business entity or other organization receiving money from the Institute; or (iii) uses or receives a substantial amount of tangible goods, services, or money from the Institute, other than reimbursement authorized by law for Oversight Committee membership, attendance, or expenses.
- Section 3.4 <u>Term.</u> Each member of the Oversight Committee will hold office for such member's term or until such member's earlier death, resignation, disqualification, or removal. Members of the Oversight Committee appointed by the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas serve at the pleasure of the appointing office for staggered six-year terms, with the terms of three members expiring on January 31 of each odd-numbered year. Not later than the 30th day after the date an Oversight Committee member's term expires, the appropriate appointing authority shall appoint a replacement.
- Section 3.5 <u>Vacancy</u>. If a vacancy occurs on the Oversight Committee, then the appropriate appointing authority shall appoint a successor, in the same manner as the original appointment, to serve for the remainder of the unexpired term. The appropriate appointing authority shall appoint the successor not later than the 30th day after the date the vacancy occurs.

- Section 3.6 <u>Resignation</u>. Any appointed or designated member of the Oversight Committee may resign at any time by notice given in writing to the appropriate appointing authority and to the Chair of the Oversight Committee or to the Vice Chair if the Chairman is resigning. The resigning member will continue to serve until such time that the appropriate appointing authority appoints a successor.
- Removal. It is a ground for removal from the Oversight Committee that a Section 3.7 member: (a) is ineligible for membership of the Oversight Committee under Section 3.3(b) of these Bylaws; (b) cannot, because of illness or disability, discharge the member's duties for a substantial part of the member's term; or (c) is absent from more than half of the regularly scheduled Oversight Committee meetings that the member is eligible to attend during a calendar year without an excuse approved by a majority vote of the Oversight Committee. If the Chief Executive Officer has knowledge that a potential ground for removal exists, then the Chief Executive Officer shall notify the Chairperson of the potential ground. The Chairperson shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. If the potential ground for removal involves the Chairperson, then the Chief Executive Officer shall notify the next highest ranking officer of the Oversight Committee, who shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. Notwithstanding, the foregoing, the validity of an action of the Oversight Committee is not affected by the fact that it is taken when a ground for removal of a committee member exists.
- Section 3.8 <u>Strategic Partnerships</u>. To the fullest extent permitted by applicable law, the Oversight Committee retains the authority and power to approve strategic partnerships, alliances, and coalitions of the Institute subject to vote of the simple majority of the members of the Oversight Committee as set forth in Section 3.13.
- Section 3.9 <u>Regular Meetings</u>. The Oversight Committee shall hold a public meeting at least once in each quarter of the calendar year, with appropriate notice and with a formal public comment period.
- Section 3.10 <u>Special Meetings</u>. Special meetings of the Oversight Committee may be held upon the call of the Chairperson of the Oversight Committee, or the Vice Chairperson of the Oversight Committee when performing the duties of the Chairperson, as he or she may deem necessary, with appropriate notice and with a formal public comment period. Emergency meetings and telephonic meetings may be held only as provided under applicable law.
- Section 3.11 Notice of Open Meetings. All meetings of the Oversight Committee are subject to the terms of the Open Meetings Act, Chapter 551 of the Texas Government Code (the "Open Meetings Act"). The Open Meetings Act provides that the public must be given notice of the time, place, and subject matter of meetings of governmental bodies. In absence of an emergency, notice of a meeting must be posted at a place that is readily accessible to the public at all times at least seven (7) days preceding the scheduled time of the meeting. In case of an emergency of urgent public necessity, which shall be clearly identified in the notice, it shall be sufficient if the notice is posted two hours before the meeting is convened.

- Section 3.12 Quorum. The presence of a simple majority of the members of the Oversight Committee present is necessary and sufficient to constitute a quorum for the transaction of business at any meeting of the Oversight Committee.
- Section 3.13 Action By Simple Majority Vote. Except as otherwise provided by these Bylaws or applicable law, the vote of a simple majority of the members of the Oversight Committee present at a meeting at which a quorum is present will be the prevailing action of the Oversight Committee.
- Section 3.14 <u>Expenses</u>. A member of the Oversight Committee is not entitled to compensation, but is entitled to reimbursement for actual and necessary expenses incurred in attending meetings of the Oversight Committee or performing other official duties authorized by the Chairperson.
- Section 3.15 <u>Training</u>. The Institute's General Counsel and Chief Compliance Officer shall provide training to all new members of the Oversight Committee and shall provide ongoing or continuing training to all members of the Oversight Committee not less than once a year. The form and substance of such training will be in the discretion of the Institute's General Counsel and Chief Compliance Officer. Each new member of the Oversight Committee shall also complete a course of training regarding his or her responsibilities under the Open Meetings Act within 90 days of becoming a member of the Oversight Committee.

# ARTICLE 4 SUBCOMMITTEES OF THE OVERSIGHT COMMITTEE

Section 4.1 Generally. The Oversight Committee may designate one or more subcommittees of the Oversight Committee, each subcommittee to consist of three or more of the members of the Oversight Committee. The Oversight Committee shall appoint and approve members of the subcommittees specifically listed in Section 4.2, except for the members of the Executive Committee, which shall be comprised of the designated members as set forth below in Section 4.3. The Oversight Committee may designate one or more members of the Oversight Committee as alternate members of any subcommittee, who may replace any absent or disqualified member at any meeting of the subcommittee. If a member of a subcommittee is absent from any meeting, or disqualified from voting thereat, 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 Unless the Oversight Committee provides otherwise, at all meetings of a member. 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, each subcommittee designated by the Oversight Committee shall adopt a subcommittee charter and may make, alter, and repeal rules and procedures for the conduct of its business. The Subcommittee charter shall be approved by a vote of a simple majority as set forth in Section 3.13. In the absence of a subcommittee charter, each subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business. subcommittee will have a chairperson, who will be selected by the Oversight Committee at large.

