CANCER PREVENTION AND RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

January 24, 2014

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Summary Overview of the January 24, 2014, Oversight Committee Meeting

Please find enclosed the meeting packet for the next meeting of the CPRIT Oversight Committee to be held on Friday, January 24, 2014, at 11:00 AM. This summary overview of major agenda items provides background on key issues for Committee consideration.

Chief Scientific Officer Program Portfolio Presentation and Grant Award Recommendations/Product Development Officer Program Portfolio Presentation and Grant Award Recommendations

- CPRIT's Chief Scientific Officer, Dr. Margaret Kripke, will provide an overview of CPRIT's scientific research program. Dr. Kripke will also present the Chief Executive Officer's recommendations for recruitment grant awards.
- Kristen Doyle, acting Product Development Officer, and Dr. Jack Geltosky, CPRIT's Product Development Review Council Chair, will discuss CPRIT's product development portfolio and present the Chief Executive Officer's recommendations for product development grant awards.

The applications recommended for scientific research and product development grant awards were submitted to CPRIT prior to the passage of SB 149. The Oversight Committee's consideration of these awards is governed by the review process in place at the time the applications were submitted. The Oversight Committee will not vote to approve each application recommended by the Chief Executive Officer but may reject a slate of proposed grant awards by a two-thirds vote of the Committee. Nothing limits the Oversight Committee from discussing one or more recommendations on the slates individually. Following the Committee's ratification of the grant awards, the Committee will consider delegating authority to negotiate and execute grant contracts to the CEO and General Counsel. For product development grant awards, the Oversight Committee will consider approval of the CEO's recommendation to provide grant funds by advance to company recipients, subject to certain contractual requirements.

NOTE: Because information related to specific grant applications recommended for grant funding is not publicly disclosed until the Oversight Committee meeting, the information is not included in the board packet. It has been made available through a secure electronic portal.

Final Order Adopting Proposed Changes to 25 T.A.C. Chapters 701 – 704

Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. The extensive changes made to CPRIT's administrative rules provisionally approved at the November 1, 2013, Oversight Committee meeting implement State

Auditor recommendations and adapt agency practices to legislative requirements enacted by Senate Bill 149. The Board Governance Subcommittee has considered the proposed administrative rules and recommends that Oversight Committee approve the new rules and rule changes as proposed in the final orders formally adopting the changes. The new rules and rule changes set expected conduct and performance requirements, including increasing transparency and accountability at all levels. Full implementation of these new rules and rule changes will help to restore credibility and public confidence in CPRIT's grant making process.

Scientific Research and Prevention Programs Committee Appointments

The Chief Executive Officer has appointed 20 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 appointments were discussed by the Nominations Subcommittee at its January 20th meeting. A biographical sketch for each appointee is included in the board packet.

Subcommittee Business

The Diversity Subcommittee met for the first time on January 17, 2014. Pursuant to Section 4.1 of the Oversight Committee Bylaws, the Diversity Subcommittee has approved a charter and nominated a subcommittee chairperson. Final approval of the Diversity Subcommittee charter and chairperson selection shall be by a vote of a simple majority of the Oversight Committee.

Executive Staff Reports

Summary reports of important program, operational, and fiscal activities will be provided by the Chief Executive Officer, the Chief Prevention and Communications Officer, the Chief Operating Officer Report, and the Chief Compliance Officer. Memos from the appropriate subcommittees recommending action have been provided for items that the Oversight Committee is expected to act upon.

Agency Planning and Operations

The Oversight Committee chair will lead a discussion related to strategic planning and operational metrics for the agency. Consideration of the Baldrige Criteria for Performance Excellence and the required state strategic planning process will be presented. Other topics will include "dashboard metrics" that can be used to regularly report on CPRIT operations and grant management.

Process to Set Annual Program Priorities Pursuant to Texas Health & Safety Code § 102.107(2)

The Oversight Committee chair will lead a discussion about initiating the Program Priorities Project to fulfill the committee's statutory responsibility to establish priorities for CPRIT's scientific research, prevention, and product development programs. A schedule and process for the Program Priorities Project will be considered.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting

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

January 24, 2014
11:00 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.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from November 22, 2013, meeting **TAB 1**
4. Chief Executive Officer Report **TAB 2**
5. Chief Scientific Officer Report **TAB 3**
   - Overview of Scientific Research Portfolio
   - Scientific Research Grant Award Recommendations
6. Interim Product Development Officer Report **TAB 4**
   - Overview of Product Development Portfolio
   - Product Development Grant Award Recommendations
7. Chief Prevention and Communications Officer Report **TAB 5**
8. Final Order Adopting Proposed Changes to 25 T.A.C. Chapters 701 – 704 **TAB 6**
9. Scientific Research and Prevention Programs Committee Appointments **TAB 7**
10. Subcommittee Business **TAB 8**
11. Chief Operating Officer Report **TAB 9**
    - FY 2013 Internal Audit Annual Report
    - FY 2014 Internal Audit Plan
    - Contract for Internal Audit Services
12. Compliance Officer Report **TAB 10**
13. Agency Planning and Operations **TAB 11**
14. Process to Set Annual Program Priorities Pursuant to Texas Health & Safety Code § 102.107(2) **TAB 12**
15. Consultation with General Counsel
16. Future Meeting Dates and Agenda Items
17. Public Comment
    Anyone wishing to make public comments is required to 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.
18. Adjourn

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Minutes

November 22, 2013

1. Meeting Called to Order

The meeting of the Oversight Committee of the Cancer Prevention and Research Institute of Texas (CPRIT) was called to order by Interim Chair Pete Geren on Friday, November 22, 2013 at 12:03 p.m.

2. Roll Call /Excused Absences

Interim Secretary Gerry Geistweidt called the roll.

Committee Members Present:

Angelos Angelou
Gerry Geistweidt
Pete Geren
Ned Holmes
Amy Mitchell
Will Montgomery
Cynthia Mulrow
William Rice
Craig Rosenfeld

3. Oath of Office

Interim Chair Geren welcomed Will Montgomery to the Oversight Committee. Mr. Geren reported that Mr. Montgomery had been appointed by the Speaker of the House to the CPRIT Oversight Committee on November 20th.

Interim Chair Geren administered the oath of office to Mr. Montgomery.

4. Adoption of Minutes from November 1, 2013 meeting

Interim Chair Geren called for discussion or corrections to the minutes as written. Hearing none, the chair called for a motion to approve the minutes of the November 1, 2013 Oversight Committee Meeting.

Motion to approve the minutes of the November 1, 2013 Oversight Committee as written made by Mr. Angelou and seconded by Dr. Rosenfeld.

MOTION CARRIED UNANIMOUSLY

5. Election of Officers

Interim Chair Geren advised that Section 5.2 of the Oversight Committee bylaws requires the committee to elect a Chairperson and Vice Chairperson at the first meeting following the adoption of the bylaws. Interim Chair Geren opened the floor for nominations for Chairperson, Vice-Chairperson and Secretary.

Mr. Holmes nominated Dr. Bill Rice as Chair, Pete Geren Vice-Chair and Amy Mitchell Secretary. As part of his motion, Mr. Holmes stated his intention that all three positions be voted on at one time. Seconded by Mr. Geistweidt.

MOTION CARRIED UNANIMOUSLY

Mr. Geren turned the gavel over to newly elected Chair William Rice.

6. Personnel Matters

Chair Rice reminded members that at the last meeting, the Oversight Committee directed CPRIT staff to post the CEO position internally for 10 days and for the Board Governance subcommittee to review applications, interview qualified applicants and make a recommendation to the Oversight Committee.

Chair Rice informed the members that the Board Governance subcommittee notified him that the subcommittee intends to address this issue in closed session.

Chair Rice called the Oversight Committee into closed session at 12:07 p.m. pursuant to Texas Open Meetings Act section 551.074 to discuss personnel issues as listed on the posted agenda. The Oversight Committee members moved to the ante-room at this time.

Chair Rice reconvened in open session at 12:28 p.m. He called on Amy Mitchell, the interim chair of the Board Governance subcommittee, to convey the subcommittee's recommendation.

Ms. Mitchell reported that the Board Governance Subcommittee worked with CPRIT's staff to draft and post a position for the Chief Executive Officer. The position was posted internally for 12 days. The Board Governance subcommittee reviewed the application submitted and interviewed the candidate.

Ms. Mitchell stated that on behalf of the Board Governance Subcommittee, the Subcommittee recommends to hiring Wayne Roberts to serve as CPRIT's Chief Executive Officer at a salary of $250,000. The salary will be effective December 1, 2013.

Chair Rice called for a motion to hire Mr. Roberts to serve as CPRIT's Chief Executive Officer at a salary of $250,000. The salary will be effective December 1, 2013.

A motion was made by Mr. Holmes and seconded by Ms. Mitchell to hire Mr. Roberts to serve as CPRIT's Chief Executive Officer at a salary of $250,000. The salary will be effective December 1, 2013.

MOTION CARRIED UNANIMOUSLY

7. Chief Executive Officer Report

The Chair recognized Mr. Roberts to provide the Chief Executive Officer's Report.
Mr. Roberts stated his appreciation for the Oversight Committee's support for his work with the agency. Mr. Roberts reported on the following topics:

- *Live Webcast and Video*
  This meeting is being webcast live and a video will be posted on CPRIT's website after this meeting. As of this morning, there were 30 views of the U-Tube link of the November 1st meeting. According to Senate media, 13 mobile devices and 97 desk top computers viewed the live webcast of our November 1st meeting.

- *Administrative Rules*
  At the last Oversight Committee meeting, Members authorized staff to post changes to the administrative rules. The proposed rules were published in the *Texas Register* on November 15, 2013. The proposed rules are also posted on CPRIT's website. CPRIT will accept public input on the new rules and rule changes through December 16, 2013. Kristen Doyle, CPRIT's General Counsel, will prepare the comments for member review as part of the formal adoption of the proposed rules in January.

- *Staffing*
  A decision has been made regarding the **Chief Compliance Officer** and an announcement will be made next week in time to meet the statutory requirement to fill this position by December 1, 2013.

  The **Chief Product Development Officer** position posting is being refined with the Product Development subcommittee and the Product Development Review Council among others and should be posted in December.

The **Internal Auditor** position, which is a direct report to the OC, is posted until December 13.

An **attorney position** will be posted today to assist General Counsel and Chief Compliance Officer positions.

The **Procurement Specialist** position will be filled quickly. This position will provide redundancy in our accounting process. A Reimbursement Specialist will also be hired to assist our grant desk review analyst.

The 83rd Legislature authorized CPRIT to add eight additional positions. These are intended to be primarily compliance and grant monitoring. The job description for the **grant specialists' positions** is still in the development stage. Tasks identified thus far:

- Ensure and facilitate programmatic and fiscal integrity
- Interact and support with three mid-level program specialist
- Support the Chief Officers of each program area including Compliance
- Customer Service orientation.
- Assist grant recipients once awards are made. This could be answering questions or concerns, facilitating timely response by other CPRIT staff and, where appropriate, review. Will also help grant recipients to meet contractual deadlines such as reporting and other requirements in a timely manner.
- Compliance element which will include onsite and desk reviews of grantees. Grant Specialist will examine, investigate and review records, reports, financial statements, management information systems, and management practices to ensure adherence to state statutes and agency regulations.
- Will conduct financial and some limited programmatic review of grants.

- *Agency Move*

  Approval has been received from the Legislative Budget Board (LBB) to delay the state budget directive to move agency from the current facility to state space in the Capitol Complex March 31, 2014. Mr. Roberts stated that the agency is committed to working with the Facilities Commission, the LBB, and the current landlord to accomplish this.

- *Agency Resuming Operations*

  State Leadership lifted the moratorium and allowed CPRIT to resume full grant-making operations on October 30, 2013, including finalizing award contracts for grant projects that had been left pending during the moratorium. CPRIT has executed 29 award contracts this month. Grantees are reviewing and updating contract documents to reflect any changes to the statement of work, the project budget, and timelines.

  In March, State Leadership authorized CPRIT to finalize recruitment grants that had been approved by the Oversight Committee in August and December 2012... Of the thirty-one grants, ten potential recruits declined because they had accepted offers elsewhere, nineteen signed and moved to Texas, one award is in negotiations with the host institution and one is still pending the recruit's decision. CPRIT is the final inducement in attracting these individuals. Due to nature of these awards, institutions cannot begin negotiations with a

candidate until CPRIT has approved the award and not all recruitment targets accept the host offer.

- *Requests For Applications (RFAs)*
  Mr. Roberts reminded the members that the Oversight Committee had discussed the impending issuance of a number of RFAs at its November 1st meeting. At this time, CPRIT expects to release seven for Scientific Research RFAs, three for Prevention RFAs and three Product Development RFAs. Mr. Roberts explained that it is important to issue the RFAs now because the time required for the review process is lengthy. Due to the moratorium, CPRIT anticipates that there may be significant pent-up demand that could affect the peer reviewer workload. Release of these RFAs should not significantly affect the OC's ability to prioritize among and within the programs. As the Oversight Committee's priorities are established, CPRIT can realign funding, if necessary, for the remainder of this fiscal year and FY 2015. As implied, a delay in this process could reduce CPRIT's ability to use all of its 2014 grant appropriations.

  It is important for the committee to know that despite the turmoil in 2012 and the January 2013 audit report, no one ever questioned the quality, appropriateness or release of CPRIT's RFAs. The RFAs are broadly written to cast a wide net in soliciting a range of applications. Mr. Roberts stated that the Oversight Committee may wish to narrow future RFAs to their specific areas of interest. Release of these RFAs will not prevent winnowing prioritization down as the agency goes forward. He pointed out that the Oversight Committee is under no obligation to fund any of these awards if they are not satisfied.

- *Slates*
  Mr. Roberts reported that he is recommending two slates for Prevention awards: Evidence-Based Cancer Prevention Services grant slate and the Health Behavior Change through Education slate. Mr. Roberts stated that these slates reflect the recommendations provided to him by the Prevention Review Council. He asked the Chair to recognize Dr. Rebecca Garcia, CPRIT's Chief Prevention Officer, to explain CPRIT's Prevention program and present the two slates. Mr. Roberts advised Members that the Compliance Officer will certify the slates before the OC can take action on these recommendations.

8. Prevention Officer Report Grant Award Recommendations and Certification of the Slates

The Chair recognized Dr. Garcia to provide the Prevention Officer Report and to introduce the Chief Executive Officer's Grant Award recommendations for Prevention grant awards.

Dr. Garcia provided an overview of the Prevention program and the peer review process. She explained that the slates being presented today were submitted to CPRIT before June 14, 2013; therefore, SB149 directs that the law in effect at the time the application is submitted governs the review process.

Hearing no further discussion, the Chair recognized Kristen Doyle, acting compliance officer, to provide the compliance certification for the award slates.

Ms. Doyle advised members that they play a role in the grant award process and are subject to CPRIT's conflict of interest standards.

Ms. Doyle noted for the record that Oversight Committee member Amy Mitchell requested to be recused from taking action on any of the Prevention award slates that will be announced in this meeting because Ms. Mitchell may have a conflict of interest with these applications. Ms. Doyle also noted that Mr. Montgomery was appointed two days prior to the meeting and has not received any grant application information. He will therefore abstain from any action on the Prevention award slates.

Ms. Doyle explained that these award recommendations are subject to the laws in effect at the time that the applications were submitted. This means that 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.

Ms. Doyle advised that as CPRIT's acting compliance officer, she is responsible for reporting to the Oversight Committee regarding the agency's compliance with applicable statutory and administrative rule requirements during the grant review process.

Ms. Doyle certified both slates by stating the following: "I have reviewed the compliance pedigrees for the grant applications submitted to CPRIT for Cancer Prevention grant awards originally intended to be made in the first prevention grant cycle of FY2013. I have conferred with staff at CPRIT and SRA International (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. I am satisfied that the application review process that resulted in the two Cancer Prevention grant award slates recommended by the Chief Executive Officer-the Evidence-Based Cancer Prevention Services grant slate and the Health Behavior Change Through Public Education grant slate, followed applicable laws and agency administrative rules. I certify these award slates for the Oversight Committee's consideration."

Chair Rice advised that the two Prevention slates will be taken up separately.

Chair Rice entertained a motion to disregard the Chief Executive Officer's funding recommendation for the Evidence-Based Cancer Prevention Services Award Slate.

Chair Rice entertained a motion to disregard the Chief Executive Officer's funding recommendation for the Health Behavior Change through Public Education Award Slate.

Hearing no motion to disregard either slate, Chair Rice asked 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 Ms. Mitchell

MOTION CARRIED UNANIMOUSLY

9. Chief Scientific Officer Report

The Chair recognized Dr. Margaret Kripke to provide the Chief Scientific Officer's report.

Dr. Kripke reported that several Research Program activities were interrupted by the moratorium that was imposed on CPRIT in December 2012. In order to resume operations now that the moratorium has been lifted, a number of actions are being taken. In order of urgency, they are:

- Execute contracts for grant programs that were approved in August and December of 2012 by the Oversight Committee
- Initiate the peer review of 5 first-time faculty recruitment grants by the Research Review Council.
- Issue Requests for Applications (RFAs) for the continuation of 5 Multi-investigator Research Awards and 7 Research Training Awards.
- Issue new RFAs for the recruitment awards, Individual Investigator Research Awards and High Impact/High Risk Awards.

Chair Rice opened the floor to discussion or questions. Hearing no questions or discussion, the Chief Scientific Officer report was accepted as presented.

10. Product Development Officer Report

The Chair recognized Kristen Doyle, Interim Chief Product Development Officer, to provide the Product Development Officer's report.

Ms. Doyle reported that the Product Development (PD) subcommittee met on November 18, 2013, and discussed the review process for applications, the PD portfolio, applications pending and the RFAs issued in the past. She stated that RFAs will be issued as soon as possible so that pent-up needs can be addressed. RFAs for PD have always been structured fairly broad. The OC will be able to screen what is being received and determine where they want to go in terms of their program priorities.

Ms. Doyle informed the members that PD had been affected by the moratorium in the same manner as Research and Prevention. Some applications were frozen in the review process. At the time of the moratorium, there were four applications that had made it all the way through the review process, past due diligence and were ready to be reviewed by the Product Development Review Council (PDRC.) In addition, as reported by Ms. Doyle, three had just emerged from the in-person presentation round of review. The next step after that would have been due diligence in both business operations and Intellectual Property. These three were recommended to proceed toward due diligence on December 17, 2012 and the moratorium was initiated on December 18, 2012.

Ms. Doyle stated that it was prudent to reach back out to the frozen applications and ask for updates on the project progress once the moratorium was lifted and whether activities over the last year impacted the scope of their project and budget.

Ms. Doyle advised that the Product Development Review Council has reviewed the updated information provided by each of the applicants and made recommendations in terms of moving them forward in the process. Two of the applicants had significant changes in their scope of work. The PDRC asked for additional due diligence. The Review Council and the primary reviewers provided questions in areas that required additional due diligence based on the updates received. No recommendations have been made for these seven applications. Ms. Doyle reports that recommendations may be ready by the January 24, 2014 OC meeting.

Ms. Doyle related that she is receiving calls every week from companies that are very eager to apply for CPRIT funding. It should be expected that we will receive a large volume of applications. A change in CPRIT's application process will be to ask applicants to submit a letter of intent to aid the agency in determining the number of reviewers needed. There are currently two panels with fifteen reviewers each that alternate review cycles. When the moratorium was instituted, there were three review cycles per year with plans to increase to four review cycles. Because of the moratorium, both panels may be required for the first round of applications. We will also reach out to reviewers that have been inactive because of the moratorium to determine their interest in continuing as a CPRIT reviewer.

Chair Rice opened the floor for discussion or questions for Ms. Doyle. Hearing no questions or discussion, the Product Development Officer report was accepted as presented.

11. <u>Appointments to Scientific Research and Prevention Programs Committees</u>

The Chair recognized Mr. Holmes, Interim Chair of the Nominations Subcommittee, to discuss the subcommittee's recommendation regarding the Chief Executive Officer's appointments to the Scientific Research and Prevention Programs Committees.

Mr. Holmes advised the Members that the Nominations subcommittee met on November 19, 2013 to discuss the appointment of Dr. Tom Sellers to the Scientific Research and Prevention Programs Committee by Mr. Roberts. Mr. Holmes stated that the Nominations subcommittee recommended that the Oversight Committee approve the appointment of Dr. Sellers to CPRIT's Scientific Review Council.

Chair Rice called for a motion to approve the Chief Executive Officer's appointment of Dr. Sellers to the Scientific Research and Prevention Programs Committee.

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

MOTION CARRIED UNANIMOUSLY

12. <u>Health & Safety Code Section 102.1062 Waivers</u>

Chair Rice advised the members that he had received a formal request from Mr. Roberts for the Oversight Committee to consider two waivers from CPRIT's conflict of interest requirements. Texas law requires that the Oversight Committee vote on the requested waivers. The chair recognized Mr. Roberts to present the waiver requests.

See Attachment A for Waiver Request

Chair Rice opened the floor for discussion or questions.

Dr. Rosenfeld stated that all members consider Conflict of Interest waivers a serious matter especially in light of previous events. He inquired about the term "exceptional circumstances." He asked if it meant unique person or unique circumstance. He also asked how both of these requests fall under the term unique circumstances.

Mr. Roberts stated that the compelling reason remains that Dr. Kripke would lose her value to members as the Chief Scientific Officer if she is not allowed to attend peer review meetings. He related that the Chief Scientific Officer is the eyes and ears of the Oversight Committee during the peer review process. While CPRIT staff are not allowed to participate in the review panel's discussion or vote on a grant application, they can bring back valuable information to the Oversight Committee about why particular grants were recommended for funding. Dr. Lakey's situation is somewhat different in that his participation on the PIC is statutorily required. The legislative offices were informed that the Department of State Health Services receives grant monies from CPRIT. His waiver addresses that particular situation.

Ms. Doyle commented that there has to be a compelling reason for exceptional circumstances. She stated that another situation that would arise would be if a review is being done for a unique or specialized application. There could be a smaller pool of reviewers due to the uniqueness of the application which could potentially require a waiver to Conflict of Interest rules. Ms. Doyle informed members that another unusual aspect about this situation is that according to CPRIT's proposed rules, the type of conflict that Dr. Kripke and Dr. Lakey have is a considered a "super" conflict. She advised that this meant that without the waiver, they would be barred from participating in any grant discussion by the PIC. She stated that in the assessment the Oversight Committee is making, they must decide if there are compelling reasons. Ms. Doyle reiterated that it is part of CPRIT's process to use a third party observer when award decisions are made, so the Oversight Committee will have someone outside of CPRIT reporting from a non- agency perspective on how the PIC functions. Ms. Doyle advised that the alternative to Dr. Lakey's waiver would be that the Department of State

Health Services would no longer be allowed to receive CPRIT grants. She further stated that without a waiver, Dr. Kripke's value to the agency on the Oversight Committee would be significantly diminished

Dr. Rosenfeld asked Mr. Roberts if he had spoken with any major institutions in the state such as Baylor College of Medicine or UT Southwestern about how they would view a waiver for Dr. Kripke. Mr. Roberts responded that he had not spoken with them directly about the waiver, however when he first arrived at CPRIT he had numerous conversations with various institutions about conflict of interest concerns and their sensitivity to them.

Mr. Roberts informed the members that by law the agency must go through this public waiver process and then post the waivers on our website. Mr. Roberts stated that he is required to inform the Governor, Lt. Governor, Speaker, Chair of the Health & Human Services Committee and the Chair of the Committee on Public Health if the waiver is approved. Mr. Roberts added his personal belief that Dr. Kripke's academic and intellectual integrity is such that she can operate within the constraints of this waiver.

Dr. Rosenfeld inquired about a plan to monitor the conflict. Ms. Doyle responded that an independent observer is required to attend peer review meetings. She advised the members that CPRIT staff are prohibited from participation in the review process. The independent observer documents adherence to the requirement.

Mr. Roberts stated that he would like to add that with respect to her recruitment and the search committee for her, the Executive Vice Chancellor for Health Affairs for the University of Texas System was a member of that committee and was aware of her relationship with MD Anderson. Mr. Roberts commented that people need to recognize that the cancer community in Texas and the United States is a relatively small pool of people and that it is very difficult to operate a program of this magnitude without people knowing each other.

Mr. Geren inquired about the communication with state officials regarding the proposed waivers. Mr. Geren asked Mr. Roberts to identify legislators with whom he had discussed these waivers ahead of time. Mr. Roberts stated that he didn't remember all of the legislators but that he certainly talked with staff of Senator Nelson and Representative Keffer, sponsors of the bill creating CPRIT. Mr. Roberts further advised that in the past week he had spoken to staff for the Governor, Lt. Governor and the Speaker who are responsible for handling these CPRIT issues.

Mr. Holmes commented that conflicts occur all the time which is why you develop processes to deal with them. He asked Mr. Roberts to repeat for the record his belief that all requirements to grant the waivers for both individuals had been satisfied. He further asked

for affirmation that it would be a continuous monitoring process and the waivers could be withdrawn at any time. Mr. Roberts responded that he believed all requirements had been met. He further stated that he takes the integrity of CPRIT seriously and understands that this matter is important to the citizens of Texas and the legislature. Mr. Roberts informed the members that he had received serious warnings from legislators and he took them as such. Mr. Roberts stated that he believes CPRIT has been given the appropriate tools to move forward.

Dr. Mulrow inquired about the process for peer reviews such as the names of the peer reviewers and what grants they reviewed and asked if any type of report is available to the public. Mr. Roberts deferred the question to Ms. Doyle who informed the members that going forward a de-identified list of all scores assigned by the review committee would be publicly available. She advised that members have the right and duty to question the processes followed.

Dr. Mulrow reiterated that the members would be able to see if all of the positive comments for a particular application came from a particular place and Ms. Doyle responded yes.

Dr. Rice questioned how the members would have visibility to the whole process. Ms. Doyle stated that one of the agenda items for the January meeting will be to show how the new rules will be implemented. Most of the new requirements and responsibilities fall on CPRIT and will dramatically increase the amount of documentation required. Members will also receive an affidavit from the CEO for every grant application recommended for funding.

Dr. Mulrow commented that it sounded like there are some transparency protections already put into place. Mr. Roberts affirmed that there were.

Chair Rice called for a motion finding that exceptional circumstances exist and to approve the waiver proposed for Dr. Margaret Kripke that will waive the conflict of interest specified in Texas Health and Safety Code Section 102.106(c)(3).

A motion finding that exceptional circumstances exist and to approve the waiver proposed for Dr. Margaret Kripke that will waive the conflict of interest specified in Texas Health and Safety Code Section 102.106(c)(3) was made by Mr. Geren and seconded by Ms. Mitchell

MOTION CARRIED UNANIMOUSLY

Chair Rice called for a motion finding that exceptional circumstances exist and to approve the waiver proposed for Dr. David Lakey that will waive the conflict of interest specified in Texas Health and Safety Code Section 102.106(c)(3).

A motion finding that exceptional circumstances exist and to approve the waiver proposed for Dr. David Lakey that will waive the conflict of interest specified in Texas Health and Safety Code Section 102.106(c)(3) was made by Mr. Holmes and seconded by Mr. Angelou.

MOTION CARRIED UNANIMOUSLY

Chair Rice inquired of Mr. Roberts if both waivers would be publicly posted on CPRIT's website and provided to the Governor, Lt. Governor, and Speaker of the House, as well as to the statutorily designated legislative committees with oversight for CPRIT operations. Mr. Roberts confirmed that they would.

13. <u>Subcommittee Business</u>

Approval of subcommittee charters and chairs

The Chair reported on Subcommittee business stating that the Oversight Committee approved appointments to the subcommittees at the previous OC meeting on November 1, 2013. He stated the Oversight Committee Bylaws require each subcommittee to adopt a subcommittee charter that will be approved by the Oversight Committee. Six of the seven subcommittees have met and have adopted subcommittee charters.

The Bylaws also require that each subcommittee will have a chairperson, who will be selected by the Oversight Committee at large. For the record, nominated interim chairs are:

Audit – Interim Chair Angelos Angelou
Board Governance – Interim Chair Amy Mitchell
Nominations – Interim Chair Ned Holmes
Prevention – Interim Chair Cynthia Mulrow
Product Development – Interim Chair Craig Rosenfeld
Scientific Research – Interim Chair Bill Rice

The Chair called for a motion to approve the proposed subcommittee charters.

A motion to approve the proposed subcommittee charters was made by Mr. Geren and seconded by Dr. Rosenfeld.

MOTION CARRIED UNANIMOUSLY

14. <u>Board Governance Subcommittee Report</u>

The Chair recognized Board Governance Interim Chair Amy Mitchell to report on the Board Governance subcommittee.

Ms. Mitchell reported that at the last Oversight Committee meeting, the Committee referred issues related to the 2014 CPRIT Conference and the Strategic Communications contract to the Board Governance subcommittee.

Ms. Mitchell stated that the Board Governance subcommittee met November 18th and discussed these issues with CPRIT staff. The subcommittee recommended instructing CPRIT staff to develop and release a Request for Proposals (RFP) to solicit venues in several major Texas cities to hold a November 2014 CPRIT conference to enable CPRIT to assess venue interest and viability of a conference. Issuing the RFP will not commit CPRIT to holding the conference. However, unless staff begins now, it may be difficult to hold a conference in 2014 because of the substantial lead time it will take to organize.

Ms. Mitchell advised that the Board Governance subcommittee also recommended that the staff prepare a RFP for the Comptroller of Public Accounts to issue on CPRIT's behalf for a strategic communications program for FY2014 and FY2015. This program would include communications planning, public outreach, public affairs, CPRIT publications support, and web site redesign and content expansion. Before any such contract can be awarded, approval from the Oversight Committee and the Legislative Budget Board will be required.

The Chair called for a motion to direct CPRIT staff to release a Request for Proposals to solicit venues in major Texas cities to hold a potential November 2014 CPRIT conference.

A motion to direct CPRIT staff to release a Request for Proposals to solicit venues in major Texas cities to hold a potential conference on November 2014 CPRIT was made by Mr. Geistweidt and seconded by Mr. Angelou.

MOTION CARRIED UNANIMOUSLY

The Chair called for a motion to direct CPRIT staff to prepare an RFP for a strategic communications program for FY2014 and FY2015.

A motion to direct CPRIT staff to prepare an RFP for a strategic communications program for FY2014 and FY2015 was made by Mr. Geistweidt and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

15. Chief Operating Officer Report

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

Ms. McConnell reported that the FY2014 request for financing to issue $300 million in debt authorized by the Oversight Committee at its November 1st meeting was sent to the Texas Public Finance Authority (TPFA) the same day. The TPFA and the Bond Review Board met on November 7th and November 21st, respectively, and both approved the request. With that approval, a request was sent to TPFA to issue $55.2 million in commercial paper notes as soon as possible. The notes will be sold on Monday, November 25th.

Ms. McConnell gave an update on the FY 2014 Operating Budget submission to the Governor's Office of Budget, Planning and Policy (GOBPP)and Legislative Budget Board (LBB). A summary of CPRIT's $297 million operating budget ($300 million less the $3 million transfer to DSHS for the Texas Cancer Registry) was presented at the last OC meeting on November 1, 2013. The agency has prepared an operating budget in a format prescribed by the GOBPP and LBB which must be submitted to both of those offices. The format requires agency budget and expenditure information for the current fiscal year and previous two fiscal years in a variety of schedules, including strategy level, method of finance, object of expense, outcome performance measures, and estimated revenue collection supporting schedules.

Ms. McConnell advised that the Oversight Committee does not have to take any action on this item but the submission will require the signature of the Oversight Committee's presiding officer as well as of the Chief Executive Officer and Financial Officer to certify that the paper copy CPRIT submits to those offices does not differ from the electronic copy submitted. The budget is due to the GOBPP and LBB by December 1.

16. <u>Compliance Report</u>

The Chair recognized Kristen Doyle who is acting as CPRIT's Interim Compliance Officer to present the Chief Compliance Officer's Report as follows.

Ms. Doyle stated that an Ethics and Compliance Program is a critical component of an organization's internal control processes and absolutely necessary when the organization is entrusted with taxpayer funds. Compliance activities have been a function of CPRIT operations since inception. Examples include ethical conduct policies, audit policies and conflict of interest policies and procedures. CPRIT created the position of Compliance Officer in August 2012 to ensure organizational compliance and to establish a formal compliance program that promotes a culture of ethical conduct and adherence to the law.

CPRIT's statute was amended during the 83rd legislative session to specifically provide for a compliance program. See Health & Safety Code Section 102.263. Establishing a compliance program is a deliberative process requiring the commitment and resources of the entire organization. CPRIT's compliance program must assess and ensure compliance with applicable laws, rules, and policies, including ethics and standards of conduct, financial reporting, internal accounting controls, and auditing. Many changes made to CPRIT's administrative rules flesh out and implement the statutory mandate related to the compliance program.

Ms. Doyle related that 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 proposed 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.

Ms. Doyle informed the Members that CPRIT has recently implemented the CPRIT Grants Management System (CGMS). CGMS is an electronic portal system that facilitates CPRIT's execution of grant contracts and the ongoing monitoring and management of grant awards, including required Grant Recipient reports and submissions. Prior to CGMS, almost all of the paperwork associated with grant contracts and grant monitoring activities were exchanged between CPRIT and the grant recipients either as physical documents or as PDF applications, which made contract execution and grant monitoring a time-intensive process. CGMS not only allows for comprehensive status update review for all required reports, but it also automatically notifies grant recipients of upcoming deadlines. The automatic notices help grant recipients maintain full compliance.

A compliance program is constantly evolving to meet the current and continuing needs of the Institute. The compliance program, however, must assure the Oversight Committee that controls are in place to manage risk, be transparent and ensure the public's trust.

With regard to monitoring submission status of required grant recipient reports, Ms. Doyle reported that as of the date of this report, CGMS information regarding delinquent grant recipient reports is as follows:

- Five active grant projects have not filed required quarterly financial status (FSR) reports by the deadline. An FSR is due to CPRIT within 90 days following the close of the fiscal quarter. Of the five delinquent reports, one grant project is less than 30 days overdue. Two are more than 30 days but less than 90 days overdue. Two grant projects are currently 90+ days overdue. For purposes of this report, I have excluded grant projects where contract execution was affected by the moratorium on new CPRIT awards.
- Three active grant projects 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. The three projects are more than 30 but less than 90 days overdue. For purposes of this report, I have excluded grant projects where contract execution was affected by the moratorium on new CPRIT awards.
- One grant project in close-out status has not filed a required FSR. The required report is more than 30 days but less than 90 days overdue. A grant project enters "close out" status on the date of the termination date stated in the contract. The close out period extends for 145 days from the termination date. During close out the grant recipient must file all final reports required by the contract.

Ms. Doyle advised that CPRIT staff will follow up with the grant projects that have delinquent reports. Currently, CPRIT may cease reimbursing or advancing grant proceeds if FSRs or other required reports such as progress reports are not on file for the grant project. The failure to timely submit required reports may also be considered an "event of default" under CPRIT's grant contract, which leads to grant termination unless the default event is cured to CPRIT's satisfaction. The Oversight Committee will be notified by the Chief Executive Officer and General Counsel in the event that the contract default option is pursued for any grant contract.

CPRIT's proposed administrative rules provide new options to address delinquent reports. For example, proposed rule 703.21(b)(2) provides, "…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 due date. The Chief Executive Officer may approve an extension of the submission deadline if, prior to the FSR due date, the grant recipient submits a written explanation for the grant recipient's inability to complete a timely submission of the FSR."

The addition of new grant monitoring staff authorized by the legislature, together with the automatic notification features in CGMS, and additional tools in the proposed administrative rules should work together so that CPRIT can ensure that grant recipients are achieving full compliance with applicable rules, requirements and policies.

Ms. Doyle reported that in the course of CPRIT's contract execution activities for grant awards that were subject to the moratorium, an issue was brought to the Chief Executive Officer's attention. She stated that she was asked to investigate the issue and report to the Chief Executive Officer and to the Oversight Committee regarding any compliance concerns. Ms. Doyle recommended that no Oversight Committee action is necessary. Because the issue raises some questions regarding impartiality of a former CPRIT employee Ms. Doyle recommended that the issue be reported to the Oversight Committee in an open meeting.

A background report on the issues was given by Ms. Doyle. At the December 5, 2012, Oversight Committee meeting, the Committee ratified three individual investigator CPRIT grant awards that were specifically designated as "Carson Leslie Awards for Pediatric Brain Cancer Research." Carson Leslie, a Dallas native, died of medulloblastoma at the age of 17 in 2010. His family established the Carson Leslie Foundation to raise funds for pediatric brain cancer research. One of Carson's last wishes was that his brain be used to enhance understanding of his disease.

To that end, CPRIT collaborated with the Carson Leslie Foundation to provide peer review of submitted applications, as well as funding and contract administration for any grant awards recommended by the reviewers and ratified by the Oversight Committee. CPRIT's Request for Application provided that any funded application must "meet CPRIT's usual high standards."

- "Applications must be submitted following the procedures and instructions for CPRIT Individual Investigator Research Awards, and applications will be reviewed in the same way, using the same criteria as all other applications submitted to this award mechanism. Both the Carson Leslie Foundation and CPRIT are committed to maintaining very high standards in choosing recipient(s) of this special award…"

Three academic institutions were recipients of these special awards: Baylor College of Medicine, Texas Tech University, and U.T. Southwestern. The three awards totaled $3,016,389. The Carson Leslie Foundation will also contribute funds for these awards. CPRIT's former Compliance Officer Patricia Vojack and Special Advisor Billy Hamilton conducted the compliance review of all award recommendations subject to the grant moratorium and concluded that the these awards were in compliance with CPRIT's processes and procedures.

However, it has recently come to CPRIT's attention that when the applications were considered by the scientific research peer review committees, Dr. Al Gilman, CPRIT's Chief Scientific Officer at the time, was also a Scientific Advisory board member for the Carson Leslie Foundation. According to Foundation personnel, Dr. Gilman's position was unpaid and largely ceremonial.

Ms. Doyle reported that CPRIT employees are governed by the agency conflict of interest rules and must recuse themselves from participation in the grant review process if the employee "has an interest in the outcome of an application such that the individual is in a position to gain financially, professionally, or personally from either a positive or negative evaluation of the grant proposal." 25 T.A.C. § 702.11(a). CPRIT's conflict of interest rules mandates that a professional conflict of interest exists if an individual subject to the rule "is a member of the board of directors, other governing board or any committee of an entity or other organization receiving or applying to receive money from the Institute."

Ms. Doyle stated that pursuant to CPRIT's rules in force at the time, she has concluded that Dr. Gilman did not have a professional conflict of interest requiring recusal. Although he was a member of a committee of the Carson Leslie Foundation, the Foundation was not receiving or applying to receive money from CPRIT. CPRIT Grant award proceeds are paid to the academic institutions that are the recipients of the Carson Leslie Awards.

Ms. Doyle further stated that although Dr. Gilman's position with the Carson Leslie Foundation did not violate conflict of interest provisions, his association might raise questions concerning the review of the applications for this award. Ms. Doyle stated that, nothing in her investigation indicates that the projects approved for Carson Leslie grant awards were subject to anything less than CPRIT's high standards and full peer review process. The final overall evaluation scores for the three funded projects ranged from 1.9 – 2.85 (on a scale from 1 – 9, with 1 being the most favorable score) and were well within the range of fundable scores for the Individual Investigator awards.

Ms. Doyle pointed out that it is important to note that CPRIT's established policy prohibits CPRIT employees from actively participating in peer review committee meetings regardless of whether the employee has a conflict. This means that the Chief Scientific Officer may attend the peer review committee meetings as an observer, but may not participate in the substantive discussion of any grant application, may not score any application, and may not vote on any application. CPRIT contracts with an independent third-party observer to document that CPRIT's observer policy is followed. I reviewed the third-party observer report for the peer review committee meetings that discussed these applications. The independent observer reported that Dr. Gilman did not participate in the discussion, scoring, or vote on any of these applications. Ms. Doyle stated that no Oversight Committee action was necessary.

Hearing no discussion or questions, the Compliance Report was accepted as presented.

17. <u>Future Meeting Dates and Agenda Items</u>

The Chair advised members that the next Oversight Committee meeting has not yet been set,

but it is anticipated that it will be in the latter half of January – most likely January 24th, 29th, 30th or 31st. At this time, issues related to CPRIT's Scientific Research and Product Development programs, as well as the peer review and grant monitoring processes will be addressed. CPRIT staff will circulate a tentative agenda.

18. Public Comment

There were no requests for public comment.

19. Adjourn (Chair)

As there was no further business the Chair moved to adjourn, seconded by Dr. Rosenfeld.

MOTION CARRIED UNANIMOUSLY

This meeting stands adjourned at 3:15 p.m.

ATTACHMENT A

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE INTERIM CHAIR PETE GEREN
FROM: WAYNE R. ROBERTS, INTERIM EXECUTIVE DIRECTOR
SUBJECT: SECTION 102.1062 WAIVER – MARGARET L. KRIPKE, PH.D.
DATE: NOVEMBER 18, 2013

Waiver Request and Recommendation:

I request that the Oversight Committee approve a conflict of interest waiver for Dr. Margaret L. Kripke, CPRIT's Chief Scientific Officer, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Dr. Kripke to effectively perform her duties as Chief Scientific Officer. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

Background:

As required by statute and CPRIT's conflict of interest policy, Dr. Kripke notified me that she has a conflict of interest with one or more scientific research applications currently pending review by the Scientific Review Council. Specifically, The University of Texas M.D. Anderson Cancer Center (M.D. Anderson) submitted two CPRIT grant applications for recruitment awards that are currently pending review. Dr. Kripke's husband, Dr. Isaiah J. Fidler, is employed by M. D. Anderson as a professor in the Department of Cancer Biology and holds an endowed chair.[1]

Health & Safety Code Section 102.106(c)(3) mandates that a professional conflict of interest exists if a CPRIT employee's spouse is an employee of an entity applying to receiving or receiving CPRIT funds. Furthermore, CPRIT's proposed administrative rule 702.13(c) categorizes this type of professional conflict of interest as one that raises the presumption that the existence of the conflict may affect the impartial review of all other grant applications submitted pursuant to the same grant mechanism in the grant review cycle. A person involved in the review process that holds one of the conflicts included in the Section 702.13(c) "super conflict" category must be recused from participating in the "review, discussion, scoring, deliberation and vote on all grant applications competing for the same grant mechanism in the entire grant review cycle, unless a waiver has been granted..."

[1] Dr. Fidler does not have a recognized administrative or leadership position at M.D. Anderson, nor has he ever applied for or received CPRIT funding.

While the conflict has been identified with regard to the five pending recruitment applications, because of M.D. Anderson's wide-ranging involvement in cancer prevention and cancer research activities in Texas, it is reasonable to expect that the same conflict will affect Dr. Kripke's participation in more than one grant review cycle in this fiscal year as well as other grant monitoring activities she will undertake. CPRIT's proposed administrative rule Section 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Dr. Kripke's Participation

In order to approve a waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. As explained below, there are compelling reasons warranting Dr. Kripke's participation in the review process when she would otherwise be excluded because of the conflict. The proposed limitations and CPRIT's existing process and procedures will substantially mitigate any potential for bias.

One of the principal duties for a CPRIT program officer is serving as the Oversight Committee's expert-in-residence for his or her particular grant program. Dr. Kripke is a respected scientist and administrator who has been recognized both nationally and internationally for her work as a cancer researcher. Her nine-year tenure on the President's Cancer Panel gives her a comprehensive overview of the cancer problem and exceptional insight into the needs and future directions of cancer research. She was recruited to CPRIT as its Chief Scientific Officer in December 2012 following an extensive national search and was deemed to be an ideal candidate for the position.

Dr. Kripke's expertise and experience are important not only to address scientific and technical questions but also when she acts as the Oversight Committee's "eyes and ears" into the peer review process. Peer review committees are primarily responsible for evaluating grant applications and recommending awards. It is standard practice for CPRIT employees to attend peer review meetings as observers; however CPRIT employees are expressly prohibited from actively participating in the peer review panel's discussion or scoring of grant applications. It is important for the Chief Scientific Officer to attend and observe the peer review committee meetings; doing so allows Dr. Kripke to credibly relay the peer reviewers' impression of the grant applications to the Oversight Committee and to address questions the Oversight Committee may have related to a scientific research grant recommendation. Dr. Kripke's attendance at peer review meetings is valuable even for those applications that are not recommended for a grant award. Grant applicants often contact the program officer after receiving the peer reviewers' written comments and overall score for their applications. Dr. Kripke will be able to provide meaningful guidance and feedback to the applicant on the proposal's strengths and weaknesses by attending the peer review committee meeting when the application was discussed. Without the waiver Dr. Kripke will be unable to effectively perform a significant aspect of her job.

Another important role for the program officer is to recruit and retain members of the program's review council. These review council members serve as strategic advisors for CPRIT's grant programs as well

as being responsible for recruiting high-quality reviewers to the peer review panels chaired by each council member. Texas has established a gold-standard peer review process directly dependent on CPRIT's scientific leader, the Chief Scientific Officer. Dr. Kripke's distinction in the cancer research arena provides Texas access to the premier cancer researchers in the world—since these are Dr. Kripke's peers. The Chairs of CPRIT review panels are all highly distinguished in their respective fields and bring enormous stature to the peer review process. Having panel chairs of this caliber distinguishes CPRIT's peer review process from all others.

The review council members and peer reviewers that serve on the CPRIT peer review panels are ineligible to receive CPRIT awards; a main attraction to serving as CPRIT peer reviewers is the opportunity for intellectual interactions with scientific colleagues. These interactions do not occur without the leadership of the Chief Scientific Officer, Dr. Kripke.

Proposed Waiver and Limitations

It is important to note that the identified conflict of interest existed at the time that Dr. Kripke was hired by CPRIT and was known to the Oversight Committee and the Executive Director. The individuals involved with the hiring process believed that Dr. Kripke's qualifications, together with protections already in place to mitigate any impact related to the conflict of interest (described more fully below), supported the decision to select Dr. Kripke as CPRIT's Chief Scientific Officer. Although I was not involved in the hiring process, I have had the opportunity to work with Dr. Kripke for the past ten months and I support the decision.

In granting the waiver of the conflict of interest set forth in Section 102.106(c)(3), I recommend that Dr. Kripke be permitted to perform the following activities and duties of the Chief Scientific Officer:

1. Assign grant applications, including M.D. Anderson grant applications, to various peer review committees for peer review evaluation;
2. Attend scientific research peer review committee meetings as an observer, including meetings where M.D. Anderson applications are discussed;
3. Attend and participate fully in the Program Integration Committee (PIC) meetings, subject to the limitation set forth under "Limitations";
4. Have access to grant applicant information developed during the grant review process, including information related to M.D. Anderson applications;
5. Provide information about grant applications recommended for grant awards to the Oversight Committee or CPRIT personnel, including answering questions raised by the Oversight Committee or CPRIT personnel about M.D. Anderson grant applications. To the extent that information is provided by Dr. Kripke on her own initiative (e.g. the Chief Scientific Officer's summary of the recommended awards) and not in response to a specific question or request, it should be general information related to the overall grant application process and not advocate specifically for grant application submitted by M.D. Anderson; and

6. Following the Oversight Committee's approval of a grant award to M.D. Anderson by the Oversight Committee, Dr. Kripke may review and approve programmatic requests associated with M.D. Anderson grant contracts and grant monitoring activities.

With regard to item number 2, Dr. Kripke will be required to follow CPRIT's established policy that CPRIT employees are prohibited from actively participating in peer review committee meetings. This means that Dr. Kripke may attend the peer review committee meetings as an observer, but may not participate in the substantive discussion of any grant application, may not score any application, and may not vote on any application. CPRIT contracts with an independent third-party observer to document that CPRIT's observer policy is followed. The independent third-party observer report will be made available to the Oversight Committee prior to any action taken related to the grant award recommendations. Following Oversight Committee action, the independent third-party observer report will be publicly available.

LIMITATION ON DUTIES AND ACTIVITIES

Dr. Kripke is a member of the PIC. As a PIC member, Dr. Kripke will be called upon to exercise discretion related to whether applications proposed for grant awards by the peer review committees should be recommended to the Oversight Committee for final approval. Dr. Kripke shall not vote on any award recommendations related to M.D. Anderson.

CPRIT's Compliance Officer is statutorily required to attend PIC meetings to document compliance with CPRIT's rules and processes, including adherence to this limitation.

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.

- This waiver is limited to the conflict of interest specified in this request. To the extent that Dr. Kripke has a conflict of interest with an application that is different from the conflict identified in Section 102.106(c)(3), then Dr. Kripke will follow the required notification and recusal process.

ATTACHMENT A

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE INTERIM CHAIR PETE GEREN
FROM: WAYNE R. ROBERTS, INTERIM EXECUTIVE DIRECTOR
SUBJECT: SECTION 102.1062 WAIVER – DAVID L. LAKEY, M.D.
CC: OVERSIGHT COMMITTEE MEMBERS
DATE: NOVEMBER 18, 2013

Waiver Request and Recommendation:

I request that the Oversight Committee approve a conflict of interest waiver for Program Integration Committee (PIC) member Dr. David L. Lakey, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Dr. Lakey is the Commissioner of the Department of State Health Services (DSHS). DSHS is also a CPRIT grant recipient, having received a grant award in September 2009, and may apply for CPRIT grants in the future. The waiver is necessary for Dr. Lakey to participate in CPRIT's review process as a PIC member. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

Background:

The DSHS Commissioner is a statutorily designated member of the PIC. As a PIC member, Dr. Lakey will be called upon to exercise discretion related to whether applications proposed for grant awards by the peer review committees should be recommended to the Oversight Committee for final approval. DSHS is a CPRIT grant recipient and may submit a CPRIT grant application in the future. Health & Safety Code Section 102.106(c)(3) mandates that a professional conflict of interest exists if a PIC member is an employee of an entity applying to receive or receiving CPRIT funds. Furthermore, CPRIT's proposed administrative rule 702.13(c) categorizes this type of professional conflict of interest as one that raises the presumption that the existence of the conflict may affect the impartial review of all other grant applications submitted pursuant to the same grant mechanism in the grant review cycle. A person involved in the review process that holds one of the conflicts included in the Section 702.13(c) "super conflict" category must be recused from participating in the "review, discussion, scoring, deliberation and vote on all grant applications competing for the same grant mechanism in the entire grant review cycle, unless a waiver has been granted..."

CPRIT's proposed administrative rule Section 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Dr. Lakey's Participation

In order to approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. Dr. Lakey's participation in the review process is compelled by the statute. In order to fulfill legislative intent that the DSHS Commissioner serve as a PIC member, the proposed waiver must be granted. The proposed limitations will substantially mitigate any potential for bias.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Section 102.106(c)(3), I recommend that Dr. Lakey be permitted to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. Attend and participate fully in the PIC meetings except that Dr. Lakey shall not participate in the PIC's discussion or vote on grant award recommendations to be made to DSHS;
2. Have access to grant application information developed during the grant review process, except for information related to DSHS applicants, if any; and
3. Provide information to the Oversight Committee or CPRIT personnel about the grant review process and applications recommended by the PIC for grant awards, including answering questions raised by the Oversight Committee or CPRIT personnel. To the extent that information is provided by Dr. Lakey on his own initiative in a review cycle in which DSHS is a grant applicant, the information provided by Dr. Lakey should be general information related to the overall grant application process and not advocate specifically for a grant application submitted by DSHS.

CPRIT's Compliance Officer is statutorily required to attend PIC meetings to document compliance with CPRIT's rules and processes, including adherence to this limitation. The Compliance Officer shall report to the Oversight Committee any violation of this waiver prior to the Oversight Committee's action on the PIC recommendations.

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval to make any changes to the waiver shall be by a vote of the Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request. To the extent that Dr. Lakey has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(3), then Dr. Lakey will follow the required notification and recusal process.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CEO
SUBJECT: AGENDA ITEM # 4 – CEO REPORT
DATE: JANUARY 20, 2014

As of this writing, the Chief Executive Officer Report for the January 24, 2014, Oversight Committee (OC) meeting includes the following.

1. Status and summary of CPRIT staff vacancy postings

- *Internal Auditor* – The position posting was extended until January 24 due to fewer than expected applicants. 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.
- *Chief Product Development Officer* – The position posting is open through January 24.
- *Attorney* – The position posting closed January 10. Candidates are being screened.
- *Procurement Specialist* – The position posting will close February 28, 2014.
- *Grant Specialists* – Position postings are being refined and should be posted prior to the February 19 Oversight Committee meeting.
- *Chief Compliance Officer* – David Reisman started work on December 16, 2013.

2. Implementation of State Auditor's Recommendations

CPRIT filed a status report with the State Auditor's Office (SAO) on December 31, 2013, addressing the agency's implementation of the 41 audit recommendations pertaining to the agency. In addition to the recommendations directed to the agency, the SAO report included 10 recommendations for legislative action affecting CPRIT. Many of the 51 recommendations were incorporated in the statute by SB 149.

Maintaining the integrity and credibility of CPRIT's mission requires a clear set of guidelines, rules and responsibilities to govern the behavior of Oversight Committee members, Program Integration Committee members, Institute employees, and peer reviewers, as well as those that apply for and receive CPRIT grants. The changes made to CPRIT's rules, policies, and practices as a result of the

SAO recommendations provide clear guidance regarding expected conduct and performance, both for the agency and its grant recipients.

CPRIT has fully implemented or is in the process of fully implementing all 51 recommendations from the SAO's January 2013 management audit.

- 33 recommendations have been fully implemented.
- 13 recommendations will be fully implemented by February 19, 2014, when the Oversight Committee takes action regarding the first set of grant applications submitted after SB 149.
- Full implementation of 4 recommendations will be phased in by June 1. Changes to CPRIT's forms and electronic grant management system requirements as well as grantee training must be completed for full implementation.
- The recommendation that CPRIT audit the Peer Review Management Information System and the Application Receipt System is underway and will be complete by the end of June.

All that can be done as of January 24th is done. The OC's approval today of the new administrative rules and rule changes completes a major phase of the implementation plan. The new administrative rules and rule changes address 37 of the 41 state auditor recommendations directed to the agency and incorporate the recommendations into CPRIT practices. (The remaining four recommendations directed to the agency are addressed separately by rules for CPRIT's contracting processes, which have been fully implemented.) However, in order for a recommendation to be considered "fully implemented," the agency must have a process in place and be using the process. By the end of this fiscal year, all will be fully implemented.

A few metrics concerning the Administrative Rules Process are instructive. Prior to January 24, CPRIT's 33 administrative rules totaled *40 pages*. After January 24, CPRIT will have 48 rules totaling *103 pages*. The new administrative rules call for more than 100 different documents or reports that must be filed by someone. Most of this burden falls on CPRIT. The rules call for more than 20 changes to CPRIT's operations that we characterize as major changes. There are at least nine major changes for grantees. These will increase grantee workloads and require training.

To that end, CPRIT is putting into place a comprehensive program to inform all grantees of the rule changes and train them on compliance requirements they must meet to implement the rules. CPRIT's goal is 100% compliance through broad-based engagement and line accountability. This requires CPRIT's compliance strategy to be well understood and fully practiced. CPRIT will provide training for grantees on newly adopted changes in administrative rules, conflict of interest policies, and state law. This will be done via on-site group sessions, webinars, and video archiving for online use and availability for those who miss the training and future grantees. CPRIT will also present this material to legislators, their staff, and legislative oversight agencies in Capitol Complex briefings.

3. Annual Report

OC members received a rough draft of the 2013 Annual Report required by V.T.C.A., Health and Safety Code Sec. 102.052. The final report must be submitted annually by January 31 to the

governor, lieutenant governor, speaker of the house, Senate Committee on Health and Human Services and the House Committee on Public Health. It must also be posted on CPRIT's website.

State law requires specific items for the annual report. In previous years not all of the requirements were met and the 2012 Annual Report included the following disclaimer:

> Some elements, most notably an assessment of the relationship between CPRIT's grants and the overall strategy of its research program and a statement of its strategic research and financial plans, are not provided in this report. The 83rd Legislature made numerous changes that will strengthen CPRIT's governance and operations and allow a more efficient, effective and transparent focus on combating cancer. These changes and enhancements include a requirement that the CPRIT Oversight Committee establish annual priorities for the research, prevention and product development grant programs. This enhancement, as well as others, will make it possible for future CPRIT annual reports to provide additional information to evaluate our performance and progress.

The report to be submitted by January 31, 2014, *will meet all statutory requirements* and contain no such disclaimer. However, it will not approach my vision for this document of providing additional information concerning grantees, increased data and analysis, links to tables maintained on the CPRIT website, and other enhancements. Time, personnel and other resource limitations restrict this iteration. However, the OC, legislative community, and the general public should anticipate steady improvements in future reports.

No Oversight Committee action is required.

4. Electronic Bulletin Board

Legislative changes made by the 83rd Legislature permit members of a governing body to communicate via an electronic bulletin board that is accessible through the agency's website and viewable in real-time by the public. This option will allow information (articles of interest, research materials, data links, etc.) to be shared by and among OC members without violating the Texas Open Meetings Act.

If this is something the OC chooses to pursue, staff can investigate and prepare options for OC consideration at a future meeting. This issue could also be referred to either the Governance or Audit subcommittee for evaluation.

5. Look Ahead to the February 19 Oversight Committee Meeting

Expect this to be a full agenda. The OC will consider truly new awards using the Program Integration Committee (PIC) process for the first time. The Commissioner of the Department of State Health Services is a statutory member of the PIC. At this time we estimate 5 Multi-Investigator and 7 Training awards from scientific research. There will be no prevention applications and we do not have an estimate of the number of product development awards at this time.

Other major items likely to be considered include:

- Presentation by SRA International, Inc., our third party application and review contractor, concerning its role and processes
- Overview of grant award contract and monitoring
- Finalization of the Strategic Communications Contract, and
- Program Priority Discussion

The latter is the OC directed iterative process for public determining the policy of how it prioritizes funding and initiatives within and among each of CPRIT's three programs of research, product development, and prevention. Specifically, Section 102.107 requires the OC to:

- Annually set priorities as prescribed by this legislature for each grant program that receives money under this chapter; and
- Consider the priorities set [above] in awarding grants under this chapter.

In addition, consideration of hiring an internal auditor is possible, subject to prior screening as discussed above

6. Dashboard Metrics

As of January 24 CPRIT has:

- Made 508 awards totaling $846.6 million (including awards proposed for approval January 24)
  - 115 prevention awards totaling $96.7 million
  - 393 research and product development awards totaling $748.6 million
- 5 research RFAs are open
- 3 product development RFAs are open
- 3 prevention RFAs are open

Moratorium-Related:

- Of the 26 recruitment awards affected by the moratorium:
  - 19 are under completed contract
  - 1 is under negotiation
  - 1 is still pending the recruit's decision
  - 5 declined the nominating institutions' offer

Thirty-five (35) of 118 research and prevention awards are finalized. This number is lower than one might expect for several reasons.

Due to the length of time of the moratorium, an award may need to revise its budget and provide additional documentation. CPRIT has contacted all grantees on items that require additional documentation. More than one-half (43) of the pending grants require additional documentation from the grantee to verify to CPRIT the availability of matching funds for the award. This results from CPRIT implementing the new matching funds verification process pursuant to the State

Auditor's management report. This is the first time for grantees to be required to comply with the new requirement.

7. Other Topics may be Added as Warranted

CPRIT's IMPLEMENTATION PLAN - STATE AUDITOR'S RECOMMENDATIONS

All SAO recommendations include the page number of the SAO report

Rec.		Status	Date
Chapter 1A - CPRIT Should Ensure That All Grant Decisions Are Free from Real or Apparent Conflicts of Interest			
01 pg 8	**Recommendation:** Establish and implement rules that prohibit the CEO from discussing grant recommendations with individual members of the oversight committee before presenting those recommendations to the full Oversight Committee.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: A new administrative rule prohibits discussion between individual members of the Oversight Committee and the Program Integration Committee (PIC) until the recommendations are presented to the full Oversight Committee. CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee. This adopted rule will be fully implemented by February 2014. **Documentation:** OC members will sign certification of non-communication following each award cycle.		
	Statute/Rule/Other: H&S Code § 102.251(d), 25 T.A.C. § 702.19(f), Code of Conduct § V.F.		
02 pg 2	**Recommendation:** Refrain from leasing office space from grantees and consider locating the offices of the chief commercialization officer, chief scientific officer, and director of scientific research in the same office location as CPRIT executive management.	**Fully implemented**	05/31/13
	Implementation: Leases were cancelled with Rice University and UTSW, effective November 30, 3012, and May 31, 2013, respectively.		
	Statute/Rule/Other: H&S Code § 102.057, 25 T.A.C. § 702.9(c)(15), Code of Conduct § II.C.(3)		
03 pg 8	**Recommendation:** Revise its rules to prohibit members of the oversight committee, peer reviewers, and employees from engaging in business activities with grant applicants and grantees.	**Fully implemented**	11/01/13
	Implementation: Oversight Committee approved changes to the Code of Conduct applicable to Oversight Committee members and employees, changes have been made to peer reviewer agreements effective September 1, 2013. **Documentation:** Code of Conduct Peer Reviewer agreements		

Rec.		Status	Date
	Statute/Rule/Other: H&S Code §§ 102.109 (b)(2), 102.156(c) 25 T.A.C. §§ 702.9(c)(8), 703.5 (g),(h), Code of Conduct § II.B.(15), C.(1)(2)		
04 pg 9	**Recommendation:** Establish and implement a process to prevent CPRIT from awarding grants to applicants that made contributions to the CPRIT Foundation, as required by the General Appropriations Acts (81st and 82nd Legislatures).	**Fully implemented**	05/3/13
	Implementation: The Chief Compliance Officer cross-checked all grant awards against the list of CPRIT Foundation donors and reported the information to CPRIT's CEO. CPRIT's CEO sent a written request to the CPRIT Foundation Executive Director to return donations to five individuals because the donations were not in compliance with state law. The CPRIT Foundation confirmed that the donations were returned on May 3, 2013. **Documentation:** List of donors to CPRIT Foundation, CCO April 22, 2013 report, CEO April 23, 2013 letter to Foundation, May 3, 2013 confirmation from CPRIT Foundation that identified donations were returned.		
	Statute/Rule/Other: H&S Code § 102.251(e), 25 T.A.C. § 703.3(h)(1)		
05 pg 9	**Recommendation:** Upon receipt of grant applications, require its chief prevention officer, chief scientific officer, and chief commercialization officer to compare the list of grant applicants to the list of donors to the CPRIT Foundation. In addition, CPRIT should consider requiring the compliance officer to review the grant applications to ensure that there are no conflicts between the grant applicants and the CPRIT Foundation.	**Fully implemented**	12/09/13
	Implementation: Beginning with applications submitted for FY 2014 awards, in order to be eligible to be considered for a CPRIT grant an applicant must certify that it has not made and will not make a donation to CPRIT or any foundation established to benefit CPRIT. The Chief Compliance Officer will confirm the information as part of the compliance pedigree for each grant application presented to the Oversight Committee for award consideration. *CPRIT notes that the 83rd Legislature amended Health and Safety Code, Chapter 102 to direct the Chief Compliance Officer, not the program officers, to perform this task.* **Documentation:** Application, list of donors to CPRIT and any supporting foundation, compliance pedigree for each application.		
	Statute/Rule/Other: H&S Code § 102.251(a)(3), 25 T.A.C. §§ 703.3(h)(4), 703.8(1)(C)		

Rec.		Status	Date
06 pg 9	**Recommendation:** Establish and implement a policy that prohibits a peer reviewer with a conflict of interest from evaluating grant applications competing for the same grant funds as the applicant for which the peer reviewer has a conflict of interest.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: A new administrative rule designates certain conflicts of interest, the nature of which raises the presumption that the conflict may affect the reviewer's impartial review of other applications. If a reviewer has one of these designated conflicts then the reviewer must be recused from participating in the review, discussion, scoring, deliberation and vote on all applications competing for the same grant mechanism in the entire cycle, unless a waiver has been granted. CPRIT notes that the proposed rule applies to all individuals involved in the review/grant monitoring process, including Oversight Committee members, PIC members, CPRIT employees, and peer reviewers. This recommendation will be fully implemented by February 2014. **Documentation:** COI notification		
	Statute/Rule/Other: 725 T.A.C. § 702.13(c)		
07 pg 9	**Recommendation:** Consistently maintain documentation to show that it identifies and takes action to address its peer reviewers' conflicts of interests.	**Incomplete/ Ongoing**	Expected 04/01/14
	Implementation: CPRIT and its third-party grant administrator are implementing changes to the software system and grants database to maintain documentation related to conflicts of interest. This recommendation will be fully implemented by April 1, 2014. Implementation of this recommendation will apply to all individuals involved in the review/ grant monitoring process, including Oversight Committee members, PIC members, CPRIT employees, and peer reviewers. **Documentation:** Documents to be collected and maintained include the Conflict of Interest Policy Agreement, Identification of Conflicts, Sign-Out Sheets, Third-Party Observer Reports, and Post-Review Statements.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(4), 25 T.A.C. §§ 703.3(i), 703.4(1)(C)		
08 pg 9	**Recommendation:** Establish and implement a documented policy on residency requirements for members of its commercialization review council.	**Fully implemented**	12/01/12
	Implementation: All members of the Product Development Review Council (formerly known as the Commercialization Review Council) and Product Development reviewers live and work		

Rec.		Status	Date
	outside of the state. Going forward, a new administrative rule establishes the policy that all reviewers must live and work outside of Texas, unless special circumstances justify using an in-state reviewer. **Documentation:** An explanation of the special needs justification must be recorded in the minutes of the Oversight Committee meeting when the reviewer's appointment is approved.		
	Statute/Rule/Other: H&S Code § 102.151(b), 25 T.A.C. § 701.17		
Chapter 1B - CPRIT Should Ensure the Transparency and Accountability of Its Peer Review Process			
09 pg 16	**Recommendation:** Update and consistently follow agency policies and procedures for reviewing grant applications.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: CPRIT has undertaken a comprehensive review and revision of the agency's administrative rules. A major project milestone will be achieved with the adoption of the revised rules and new rules on January 24, 2014. Following the formal adoption of the rules, CPRIT will release an updated Process and Procedures Guide for grant applicants and recipients that will describe the all stages of the grant application, review, award, and monitoring process. CPRIT is also working with its third party administrator to update the electronic grant application receipt system and grant review scoring system to implement standardized procedures associated with reviewing grant applications. The processes specified by the new rules and rule changes will be applicable to grant applications submitted in response to FY 2014 Cycle 1 requests for applications (RFAs). **Documentation:** Process and Procedures Guide, Grant Review Process records		
	Statute/Rule/Other: H&S Code § 102.051(d)(1), 725 T.A.C. § 03.8(1)(A)		
10 pg 16	**Recommendation:** Require the CEO to provide a written affidavit for each grant recommendation presented to the oversight committee certifying that the grant application was subject to the peer review process with the attached peer review score, including due diligence reviews and intellectual property reviews, when applicable.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: A new administrative rule specifies the information to be included in the CEO affidavit and the timing of the affidavits' submission to the Oversight Committee. This is expected to be fully implemented in February 2014 **Documentation:** The CEO affidavit presented for each grant award recommendation will become part of the Grant Review Process records.		

Rec.		Status	Date
	Statute/Rule/Other: H&S Code § 102.251(c), 25 T.A.C. § 703.7(h)		
11 pg 16	**Recommendation:** Ensure that reviews of all research grant applications, including recruitment grant applications, are subject to the same review process, including processes for documenting peer reviews in the Peer Review Management Information System.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: CPRIT has standardized its review process for grant applications among programs, including specifying variations applicable to a particular program and/or grant mechanism. These processes will be applicable for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications (RFAs) released 12/09/2013. **Documentation:** CPRIT has revised its grant management system to retain documentation of peer review.		
	Statute/Rule/Other: H&S Code § 102.251, 25 T.A.C. § 703.4(1)(A)		
12 pg 16	**Recommendation:** Maintain and secure data that supports why grant applications are withdrawn from the peer review process.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: CPRIT has developed a process to document reasons for withdrawing applications from review. The process will be implemented for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications (RFAs) released 12/09/2013. **Documentation:** The reasons for withdrawing applications from review will be maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(1), 25 T.A.C. § 703.4(1)(B)		
13 pg 16	**Recommendation:** Require peer review councils to document how applications recommended for grants meet one or more of the recommendation standards.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: CPRIT has developed a process for Review Councils to document reasons for recommending grants according to specified standards. The process will be implemented for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications (RFAs) released 12/09/2013. **Documentation:** The Review Council's reasons for recommending grants according to specified standards will be maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system.		

Rec.		Status	Date
	Statute/Rule/Other: H&S Code § 102.251(a)(1)(B), 25 T.A.C. §§ 703.4(1)(B), 703.6(d)(2)(A)		
14 pg 16	**Recommendation:** Ensure that the [Program Integration Committee] documents the factors considered in deciding on grant recommendations and that those grant recommendations are substantially supported by the grant recommendations made by CPRIT's peer review councils.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: CPRIT has developed a process for the Program Integration Committee (PIC) to document the factors considered when recommending grant awards, including demonstrating that the recommendations are substantially supported by the grant recommendations made by CPRIT's peer review councils. CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee. The rule and process changes implemented by CPRIT are applicable to the PIC and will be implemented for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications (RFAs) released 12/09/2013. **Documentation:** The factors considered by the PIC in deciding on grant recommendations will be submitted to the Oversight Committee at the time that the awards are recommended; the information will be maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.251(a)(2)(A)and (B), 25 T.A.C. § 703.7(3)(A) and (C)		
15 pg 16	**Recommendation:** Maintain documentation that supports how recommended grant amounts are determined by the peer review councils and the [Program Integration Committee].	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: CPRIT has developed a process for creating and maintaining documentation that supports how recommended grant amounts are determined by the peer review councils and the Program Integration Committee. The process will be implemented for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications (RFAs) released 12/09/2013. **Documentation:** Written information reflecting the Review Council's and PIC's determination regarding grant award amounts will be maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(1), 25 T.A.C. §§ 703.4(1)(B), 703.6(d)(2)(C) 703.7(3)(E), 703.4(1)(B)		

Rec.		Status	Date
Chapter 1C- CPRIT Should Verify the Accuracy and Availability of Grantees' Matching Funds			
16 pg 20	**Recommendation:** Obtain documentation to verify the amount and availability of matching funds that grantees report.	**Fully implemented**	12/06/13
	Implementation: CPRIT has developed and implemented a process that requires grant recipients to submit documentation verifying the amount and availability of matching funds. In addition to the certification of available matching funds that the grantee must submit at the beginning of the grant award and each grant award year (if the grant recipient is demonstrating matching funds on a year-by-year basis), the grantee must submit supporting documentation that shows available funds to be used as match. Grantees must provide information and supporting documentation about the actual expenditures of funds counted as match toward grants at the end of each award year. The failure to submit the required documentation by the grantee will result in a suspension of grant funding by CPRIT until sufficient documentation is provided and may serve as a basis for terminating the grant contract. **Documentation:** Matching funds certification, supporting documentation showing available funds, year-end information showing how grantee matching funds were used on the project; this information is maintained as part of the complete grant award records kept by CPRIT's electronic grants management system. If the grant recipient is an academic institution, the grant recipient may provide the letter from the government approving the federal indirect cost rate for the institutions.		
	Statute/Rule/Other: H&S Code §102.255(c)(3)(A)&(C),(6), (d)(8) and (9), 25 T.A.C. §§ 703.4(1)(E), 703.10(c)(21), 703.11(g), (j), 703.21(b)(3)(A)(x)		
17 pg 20	**Recommendation:** Require grantees to comply with matching fund requirements in statute and CPRIT rules.	**Fully implemented**	12/06/13
	Implementation: CPRIT has developed and implemented a process that requires grant recipients to submit documentation verifying the amount and availability of matching funds. Grantees must provide information and supporting documentation about the actual expenditures of funds counted as match toward grants at the end of each award year. Failure to submit the required documentation suspends grant funding until sufficient documentation is provided. Failure to provide documentation may serve as a basis for terminating the grant contract. **Documentation:** Matching funds certification, supporting documentation showing available		

Rec.		Status	Date
	funds, year-end information showing how grantee matching funds were used on the project; this information is maintained as part of the complete grant award records kept by CPRIT's electronic grants management system.		
	Statute/Rule/Other: H&S Code §§ 102.255(c)(2), 102.255(c)(3)(A) & (C), 102.260(d), (f), 25 T.A.C. §§ 703.4(1)(E), 703.10(c)(21), 703.11 (g), 703.21(b)(3)(A)(i), (x)		
Chapter 2A - CPRIT Should Establish Requirements for Advance Payments and Reimbursements It Makes to Grantees			
18 pg 24	**Recommendation:** Adopt and implement a policy regarding advance payments to grantees.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: CPRIT has established a process whereby the CEO must seek approval by a simple majority of the Oversight Committee to disburse grant funds by advance payment. The CEO must provide a list of applications recommended for advance payment at least three business days prior to the Oversight Committee meeting. The CEO's list shall include the reasons supporting the recommendation to advance funds. **Documentation:** The advance payment request and approval will be reflected in minutes of the Oversight Committee meeting. The grant contract must specify the amount, schedule, and requirements for advance payment of grant funds. The grant recipient receiving advance payment must maintain or demonstrate the willingness and ability to maintain procedures to minimize the time elapsing between the transfer of the grant funds and disbursement. The grant recipient must also comply with all financial reporting requirements regarding the use of grant funds.		
	Statute/Rule/Other: H&S Code § 102.255(e), 25 T.A.C. §§ 701.19, 703.7(j), 703.10(c)(14)		
19 pg 24	**Recommendation:** Obtain sufficient documentation to support the appropriateness of all payments it makes to grantees.	**Fully implemented**	07/18/13
	Implementation: CPRIT requires grant recipients to submit quarterly financial status reports (FSR) and general ledger data supporting the FSR prior to releasing funds for reimbursement. The failure to timely submit the quarterly FSR information may waive reimbursement for the expenses in that quarter. **Documentation:** CPRIT maintains quarterly FSRs and general ledger information submitted by grant recipients, as well documentation of the agency's review and approval of the FSRs in its electronic grants management system.		

Rec.		Status	Date
	Statute/Rule/Other: H&S Code §§ 102.0535(a)(2), 102.260(a), 25 T.A.C. §§ 703.4(1)(E), 703.21(b)(1)		
Chapter 2B - CPRIT Should Improve Processes for Monitoring Grantee Expenditures and Research Progress			
20 pg 27	**Recommendation:** Retain documentation of all financial and progress reports received and all reviews of those reports.	**Fully implemented**	07/18/13
	Implementation: CPRIT has deployed a fully electronic grants management system that supports the agency's grant award compliance monitoring by maintaining complete grant award records, including the grant contract and matching funds certification, required grant award financial reports and grant progress reports, and CPRIT's review of those reports **Documentation:** CPRIT maintains quarterly FSRs and general ledger information submitted by grant recipients, as well documentation of the agency's review and approval of the FSRs in its electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(3), (5), 25 T.A.C. § 703.4(1)(E)		
21 pg 27	**Recommendation:** Establish and implement a process to track the dates on which grantees' reports are due and received, and follow up on all missing reports.	**Substantially Implemented**	Expected 02/2014
	Implementation: CPRIT has deployed a fully electronic grants management system that supports the agency's grant award compliance monitoring by tracking the due dates and submission status for required grant award reports; monitoring the status of past-due required financial reports and grant progress reports; sending automatic reminders and notifications to grant recipients of upcoming deadlines and past due reports. CPRIT anticipates that full implementation of tracking report due dates and the supporting financial reporting documentation for all grantees in the electronic grants management system will be February 1, 2014. **Documentation:** Documentation of all progress and financial reports as well as any supporting documentation are maintained in the grants management system. The Chief Compliance Officer will report to the Oversight Committee quarterly regarding the status of grantee reports.		
	Statute/Rule/Other: H&S Code §§ 102.051(a)(5), 102.260(e), 25 T.A.C. § 703.4(1)(F)(G)		
22 pg 27	**Recommendation:** Follow the process established by CPRIT to perform desk reviews of financial reports that grantees submit.	**Substantially Implemented**	Expected 03/01/14

Rec.		Status	Date
	Implementation: CPRIT has a process to conduct a desk review to assess 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. CPRIT will use a risk-based methodology to perform desk reviews of financial reports and implement this process by March 1, 2014.		
	Statute/Rule/Other: 25 T.A.C. § 703.21(b)(4)		
23 pg 27	**Recommendation:** Establish criteria for peer reviewers to follow when evaluating and documenting reviews of grantees' progress reports.	**Fully Implemented**	06/19/13
	Implementation: CPRIT has developed standard evaluation criteria for the prevention, research and product development grantee progress reports and has been documenting the evaluation of grant progress against the particular grant goals or milestones and programmatic acceptance of the evaluation in the electronic grants management system. Peer reviewers complete the evaluations of prevention and product development progress reports and report those evaluations to the respective program officers who finalize the recommendations on continuing the grant or addressing weaknesses in the progress; however, due to the volume of research progress reports, CPRIT is using staff with scientific expertise from its grant management support contractor, SRA to perform research grant evaluations. The research evaluations are sent to the research program officer who finalizes the recommendation, the same process in the other two programs. **Documentation:** CPRIT maintains the standard criteria and documentation of the agency's review and approval of the progress reports in its electronic grants management system.		
	Statute/Rule/Other: 25 T.A.C. § 703.21(b)(3)(C)		
24 pg 27	**Recommendation:** Ensure that public higher education institutions obtain and submit reports from required audits.	**Incomplete/ Ongoing**	Expected 05/31/14
	Implementation: CPRIT issued guidance to all grantees, including public higher education institutions, to clarify the methodology required for the annual audit of grants awards with expenditures of $500,000 or more. In the guidance, CPRIT instructed public higher education institutions to complete program specific audits by an institution's internal audit department to retrospectively address the audit requirements for fiscal years 2010, 2011, and 2012. These audits are due by June 30, 2014. The public higher education institutions must have independent auditors complete the required audit for fiscal year 2013. All organizations have		

Rec.		Status	Date
	nine months after the end of the fiscal year to have the independent audits completed and submitted. The public higher education institutions follow the state fiscal year, so any required audit report is due by May 31, 2014. **Documentation:** CPRIT maintains grantee audits and any corrective action plans in its electronic grants management system.		
	Statute/Rule/Other: 25 T.A.C. § 703.13		
Chapter 2C - CPRIT Should Strengthen Certain Contract Management Processes			
25 pg 31	**Recommendation:** Develop, document, and implement a process for closing out grants and renewing grants, as well as develop, document, and implement procedures for extending grants.	**Incomplete/ Ongoing**	Expected 03/01/14
	Implementation: The processes CPRIT has developed for closing out, renewing, and extending grants in conjunction with the approval of the new administration rules will become effective on March 1, 2014. In the interim between approval of the new rules and the implementation of the required processes, CPRIT will educate its grantees about the compliance requirements they will have to meet with the implementation of the rules. **Documentation:** CPRIT maintains requests to extend grants in its electronic grants management system. Processes for closing out and extending grants will be described in the Process and Procedures manual.		
	Statute/Rule/Other: 25 T.A.C. § 703.14(c)		
26 pg 31	**Recommendation:** Ensure that all grant agreements include all reporting requirements.	**Substantially Completed**	Expected 01/24/14
	Implementation: All CPRIT grant award contracts include a list of required reports to be submitted by the grantee. Grant award contracts effective on or after March 1, 2014 will reflect the updated reporting requirements set forth in the new administrative rules. Grant award contracts that have an effective date prior to March 1, 2014 are subject to the updated reporting requirements pursuant to a contract term that specifies that the grantee is obligated to report any information covering its activities related to the grant award that is requested by CPRIT, the Legislature, or any other funding or regulatory bodies. **Documentation:** CPRIT Grant Contract		
	Statute/Rule/Other: H&S § Code 102.260(d), 25 T.A.C. § 703.10(c)(8), (9), (15)		

Rec.		Status	Date
Chapter 3 - CPRIT Should Improve Its Management of the CTNeT Research Grant and Other Administrative Practices			
27 pg 35	**Recommendation:** Refrain from involvement in CTNeT's business decisions.	**Fully Implemented**	02/25/13
	Implementation: CPRIT began implementing the Chapter 3 recommendations related to the management of the CTNeT grant during the audit or immediately following the release of the audit report. While CPRIT believes it has fully implemented the recommendations within the scope of its overall grants management processes, CPRIT was unable to resolve some of the recommendations through management of the CTNeT grant itself because CTNeT ceased operations in February 2013. Going forward, CPRIT has clarified its administrative rules and adopted Code of Conduct and Ethics provisions to prohibit involvement in a grantee's business decision by an Oversight Committee member or CPRIT employee.		
	Statute/Rule/Other: H&S § Code 102.109(b)(2), 25 T.A.C. § 702.9(c)(2), (8), Code of Conduct		
28 pg 35	**Recommendation:** Prohibit CPRIT employees from serving on CTNeT's board of directors.	**Fully Implemented**	02/25/13
	Implementation: CTNeT ceased operations in February 2013. Going forward, CPRIT has clarified its administrative rules and adopted Code of Conduct and Ethics provisions to prohibit involvement in a grantee's business decision by an Oversight Committee member or CPRIT employee.		
	Statute/Rule/Other: H&S Code § 102.109((b)(8)(9), 25 T.A.C. § 702.9(c)(2),(8), (11), Code of Conduct		
29 pg 35	**Recommendation:** Prohibit CTNeT board members from serving on CPRIT's commercialization review council.	**Fully Implemented**	01/29/13
	Implementation: The member of the commercialization review council who also served on the CTNeT board, resigned from the council on January 29, 2013, resolving the issue of having a member of the council on the CTNeT board. Going forward, CPRIT has clarified its administrative rules to prohibit a reviewer from serving on a grantee's board of directors.		
	Statute/Rule/Other: H&S Code § 102.156(c), 25 T.A.C. § 703.5(h)		
30 pg 35	**Recommendation:** Ensure that all payments to CTNeT comply with the terms of the grant.	**Fully Implemented**	12/01/12
	Implementation: CPRIT did not make any payments to CTNeT after November 2012. CTNeT ceased operations in February 2013 before the issues on matching funds and progress reports could be addressed. Going forward, CPRIT has clarified its administrative rules to suspend disbursement of funds if a grantee is not in compliance with contractual requirements		

Rec.		Status	Date
	regarding submission of progress reports and certification of matching funds.		
	Statute/Rule/Other: H&S Code §§ 102.260(b), 102.051(a)(5), 102.260(d), 25 T.A.C. § 703.21(b)(1)		
31 pg 35	**Recommendation:** Withhold payments to CTNeT until after CPRIT has recovered the advanced funds that CTNeT spent on unallowable costs.	**Fully Implemented**	12/01/12
	Implementation: CPRIT did not make any payments to CTNeT after November 2012. CTNeT ceased operations in February 2012 before the organization could correct expenditures on unallowable costs. Going forward, CPRIT has clarified its administrative rules to prohibit disbursement of grant funds if a grantee is not in compliance with contractual requirements. The administrative rule changes make it clear that CPRIT can stop advance payments and may seek repayment of grant funds spent on unallowable costs.		
	Statute/Rule/Other: H&S Code § 102.260(b), 25 T.A.C. §§ 701.19(3),(4),(5), 703.10(c)(14)		
32 pg 35	**Recommendation:** Require CTNeT to comply with requirements regarding matching funds and annual progress reporting.	**Fully Implemented**	12/06/13
	Implementation: CTNeT ceased operations in February 2013. Going forward, CPRIT has clarified its administrative rules to require all research award grantees to demonstrate the availability matching funds for expenditures at the time of certification and comply with the annual progress reporting requirement that the grantee explain how matching funds were spent in the previous year. Failure to provide the matching fund documentation or to timely submit the annual progress report will result in the suspension of funding, and may make the grantee ineligible for future awards. Continued failure to submit the required reports will result in contract termination.		
	Statute/Rule/Other: H&S Code § 102.255(d), 25 T.A.C. §§ 703.7(3)(c), 703.10(c)(21), 703.11(g), (j), 703.21(b)(3)(A)(i), (x)		
Chapter 4A - CPRIT Should Ensure That Contracted Services and Related Costs Are Reasonable and Necessary			
33 pg 40	**Recommendation:** Ensure that it properly identifies and defines its services needs and the associated costs prior to executing service contracts.	**Substantially Implemented**	Expected 03/01/14
	Implementation: CPRIT strives to procure contracted services competitively following the state procurement law as stated in the State of Texas Procurement Manual and other publications provided by the Comptroller of Public Accounts as well as the procurement practice guidelines		

Rec.		Status	Date
	documented in the agency's administrative policies and procedures. CPRIT will revise its internal administrative policies and procedures to further document the practice of identifying and defining its needs for contracted services and prohibiting the awarding of contracts to parties that assist in the needs assessment for service contracts by March 1, 2013. In practice, CPRIT has issued a request for proposal for communication services that has defined needs and costs and was approved by the Oversight Committee's Governance Subcommittee on November 18, 2013.		
	Statute/Rule/Other: State of Texas Procurement Manual		
34 pg 40	**Recommendation:** Prohibit the awarding of contracts to parties that assist in the needs assessment process for the contracted services.	**Substantially Implemented**	Expected 03/01/14
	Implementation: CPRIT will revise its internal administrative policies and procedures to further document the practice of identifying and defining its needs for contracted services and prohibiting the awarding of contracts to parties that assist in the needs assessment for service contracts by March 1, 2013. In practice, CPRIT has issued a request for proposal for communication services that has defined needs and costs and was approved by the Oversight Committee's Governance Subcommittee on November 18, 2013.		
	Statute/Rule/Other: State of Texas Procurement Manual		
35 pg 40	**Recommendation:** Require vendor invoices to include specific information that clarifies the work products and services the vendors provided during the billing cycle.	**Fully Implemented**	04/10/13
	Implementation: CPRIT addressed the insufficient details in the identified contractor's invoices by requiring additional information to support the vendor's labor charges after CPRIT received the requested additional information for the December 2012 invoice and was able to process the payment for the invoice on April 10, 2013. CPRIT continues to review the documentation for all of its vendors to ensure there is appropriate detail to support the invoices.		
	Statute/Rule/Other: State of Texas Procurement Manual		
36 pg 40	**Recommendation:** Competitively procure all contracted services, and require its contractors to competitively procure all subcontracted services.	**Fully Implemented**	06/28/12
	Implementation: CPRIT strives to procure contracted services competitively following state procurement law as stated in the State of Texas Procurement Manual and other publications provided by the Office of the Comptroller of Public Accounts. At this time, CPRIT has one		

Rec.		Status	Date
	contractor that procures subcontracted services. That contractor completed a competitive procurement of those subcontracted services in June 2012.		
	Statute/Rule/Other: State of Texas Procurement Manual		
Chapter 4B - CPRIT Should Ensure That Its Honorarium Payments Are Appropriate			
37 pg 43	**Recommendation:** Establish minimum requirements for documentation that must be submitted for payments to reviewers for their services.	**Fully Implemented**	09/01/13
	Implementation: CPRIT's CEO adopted CPRIT's Honorarium Policy effective September 1, 2013. The written Honorarium Policy describes the expected duties and responsibilities for Review Council chairs, Review Council members, and peer review panel members, specifies the expected time commitment, and lists the hourly rate comparisons used to develop the honorarium amounts. The policy establishes minimum requirements for documentation that must be submitted for payments to reviewers for their services, as well documents the process to support and justify all changes in the honorarium amount paid to reviewers. **Documentation:** CPRIT's Honorarium Policy		
	Statute/Rule/Other: H&S Code § 102.151(e), 25 T.A.C. § 701.15(4), *CPRIT's Honoraria Policy*		
38 pg 43	**Recommendation:** Implement a documented process to support and justify all changes in the amount of honorarium paid to reviewers.	**Fully Implemented**	09/01/13
	Implementation: CPRIT's CEO adopted CPRIT's Honorarium Policy effective September 1, 2013. The written Honorarium Policy describes the expected duties and responsibilities for Review Council chairs, Review Council members, and peer review panel members, specifies the expected time commitment, and lists the hourly rate comparisons used to develop the honorarium amounts. The policy establishes minimum requirements for documentation that must be submitted for payments to reviewers for their services, as well documents the process to support and justify all changes in the honorarium amount paid to reviewers. **Documentation:** CPRIT's Honorarium Policy		
	Statute/Rule/Other: H&S Code § 102.151(e), 25 T.A.C. § 701.15(1), *CPRIT's Honoraria Policy*		
39 pg 43	**Recommendation:** Ensure that honorarium payment rates are reasonable and competitive for the value CPRIT receives.	**Fully Implemented**	09/01/13

Rec.		Status	Date
	Implementation: CPRIT's CEO adopted CPRIT's Honorarium Policy effective September 1, 2013. The written Honorarium Policy designates other entities that also conduct peer review and pay honoraria and compares and contrasts the roles, responsibilities, and expected time commitment for CPRIT reviewers to these entities to document that CPRIT's honorarium payment rates are reasonable and competitive for the value CPRIT receives. **Documentation:** CPRIT's Honoraria Policy		
	Statute/Rule/Other: H&S Code § 102.151(e), 25 T.A.C. § 701.15(3), *CPRIT's Honoraria Policy*		
Chapter 5 - CPRIT Should Ensure That Its Outsourced Information Systems Maintain Valid and Reliable Grant Management Data			
40 pg 46	**Recommendation:** Obtain audits of the Peer Review Management Information System and CPRIT Application Receipt System and ensure that the grant management contractor corrects all weaknesses identified.	**Incomplete/ Ongoing**	Expected 06/30/14
	Implementation: CPRIT has been working with its grants management contractor, SRA International, to address recommendations identified in the audit with these two SRA systems, the Peer Review Management Information System (P^2RMIS) and the CPRIT Application Receipt System (CARS), as well as the CPRIT grants management system. SRA conducted an internal assessment of P^2RMIS against National Institute of Standards and Technology (NIST) moderate controls in 2011 and SRA has corrected relevant findings. However, there is no formal report documenting the findings, and it was not an independent assessment of the controls in P^2RMIS related to securing CPRIT data. Similarly, a review of CARS was within the scope of an ISO-9000 audit conducted by an independent auditor, Orion Registrar, for SRA in 2012. However, this was not an assessment of the controls for the portion of the system related to securing CPRIT data. CPRIT will have to procure its own audit of the controls for securing CPRIT data in both systems and believes it can be incorporated with the internal audit of the grants management system. An audit report could be completed by June 30, 2014.		
	Statute/Rule/Other: H&S Code § 102.0535(b), 25 T.A.C. § 703.4(3)		
41 pg 46	**Recommendation:** Ensure that the Peer Review Management Information System maintains a complete record of all grant applications that receive a peer review and the scores associated with the review.	**Incomplete/ Ongoing**	Expected 04/01/14
	Implementation: CPRIT has been working with its grants management contractor, SRA International, to address recommendations identified in the audit with these two SRA systems,		

Rec.		Status	Date
	the Peer Review Management Information System (P^2RMIS) and the CPRIT Application Receipt System (CARS), as well as the CPRIT grants management system. The development of requirements and change management require some of the same resources at SRA to ensure that the changes are fully integrated for changes that require data to be carried from one system to another. As part of the implementation of new statutorily required processes, CPRIT has had to re-engineer its procedures and frequency that conflicts of interest have to be indicated by reviewers and stored. Requirements for these P^2RMIS changes will be developed and implemented sequentially over the course of the next three months with completion by April 1, 2014.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(1), 25 T.A.C. § 703.4(1)(B),(C)		
The Legislature Should Consider Clarifying Certain Statutory Requirements to Increase Transparency and Accountability at CPRIT			
42 pg 49	**Recommendation:** Allow peer reviewers to provide their grant recommendations to the CEO and members of the CPRIT oversight committee at the same time.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: CPRIT has revised its administrative rules so that the review council's recommendations are submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. *CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee.* **Documentation:** Review Council written list of recommendations and transmittal letter		
	Statute/Rule/Other: H&S Code § 102.251(a)(1), 25 T.A.C. § 703.6(d)(2)		
43 pg 49	**Recommendation:** Clarify what funds can be used and the intended use of matching funds reported by grantees.	**Fully Implemented**	06/14/13
	Implementation: CPRIT has revised its administrative rules to reflect a process for a grantee that is a public and private institution of higher education to credit toward its matching funds obligation the dollar amount equivalent to the difference between the grantees federal indirect cost rate and CPRIT's five percent indirect cost rate allowance. **Documentation:** Matching Funds Certification		
	Statute/Rule/Other: H&S Code § 102.255(d)(2)(B) & (d)(4), 25 T.A.C. § 703.11		
44 pg 49	**Recommendation:** Clarify whether contributions made by non-profit foundations affiliated with grantees are appropriate.	**Fully Implemented**	06/14/13

Rec.		Status	Date
	Implementation: CPRIT revised its administrative rules to make clear that a grant applicant that makes a contribution to CPRIT or a nonprofit foundation established to benefit CPRIT is ineligible to receive a CPRIT grant. **Documentation:** Grant Pedigree		
	Statute/Rule/Other: H&S Code § 102.251(a)(3), (e), 25 T.A.C. § 703.3(h)(1)		
45 pg 49	**Recommendation:** Prohibit an interlocking directorate between CPRIT and the CPRIT Foundation.	**Fully Implemented**	02/25/13
	Implementation: The Oversight Committee adopted Bylaws prohibiting the presiding officer and vice presiding officer from holding position on the board of directors of a foundation that was established to benefit CPRIT. **Documentation**: Oversight Committee Bylaws		
	Statute/Rule/Other: 25 T.A.C. § 701.5(1)(F), CPRIT Oversight Committee Bylaws § 5.3		
46 pg 49	**Recommendation:** Prohibit CPRIT employees from serving on grantee's board of directors and related foundations.	**Fully Implemented**	02/25/13
	Implementation: The Oversight Committee adopted a Code of Conduct and Ethics to prohibit CPRIT employees, Oversight Committee members, and PIC members from serving on a grantee's board of directors or the board of a related foundation. **Documentation:** Code of Conduct and Ethics		
	Statute/Rule/Other: H&S Code § 102.109((b)(8)(9), 25 T.A.C. § 702.9(c)(2), (11), Code of Conduct § II.B.(15)		
47 pg 49	**Recommendation:** Clarify the positions of the oversight committee's presiding officer and other officers, including the responsibilities and specific term of service for those positions.	**Fully Implemented**	02/25/13
	Implementation: The Oversight Committee adopted Bylaws specifying the term of office and specific responsibilities for the presiding officer, **Documentation**: Oversight Committee Bylaws		
	Statute/Rule/Other: H&S Code § 102.104(c)(1)(2), 25 T.A.C. § 701.5(1)(C)(D), CPRIT Oversight Committee Bylaws § 5.2, 5.3		
48 pg 49	**Recommendation:** Allow members of the oversight committee to affirmatively vote to approve the CEO's recommendations.	**Incomplete/ Ongoing**	Expected 02/2014

Rec.		Status	Date
	Implementation: CPRIT's administrative rules have been changed to provide for a process for the Oversight Committee to affirmatively vote to approve the grant awards recommended by the Program Integration Committee (PIC). *CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee.* **Documentation:** Oversight Committee meeting minutes		
	Statute/Rule/Other: H&S Code § 102.252, 25 T.A.C. § 703.8		
49 pg 49	**Recommendation:** Remove the Attorney General and the Comptroller of Public Accounts from CPRIT's oversight committee so that their statutory duties and responsibilities would not be impaired.	**Fully Implemented**	6/14/13
	Statute/Rule/Other: H&S Code § 102.101(b)(4),(5)		
50 pg 49	**Recommendation:** Allow the CEO to provide CPRIT's oversight committee, along with grant recommendations, documentation of the other factors that the CEO considered for making grant recommendations.	**Incomplete/ Ongoing**	Expected 02/2014
	Implementation: CPRIT has developed a process for the Program Integration Committee (PIC) to document the factors considered in deciding grant recommendations. The rule and process changes implemented by CPRIT are applicable to the PIC and will be implemented for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications (RFAs) released 12/09/2013. *CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee.* **Documentation:** The factors considered by the PIC in deciding on grant recommendations will be submitted to the Oversight Committee at the time that the awards are recommended; the information will be maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.251(a)(2)(A)and (B), 25 T.A.C. § 703.7(3)(A) and (C)		
51 pg 49	**Recommendation:** Require the CPRIT Foundation to make its records, books, and reports available to the public.	**Fully Implemented**	06/14/13
	As of May, 2013, the CPRIT Foundation has ceased operations. Going forward, CPRIT has clarified its administrative rules to require that the records, books, and reports of a nonprofit		

Rec.		Status	Date
	foundation established to benefit CPRIT will be made publicly available.		
	Statute/Rule/Other: H&S Code § 102.262(c), (d), 25 T.A.C. § 701.27(13)		

How Texas' cancer-fighting agency overcame scandal and came back from the dead

Dallas Morning News

August 9, 2013

By: James Drew

AUSTIN — On the eve of this year's legislative session, Texas' cancer-fighting agency was near death.