- Section 4.2 <u>Certain Subcommittees</u>. Without limiting in any way the previous Section, the following are subcommittees of the Oversight Committee (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):
  - (a) Executive Subcommittee;
  - (b) Audit Subcommittee;
  - (c) Board Governance and Ethics Subcommittee;
  - (d) Nominations Subcommittee:
  - (e) Product Development Subcommittee;
  - (f) Scientific Research Subcommittee;
  - (g) Prevention Subcommittee; and
  - (h) Diversity Subcommittee.
- Section 4.3 <u>Executive Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Executive Subcommittee (the "Executive Subcommittee").
- (a) The purpose of the Executive Subcommittee is to transact all normal business referred to it by the Oversight Committee and to conduct the Chief Executive Officer's annual performance review.
- (b) The Executive Subcommittee will be composed of no more than four (4) members of the Oversight Committee. Members of the Executive Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal from their positions by action of the Oversight Committee.
- (c) The Executive Subcommittee shall meet as often as the Chair deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- (d) Meetings of the Executive Subcommittee shall be conducted in accordance with the Texas Open Meetings Act.
- Section 4.4 <u>Audit Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Audit Subcommittee (the "<u>Audit Subcommittee</u>").
- (a) The purpose of the Audit Subcommittee is to review and make recommendations to the Oversight Committee with respect to the following:
  - (i) The annual operating budget and strategic plan;
- (ii) The Chief Executive Officer's senior staff hires or dismissals and related compensation;
  - (iii)(ii) Policies for monitoring grant performance;

(iv)(iii) Variances in the operating budget of the Institute of more than 5% or \$25,000:

- (v)(iv) Non-grant contracts exceeding \$100,000; and
- (vi)(v) Any variance of more than 10% in any announced grant award.
- (b) The members of the Audit Subcommittee will be appointed by the Oversight Committee. The Audit Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Audit Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Audit Subcommittee.
- (c) The Audit Subcommittee shall meet as often as the Chairperson of the Audit Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.5 <u>Board Governance and Ethics Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Board Governance and Ethics Subcommittee (the "Board Governance and Ethics Subcommittee").
- (a) The purpose of the Board Governance and Ethics Subcommittee is to review and recommend proposed changes for approval to the Oversight Committee with respect to the following:
  - (i) These Bylaws;
  - (ii) Any policies or administrative rules of the Institute;
  - (iii) Legislation regarding or affecting the Institute;
  - (iv) The delegation of authority to the Chief Executive Officer;
  - (v) The ethics policies of the Institute and their administration; and
  - (vi) An annual review of the internal policies and processes of the Oversight Committee.
- (b) The members of the Board Governance and Ethics Subcommittee will be appointed by the Oversight Committee. The Board Governance and Ethics Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Board Governance and Ethics Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Board Governance and Ethics Subcommittee.
- (c) The Board Governance and Ethics Subcommittee shall meet as often as the Chairperson of the Board Governance and Ethics Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

- Section 4.6 <u>Nominations Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Nominations Subcommittee (the "<u>Nominations Subcommittee</u>").
- (a) The purpose of the Nominations Subcommittee is to identify members for the Institute's advisory committees.
- (b) The members of the Nominations Subcommittee will be appointed by the Oversight Committee. The Nominations Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Nominations Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Nominations Subcommittee.
- (c) The Nominations Subcommittee shall meet as often as the Chairperson of the Nominations Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.7 <u>Product Development Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Product Development Subcommittee (the "<u>Product Development Subcommittee</u>").
- (a) The purpose of the Product Development Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer. In addition, the Product Development Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT product development research grants.
- (b) The members of the Product Development Subcommittee will be appointed by the Oversight Committee. The Product Development Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Product Development Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Product Development Subcommittee.
- (c) The Product Development Subcommittee shall meet as often as the Chairperson of the Product Development Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.8 <u>Scientific Research Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Scientific Research Subcommittee (the "<u>Scientific Research Subcommittee</u>").
- (a) The purpose of the Scientific Research Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT scientific research grants. The purpose of the Scientific

Research Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for research into the causes of and cures for all types of cancer in humans and 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 cancer and cures for cancer. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT research grants.

- (b) The members of the Scientific Research Subcommittee will be appointed by the Oversight Committee. The Scientific Research Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Scientific Research Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Scientific Research Subcommittee.
- (c) The Scientific Research Subcommittee shall meet as often as the Chairperson of the Scientific Research Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.9 <u>Prevention Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Prevention Subcommittee (the "<u>Prevention Subcommittee</u>").
- (a) The purpose of the Prevention Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants. The purpose of the Prevention Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for cancer prevention and control programs to mitigate the incidence of all types of cancers in humans and to implement the Texas Cancer Plan. In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants.
- (b) The members of the Prevention Subcommittee will be appointed by the Oversight Committee. The Prevention Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Prevention Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Prevention Subcommittee.
- (c) The Prevention Subcommittee shall meet as often as the Chairperson of the Prevention Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.10 <u>Diversity Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Diversity Subcommittee (the "<u>Diversity Subcommittee</u>").