In the course of a few months, three high-ranking officials of the Cancer Prevention and Research Institute of Texas had resigned. The agency announced it had failed to follow its process in awarding an $11 million grant to a Dallas firm, triggering criminal and civil investigations.

And the state's political leadership had ordered CPRIT to stop awarding grants, mothballing the agency.

The agency responded in December by turning to a pair of state Capitol insiders. Wayne Roberts, who was hired as interim executive director, and consultant Billy Hamilton were assigned to save CPRIT.

Now, after enduring months of legislative intrigue, political attacks and press scrutiny, the small institute appears poised for rebirth. In the next few months, it is expected to resume handing out millions of dollars for cancer prevention, for university research and for companies trying to develop better ways to treat cancer.

Emails and memos obtained from CPRIT by The Dallas Morning News show that by the end of the regular legislative session, the agency credited two legislators for its second chance.

By convincing their colleagues that a complex bill to overhaul CPRIT's operations would provide the necessary safeguards, Sen. Jane Nelson, R-Flower Mound, and Rep. Jim Keffer, R-Eastland, enabled the agency to not only survive but also to get all the money it wanted from the state budget.

Roberts privately mused about the price of that victory, a 38-page bill that Gov. Rick Perry signed into law.

"Something that won't be avoidable is our processes are going to be cumbersome due to all the checks and balances, stop points to check conflicts of interest, and attestations that processes were followed," Roberts said in an email to a member of CPRIT's governing board.

"We and our grant recipients are just going to have to deal with it — price for lousing things up," he added.

Nelson this week said she agrees.

"CPRIT lost the benefit of the doubt, and rightfully so," she said. "The eyes of Texas are now on CPRIT, and they need to see the agency embrace these reforms, put them into action and commit to 100 percent transparency and accountability.

"Yes, these regulations are going to be cumbersome, but they are essential in restoring the public trust — not to mention a whole lot better than being non-existent," Nelson added.

Political interference

In 2007, Texas voters approved a $3 billion program to fight cancer. The state agency created to spend it, CPRIT, became the nation's second-largest source of money for that effort. It trailed only the federal government's National Cancer Institute.

CPRIT didn't attract much scrutiny until May 2012, when its chief scientific officer, Nobel laureate Dr. Alfred Gilman, announced he would step down later that year.

Gilman, former dean of the UT Southwestern Medical School, said he was told to resign after he objected to what he saw as political interference in the awarding of grants.

The controversy simmered for several months. It didn't reach a boil until late last year, when CPRIT said it had awarded $11 million two years earlier to Peloton Therapeutics, a Dallas-based biotechnology firm, without the required business and scientific review.

Bill Gimson, the agency's executive director, resigned soon after.

The Travis County district attorney opened a criminal investigation. Attorney General Greg Abbott said his office would examine potential civil charges.

To replace Gimson, CPRIT's governing board, referred to as the Oversight Committee, chose two Capitol veterans who knew the inner workings of the Legislature.

Roberts, a former budget director for Perry who worked for 18 years at the Legislative Budget Board, was named interim executive director. Hamilton, former deputy comptroller of public accounts, was hired as a senior adviser.

A month after the legislative session began, the state auditor released a scathing report that found flaws in how CPRIT reviewed grant applications, and also raised questions about the agency's ethics.

Nelson worked with Keffer in 2007 on the legislation to create CPRIT. Now they reunited to save it.

Nelson had introduced a bill to overhaul the agency's operations. Shortly after the audit was released, she amended the measure to add the recommendations.

On April 3, the Senate voted 31-0 to approve her bill. But the bigger battle would be in the House.

'Everyone tainted'

Although three high-ranking CPRIT officials had resigned in 2012, none of the Oversight Committee members had stepped down as a result of the problems. They had denied any wrongdoing in the awarding of the three grants totaling $56 million that had contributed to the scandal.

Of the 11 members, six were on the panel when it ratified the Peloton award, including chairman Jimmy Mansour, vice chairman Dr. Joseph Bailes and Houston businessman Charles Tate.

As House members discussed the overhaul bill, it soon became clear there was a desire to sweep away all Oversight Committee members appointed before Jan. 1 of this year.

"Everyone was tainted," Keffer said.

To accomplish the sweep, House members decided to end the staggered terms of all Oversight Committee members on the day the new bill took effect.

That would force the appointing powers — the governor, lieutenant governor and House speaker — to reappoint or pick new committee members. The House also decided to require them to appoint at least one member who is a physician or a scientist with experience in oncology or public health.

The governor's office asked Roberts who was behind that proposal. He replied that Keffer said it "came up repeatedly."

A high-ranking Perry aide floated a counterproposal.

The Oversight Committee would be pared to seven members — all of them appointed by the governor, cutting out the lieutenant governor and speaker. The governor would appoint one member who is a physician or a scientist with experience in oncology or public health.

"Give 7 [governor] appointees, total … and we will accept qualifications for one of them," wrote Mike Morrissey, the governor's deputy chief of staff and senior adviser.

But Perry's office didn't prevail — another reminder of the limitations on the governor's power when the Legislature is in session.

"Let's say we didn't give it a whole lot of thought," Keffer said this week.

The "reboot" of the Oversight Committee that House members crafted was added to the bill. By a 140-3 vote, the House approved it in late May.

"Representative Keffer just called from the House floor to offer his congratulations to all of you," Roberts told CPRIT employees. "Please remember him and Senator Nelson. You owe your jobs to these two public servants."

Perry signed the bill into law.

In recent weeks, a spokesman for Lt. Gov. David Dewhurst said Mansour, Bailes and Tate would not be reappointed. The status of other Oversight Committee members is unclear.

Roberts said some of the committee members are "feeling a little bruised right now."

"They did not act with ill intent," he said. "Things just got away from them, and it happens all the time as you are ramping up new programs. You are interested in getting the program up and going, and the process is not quite as interesting.

"But this is another example of why you have to pay attention to those processes, a lesson to be learned and relearned," Roberts added.

No third chance

The early version of the proposed state budget included no new grant money for CPRIT.

Roberts and Hamilton met with all of the lawmakers whom they predicted would be named to a committee that hashes out conflicting versions of the budget.

In the end, CPRIT got what it wanted — the ability to spend $300 million annually from bond proceeds.

"We kept laying our cards out on the table to the legislators and developed a trust, and the quid pro quo is they agreed to allow us to continue and fully fund us," Roberts said recently.

Roberts said when Perry, Dewhurst and Speaker Joe Straus, R-San Antonio, appoint members of the new Oversight Committee, he anticipates they will lift the 8-month-old freeze on grant awards.

If the new committee members have an interest in his staying, Roberts is open to having "interim" removed from the title of his $212,000-a-year job.

The only reason for pause, Roberts said, is CPRIT will be "real bureaucratic" under the overhaul. But he said the institute did not accept too much regulation in exchange for survival.

"We won't get a third chance," Roberts said. "If we screw this up again, it will be the death knell for it."

The legislation signed into law by Gov. Rick Perry is designed to clarify and strengthen conflict-of-interest provisions at CPRIT. Among its provisions:

CPRIT must maintain "complete records" of the peer review of each grant application, including the score assigned by reviewers.

CPRIT employees, Oversight Committee members and members of a peer review committee must recuse themselves if they or a relative have a "professional or financial interest" in an entity receiving or applying for money.

The oversight committee is reduced from 11 to nine members. The governor, lieutenant governor and House speaker each appoint three members to six-year staggered terms. At least one appointee must be a physician or a scientist with extensive experience in the field of oncology or public health.

A person cannot serve on the oversight committee if he or his spouse owns or controls an interest in a business or organization receiving money from CPRIT.

Oversight committee members are required to disclose to CPRIT each political contribution to a candidate for state or federal office over $1,000 in the five years before they are appointed, and each year until their term expires. CPRIT must post a report of those contributions on its website.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MARGARET KRIPKE, PH.D., CHIEF SCIENTIFIC OFFICER
SUBJECT:	UPDATE OF RESEARCH ACTIVITIES, OVERVIEW OF THE CPRIT SCIENTIFIC RESEARCH PROGRAM AND FUTURE DIRECTIONS, AND RECOMMENDATION FOR RECRUITMENT AWARDS
DATE:	JANUARY 20, 2014

Since the last CPRIT Oversight Committee meeting several actions were taken to restart the Research Program, these are as follows:

1. Five first-time faculty recruitment grants were reviewed by the Research Scientific Review Council (SRC). These grants were submitted prior to the moratorium. These will be presented to the Oversight Committee for approval in this meeting.

2. Requests for Applications (RFAs) for the continuation of 7 Research Training Awards (RTA) and Multi-investigator Research Awards (MIRA) were issued on December 9 and 16, 2013 respectively. The Scientific Review Council (SRC) will discuss the RTA applications on January 31, 2014 and the MIRA applications on February 3, 2014. The recommendations for award will be presented at the February Oversight Committee meeting.

3. New RFAs for the Individual Investigator Research Awards and High Impact/High Risk Awards were issued on December 9, 2013 and are due to be submitted to CPRIT on February 3. These applications will be reviewed by the peer review panels; and applications that are recommended following the peer review process will come to the Oversight Committee for approval. We anticipate that these grants will be presented at the August 2014 meeting.

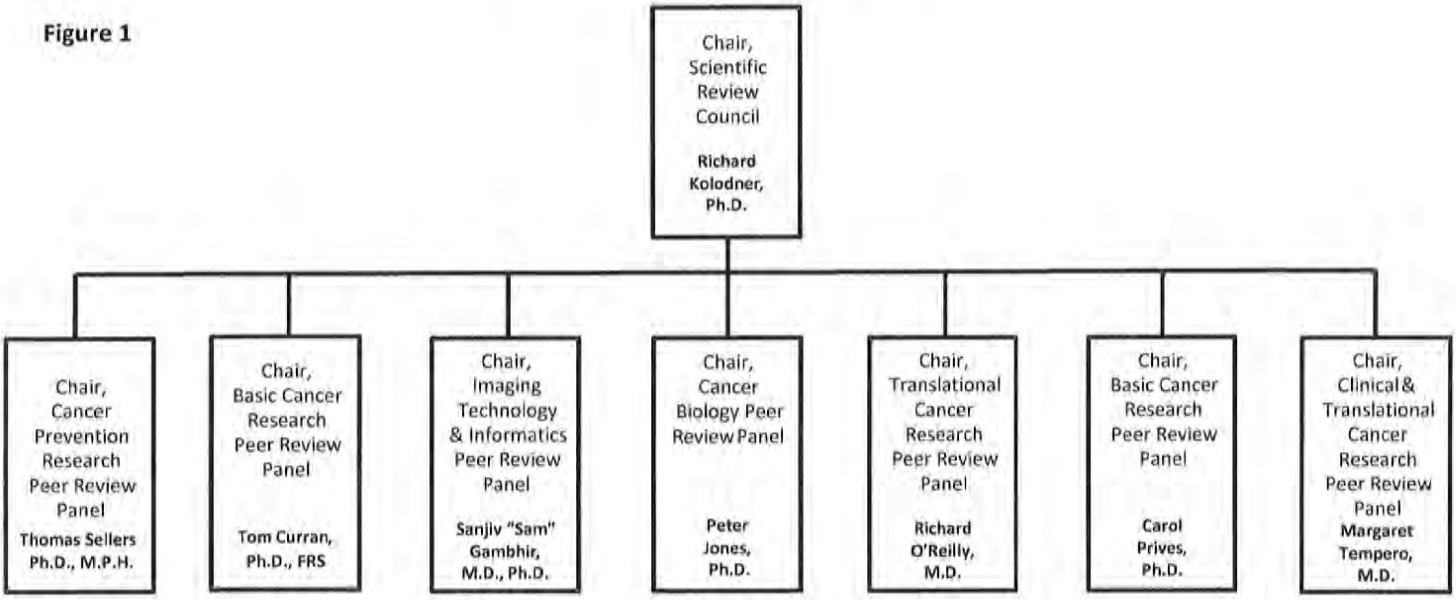
Overview of the CPRIT Scientific Research Grant Program

Goals of the Research Grant Program

The goal of CPRIT's scientific research program is 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. CPRIT's strategy has been to support the most creative ideas and the most meritorious projects, without regard to cancer type or geographic distribution. This has been achieved by assembling 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 the State 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 highly-distinguished cancer researcher. These chairs make up the Scientific Review Council, which is chaired by a world-renown scientist. (Figure 1)

CPRIT Scientific Review Council

Figure 1



Research Grant Mechanisms

CPRIT uses a variety of award mechanisms to achieve the goals of the research program. CPRIT 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. CPRIT 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. Building a critical mass of cancer researchers in the State of 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 post-doctoral fellows are educated to become cancer researchers. A description of these grant mechanisms is shown below in Table 1.

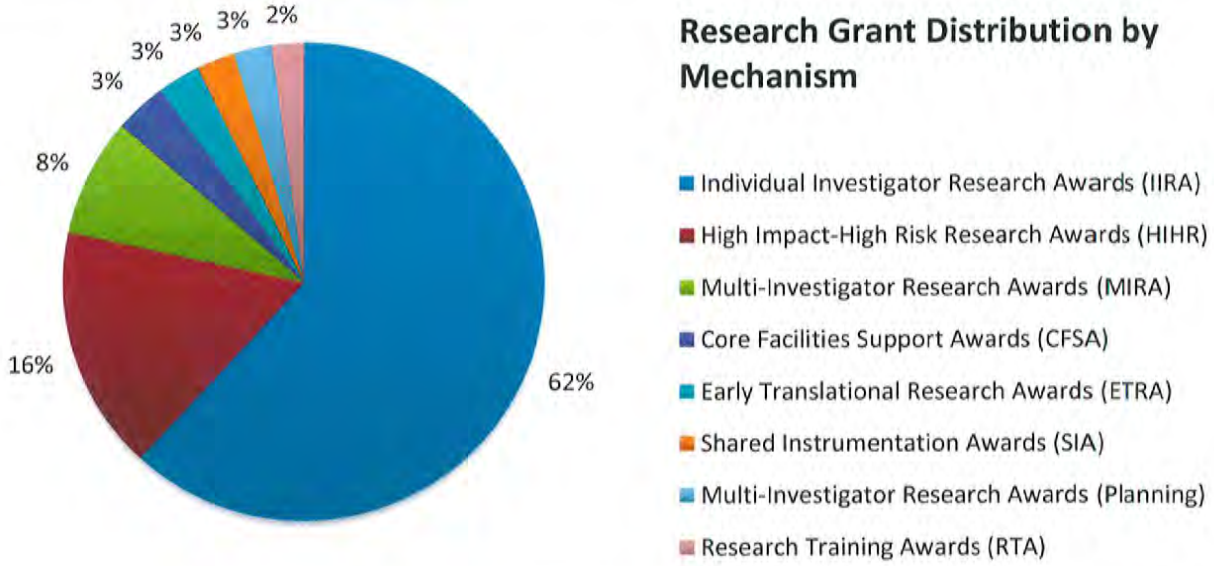
Table 1

Award Mechanism	Award Maximum/ Project Duration	Award Mechanism Description	# of Projects Awarded	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	$182,736,832
Multi-Investigator Research Awards-Planning	Up to $25,000 8 months	Support to assist applicants for the Multi-Investigational Research Award to coordinate 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 career in cancer research. Also supports undergraduate summer research internships and Master's degree-level trainees.	7	$17,690,538
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.	9	$8,283,557
			315	$458,430,154

The Research Grant Portfolio

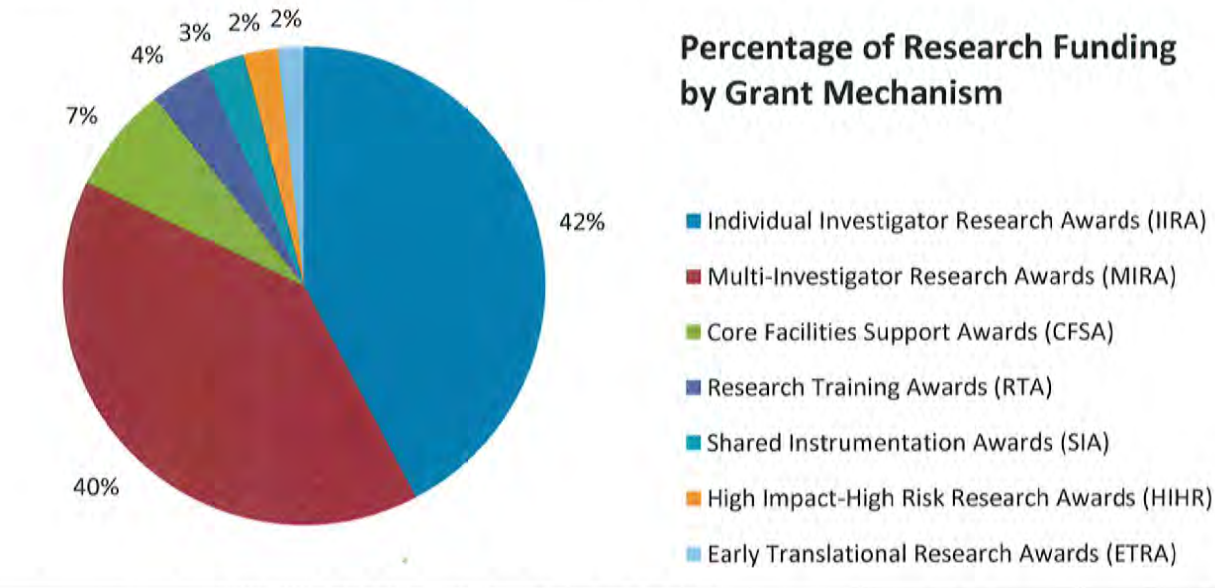
The majority (62%) of research grants funded by CPRIT supports Individual Investigator Research Awards. These 195 awards are designed to fund individual investigators who propose innovative research projects that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. These awards are highly competitive, with only 10% of the applications receiving funding. High Impact-High Risk grants fund 2-year projects designed to explore new avenues in cancer research. Only a limited number of applications is accepted from academic institutions and only 13% of the applications submitted are funded. The remaining 22% of the grants support: Multi-Investigator Research Awards (25) that fund large-scale, cross-disciplinary research programs requiring both innovation and collaboration; Shared Instrumentation (8) and Core Facility Awards (11) that provide infrastructure to support the cancer research of many investigators; Early Translational Research Awards (9) that support projects leading to the development of cancer therapeutic agents, devices, or diagnostics; and Research Training Awards (7) that support the training of the next generation of cancer researchers. (Figure 2)

Figure 2



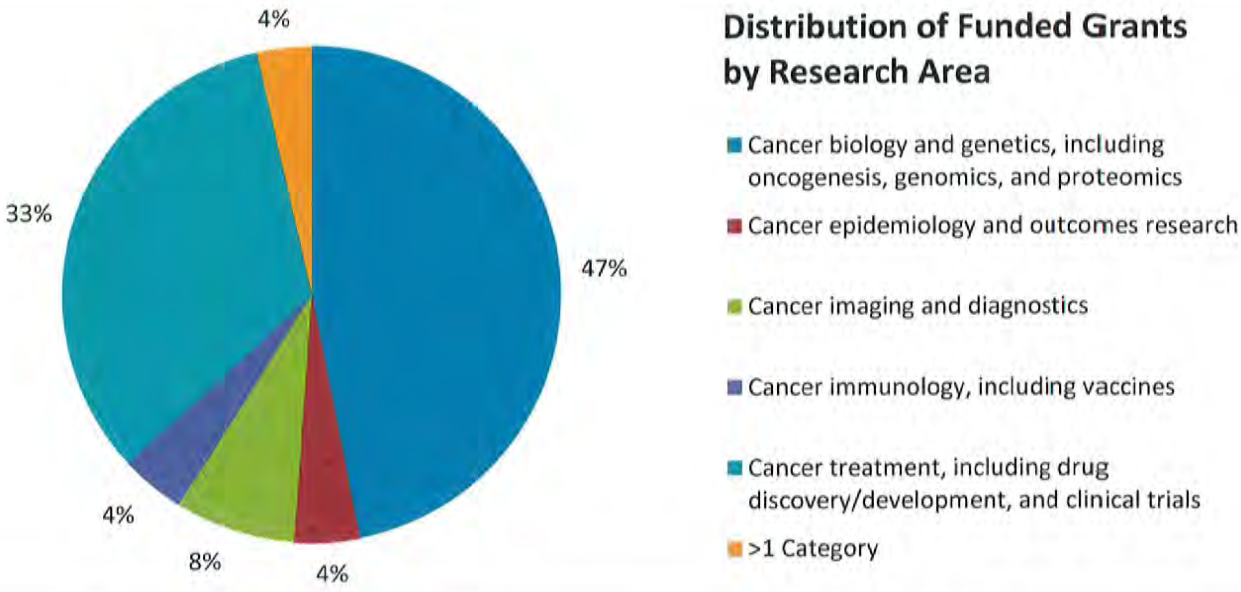
CPRIT has awarded in excess of $458M in research program funding. Approximately $193M has been awarded to 15 institutions in Texas for the IIRA grant program. Fifty-two HIHR awards have been made to 20 institutions, totaling more than $10M. CPRIT has awarded almost $183 to support 25 MIRAs that encompass 158 individual projects. The remaining $72M has been distributed among smaller programs. (Figure 3)

Figure 3



The subject matter of research grants is quite broad and encompasses nearly all areas of cancer research. Roughly 47% of the funded grants address problems in basic science, including cancer biology, genetics, carcinogenesis, and proteomics, 33% involve translating research findings into clinical use or products for treating cancer, and the remaining 20% address cancer epidemiology and outcomes research, cancer imaging and diagnostics, and cancer immunology including vaccine development. (Figure 4)

Figure 4



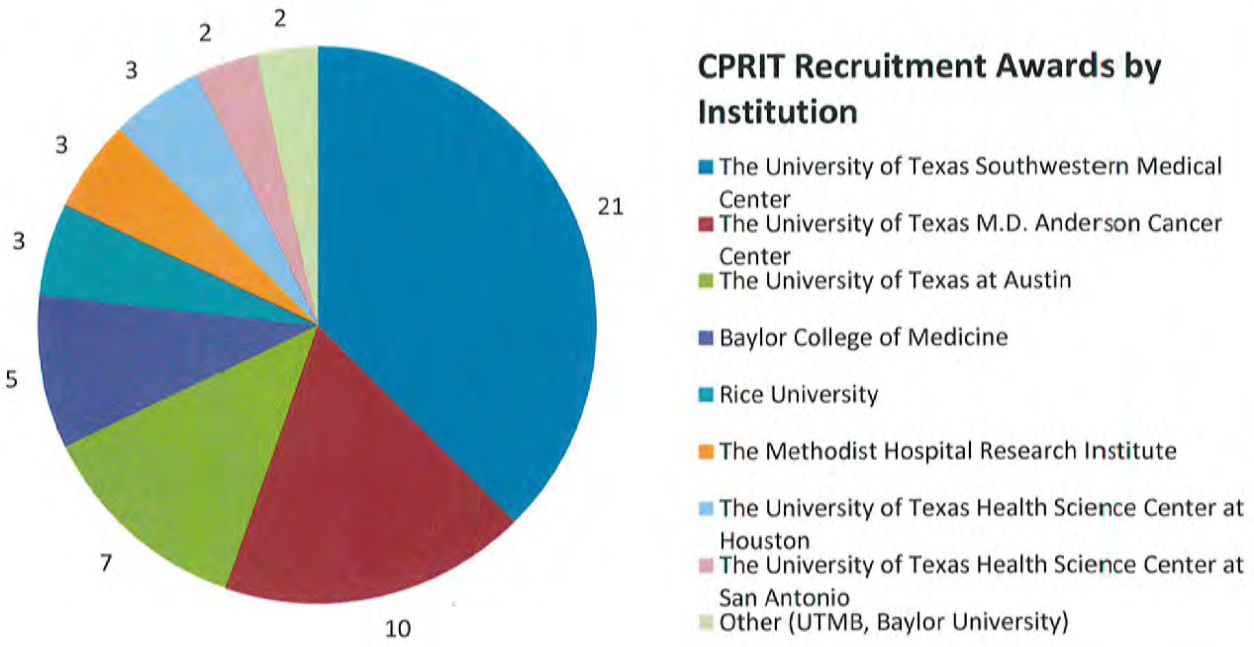
Recruitment Grants

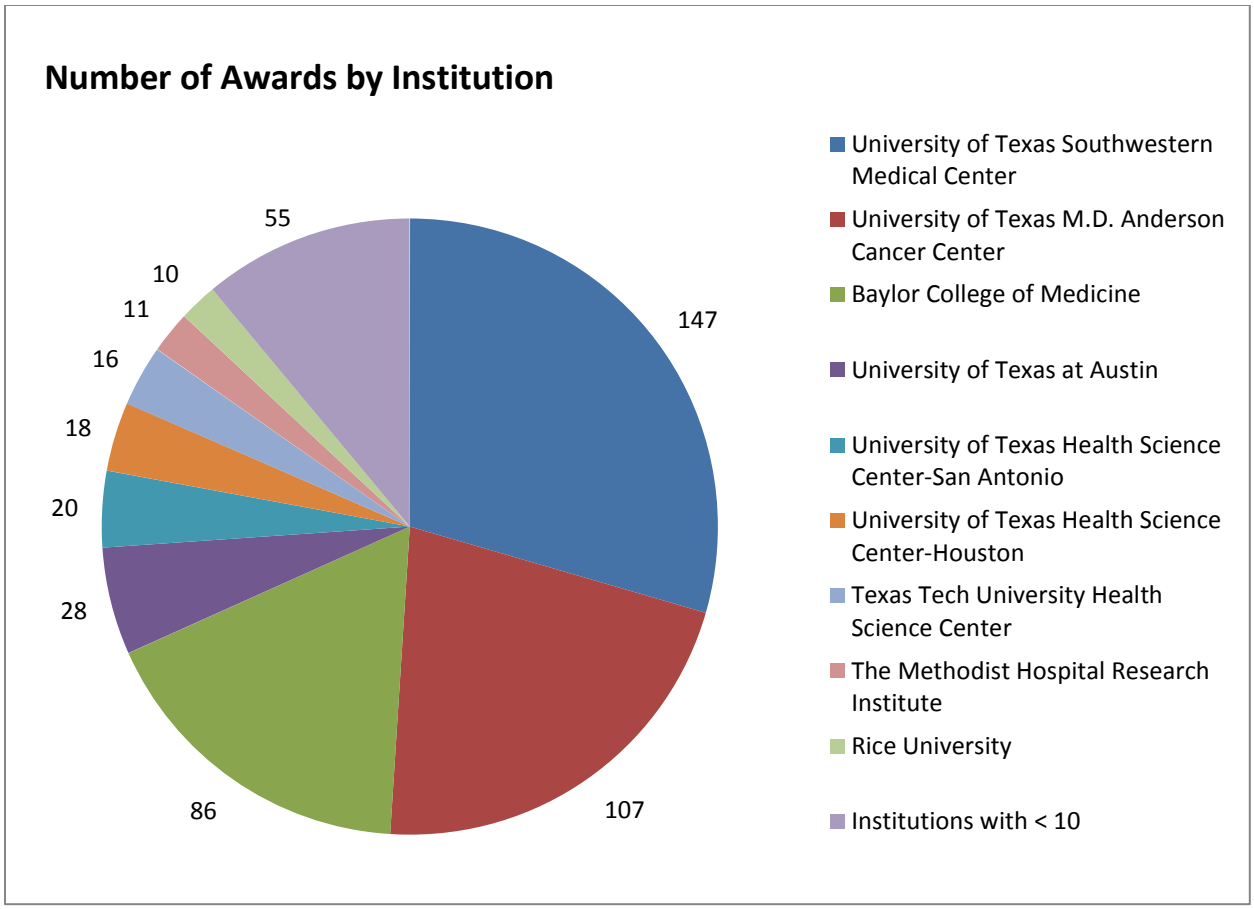
Building a critical mass of cancer researchers in the State of Texas is addressed by supporting recruitment of cancer scientists and clinicians, at all career levels, to academic institutions in Texas and through training programs in which pre- and post-doctoral fellows are educated to become cancer researchers. Since its inception, CPRIT has supported the recruitment of 56 outstanding cancer researchers to 10 academic institutions in Texas. (Table 2/Figure5) This program has been highly successful in enhancing Texas' cancer research efforts and increasing the external visibility of the State in this field.

Table 2

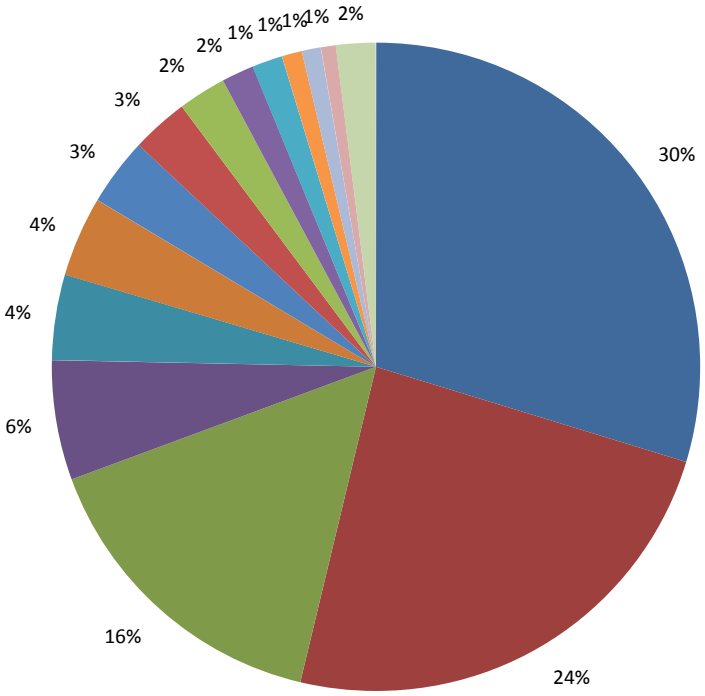
Award Mechanism	Award Maximum/ Duration	Award Mechanism Description	# of Recruits	Total Award Amounts
Recruitment of Established Investigators	Up to $10M 5 years	Support to recruit senior research faculty with distinguished professional careers and established cancer research programs.	14	**$78,715,750**
Recruitment of First-Time, Tenure-Track Faculty	Up to $2M 5 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**
			56	**$169,120,657**

Figure 5


CPRIT Recruitment Awards by Institution
21
10
7
5
3
3
3
2
2
The University of Texas Southwestern Medical Center
The University of Texas M.D. Anderson Cancer Center
The University of Texas at Austin
Baylor College of Medicine
Rice University
The Methodist Hospital Research Institute
The University of Texas Health Science Center at Houston
The University of Texas Health Science Center at San Antonio
Other (UTMB, Baylor University)

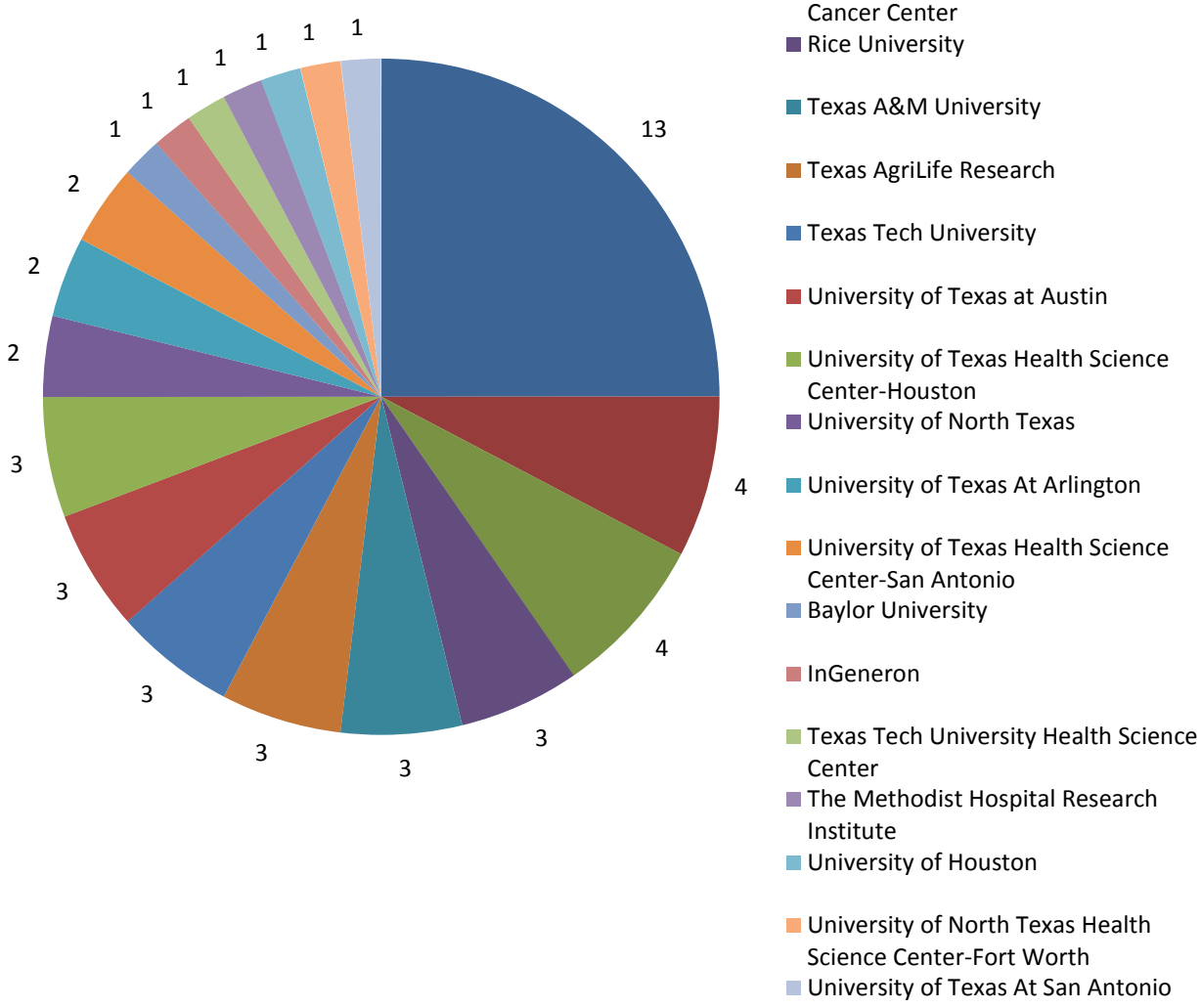

Number of Awards by Institution
147
107
86
28
20
18
16
11
10
55
University of Texas Southwestern Medical Center
University of Texas M.D. Anderson Cancer Center
Baylor College of Medicine
University of Texas at Austin
University of Texas Health Science Center-San Antonio
University of Texas Health Science Center-Houston
Texas Tech University Health Science Center
The Methodist Hospital Research Institute
Rice University
Institutions with < 10

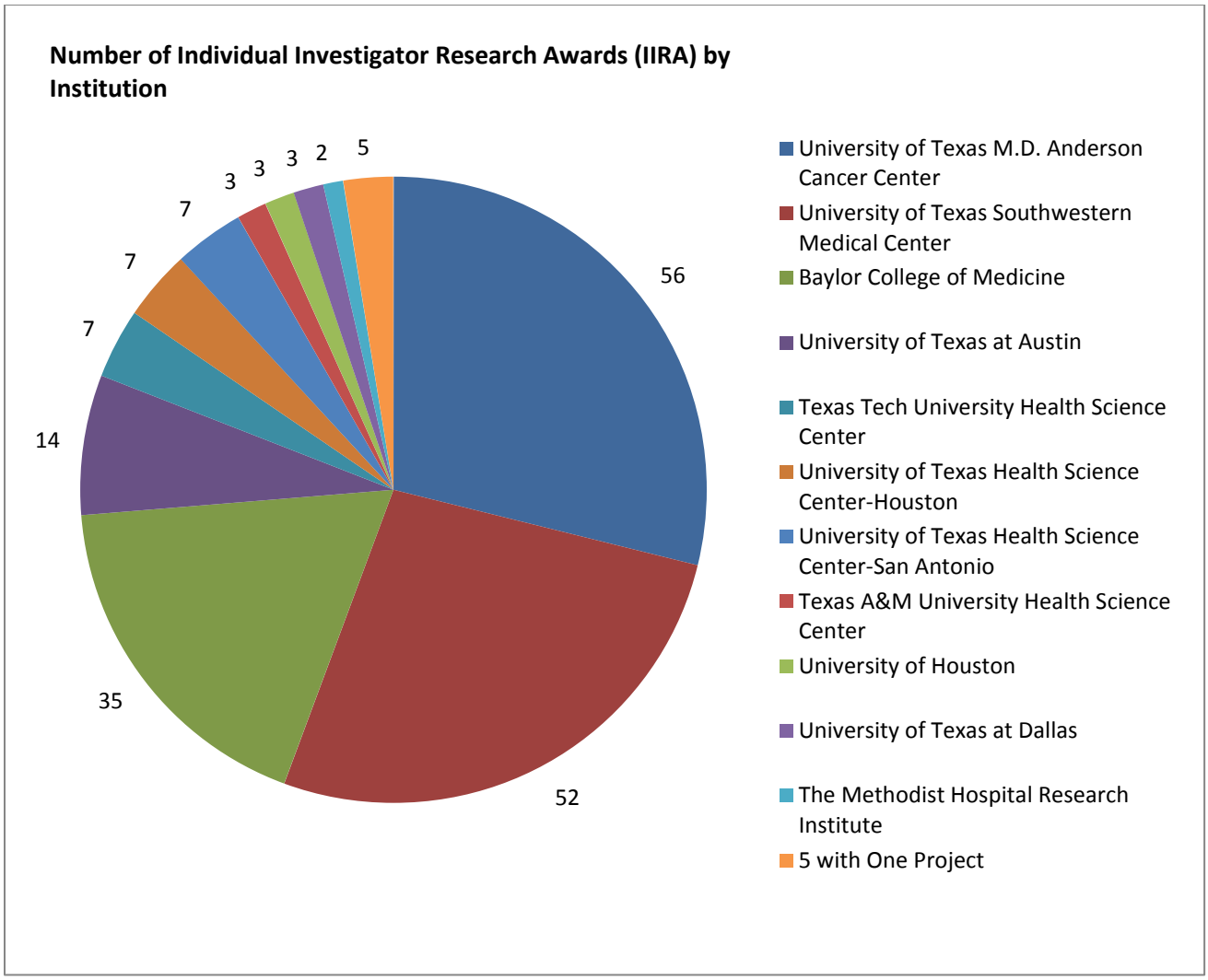
Percentage of Funding by Institution

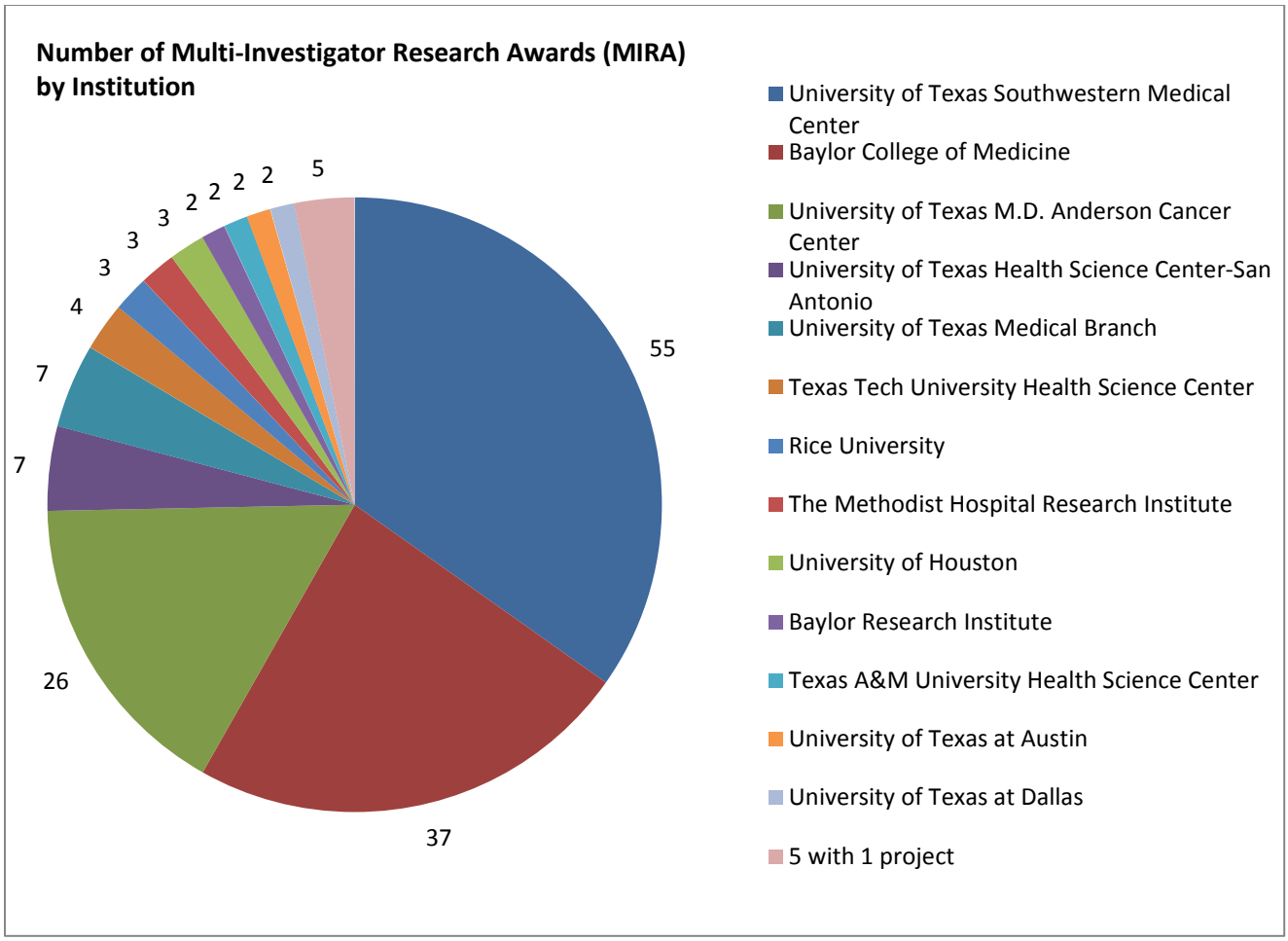


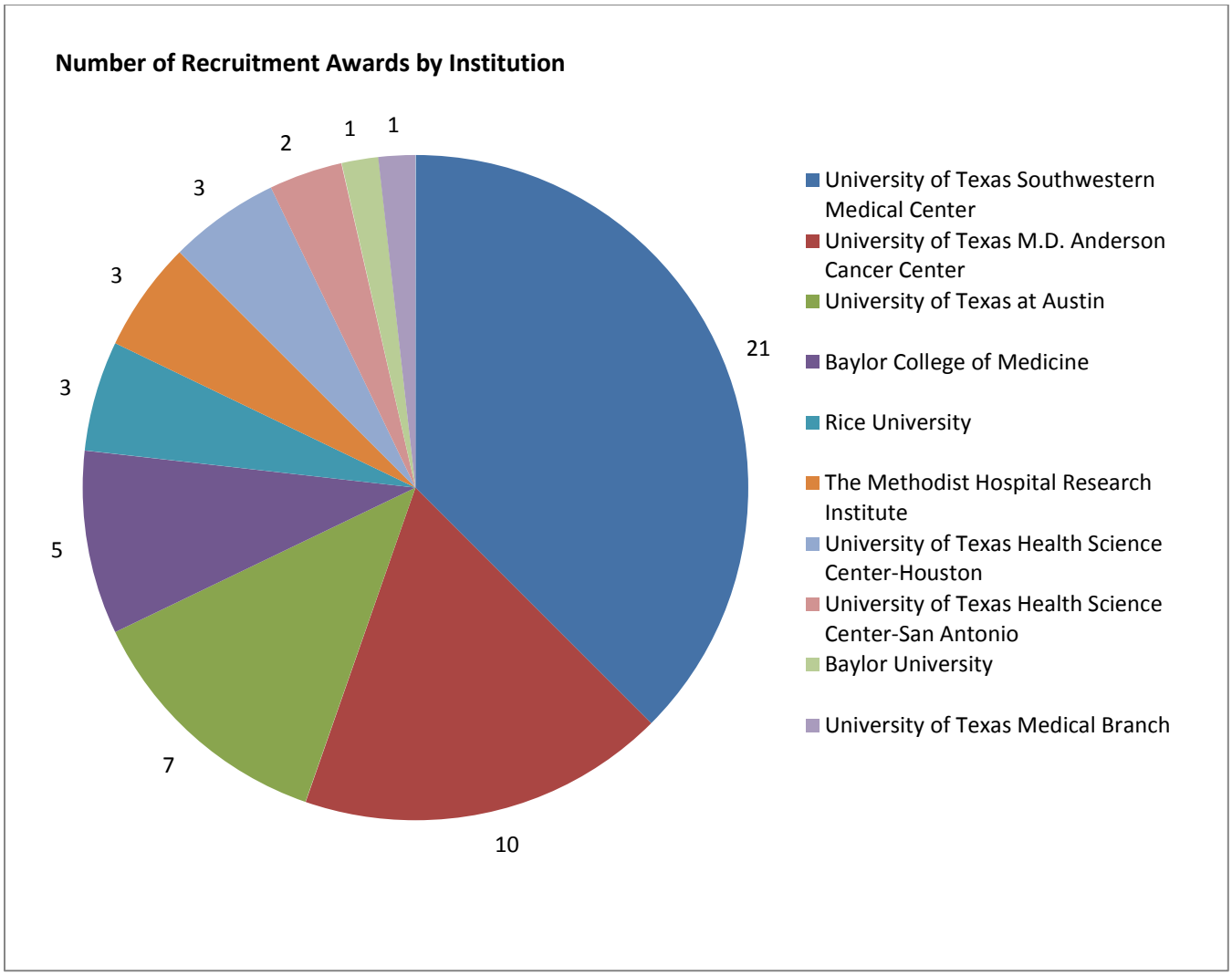
- University of Texas Southwestern Medical Center
- University of Texas M.D. Anderson Cancer Center
- Baylor College of Medicine
- University of Texas at Austin
- The Methodist Hospital Research Institute
- Rice University
- University of Texas Health Science Center-Houston
- University of Texas Health Science Center-San Antonio
- Texas Tech University Health Science Center
- Texas A&M University Health Science Center
- University of Houston
- University of Texas at Dallas
- University of Texas Medical Branch
- Baylor University
- Institutions receiving < 3% of total funding

Number of High-Impact, High-Risk Research Awards (HIHR) by Institution




Number of Individual Investigator Research Awards (IIRA) by Institution
56
52
35
14
7
7
7
3
3
3
2
5
University of Texas M.D. Anderson Cancer Center
University of Texas Southwestern Medical Center
Baylor College of Medicine
University of Texas at Austin
Texas Tech University Health Science Center
University of Texas Health Science Center-Houston
University of Texas Health Science Center-San Antonio
Texas A&M University Health Science Center
University of Houston
University of Texas at Dallas
The Methodist Hospital Research Institute
5 with One Project


Number of Multi-Investigator Research Awards (MIRA) by Institution
55
37
26
7
7
4
3
3
3
2
2
2
2
5
University of Texas Southwestern Medical Center
Baylor College of Medicine
University of Texas M.D. Anderson Cancer Center
University of Texas Health Science Center-San Antonio
University of Texas Medical Branch
Texas Tech University Health Science Center
Rice University
The Methodist Hospital Research Institute
University of Houston
Baylor Research Institute
Texas A&M University Health Science Center
University of Texas at Austin
University of Texas at Dallas
5 with 1 project


Number of Recruitment Awards by Institution
21
10
7
5
3
3
3
2
1
1
University of Texas Southwestern Medical Center
University of Texas M.D. Anderson Cancer Center
University of Texas at Austin
Baylor College of Medicine
Rice University
The Methodist Hospital Research Institute
University of Texas Health Science Center-Houston
University of Texas Health Science Center-San Antonio
Baylor University
University of Texas Medical Branch

Future Directions: The Challenge for CPRIT 2.0

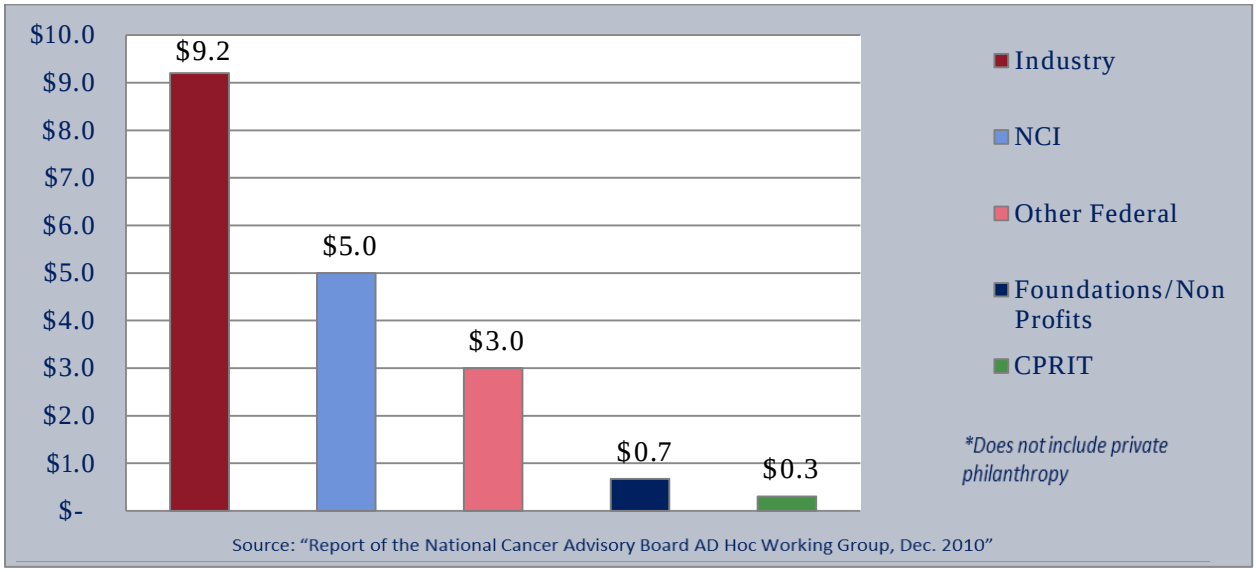
The Challenge for CPRIT 2.0: Reducing the Burden of Cancer through Research

Introduction

The mission of CPRIT's Scientific Office is to support research that leads to reductions in cancer incidence, morbidity, and mortality. In its first four years of operation, CPRIT's research programs focused mainly on investigator-initiated, basic and translational research projects and on recruitment of talented cancer researchers to the State of Texas. The direction of research was determined solely by the quality of the proposals received. The high quality of the research funded and recruitment candidates selected was ensured by the superb peer review system created by the previous Chief Scientific Officer for this purpose.

As CPRIT enters its second phase of operation, it is necessary to ask whether there are ways to accelerate progress in cancer research beyond those previously employed. Although the CPRIT investment represents an enormous commitment of research funds by and within the State of Texas, it is only a small fraction of the amount spent on cancer research across the USA by pharmaceutical companies, federal agencies, and foundations. Therefore, CPRIT funds must be deployed strategically if they are to make a real difference in reducing the burden of cancer. Adding incrementally to the types of cancer research funded by other agencies will not achieve this goal.

Cancer Research Funding*



Guiding Principles

Going forward, two principles should guide the awarding of CPRIT funds. The first is scientific excellence. This has been the cornerstone of CPRIT-funded research from the start. It can only be maintained by continuing to engage senior, distinguished researchers as peer reviewers of the research proposals and recruitment grants and by ensuring a transparent process free of conflicts of interest.

The second principle is impact on cancer. Excellence and the creation of new knowledge are insufficient for research to make a noticeable impact on the cancer problem. CPRIT-funded research must address questions whose answers have the potential to reduce cancer incidence, morbidity, and mortality. This can be achieved by recruiting scientists and clinicians who are dedicated to reducing the burden of cancer as chairs of the peer review committees, by increasing the number of peer reviewers who work directly on the cancer problem, and by the addition of a cancer advocate on each peer review panel. The funding of projects and recruits that are of both high quality and high impact on cancer should be the major goal of the CPRIT grant program.

Areas of Opportunity

The strategic focus of CPRIT's research programs should be primarily in areas that are not well represented in other funding portfolios. Developing a unique niche for CPRIT in such areas would provide benefits beyond simply adding an incremental amount of funding directed at the cancer problem.

Cancer Prevention and Early Detection

A major opportunity for investment in cancer research is the area of cancer prevention. Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence. This has the added advantage of sparing people and families from the psychological and emotional trauma of a cancer diagnosis, the often devastating physical consequences of cancer therapies, and the financial burdens associated with cancer treatment. This is best illustrated by the problem of lung cancer. Little progress in reducing mortality from lung cancer has been made in the past half-century. If a curative targeted therapy for bronchial adenocarcinoma suddenly became available, this would reduce lung cancer mortality by about 35%, which would represent a remarkable advance. On the other hand, if we could eliminate tobacco use, 80% of deaths from lung cancer and 30% of deaths from all cancers would be avoided, along with the financial and emotional consequences of cancer treatment. Thus, approaches to cancer prevention can bring major reductions in the cancer burden, although these reductions would not be apparent for one to two decades.

A second consideration is that thus far, our attempts to control cancer by chemotherapy and even targeted therapies have been thwarted by the ability of cancer cells to develop resistance. The plasticity, genetic instability, and mobility of cancer cells provide daunting barriers to attempts to cure cancer, particularly late stage, metastatic disease. Intervening in the process at earlier stages of cancer development, before genetic instability becomes widespread, holds greater promise of successfully eliminating cells destined to become cancer cells. Basic research on the identification and control of premalignant cells, the role of the tumor cell microenvironment in tumor development, environmental drivers of malignancy, and predictive markers for tumor progression hold promise of providing new avenues for intervening early in the process of cancer development. Such areas of cancer research receive little funding relative to that devoted to curing advanced cancer, even as advances in technology are providing new opportunities for progress in these areas.

Early detection is another approach that has proven to be instrumental in reducing cancer morbidity and mortality. Cutaneous melanomas, when detected early, can be cured by surgery alone. However, once melanoma has spread to distant organs, treatment is complex, invasive, and frequently not curative. In fact, the lack of progress in curing lung, liver, and pancreatic cancers is due in large part to the fact that these cancers are most often diagnosed late in the course of the disease when surgery is not curative. Thus, detecting cancer early in its development is a highly desirable approach to cancer control. More work in this area is sorely needed.

It is important to note that by statute, CPRIT expends 10% of its budget on cancer prevention. However, its programs focus exclusively on the delivery of evidence based prevention interventions—interventions that research has shown to be effective. These interventions include public and professional education and training on cancer prevention, early detection, and survivorship, and clinical preventive services, such as screening for breast, cervical and colorectal cancer, vaccination, and tobacco cessation programs. The program does not fund prevention research, and although historically, the research program has supported some prevention research, it has been minimal. There is a unique opportunity for the research and prevention programs to fund research on behavioral change, effectiveness of various interventions, and how best to deliver prevention and survivorship services to culturally diverse populations, and then move this research into practice through the prevention program.

Orphan Diseases and Intractable Cancers

In the past few decades, considerable attention has been devoted to research on breast and prostate cancers. This is appropriate, considering their prevalence in the population and the interest of advocacy groups and cancer survivors in curing these diseases. However, research on certain other types of cancer, such as pediatric cancers, esophageal cancer, and sarcoma has languished, for a variety of reasons. For example, pharmaceutical companies are reluctant to invest in treatments for rare cancers, the so-called orphan diseases, because of the small return on the investment, compared with other cancers. Such cancers are also difficult to study because of their infrequency in the population and the limited availability of tumor tissue. Other cancers have simply been resistant to conventional therapies, such as lung, liver, pancreas, and brain cancers, and new approaches are needed if progress is to be made. Thus, rare cancers and cancers that are difficult to treat would seem to be another appropriate niche for CPRIT funding.

Bridging the Gap

One well-documented impediment to bringing the benefits of basic research to bear on the cancer problem is the lack of funding to translate new discoveries into practical advances for cancer patients. Considerable research and development are needed between the stages of discovery science, traditionally funded by grants from federal sources and foundations, and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals, traditionally funded by private industry. Such translational research is underfunded and would benefit from additional investment. Funding such research and development by CPRIT could have the added advantages of stimulating public-private partnerships and bringing new commercial investments to the State. Funding translational research that bridges the gap between basic research and product development represents another opportunity for strategic investment by CPRIT.

Meeting the Challenge

To address the challenge of reducing the burden of cancer through research, the following **Research Program Priorities** are proposed:

1. Continue to fund a broad range of innovative, investigator-initiated research projects that will reduce the incidence, morbidity, and mortality of cancer.
2. Increase CPRIT funding in areas not well represented in other research portfolios, including:
    - Cancer prevention and early detection
    - Rare cancers (e.g., pediatric cancer, sarcoma, esophageal cancer)
    - Intractable cancers (lung, liver, brain, and pancreas)
    - Translational research that bridges the gap between basic science and product development.
3. Recruit superb scientists whose work has a high potential impact on cancer.

The tactics that will be employed to achieve a more focused research program are the following:

1. Ensure that the review panel members and chairs understand and support the new strategic agenda.
2. Appoint a cancer advocate as a member of each review panel to maintain the focus on human cancer.
3. Create a new review panel for prevention and early detection research to review applications in these areas.

4. Develop new RFAs for prevention, epidemiology, and early detection research, in collaboration with the Chief Prevention Officer.
5. Target some of the RFAs toward rare cancers and intractable cancers.
6. Continue to offer Early Translational Research Awards.
7. Focus recruitment awards on individuals whose work has a high potential to reduce the burden of cancer.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE
FROM: MARGARET KRIPKE, PH.D., CHIEF SCIENTIFIC OFFICER
SUBJECT: RESEARCH GRANT RECOMMENDATIONS
DATE: JANUARY 15, 2014

Summary and Recommendation:

The Oversight Committee should ratify the CEO's grant award recommendations for 3 recruitment awards totaling $6,000,000. The grant mechanism underlying these recommendations is as follows:

- **First-time Tenure Track Faculty Members**

The applications were submitted in response to a CPRIT request for application (RFA) issued in 2012. However, due to the moratorium and the dissolution of the Scientific Review Council, these applications were not reviewed until December, 2013.

Background:

The aim of the recruitment awards is to bolster cancer research in Texas by providing financial support to help attract outstanding researchers to the State. The awards under consideration are for promising investigators who are pursuing their first faculty appointment at the level of assistant professor (Recruitment of First-time Tenure Track Faculty Members). The candidates must have demonstrated academic excellence, innovation, excellent training, a commitment to pursuing cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

The new Scientific Review Council reviewed 5 applications on December 20, 2013 and recommended that 3 be forwarded to the CEO for transmission to the Oversight Committee for their approval.

SB 149 directs that the law in effect at the time the application was submitted governs the review process. The Program Integration Committee (PIC) was created by SB 149, so in accordance with the legislative directive, there is no PIC review of these applications. In addition, consistent with the process in place at the time that these applications were submitted, the Oversight Committee will not vote to approve each application recommended by the PIC. Instead, the Oversight Committee is authorized to reject this slate of proposed grant awards by a two-thirds vote of the Committee. Nothing limits the Committee from discussing one or more recommendations on the slate individually.

Funding for these awards will come from the amount allocated for research grants in FY2014.

Information for this item has been provided under separate cover.

Cancer Prevention and Research Institute of Texas

Prevention Program Report

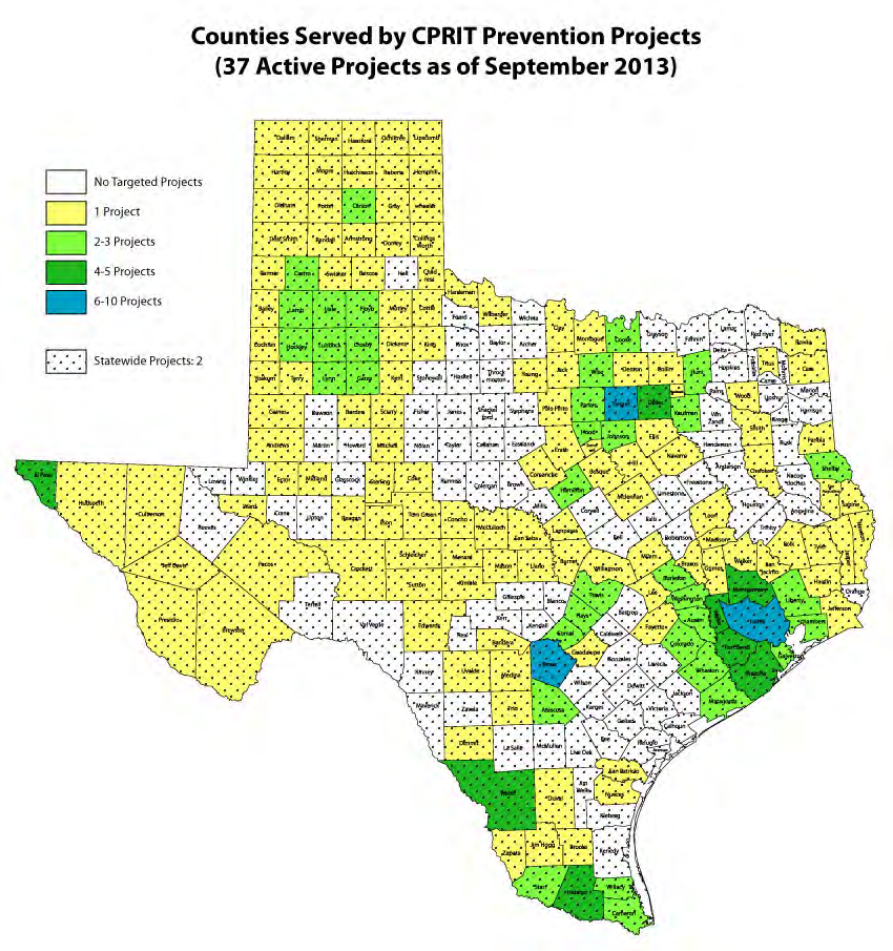
Rebecca Garcia, PhD, Chief Prevention and Communications Officer

Prevention Program Overview

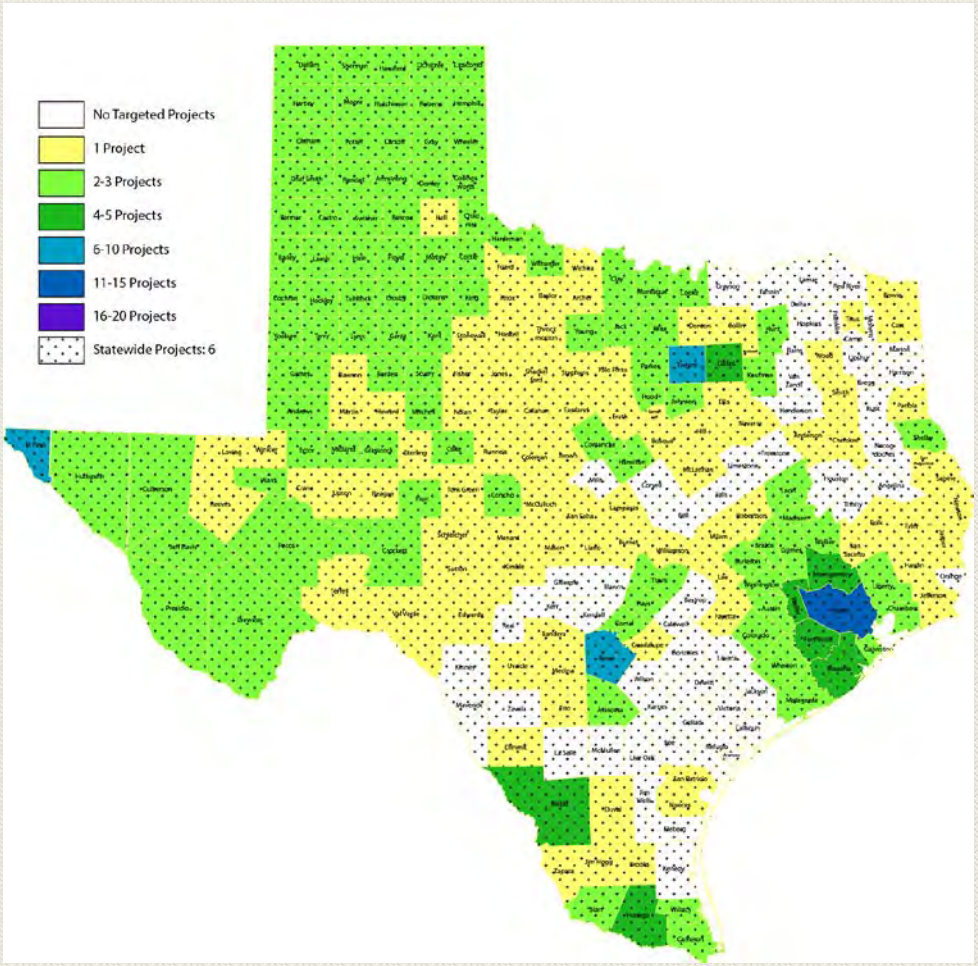
10% of CPRIT funding~$30M a year

- Evidence-based programs and services; not research
- Focus on underserved populations
- Support primary, secondary, tertiary prevention
- Address any cancer type that has evidence-based prevention intervention

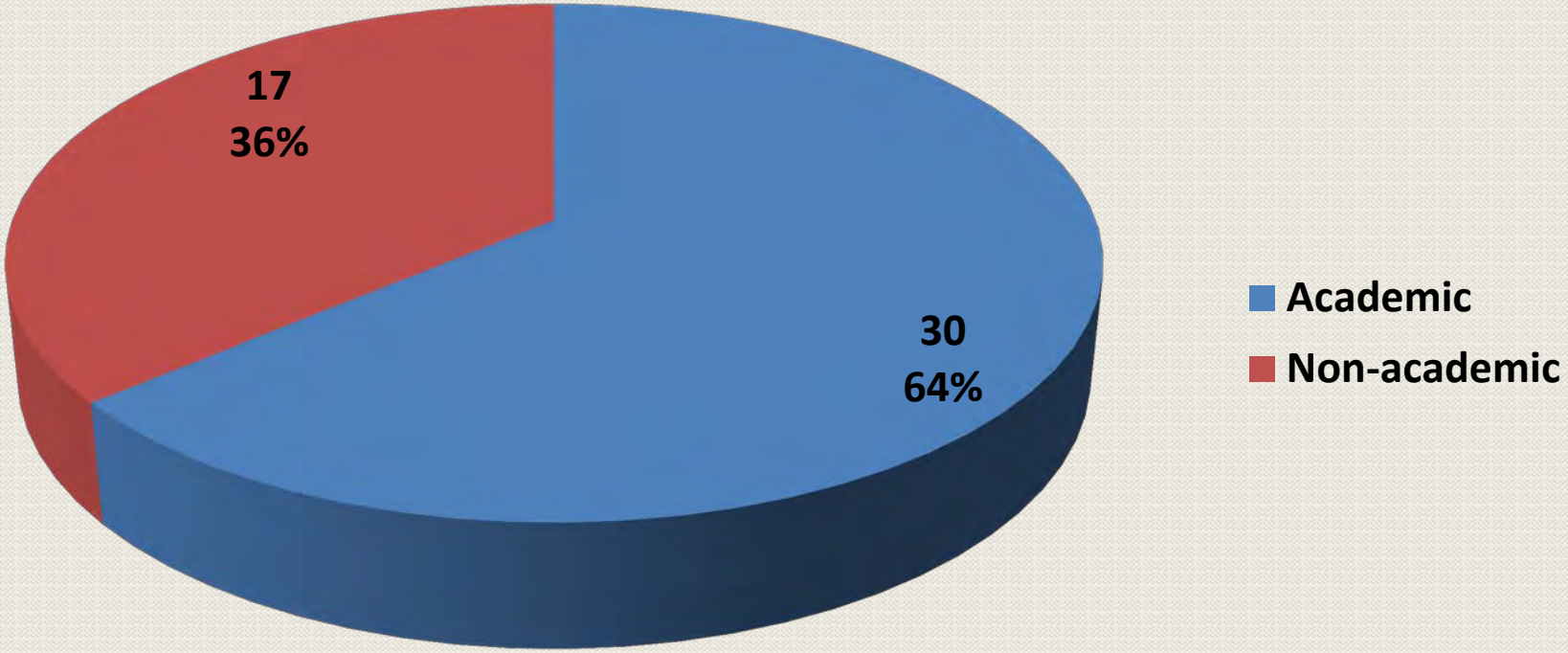
Geographic Coverage
Grants active (37) as of September 2013



Geographic Coverage
Current Portfolio -47 Projects

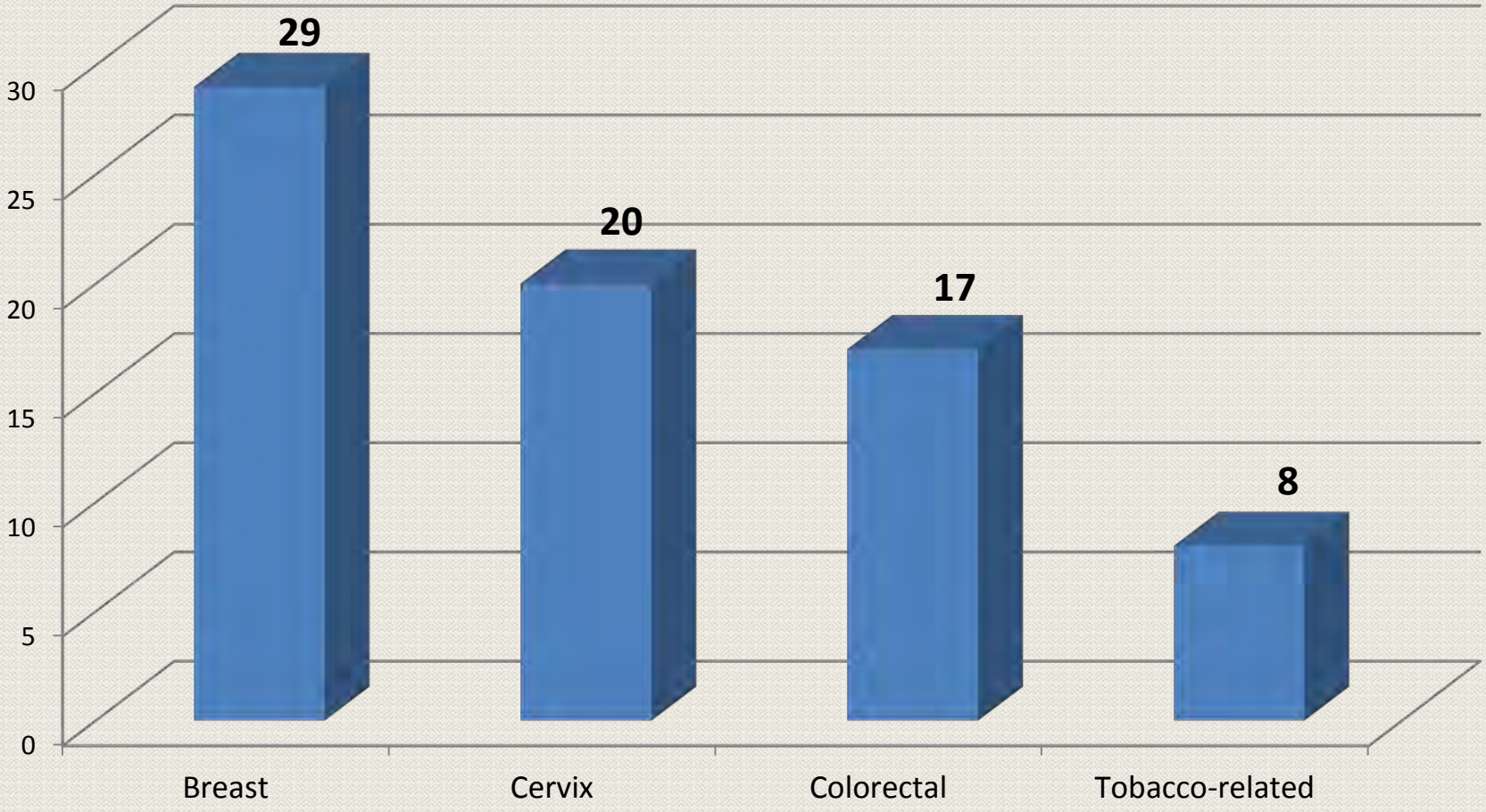


Current Portfolio-47 Projects
of Projects by Organization Type



Current Portfolio- 47 Projects

of Projects by Cancer Type



Review timeline

Post RFAs (EBP, CCE, PE)	12/9/13
Application Deadline	2/27/14
Reviewer COI and assignments	3/25/14
Critiques due	4/29/14
Peer review panel meetings start	5/5/14
Peer review panel meetings end	5/7/14
Prevention Review Council (PRC) meeting	6/27/14
Forward PRC recommendations to PIC and OC	7/14
PIC forwards recommendations to OC	7/14
OC Meeting	8/20/14

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE
FROM: AMY MITCHELL, CHAIR BOARD GOVERNANCE SUBCOMMITTEE
SUBJECT: CONFERENCE RFP
DATE: JANUARY 24, 2014

Recommendation:
That staff be directed to release an RFP to solicit proposals for venues and dates in 2015 and 2016 for a CPRIT Conference.

Discussion:
At its November 22, 2013 meeting, the Oversight Committee approved the release of a Request for Proposals to solicit venues in major Texas cities to hold a potential November 2014 CPRIT conference.

After careful consideration, CPRIT staff recommends that given other agency priorities, available staff resources, and the lead time it would take to implement a conference in 2014, it would not be in the best interest of the agency to hold a conference in 2014. This concern was discussed with the Governance Subcommittee on January 7, 2014, where there was agreement with the staff concerns.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE INTERIM CHAIR

SUBJECT: INTENTION TO RECOMMEND APPROVAL OF THE FINAL ORDERS ADOPTING ADMINISTRATIVE RULE CHANGES

DATE: JANUARY 20, 2014

Summary and Recommendation:

The Board Governance subcommittee recommends that the Oversight Committee vote to approve new CPRIT administrative rules and rule changes at its January 24, 2014 meeting. The Board Governance Subcommittee discussed the new rules and rule changes with CPRIT's General Counsel, Kristen Doyle, at its meeting on January 7, 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 January 7, 2014, to discuss the new administrative rules and rule changes proposed for adoption.

The extensive changes made to CPRIT's administrative rules implement State Auditor recommendations and adapt agency practices to legislative requirements enacted by Senate Bill 149. The proposed administrative rule changes were provisionally approved by the Oversight Committee at the November 1, 2013, meeting and were released for public review later that month. Ms. Doyle summarized the public input related to the rule changes and proposed three revisions to make the rules consistent with the recommendations.

The Board Governance Subcommittee has considered the proposed administrative rules as revised and recommends that the Oversight Committee approve the new rules and rule changes as proposed in the final orders formally adopting the changes. The new rules and rule changes set expected conduct and performance requirements, including increasing transparency and accountability at all levels. Full implementation of these new rules and rule changes will help to restore credibility and public confidence in CPRIT's grant making process.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: AGENDA ITEM #8 - ADOPTION OF CHANGES TO CPRIT'S ADMINISTRATIVE RULES
DATE: JANUARY 20, 2014

Summary and Recommendation:

I recommend that the Oversight Committee approve final orders adopting new administrative rules and rule changes for Chapters 701 – 704 in the Texas Administrative Code, including rule revisions suggested by the public. The Oversight Committee should also approve an implementation plan that will permit adequate time to inform, educate and train grantees regarding new requirements and enforcement tools included in the new rules. The extensive changes made to CPRIT's administrative rules implement the State Auditor's recommendations and update agency practices to comply with legislative requirements enacted by SB 149.

Rulemaking Background:

A state agency with rulemaking authority may adopt new administrative rules or changes to existing rules following a process set out in the Texas Government Code. The process begins with the agency notifying the public via publication of proposed rules and rule changes in the *Texas Register,* a weekly publication of the Secretary of State. The agency must consider any input from the public before it may officially adopt the proposed changes. The agency can act upon the public input by incorporating the recommendation into the text of the final rule when the rule is adopted. However, if the agency decides not to make a change suggested by the public, then Texas law requires the agency to explain why the change will not be made and include the justification as part of the final order approving the rules. The agency's rule change is formally adopted and included in the Texas Administrative Code once a final order approving the change has been filed with the Secretary of State.

Changes to CPRIT's Rules

The Oversight Committee is statutorily authorized to adopt administrative rules to carry out the directives of Health & Safety Code Chapter 102. CPRIT initiated a major rulemaking project on November 1, 2013, when the Oversight Committee approved public release of proposed amendments and new rules. The proposed revisions implement 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, and conform agency practices to legislative requirements enacted by the 83rd Legislative Session. The changes affect each of the four chapters dedicated to CPRIT in the Texas Administrative Code: Chapter 701 *Policies and Procedures*, Chapter 702 *Institute Standards on Ethics and Conflicts, Including Acceptance of Gifts and Donations to the Institute*, Chapter 703 *Grants for Cancer Research and Prevention*, and Chapter 704 *Texans Conquer Cancer Program*. As part of the revisions process, CPRIT proposed deleting Chapter 704 in its entirety.

Adopting the proposed changes for Chapters 701 – 703 increases the number of CPRIT's administrative rules from 33 rules to 48 rules. In addition to substantive changes made to 19 existing rules, there are 18 new rules. The new rules and rule changes address 37 of the 41 State Auditor's recommendations for CPRIT.

An overview describing each chapter and significant rules changes is provided at the end of this memo.

Public Input

CPRIT's proposed rule changes were published in the *Texas Register* on November 15, 2013, and posted on CPRIT's website. Public feedback was solicited through December 16, 2013. CPRIT received written comments from three groups: University of Houston System (UH), Texas Tech University System (TTUS), and the Crosetto Foundation to End Premature Cancer Deaths (Crosetto Foundation). UH and TTUS suggested changes to proposed rule revisions for Chapters 701 and 703. The Crosetto Foundation recommended changes to Chapter 703. No comments were submitted related to proposed changes for Chapters 702 and 704. The final orders proposed for the Oversight Committee's approval for Chapters 701 and 703 include a summary of the public input and the agency's response to each suggestion.

Recommended Adoption of Final Orders

I recommend that the Oversight Committee approve the final orders adopting the rule amendments as proposed by CPRIT on November 1, 2013, except for the changes suggested by UH and TTUS for the following proposed rules: §§ 701.21(1), 703.3(h), and 703.13(a). The changes are noted in the Chapter 701 and Chapter 703 final orders. In addition, changes should be made to §§ 701.03(39) and 703.11(b) to correct typographical errors.

Maintaining the integrity and credibility of CPRIT's mission requires a clear set of guidelines, rules and responsibilities to govern the behavior of Oversight Committee members, Program Integration Committee members, Institute employees, and peer reviewers, as well as those that apply for and receive CPRIT grants. I believe that the new rules and rule changes provide clear guidance regarding expected conduct and performance.

Credibility and public confidence are vital throughout the grant making process. These rules stand for the commitment that CPRIT is making to Texans to transparently operate its grant award program with integrity and accountability while also serving its important mission.

Proposed Implementation Plan

CPRIT will begin implementing most of the new rules and rule changes immediately. However, some changes impose new reporting requirements and/or new consequences for grantees that fail to timely meet their obligations. Other changes require updates, revisions, and new forms to be created for CPRIT's grant management system. While it is possible to implement all of the new rules and rule changes immediately, doing so may be counterproductive and confusing. I recommend that the Oversight Committee approve an implementation plan as set forth below.

By February 19:

- Fully implement new rules and rule changes applicable to the Program Integration Committee (PIC) consideration and recommendation process
- Fully implement new rules and rule changes for the Oversight Committee's affirmative approval of grant recommendations
- Provide an overview of new rules and rule changes along with the implementation plan and training opportunities to CPRIT grantees and the sponsored programs offices (if applicable)

On or before March 1:

- Issue CPRIT's updated *Process and Procedures Guide* that describes each step of the grant application, review, award, and fiscal and performance monitoring processes
- Make publicly available all information that CPRIT has committed to publish through its website for viewing. Some of the information is already available on the website, but other information requires new web pages to be created to house the documents. CPRIT's standard operating procedure will be to release the information on the website as soon as the necessary new webpage is operable
- Host at least one webinar providing an overview of new rules and rule changes applicable to grantees
- Post FAQs on its website addressing the new rules and rule changes

March – May:

- Make on-site presentations to grantees explaining the new rules and rule changes, including the changes made to CPRIT's grant management system
- Host at least one additional webinar to address grantee questions prior to June 1, 2014, when the requirements and consequences will be fully implemented
- Roll out changes to CPRIT's grant management system as updates, revisions, and new forms are completed

June 1:

- Fully implement required changes for grantee reporting and imposition of new consequences for failing to comply with the required changes.

The proposed plan allows time to educate grant recipients about the extensive changes CPRIT has made following the State Auditor's report and enactment of SB 149. CPRIT time and resources spent on grantee training over the next four months will be the foundation for ensuring 100% compliance with CPRIT's rules and contractual requirements. I will regularly update the Oversight Committee regarding CPRIT's progress on meeting the implementation plan milestones. The implementation plan is intended to assist and support grantees; however, this is not intended to excuse grantees from complying with existing contractual provisions or from fulfilling existing statutory or administrative requirements.

CPRIT's Administrative Rules Overview

Chapter 701 - Policies and Procedures

Chapter 701 administrative rules address CPRIT policies and procedures, including several policies referenced by CPRIT's statute, Chapter 102 of the *Texas Health and Safety Code*. Many of the overarching issues of transparency, accountability and compliance are covered in this chapter, such as board governance requirements, a compliance and ethics program, and CPRIT's commitment to make information documenting many of the agency's critical, high-profile functions easily accessible and publicly available.

Chapter 701 rule highlights include:

- A mandate to adopt Oversight Committee Bylaws to govern its operation and management of the Institute, including a process for establishing grant program requirements annually.
- Implementation of the Compliance and Ethics Program authorized by CPRIT's statute and a system for the anonymous reporting, investigation, and remediation of suspected compliance violations.
- A framework for the development, implementation, continual monitoring, and revisions to the Texas Cancer Plan.
- Appointment and reporting requirements for CPRIT's external advisory committees such as the University Advisory Committee, the Advisory Committee on Childhood Cancer, and other ad hoc committees created by the Oversight Committee.
- Honoraria and residency policies for CPRIT's Scientific Research and Prevention Program committee members (the formal name for CPRIT's peer reviewers).
- Guidelines regarding the use of grant funds, including when grant funds may be paid in advance and the use of Texas suppliers and HUBs when expending grant funds.
- A comprehensive list of publicly available grant review and award process documents and other important agency reports to increase transparency on agency actions and operations.
- Policies related to open records, including protecting sensitive third-party information submitted as part of the grant application process.

Chapter 702 - Institute Standards on Ethics and Conflicts, Including Acceptance of Gifts and Donations to the Institute

Chapter 702 administrative rules define personal, professional, and financial interests that may conflict with an individual's objective review of a grant application. Guidelines are provided for recusing individuals with conflicts of interest and for ensuring transparency and accountability. This chapter also addresses CPRIT's Code of Conduct and Ethics, which serves as a central tenet guiding Oversight Committee and CPRIT employee actions going forward.

Chapter 702 rule highlights include:

- Guidelines for the acceptance and public disclosure of gifts and donations to Oversight Committee members, institute employees, or the agency, including a restriction against supplementing a CPRIT employee's salary with gifts or donations.
- A mandate to adopt a Code of Conduct and Ethics that incorporates specific provisions.
- A comprehensive system of identifying, disclosing, recusing, and monitoring conflicts of interest in the awarding of CPRIT funds, including designating a category of conflicts that require a reviewer's recusal from the entire review cycle.
- The process for reporting and investigating undisclosed conflicts of interest.
- A procedure for granting a waiver to allow a reviewer with a conflict to participate in the grant review process upon a showing of exceptional circumstances.
- A moratorium on individual communication about grant applications between Oversight Committee members and Program Integration Committee members while grant award decisions are being made.
- Restriction on communication between a grant applicant and anyone involved in the grant award process during the grant review cycle.

Chapter 703 - Grants for Cancer Research and Prevention

Chapter 703 administrative rules set forth CPRIT's grant review process to provide applicants a fair, timely, transparent evaluation free from professional, financial or personal bias. The review process is designed to identify and fund projects that are in the best overall interest of the state. This chapter describes the entire grant review process, from submission of the grant application through peer review, Program Integration Committee recommendation, and Oversight Committee approval. The chapter also outlines the grant contracting process, including comprehensive monitoring of financial and programmatic contractual obligations, revenue sharing requirements and contract termination.

Chapter 703 rule highlights include:

- Specifies the major components of CPRIT's Request for Applications, such as the evaluation criteria and scoring guidance, mandatory eligibility requirements for applicants, and disclosure of all sources of the applicant's funding for purposes of identifying conflicts of interest.
- Establishes CPRIT's newly-implemented electronic grant management system as the repository to maintain complete records for the application submission, review, award, contracting, and monitoring of CPRIT grant awards.
- Prohibits peer reviewers from engaging in business activities with grant recipients, including a prohibition on providing professional services to a grant recipient or serving on the grant recipient's board of directors.
- Implements the process for recruiting and training patient advocates to be added to peer review committees.
- Describes the grant peer review process step-by-step, including the assignment of an Overall Evaluation Score to every application and processes that are unique to particular grant mechanisms or grant programs.

- Sets forth the process for the newly-created Program Integration Committee to consider and recommend grant awards to the Oversight Committee.
- Establishes the process for the Oversight Committee to approve grant award recommendations, including consideration of the Compliance Officer's certification and the CEO affidavit accompanying every grant recommendation.
- Limits grounds for reconsidering a grant application decision to an undisclosed conflict of interest.
- Specifies required grant contract provisions, including repayment provisions if the grant recipient fails to live up to the grant contract.
- Guidelines for the matching funds obligation, including a description of appropriate sources of matching funds, reporting requirements, and penalty provisions.
- Restrictions on the use of grant award funds, including a list of expenses that are not authorized to be made with grant funds.
- Describes grant recipient audit requirements and provides penalties for the failure to timely submit required audits to CPRIT.
- Sets forth processes for terminating, extending, and closing out grant contracts.
- Describes the various methods that CPRIT uses to monitor grant award performance and expenditures, including annual verification and certification by the grant recipient of compliance with grant contract provisions.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 701. Policies and Procedures

The Cancer Prevention and Research Institute of Texas (Institute) adopts the repeal of 25 TAC Chapter 701 concerning Policies and Procedures in its entirety. The proposed repeal and the proposed text for the new Chapter 701 provisions were published in the November 15, 2013, issue of the Texas Register (38 TexReg 8055).