- (a) The purpose of the Diversity Subcommittee is to ensure that the Institute makes every effort to outreach to all communities about the cancer research and prevention funding opportunities in the State of Texas.
- (b) The members of the Diversity Subcommittee will be appointed by the Oversight Committee. The Diversity Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Diversity Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Diversity Subcommittee.
- (c) The Diversity Subcommittee shall meet as often as the Chairperson of the Diversity Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

# ARTICLE 5 CHAIRPERSON AND VICE CHAIRPERSON

- Section 5.1 <u>Election</u>. The Oversight Committee shall elect from among its members a Chairperson and a Vice Chairperson in accordance with the selection provisions of these Bylaws. Nothing herein restricts the ability of the Oversight Committee to elect additional officers from among its members by a vote of a simple majority of the members of the Oversight Committee.
- Election, Term of Office and Removal. At the first regular Oversight Section 5.2 Committee meeting following the adoption of these bylaws, the members of the Oversight Committee shall elect the Chairperson and Vice Chairperson by a vote of a simple majority as set forth in Section 3.13. Thereafter, the members of the Oversight Committee shall elect the Chairperson and Vice Chairperson by a vote of a simple majority of as set forth in Section 3.13 at the last regular Oversight Committee meeting of the state fiscal year in each odd-numbered year. The Chairperson and the Vice Chairperson will hold office until death, resignation, or removal from office, or the election and qualification of a successor, whichever occurs first; provided, however, that neither the Chairperson nor the Vice Chairperson may hold office for two consecutive terms. If the person holding the office or Chairperson or Vice Chairperson holds office for one term, and a successor has not been elected by the Oversight Committee to take office at the expiration of the term, then the person holding the office of Chairperson or Vice Chairperson, as applicable, shall continue to hold the office until such time that a quorum of the Oversight Committee can meet and elect a successor. The Chairperson or the Vice Chairperson may be removed at any time, with or without cause, by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13. If the office of the Chairperson or the Vice Chairperson becomes vacant for any reason, including by the expiration of the term, then the vacancy must be filled by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13.
- Section 5.3 <u>Chairperson</u>. The Chairperson is the presiding officer of the Oversight Committee. The Chairperson shall preside at each meeting of the Oversight Committee. The Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by applicable law or recommended by the Board Governance and Ethics Subcommittee and approved by the Oversight Committee. The Chairperson may authorize official duties of members of the Oversight Committee, the University Advisory Committee, or any Ad Hoc

Advisory Committee in accordance with applicable law. The Chairperson <u>may not serve as the presiding officer for</u> any other foundation or organization created to specifically benefit the Institute.

- Section 5.4 <u>Vice Chairperson</u>. The Vice Chairperson shall, in the absence of the Chairperson, preside at each meeting of the Oversight Committee. The Vice Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by the Board Governance and Ethics Subcommittee or applicable law and approved by the Oversight Committee.
- Section 5.5 <u>Presiding Officers in the Absence of the Chairperson and Vice Chairperson.</u> In the absence of the Chairperson and Vice Chairperson, the Chairperson of the Scientific Research Subcommittee shall preside at each meeting of the Oversight Committee. In the absence of Scientific Research Subcommittee Chairperson, then the Chairperson of the Product Development Subcommittee shall preside. In the absence of the Chairpersons of the Scientific Research and Product Development Subcommittees, then the Chairperson of the Prevention Subcommittee shall preside.

# ARTICLE 6 THE CHIEF EXECUTIVE OFFICER

- Section 6.1 <u>General Powers</u>. There will be one Chief Executive Officer of the Institute (the "<u>Chief Executive Officer</u>"). The Chief Executive Officer has such powers as are delegated to the Chief Executive Officer by the Oversight Committee and such powers as are vested in the Chief Executive Officer pursuant to applicable law.
- Section 6.2 <u>Selection by the Oversight Committee</u>. The Oversight Committee shall hire the Chief Executive Officer.
- Section 6.3 <u>Performance of Duties</u>. The Chief Executive Officer shall perform the duties of the Chief Executive Officer as provided by these Bylaws, applicable law, or the Oversight Committee.
- Section 6.4 <u>Grant Review</u>. The Chief Executive Officer shall oversee the grant review process and may terminate grants that do not meet contractual obligations.
- Section 6.5 <u>Quarterly Report</u>. Each quarter, the Chief Executive Officer shall report to the Oversight Committee on any new grant awards and the progress and continued merit of scientific research and prevention programs previously awarded funding. The report must include a summary of the allocation of funding among scientific research and prevention programs and details regarding the final results of completed projects under these programs.
- Section 6.6 <u>Duties Regarding Foundations or Organizations Created to Specifically Benefit CPRIT</u>. The Chief Executive Officer shall annually report to the Oversight Committee on guidelines for the governance of any foundation or organization created specifically to benefit CPRIT and the relationship between the Institute and the foundation or organization. The Chief Executive Officer shall also annually solicit a report from the foundation or organization created specifically to benefit the Institute regarding the funds the foundation or organization holds, the pledges it has received, and the identities of contributors.