The purpose of the repeal is to replace the deleted sections with new rules that encompass agency policies and procedures as established by the statute, Chapter 102 of the Texas Health and Safety Code. The matters addressed by the repealed provisions are incorporated into a new Chapter 701.

The Institute accepted public comments in writing and by fax through December 16, 2013. No comments were received concerning the proposed repeal of Chapter 701.

The Oversight Committee approved the final order adopting the repeal of Chapter 701 on January 24, 2014.

The repeal is undertaken pursuant to the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad authority to adopt rules to administer the chapter.

The Institute hereby certifies that the repeal has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of the Secretary of State on January 27, 2014.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 701. Policies and Procedures

The Cancer Prevention and Research Institute of Texas (Institute) adopts a new Chapter 701, §§ 701.1 – 701.33, addressing administrative policies and procedures of the Institute. The proposed text for the new Chapter 701 provisions were published in the November 15, 2013, issue of the Texas Register (38 TexReg 8055).

Reasoned Justification

The purpose of new rules is to replace repealed Chapter 701 sections and to address agency policies and procedures as established by the statute, Chapter 102 of the Texas Health and Safety Code, including changes required based on the passage of Senate Bill (SB) 149 (83rd Regular Session). The Institute adopts new rules in Chapter 701 to set forth policies and procedures referenced by the statute, Texas Health and Safety Code Chapter 102, and for consistency with other Chapters. The new rules are adopted pursuant to and in satisfaction of the provisions of Texas Health and Safety Code, Chapter 102, and other relevant statutes.

Summary of Public Comments and Staff Recommendations

The Institute accepted public comments in writing and by fax through December 16, 2013. No comments were received regarding the following new rules: §§ 701.3, 701.5, 701.7, 701.9, 701.11, 701.13, 701.15, 701.17, 701.19, 701.23, 701.25, 701.27, 701.29, 701.31, and 701.33. These rules will be adopted as published in the November 15, 2013 is of the *Texas Register* and will not be republished.

Comments were received from the University of Houston System ("UH") and from the Texas Tech University System ("TTUS") regarding one of the chapter's proposed new rules, § 701.21. The rule as proposed sets forth the Institute's policy to encourage grant recipients' purchase of goods and services required for the grant award to be purchased from Texas suppliers when possible. The rule also specifies penalty provisions for non-compliance with this policy.

UH comments that Section 701.21(1) "looks like an overregulation and might hinder the scientific process." UH asserts that many vendors for research products and services, including equipment, are procured based on scientific needs "so this regulation would slow down research." Similarly, TTUS comments that compliance with §701.21 will add to the administrative burden on researchers to closely monitor expenditures and submit additional required reports when expenditures outside of the State exceed 40% of the grant award funds. TTUS reports that it does not currently flag vendors as in-state or track expenditures as in-state and out-of-state unless issuing a specific bid.

Response: The Institute agrees in part with the submitted comments and modifies § 701.21(1). The phrase, "A Grant Recipient must purchase products and materials produced in the state of

Texas…" is revised to read, "A Grant Recipient must use good faith efforts to purchase goods and services from suppliers in the State…" The new rule with the proposed change implements Section 102.258 of the Texas Health and Safety Code, which requires the Oversight Committee "to establish standards to ensure that grant recipients purchase goods and services from suppliers in this state to the extent reasonably possible in a good faith effort to achieve a goal of more than 50 percent of such purchases from suppliers in this state." As revised, the new rule more accurately reflects the legislative directive to employ good faith efforts to meet the statutory goal.

In addition to the change to § 701.21(1), the Institute notes a change to be made to § 701.03(39) to correct a typographical error. The statutory reference to "Section 102.2003(c), Texas Health and Safety Code" inadvertently contains an extra "0". The subsection has been changed to reflect the correct statutory reference, Section 102.203(c), Texas Health and Safety Code.

The Oversight Committee approved the final order adopting the repeal of Chapter 701 and new Chapter 701 rules on January 24, 2014.

The rules are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad authority to adopt rules to administer the chapter.

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of the Secretary of State on January 27, 2014.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 702. Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute

The Cancer Prevention and Research Institute of Texas (Institute) adopts the amendments to §§ 702.3, 702.5, 702.7, 702.9, 702.11, 702.13, 702.15, 702.17 and 702.19, regarding institute standards on ethics and conflicts, including relationships between the institute and private organizations and donors. The proposed amendments for Chapter 702 were published in the November 15, 2013, issue of the Texas Register (38 TexReg 8065).

Reasoned Justification

The amendments clarify existing requirements, reflect changes to the statute based on the passage of Senate Bill (SB) 149 (83rd Regular Session), provide additional guidance regarding applicable conflict of interest standards and restrictions on communication that may provide certain applicants unfair advantages, add to procedures for recusal from the review process for conflicts of interest, and ensure consistency with other Chapters. The amendments also promulgate more comprehensive rules regarding the acceptance of gifts and donations to the Institute.

The Texas Health and Safety Code, § 102.106 directs the Institute's Oversight Committee to adopt conflict of interest rules to apply to the Oversight Committee, the Program Integration Committee, and Institute employees,. In addition, these amendments are adopted pursuant to and in satisfaction of the provisions of Texas Government Code, Chapters 572 and 2255, Texas Health and Safety Code, Chapter 102, and other relevant statutes.

The Institute accepted public comments in writing and by fax through December 16, 2013. No comments were received concerning the proposed amendments for Chapter 702. The amendments to Chapter 702 rules will be adopted as published in the November 15, 2013 edition of the *Texas Register* and will not be republished.

The Oversight Committee approved the final order adopting the amendments to Chapter 702 rules on January 24, 2014.

The rules are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.106, which directs the Oversight Committee to adopt conflict of interest rules and § 102.108, which provides the Institute with broad authority to adopt rules to administer the chapter.

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of the Secretary of State on January 27, 2014.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Research and Prevention

The Cancer Prevention and Research Institute of Texas (Institute) adopts the amendments to §§ 703.1, 703.2, 703.3, 703.4, 703.5, 703.6, 703.7, 703.8, 703.9, 703.10, 703.11, 703.12, 703.13, 703.14, 703.15, 703.16, 703.17, 703.18, 703.19, 703.20, and new rule § 703.21 The proposed amendments for Chapter 703 regarding the Institute's grant application review and award process and procedures, including the monitoring of grant award contracts, were published in the November 15, 2013, issue of the Texas Register (38 TexReg 8074).

Reasoned Justification

The purpose of the amendments and new rule is to clarify several existing rules, to reflect changes to the statute as amended by the passage of Senate Bill (SB) 149 (83rd Regular Session), for consistency with other Chapters, and to provide additional guidance regarding the grant application review and award process and procedures, including the monitoring of grant award contracts. In addition, these amendments are adopted pursuant to and in satisfaction of the provisions Texas Health and Safety Code, Chapter 102, and other relevant statutes.

Summary of Public Comments and Staff Recommendations

The Institute accepted public comments in writing and by fax through December 16, 2013. No comments were received regarding the following rule amendments: §§ 703.1, 703.2, 703.4, 703.7, 703.8, 703.9, 703.12, 703.15, 703.16, 703.17, 703.18, 703.19, and 703.20. Comments were received from the University of Houston System ("UH"), the Texas Tech University System ("TTUS"), and the Crosetto Foundation to End Premature Cancer Deaths (Crosetto Foundation) regarding certain Chapter 703 rules. The observations and suggested changes are provided in the following section-by-section summary of the comments received and the Institute's response. Changes were made to three rule amendments, §§ 703.3(h), 703.11(b), and 703.13(a) based on the comments submitted and to correct a typographical error. Except for the changes made to the three rule amendments by the Institute, the rule amendments as published in the November 15, 2013 edition of the *Texas Register* will be adopted as published in the November 15, 2013 edition of the *Texas Register*. The rule amendments will not be republished.

§ 703.3. Grant Applications

UH and TTUS comment with regard to the proposed change at 703.3(h)(3) and suggest revisions. Generally, subsection 703.3(h) refers to the required certification by the grant applicant that the applicant organization has not made and will not make a donation to the Institute or a supporting foundation. For purposes of the applicant's certification, subsection (h)(2) expressly includes the principal investigator, program director, or company representative, as well as the grant applicant's officers, directors, and senior members or key personnel listed on the application. In addition to those individuals, Subsection (h)(3) requires the grant applicant's

certification to account for any employee of the applicant organization, or a relative of the employee within the second degree of consanguinity or affinity, that makes a donation exceeding $500 to the Institute or a supporting foundation. UH and TTUS comments are limited to the inclusion of employees' relatives in the mandatory certification. UH points out that a principal investigator or project director may not have knowledge of donations that are made by relatives, particularly those that are related by a second degree connection. UH suggests restricting the certification to the primary investigator, project directors, and their immediate family members. TTUS comments that as a public institution of higher education, disclosing the identities of an employee's relatives is not required, nor is the information maintained as a condition of employment. Therefore, TTUS asserts that it is not feasible to require that an applicant certify at this level for purposes of 703.3(h)(3).

Response: The Institute agrees in part with the submitted comments and modifies § 703.3(h)(3) retaining the majority of the proposed new language but changing the subsection to exclude "a Relative of an employee" from the application of the rule. The Institute notes that although both UH and TTUS purport to address subsection (h)(3) specifically, their comments also encompass subsection (h)(2). The Institute amends subsection (h)(2) to delete the reference to "Relative of the following individuals" and replace it with "spouse or dependent child(ren) of the following individuals." The subsections as amended appropriately balances the Institute's interest in ensuring that grants are not awarded to grant applicants that contribute to the Institute or a supporting foundation while recognizing the limits of the applicant organization's information with regard to the identity and charitable donations made by extended relatives of its employees.

Although TTUS does not recommend a specific rule change, it points out that requiring the grant applicant certification to be made at the time that the application is submitted may be problematic if donations are continuously accepted by the Institute. TTUS contends that the only time that an institution can make this certification is immediately following review of the list of donors provided by the Institute or any supporting foundation.

Response: The Institute's Chief Compliance Officer is statutorily charged with ensuring observance with the prohibition against donations. The Chief Compliance Officer is required to compare each grant application to a list of donors to the Institute or a supporting foundation before the application undergoes peer review and again before any grant is awarded to the applicant. The certification mandated by § 703.3(h) assists the Institute in fulfilling the statutory directive. The Institute will facilitate the certification process by making a list of donors to the Institute or any supporting foundation publicly available. An amendment adopted for § 702.7, *Acceptance of Gifts and Donations by the Institute*, requires that the Institute report information pertaining to gifts, grants, or other consideration provided to the Institute, an Institute employee, or an Institute committee member by posting the information on the Institute's website, including the donor's name, the date of the donation, and the amount of the donation.

In its comments regarding subsection (b) and (e) in this rule, the Crosetto Foundation proposes that the Institute adopt standard evaluation criteria for all applications. The standard evaluation criteria require the applicant to demonstrate the objective capability to reduce cancer deaths and quantify the cost per each life saved compared to current costs. The Crosetto Foundation further suggests that applicants be required to quantify the expected percentage of cancer deaths and cost

savings when the proposed project is tested on a sample population.

Response: The Institute declines to make the changes proposed by the Crosetto Foundation because the changes are too specific to provide general guidance. The Institute was established to create and expedite innovation in the area of cancer research leading to the medical or scientific breakthroughs in the prevention of cancer and cures for cancer; to attract, create, and expand research capabilities in the state to promote a substantial increase in cancer research and high quality jobs; and to develop and implement the Texas Cancer Plan. The potential areas for research and prevention projects included in the rule are broad in scope and may encompass areas addressed by Crosetto Foundation without the requested change to the rule. However, including the Crosetto Foundation's proposed changes may serve to unduly restrict the types of projects eligible for funding. It may be impossible to calculate with precision the Crosetto Foundation's criterion related to the expected reduction of cancer deaths for most, if not all, cancer research projects at the time applications are submitted. The Institute notes that the Crosetto Foundation's proposed requirement that applicants specifically quantify the reduction of cancer deaths and cost savings on a sample population appears to suggest that only those projects that are currently in clinical trials be eligible for funding. One of the Institute's statutory powers and objectives is to support research "in all stages in the process of finding the causes of all types of cancer in humans and developing cures, from laboratory research to clinical trials and including programs to address the problem of access to advanced cancer treatment." It is within the Institute's discretion to design grant programs to achieve these statutory objectives; the statute does not compel the Institute to restrict funding to a particular stage of research. The potential for scientific discoveries that will make a meaningful difference to cancer patients may occur at any stage in the research process. If the Institute limits funding at the outset to only those proposals that claim to demonstrate an immediate reduction in cancer deaths, early stage and developing research would suffer and potential treatment-altering innovations may be missed. The Institute notes that the rule as proposed does not prohibit the Institute from seeking the information suggested by the Crosetto Foundation or using the information as a specific criterion to evaluate the merit of the Grant Application.

§703.5. Scientific Research and Prevention Program Committee Members

The Crosetto Foundation proposes two changes to subsection (c). The first change is to require each reviewer to provide scientific arguments and and/or references, calculations, demonstrations supporting his rejection of an applicant's project claim and/or the superiority in efficiency and potential of another project that the reviewer recommends for funding.

Response: The Institute declines to make this change because it describes a process that is inconsistent with the peer review process set forth in Chapter 703, particularly with regard to the Crosetto Foundation's recommended standard evaluation criteria. (See the Institute's response to the Crosetto Foundation's proposed standard evaluation criteria and other suggested revisions for § 703.3.) The decision to recommend funding for an application is the purview of the scientific research and prevention program committee and is based on the sufficiency, scientific merit and, if applicable, the commercial prospects of the application. Requiring the reviewer to provide specific scientific counter-arguments for those projects not recommended for funding and comparisons to projects recommended for funding will significantly increase the time, expense,

and resources necessary for the evaluation of grant applications.

The second change to subsection (c) suggested by the Crosetto Foundation is to include language that "Reviewers who had the vision of the benefit to the public from an innovation that proved reduction of cancer deaths and cost will be included in a list of expert reviewers in the field. Those who rejected funding for a project that later had success for the above goal (with CPRIT funding or funding from a different source) will be placed in a lower priority in the list of experts in the field." The Crosetto Foundation does not provide an explanation supporting this recommendation.

Response: The Institute declines to make this change. The Institute interprets the Crosetto Foundation's suggested revision to propose an eligibility criterion for Scientific Research and Prevention Program committee members that gives priority to a reviewer that previously approved grant funding for a project that proved to reduce cancer deaths and costs, while giving lesser priority to a potential reviewer that did not approve funding for a project that later was proven to reduce cancer deaths and costs. The change will not be made because the criterion creates an unreasonable burden on the agency and is too difficult to implement. It may be impossible for the Institute or a reviewer to determine whether a potential reviewer had the "vision of the benefit to the public" or the "proved reduction of cancer deaths and cost" for one or more previous grant or grants. Moreover, there may be reasons that are unrelated to a particular reviewer's evaluation of an application that the project was not funded by CPRIT or another grant-making entity, even if that project later proved to successfully achieve its aims.

The Crosetto Foundation suggests striking the phrase, "exceeding $5,000" from subsection (g). He does not provide an explanation for this recommendation.

Response: The Institute declines to make the suggested change. The $5,000 limit for compensation for professional services rendered to a grant recipient within one year of the grant award is *de minimis* and balances the Institute's interest in ensuring the integrity of its grant review process while not unreasonably restricting the reviewer's employment opportunities.

§ 703.6 Grants Review Process

UH comments that in order to avoid a conflict of interest, "all applicants should disclose their collaborators, mentors, and postdoctoral fellows so that an unbiased scientific merit of the proposal can be obtained."

Response: The Institute declines to make this change because the issue is addressed by another rule, § 702.11(d), which defines professional conflicts of interest requiring recusal from the grant review, discussion, and deliberation. Specifically, § 702.11(d)(5) states that a professional conflict of interest exists if the individual subject to this rule is "a colleague, scientific mentor, or student of a senior member or key personnel of the research or prevention program team listed on the grant application, or is conducting or has conducted research or other significant professional activities with a senior member or key personnel of the research or prevention program team listed on the grant application within three years of the date of the review."

TTUS comments that the review of grant applications should take into account geographic considerations. TTUS acknowledges that the review of applications for prevention grants does incorporate geographic considerations, but contends that accounting for the "well documented geographic disparity in cancer research, care and prevention" would benefit West Texas "if reviewers were tasked with also looking at the geographic aspects of the grant." TTUS does not provide specific changes to the proposed rule text.

Response: The Institute declines to make a change to § 703.6 because the suggested changes are already addressed in § 703.7, *Program Integration Committee Funding Recommendation*. Rule 703.7 reflects the statutory requirement that the Program Integration Committee give priority to proposals that, among other considerations, enhance research superiority at institutions of higher education in this state by creating new research superiority or attracting existing research superiority from institutions not located in this state. Another priority consideration the Program Integration Committee may consider in making its award recommendations is the ability of the grant project to fulfill the goals of the Texas Cancer Plan. TTUS acknowledges that the Texas Cancer Plan calls for addressing the disparities in available cancer research and care that occur in rural areas of Texas.

The Crosetto Foundation provides two comments for subsection (a)(1). First, the Crosetto Foundation proposes all applicants "should estimate and then provide a plan to measure the results on a sample population." He contends "that a difference or no difference in the mortality rate will quantify the success or failure of a proposed solution." The Crosetto Foundation supports this change by referring to a mandate "for a significant reduction in cancer deaths and cost per life saved compared to current cost." The Crosetto Foundation's second suggested change is to add "with the highest potential to reduce cancer deaths and cost per each life saved compared to the current cost" following the words "Cancer Prevention and Control projects."

Response: The Institute declines to make these changes because the changes describe a process that is inconsistent with the peer review process set forth in Chapter 703, particularly with regard to the Crosetto Foundation's recommended standard evaluation criteria. (See the Institute's response to the Crosetto Foundation's proposed standard evaluation criteria and suggested revisions for § 703.3.) The proposed change limits the legislative purpose for the Institute and unduly restricts the types of projects eligible for funding by requiring a specific quantification of the reduction of cancer deaths. Pursuant to Health and Safety Code § 102.002, the Institute was established 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; to attract, create or expand research capabilities of institutions of higher education and other public or private entities; and to develop and implement the Texas Cancer Plan. The potential for innovative scientific discoveries that will make a meaningful difference to cancer patients can occur at any stage in the research process. If the Institute limits funding at the outset to only those proposals that claim to demonstrate an immediate reduction in cancer death, early stage and developing research would suffer and potential treatment-altering innovations may be missed. Furthermore, it may be impossible to calculate this figure with precision for most, if not all, basic and translational cancer research projects at the time applications are submitted. The Institute notes that the rule as proposed does not prohibit the Institute from seeking the information suggested by the Crosetto Foundation or using the information as a specific criterion

to evaluate the merit of the Grant Application.

The Crosetto Foundation proposes two changes to subsection (c)(3). The first change requires each reviewer to provide scientific arguments, calculations, reference data, and logical reasoning that comply with the Crosetto Foundation's proposed standard evaluation criteria for determining whether to approve or reject an application.

Response: The Institute declines to make this change because it describes a process that is inconsistent with the peer review process set forth in Chapter 703, particularly with regard to Crosetto Foundation's recommended standard evaluation criteria. (See the Institute's response to the proposed standard evaluation criteria and suggested revisions for § 703.3.)

The Crosetto Foundation's second change to subsection (c)(4) proposes a post hoc evaluation of the reviewer. According the Crosetto Foundation's proposal, a reviewer will be judged as "an expert, knowledgeable person" based upon the successful experimental results on a sample population of a project approved by the reviewer and will be included on a list of "experts to reduce cancer deaths and cost." Conversely, the Crosetto Foundation recommends that "reviewers that could not recognize the scientific value and potential of a proposal that demonstrated benefits or who approved projects that demonstrated a failure will be removed from the list of experts in reducing cancer deaths and their arguments to reject or approve projects will be included in a list of pitfalls so that the same errors should not be repeated in the future of stopping or delaying the benefits from innovations."

Response: The Institute declines to make this change because it describes a process that is inconsistent with the peer review process set forth in Chapter 703. Furthermore, a real-time assessment of the success or failure of a project to reduce cancer deaths over a sample population may be impossible, rendering the recommendation unduly burdensome to implement.

The Crosetto Foundation proposes a change to subsection (e)(1) that requires the Peer Review Panel chairperson to determine the applications that should move forward for further review based on the Crosetto Foundation's proposed standard evaluation criteria rather than the preliminary evaluation score.

Response: The Institute declines to make the change because the Crosetto Foundation's recommended standard evaluation criteria will not be used in the Institute's application evaluation and funding recommendation process. (See the Institute's response to the Crosetto Foundation's proposed standard evaluation criteria and suggested revisions for § 703.3.) It is within the Institute's discretion to establish the evaluation criteria used to score grant applications, as guided by the statute.

The Crosetto Foundation recommends changing the text of subsection (e)(2) that requires the Review Council members to confirm or provide objections supported by scientific arguments in regard to the calculations, references, material, and logical reasoning that was provided by the reviewers.

Response: The Institute declines to make this change because it describes a process that is inconsistent with the peer review process set forth in Chapter 703.

The Crosetto Foundation proposes a change to subsection (g)(1) that requires the third party observer to record all comments/remarks from any observer from the public that "provides useful information" in comparing and identifying projects with the highest potential to reduce cancer deaths and cost.

Response: The Institute declines to make this change because it describes a process that is inconsistent with the peer review process set forth in Chapter 703. Specifically, the only individuals permitted to participate in peer review discussions are Scientific Research and Prevention Program committee members; peer review panel meetings are not open to the public.

§ 703.10. Awarding Grants by Contract

UH comments that the requirement in subsection (c)(15) that grant recipients provide supporting documentation for expenses submitted for reimbursement creates an administrative burden and is redundant because all projects will be audited at different stages. TTUS elaborated on this point, asserting the submission of supporting documentation is time consuming and will require additional resources. TTUS reports that providing this level of documentation is not typical of external funding agencies, which rely upon external audits and compliance functions to identify reimbursement concerns. TTUS suggested amending the proposed rule to make the supporting information necessary "upon request."

Response: The Institute declines to make this change. In the State Auditor's Office report on the Institute's grant management practices issued in January 2013, the State Auditor determined that, "CPRIT cannot ensure the accuracy and appropriateness of grantees' reported expenditures without obtaining detailed information and adequate documentation to support expenditures reported on [spreadsheets summarizing expenditures to be reimbursed] for the applicable reporting period." (See pg. 24, Report No. 13-018, *An Audit Report on Grant Management at the Cancer Prevention and Research Institute of Texas and Selected Grantees*, January 2013.) Subsection (c)(15) fulfills the State Auditor's recommendation that CPRIT obtain sufficient documentation to support the appropriateness of all payments it makes to grantees.

The Crosetto Foundation proposes two changes regarding subsection (c). First, the Crosetto Foundation suggests adding language related to its standard evaluation criteria including "measurable milestones in the contract that should be verified as the project is funded and implemented."

Response: The Institute declines to make this change because the requirement is already addressed in subsection (c)(22). Specifically, project deliverables as described in the grant application must be included in the contract's scope of work. In addition, verification of the progress made by the grant recipient related to the information included in the scope of work and grant award timeline is addressed in proposed rule § 703.21(b)(3). Grant recipients are required to provide a report, at least annually, for the Institute's review regarding the progress made toward completing the scope of work, including information, data, and program metrics regarding achievement of project goals and timelines.

The second proposed change to subsection (c) is to delete subsection (c)(1) in its entirety. The Crosetto Foundation asserts that grant funds should be used to support the research project and not for building capital improvements that are not directly used for the research project.

Response: The Institute declines to make the change. Building capital improvements is a statutorily-authorized use of grant funds, subject to specific approval by the Institute and pursuant to certain terms and conditions. This subsection reflects the statutory requirements.

§ 703.11. Requirement to Demonstrate Available Funds for Cancer Research Grants

UH comments that subsection (c)(5) should clarify that institutions of higher education are not eligible to use unrecovered indirect costs as matching funds. TTUS also suggests clarifying that the entire subsection (c)(5) is not applicable to institutions of higher education.

Response: The Institute declines to make the change because subsection (c)(5)(D) explicitly excludes public and private institutions of higher education from using subsection (c)(5). Public and private institutions of higher education may not rely upon subsection (c)(5) to demonstrate available matching funds because the statute permits these entities to use the dollar equivalent of the individual entity's federal indirect cost rate as credit toward the required matching funds obligation. This option is unique to the institutions of higher education. Subsection (c)(5) explicitly excludes the institutions of higher education in order to avoid double-counting the benefit of the indirect cost rate credit.

The Crosetto Foundation proposes deleting § 703.11 in its entirety, contending that the Institute's creation and statutory authority to award grant funds do not require the grant recipient to show that it has matching funds dedicated to the cancer research project.

Response: The Institute declines to make the change. The constitutional amendment creating the Institute includes a provision that prohibits the Institute from issuing grant funds until the recipient of the grant has an amount of funds equal to one-half the amount of the grant dedicated to the research that is the subject of the grant request. The matching funds requirement for all cancer research projects is also reflected in the statute.

The Institute notes a change to be made to § 703.11(b) to correct a typographical error. The statutory reference to "Section 102.2003(c), Texas Health and Safety Code" inadvertently contains an extra "0". The subsection has been changed to reflect the correct statutory reference, Section 102.203(c), Texas Health and Safety Code.

§ 703.13. Audits and Investigations

TTUS proposes amending length of the period following the termination of the contract that the Institute, the State Auditor, and/or the Comptroller of Public Accounts may review, inspect, or audit the grantee's grant contract records. TTUS recommends replacing the four-year period set forth in subsection (a) with "a fiscal year-end plus three years" period to make this section consistent with the State record retention requirement.

Response: The Institute agrees with the change and the text of 703.13(a) has been revised to reflect the time period that the Institute or other associated auditors or investigators may review, inspect, audit, copy or abstract the grantee's records pertaining to the specific grant contract for the "three year period following the end of the Grant Recipient's fiscal year during which the Grant Contract was terminated."

UH and TTUS both propose amending subsection (b) so that the requirement to obtain a single audit does not apply to state agencies. UH reports that state agencies that are recipients of federal funds rely on the statewide audit to meet the audit requirements of federal sponsors. UH contends that obtaining a single audit for a state agency would be redundant and expensive, costing "in excess of $500,000 and probably closer to $1,000,000." TTUS cited the cost-savings to the State when the Single Audit Act was implemented, eliminating the individual independent audits of each state agency. TTUS asserts that a single audit would be an audit of the institutions' financial statements. Both UH and TTUS recommend requiring that for state agencies, program specific audits should be clarified to include an Agreed-Upon Procedures Engagement, as defined by the American Institute of Certified Public Accountants, and report on findings on specific procedures performed on subject matter.

Response: The Institute declines to make this change because the use of an Agreed-Upon Procedures Engagement is not addressed in the Uniform Grant Management Standards (UGMS). The Institute previously accepted the Statewide Single Audit by state institutions of higher education to fulfill the audit requirement in this section. However, the State Auditor's Office determined that submission of the Statewide Single Audit by grantees did not comply with the audit requirement of the Uniform Grant Management Standards (UGMS) because the Statewide Single Audit does not include a review of state-funded grant awards, such as Institute grants. UGMS would need to be revised to allow for an Agreed-Upon Procedures Engagement.

§ 703.14. Termination, Extension, and Close Out of Grant Contracts

UH proposes a change to subsection (c)(2) that would replace the six-month no cost extension period with a one year term. UH asserts that there are a variety of reasons not controlled by the grant recipients that may justify more time to complete projects.

Response: The Institute declines to make this change because the rule as proposed permits additional time beyond the standard six-month no cost extension period so long as the grant recipient can demonstrate special circumstances justifying additional time to complete the work of the project.

UH proposes replacing the term "termination date" with "expiration date" to better describe the official end of the project.

Response: The Institute declines to make the change because the term "termination date" encompasses all of events that may cause the grant contract to end, including termination for an event of default, as well as a natural termination under the terms of the contract.

§ 703.21 Monitoring Grant Award Performance and Expenditures

UH proposes deleting the requirement included in subsection (b)(3)(B)(iii) that grant recipients report on the number of new jobs created and the number of jobs maintained as a result of grant award funds. UH contends that the requirement to track the number of jobs created was part of the American Recovery Reinvestment Act Fund and is not one that is usually done by the university. Collecting and reporting the information would be burdensome and deviate from the main goal of conducting research. Similarly, TTUS supports deleting subsection (b)(3)(B)(iii), contending that these are generally not appropriate measures of success for research and cancer prevention projects.

Response: The Institute declines to make this change. The creation and maintenance of jobs through the use of grant funds is one of the metrics the Institute must report annually to the Legislative Budget Board; the proposed subsection assists the Institute in complying with its reporting requirements. One of the statutory purposes for the Institute is to attract, create, or expand research capabilities of institutions of higher education and other entities in order to substantially increase cancer research and to create high quality new jobs in the state. Similarly, the statute emphasizes the importance of creating high quality jobs in the state by designating it as one of the priorities for funding grant proposals.

The Crosetto Foundation suggests two changes to subsection (b)(3)(C). First, the Crosetto Foundation recommends adding the words, "demonstrating the completion of the construction of the project," following the words "a final Grant Progress Report." The Crosetto Foundation provides no explanation for the additional text.

Response: The Institute declines to make the change because the information sought by the additional text is already encompassed by the proposed subsection's requirement that the grant recipient provide a comprehensive description of the progress made completing the scope of work. Furthermore, adding the proposed text may unduly limit the information to be included in the final progress report to only that information addressing construction projects.

The second change to subsection (b)(3)(C) proposed by the Crosetto Foundation is to include a "report of the measurements on a sample population that will quantify how successful the project was…"

Response: The Institute declines to make this change because it is based on the Crosetto Foundation's suggested standard evaluation criteria that is inconsistent with the peer review process described elsewhere in Chapter 703. (See the Institute's response to the Crosetto Foundation's proposed standard evaluation criteria and other suggested revisions for § 703.3.) The Institute notes that information about the project results, including efficacy metrics, will be required as part of the final progress report even without the suggested change.

The Oversight Committee approved the final order adopting the Chapter 703 rule amendments and new rule on January 24, 2014.

The rule amendments and new rule are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108 and § 102.251, which provide the Institute's Oversight

Committee with broad rulemaking authority and direct the Institute to adopt rules relating to grant award procedures.

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of the Secretary of State on January 27, 2014.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 704. Texans Conquer Cancer Program

The Cancer Prevention and Research Institute of Texas (Institute) adopts the repeal of Chapter 704, §§ 704.1 – 704.13, addressing the Texans Conquer Cancer program that awards funds for cancer support services. The proposed repeal was published in the November 15, 2013, issue of the Texas Register (38 TexReg 8093).

The rules currently in Chapter 704 are no longer applicable because the 2007 Texas Legislature abolished the Texans Conquer Cancer Advisory Committee and the current rules, based upon the existence of this Committee, are inadequate to address the Texans Conquer Cancer Program. The matters addressed by the repealed provisions will be incorporated into a new Chapter 704.

The Institute accepted public comments in writing and by fax through December 16, 2013. No comments were received concerning the proposed repeal of Chapter 704.

The Oversight Committee approved the final order adopting the repeal of Chapter 704 on January 24, 2014.

The repeal is undertaken pursuant to the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad authority to adopt rules to administer the chapter.

The Institute hereby certifies that the repeal has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of the Secretary of State on January 27, 2014.

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CHAPTER 701 – POLICIES AND PROCEDURES

RULE §701.1 Intent

The Institute shall:

(1) Create and expedite innovation in the area of cancer research and enhance the potential for medical or scientific breakthrough in the prevention of cancer and cures for cancer;

(2) 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 Texas; and

(3) Develop and implement the Texas Cancer Plan.

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RULE §701.3 Definitions

The following words and terms, when used in this Chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) **Advisory Committee**--a committee of experts, including practitioners and patient advocates, created by the Oversight Committee to advise the Oversight Committee on issues related to cancer.

(2) **Allowable Cost**--a cost that is reasonable, necessary for the proper and efficient performance and administration of the project, and allocable to the project.

(3) **Annual Public Report**--the report issued by the Institute pursuant to Texas Health and Safety Code Section 102.052 outlining Institute activities, including Grant Awards, research accomplishments, future Program directions, compliance, and Conflicts of Interest actions.

(4) **Authorized Expense**--cost items including honoraria, salaries and benefits, consumable supplies, other operating expenses, contracted research and development, capital equipment, construction or renovation of state or private facilities, travel, and conference fees and expenses.

(5) **Approved Budget**--the financial expenditure plan for the Grant Award, including revisions approved by the Institute and permissible revisions made by the Grant Recipient. The Approved Budget may be shown by Project Year and detailed budget categories.

(6) **Authorized Signing Official (ASO)**--the individual, named by the Grant Applicant, who is authorized to act for the Grant Applicant or Grant Recipient in submitting the Grant Application and executing the Grant Contract and associated documents or requests.

(7) **Bylaws**--the rules established by the Oversight Committee to provide a framework for its operation, management, and governance.

(8) **Cancer Prevention**--a reduction in the risk of developing cancer, including early detection, control and/or mitigation of the incidence, disability, mortality, or post-diagnosis effects of cancer.

(9) **Cancer Prevention and Control Program**--effective strategies and interventions for preventing and controlling cancer designed to reduce the incidence and mortality of cancer and to enhance the quality of life of those affected by cancer.

(10) **Cancer Prevention and Research Fund**--the dedicated account in the general revenue fund consisting of legislative appropriations, gifts, grants, other donations, and earned interest.

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(11) **Cancer Research**--research into the prevention, causes, detection, treatments, and cures for all types of cancer in humans, including basic mechanistic studies, pre-clinical studies, animal model studies, translational research, and clinical research to develop preventative measures, therapies, protocols, medical pharmaceuticals, medical devices or procedures for the detection, treatment, cure or substantial mitigation of all types of cancer and its effects in humans.

(12) **Chief Compliance Officer**--the individual employed by the Institute to monitor and report to the Oversight Committee regarding compliance with the Institute's statute and administrative rules. The term may also apply to an individual designated by the Chief Compliance Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(13) **Chief Executive Officer**--the individual hired by the Oversight Committee to perform duties required by the Institute's Statute or designated by the Oversight Committee. The term may apply to an individual designated by the Chief Executive Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(14) **Chief Prevention Officer**--the individual hired by the Chief Executive Officer to oversee the Institute's Cancer Prevention program, including the Grant Review Process, and to assist the Chief Executive Officer in collaborative outreach to further Cancer Research and Cancer Prevention. The term may also apply to an individual designated by the Chief Prevention Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(15) **Chief Product Development Officer**--the individual hired by Chief Executive Officer to oversee the Institute's Product Development program for drugs, biologicals, diagnostics, or devices arising from Cancer Research, including the Grant Review Process, and to assist the Chief Executive Officer in collaborative outreach to further Cancer Research and Cancer Prevention. The term may apply to an individual designated by the Chief Product Development Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(16) **Chief Scientific Officer**--the individual hired by the Chief Executive Officer to oversee the Institute's Cancer Research program, including the Grant Review Process, and to assist the Chief Executive Officer in collaborative outreach to further Cancer Research and Cancer Prevention. The term may apply to an individual designated by the Chief Scientific Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(17) **Code of Conduct and Ethics**--the code adopted by the Oversight Committee pursuant to Texas Health and Safety Code 102.109 to provide guidance related to the ethical conduct expected of Oversight Committee Members, Program Integration Committee Members, and Institute Employees.

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(18) **Compliance Program**--a process to assess and ensure compliance by the Oversight Committee Members and Institute Employees with applicable laws, rules, and policies, including matters of ethics and standards of conduct, financial reporting, internal accounting controls, and auditing.

(19) **Conflict(s) of Interest**--a financial, professional, or personal interest held by the individual or the individual's Relative that is contrary to the individual's obligation and duty to act for the benefit of the Institute.

(20) **Encumbered Funds**--funds that are designated by a Grant Recipient for a specific purpose.

(21) **Financial Status Report**--form used to report all Grant Award related financial expenditures incurred in implementation of the Grant Award. This form may also be referred to as "FSR" or "Form 269-A."

(22) **Grant Applicant**--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 the Institute. Unless otherwise indicated, this term includes the Principal Investigator or Program Director.

(23) **Grant Application**--the written proposal submitted by a Grant Applicant to the Institute in the form required by the Institute that, if successful, will result in a Grant Award.

(24) **Grant Award**--funding, including a direct company investment, awarded by the Institute pursuant to a Grant Contract providing money to the Grant Recipient to carry out the Cancer Research or Cancer Prevention project in accordance with rules, regulations, and guidance provided by the Institute.

(25) **Grant Contract**--the legal agreement executed by the Grant Recipient and the Institute setting forth the terms and conditions for the Cancer Research or Cancer Prevention Grant Award approved by the Oversight Committee.

(26) **Grant Management System**--the electronic interactive system used by the Institute to exchange, record, and store Grant Application and Grant Award information.

(27) **Grant Mechanism**--the specific Grant Award type.

(28) **Grant Program**--the functional area in which the Institute makes Grant Awards, including research, prevention and product development.

(29) **Grant Progress Report**--The required report submitted by the Grant Recipient at least annually and at the close of the grant award describing the activities undertaken to achieve

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the goals and objectives of the funded project and including information, data and program metrics. Unless the context clearly indicates otherwise, the Grant Progress Report also includes other required reports such as a Historically Underutilized Business and Texas Supplier form, a single audit determination form, an inventory report, a single audit determination form, a revenue sharing form, and any other reports or forms designated by the Institute.

(30) **Grant Recipient**--the entire legal entity responsible for the performance or administration of the Grant Award pursuant to the Grant Contract. Unless otherwise indicated, this term includes the Principal Investigator, Program Director, or Company Representative.

(31) **Grant Review Cycle**--the period that begins on the day that the Request for Applications is released for a particular Grant Mechanism and ends on the day that the Oversight Committee takes action on the Grant Award recommendations.

(32) **Grant Review Process**--the Institute's processes for Peer Review, Program Review and Oversight Committee approval of Grant Applications.

(33) **Indirect Costs**--the expenses of doing business that are not readily identified with a particular Grant Award, Grant Contract, project, function, or activity, but are necessary for the general operation of the Grant Recipient or the performance of the Grant Recipient's activities.

(34) **Institute**--the Cancer Prevention and Research Institute of Texas or CPRIT.

(35) **Institute Employee**--any individual employed by the Institute, including any individual performing duties for the Institute pursuant to a contract of employment. Unless otherwise indicated, the term does not include an individual providing services to the Institute pursuant to a services contract.

(36) **Intellectual Property Rights**--any and all of the following and all rights in, arising out of, or associated therewith, but only to the extent resulting from the Grant Award:

(A) The United States and foreign patents and utility models and applications therefore and all reissues, divisions, re-examinations, renewals, extensions, provisionals, continuations and such claims of continuations-in-part as are entitled to claim priority to the aforesaid patents or patent applications, and equivalent or similar rights anywhere in the world in Inventions and discoveries;

(B) All trade secrets and rights in know-how and proprietary information;

(C) All copyrights, whether registered or unregistered, and applications therefore, and all other rights corresponding thereto throughout the world excluding scholarly and

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academic works such as professional articles and presentations, lab notebooks, and original medical records; and

(D) All mask works, mask work registrations and applications therefore, and any equivalent or similar rights in semiconductor masks, layouts, architectures or topography.

(37) **Invention**--any method, device, process or discovery that is conceived and/or reduced to practice, whether patentable or not, by the Grant Recipient in the performance of work funded by the Grant Award.

(38) **License Agreement**--an understanding by which an owner of Technology and associated Intellectual Property Rights grants any right to make, use, develop, sell, offer to sell, import, or otherwise exploit the Technology or Intellectual Property Rights in exchange for consideration.

(39) **Matching Funds**--the Grant Recipient's 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. For public and private institutions of higher education, this includes 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 the Section 102.203(c), Texas Health and Safety Code.

(40) **Numerical Ranking Score**--the score given to a Grant Application by the Review Council that is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also signifies the Review Council's view related to 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.

(41) **Overall Evaluation Score**--the score given to a Grant Application during the Peer Review Panel review that signifies the reviewers' overall impression of the Grant Application. Typically it is the average of the scores assigned by two or more Peer Review Panel members.

(42) **Oversight Committee**--the Institute's governing body, composed of the nine individuals appointed by the Governor, Lieutenant Governor, and the Speaker of the House of Representatives.

(43) **Oversight Committee Member**--any person appointed to and serving on the Oversight Committee.

(44) **Patient Advocate**--a trained individual who meets the qualifications set by the Institute and is appointed to a Scientific Research and Prevention Programs Committee to specifically

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represent the interests of cancer patients as part of the Peer Review of Grant Applications assigned to the individual's committee.

(45) **Peer Review**--the review process performed by Scientific Research and Prevention Programs Committee members and used by the Institute to provide guidance and recommendations to the Program Integration Committee and the Oversight Committee in making decisions for Grant Awards. The process involves the consistent application of standards and procedures to produce a fair, equitable, and objective evaluation of scientific and technical merit, as well as other relevant aspects of the Grant Application. When used herein, the term applies individually or collectively, as the context may indicate, to the following review process(es): Preliminary Evaluation, Individual Evaluation by Primary Reviewers, Peer Review Panel discussion and Review Council prioritization.

(46) **Peer Review Panel**--a group of Scientific Research and Prevention Programs Committee members conducting Peer Review of assigned Grant Applications.

(47) **Prevention Review Council**--the group of Scientific Research and Prevention Programs Committee members designated as the chairpersons of the Peer Review Panels that review Cancer Prevention program Grant Applications. This group includes the Review Council chairperson.

(48) **Primary Reviewer**--a Scientific Research and Prevention Programs Committee member 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 general impression of the Grant Application's merit.

(49) **Principal Investigator, Program Director, or Company Representative**--the single individual designated by the Grant Applicant or Grant Recipient to have the appropriate level of authority and responsibility to direct the project to be supported by the Grant Award.

(50) **Product Development Review Council**--the group of Scientific Research and Prevention Programs Committee Members designated as the chairpersons of the Peer Review Panels that review Grant Applications for the development of drugs, drugs, biologicals, diagnostics, or devices arising from earlier-stage Cancer Research. This group includes the Review Council chairperson.

(51) **Product Development Prospects**--the potential for development of products, services, or infrastructure to support Cancer Research efforts, including but not limited to pre-clinical, clinical, manufacturing, and scale up activities.

(52) **Program Income**--income from fees for services performed, from the use or rental of real or personal property acquired with Grant Award funds, and from the sale of commodities

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or items fabricated under the Grant Contract. Except as otherwise provided, Program Income does not include rebates, credits, discounts, refunds, etc. or the interest earned on any of these items. Interest otherwise earned in excess of $250 on Grant Award funds is considered Program Income.

(53) **Program Integration Committee**--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 Program Integration Committee recommends for Grant Awards.

(54) **Project Results**--all outcomes of a Grant Award, including publications, knowledge gained, additional funding generated, and any and all Technology and associated Intellectual Property Rights.

(55) **Project Year**--the intervals of time (usually 12 months each) into which a Grant Award is divided for budgetary, funding, and reporting purposes. The effective date of the Grant Contract is the first day of the first Project Year.

(56) **Real Property**--land, including land improvements, structures and appurtenances thereto, excluding movable machinery and equipment.

(57) **Relative**--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.

(58) **Request for Applications**--the invitation released by the Institute seeking the submission of Grant Applications for a particular Grant Mechanism. It provides information relevant to the Grant Award to be funded, including funding amount, Grant Review Process information, evaluation criteria, and required Grant Application components.

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(59) **Review Council**--the term used to generally refer to one or more of the Prevention Review Council, the Product Development Review Council, or Scientific Review Council.

(60) **Scientific Research and Prevention Programs Committee**--a group of experts in the field of Cancer Research, Cancer Prevention or Product Development, including trained Patient Advocates, appointed by the Chief Executive Officer and approved by the Oversight Committee for the purpose of conducting Peer Review of Grants Applications and recommending Grant Awards. A Peer Review Panel is a Scientific Research and Prevention Programs Committee, as is a Review Council.

(61) **Scientific Research and Prevention Programs Committee Member**--an individual appointed by the Chief Executive Officer and approved by the Oversight Committee to serve on a Scientific Research and Prevention Programs Committee. Peer Review Panel Members are Scientific Research and Prevention Programs Committee Members, as are Review Council Members.

(62) **Scientific Review Council**--the group of Scientific Research and Prevention Programs Committee Members designated as the chairpersons of the Peer Review Panels that review Cancer Research Grant Applications. This group includes the Review Council chairperson.

(63) **Scope of Work**--the goals and objectives of the Cancer Research or Cancer Prevention project, including the timeline and milestones to be achieved.

(64) **Senior Member or Key Personnel**—the Principal Investigator, Project Director or Company Representative and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not the individuals receive salary or compensation under the Grant Award.

(65) **Technology**--any and all of the following resulting or arising from work funded by the Grant Award:

(A) Inventions;

(B) Third-Party Information, including but not limited to data, trade secrets and know-how;

(C) databases, compilations and collections of data;

(D) tools, methods and processes; and

(E) works of authorship, excluding all scholarly works, but including, without limitation, computer programs, source code and executable code, whether embodied in software, firmware or otherwise, documentation, files, records, data and mask works; and all instantiations of the foregoing in any form and embodied in any form, including but not

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limited to therapeutics, drugs, drug delivery systems, drug formulations, devices, diagnostics, biomarkers, reagents and research tools.

(66) **Texas Cancer Plan**--a coordinated, prioritized, and actionable framework that helps to guide statewide efforts to fight the human and economic burden of cancer in Texas.

(67) **Third-Party Information**--generally, all trade secrets, proprietary information, know-how and non-public business information disclosed to the Institute by Grant Applicant, Grant Recipient, or other individual external to the Institute.

(68) **Tobacco**--all forms of tobacco products, including but not limited to cigarettes, cigars, pipes, water pipes (hookah), bidis, kreteks, electronic cigarettes, smokeless tobacco, snuff and chewing tobacco.

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RULE §701.5 Oversight Committee Bylaws

The Oversight Committee shall adopt Bylaws to govern the conduct of its meetings and its management of the Institute, consistent with applicable law.

(1) The Bylaws shall include:

(A) A process to elect a presiding officer, assistant presiding officer, and any other officer positions that may be created by the Oversight Committee and to set terms of service for such positions;

(B) A meeting schedule that permits a public meeting to be held no less than once each calendar quarter, with appropriate notice and opportunity for a formal public comment period;

(C) Duties and responsibilities for the presiding officer and assistant presiding officer, as well as other additional officer positions that may be created by the Oversight Committee;

(D) Responsibilities of the Oversight Committee and the Committee's officers that are distinguished from responsibilities of the Chief Executive Officer and Institute employees;

(E) A process for the Oversight Committee to review the financial practices of the Institute, including a review of the annual financial audit of the Institute's activities and the Comptroller of Public Accounts' report and evaluation of the Institute's annual financial audit;

(F) A prohibition against an interlocking directorate between the Oversight Committee and any foundation established to benefit the Institute;

(G) A process for hiring a Chief Executive Officer and evaluating the Chief Executive Officer's job performance; and

(H) A designation of grounds for removal from the Oversight Committee based on illness, absence, or ineligibility and provide process for removal.

(2) The Bylaws must be posted on the Institute's Internet website.

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RULE §701.7 Compliance Program

(a) Oversight Committee Members, Institute Employees, Scientific Research and Prevention Program Committee Members, Program Integration Committee Members, Grant Applicants, Grant Recipients, and contract service providers are expected to comply with applicable laws, rules, regulations, and policies in conduct of their official duties and responsibilities as well as professional standards of business and personal ethics.

(b) The Institute's Compliance Program shall ensure that agency operations conform to federal and state regulations, and that such operations are undertaken consistent with the Institute's administrative rules, policies, and procedures.

(1) The Compliance Program shall specifically address at least the following agency operations: Grant Review Process, Grant Award financial reporting and performance monitoring, Institute financial reporting, internal accounting controls, and auditing.

(2) The Compliance Program shall implement and oversee systems and activities to detect and report instances of conduct that do not conform to applicable law or policy, as well as the timely response to non-conforming conduct and to prevent future similar conduct;

(3) The Compliance Program shall implement and enforce the Code of Conduct and Ethics as well as the consistent enforcement of other compliance standards and procedures adopted by the Oversight Committee.

(c) The Compliance Program shall operate under the direction of the Chief Compliance Officer.

(1) In performing the duties under this program, the Chief Compliance Officer shall have direct access to the Oversight Committee.

(2) 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.

(A) The Chief Compliance Officer shall report at least quarterly to the Oversight Committee on the Institute's compliance with the applicable laws, rules and Institute policies. The Chief Compliance Officer may report more frequently to the Audit Subcommittee of the Oversight Committee.

(B) The Chief Compliance Officer shall report at least annually on the Institute's compliance program activities, including any proposed legislation or other recommendations identified through the activities. The compliance report shall be included in the Institute's Annual Public Report.

(C) The Chief Compliance Officer shall report at least annually to the Oversight Committee on the Grant Recipients' compliance with the terms and conditions of the

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Grant Contracts. This report shall be made at the first Oversight Committee meeting following the submission of the Institute's Annual Public Report.

(D) The Chief Compliance Officer shall 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.

(d) Oversight Committee Members and Institute Employees shall participate in periodic Compliance Program training.

Proposed

RULE §701.9 **Report and Investigation of Compliance Violations**

(a) The Chief Compliance Officer oversees the Institute's activities related to the report and investigation of suspected compliance violations.

(b) To encourage good faith reporting of suspected noncompliance, the Institute shall establish a system to receive confidential reports of suspected instances or events that failed to comply with the Institute's applicable laws, rules and policies. The Institute may use a telephonic and/or electronic mailbox system, such as an "ethics hotline" to preserve confidentiality of communications regarding suspected compliance violations and the anonymity of a person making a compliance report or participating in a compliance investigation.

(1) Information describing how to report a suspected compliance violation, including a designated telephone number and electronic mail address for confidentially reporting suspected compliance violations, shall be displayed on the Institute's Internet website and included in all Institute contracts and agreements.

(2) Information describing how to report a suspected compliance violation shall be included in the Institute's employee policies manual, and discussed internally with Institute Employees and included in ethics training sessions.

(3) Only good faith reports made to the designated telephone number or electronic mailbox shall be investigated.

(c) The Institute shall implement procedures to investigate a good faith report of a suspected violation, including:

(1) The prompt initiation of an investigation by the Chief Compliance Officer;

(2) Assignment to an appropriate individual or individuals to conduct the investigation, including the Audit Subcommittee, the Compliance Office, General Counsel, the Internal Auditor, or outside experts or advisors; and

(3) A recommendation for appropriate corrective actions, if any are warranted by the investigation, made to the Oversight Committee.

(d) To the extent allowed by law, the Institute will preserve the confidential nature of the good faith report of a suspected violation, including the identity of the individual submitting the report.

(e) The Chief Compliance Officer shall maintain a log that tracks the receipt, investigation, and resolution of reports made regarding compliance violations.

(f) In performing duties under this rule, the Chief Compliance Officer has direct access to the Oversight Committee. The Chief Compliance Officer shall report to the Oversight Committee at least quarterly on compliance activity.

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(g) The following information is confidential and not subject to disclosure under Chapter 552, *Government Code*, unless the information relates to an individual who consents to the disclosure:

(1) information that directly or indirectly reveals the identity of an individual who made a report to the Institute's Compliance Program office, sought guidance from the office, or participated in an investigation conducted under the Compliance Program;

(2) information that directly or indirectly reveals the identity of an individual who is alleged to have or may have planned, initiated, or participated in activities that are the subject of a report made to the Compliance Program if, after completing an investigation, the Compliance Program determines the report to be unsubstantiated or without merit; and

(3) other information that is collected or produced in a Compliance Program investigation if releasing the information would interfere with an ongoing compliance investigation.

(h) The Oversight Committee may meet in a closed session under Chapter 551, *Government Code*, to discuss an on-going compliance investigation into issues related to fraud, waste or abuse of state resources.

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RULE §701.11 **Texas Cancer Plan**

The Institute shall develop, implement, continually monitor, and revise the Texas Cancer Plan as necessary.

(1) The intent of the Texas Cancer Plan is to reduce the cancer burden across the state and improve the lives of Texans by providing a coordinated, prioritized, and actionable framework that will help guide statewide efforts to fight the human and economic burden of cancer in Texas.

(2) Activities undertaken by the Institute to monitor the Texas Cancer Plan will be described in the Annual Public Report required by Texas Health and Safety Code Section 102.052.

(3) The Institute will periodically update the Texas Cancer Plan by issuing a revised version of the Texas Cancer Plan every seven (7) years, unless a different timeline for a revised version of the Texas Cancer Plan is approved by a simple majority of the Oversight Committee.

(4) The Institute may solicit input from public or private institutions, government organizations, non-profit organizations, other public entities, private companies, and individuals affected by cancer to assist the Institute in monitoring, implementing, and revising the Texas Cancer Plan.

(5) The most recent version of the Texas Cancer Plan shall be posted on the Institute's Internet website. A hard copy of the Texas Cancer Plan may be requested by contacting the Institute directly.

Proposed

RULE §701.13 **Advisory Committees**

The Oversight Committee may rely upon Advisory Committees of experts to advise the Oversight Committee on issues related to cancer and to inform Institute policies and procedures.

(1) The University Advisory Committee shall advise the Oversight Committee and Review Councils regarding the role of higher education in Cancer Research. The committee's membership is composed of the members specified by Section 102.154, *Health and Safety Code*.

(2) The Oversight Committee shall create an ad hoc Advisory Committee to address childhood cancers.

(3) The Oversight Committee may create additional ad hoc Advisory Committees to advise the Oversight Committee on issues related to cancer.

(4) The presiding officer of the Oversight Committee appoints experts, including practitioners and patient advocates, to serve as ad hoc Advisory Committee members, subject to approval by the Oversight Committee, for terms of service determined by the Oversight Committee.

(A) When used in this Section, the term "patient advocates" is not intended to and does not have the meaning ascribed to the same term defined by Section 701.3 of this Chapter. The term, when used herein, applies more generally to the broad category of individuals that advocate, either personally or professionally, on behalf of a group of individuals affected by cancer. A patient advocate serving on an ad hoc Advisory Committee does not undergo the selection process or receive science-based training required by Patient Advocates under Chapter 703, Section 703.5.

(B) An Institute Employee, Oversight Committee Member, or Scientific Research and Prevention Programs Committee Member may not be a member of any Advisory Committee of the Institute.

(C) Grant Applicants and Grant Recipients may be Advisory Committee members.

(5) The Institute may reimburse Advisory Committee members for reasonable and necessary expenses incurred to attend meetings or perform other official duties authorized by the presiding officer of the Oversight Committee.

(6) Each Advisory Committee shall create a committee charter for approval by the Oversight Committee that delineates the role of the Advisory Committee and expected activities.

(7) The Oversight Committee shall establish a process for each Advisory Committee to report no less than annually to the Oversight Committee regarding the activities of the Advisory Committee.

Proposed

(8) A list of the Institute's Advisory Committees and the reports presented to the Oversight Committee by each Advisory Committee shall be maintained on the Institute's Internet website.

Proposed

RULE § 701.15 **Scientific Research and Prevention Programs Committee Honoraria Policy**

The Institute recruits high level, highly respected, well established members of the Cancer Research, Product Development, or Cancer Prevention communities for appointments to Scientific Research and Prevention Programs Committees to conduct Peer Review of Grant Applications. The Institute may pay an honorarium to a Scientific Research and Prevention Programs Committee Member, pursuant to the Institute's honoraria policy.

(1) The honoraria policy shall be set by the Chief Executive Officer in consultation with the Oversight Committee and updated from time to time as necessary upon written notification to the Oversight Committee. Changes made to the honoraria policy must be supported by written justification.

(2) Honoraria rates paid by the Institute must be based upon the responsibilities, hours committed, and hourly rate commensurate with the expertise and professional background of the Scientific Research and Prevention Programs Committee Members.

(3) The honoraria policy may provide a comparison to honoraria and related compensation paid by other similar grant-making organizations to ensure that honoraria payment rates are reasonable and competitive for the value the Institute receives.

(4) Minimum documentation requirements for honoraria payments shall be set forth in the honoraria policy.

(5) The Institute's honoraria policy shall be publicly available.

Proposed

RULE § 701.17 **Scientific Research and Prevention Programs Committee Member Residency Policy**

(a) To minimize the potential for Conflicts of Interest in the Peer Review of Grant Applications, the Institute recruits individuals who live and work outside of the State to serve as Scientific Research and Prevention Programs Committee Members, including Patient Advocates, unless a special need justifies using one or more individuals living or working in Texas.

(b) If an individual who lives or works in Texas is appointed to serve as a Scientific Research and Prevention Programs Committee Member, an explanation of the special need must be provided at the time the Chief Executive Officer's appointment is approved by the Oversight Committee and recorded in the minutes of the Oversight Committee meeting.

Proposed

RULE §701.19 **Advance Payment of Grant Award Funds**

It is the Institute's policy to disburse Grant Award funds on a reimbursement basis; however, the nature and circumstances of the Grant Mechanism or a particular Grant Award may justify advance payment of funds by the Institute pursuant to the Grant Contract.

(1) The Chief Executive Officer shall seek approval from the Oversight Committee to disburse Grant Award funds by advance payment. The Chief Executive Officer's advance payment recommendation for the Grant Award must be approved by a simple majority of Oversight Committee Members present and voting. Unless specifically stated, the Oversight Committee's approval to disburse Grant Award funds by advance payment is effective for the term of the project.

(2) The Grant Contract must specify the amount, schedule, and requirements for advance payment of Grant Award funds.

(3) The Grant Recipient receiving advance payment of Grant Award funds must maintain or demonstrate the willingness and ability to maintain procedures to minimize the time elapsing between the transfer of the Grant Award funds and disbursement by the Grant Recipient.

(4) Grant Recipient must comply with all financial reporting requirements regarding use of Grant Award funds.

(5) Nothing herein creates an entitlement to advance payment of Grant Award funds; the Institute may determine in its sole discretion that circumstances justify limiting the amount of Grant Award funds eligible for advance payment, may restrict the period that advance payment of Grant Award funds will be made, or may revert to payment on a reimbursement-basis.

Proposed

RULE §701.21 **Preference for Texas Suppliers for Purchases Made by Grant Recipients**

It is the policy of the Institute to encourage the purchase of goods and services required for the Grant Award from suppliers in the State to the extent reasonably possible. A Grant Recipient shall undertake good faith efforts to purchase from suppliers in the State at least fifty percent (50%) of the goods and services purchased with Grant Award funds.

(1) A Grant Recipient must use good faith efforts to purchase goods and services from suppliers in the State when available at a price and time comparable to products and materials purchased outside of the State.

(2) A Grant Recipient that expends more than forty percent (40%) of the Grant Award funds budgeted for a Project Year on goods and services purchased outside of the State must notify the Institute in writing and provide an explanation of the good faith efforts undertaken to purchase the goods or services from suppliers in the State, including a statement that products and materials were not available in the State at a comparable price and time. Such notification and explanation may be accomplished by completing the Historically Underutilized Business and Texas Supplier form submitted as part of the annual Grant Progress Report.

(3) The Institute may deny reimbursement or require repayment of Grant Award funds already expended if the Grant Recipient fails to provide a statement as required by subsection (2) with a reasonable explanation of the good faith efforts undertaken to purchase the goods or services from suppliers in the State of Texas.

Proposed

RULE §701.23 **Historically Underutilized Businesses Policy for Grant Recipients**

It is the policy of the Institute to encourage the use of historically underutilized businesses (HUBs) by Grant Recipients to promote full and equal business opportunities for all businesses.

(1) A Grant Recipient is expected to undertake good faith efforts to utilize HUBs in subcontracts for construction, commodities purchases, and other services, including professional and consulting services, paid for with Grant Award funds.

(2) A Grant Recipient must report to the Institute at least annually regarding efforts undertaken by the Grant Recipient to utilize HUBs in the performance of the Grant Contract by completing the Historically Underutilized Business and Texas Supplier form submitted as part of the annual Grant Progress Report.

Proposed

RULE §701.25 **Electronic Signature Policy**

A Grant Recipient's use of the Institute's electronic Grant Management System to create, exchange, execute, submit, and verify legally binding Grant Contract documents and Grant Award reports shall be pursuant to an agreement between the Institute and the Grant Recipient regarding the use of binding electronic signatures. Such agreement shall include at least the following minimum standards:

(1) The Grant Recipient agrees that by entering the Authorized Signing Official's password in the electronic Grant Management System at certain specified points, the Grant Recipient electronically signs the Grant Contract document or related form. The Grant Recipient further agrees that the electronic signature is the legal equivalent of the Authorized Signing Official's manual signature.

(2) The Institute may rely upon the electronic signature rendered by entering the Authorized Signing Official's password as evidence that the Grant Recipient consents to be legally bound by the terms and conditions of the Grant Contract or related form as if the document was manually signed.

(3) The Grant Recipient shall provide prompt written notification to the Institute of any changes regarding the status or authority of the individual(s) designated by the Grant Recipient to be the Grant Recipient's Authorized Signing Official. The notice must be provided to an individual designated by the Institute.

Proposed

RULE §701.27 **Publicly Available Institute Reports and Records**

To promote transparency in its activities, the Institute maintains the information described below and makes such information publicly available through the Institute's Internet website or upon request.

(1) The Texas Cancer Plan;

(2) The Institute's Annual Public Report;

(3) The Conflict of Interest information described below for the previous 12 months:

(A) A list of disclosed Conflicts of Interest requiring recusal.

(B) Any unreported Conflicts of Interest confirmed by an Institute investigation and actions taken by the Institute regarding same.

(C) Any Conflict of Interest waivers granted.

(4) An annual report of political contributions exceeding $1,000 made to candidates for state or federal office by Oversight Committee Members for the five years preceding the Member's appointment and each year after the Member's appointment until the Member's term expires;

(5) The annual Grant Program priorities set by the Oversight Committee;

(6) Oversight Committee Bylaws;

(7) Code of Conduct and Ethics;

(8) A list, separated by Grant Program and Peer Review Panel, of the Scientific Research and Prevention Programs Committee Members provisionally appointed or approved by the Oversight Committee;

(9) The Institute's honoraria policy for Scientific Research and Prevention Programs Committee Members;

(10) The supporting documentation regarding the Institute's implementation of its Conflict of Interest policy and actions taken to exclude a conflicted Oversight Committee Member, Program Integration Committee Member, Scientific Research and Prevention Programs Committee Member or Institute Employee from participating in the review, discussion, deliberation and vote on the Grant Application.

(11) The Chief Executive Officer's annual report to the Oversight Committee on the progress and continued merit of each research Program funded by the Institute;

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(12) Grant Applicant information:

(A) Name and address;

(B) Amount of funding applied for;

(C) Type of cancer addressed by the Grant Application; and

(D) A high-level summary of work proposed to be funded by the Grant Award.

(13) Information related to Grant Awards, including the name of the Grant Recipient, the amount of the Grant Award approved by the Oversight Committee, the type of cancer addressed, and a high-level summary of the work funded by the Grant Award.

(14) Records of a nonprofit organization established to provide support to the Institute;

(15) Information related to any gift, grant, or other consideration provided to the Institute, Institute Employee, or a member of an Institute committee. Such information shall state:

(A) Donor's name;

(B) Amount of donation; and

(C) Date of donation.

(16) A list of the Institute's Advisory Committees and the reports presented to the Oversight Committee by each Advisory Committee.

(17) The Institute's approved internal audit annual report and the internal audit plan posted no later than thirty (30) after approval by the Oversight Committee, or the Chief Executive Officer if the Oversight Committee is unable to meet.

(18) A detailed summary of the weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit plan or annual report and a summary of the action taken by the Institute to the address concerns, if any, that are raised by the audit plan or annual report.

(19) Information regarding staff compensation in compliance with Section 659.026, *Government Code*.

Proposed

RULE §701.29 **Third-Party Information Held by the Institute**

(a) In order to protect the actual or potential value of information submitted to the Institute by a Grant Applicant or a Grant Recipient, the Institute shall undertake reasonable efforts to protect Third-Party Information as described herein from unauthorized public disclosure, consistent with the requirements of Chapter 552, *Government Code*.

(b) With the exception of information set forth in section (f), the Institute shall consider the following material confidential:

(1) Information that relates to a Grant Applicant's or Grant Recipient's product, device, or process that has the potential for being sold, traded, or licensed for a fee, including the application or use of such product, device, or process;

(2) All technological or scientific information developed in whole or in part by the Grant Applicant or Grant Recipient that has the potential for being sold, traded, or licensed for a fee;

(3) All information that relates to the plans, specifications, blueprints, and designs, including related proprietary information, of a scientific research and development facility;

(4) Written comments made by one or more Scientific Research and Prevention Programs Committee Members that reveals, directly or indirectly, information relating to the Grant Applicant's or Grant Recipient's product, device, or process that has the potential for being sold, traded, or licensed for a fee, including the application or use of such product, device, or process; and

(5) Information included in the business operations and management due diligence and intellectual property reviews conducted for the Grant Review Process that reveals, directly or indirectly, information relating to the Grant Applicant's or Grant Recipient's product, device, or process that has the potential for being sold, traded, or licensed for a fee.

(c) The Institute shall consider that a product, device, or process and the technological or scientific information described in the Grant Application submitted to the Institute has the potential for being sold, traded, or licensed for a fee unless the Grant Applicant informs the Institute that no economic potential exists.

(d) The confidential nature of the information submitted by the Grant Applicant or Grant Recipient is not dependent upon whether the information is patentable or capable of being registered under copyright or trademark laws.

(e) Oversight Committee Members, Institute Employees, Program Integration Committee Members, and Scientific Research and Prevention Programs Committee Members may access Third-Party Information solely for Institute purposes. All Third-Party Information in the

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individual's possession must be returned to the Institute or destroyed immediately upon the Institute's request or upon the termination of individual's employment with or service to the Institute, whichever comes first. An individual given access to Third-Party Information described herein shall not:

(1) Publicly disclose Third-Party Information for any reason unless the Institute's General Counsel determines that the disclosure is either permitted or required by law;

(2) Use non-public Third-Party Information for the individual's own personal gain or for the gain of other parties; or

(3) Copy Third-Party Information, for any reason, except as required to fulfill their duties for the Institute.

(e) The Institute may establish procedures to protect non-public Third-Party Information from unauthorized disclosure such as the use of non-disclosure agreements.

(f) Notwithstanding the foregoing, the following Third-Party Information is public information and shall be disclosed under Chapter 552, *Government Code*:

(1) The Grant Applicant's name and address;

(2) The amount of Grant Award funding applied for;

(3) The type of cancer to be addressed under the Grant Application;

(4) The high-level summary of the Grant Application specifically created to be publicly disclosed;

(5) Any other Third-Party Information submitted to the Institute by a Grant Applicant or Grant Recipient if the third-party consents to the disclosure of the information; and

(6) The records of a nonprofit organization established to provide support to the Institute.

Proposed

RULE §701.31 **Charges for Copies of Public Records**

(a) The charge to any person requesting copies of any public record of the Institute will be:

(1) Standard paper copy--$.10 per page.

(2) Nonstandard-size copy:

(A) Diskette: $1.00;

(B) Magnetic tape: actual cost;

(C) Data cartridge: actual cost;

(D) Tape cartridge: actual cost;

(E) Rewritable CD (CD-RW)--$1.00;

(F) Non-rewritable CD (CD-R)--$1.00;

(G) Digital video disc (DVD)--$3.00;

(H) JAZ drive--actual cost;

(I) Other electronic media--actual cost;

(J) VHS video cassette--$2.50;

(K) Audio cassette--$1.00;

(L) Oversize paper copy (e.g.: 11 inches by 17 inches, greenbar, bluebar, not including maps and photographs using specialty paper)--$.50 per page;

(M) Specialty paper (e.g.: Mylar, blueprint, blueline, map, photographic)--actual cost.

(3) Labor charge:

(A) For programming--$28.50 per hour;

(B) For locating, compiling, and reproducing--$15 per hour.

(4) Overhead charge-- 20% of labor charge.

(5) Microfiche or microfilm charge:

(A) Paper copy--$.10 per page;

(B) Fiche or film copy--Actual cost.

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(6) Remote document retrieval charge--Actual cost.

(7) Computer resource charge:

(A) Mainframe--$10 per CPU minute;

(B) Midsize--$1.50 per CPU minute;

(C) Client/Server system--$2.20 per clock hour;

(D) PC or LAN--$1.00 per clock hour.

(8) Miscellaneous supplies--Actual cost.

(9) Postage and shipping charge--Actual cost.

(10) Photographs--Actual cost.

(11) Maps--Actual cost.

(12) Other costs--Actual cost.

(13) Outsourced/Contracted Services--Actual cost for the copy.

(b) The Institute may reduce or waive these charges at the discretion of the Chief Executive Officer if there is a public benefit.

(c) No Sales Tax shall be applied to copies of public information.

Proposed

RULE § 701.33 **Negotiation and Mediation of Certain Breach of Contract Claims**

(a) In accordance with Government Code, Section 2260.052(c), the Institute adopts herein by reference the model rules provided by the Office of the Attorney General relating to procedures for the negotiation and mediation of certain contract claims asserted by contractors against the Institute.

(b) The procedures, as adopted, are exclusive and required prerequisites to suit against the Institute under the Civil Practice & Remedies Code, Chapter 107, and the Government Code, Chapter 2260.

(c) Nothing herein waives the Institute's sovereign immunity to suit or liability.

(d) Unless specifically provided for by the Grant Contract, this rule does not apply to Grant Contracts. The Grant Contract shall specify the process and procedures for terminating a Grant Award, as well as any associated remedy.

Proposed

CHAPTER 702 - INSTITUTE STANDARDS ON ETHICS AND CONFLICTS, INCLUDING ACCEPTANCE OF GIFTS AND DONATIONS TO THE INSTITUTE

RULE §702.1 **Authority**

This chapter is adopted pursuant to and in satisfaction of the provisions of Texas Government Code Annotated, Chapters 572 and 2255, Texas Health and Safety Code, Chapter 102, and other relevant statutes.

Proposed

RULE §702.3 **Definitions**

The words and terms used in this chapter shall have the meanings provided in Chapter 701 Section 701.3 (relating to Definitions), unless the context clearly indicates otherwise.

Proposed

RULE §702.5 **Intent**

It is the intent of the Institute that the Institute's Grant Review process provide Grant Applicants a fair and unbiased merit-based assessment free from conflicts of interest, impropriety and self-dealing. To implement this policy, this chapter provides standards of conduct and conflict of interest disclosure requirements to be observed by those individuals that are a part of the Grant Review Process and the execution of Grant Contracts. Individuals subject to this chapter include Oversight Committee Members, Program Integration Committee Members, Scientific Research and Prevention Programs Committee Members, and Institute Employees. Independent contractors, such as outside legal counsel, grant management system contractors, and subject matter experts, shall be subject to applicable provisions of this chapter to the extent that the individuals are performing duties associated with Grant Applications under consideration for Grant Awards.

Proposed

RULE §702.7 **Acceptance of Gifts and Donations by the Institute**

(a) As authorized by Texas Health and Safety Code Section 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;

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(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.

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(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 below.

(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;

(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:

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(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.

(D) Items of nominal intrinsic value less than $50, 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 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 value less than $50, 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 that the following items are not considered gifts, grants or consideration subject to the reporting requirement:

(1) 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;

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(2) Items of nominal intrinsic value less than $50, 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.

(B) 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.

Proposed

RULE §702.9 **Code of Conduct and Ethics for Oversight Committee Members, ~~and~~ Institute Employees, and Program Integration Committee Members**

(a) All Oversight Committee Members, Program Integration Committee Members, and Institute Employees shall avoid acts which are improper or give the appearance of impropriety in the disposition of state funds.

(b) The Oversight Committee shall adopt a Code of Conduct and Ethics to provide guidance related to the ethical conduct required of Oversight Committee Members, Program Integration Committee Members, and Institute Employees. The Code of Conduct and Ethics shall be distributed to each new Oversight Committee Member, Program Integration Committee Member, and Institute Employee not later than the third business day after the date that the person begins employment with or service to the Institute.

(c) The Code of Conduct and Ethics shall include at least the following requirements and prohibitions. Nothing herein prevents the Oversight Committee from adopting stricter standards:

(1) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not accept or solicit any gift, favor, or service that could reasonably influence him or her in the discharge of official duties or that he or she knows or should know is being offered with the intent to influence him or her with the intent to influence the member or employee's official conduct.

(2) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not accept employment or engage in any business or professional activity that would reasonably require or induce that person to disclose confidential information acquired by reason of the member or employee's official position.

(3) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not accept other employment or compensation that could reasonably impair his or her independent judgment in the performance of the member or employee's official duties.

(4) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not make personal investments or have a financial interest that could reasonably create a substantial conflict between his or her private interest and the member or employee's official duties.

(5) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not intentionally or knowingly solicit, accept, or agree to accept any benefit for exercising his or

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her official powers or performing the member or employee's official duties in favor of another.

(6) An Oversight Committee Member, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not lease, directly or indirectly, any property, capital equipment, employee or service to a Grant Recipient.

(7) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not submit a Grant Application to the Institute.

(8) A member of the Oversight Committee, the member's spouse, or an Institute Employee shall not be employed by or participate in the management of a business entity or other organization receiving money from the Institute.

(9) A member of the Oversight Committee or the member's spouse shall not own or control, directly or indirectly, an interest in a business or entity or other organization receiving money from the Institute.

(10) A member of the Oversight Committee or the member's spouse shall not use or receive a substantial amount of tangible goods, services, or money from the Institute other than reimbursement authorized for Oversight Committee Members~~,~~ attendance~~,~~ or expenses.

(11) A member of the Oversight Committee, Institute Employee, Program Integration Committee Member, or the spouse of an individual governed by this provision shall not serve on the 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.

(12) A member of the Oversight Committee, Institute Employee, Program Integration Committee Member, or the spouse of an individual governed by this provision shall not use non-public Third-Party Information, or knowledge of non-public decisions related to Grant Applicants, received by virtue of the individual's employment or official duties associated with the Institute to make an investment or take some other action to realize a personal financial benefit.

(13) A member of the Oversight Committee, Institute Employee, or a Program Integration Committee Member who is a member of a professional organization shall comply with any standards of conduct adopted by the organizations of which he or she is a member.

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(14) A member of the Oversight Committee, Institute Employee, or a Program Integration Committee Member shall be honest in the exercise of all duties and may not take actions that will discredit the Institute.

(15) A member of the Oversight Committee or an Institute Employee shall not have an office in a facility owned by an entity receiving or applying to receive money from the Institute.

(16) An Oversight Committee Member, Institute Employee, or Program Integration Committee Member shall report to the Institute's Chief Executive Officer any gift, grant, or consideration received by the individual as soon as possible, but no later than thirty (30) days after receipt of the gift, grant or consideration. The individual shall provide the name of the donor, the date of receipt, and amount of the gift, grant, or consideration.

(17) An Oversight Committee Member or Institute Employee may not solicit, agree to accept, or accept an honorarium in consideration for services the Oversight Committee Member or Institute Employee would not have been asked to provide but for the person's official position.

(18) An Oversight Committee Member and the Chief Executive Officer shall not make any communication to or appearance before an Institute officer or employee before the second anniversary of the date the Oversight Committee Member or Chief Executive Officer ceased to be a Oversight Committee Member or Chief Executive Officer if the communication or appearance is made:

(A) with the intent to influence; and

(B) on behalf of any person in connection with any matter on which the person seeks official action.

(19) An Oversight Committee Member or Institute Employee who ceases service or employment with the Institute may not represent any person or receive compensation for services rendered on behalf of any person regarding a particular matter in which the former Oversight Committee Member or Institute Employee participated during the period of state service or employment, either through personal involvement or because the issue was a matter within the Oversight Committee Member's or Institute Employee's official responsibility.

(A) This subsection applies to an Institute 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.

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(B) This subsection does not apply to a rulemaking proceeding that was concluded before the Oversight Committee Member's or Institute Employee's service or employment ceased.

(C) For purposes of this subsection, "participated" means to have taken action as an Oversight Committee member or Institute Employee through decision, approval, disapproval, recommendation, giving advice, investigation or similar matter.

(D) For purposes of this subsection, "particular matter" means a specific investigation, application, request for ruling or determination, rulemaking proceeding, contract, claim, charge, accusation, or judicial or other proceeding.

(d) The Code of Conduct and Ethics shall include information about reporting an actual or potential violation of the standards adopted by the Oversight Committee.

(e) Any reports due under Texas Government Code Chapter 572.021 shall be simultaneously filed with the Institute.

Proposed

RULE §702.11 **Conflicts of Interest Requiring Recusal**

(a) For purposes of this chapter, a Conflict of Interest exists when an individual subject to this rule has an interest in the outcome of a Grant Application submitted by an entity receiving or applying to receive money from the Institute such that the individual is in a position to gain financially, professionally, or personally from either a positive or negative evaluation of the Grant Application. Individuals subject to this rule are:

(1) Oversight Committee Members;

(2) Institute Employees;

(3) Scientific Research and Prevention Programs Committee Members;

(4) Program Integration Committee Members; and

(5) Independent Contractors that perform services associated with the Grant Review Process on behalf of the Institute, such as facilitating grant review activities, evaluating the intellectual property held by or licensed to a Grant Applicant, or performing a business management due diligence review.

(b) Except under exceptional circumstances as provided in §702.17 of this chapter (relating to Exceptional Circumstances Requiring Participation), an individual who has a financial, professional, or personal interest, as set forth herein, in an entity receiving or applying to receive money from the Institute shall recuse himself or herself and may not participate in the review, discussion, deliberation, or vote related to the entity.

(c) A financial Conflict of Interest exists if the individual subject to this rule or a Relative of the individual subject to this rule:

(1) Owns or controls, directly or indirectly, an ownership interest in an entity receiving or applying to receive money from the Institute or in a foundation or similar organization affiliated with the entity.

(A) Interests subject to this provision include sharing in profits, proceeds, or capital gains. Examples of ownership or control, include but are not limited to owning shares, stock, or otherwise, and are not dependent on whether voting rights are included.

(B) It is not a financial Conflict of Interest if the ownership interest is limited to shares owned via an investment in a publicly traded mutual fund or similar investment vehicle so long as the individual subject to this rule does not exercise any discretion or control regarding the investment of the assets of the fund or other investment vehicle.

(2) Could reasonably foresee that an action taken by the Scientific Research and Prevention Programs Committee, the Program Integration Committee, the Institute, or its Oversight

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Committee related to an entity receiving or applying to receive money from the Institute could result in a financial benefit to the individual.

(3) Has received a financial benefit from the Grant Applicant unrelated to the Grant Application of more than $5,000 within the past twelve months. This total includes fees, stock and other benefits. It also includes current stock holdings, equity interest, intellectual property or real property interest, but does not include diversified mutual funds or similar investment vehicle in which the person does not exercise any discretion or control regarding the investment of the assets of the fund or other investment vehicle.

(d) For purposes of this rule, a professional Conflict of Interest exists if the individual subject to this rule or a Relative of the individual subject to this rule:

(1) Is a member of the board of directors, other governing board or any committee of an entity or of a foundation or similar organization affiliated with an entity receiving or applying to receive money from the Institute during the same Grant Review Cycle;

(2) Serves as an elected or appointed officer of an entity receiving or applying to receive money from the Institute or of a foundation or similar organization affiliated with the entity;

(3) Is an employee of or is negotiating future employment with an entity receiving or applying to receive money from the Institute or a foundation or similar organization affiliated with the entity;

(4) Represents in business or law an entity receiving or applying to receive money from the Institute or a foundation or similar organization affiliated with the entity;

(5) Is a colleague, scientific mentor, or student of a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application, or is conducting or has conducted research or other significant professional activities with a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application within three years of the date of the review;

(6) Is a student, postdoctoral associate, or part of a laboratory research group for a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application or has been within the past six years;

(7) Is engaged or is actively planning to be engaged in collaboration with a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application; or

(8) Has long-standing scientific differences or disagreements with a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application that are known to the professional community and could be perceived as affecting objectivity.

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(e) For purposes of this rule, a personal Conflict of Interest exists if a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application or an applicant is a Relative or close personal friend of an individual subject to this rule.

(f) Nothing herein shall prevent the Oversight Committee from adopting more stringent standards with regard to prohibited conflicts of interest.

(g) The General Counsel and Chief Compliance Officer may provide guidance to individuals subject to this section on what interests would constitute a Conflict of Interest or an appearance of a Conflict of Interest.

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RULE §702.13 **Disclosure of Conflict of Interest and Recusal from Review**

(a) If an Oversight Committee Member or a Program Integration Committee Member has a Conflict of Interest as described in this chapter with respect to an entity or Grant ~~a~~ Application that comes before the individual for review or other action, the Member shall:

(1) Provide written notice of the Conflict of Interest to the Chief Executive Officer and the presiding officer of the Oversight Committee or the next ranking member of the Oversight Committee if the presiding officer has the Conflict of Interest;

(2) Disclose the Conflict of Interest in an open meeting of the Oversight Committee; and

(3) Recuse himself or herself from participation in the review, discussion, deliberation and vote on the entity or Grant Application, including access to information regarding the matter to be decided, unless a waiver has been granted pursuant to Section 702.15.

(b) If a Scientific Research and Prevention Programs Committee Member has a Conflict of Interest as described in this chapter with respect to a Grant Application that comes before the individual for review or other action, the member shall:

(1) Provide written notice of the Conflict of Interest to the Chief Executive Officer; and

(2) Recuse himself or herself from any participation in the review, discussion, scoring, deliberation and vote on the Grant Application, including access to information regarding the matter to be decided, unless a waiver has been granted pursuant to Section 702.15.

(c) Some Conflicts of Interest are such that the existence of a conflict with a Grant Applicant applying for a Grant Mechanism raises the presumption that the conflict may affect the individual's impartial review of other Grant Applications pursuant to the same Grant Mechanism in the Grant Review Cycle. The Institute has determined that the existence of one or more of the following Conflicts of Interest for an Oversight Committee Member, Scientific Research and Prevention Programs Committee Member, Program Integration Committee Member, Institute employee, Independent Contractor or a Relative of an individual subject to this rule shall require recusal of the individual from participating in the review, discussion, scoring, deliberation and vote on all Grant Applications competing for the same Grant Mechanism in the entire Grant Review Cycle, unless a waiver has been granted pursuant to Section 702.15:

(1) The individual subject to this provision is an employee of a Grant Applicant;

(2) The individual subject to this provision is actively seeking employment with a Grant Applicant. For the purposes of this subsection, "actively seeking employment" includes activities such as submission of an employment application, resume, curriculum vitae, or similar document and/or interviewing with one or more representatives from the organization with no final action taken by the organization regarding consideration of such employment;

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(3) The individual subject to this provision serves on the board of directors or as an elected or appointed officer of a Grant Applicant or a foundation or similar organization affiliated with the Grant Applicant; or

(4) The individual subject to this provision owns or controls, directly or indirectly, an ownership interest in a Grant Applicant or a foundation or similar organization affiliated with the Grant Applicant. Interests subject to this provision include sharing in profits, proceeds, or capital gains. Examples of ownership or control, include but are not limited to owning shares, stock, or otherwise, and are not dependent on whether voting rights are included.

(d) If an Institute Employee or independent contractor involved in the Grant Review Process has a Conflict of Interest as described in this chapter with respect to a Grant Application that comes before the individual for review or other action, the Institute Employee or independent contractor shall:

(1) Provide written notice to the Chief Executive Officer of the Conflict of Interest; and

(2) Recuse himself or herself from participation in the review of the Grant Application and be prevented from accessing information regarding the matter to be decided, unless a waiver has been granted pursuant to Section 702.15.

(e) The Institute shall retain supporting documentation regarding the implementation of its Conflict of Interest policy and actions taken to exclude a conflicted Oversight Committee Member, Program Integration Committee Member, Scientific Research and Prevention Programs Committee Member or Institute Employee from participating in the review, discussion, deliberation and vote on the Grant Application.

(1) The supporting documentation retained by the Institute may be stored by the Institute's electronic Grant Management System.

(2) For purposes of this rule, "supporting documentation" may include Conflict of Interest agreements, Conflict of Interest disclosure forms, action taken to address a previously unreported Conflict of Interest after its existence is determined, approved waivers, sign-out sheets, independent third party observation reports, post-review certifications and Oversight Committee meeting minutes.

(3) All supporting documentation shall be publicly available, except that information included in the supporting documentation that is otherwise protected by Chapter 552, *Government Code* may be redacted.

(f) Individuals subject to this chapter are encouraged to self-report. Any individual who self-reports a potential Conflict of Interest or any impropriety or self-dealing, and who fully complies with any recommendations of the General Counsel and recusal from any discussion, voting, deliberation or access to information regarding the matter, shall be considered by the Institute to

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be in compliance with this chapter. The individual is still subject to the operation of other laws, rules, requirements or prohibitions. Substantial compliance with the procedures provided herein constitutes compliance.

(g) Intentional violations of this rule may result in the removal of the individual from further participation in the Institute's Grant Review Process.

Proposed

RULE §702.15 **Investigation of Unreported Conflicts of Interest Affecting the Grant Review Process**

(a) An Oversight Committee Member, a Program Integration Committee Member, a Scientific Research and Prevention Programs Committee Member, or an Institute Employee who becomes aware of a potential Conflict of Interest described by Section 702.11 that has not been reported shall immediately notify the Chief Executive Officer of the potential Conflict of Interest. If the potential Conflict of Interest is held by the Chief Executive Officer, then the report shall be made directly to the presiding officer of the Oversight Committee. Upon notification, the Chief Executive Officer must notify the presiding officer of the Oversight Committee and the General Counsel of the unreported conflict.

(b) A Grant Applicant seeking an investigation regarding whether an individual subject to this chapter failed to report a Conflict of Interest described by Section 702.11 shall file a written request with the Institute's Chief Executive Officer. The Grant Applicant shall:

(1) Provide all facts regarding the alleged Conflict of Interest known to the Grant Applicant requesting the investigation; and

(2) Submit the request for investigation not later than the 30th day after the Chief Executive Officer presents final funding recommendations for the affected Grant Review Cycle to the Oversight Committee. Nothing herein prohibits the Chief Executive Officer from initiating an investigation if the Grant Applicant fails to submit the request by the deadline set herein, so long as the Grant Applicant shows good cause for failing to meet the deadline.

(c) On notification of an alleged Conflict of Interest under subsection (a) or (b), the General Counsel shall:

(1) Investigate the matter; and

(2) Provide an opinion to the Chief Executive Officer and presiding officer of the Oversight Committee. If the alleged conflict is held by the presiding officer, then the opinion shall be provided to the next ranking member of the Oversight Committee who has no conflict. The opinion shall include:

(A) A statement of the facts giving rise to the alleged conflict;

(B) A determination of whether a Conflict of Interest, another impropriety, or self-dealing exists; and

(C) If the opinion finds that a Conflict of Interest or another impropriety or self-dealing exists, then recommendations for any appropriate course of action.

(d) After receiving the General Counsel's opinion and consulting with the presiding officer (or, if appropriate, the next highest ranking Oversight Committee Member), the Chief Executive

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Officer shall take immediate actions regarding the recusal of the individual from any discussion of or access to information regarding the matter at issue. If the alleged Conflict of Interest is held by the Chief Executive Officer, the presiding officer of Oversight Committee shall take actions regarding recusal.

(e) A determination regarding the existence of a Conflict of Interest involving an individual subject to this chapter shall be made by the Chief Executive Officer, or by the presiding officer of the Oversight Committee if the alleged Conflict of Interest is held by the Chief Executive Officer, and reported to the Oversight Committee. The determination will be considered final unless three or more Oversight Committee Members request that the issue be added to the agenda of the Oversight Committee. The determination must include actions to be taken, if any, to address the Conflict of Interest, impropriety, or self-dealing, including:

(1) Reconsideration of the Grant Application; or

(2) Referral of the Grant Application to a different Scientific Research and Prevention Programs Committee for review.

(f) The Chief Executive Officer or, if applicable, the presiding officer of the Oversight Committee must provide written notice of the final determination to the person requesting the investigation, including a description of further actions to be taken, if any.

(g) Unless specifically stated in the final determination, the validity of an action taken with regard to a Grant Application is not affected by the fact that an individual that failed to report a Conflict of Interest participated in the action.

Proposed

RULE §702.17 **Exceptional Circumstances Requiring Participation**

In exceptional cases, as determined by a vote of the simple majority of the Oversight Committee present and voting, the participation of an Oversight Committee Member, Institute Employee, Program Integration Committee Member, independent contractor, or Scientific Research and Prevention Programs Committee Member in the Grant Review Process, the Grant Contract process, or the monitoring of the Grant Award outweighs the potential bias posed by a Conflict of Interest held by the individual and a waiver from recusal required by Section 702.13 may be granted by the Oversight Committee, unless otherwise prohibited by state or federal law.

(1) The Chief Executive Officer or an Oversight Committee Member may propose granting a waiver on behalf of the Oversight Committee Member, the Institute Employee, the Program Integration Committee Member, independent contractor, or the Scientific Research and Prevention Programs Committee Member by submitting a written statement to the presiding officer of the Oversight Committee. The statement must include:

(A) information about the Conflict of Interest, including the name and position of the person with the conflict to be waived;

(B) the exceptional circumstances justifying a waiver of one or more of the Institute's Conflict of Interest provisions;

(C) that the integrity of the Grant Review Process, the Grant Contract process, the monitoring of Grant Awards, or committee action would not be impaired by the individual's participation; and

(D) any proposed limits on certain activities to be taken by the individual.

(2) Oversight Committee and publicly reported at the Oversight Committee meeting. The waiver is granted if a majority of the Oversight Committee Members present and voting approve the waiver. The vote on a proposed waiver may take place prior to the Oversight Committee's decision regarding the Grant Applications recommended for funding.

(3) If the Conflict of Interest is one that is reasonably expected to affect more than one Grant Review Cycle or grant monitoring activities in a fiscal year, the waiver proposal may request that the waiver apply for all activities associated with the Grant Review Process, Grant Contract process, or grant monitoring process during the fiscal year.

(4) The Institute shall report annually to the Governor, the Lieutenant Governor, and the Speaker of the House of Representatives, and the standing committee of each house of the legislature with primary jurisdiction over Institute matters on all waivers granted for the past twelve months. The reporting obligation is fulfilled by including the information in the Institute's Annual Public Report required by Texas Health and Safety Code Section 102.052.

Proposed

RULE §702.19 **Restriction on Communication Regarding Pending Grant Application**

(a) Communication regarding the substance of a pending Grant Application between the Grant Applicant and an Oversight Committee Member, a Program Integration Committee Member, or a Scientific Research and Prevention Programs Committee Member is prohibited.

(b) The prohibition on communication begins on the first day that Grant Applications for the Grant Mechanism are accepted by the Institute and extends until the Grant Applicant receives notice regarding a final decision on the Grant Application.

(1) The prohibition on communication does not apply to the time period when pre-applications or letters of interest are accepted.

(2) In special circumstances, an Oversight Committee Member or a Program Integration Committee Member may respond to a question or request for more information from a Grant Applicant so long as the response is made available to all Grant Applicants.

(c) Intentional, serious, or frequent violations of this rule may result in the disqualification of the Grant Applicant from further consideration for a Grant Award.