# ARTICLE 7 OTHER OFFICERS OF THE INSTITUTE

- Section 7.1 <u>Creation and Selection of Other Officers of the Institute</u>. The Oversight Committee may direct the Chief Executive Officer to create other officer positions of the Institute and to hire individuals to fill such positions.
- Section 7.2 <u>Certain Officers</u>. Without limiting in any way the previous Section, the following officer positions of the Institute have been created (each of which has the duties and authority set forth in this Article in addition to any other duties and authority as may be delegated to such officer by the Oversight Committee):
- (a) Chief Operating Officer, whose duties include oversight of the Institute's daily operations, including financial administration, grants management administration, communications, governmental relations, and information technology services;
- (b) Chief Compliance Officer, whose duties include reporting to the Oversight Committee on the agency's compliance with applicable law, administrative rules, and policies, and building, developing, and maintaining a compliance program that fosters ethical business behavior and includes requirements for risk assessments, program governance, metrics, and reporting;
- (c) Chief Scientific Officer, whose duties include oversight of the scientific research application submission process, coordinating the review of research proposals, monitoring grant progress, and fostering collaboration among the cancer and disease scientific research community to maximize the Institute's impact
- (d) Chief Product Development Officer, whose duties include oversight of the cancer research development application submission process, coordinating review of the cancer research product development proposals, monitoring grant progress and fostering collaboration among the bioscience community to maximize the Institute's impact;
- (e) Chief Prevention Officer, whose duties include oversight of the prevention application submission process, coordinating the review of prevention proposals, monitoring grant progress, and fostering collaboration among the cancer and disease prevention community to maximize the Institute's impact; and
- (f) General Counsel, whose duties include oversight of the legal issues that arise as part of the Institute's operations.

# ARTICLE 8 COMMITTEES OF THE INSTITUTE

- Section 8.1 <u>Creation of Committees of the Institute</u>. Pursuant to applicable law and in accordance with this Article, the Oversight Committee may create Committees of the Institute and appoint and approve members of such committees.
- Section 8.2 <u>Scientific Research and Prevention Program Committee</u>. There will be one or more scientific research and prevention programs committees of the Institute (each, a

"Scientific Research and Prevention Programs Committee"). Each Scientific Research and Prevention Programs Committee has such powers as are vested in it pursuant to applicable law. The Chief Executive Officer, with approval by simple majority of the members of the Oversight Committee as set forth in Section 3.13, shall appoint as members of one or more Scientific Research and Prevention Programs Committees experts in the field of cancer research, prevention, and patient advocacy to serve for terms as determined by the Chief Executive Officer. Individuals appointed to a Scientific Research and Prevention Programs Committee may be residents of another state. A member of a Scientific Research and Prevention Programs Committee may receive an honorarium according to a policy developed by the Chief Executive Officer in consultation with the Oversight Committee.

- Section 8.3 <u>University Advisory Committee</u>. There will be one university advisory committee of the Institute (the "<u>University Advisory Committee</u>"). The University Advisory Committee has such powers as are vested in it pursuant to applicable law. The University Advisory Committee shall advise the Oversight Committee and each Scientific Research and Prevention Programs Committee regarding the role of institutions of higher education in cancer research. The University Advisory Committee is composed of the following members to serve for the term as determined by the appropriate appointing authority appointing such member:
- (a) two members appointed by the chancellor of The University of Texas System to represent:
  - (i) The University of Texas Southwestern Medical Center at Dallas;
  - (ii) The University of Texas Medical Branch at Galveston;
  - (iii) The University of Texas Health Science Center at Houston;
  - (iv) The University of Texas Health Science Center at San Antonio;
  - (v) The University of Texas Health Center at Tyler; or
  - (vi) The University of Texas M. D. Anderson Cancer Center;
- (b) one member appointed by the chancellor of The Texas A&M University System to represent:
  - (i) The Texas A&M University System Health Science Center; or
- (ii) the teaching hospital for The Texas A&M Health Science Center College of Medicine;
- (c) one member appointed by the chancellor of the Texas Tech University System to represent the Texas Tech University Health Sciences Center;
- (d) one member appointed by the chancellor of the University of Houston System to represent the system;
- (e) one member appointed by the chancellor of the Texas State University System to represent the system;

- (f) one member appointed by the chancellor of the University of North Texas System to represent the system;
  - (g) one member appointed by the president of Baylor College of Medicine;
  - (h) one member appointed by the president of Rice University; and
- (i) members appointed at the Chief Executive Officer's discretion by the chancellors of other institutions.
- Section 8.4 Ad Hoc Advisory Committee on Childhood Cancers. The Oversight Committee shall create an ad hoc committee of experts to address childhood cancers. Members of the Ad Hoc Advisory Committee on Childhood Cancers shall be appointed by the Oversight Committee and serve for terms determined by the Oversight Committee. The Ad Hoc Advisory Committee on Childhood Cancers has the duties and authority set forth in the advisory committee's charter in addition to any other duties and authority as may be delegated by the Oversight Committee.
- Section 8.5 Other Ad Hoc Advisory Committees of the Institute. The Oversight Committee, as necessary, may create additional ad hoc committees of experts to advise the Oversight Committee on issues relating to cancer. The number of members of each Ad Hoc Committee will be determined by the Oversight Committee. Ad Hoc Advisory Committee members are appointed by the Oversight Committee and serve for terms determined by the Oversight Committee.
- Section 8.6 <u>Certain Ad Hoc Advisory Committees of the Institute</u>. Without limiting in any way the previous Section, the following are the Ad Hoc Advisory Committees of the Institute (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):
  - (a) Scientific and Prevention Advisory Council; and
  - (b) Commercialization Product Development Advisory Committee;
- Section 8.7 <u>Annual Report to the Oversight Committee</u>. Each Committee of the Institute shall report to the Oversight Committee at least annually regarding the work undertaken by such committee pursuant to a schedule and format dictated by the Oversight Committee.

# ARTICLE 9 CODE OF CONDUCT AND ETHICS POLICY

Section 9.1 <u>Adopted by Reference</u>. The Oversight Committee herein by reference incorporates the *Code of Conduct and Ethics Policy* as approved by the Oversight Committee on February 25, 2013 and all approved amendments.

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#### STATEMENT OF REVISIONS

Approved November 1, 2013

Changes made to Sections 2.2, 3.2, 3.3(a) and (b), 3.4, 3.7, 3.15, 4.1, 4.2, 4.3(a) and(b), 4.4(a)(iii), 4.5(a)(iv), 4.6, 4.7, 4.8(a) and(b), 4.9(a) and(b), 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 7.1, 7.2(b) and (d), 8.2, 8.3(i), 8.4, 9.1, Article 6 (title), and Article 9 (title) and text.

Reason for change(s): Revisions made to reflect statutory changes adopted in 2013 legislative session.

Approved May 21, 2014

Changes made to Sections 4.4(a)(ii), 8.6(b)

Reason for change(s): Revision made to reflect statutory changes adopted in 2014 legislative session and to change name of certain ad hoc advisory committees.



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### **CODE OF CONDUCT and ETHICS**

#### I. OVERVIEW

### A. Authority

Pursuant to Section 572.051(c) of the Government Code and Section 102.109 of the Health & Safety Code, the Cancer Prevention and Research Institute of Texas (CPRIT) promulgates the following Code of Conduct and Ethics (Code).

# **B.** General Principles

- (1) This Code recognizes CPRIT's unique role as the steward of taxpayer funds in furtherance of CPRIT's mission and the ultimate beneficiaries of the funds, the citizens of the State of Texas and sets forth the basic principles and guidelines for Oversight Committee Members, PIC Members, and Employees.
- (2) Oversight Committee Members, PIC Members, and Employees are expected to discharge their duties in a manner that promotes and preserves public trust, proper stewardship, and confidence in the integrity of CPRIT and be guided by the basic principles of loyalty, prudence, honesty and fairness in conducting CPRIT's affairs.

#### C. Definitions

In this Code:

- (1) "Audit Subcommittee" means the standing Audit Subcommittee of the Oversight Committee established by CPRIT bylaws.
- (2) "Business entity" means any entity recognized by law through which business for profit is conducted, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership, or trust. Tex. Gov't Code Ann. § 572.002(2).
- (3) "CPRIT" means the Cancer Prevention and Research Institute of Texas.

- (4) "CEO" means the Chief Executive Officer of CPRIT.
- (5) "Employee" means a person working for CPRIT in an employer-employee relationship.
- (6) "Grant Applicant" means the public or private institution of higher education, as defined by §61.003, Education Code, research institution, government organization, non-governmental organization, non-profit organization, other public entity, private company, individual, or consortia, including any combination of the aforementioned, that submits a grant application to CPRIT. Unless otherwise indicated, this term includes the Principal Investigator or Program Director.
- (7) "Grant Recipient" means the entire legal entity responsible for the performance or administration of the CPRIT grant. Unless otherwise indicated, this term includes the Principal Investigator, Program Director, or Company Representative.
- (8) "Oversight Committee Member" means a member of the CPRIT Oversight Committee.
- (9) "Oversight Committee" means CPRIT's governing body, composed of the nine individuals appointed by the Governor, Lieutenant Governor, and the Speaker of the House of Representatives.
- (10) "Program Integration Committee" (PIC) means the group composed of the Chief Executive Officer, the Chief Scientific Officer, the Chief Product Development Officer, the Commissioner of State Health Services, and the Chief Prevention Officer that is responsible for submitting to the Oversight Committee the list of grant applications the PIC recommends for grant awards.
- (11) "PIC Member" means a member of the PIC.
- (12) "Relative" means a person related within the second degree by consanguinity or affinity determined in accordance with Sections 573.021 573.025, *Government Code*. For purposes of this definition:
  - (A) examples of an individual within the second degree by consanguinity are a child, grandchild, parent, grandparent, brother, sister, uncle, aunt, niece, or nephew;
  - (B) examples of an individual within the second degree by affinity are a spouse, a person related to a spouse within the second degree by consanguinity, or a spouse of such a person;
  - (C) an individual adopted into a family is considered a Relative on the same basis as a natural born family member; and
  - (D) an individual is considered a spouse even if the marriage has been dissolved by death or divorce if there are surviving children of that marriage.

#### D. Enforcement

- (1) The Oversight Committee shall enforce this Code with respect to Employees through the CEO. The CEO is responsible for implementing this Code with respect to Employees and PIC Members. An Employee who violates any provision of the Code is subject to termination of the employee's employment or another employment-related sanction.
- (2) The Oversight Committee shall enforce this Code with respect to individual Oversight Committee Members through resolutions of reprimand, censure, or other appropriate parliamentary measures, including requests for resignation.
- (3) An Oversight Committee Member, PIC Member, or Employee who violates any applicable federal or Texas law or rule may be subject to civil or criminal penalties in addition to any employment-related sanction.

#### II. STANDARDS OF CONDUCT

### A. Expected Conduct of Oversight Committee Members, PIC Members, and Employees

All Oversight Committee Members, PIC Members, and Employees shall:

- (1) familiarize themselves with the Code and should be specifically knowledgeable of Chapter 102, *Health & Safety Code*, Chapter 572, *Government Code*, and Sections 36.02 (Bribery), 36.07 (Acceptance of Honorarium), 36.08 (Gift to Public Servant), 39.02 (Abuse of Official Capacity), and 39.06 (Misuse of Official Information), *Penal Code*;
- (2) abide by all applicable federal and Texas laws, administrative rules, and CPRIT conduct policies, including this Code. The Code does not supersede any applicable federal or Texas law or administrative rule;
- (3) perform his or her official duties in a lawful, professional, and ethical manner;
- (4) practice responsible stewardship of CPRIT resources; and
- (5) report any conduct or activity that the employee believes to be in violation of this Code of Conduct policy to the Chief Compliance Officer or the General Counsel, as may be appropriate. Retaliatory action may not be taken against a person who makes a good faith report of a violation involving another person.