(d) This rule is not intended to prohibit open dialogue between the public and the Chief Executive Officer, a Program Integration Committee Member, or a member of the Oversight Committee regarding the general status or nature of pending Grant Applications.

(e) The Chief Executive Officer may grant a waiver from the general prohibition on communication upon finding that the waiver is in the interest of promoting the objectives of the Institute and is not intended to give one or more Grant Applicants an unfair advantage. The waiver shall be in writing and state the reasons for the granting the waiver. The waiver shall be publicly available.

(f) A Program Integration Committee Member shall not communicate individually with one or more Oversight Committee Members about a Grant Award recommendation for a Grant Application in a pending Grant Review Cycle until such time that the Program Integration Committee has submitted the list of Grant Award Recommendations to the Oversight Committee and the Chief Executive Officer has submitted the written affidavit required by Section 703.7. Nothing herein shall prohibit the Chief Executive Officer or a Program Integration Committee Member from responding to an individual Oversight Committee Member's question or request for more information so long as the response is made available to all Oversight Committee Members.

Proposed

RULE §702.21 **Availability of Information**

The members of the Oversight Committee shall receive training on the Texas Public Information Act and the Texas Open Meetings Act after the conclusion of each regular session of the Texas Legislature. This requirement is in addition to any statutorily required training and may be met by attending a training session during a meeting of the Oversight Committee, or via other form of in-person, video, or on-line training approved by the Attorney General.

Proposed

CHAPTER 703 – GRANTS FOR CANCER RESEARCH AND PREVENTION

RULE §703.1 **Purpose and Application**

(a) Grant Awards from the Institute shall fund:

(1) Research into the causes of and cures for all types of cancer in humans;

(2) Facilities for use in research into the causes 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;

(4) Cancer Prevention and Control Programs in this state to mitigate the incidence of all types of cancer in humans;

(5) Support for institutions of learning and advanced medical research facilities and collaborations in this state in all stages in the process of finding the causes of all types of cancer in humans and developing cures, from laboratory research to clinical trials and including programs to address the problem of access to advanced cancer treatment; and

(6) Implementation of the Texas Cancer Plan.

(b) The Oversight Committee shall annually set priorities for each of the Institute's Grant Programs to be considered during the Institute's Grant Review Process,

(1) The presiding officer of the Oversight Committee is responsible for establishing a process to develop annual Grant Program priorities.

(2) The annual Grant Program priorities shall be approved by a simple majority of the Oversight Committee and posted on the Institute's Internet website.

Proposed

RULE §703.2 **Definitions**

The words and terms, when used in this chapter, shall have the meanings provided in Chapter 701 Section 701.3 (relating to Definitions), unless the context clearly indicates otherwise.

Proposed

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 Section 703.6 of this Chapter 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;

Proposed

(8) Implementation of the Texas Cancer Plan; and

(9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.

(d) An 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 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.

Proposed

(3) Notwithstanding the foregoing, one or more donations exceeding $500 by an employee of a Grant Applicant not described by subsection (2) shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.

(3) The certification shall be made at the time the Grant Application is submitted.

(4) 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.

(5) 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.

(6) 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.

(7) 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 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.

Proposed

(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.

Proposed

RULE §703.4 **Grants Management System**

The Institute may engage third-party grants management services. Such services may include the deployment and maintenance of an electronic Grants Management System to facilitate the Institute's receipt and review of Grant Applications, execution of Grant Contracts, and the ongoing monitoring and management of Grant Awards, including required Grant Recipient reports and submissions.

(1) The Institute may use the electronic Grants Management System to:

(A) Facilitate the Institute's receipt and review of Grant Applications;

(B) Maintain complete Grant Review Process records for Grant Applications undergoing Peer Review, including the final Overall Evaluation Score and Numerical Ranking Score assigned to Grant Applications during the Peer Review Process;

(C) Maintain supporting documentation regarding the implementation of the Institute's Conflict of Interest process for each Grant Review Cycle, including a list of any Conflicts of Interest requiring recusal, any unreported Conflicts of Interest confirmed by an investigation and the actions taken, any waivers, the identity of the Primary Investigator, Program Director or Company Representative and the funding sources for the Grant Award project;

(D) Expedite execution of Grant Contracts and the electronic submission of Grant Contract change requests and required Grant Award reports;

(E) Maintain complete Grant Award records, including the Grant Contract and Matching Funds certification, required Grant Award financial reports and Grant Progress Reports, and the Institute's review of those reports;

(F) Support the Institute's Grant Award compliance monitoring by tracking the due dates and submission status for required Grant Award reports; and

(G) Monitor the status of past-due required Grant Award financial reports and Grant Progress Reports.

(2) The Institute may require, as a condition of receiving a Grant Award, that the Grant Recipient use the Institute'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 the Institute's electronic signature policy as set forth in Chapter 701, Section 701.25 (relating to Electronic Signature Policy).

(3) The Institute shall require periodic audits of any electronic Grant Management System. Weaknesses identified by system audits must be timely addressed pursuant to a specified timeline.

Proposed

RULE §703.5 **Scientific Research and Prevention Programs Committees ~~Members~~**

(a) The Oversight Committee shall establish Scientific Research and Prevention Programs Committees for the purpose of conducting Peer Review of Grant Applications submitted to the Institute. The Chief Executive Officer, with approval by simple majority of the Oversight Committee, is responsible for appointing experts in the fields of Cancer Research, Prevention, life science Product Development, and patient advocacy to serve as Scientific Research and Prevention Programs Committee members for terms designated by the Chief Executive Officer.

(b) The Chief Executive Officer may provisionally appoint an individual as a Scientific Research and Prevention Programs Committee Member until such time that the individual can be considered for approval by the Oversight Committee. The provisional appointee may participate in the Peer Review Process prior to a vote of the Oversight Committee on the appointment so long as the appointment is considered at the next regular Oversight Committee meeting.

(c) A Scientific Research and Prevention Programs Committee Member~~s~~ is responsible for conducting Peer Review of the Grant Applications assigned to the individual member's Peer Review Panel.

(d) A Scientific Research and Prevention Programs Committee Member may receive an honorarium in accordance with the policy described in Chapter 701, Section 701.15 of this title (relating to the Scientific Research and Prevention Programs Committee Honoraria Policy).

(e) A member of a Scientific Research and Prevention Programs Committee is prohibited from attempting to use the committee member's official position to influence a decision to approve or award a grant or contract to the committee member's employer.

(f) A member of a Scientific Research and Prevention Programs Committee must comply with 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, Health and Safety Code.

(g) The Scientific Research and Prevention Programs Committee Member shall not provide professional services for compensation exceeding $5,000 to any Grant Recipient that was reviewed by the Scientific Research and Prevention Programs Committee Member's Peer Review Panel.

(1) The term of this restriction is for a period of one year from the effective date of the Grant Award, unless waived by a vote of the Oversight Committee.

(2) For purposes of this restriction, "professional services" do not include those services for which an honorarium is paid; however, honoraria exceeding $5,000 paid to a Scientific Research and Prevention Programs Committee Member by a Grant Recipient while the

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individual is serving as a Committee Member shall be reported within 30 days to the Institute's Chief Executive Officer.

(3) Even if a payment to a Scientific Research and Prevention Programs Committee Member is not otherwise prohibited, a Grant Recipient shall not pay a Scientific Research and Prevention Programs Committee Member with Grant Award funds.

(h) An individual that serves as a Scientific Research and Prevention Programs Committee Member may not concurrently serve on the Board of Directors or other governing board of a Grant Recipient or of a foundation or similar organization affiliated with the entity. This prohibition lasts so long as the Grant Recipient receives Grant Award funds or the Scientific Research and Prevention Programs Committee Member receives an honorarium from the Institute, whichever ends first.

(i) The Scientific Research and Prevention Programs Committee Member shall not use non-public Third-Party Information or knowledge of non-public decisions related to Grant Applicants, gained by virtue of the individual's participation in the Institute's Peer Review Process, to make an investment or take some other action resulting in a financial benefit to the individual or the individual's employer.

(j) A violation of any requirement of this section may result in the removal of the Scientific Research and Prevention Programs Committee Member from further participation in the Institute's Peer Review Process.

(k) The Institute shall provide on the Institute's Internet website a register of the individuals appointed as Scientific Research and Prevention Programs Committee Members, including provisional members. The register may list the Scientific Research and Prevention Programs Committee members by Peer Review Panel. For the purpose of identifying undisclosed Conflicts of Interest, a Grant Applicant may be notified of the Peer Review Panel to which the Grant Application has been assigned.

(l) The Chief Executive Officer shall ensure that at least one Patient Advocate is appointed to each Peer Review Panel. To be considered for a Patient Advocate appointment by the Chief Executive Officer as a Scientific Research and Prevention Programs Committee Member, an applicant must:

(1) Represent an organization or other community of people;

(2) Demonstrate prior community involvement or other work on behalf of cancer patients;

(3) Possess good communication and writing skills, including the ability to analyze information and make judgments with consideration of patient impact;

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(4) Express interest in and fundamental knowledge of the medical research process, including basic and translational scientific research and prevention concepts;

(5) Reside outside of the state of Texas;

(6) Have science-based training. This training requirement shall be considered fulfilled if the Patient Advocate has:

(A) attended a science-based training program from the American Association for Cancer Research Survivor-Scientist Program, American Society of Clinical Oncology Research Review Sessions for Patient Advocates, Research Advocacy Network Advocate Institute or National Breast Cancer Coalition Project LEAD no more than three years prior to appointment to the Institute's Scientific Research and Prevention Programs Committee; or

(B) participated in at least one full cycle of grant review conducted by the Institute, National Institutes of Health, Department of Defense Congressionally Directed Medical Research Programs, Federal Drug Administration or Patient-Centered Outcomes Research Institute no more than three years prior to appointment to the Institute's Scientific Research and Prevention Programs Committee.

(m) An individual interested in a Patient Advocate appointment shall submit an application, in a format specified by the Institute that includes at least the following information:

(1) Dates of service on a peer review panel within the past three years, or dates of attendance at advocate training programs within the past 3 years as documentation of the fulfillment of the science-based training program requirement;

(2) Current resume or curriculum vitae;

(3) A letter of recommendation from a community-based organization and a personal statement on advocacy and education if the applicant has attended a training program but not yet served on a peer review panel.

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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, *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), 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

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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.

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(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). 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). 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 chairperson is responsible for determining the Grant Applications that move forward to initial review as described in subsection (c). 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.

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(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

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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

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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 Section 702.17, 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 Section 703.9 of this Chapter, 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

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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.

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RULE §703.7 **Program Integration Committee Funding Recommendation**

(a) The Institute uses a Program Review process undertaken by the Institute's Program Integration Committee to identify and recommend for funding a final list of meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control Program projects that are in the best overall interest of the State.

(b) Program Review shall 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, Health and Safety Code.

(c) The Program Integration Committee shall meet pursuant to a schedule established by the Chief Executive Officer, who serves as the Committee's presiding officer, to consider the prioritized list of Grant Applications submitted by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council.

(d) The Program Integration Committee shall approve by a majority vote a final list of Grant Applications recommended for Grant Awards to be provided to the Oversight Committee. In composing the final list of Grant Applications recommended for Grant Award funding, the Program Integration Committee shall:

(1) Substantially base the list upon the Grant Award recommendations submitted by the Review Council.

(2) To the extent possible, give priority for funding to Grant Applications that:

(A) Could lead to immediate or long-term medical and scientific breakthroughs in the area of Cancer Prevention or cures for cancer;

(B) Strengthen and enhance fundamental science in Cancer Research;

(C) Ensure a comprehensive coordinated approach to Cancer Research and Cancer Prevention;

(D) Are interdisciplinary or interinstitutional;

(E) Address federal or other major research sponsors' priorities in emerging scientific or Technology fields in the area of Cancer Prevention, or cures for cancer;

(F) Are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;

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(G) Are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;

(H) Have a demonstrable economic development benefit to this state;

(I) Enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources;

(J) Expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or Technology research capabilities; and

(K) Address the goals of the Texas Cancer Plan.

(3) Document the factors considered in making the Grant Award recommendations, including any factors not listed in subsection (d)(2) of this section;

(4) Explain in writing the reasons for not recommending a Grant Application that was recommended for a Grant Award by the Review Council;

(5) Specify the amount of Grant Award funding for each Grant Application.

(A) Unless otherwise specifically stated, the Program Integration Committee adopts the changes to the Grant Award amount recommended by the Review Council.

(B) If the Program Integration Committee approves a change in the Grant Award amount that was not recommended by the Review Council, then the Grant Award amount and a written explanation for the change shall be provided.

(6) Specify changes, if any, to the Grant Application's goals and objectives or timeline recommended for a Grant Award and provide an explanation for the changes made; and

(7) Address how the funding recommendations meet the annual priorities for Cancer Prevention, Cancer Research and Product Development programs and affect the Institute's overall Grant Award portfolio established by the Oversight Committee.

(e) In the event that the Program Integration Committee's vote on the final list of Grant Award recommendations is not unanimous, then the Program Integration Committee Member or Members not voting with the majority may submit a written explanation to the Oversight Committee for the vote against the final list of Grant Award recommendations. The explanation

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may include the Program Integration Committee Member or Members' recommended prioritized list of Grant Award recommendations.

(f) 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. A Grant Application not included on the prioritized list created by the Program Integration Committee shall not be considered further during the Grant Review Cycle, except for the following:

(1) In the event that the Program Integration Committee's vote on the final list of Grant Award recommendations is not unanimous, then, upon a motion of an Oversight Committee Member, the Oversight Committee may also consider the Grant Award recommendations submitted by the non-majority Program Integration Committee Member or Members; or

(2) A finding of an undisclosed Conflict of Interest as set forth in Section 703.9 of this Chapter.

(g)The Chief Compliance Officer shall attend and observe Program Integration Committee meetings to document compliance with Chapter 102, *Health and Safety Code* and the Institute's administrative rules.

(h) At the time that the Program Integration Committee's final Grant Award recommendations are formally submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the Program Integration Committee containing relevant information related to the Grant Application recommendation.

(1) Information to be provided in the Chief Executive Officer's affidavit may include:

(A) The Peer Review process for the recommended Grant Application, including:

(i) The Request for Applications applicable to the Grant Application;

(ii) The number of Grant Applications submitted in response to the Request for Applications;

(iii) The name of the Peer Review Panel reviewing the Grant Application;

(iv) Whether a preliminary review process was used by the Peer Review Panel for the Grant Mechanism in the Grant Review Cycle;

(v) An overview of the Conflict of Interest process applicable to the Grant Review Cycle noting any waivers granted; and

(vi) A list of all final Overall Evaluation Scores for all Grant Applications submitted pursuant to the same Grant Mechanism, de-identified by Grant Applicant.

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(B) The final Overall Evaluation Score and Numerical Ranking Score assigned for the Grant Applications recommended during the Peer Review process; and

(C) A high-level summary of the business operations and management due diligence and intellectual property reviews, if applicable, conducted for a Cancer Research Product Development Grant Application.

(2) In the event that the Program Integration Committee's final Grant Award recommendations are not unanimous and the Program Integration Committee Member or Members in the non-majority recommend Grant Applications not included on the final list of Grant Award recommendations, then the Chief Executive Officer shall also prepare a written affidavit for each Grant Application recommended by the non-majority Program Integration Committee Member or Members.

(i) To the extent that the information or documentation for one Grant Application is the same for all Grant Applications recommended for Grant Award funding pursuant to the same Grant Mechanism, it shall be sufficient for the Chief Executive Officer to provide the information or documentation once and incorporate by reference in each subsequent affidavit.

(j) At least three business days prior to the Oversight Committee meeting held to consider the Grant Applications for Grant Award funding, the Chief Executive Officer shall provide a list of Grant Applications, if any, recommended for an advance of Grant Award funds upon execution of the Grant Contract. The list shall include the reasons supporting the recommendation to advance funds.

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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) 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.

(3) 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.

(4) The Oversight Committee may not award more than $300 million in Grant Awards in a fiscal year.

Proposed

RULE §703.9 **Limitation on Review of Grant Process**

(a) The decision to recommend a Grant Application for funding is based upon the sufficiency, merit, and, if applicable, Product Development prospects of the Grant Application, as determined by the Institute's Peer Review and Program Review processes as described in the Chapter.

(b) By submitting a Grant Application, the Grant Applicant understands and accepts that grounds for reconsideration of the Institute's final decision regarding a Grant Application are limited to an undisclosed Conflict of Interest as 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).

(c) The Grant Applicant shall file a request with the Chief Executive Officer for a review of the Grant Review Process based on the undisclosed Conflict of Interest pursuant to the process and timeline set forth in Chapter 702 of this title.

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RULE §703.10 **Awarding Grants by Contract**

(a) The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds and enter into a written contract with the Grant Recipient.

(b) The Oversight Committee may delegate Grant Contract negotiation duties to the Chief Executive Officer and the General Counsel for the Institute. The Chief Executive Officer may enter into a written contract with the Grant Recipient on behalf of the Oversight Committee.

(c) The Grant Contract shall include the following provisions:

(1) If any portion of the Grant Contract has been approved by the Oversight Committee to be used to build a capital improvement, the Grant Contract shall specify that:

(A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale;

(2) Terms relating to Intellectual Property Rights and the sharing with the Institute of revenues generated by the sale, license, or other conveyance of such Project Results consistent with the standards established by this chapter;

(3) Terms relating to publication of materials created with Grant Award funds or related to the Cancer Research or Cancer Prevention project that is the subject of the Grant Contract, including an acknowledgement of Institute funding and copyright ownership, if applicable;

(4) Repayment terms, including interest rates, to be enforced if the Grant Recipient has not used Grant Award funds for the purposes for which the Grant Award was intended;

(5) A statement that the Institute does not assume responsibility for the conduct of the Cancer Research or Cancer Prevention project, and that the conduct of the project and activities of all investigators are under the scope and direction of the Grant Recipient;

(6) A statement that the Cancer Research or Cancer Prevention project is conducted with full consideration for the ethical and medical implications of the project and that the project will comply with all federal and state laws regarding the conduct of the Cancer Research or Prevention project;

(7) Terms related to the standards established by the Oversight Committee in Chapter 701 to ensure that Grant Recipients, to the extent reasonably possible, demonstrate good faith effort to purchase goods and services for the Grant Award project from suppliers in this state and

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from historically underutilized businesses as defined by Chapter 2161, Government Code, and any other state law;

(8) An agreement by the Grant Recipient to submit to regular inspection reviews of the Grant Award project by Institute staff during normal business hours and upon reasonable notice to ensure compliance with the terms of the Grant Contract and continued merit of the project;

(9) An agreement by the Grant Recipient to submit Grant Progress Reports to the Institute on a schedule specified by the Grant Contract that include information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Institute funding;

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

(11) An agreement that the Grant Recipient will abide by the Uniform Grant Management Standards (UGMS) adopted by the Governor's Office, if applicable, unless one or more standards conflicts with a provision of the Grant Contract, Chapter 102, *Health and Safety Code*, or the Institute's administrative rules. Such interpretation of the Institute rules and UGMS shall be made by the Institute;

(12) An agreement that the Grant Recipient is under a continuing obligation to notify the Institute of any adverse conditions that materially impact milestones and objectives included in the Grant Contract;

(13) An agreement that the design, conduct, and reporting of the Cancer Research or Prevention project will not be biased by conflicting financial interest of the Grant Recipient or any individuals associated with the Grant Award. This duty is fulfilled by certifying that an appropriate written, enforced Conflict of Interest policy governs the Grant Recipient.

(14) An agreement regarding the amount, schedule, and requirements for payment of Grant Award funds, if such advance payments are approved by the Oversight Committee in accordance with this Chapter. Notwithstanding the foregoing, the Institute may require that up to ten percent of the final tranche of funds approved for the Grant Award must be expended on a reimbursement basis. Such reimbursement payment shall not be made until close out documents described in this section and required by the Grant Contract have been submitted and approved by the Institute;

(15) An agreement to provide quarterly Financial Status Reports and supporting documentation for expenses submitted for reimbursement or, if appropriate, to demonstrate how advanced funds were expended;

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(16) A statement certifying that, as of June 14, 2013, the Grant Recipient has not made and will not make a contribution, during the term of the Grant Contract, to the Institute or to any foundation established specifically to support the Institute;

(17) A statement specifying the agreed effective date of the Grant Contract and the period in which the Grant Award funds must be spent. If the effective date specified in the Grant Contract is different from the date the Grant Contract is signed by both parties, then the effective date shall control;

(18) A statement providing for reimbursement with Grant Award funds of expenses made prior to the effective date of the Grant Contract at the discretion of the Institute. Pre-contract reimbursement shall be made only in the event that:

(A) The expenses are allowable pursuant to the terms of the Grant Contract;

(B) The request is made in writing by the Grant Recipient and approved by the Chief Executive Officer; and

(C) The expenses to be reimbursed were incurred on or after the date the Grant Award recommendation was approved by the Oversight Committee.

(19) Requirements for closing out the Grant Contract at the termination date, including the submission of a Financial Status Report, a final Grant Progress Report, a equipment inventory, a HUB and Texas Business report, a revenue sharing form, a single audit determination report form and a list of contractual terms that extend beyond the termination date;

(20) A certification of dedicated Matching Funds equal to one-half of the amount of the Research Grant Award that includes the name of the Research Grant Award to which the matching funds are to be dedicated, as specified in Section 703.11 of this Chapter;

(21) The project deliverables as described by the Grant Application and stated in the Scope of Work for the Grant Contract reflecting modifications, if any, approved during the Peer Review process or during Grant Contract negotiation; and

(22) An agreement that the Grant Recipient shall notify the Institute and seek approval for a change in effort for any of the Senior Members or Key Personnel of the research or prevention team listed on the Grant Application.

(d) The Grant Recipient's failure to comply with the terms and conditions of the Grant Contract may result in termination of the Grant Contract pursuant to the process prescribed in the Grant Contract and trigger repayment of the Grant Award funds.

Proposed

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 Recipients 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 Section 61.003, 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 the Section 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) 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

Proposed

(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;

(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 Section 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.

Proposed

(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) based upon the specific reasons for the deficiency. To the extent that other action not described herein is taken by the Institute, such action shall be documented in writing and included in Grant Contract records. The options described in subsections (h)(1) and (2) 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.

Proposed

(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.

Proposed

RULE §703.12 **Limitation on Use of Funds**

(a) A Grant Recipient may use Grant Award funds only for Cancer Research and Cancer Prevention projects consistent with the purpose of the Act, and in accordance with the Grant Contract. Grant Award funds may not be used for purposes other than those purposes for which the grant was awarded. The Institute may require a Grant Recipient to repay Grant Award funds if the Grant Recipient fails to expend the Grant Award funds in accordance with the terms and conditions of the Grant Contract and the provisions of this chapter.

(b) Grant Award funds must be used for Authorized Expenses.

(1) Expenses that are not authorized and shall not be paid from Grant Award funds, include, but are not limited to:

(A) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(B) Contributions to a contingency reserve or any similar provision for unforeseen events.

(C) Contributions and donations made to any individual or organization.

(D) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(E) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(F) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(G) An honorary gift or a gratuitous payment.

(H) Interest and other financial costs related to borrowing and the cost of financing.

(I) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(J) Liability insurance coverage.

(K) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(L) Professional association fees or dues for the Grant Recipient or an individual.

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(M) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(N) Patient support services costs relating to services such as personal care items and financial assistance for low-income clients.

(2) Additional guidance regarding Authorized Expenses for a specific program may be provided by the terms of the Grant Contract and by the Uniform Grant Management Standards (UGMS) adopted by the Governor's Office. If guidance from UGMS on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, *Health and Safety Code*, or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(3) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Authorized Expense.

(c) A Grant Recipient of Grant Award funds for a Cancer Research project may not spend more than five percent (5%) of the Grant Award funds for Indirect Costs.

(d) The Institute may not award more than five percent (5%) of the total Grant Award funds for each fiscal year to be used for facility purchase, construction, remodel, or renovation purposes during any year. Any Grant Award funds that are to be expended by a Grant Recipient for facility purchase, construction, remodel, or renovations are subject to the following conditions:

(1) The use of Grant Award funds must be specifically approved by the Chief Executive Officer with notification to the Oversight Committee;

(2) Grant Award funds spent on facility purchase, construction, remodel, or renovation projects must benefit Cancer Prevention and Research;

(3) If Grant Award funds are used to build a capital improvement, then the state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award funds used to pay for the capital improvement. If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award funds used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale.

(e) The Institute may not award more than ten percent (10%) of the money awarded from the Cancer Prevention and Research Fund or from the proceeds of bonds issued on behalf of the Institute to be used for Cancer Prevention and Control programs during any year. Grant Awards for Cancer Prevention research projects shall not be counted toward the Grant Award amount limit for Cancer Prevention and Control Programs. For purposes of this subsection, the Institute is presumed to award the full amount of funds available.

Proposed

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 no later than nine (9) months 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.

(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.

Proposed

(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 a Grant Award until the required audit and corrective action plan is 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 a Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

Proposed

RULE §703.14 **Termination, Extension, and Close Out of Grants 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 subsections (a)(1) or (a)(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.

(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. The final reimbursement payment shall not

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be made until such close out documents have been submitted and approved by the Institute. Failure to submit close out documents within 180 days of the Grant Contract termination date may result in the Grant Recipient being ineligible for other Institute Grant Awards until such time that the close out documents are submitted.

(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.

Proposed

RULE §703.15 **Multiyear Projects**

(a) The Oversight Committee may approve Grant Award funds for a multiyear project. The total amount of Grant Award funds for the project shall be specified at the time that the Grant Award recommendation is approved by the Oversight Committee.

(b) The Grant Contract shall include an Approved Budget that reflects the amount of the Grant Award funds to be spent for each Project Year.

(c) The Institute shall distribute Grant Award funds to reimburse Allowable costs as reflected in the Approved Budget and pursuant to the Grant Recipient's submission of the quarterly Financial Status Report or the request to advance Grant Award funds. Remaining Grant Award funds shall be distributed as needed in each subsequent Project Year of the Grant Contract.

(d) A Grant Recipient awarded a Grant Award for a multiyear project that fails to expend the total Project Year budget may carry forward the unexpended budget balance to the next Project Year. If the amount of the unexpended budget balance to carry forward exceeds ten percent (10%) of the total Grant Award amount, the Grant Recipient must provide specific justification for why the total Grant Award amount should not be reduced by the unexpended balance.

Proposed

RULE §703.16 **Intellectual Property Agreement**

(a) To the extent that there is a conflict between this chapter and the Grant Contract between the Institute and the Grant Recipient, the Grant Contract terms will control.

(b) The Grant Recipient may retain, assign or transfer all or a portion of any of the Intellectual Property Rights relating to the project results. Any such assignment or transfer to a third party is subject to the following requirements:

(1) The Grant Recipient shall notify the Institute of the proposed transfer or assignment;

(2) The Grant Recipient shall ensure that the assignment or transfer is subject to the licenses, interests and other rights provided to the Institute pursuant to the Grant Contract and any applicable law or regulation; and

(3) Unless the transfer is taking place pursuant to an exercise of the United States government's rights under 35 U.S.C. §203, the Institute may provide comments to the Grant Recipient related to the proposed transfer or assignment of rights, which the Grant Recipient shall consider in good faith and use reasonable efforts to account for and incorporate such comments into the actual transfer or assignment of such rights.

(c) Unless specifically authorized by the Institute, Grant Award proceeds shall not be used to pay the costs or expenses associated with the efforts to protect the Intellectual Property Rights or to pay the costs or expenses associated with commercialization activities.

(d) As a condition of accepting Grant Award funding from the Institute, the Grant Recipient agrees to the following required commitments as defined in the Grant Contract with regard to any project results:

(1) To use commercially reasonable efforts to protect, develop, commercialize, or otherwise bring Project Results to practical application to the fullest extent feasible as determined by the Grant Recipient. The Grant Recipient is relieved of its obligations pursuant to this section so long as the Grant Recipient complies with paragraph (3) of this subsection and §703.19 of this chapter.

(2) To share with the Institute a portion of the benefit derived from the commercial development of the Project Results, as set forth in the Grant Contract.

(3) To notify the Institute in writing prior to declining to pursue, abandoning, waiving or disclaiming some or all Intellectual Property Rights related to the Project Results. Such notification shall be made with sufficient time to provide the Institute an opportunity to license or pursue the appropriate applications and other protections for such Intellectual Property Rights to the fullest extent permitted by law.

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(4) To keep the Institute promptly and reasonably informed regarding the activities undertaken by the Grant Recipient to protect and/or commercialize the Project Results and to consider in good faith Institute input, if any, regarding same. Such activities may include, but are not limited to, the following:

(A) Filing of an invention disclosure forms (including updates and revisions);

(B) Creation of commercial development plans;

(C) Application, issuance, prosecution and maintenance of patents; and

(D) Negotiation of final term sheets and License Agreements.

(5) To allow access to the books and records of the Grant Recipient for the purpose of conducting an audit during normal business hours with reasonable notice to verify amounts paid to the Institute pursuant to this chapter. Notwithstanding the time limitation provided in §703.13 of this chapter, the right to audit the books and records of the Grant Recipient to verify amounts required to be paid to the Institute shall continue for so long as the payments shall be made.

(6) To report to the Institute at least annually describing commercialization activities for the Project Results in a manner and form to be prescribed by the Institute.

Proposed

RULE §703.17 **Revenue Sharing Standards**

(a) The Institute shall share in the financial benefit received by the Grant Recipient resulting from the patents, royalties, assignments, sales, conveyances, licenses and/or other benefits associated with the Project Results, including interest or proceeds resulting from securities and equity ownership. Such payment may include royalties, income, milestone payments, or other financial interest in an existing company or other entity.

(b) The Institute's election as to form of payment and the calculation of such payment shall be specified in the Grant Contract.

(c) Unless otherwise provided by the Grant Contract between the Institute and the Grant Recipient, payments to the Institute required by this section shall be made no less than annually pursuant to a schedule set forth in the Grant Contract and shall be accompanied by an appropriate financial statement supporting the calculation of the payment.

(d) Nothing herein shall affect or otherwise impair the application of federal laws for projects receiving some portion of funding from the U.S. Government.

Proposed

RULE §703.18 **Licensing and Assignment of Intellectual Property Rights**

(a) The Grant Recipient bears the responsibility for licensing activities including identification of potential licensees, negotiation of License Agreements, documentation of the progress and development under a License Agreement, monitoring the performance of the licensee, and taking commercially reasonable actions to enforce the terms of the License Agreements.

(b) Each License Agreement for Project Results entered into by the Grant Recipient shall include an acknowledgement by the licensee that such License Agreement is subject to the Institute's licenses, interests and other rights, if any.

(c) Nothing herein prohibits the Grant Recipient from negotiating an exclusive License Agreement for Project Results if exclusivity is reasonably believed by the Grant Recipient to provide an economic incentive necessary for achieving commercial development and availability of the Project Results. The Grant Recipient shall take reasonable action to enforce the terms of the exclusive license and report any default notice to the Institute.

(d) A not-for-profit Grant Recipient negotiating exclusive or non-exclusive License Agreements shall seek to retain the right to exploit the use of its Project Results and utilize the same for its non-commercial purposes.

Proposed

RULE §703.19 **Opt-Out and Default**

(a) The Institute shall have the option, but not the obligation, to pursue protection of the applicable Intellectual Property Rights and/or to commercialize or otherwise bring to practical application the applicable Project Results either directly or through one or more licensees, in the event of the following:

(1) Upon receipt of Grant Recipient's notice of its election to abandon, waive or disclaim any Intellectual Property Rights or to cease its efforts to commercialize or otherwise bring to practical application any particular Project Results; or

(2) Grant Recipient 's failure to materially comply with its obligations to protect the Intellectual Property Rights or to use diligent and commercially reasonable efforts to commercialize or otherwise bring to practical application the Project Results in accordance with the Grant Recipient's commercial development plan(s), and Grant Recipient fails to cure such non-compliance within a reasonable period of time following written notice from the Institute specifically describing the events of non-compliance.

(b) If the Institute elects to exercise its options pursuant to this section, it shall notify the Grant Recipient in writing of such election. Upon receipt of notification, the Grant Recipient shall:

(1) Fully cooperate with the Institute's efforts to protect, commercialize or otherwise bring to practical application the applicable Project Results at the Institute's cost, including but not limited to the transfer to the Institute or the Institute's designee of the Grant Recipient's rights, title and interest in and to the applicable Project Results, to the maximum extent allowed by law;

(2) Not take any action that would materially impede the Institute's ability to protect, commercialize or otherwise bring to practical application the applicable Project Results.

(c) If the Institute exercises its option under this section, the Grant Recipient shall have no further claim to or interest in ~~or~~ to the applicable Project Results and shall not be entitled to any share of the revenue or other compensation with respect to such Project Results, except to the minimum extent required by law, if any.

(d) The Institute's exercise of rights pursuant to this section is subject to any applicable rights of the United States government.

Proposed

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, 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.

Proposed

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 due date. The Chief Executive Officer may approve an extension of the submission deadline if, prior to the FSR due date, the grant recipient submits a written explanation for the grant recipient'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;

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(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

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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 Section 703.14 of this Chapter.

(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.

(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 Section 703.13 of this Chapter.

(A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.

(B) The written plan shall be retained by the Institute as part of the Grant Contract record.

(c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.

(d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.

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(1) To the extent that the methods described in subsection (b) are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.

(2) Records will be maintained in the electronic Grant Management System as described in Section 703.4.

(e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.

(f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.

(g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff.

Proposed

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	NED HOLMES, NOMINATIONS SUBCOMMITTEE INTERIM CHAIR
SUBJECT:	AGENDA ITEM # 9 - INTENTION TO RECOMMEND APPROVAL OF THE CHIEF EXECUTIVE OFFICER'S APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	JANUARY 20, 2014

Summary and Recommendation:

The Chief Executive Officer has appointed 20 people to the CPRIT's Scientific Research and Prevention Programs Committee. The Nominations Subcommittee discussed these appointments at its meeting on January 20, 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 January 24, 2014, meeting.

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.

Cancer Biology
Peter Jones, Ph.D., Chair

Peer Review Panel Members for Approval

1. Steven Bilinsky, Ph.D.
2. Geoffrey Greene, Ph.D.
3. Elizabeth Lawlor, M.D./Ph.D.
4. Charles Roberts, M.D./Ph.D.
5. Zena Werb, Ph.D.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Steven A. Belinsky	Senior Scientist
eRA COMMONS USER NAME (credential, e.g., agency login)	
SBELINSKY	

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
The University of North Carolina, Chapel Hill, NC	B.S.	1978	Biology
The University of North Carolina, Chapel Hill, NC	Ph.D.	1984	Toxicology

A. Personal Statement

I have worked in the field of tobacco carcinogenesis for > 25 years conducting basic and translational research on lung cancer. My group first demonstrated that the tobacco specific nitrosamine NNK causes DNA adducts that accumulate in the lung and lead to mutation of the K-ras oncogene. My research in epigenetics began in the 1990s with initial key studies identifying silencing of the p16 gene as an early event in lung cancer, the detection of promoter methylation of specific genes in sputum up to three years prior to clinical diagnosis, and that the combination of a demethylating agent and inhibitor of histone deacetylase can prevent lung cancer development. I have extended all these research areas with focus on identifying pathways, genes, and microRNAs driving pre-malignancy, implementing a multi-compartment strategy for developing and validating biomarkers for risk assessment and prognosis, and using animal models and human subjects for evaluating novel therapeutic and preventive approaches for lung cancer.

Positions and Honors

Positions and Employment

1978 - 1979 Research Technician, Department of Pharmacology, The University of North Carolina, Chapel Hill, NC
1980 - 1984 Graduate Student, Curriculum in Toxicology, The University of North Carolina, Chapel Hill, NC
1984 - 1986 Postdoctoral Fellow, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1986 - 1990 Senior Staff Fellow, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1990 - 1996 Staff Scientist, Inhalation Toxicology Research Institute, Albuquerque, NM
1991 - Present Clinical Associate Professor, College of Pharmacology, University of New Mexico, Albuquerque, NM
1991 - Present Associate Scientist, University of New Mexico Cancer Center, University of New Mexico, Albuquerque, NM
1992 - Present Adjunct Associate Professor, Department of Veterinary Pathology, Purdue University, West Lafayette, IN
1997 - Present Program Manager, Molecular Biology and Lung Cancer Program; Senior Scientist, Lovelace Respiratory Research Institute, Albuquerque, NM
2001 - 2007 Deputy Director, New Mexico NIEHS Center
2002 - Present Co-Director, Population Sciences Program, New Mexico Cancer Center
2010 - Present Vice President for Academic Research, Lovelace Respiratory Research Institute

Honors

1982 - 1984 Predoctoral Fellow, Environmental Toxicology, National Institute of Environmental Health Sciences
1984 - 1986 Postdoctoral Fellow, National Research Service Award, National Institute of Environmental Health Sciences
2007 Loyd E. Harris Lecturer, University of Oklahoma, College of Pharmacy
2009 The Alton Ochsner Award Relating Smoking and Health

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Geoffrey L. Greene	Professor
eRA COMMONS USER NAME (credential, e.g., agency login) GGREENE	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
The College of Wooster, Wooster, OH	B.A.	1969	Chemistry
Northwestern University, Evanston, IL	Ph.D.	1974	Chemistry
University of Chicago, Chicago, IL	Postdoctoral Trainee	1974-1977	Biochemical Endocrinology

A. Positions and Honors

Positions and Employment

1974-77 Postdoctoral Trainee, Ben May Laboratory for Cancer Research, University of Chicago
1977-80 Research Associate (Assistant Prof.), Ben May Laboratory for Cancer Research
1980-84 Assistant Professor, Ben May Laboratory for Cancer Research
1984-86 Assistant Professor, Ben May Laboratory for Cancer Research and the Department of Biochemistry and Molecular Biology
1986-91 Associate Professor, Ben May Institute and the Department of Biochemistry and Molecular Biology
1991- Professor, Ben May Institute and the Department of Biochemistry and Molecular Biology
2004- Chair, Committee on Cancer Biology
2006- Co-Director, Ludwig Center for Metastasis Research

Other Experience and Professional Memberships

1978 Exchange Scientist; US/France Cooperative Science Program (NCI/INSERM)
1982 Exchange Scientist; US/France Cooperative Science Program (NCI/INSERM)
1984 Exchange Scientist; US/France Cooperative Science Program (NSF/CNRS)
1991 Visiting Professor, University of Modena, Modena, Italy
2004 Visiting Professor, University of Parma, Parma, Italy

Honors and Awards

1988 Ernst Oppenheimer Award; The Endocrine Society
1992 John Brewer Distinguished Alumni Lectureship, Northwestern University Medical School
1997 Tartikoff-Semel Award, Revlon/UCLA Women's Cancer Research Program
1998 Distinguished Visiting Scientist, UCLA Brain Research Institute, Los Angeles
1998 Inaugural Lecturer, Olof Pearson Lectureship, Case Western Reserve University
2003 Virginia and D. K. Ludwig Professor for Cancer Research
2006 NAMS/Wyeth Pharmaceutical SERMs award from the North American Menopausal Society
2009 Susan G. Komen for the Cure Brinker Award for Scientific Distinction

B. Selected Peer-reviewed Publications

1. Nettles KW, Greene GL 2005 Ligand control of coregulator recruitment to nuclear receptors. Annu Rev Physiol 67:309-333
2. Wu YL, Yang X, Ren Z, McDonnell DP, Norris JD, Willson TM, Greene GL 2005 Structural basis for an unexpected mode of SERM-mediated ER antagonism. Mol Cell 18:413-424
3. Hsieh RW, Rajan SS, Sharma SK, Guo Y, DeSombre ER, Mrksich M, Greene GL 2006 Identification of ligands with bicyclic scaffolds provides insights into mechanisms of estrogen receptor subtype selectivity. J

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
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NAME	POSITION TITLE
Elizabeth R. Lawlor	Russell G. Adderley Professor of Pediatric Oncology Associate Professor, Department of Pediatrics Associate Professor, Department of Pathology

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
McMaster University, Hamilton, Ontario, Canada	B.Sc.	1986	Biology
McMaster University, Hamilton, Ontario, Canada	M.D.	1989	Medicine
University of British Columbia, Vancouver, Canada	Ph.D.	2002	Pathology & Lab Medicine
UCSF Cancer Center, San Francisco, California	Post-doctoral Fellow	2001-2003	Molecular mechanisms of tumorigenesis

A. PERSONAL STATEMENT

I was initially trained as a clinical pediatric oncologist and subsequently as a cancer biologist. Since starting my own lab in 2004 I have focused my research on investigating how hijacking of normal stem cell and developmental processes contributes to the initiation and progression of Ewing sarcoma. In addition, I maintain a close connection to clinical research as a member of the Bone Tumor Steering Committee of the Children's Oncology Group (COG) and Vice-chair of the Ewing's Biology Committee. The central hypothesis underlying my research program is that human cancers depend on dysregulation of genes and pathways that are integral to normal stem cell biology. The overall goal is to discover and define similarities and differences between normal stem cells and cancer cells. To achieve this we work with human stem cell models as well as mouse models and tumor cell lines. Particular areas of interest include defining the roles of the stem cell associated genes *BMI-1, CXCR4,* and *LGR5* in Ewing sarcoma initiation, maintenance and progression. In addition, in collaboration with Dr. Jeff Martens, we are investigating the role of ion channel suppression in promoting cancer stem cell survival. Extensive work is also ongoing in the lab to investigate neural crest cells as Ewings' cells of origin. Using an innovative model of human as well as primary murine neural crest cells we are elucidating the mechanisms by which the EWS-FLI1 oncogene disrupts normal differentiation and development. It is the long-term objective of the research that improved understanding of the differences between normal stem cell and cancer cell biology will lead to the development of novel therapies that target tumor cells whilst sparing normal developing tissues.

As a physician-scientist I am committed to educating the next generation of basic and translational researchers. I am dedicated to both graduate and post-graduate education in the arenas of cancer biology and pediatric oncology and am an active member of both the Molecular Cellular Pathology and Cancer Biology graduate programs at UM. I have trained numerous students and fellows in my lab (including 2 Masters, 3 PhD and 2 MD/PhD students, 3 Pediatric Hematology-Oncology fellows and 7 post-PhD post-doctoral fellows). I have also mentored 6 high school and undergraduate students during summer and academic rotations. I have served as a member of 10 PhD thesis advisory committees for students outside my lab.

B. POSITIONS AND HONORS

1989-1990 General medical/surgical Intern, Greater Victoria Hospital Society, Victoria, BC
1990-1991 Pediatric Resident, BC's Children's Hospital, UBC, Vancouver, BC, Canada
1991-1994 Pediatric Resident, Children's Hospital of Eastern Ontario, Ottawa, ON, Canada

1994-1996	Clinical Fellow, Pediatric Hematology-Oncology & BMT, BC's Children's Hospital, UBC, Vancouver, BC, Canada
1996-2000	Pediatric Oncologist (0.2 FTE): BC's Children's Hospital
1996–2001	Post-MD Research Fellow, BC's Children's Hospital and the BC Research Institute for Children's and Women's Health. Department of Pathology and Laboratory Medicine, UBC
1997–2001	PhD Student, Department of Pathology and Laboratory Medicine, University of British Columbia. Mentor: Dr. Poul H. B. Sorensen
2001-2003	Post-doctoral fellow, UCSF Cancer Center, San Francisco. Mentor: Dr. Gerard I. Evan
2004-2009	Assistant Professor, Pediatrics & Pathology, Keck School of Medicine, University of Southern California. Division of Pediatric Hematology-Oncology, Children's Hospital LA
2010-2011	Assistant Professor, Pediatrics & Pathology, Division of Pediatric Hematology-Oncology, University of Michigan
2011-	Associate Professor, Pediatrics (with tenure) & Pathology, Division of Pediatric Hematology Oncology, University of Michigan

Selected Honors/Awards

1996-1998	BC Research Institute for Women's and Children's Health, Mining for Miracles Post-Doctoral Research Fellowship
1997	AACR Young Investigator Travel Grant: Special Conference on Disrupted Transcription Factors in Cancer
1999	AACR/ASCO Methods in Clinical Cancer Research Workshop
1998-2001	Medical Research Council of Canada Post-Doctoral Fellowship
2001-2003	Canadian Institutes of Health Research Senior Research Fellowship
2003	AACR-AFLAC Scholar-in-Training Award; International Conference on Molecular Targets & Cancer Therapeutics
2004	V Foundation Scholar Award
2006	Stop Cancer Foundation Career Development Award
2009	**USC Mellon Mentoring Award - Faculty Mentoring Graduate Students (1 of 10 faculty awardees in the University and 1 of only 2 faculty from the Medical School)**
2009	Stand Up to Cancer/AACR Innovative Research Grant
2011-	Russell G. Adderley Professor of Pediatric Oncology, University of Michigan

Professional Memberships

1991	Licentiate of the Medical Council Of Canada, LMCC
1994-2007	Fellow of the Royal College of Physicians of Canada (FRCPC)
1994-2003	College of Physicians and Surgeons of British Columbia, Pediatrician
1998-Present	American Association for Cancer Research
2005-Present	International Society for Stem Cell Research
2006-Present	COG Ewing's Sarcoma Biology Committee Member (Vice chair effective 2012)
2007-Present	COG Bone Tumor Committee, Member Steering Committee
2009-Present	COG Translational Research Committee, Member
2010-Present	Society for Pediatric Research

C. Peer-reviewed Publications (from total of 38; *denotes trainee in PI's lab)

1. **Lawlor ER**, Lim JF, Tao W, Chow CJ, Kalousek IV, Kovar H, MacDonald TJ, Sorensen PHB (1998) The Ewing Tumour Family of Peripheral Primitive Neuroectodermal Tumours Expresses Human Gastrin-Releasing Peptide (GRP). Cancer Res; 58:2469-2476. PMID: 9622091
2. **Lawlor ER,** Scheel C, Irving J, Sorensen PHB (2002) Anchorage-Independent multi-cellular spheroids as an *in vitro* model of growth signaling in Ewing tumors. Oncogene; 21:307-318. PMID: 11803474
3. Christophorou MA, Martin-Zanca D, Soucek L, **Lawlor ER**, Verschuren V, Brown-Swigart L, Evan GI (2005) Temporal dissection of p53 function *in vitro* and *in vivo*. Nat Genet; 37:718-26. PMID: 15924142

BIOGRAPHICAL SKETCH

NAME Charles Willard Mortimer Roberts, MD, PhD	POSITION TITLE Associate Professor of Pediatric Hematology-Oncology
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Wisconsin – Madison	BS	1984	Zoology
Washington University, St. Louis, MO	MD, PhD	1995	Medicine/Immunology
Children's Hospital Boston, MA	Internship Training	1995-1996	Pediatrics
Children's Hospital Boston	Medical Residency	1996-1997	Pediatrics
Children's Hospital Boston / Dana-Farber Cancer Institute, Boston, MA	Subspecialty Fellowship	1997-2001	Pediatric Hematology-Oncology

A. Personal Statement

The central theme of my laboratory is focused upon understanding the role of dysfunctional chromatin remodeling and epigenetic regulation in the genesis of cancer. It is increasingly clear that epigenetic aberration plays a critical role in the development of cancer. In particular, the SWI/SNF complex, which utilizes ATP hydrolysis to remodel chromatin, has a potent tumor suppressor role. We first became interested in this complex when a core subunit, SNF5/SMARCB1, was found to be inactivated in nearly all cases of malignant rhabdoid tumor, a highly aggressive type of pediatric cancer. Recent cancer genome sequencing studies have now revealed that at least eight genes encoding subunits of the SWI/SNF complex are specifically mutated at high frequency in a wide variety of pediatric and adult cancers, thus revealing mutation of the complex to be one of the most frequent lesions identified in cancer. We have demonstrated essential roles for SNF5 in tumor suppression using genetically engineered mice. Additionally, our recent work demonstrates that SNF5 loss was the sole recurrent event detected in the exomes of 32 of these cancers from children. Collectively, our efforts have established a central role for epigenetic mechanisms promoting cancer following SNF5 mutation. Our focus now is to generate mechanistic and therapeutic insight into SWI/SNF mutant cancers.