#### **B.** Prohibited Conduct

An Oversight Committee Member, a PIC Member, an Employee, or the spouse of an Oversight Committee Member, a PIC Member, or an Employee shall not:

- (1) accept or solicit any gift, favor, or service that could reasonably tend to influence member or employee in the discharge of official duties, or that the member, employee, or spouse of the member or employee knows or should know is being offered with the intent to influence the member's or employee's official conduct;
- (2) intentionally or knowingly solicit, accept, or agree to accept any benefit for exercising the member's official powers or performing the member's or employee's official duties in favor or another;
- (3) disclose confidential information, information that is excepted from public disclosure under the Texas Public Information, or information that has been ordered sealed by a court, that was acquired by reason of the member's or employee's official position, or accept other employment, including self-employment, or engage in a business, charity, nonprofit organization, or professional activity that the member or employee might reasonably expect would require or induce the member or employee to disclose confidential information, information that is excepted from public disclosure under the Texas Public Information Act, or information that has been ordered sealed by a court, that was acquired by reason of the employee's official position;
- (4) accept other employment, including self-employment, or compensation that could reasonably impair the member's or employee's independent judgment in the performance of the official duties;
- (5) make personal investments or have a financial interest that could reasonably create a substantial conflict between the member's or employee's private interest and the member's or employee's official duties;
- (6) utilize state time, property, facilities, or equipment for any purpose other than official state business, unless such use is reasonable and incidental and does not result in any direct cost to the state or CPRIT, interfere with the member's or employee's official duties, and interfere with CPRIT functions;
- (7) utilize the member's or employee's official position, or state issued items, such as a badge, indicating such position for financial gain, obtaining privileges, or avoiding consequences of illegal acts;
- (8) knowingly make misleading statements, either oral or written, or provide false information, in the course of official state business;
- (9) engage in any political activity while on state time or utilize state resources for any political activity.

- (10) lease, directly or indirectly, any property, capital equipment, employee or service to a Grant Recipient;
- (11) submit a grant application to CPRIT;
- (12) participate in a matter before CPRIT that involves a business, contract, property, or investment held by the person if it is reasonably foreseeable that CPRIT action on the matter would confer a benefit to the person by or through the business, contract, property, or investment:
- (13) recommend or cause discretionary CPRIT business to be transacted with or for the benefit of a Relative;
- (14) represent any person in any action or proceeding before or involving the interests of CPRIT except as a duly authorized representative or agent of CPRIT;
- (15) serve on a CPRIT Grant Recipient's board of directors or similar committee that exercises governing powers over the Grant Recipient. This prohibition also applies to serving on the board of directors or similar committee of a non-profit foundation established to benefit the Grant Recipient;
- (16) use confidential information, or knowledge of non-public decisions related to CPRIT Grant Applicants, received by virtue of the individual's employment or official duties associated with CPRIT, to make an investment or take some other action to realize a personal financial benefit; or
- (17) copyright or patent any work produced or developed as part of the individual's service to or employment with CPRIT when the work is related to a CPRIT goal, project, or concern.

#### C. Special Provisions

- (1) An Oversight Committee Member, an Employee, or the spouse of an Oversight Committee Member shall not be employed by or participate in the management of a business entity or other organization receiving money from CPRIT.
- (2) An Oversight Committee Member, an Employee, or the spouse of an Oversight Committee Member shall not own or control, directly or indirectly, an interest in a business or entity or other organization receiving money from CPRIT, except that the prohibition does not apply to ownership of shares in a publicly traded mutual fund or similar investment vehicle in which the person does not exercise any discretion regarding the investment of the assets of the fund or other investment vehicle.
- (3) An Oversight Committee Member or Employee shall not have an office in a facility

owned by a business entity or other organization receiving or applying to receive money from CPRIT.

- (4) An Oversight Committee Member or Employee shall not solicit, agree to accept, or accept an honorarium in consideration for services the Oversight Committee Member or the Employee would not have been asked to provide but for the person's official position.
- (5) An Oversight Committee Member or the spouse of an Oversight Committee Member shall not use or receive a substantial amount of tangible goods, services, or money from CPRIT other than reimbursement authorized for Oversight Committee Members attendance or expenses.
- (6) A former Oversight Committee Member or former CEO may not make any communication to or appearance before a current Oversight Committee Member or Employee before the second anniversary of the date the former Oversight Committee Member or former CEO ceased to be an Oversight Committee Member or CEO if the communication is made:
  - (a) with the intent to influence a decision or with intent to cause any action or inaction; and
  - (b) on behalf of any person or business entity in connection with any matter on which the former Oversight Committee Member or former CEO seeks action by CPRIT.
- (7) A former Oversight Committee Member or former Employee may not represent any person or entity, or receive compensation for services rendered on behalf of any person or entity, regarding a particular matter in which the former Oversight Committee Member or Employee participated during the period of state service or employment, either through personal involvement or because the case or proceeding was a matter within the Oversight Committee Member's or Employee's official responsibility.
  - (a) This subsection applies to an Employee who is compensated, as of the last date of state employment, at or above the amount prescribed by the General Appropriations Act for step 1, salary group 17, of the position classification salary schedule, including an employee who is exempt from the state's position classification plan.
  - (b) For purposes of this subsection, the term "participated" means to have taken action through decision, approval, disapproval, recommendation, giving advice, investigation, or similar action.
  - (c) For purposes of this subsection, the term "particular matter" means a specific investigation, application, request for a ruling or determination, rulemaking proceeding, contract, claim, accusation, charge, arrest, or judicial or other proceeding, except that the

prohibition of this subsection does not apply to a rulemaking proceeding that was conducted before the Oversight Committee Member's or Employee's service or employment ceased.

(8) CPRIT may not enter into an agreement or transaction with a former Oversight Committee Member or former Employee, or a business entity or other organization in which a former Oversight Committee Member or former Employee owns or controls an interest or serves on the governing board, on or before the first anniversary of the date the person ceased to be an Oversight Committee Member or Employee. Nothing herein prevents a business entity or organization that would otherwise be prohibited from entering into an agreement or transacting with CPRIT under this subsection from applying for or receiving grant funds.

### D. Nepotism

- (1) Except as provided in subsection (2), CPRIT may not employ a person who is a Relative of an Oversight Committee Member or Employee. For purposes of this section, the prohibition on employment includes employment as a consultant to CPRIT.
- (2) This subsection does not prohibit the continued employment of a person who has been working for CPRIT for at least 90 consecutive days before the date of the related Oversight Committee Member's appointment.

### E. Outside Employment or Business Activity

- (1) An Employee may not engage in outside employment, business, or other activities that detract from the individual's ability to reasonably fulfill responsibilities to CPRIT.
- (2) An Employee (other than the CEO) must obtain advance written approval from the CEO for any outside employment or business activity, including service on the board of directors of a business or non-profit organization. The CEO shall notify the Audit Subcommittee in writing concerning any approval given for outside employment or other business activity by Employees, including the nature of the employment or other business activity.
- (3) The CEO must obtain advance approval from the Oversight Committee if the CEO intends to engage in outside employment or other business activities, including service on the board of directors for a business or non-profit organization.
- (4) The CEO shall report to the Oversight Committee annually all approved outside employment or business activities of Employees.

#### III. CONFLICTS OF INTEREST

# A. Decision-Making Based on Merit.

Oversight Committee Members, PIC Members, and Employees shall base CPRIT business transactions on professional integrity and competence, financial merit and benefit to CPRIT, and, as required, in accordance with procurement laws for state agencies.

### **B.** Conflict of Interest Requirements.

- (1) The Oversight Committee adopts herein by reference the statutory requirements regarding conflicts of interest, Sections 102.106 102.1064, *Health & Safety Code*, and CPRIT's administrative rules, Section 702.11 702.17, and any updates thereto.
- (2) 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.

#### IV. GIFTS AND ENTERTAINMENT

# A. Prohibition Against Acceptance of Gifts or Consideration

Except as provided herein, Oversight Committee Members, PIC Members, and Employees may not accept gifts, benefits, consideration or anything reasonably regarded as a financial gain or advantage.

#### **B.** Exceptions

The prohibition against acceptance of a gift or consideration does not apply to the following items so long as the acceptance of such an item does not violate Section II(B)(1) or any other applicable law and the Oversight Committee, PIC Member, or Employee has no reason to believe that a gift or consideration that would otherwise be prohibited is being offered through an intermediary:

- (1) an non-cash-item with a value less than \$50, excluding cash or a negotiable instrument as described by 3.104, Business & Commerce Code or a gift or other benefit conferred on account of kinship;
- (2) gifts or consideration of any value provided to the Oversight Committee Member, PIC Member, or Employee by a Relative;

gifts or consideration of any value provided to the Oversight Committee Member, PIC Member, or Employee by a personal friend or colleague, so long as:

- (a) The gift or consideration is given based solely on an existing personal, professional, or business relationship independent of the Oversight Committee Member's, PIC Member's, or Employee's official status;
- (b) The personal friend or colleague, or a Relative of the personal friend or colleague, is not an employee or the member of the governing board of an entity receiving or applying to receive money from CPRIT; and
- (c) The Oversight Committee Member, the PIC Member, or the Employee has no reason to believe that the gift or consideration is being offered through the personal friend or colleague as an intermediary; and
- (<u>3</u>4) payments to which the Oversight Committee Member, PIC Member, or Employee is lawfully entitled in a capacity other than the individual's official status;
- (45) a political contribution as defined by Title 15, Election Codes;
- (76) items issued by CPRIT or other governmental entities to the Oversight Committee Member, PIC Member, or Employee that allow the use of property or facilities owned, leased, or operated by CPRIT or other governmental entity;
- (<u>67</u>) food, lodging, transportation, or entertainment accepted as a guest with the donor present, and, if the done is required by law to report those items, reported by the done in accordance with that law;
- (78) Lfood, lodging, transportation, and meals described by Chapter 36, Section 36.07(b) (Acceptance of Honorariums), Penal Code/or a speaker gift of nominal intrinsic value (less than \$50) in connection with a speech given by the Oversight Committee Member, PIC Member, or Employee in the individual's official capacity, so long as the speech is not merely perfunctory;
- (89) books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of an Oversight Committee Member, Employee, or PIC Member and that are accepted by the individual on behalf of CPRIT for use in performing the individual's job duties; and
- (910) registration or admittance fees for seminars, conferences, or other sponsored events that may involve entertainment or recreation. If the seminar, conference, or other sponsored event is hosted or paid for by a business entity or organization applying for or receiving CPRIT funds, prior written approval to attend the event is required and the entity sponsoring or paying for the event must attend. For Oversight Committee Members, approval may be provided by the Oversight Committee chair (or vice chair if the chair is seeking approval).

For a PIC Member or Employee, approval may be provided by the CEO (or the Oversight Committee chair if the CEO is seeking approval.)

#### C. Gifts or Consideration from Lobbyists

An Oversight Committee Member, PIC Member, or Employee shall immediately report to the Chief Compliance Officer any gift or consideration if the gift or consideration is provided by a registered lobbyist.

#### D. Return of Prohibited Gifts or Consideration

An Oversight Committee Member, PIC Member, or Employee who receives a prohibited gift or other prohibited consideration shall make every effort to return the gift or consideration to its source or, if that is not possible or feasible, donate the gift or consideration to a recognized tax-exempt charitable organization formed for educational, religious, or scientific purposes.

## E. Reporting Requirements

An Oversight Committee Member, PIC Member, or Employee shall report to CPRIT's Chief Compliance Officer any gift, grant, or consideration provided to the individual as soon as possible, but no later than thirty (30) days after receipt of the gift, grant or consideration.

- (1) The individual shall provide the name of the donor, the date of receipt, and amount of the gift, grant, or consideration.
- (2) The reporting requirement applies to any gifts, grants, or other consideration provided to an Oversight Committee Member, PIC Member, or Employee, except for those specified in subsection (B).
- (3) Notwithstanding the foregoing, information related to subsections (B)(7) and (9) shall be reported to the Chief Compliance Officer.

### V. FINANCIAL DISCLOSURE AND COMPLIANCE STATEMENTS

Unless otherwise directed, the following statements and certifications shall be completed and returned to the Chief Compliance Officer. Unless otherwise specified, the statements and certifications shall be filed with the Chief Compliance Officer no later than 30 days following the date of the member's or employee's appointment or employment and then annually thereafter on or before September 30th. The CEO may postpone a filing deadline for not more than 60 days on the written request of an Oversight Committee Member, PIC Member, or Employee, or for an additional period for good cause.

#### A. Financial Disclosure Statements.

- (1) An Oversight Committee Member and the CEO shall file a financial disclosure statement with the Chief Compliance Officer not later than the 30th day after the date of appointment or employment, and not later than April 30 of each year thereafter.
- (2) CPRIT must maintain a financial disclosure statement for at least five years after the date it is filed
- (3) Oversight Committee Members who are required to file disclosure statements with the Texas Ethics Commission shall file those statements in the form and time prescribed by law.

#### **B.** Ethics Compliance Statements.

An Oversight Committee Member, PIC Member, or Employee, including an interim Employee, must sign, date, and file an ethics compliance statement acknowledging that the individual has received and read this Code, that the individual will comply with its provisions, and that it is the individual's duty to report knowledge of any act or failure to act that is a violation of this Code.

# C. Conflict of Interest Compliance Statements.

An Oversight Committee Member, PIC Member, or Employee, including an interim Employee, must sign, date, and file a conflict of interest compliance statement acknowledging that the individual has received and read the statutory and administrative rules related to conflicts of interest, that they will comply with its provisions, and that it is their duty to report when they have knowledge of any act or failure to act that is a violation of the conflict of interest statutes or rules.

#### **D. Non-Disclosure Agreements**

An Oversight Committee Member, PIC Member, or Employee, including an interim Employee, must sign, date, and file a non-disclosure agreement.

# E. Certification of No Financial Interest.

- (1) Before the Oversight Committee votes on proposed grant awards, each Oversight Committee Member shall certify that he or she does not have a financial interest in a business entity or other organization applying for or receiving CPRIT funds.
- (2) For purposes of this certification, "financial interest" means:
  - (a) ownership of stock or shares of the business entity; or
  - (b) ownership of any sum of the fair market value of the business entity; or

- (c) receipt of any sum of the person's gross income for the preceding calendar year from the business entity; or
- (d) any private investment in the business entity, such as debt obligation or equity interest that is not a publicly traded security.
- (3) Oversight Committee Members shall sign, date, and file the certification not later than the day preceding the date of the Oversight Committee meeting scheduled to consider the proposed grant awards.
- (4) An Oversight Committee Member is prohibited from participating in any action taken regarding the proposed grant awards if the member fails to file the required certification prior to the day preceding the Oversight Committee meeting. However, upon a showing of good cause, the Oversight Committee may vote to allow the Oversight Committee Member to participate in action taken related to the proposed grant awards, so long as the member certifies for the record in the open meeting that the member does not have a financial interest in a business entity or other organization applying for or receiving grant funds. Immediately following the meeting, the Oversight Committee Member must complete the certification.

### F. Statement of No Communication.

- (1) Before the Oversight Committee awards a grant, each Oversight Committee Member and PIC Member shall certify that he or she has not communicated with any Grant Applicant for CPRIT funds regarding the substance of a pending application. The period of the restricted communication begins on the first day that grant applications are accepted by CPRIT until the Grant Applicant receives notice regarding a final decision on the grant application.
- (2) In addition to the certification required in subsection (1), each PIC Member must also certify that the PIC Member did not communicate individually with one or more Oversight Committee members about a pending grant recommendation prior to the time that the PIC submits its list of recommendations to the Oversight Committee and the CEO has submitted the affidavits required by statute. Communication that involves one or more PIC members responding to a question raised by an Oversight Committee Member does not constitute a prohibited communication so long as the question and the response is provided in writing to all Oversight Committee Members contemporaneously.