B. Positions and Honors

Positions and Employment

2001-2003 Instructor in Pediatric Hematology-Oncology, Children's Hospital Boston/ Dana-Farber Cancer Institute, Boston, MA
2003-2010 Assistant Professor of Pediatric Hematology-Oncology, Dana-Farber Cancer Institute / Children's Hospital Boston/Harvard Medical School, Boston, MA
2011-present Associate Professor of Pediatric Hematology-Oncology, Dana-Farber Cancer Institute /Boston Children's Hospital/ Harvard Medical School, Boston, MA

Honors

1987 Knapp-Brittingham Research Award, University of Wisconsin
1988 Graduated from Honors Program, Zoology, University of Wisconsin

1988-1995	United States Public Health Service Medical Scientist Training Awardee, Washington University
1993	Spencer T. and Ann W. Olin Medical Scientist Fellowship
1995	George F. Gill Prize in Pediatrics, Washington University
1995	Alpha Omega Alpha Medical Honor Society, Washington University
2002	American Board of Pediatrics board certification in pediatric hematology-oncology
2003	"Outstanding Presentation" award at Children's Hospital research day
2003	American Association for Cancer Research Scholar-in-Training Award to support attendance at the 2003 AACR Mouse Models of Cancer Meeting
2004	Stephen E. Sallan Leadership Award. This annual award recognizes Pediatric Oncology staff "Who are our leaders…for their ability to guide, inspire and motivate others".
2007	Elected to membership in the Society for Pediatric Research
2007	Claudia Adams Barr Innovative Basic Science Research Investigator
2010	Elected to membership in the American Society of Clinical Investigation
2012	Invited to present Tal Doron Keynote address, Rhabdoid tumors, 15th annual International Symposium on Pediatric Neuro-Oncology, Toronto, Ontario, Canada

C. Selected Peer-reviewed Publications

Original Research:

1. Hatano M, **Roberts CWM**, Minden M, Crist WM, Korsmeyer SJ. Deregulation of a homeobox gene, HOX11, by the t(10;14) in T cell leukemia. Science 1991; 253: 79-82.
2. **Roberts CWM**, Shutter JR, Korsmeyer SJ. *Hox11* controls the genesis of the spleen. Nature 1994; 368: 747-749.
3. **Roberts CWM**, Galusha SA, McMenamin ME, Fletcher CDM and Orkin SH. Haploinsufficiency of Snf5 (integrase interactor 1) predisposes to malignant rhabdoid tumors in mice. Proceedings of the National Academy of Sciences, USA 2000; 97: 13796-13800.
4. **Roberts CWM**, Leroux MM, Fleming MD, Orkin SH. Highly penetrant, rapid tumorigenesis through conditional inversion of the tumor suppressor gene Snf5. Cancer Cell 2002; 2: 415-425.
5. McKenna ES, Sansam CG, Cho YJ, Greulich H, Evans JA, Thom CS, Moreau LA, Biegel JA, Pomeroy SL and **Roberts CWM**. Loss of the epigenetic tumor suppressor SNF5 leads to cancer without genomic instability. Molecular and Cellular Biology 2008; 28: 6223-33.
6. Wang X, Sansam CG, Thom CS, Metzger D, Evans JA, Nguyen PTL and **Roberts CWM.** Oncogenesis caused by loss of the SNF5 tumor suppressor is dependent upon activity of BRG1, the ATPase of the SWI/SNF chromatin remodeling complex. Cancer Research 2009; 69: 8094-8101.
7. Wilson BG, Wang X, Shen X, McKenna ES, Lemieux ME, Cho YJ, Koellhoffer EC, Pomeroy SL, Orkin SH, **Roberts CWM.** Epigenetic antagonism between Polycomb and SWI/SNF complexes during oncogenic transformation. Cancer Cell 2010, Oct 19;18(4):316-28.
8. Jagani Z, Mora-Blanco EL, Sansam CG, McKenna ES, Wilson B, Chen D, Klekota J, Tamayo P, Nguyen PTL, Tolstorukov M, Park PJ, Cho YJ, Hsiao K, Buonamici S, Pomeroy SL, Mesirov JP, Ruffner H, Bouwmeester T, Luchansky S, Murtie J, Kelleher J, Warmuth M, Sellers WR, **Roberts CWM***, and Dorsch M* (***Co-corresponding senior authors and contributed equally**). Loss of the Tumor Suppressor Snf5 Leads to Aberrant Activation of the Hedgehog-Gli Pathway. Nature Medicine 2010; 16: 1374-6.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Zena Werb, Ph.D.	**Professor and Vice-chair of Anatomy**
eRA COMMONS USER NAME (credential, e.g., agency login) werbzena	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Toronto, Toronto, Canada	B.Sc.	06/1966	Biochemistry
Rockefeller University, New York	Ph.D.	06/1971	Cell Biology
Strangeways Research Laboratory, Cambridge UK	Postdoc	1971-73	Protein Chemistry

A. Personal Statement

I have studied the cell biology of cell adhesion, matrix metalloproteinases, extracellular matrix, inflammatory cells and the epithelial microenvironment in development and breast cancer for well over 3 decades. I have concentrated on the molecular mechanisms involved in extracellular matrix remodeling and inflammatory cell function in mammary development and breast cancer. I have used a variety of technologies ranging from molecular biology to genetically engineered mouse models to intravital microscopy and 3D culture models. My interests are in driving the field of the extracellular microenvironment in inflammation, fibrosis, tumor biology and metastasis forward technically and conceptually. I have also put considerable effort into mentoring young scientists.

B. Positions and Honors (partial list)

Positions and Employment:

1973-5, Research Scientist, Strangeways Research Laboratory, Cambridge, U.K.;
1975-6, Visiting Assistant Prof. of Medicine, Dartmouth Medical School, Hanover, NH;
1976-80 Assist. Prof. Radiobiology, Radiology, Univ. of California, San Francisco;
1979-80, Assist. Prof. Anatomy, UCSF;
1980-3, Assoc. Prof. of Anatomy and Radiology, UCSF;
1983-present, Prof. Anatomy, UCSF;
1985-6, Visiting Prof., Sir William Dunn School of Pathology, Univ. of Oxford, U.K.;
1998, Visiting Prof., Institut Curie, Paris;
1999-present, Vice-chair, Dept. Anatomy, UCSF;
2006-8, Visiting Prof., Max-Planck Institute for Biochemistry, Martinsried, Germany.

Other Experience and Professional Memberships:

*Editorial Boards**:***
1983-5, *Journal of Cell Biology*;
1982-7, *American Journal of Physiology*;
1985-2004, *Journal of Experimental Medicine*;
1990-2001, *Science*;
1999-2013, *Matrix Biology;*
1999-present, *Neoplasia*;
2000-9, *Cell*;
2001-present, *Developmental Cell*;
2001-present *Cancer Cell*;
2002-6, *Molecular Biology of the Cell*;
2007-9, *Genes & Development;*
2009-present, Current Opinion in Cell Biology.
2010-present, Guest Editor, *Proc. Natl. Acad. Sci. USA*
2010-present, Member, Editorial Board, *Disease Models and Mechanisms*

Professional Memberships:

1976-present, American Society for Cell Biology
1979-present, American Society for Biochemistry and Molecular Biology
1967-71, 1979-present, American Association for the Advancement of Science
1988-present, Society for Developmental Biology
2001-present, American Association for Cancer Research
2001-present, American Society for Matrix Biology
2004-present, International Society for Differentiation

Scientific Leadership:
1980-2, Member, advisory committee for Cell Physiology Program, NSF;
1984, Chair, Program Committee, American Society for Cell Biology Annual Meeting
1990-2, Member, Cell and Molecular Biology Panel, National Cancer Institute of Canada;
1991-5, Member, Board of Scientific Counselors, NIAMS;
1992-5 Council Member, American Society for Cell Biology;
1993-5 Council Delegate, Am. Assoc. for the Advancement of Science;
1994-2001, Member, Scientific Advisory Board, Keystone Symposia;
1998, Organizer, Keystone Symposium on ECM and Signaling;
2001-3 Council Member, American Society for Matrix Biology;
2001, NIH, Oncological SS Boundaries Team;
2002, NIH Biochem SS, ad hoc;
2002, Co-Organizer, Pezcoller Symposium on Co-conspiratory Cell Types In Tumors and Carcinogenesis
2003-5, Council Member, International Society for Matrix Biology;
2003-6, Member, Board of Directors, AACR;
2004, Co-Organizer (with Judah Folkman and Peter Carmeliet), AACR Meeting on Angiogenesis;
2005, Chair, Gordon Research Conference Matrix Metalloproteinases
2005, President, American Society for Cell Biology;
2007-9, Nominating Committee, AACR;
2007, Member, NIH ZRG1 ICI–D01;
2008, Reviewer, NIH Pioneer Awards;
2008, Chair, NIH ZRG1 MOSS-A (02);
2008-12, Chair, Scientific Advisory Committee, Children's Hospital Boston, Harvard Medical School
2008-10, Chair, NIH ICI Study Section.
2009-12, Chair, American Academy of Arts and Sciences, Membership Selection Committee Class II, section 5
2010, Co-organizer, CNIO Cancer Symposium on Frontiers in Invasion and Metastasis, Madrid
2011-present, Member, Steering Committee, AACR Council of Scientific Advisors
2011-16, Member, Scientific Advisory Board, Max Planck Institute for Biology of Ageing, Cologne, Germany

Honors
Awards:
1971-3, Fellow, Medical Research Council, Canada;
1982, R.R. Bensley Memorial Award, American Association of Anatomists;
1985-6, Fellow, John Simon Guggenheim Foundation
1992, Elected Fellow, American Association for the Advancement of Science;
1996, FASEB Excellence in Science Award;
1998, Rotschild/Mayent Fellowship, Institut Curie;
2001, Charlotte Friend Lecture Award, AACR
2002, Elected Member, Institute of Medicine;
2003, Elected Fellow, American Academy of Arts and Sciences;
2003, Doctor of Medicine (honoris causa), University of Copenhagen;
2006-7, Alexander von Humboldt Foundation Research Award (Germany);
2007, E.B. Wilson Medal, American Society for Cell Biology;
2009, Colin Thomson Memorial Medal, Association for International Cancer Research;
2010, Elected Member, National Academy of Sciences;
2010, American Society for Cell Biology, Women in Cell Biology Senior Award
2011, Zero Breast Cancer 2011 Community Breast Cancer Research Award,

Named Lectureships (selected):

Cancer Prevention Research
Thomas Sellers, Ph.D./M.P.H., Chair

Peer Review Panel Members for Approval

1. William Barlow, Ph.D.
2. Thomas Brandon, Ph.D.
3. Zigang Dong, M.D./Ph.D.
4. Brooke Fridley, Ph.D.
5. Larry Kushi, Sc.D.
6. Susan Mayne, Ph.D.
7. Lorelei Mucci, Sc.D./M.P.H.
8. Andrew Olshan, Ph.D.

BIOGRAPHICAL SKETCH

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NAME	POSITION TITLE
Barlow, William E	Senior Biostatistician Research Professor
eRA COMMONS USER NAME (credential, e.g., agency login) BillBarlow	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Western Washington University	B.A.	06/74	Psychology
University of Toronto	M.A.	06/76	Psychology
University of Washington	M.S.	06/82	Biostatistics
University of Washington	Ph.D.	06/86	Biostatistics

A. Personal Statement

William Eric Barlow, PhD, is a Senior Biostatistician at Cancer Research And Biostatistics (CRAB) , Adjunct Member at the Fred Hutchinson Cancer Research Center, and Research Professor, Biostatistics, University of Washington. He has co-authored 89 publications in breast cancer research and has published in several other areas as well. Many publications have been widely cited suggesting that there has been a large impact from these lines of research. Dr. Barlow has been the lead statistician for the SWOG Breast Committee since 2004. He is a statistician for the SWOG Outcomes and Comparative Effectiveness Committee and the Symptom Control and Quality of Life Committee. From 1994-2005, he was PI of the Statistical Coordinating Center for the Breast Cancer Surveillance Consortium. Currently, he is now PI of the Coordinating Center for PROSPR, a NCI-funded initiative studying screening for breast, colorectal, and cervical cancer. This is an opportunity to integrate PROSPR and NCORP together to assess screening implementation in community settings and testing how it could be improved.

B. Positions and Honors

Positions and Employment

1977-1979 Instructor of Psychology, University of Toronto, Scarborough College, West Hill, Ontario
1982-1984 Research Fellow, Radiation Effects Research Institute, Hiroshima, Japan
1986-1989 Assistant Professor & Co-Director of Biometry, Dept of Preventive Medicine, USC, LA CA
1989-2012 Scientific Investigator, Group Health Research Institute, Seattle, WA
1989-Present Research Professor, Biostatistics, Univ. of Washington, Seattle, WA
2003-Present Senior Biostatistician, Cancer Research and Biostatistics, Seattle, WA
2011-Present Adjunct Member, Fred Hutchinson Cancer Research Center, Seattle, WA

Other Experience and Professional Memberships

1989-present Member, Biometrics Society
2009-present Member, American Society Clinical Oncology
1989-present Data Safety and Monitoring Committee Chair and member, NEI sponsored clinical trials
2008-present NIH Breast Cancer Steering Committee for clinical trials
2010-present Editorial Board, Journal of Clinical Oncology
2010-present Statistical Editor, Journal of the National Cancer Institute
2013-present Deputy Editor, Clinical Cancer Research

Honors

1996 University of Washington School of Public Health Outstanding Teaching Award

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Thomas H. Brandon	Chair, Department of Health Outcomes & Behavior H. Lee Moffitt Cancer Center & Research Institute
eRA COMMONS USER NAME tbrandon	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of California, Berkeley	A.B.	1981	Psychology
University of Wisconsin – Madison	M.S.	1985	Psychology (Clinical)
University of Wisconsin – Madison	Ph.D.	1990	Psychology (Clinical)

A. Personal Statement

Within the field of behavioral medicine, I have 30 years of research experience focused on the study of factors that maintain tobacco dependence as well as the development of novel tobacco-cessation and relapse-prevention interventions. My research has examined the problem of cigarette smoking and smoking relapse via several different modalities, ranging from basic human laboratory research on smoking motivation through applied research on smoking cessation and relapse prevention. In particular, I have been developing tobacco-related interventions that are designed to be cost-effective and easy to disseminate and implement. I anticipate leading related efforts as part of the Moffitt NCORP Research Base, and I look forward to participating in this transdisciplinary collaboration.

B. Positions and Honors:

Professional Positions

1989-1990 Adjunct Lecturer, Indiana University-Purdue University at Indianapolis.
1989-1990 Clinical Intern, Indiana University Medical Center, Indianapolis.
1990-1997 Assistant-Associate Professor of Psychology, State University of New York at Binghamton.
1997-present Director, Tobacco Research & Intervention Program, H Lee Moffitt Cancer Center & Research Institute, Tampa.
1997-2001 Associate Professor of Psychology, University of South Florida.
2001-present Professor of Psychology, University of South Florida. (Joint appointment in Department of Oncologic Sciences, USF College of Medicine; Courtesy appointment, Department of Epidemiology and Health Policy Research, University of Florida College of Medicine.)
2004-2005 Interim Director of Clinical Training, Department of Psychology, University of South Florida.
2011-2012 Vice Chair, Department of Health Outcomes and Behavior, Moffitt Cancer Center
2012-present Chair, Department of Health Outcomes and Behavior, Moffitt Cancer Center

Honors, Awards, and Elected Positions

1992 American Cancer Society Junior Faculty Research Award.;
1998-2000 President, Addictive Behaviors Special Interest Group, Association for Advancement of Behavior Therapy.
2001 Elected Fellow, American Psychological Association (current fellow of Division 12, 28, 50).
2005 Elected to Sigma Xi, Research Honor Society.
2007 Elected Fellow, Society of Behavioral Medicine.
2008-2009 President, Society of Addiction Psychology (APA Division 50).
2012 Educator of the Year, Moffitt Cancer Center

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Zigang Dong	Professor
eRA COMMONS USER NAME (credential, e.g., agency login) ZIGANGDONG	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Department of Medicine, Henan Medical University, China	M.D.	1978-83	Medicine
Department of Pathophysiology, Henan Medical University, China	M.S.	1983-86	Pathophysiology
School of Public Health, Columbia University, NY	Dr.P.H.	1987-91	Environmental Science
Department of Medicine, Henan Medical University, China	M.D.	1978-83	Medicine

A. Personal Statement

Dr. Dong has a Doctor of Public Health degree from Columbia University in New York and post-doctoral training at the National Cancer Institute. He has served as a member on many grant application review study sections with the National Institutes of Health and has published more than 310 articles in prestigious journals such as *Nature, Nature Structure and Molecular Biology, Nature Cancer Reviews, Science Signaling, Cancer Research, and Molecular Cell*. He also serves as a member of editorial board, editor or associate editor of several journals including *Cancer Research, Carcinogenesis, Molecular Carcinogenesis, Cancer Prevention Research, and JBC*. He has many years of experience and is a leader in the elucidation of molecular mechanisms of carcinogenesis, such as ultraviolet light-induced signal transduction in human cancer development and prevention. His research interests include the identification of molecular and cellular targets in carcinogenesis and chemoprevention.

B. Positions and Honors

Employment

1995 - present Section Chief, Cellular & Molecular Biology Section, The Hormel Institute, University of Minnesota, Austin, MN
1995 - 1997 Assistant Professor, The Hormel Institute, University of Minnesota, Austin, MN
1996 - present Director of America side, China-America Signal Transduction Research Center, University of Minnesota, Austin, MN
1998 - 1999 Associate Professor, The Hormel Institute, University of Minnesota, Austin, MN
2000 - present Full Professor, The Hormel Institute, University of Minnesota, Austin, MN
2001 - present Executive Director, The Hormel Institute, University of Minnesota, Austin, MN

Honors

2000 - present Honorary Professor, The Fourth Military Medical University, Xian, Shanxi, China.
2000 Honorable Mention, Alice Hamilton Award, Biological Science category, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC) for research presented in JBC 274: 30611-30616, 1999 (Publication # HI 1442)
2001 Hormel-Knowlton Professor, The Hormel Institute, University of Minnesota
2001 - present Hormel-Knowlton Professor, The Hormel Institute, University of Minnesota
2005 - present Member of selection panel on Chongqing Scholars (Chongqing Special Professor and Chongqing Chair Professor) of Minister of Education, Chinese Government, P.R. China
2006 - present University of Minnesota McKnight Presidential Professor in Cancer Prevention
2008 National Institutes of Health Merit Award
2010 - present Internal Advisory Committee, Center for Translational Science Activities, Mayo Clinic

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
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NAME	POSITION TITLE
Brooke L. Fridley	Associate Professor of Biostatistics Site Director for the K-INBRE Bioinformatics Core Director of the Biostatistics and Informatics Shared Resource for the University of Kansas Cancer
eRA COMMONS USER NAME FRIDLEY1	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Truman State University, Kirksville, MO	B.S.	1997	Mathematics
Iowa State University, Ames, IA	M.S.	2000	Statistics
Iowa State University, Ames, IA	Ph.D.	2003	Statistics

A. Personal Statement

My role on this grant application would be to assist and oversee the statistical and bioinformatics related analyses outlined in this grant application. I joined the faculty at The University of Kansas Medical Center in September of 2012 as the Director of the Biostatistics and Informatics Shared Resource for The University of Kansas Cancer Center and the Site Director of the Kansas-INBRE Bioinformatics Core. My research over the last ten years has been in the area of statistical genomics and the genomic basis of complex phenotypes and human diseases related to disease diagnosis, etiology, progression, treatment and prevention. In particular, my research is focused on the development of sophisticated statistical and bioinformatics tools for the analysis of high-dimensional 'omic data with the integration of prior biological knowledge and multiple types of genomic data in the analysis. I have collaborated on multiple NIH funded research projects as a Co-Investigator, particularly dealing with studies involving ovarian cancer and pharmacogenomics. Through these collaborations I have gained extensive experience in genomic study design, pharmacogenomics, ovarian cancer and the analysis of genotypic, DNA methylation, IHC, mRNA expression, miRNA expression and copy number data produced from a variety of technologies. This diverse background in multiple types of 'omic data and both statistical and bioinformatics background will allow me to lead various analyses outlined in this grant application.

B. Positions and Honors

Positions and Employment

1998	Lab Instructor, Stat101, Iowa State University
1999	Biostatistics Intern, Quintiles
1998-2002	Instructor, Stat101, Iowa State University
2001-2002	Biostatistics Intern, Mayo Clinic
2002-2003	Statistical Consultant, College of Family & Consumer Science, Iowa State University
2003-2006	Assistant Professor, University of Wisconsin, La Crosse
2006-2008	Research Associate, Mayo Clinic
2006-2010	Assistant Professor of Biostatistics, Mayo Clinic
2008-2012	Associate Consultant, Mayo Clinic
2009-2012	Adjunct Assistant Professor of Biostatistics, School of Public Health, University of Minnesota
2010-2012	Associate Professor of Biostatistics, Mayo Clinic
2012-Present	Associate Professor of Biostatistics, University of Kansas Medical Center
2012-Present	Director of the Biostatistics and Informatics Share Resource for the University of Kansas Cancer Center
2012-Present	Site Director of the K-INBRE Bioinformatics Core, University of Kansas Medical Center

Honors

1993-1997	President's Combined Ability Scholarship, Truman State University
1997	Magnum Cum Laude, Truman State University
1999-2000	Vera David Graduate Fellowship, Statistics Department, Iowa State University

BIOGRAPHICAL SKETCH

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NAME	POSITION TITLE
Lawrence Haruo Kushi, Sc.D.	Director of Scientific Policy
eRA COMMONS USER NAME lhkushi	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Amherst College, Amherst, MA	AB	1978	Asian Studies
Harvard School of Public Health, Boston, MA	ScD	1984	Nutrition
University of Minnesota School of Public Health, Minneapolis, MN	Post-Doc	1987	Epidemiology

A. PERSONAL STATEMENT

[Insert Personal Statement Here]

B. POSITIONS AND HONORS

RESEARCH AND PROFESSIONAL EXPERIENCE

1987-1989 Staff Scientist, Cancer Prevention Research Program, Fred Hutchinson Cancer Research Center, Seattle, WA
1988-1989 Clinical Assistant Professor, Department of Epidemiology, School of Public Health & Community Medicine, University of Washington, Seattle, WA
1989-1994 Assistant Professor, Divisions of Human Development & Nutrition ('89-'92) and Epidemiology ('92-94), University of Minnesota School of Public Health, Minneapolis, MN
1994-1999 Associate Professor, Division of Epidemiology, University of Minnesota School of Public Health, Minneapolis, MN
1994-1999 Member, University of Minnesota Cancer Center, Minneapolis, MN
1999-2002 Ella McCollum Vahlteich Professor of Human Nutrition, Teachers College, Columbia University, New York, NY
1999-2002 Member, Herbert Irving Comprehensive Cancer Center, College of Physicians & Surgeons, Columbia University, New York, NY
2002-2010 Adjunct Professor of Nutrition, Teachers College, Columbia University, New York, NY
2002-2012 Associate Director, Division of Research, Kaiser Permanente Northern California, Oakland, CA
2010-Present Adjunct Professor, Department of Internal Medicine, UC Davis Medical School, Sacramento, CA
2010-Present Member, UC Davis Comprehensive Cancer Center, Sacramento, CA
2012-Present Director of Scientific Policy, Division of Research, KP Northern California, Oakland, CA

SELECTED BOARDS AND COMMITTEES

Editorial Board, Integrative Cancer Therapies, 2001-present
Epidemiology and Disease Control-2 Study Section, NIH, 1994-1998
Breast Cancer Research Program Integration Panel, Department of Defense, 1999-2001
Council for Extramural Grants, American Cancer Society, 2003-2007, 2010
External Advisory Boards, Committees or Working Groups:
Shanghai Women's Health Study (5R37 CA070867, Wei Zheng, Vanderbilt Univeristy, PI), 1999-present
Adventist Health Study (U01 CA152939, Gary Fraser, Loma Linda University, PI), 2002-present
NIH-AARP Diet and Health Study (Yikyung Park, National Cancer Institute, Project Director), 2005-present
ACS Cancer Prevention Study-3, Diet Subcommittee (Chair) (Marji McCullough, ACS), 2007-present
CHAMACOS Study (P01 ES009605, Brenda Eskenazi, UC Berkeley, PI), 2010-present
Legacy Study (R01 CA138638, Esther John, Cancer Prevention Institute of California, PI), 2010-present
Shanghai Men's Health Study (UM1 CA173640, Xiao-Ou Shu, Vanderbilt University, PI), 2012-present

BIOGRAPHICAL SKETCH

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NAME	POSITION TITLE
Susan Taylor Mayne, Ph.D., F.A.C.E.	Professor and Department Chair, with Tenure
eRA COMMONS USER NAME (credential, e.g., agency login) smayne	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Colorado, Boulder, CO	B.A.	05/82	Chemistry/Biochem.
Cornell University, Ithaca, NY	Ph.D.	05/87	Nutritional Biochem.
Yale Univ. School of Medicine, New Haven, CT	(Postdoc)	1987-1988	Cancer Epidemiology

A. Personal Statement

I am a cancer epidemiologist and have led the population sciences program of the Yale Comprehensive Cancer Center for the past 18 years. My own research emphasizes modifiable lifestyle factors in the etiology and prevention of various cancers. I have studied diet, tobacco, alcohol, physical activity, obesity, and most recently indoor tanning. I have extensive experience leading large research teams. I have served as both P.I. and co-Investigator of several population-based studies in Connecticut over the past 20 years. In my work, I partner with basic, clinical and behavioral investigators on a routine basis. Nearly all of the work I do is multidisciplinary. I have significant leadership experience, having served on the Board of Scientific Counselors for the U.S. National Cancer Institute. I am also P.I. of a T32 training program in cancer epidemiology and genetics from the NCI. I have most recently applied these skills to the Yale SPORE in skin cancer grant, serving as Co P.I. of a large case-control study on the epidemiology and genetics of early onset skin cancer. My knowledge and experience performing population sciences research, both observational and interventional, at Yale is critical in my role as Associate Director for Population Sciences of the Cancer Center.

B. Positions

1988-1990 **Research Faculty and Lecturer,** Department of Epidemiology and Public Health, Yale Univ. School of Medicine, and Cancer Prevention Research Unit for CT at Yale.
1990-1995 **Assistant Professor**, Dept. of Epidemiology and Public Health, Yale Univ. School of Medicine.
1993-2010 **Program Leader**, Cancer Prevention and Control Research Program, Yale Cancer Center
1995- **Associate Director** for Population Sciences, Yale Cancer Center.
1995-2004 **Associate Professor (term 1995-2001; tenure, 2001-4)**, Department of Epidemiology and Public Health, Yale University School of Medicine.
2004- **Professor,** Department of Epidemiology and Public Health, Yale University School of Medicine.
2009- **Division Head,** Chronic Disease Epidemiology, Yale School of Public Health.
2012- **Department Chair**, Chronic Disease Epidemiology, Yale School of Public Health.

Memberships and Honors (selected)

- NIH research recognition for extraordinary research contributions in nutrition and cancer (Nutrition Stars Program), Bethesda, MD 2013.
- C.-E.A. Winslow Endowed Chair recipient, Yale School of Public Health, 2012.
- Lifetime National Associate, National Research Council, National Academy of Sciences, for extraordinary service, 2012.
- Fellow, Executive Leadership in Academic Medicine Program for Women, 2008-9.
- NCI Board of Scientific Counselors, 2004-2009.
- Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, 2007-2013.
- Recipient of the Distinguished Teaching Award, Yale School of Public Health, 2000.
- Editorial Boards (current): Cancer Epidemiology, Biomarkers and Prevention; Nature Clinical Practice Oncology; The Cancer Journal: the Journal of Principles and Practice of Oncology; Cancer Prevention Research.

BIOGRAPHICAL SKETCH

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NAME	POSITION TITLE
Lorelei Mucci	Associate Professor of Epidemiology Associate Epidemiologist
eRA COMMONS USER NAME Mucci1	

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Tufts University, Medford, MA	B.S.	1989	Biology
Boston University School of Public Health, Boston, MA	M.P.H.	1997	Epidemiology,
Harvard School of Public Health, Boston, MA	Sc.D.	2003	Epidemiology

A. Personal Statement

I am an Associate Professor of Epidemiology at the Harvard School of Public Health and co-lead the Cancer Epidemiology program at the Dana Farber/Harvard Cancer Center (DF/HCC). My research over the past 10 years has focused on biomarker studies investigating the etiology of cancer risk as well as studying lifestyle and molecular factors associated with cancer progression. For the past eight years, my research focus has turned to prostate cancer with a specific focus on tumor biomarkers. I am Principal Investigator of several funded grants across various aspects of prostate cancer etiology, molecular subclassification and prognostication. I oversee the tumor biorepository of 3,000 prostate cancer patients who are participants in the US Physicians' Health Study and the Health Professionals Follow-up Study. Moreover, I am co-leader of a multi-disciplinary, international prostate cancer patho-epidemiology collaboration of researchers at Harvard with medical institutions in Sweden, Iceland, Ireland and Italy. My research includes studies focused on immunohistochemistry and large-scale genome wide expression profiling study within large cohorts of men with prostate cancer. Teaching and mentoring have been core components of my academic work. I have mentored of 25 graduate students, post-doctoral fellows and clinical fellows, and served as co-Director of a peer-mentoring program of 40 fellows and instructors.

B. Positions and Honors

Positions

1998-02	Graduate Research Assistant in Epidemiology, Harvard School of Public Health
2002-03	Research Fellow in Medical Epidemiology, Karolinska Institutet, Stockholm, Sweden
2003-06	Research Fellow in Cancer Epidemiology, Harvard School of Public Health, Boston MA
2003-06	Instructor of Medicine, Harvard Medical School, Boston, MA
2003-	Associate Epidemiologist, Brigham and Women's Hospital, Boston, MA
2006-	Assistant Professor of Medicine, Harvard Medical School, Boston, MA
2006-10	Assistant Professor in the Department of Epidemiology, Harvard School of Public Health,
2008-	Visiting Professor of Epidemiology, University of Iceland, Reykjavik, Iceland
2010-	Associate Professor of Epidemiology, Harvard School of Public Health
2011-	Head, Cancer Epidemiology Area of Concentration, Harvard School of Public Health
2011-	Leader of the Cancer Epidemiology Program, Dana Farber/Harvard Cancer Center

Selected Awards and Honors

2000-02	Department of Epidemiology Scholarship, Harvard School of Public Health
2003-05	National Research Service Award Post-Doctoral Fellowship
2003-08	NIH Loan Repayment Award Recipient, National Institutes of Health
2003	Dunning Award, Harvard School of Dental Medicine
2005	American Society for Clinical Oncology Merit Award
2007	American Cancer Society Travel Award
2007-08	Scientific Advisory Board, US Environmental Protection Agency
2008	Michael Milken Scholar, Prostate Cancer Foundation
2009	Top Performing Young Investigator, Prostate Cancer Foundation
2010-	Scientific Advisory Board, Prostate Cancer Foundation

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Andrew Olshan	Professor and Chair
eRA COMMONS USER NAME (credential, e.g., agency login) ANDY_OLSHAN	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Arizona State University, Tempe, Arizona	B.A.	1978	Anthropology
University of Washington, Seattle, WA	M.S.	1982	Epidemiology
University of Washington, Seattle, WA	Ph.D.	1987	Epidemiology
University of British Columbia, Vancouver	Post-Doc	1987-89	Medical Genetics

A. Personal Statement

Dr. Olshan is an experienced cancer and pediatric epidemiologist, mentor, and administrator. He has also been the principal investigator for 5 NIH funded studies, including North Carolina Head and Neck Cancer Study (CHANCE) and the Carolina Breast Cancer Study. He directs UNC's Rapid Ascertainment and Biospecimens Processing core facilities. He is Chair of the Department of Epidemiology, Gillings School of Global Public Health, Associate Director for Population Sciences and leader of the cancer epidemiology program at the UNC Lineberger Comprehensive Cancer Center.

B. Positions and Honors

1987-89	Postdoctoral Fellow, Department of Medical Genetics, Univ of British Columbia, Vancouver, B.C.
1989-91	Assistant Professor, Department of Clinical Epidemiology and Preventive Medicine, University of Pittsburgh, Pittsburgh, PA.
1989-91	Affiliate Member, Pittsburgh Cancer Institute, Pittsburgh, PA
1990-91	Assistant Professor, Department of Human Genetics, University of Pittsburgh, Pittsburgh, PA.
1991- 96	Assistant Professor, Dept. of Epidemiology, School of Public Health, Univ. of North Carolina, Chapel Hill, NC.
1992-	Member, Lineberger Cancer Center, University of North Carolina, Chapel Hill, NC
1992-	Fellow, Carolina Population Center, University of North Carolina, Chapel Hill, NC
1994-97	Research Assistant Professor, Department of Surgery, School of Medicine, Univ of North Carolina
1996- 2001	Associate Professor, Dept of Epidemiology, School of Public Health, Univ of North Carolina
1997-	Research Associate Professor, Dept of Surgery, School of Medicine, University of North Carolina
2001-	Research Professor, Dept. of Otolaryngology/Head and Neck Surgery, Sch of Medicine University of North Carolina
2001-	Professor, Department of Epidemiology, School of Public Health, University of North Carolina
2006-	Chair, Department of Epidemiology, School of Public Health, University of North Carolina
2012-	Associate Director, Population Sciences, UNC Lineberger Comprehensive Cancer Center

C. Selected Peer-reviewed Publications

Clinical and Translational Cancer Research
Margaret Tempero, Chair

Peer Review Panel Members for Approval

1. Larry Fong, M.D.
2. Howard Hockster, M.D.
3. Elizabeth Jaffee, M.D.
4. Kenneth Pienta, M.D.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
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NAME	POSITION TITLE
Fong, Lawrence	Associate Professor of Medicine
eRA COMMONS USER NAME LHFONG	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Columbia University, New York, NY	BA	1984-1988	Economics
Stanford University, Stanford, CA	MD	1988-1992	Medicine
University of Washington, Seattle, WA	Residency	1992-1994	Internal Medicine
Stanford University, Stanford, CA	Fellowship	1994-1997	Oncology

A. Personal Statement

I have focused on modulating immune responses to tumors for cancer immunotherapy throughout my career. After completing Oncology Fellowship at Stanford, I complete post-doctoral training with Drs. Ed Engleman and Mark Davis focused on tumor immunology. I then began my independent research program at UCSF and have continued to focus on how the immune system interacts with cancer as well as developing tumor immunotherapies in both humans and mouse models. We described the immunogenicity of prostate acid phosphatase (PAP), which is the target antigen for sipuleucel-T, now an FDA-approved immunotherapy for prostate cancer. We were also involved with the first-in-man clinical trials with ipilimumab, an anti-CTLA4 antibody that is now FDA approved for melanoma. We continue to investigate how immunotherapies such as CTLA-4 blockade and vaccines can impact anti-tumor immunity in patients. We also utilize autoimmune prone mouse models to define tumor-associated antigens, which may represent novel vaccine candidates. I have also served on multiple NIH study sections and on the NCI Steering Committees for Genitourinary Cancers and Investigational Drugs-Immunotherapy. I have also served on the education program committee of ASCO, including serving as track chair (Developmental Therapeutics) and as current faculty for the annual AACR/ASCO Vail Methods in Clinical Research Workshop. I am also the site (UCSF) PI for the NCI Cancer Immunotherapy Trials Network (CITN).

B. Positions and Honors

Positions and Employment

1996-2001	Post-Doctoral Fellow, Department of Pathology, Stanford University School of Medicine
2001-2002	Acting Assistant Professor, Department of Pathology, Stanford University School of Medicine
2002-2008	Assistant Professor, Department of Medicine, Division of Heme/Onc, University of California, San Francisco
2008-	Associate Professor, Department of Medicine, Division of Heme/Onc, University of California, San Francisco

Other Experience and Professional Memberships

1996	American Board of Internal Medicine	Diplomat
1997,2007	American Board of Internal Medicine, Medical Oncology	Diplomat
2004-2005	NIH, NCI P01 Review Panel	Ad Hoc Member
2007-2011	Journal of Clinical Oncology	Editorial Board
2009-2011	NIH, NCI CII Study Section	Ad Hoc Member
2006-present	NIH, NCI Special Emphasis Panels - Clinical P01	Ad Hoc Member

2007-present	NIH, NCI CONC Study Section	Member
2011-present	Cancer Vaccine Collaborative (CVC)	Coordinating and Review Committee
2012-present	NCI Investigational Drug Steering Committee (IDSC)	Immunotherapy Task Force
2012-present	NCI Genitourinary Cancers Steering Committee (GUSC)	Elected Member
2012-present	Journal of Immunotherapy of Cancer	Associate Editor
2012-present	Cancer Immunology Research	Senior Editor

Honors

1990	Stanford Alumni Medical Scholar
1993	Alpha Omega Alpha
1997	American Society of Clinical Oncology Young Investigator Award
1997	American Cancer Society Post-Doctoral Fellowship Award
1997	American Association for Cancer Research AFLAC Award
2002	American Association for Cancer Research Scholar-in-Training Award
2003	V Foundation Scholar

C. Selected peer-reviewed publications (from over 40 publications)

1. **Fong L**, Ruegg C, Brockstedt DG, Engleman EG, Laus R. Cutting Edge: Induction of tissue-specific autoimmune prostatitis with prostatic acid phosphatase immunization: Implications for prostate cancer immunotherapy. J Immunol 159:3113-3118, 1997. [http://www.ncbi.nlm.nih.gov/pubmed/9317107]
2. **Fong L**, Hao Y, Rivas A, Benike C, Yuen A, Fisher G, Davis MM, Engleman EG. Altered peptide ligand vaccination with Flt3 ligand expanded dendritic cells for tumor immunotherapy. Proc Natl Acad Sci 98(15):8809-14, 2001. [http://www.ncbi.nlm.nih.gov/pubmed/11427731]
3. Small EJ, Tchekmedyian NS, Rini BI, **Fong L**, Lowy I, Allison JP. A Pilot Trial of CTLA-4 Blockade with Human Anti-CTLA-4 in Patients with Hormone-Refractory Prostate Cancer. Clin Cancer Res 13(6):1810-5, 2007. [http://www.ncbi.nlm.nih.gov/pubmed/17363537]
4. Fasso M, Waitz R, Rim T, Hou Y, Greenberg NM, Shastri N, **Fong L**, Allison JP. SPAS-1 (stimulator of prostatic adenocarcinoma specific T cells-1)/SH3GLB2: A prostate tumor antigen identified by CTLA-4 blockade. Proc Natl Acad Sci 105(9):3509-14, 2008. [http://www.ncbi.nlm.nih.gov/pubmed/18303116]
5. Hou Y, Kavanagh B, **Fong L**. Distinct CD8+ T cell repertoires primed with agonist and native peptides derived from a tumor-associated antigen. J Immunol 180(3):1526-34, 2008. [http://www.ncbi.nlm.nih.gov/pubmed/18209048]
6. Kavanagh B, O'Brien S, Hou Y, Weinberg V, Rini B, Allison JP, Small EJ, **Fong L**. CTLA4 blockade expands FoxP3+ regulatory and activated effector CD4+ T cells in a dose-dependant fashion. Blood 112(4):1175-83, 2008. [http://www.ncbi.nlm.nih.gov/pubmed/18523152]
7. **Fong L**, Kwek SS, O'Brien S, Kavanagh B, Weinberg V, Lin A, Rosenberg J, Ryan CJ, McNeel D, Rini B, Small EJ. Potentiating endogenous antitumor immunity to prostate cancer through combination immunotherapy with CTLA4 blockade and GM-CSF. Cancer Res 69, 609-615, 2009. [http://www.ncbi.nlm.nih.gov/pubmed/19147575]
8. Hou Y, Devoss J, Dao V, Kwek SS, Simko J, McNeel D, Anderson MS, **Fong L**. An aberrant prostate antigen-specific immune response causes prostatitis in mice and is associated with chronic prostatitis in humans. J Clin Invest 119: 2031-2041, 2009. [http://www.ncbi.nlm.nih.gov/pubmed/19603556]
9. Shum AK, DeVoss J, Tan CL, Hou Y, Johannes K, O'Gorman CS, Jones KD, Sochett EB, **Fong L**, Anderson MS. Identification of an autoantigen demonstrates a link between interstitial lung disease and a defect in central tolerance. Science- Transl Med, 1:9ra20, 2009. [http://www.ncbi.nlm.nih.gov/pubmed/20368189]
10. Ryan CJ, Smith MR, **Fong L**, Rosenberg JE, Kantoff P, Raynaud F, Martins V, Lee G, Kheoh T, Kim J, Molina A, Small EJ. Phase I clinical trial of the CYP 17 inhibitor abiraterone acetate (CB7630), Demonstrating clinical activity in castration-resistant prostate cancer patients with prior ketoconazole therapy. J Clin Oncol, 28:1481-1488, 2010. [http://www.ncbi.nlm.nih.gov/pubmed/20159824]
11. Chung K, Gore I, **Fong L**, Vennok A, Beck SB, Dorazio P, Crisciteiello PJ, Healey DI, Huang B, Gomez-Navarro J, Saltz LB. A Phase II Study of the Anti-CTLA4 Monoclonal Antibody, Tremelimumab, in Patients

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Follow sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Howard S. Hochster, M.D.	Professor of Medicine, Yale Cancer Center

EDUCATION *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

eRA COMMONS USER NAME (credential, e.g., agency login)
hochsh01

INSTITUTION AND LOCATION	YEAR DEGREE	CONFERRED	FIELD OF STUDY
Yale University, New Haven, CT	B.S.	1976	Chemistry
Yale University, New Haven, CT	M.S.	1976	Chemistry
Yale University School of Medicine, New Haven, CT	M.D.	1980	Medicine

A. Personal Statement

Dr. Howard Hochster serves the Yale Cancer Center as Associate Director for Clinical Sciences. Dr Hochster has a long record of clinical trial experience and publications relating to new drug development in medical oncology. He published widely on the use of topoisomerase-1 inhibitors and developed pharmacodynamic measures in conjunction with improved drug scheduling. He has investigated intracellular pharmacology of gemcitabine metabolism in clinical trials using PBMC tissue and 19F Magnetic Resonance Spectroscopy (for which he was recently awarded an R0-1 grant). He has published numerous phase II and III trials both investigator initiated and through ECOG, where he has been a major contributor. He has been on the GI Steering Committee for ECOG for more than 10 years and is among the GI leadership at NSABP, currently working on phase III adjuvant trials in colon and gastric cancer.

Dr Hochster will lead the clinical research efforts at the YCC. In this role his goals are to improve the research support infrastructure for day to day trial accrual. He will streamline and further support the protocol development process and regulatory approval process. He has a major focus on extending clinical trial access to the Smilow Care Centers. He will encourage and develop translational investigator initiated trials by securing tissue access coupled to robust clinical data and assist investigators in securing funding for such trials. He also will develop cooperative group participation and use high priority cooperative group protocols to serve as the foundation for invigorating and expanding a regional network of collaborating physicians and institutions in the Yale Cancer Network. We expect that we will continue to have increasing accrual to therapeutic trials, reaching 1000 per year in the grant period.

B. Positions and Honors

Positions and Employment

1980-1983	Internship and Residency in Internal Medicine, New York University-Bellevue Hospital, NY, NY.
1983-1986	Fellowship, Divisions of Hematology and Oncology, NYU School of Medicine, NY.
1985-1986	Visiting Fellow, Jules Bordet Institute, Brussels, Belgium
1986-1989	Instructor of Medicine, Department of Medicine, New York University Medical Center, NY.
1986-present	NYU Tisch Hospital, Attending Physician, New York University Medical Center, NY.
1986-present	Attending Physician, Bellevue Hospital Center, NY, NY.
1989-1995	Assistant Professor of Medicine, Department of Medicine, NYU Medical Center, NY.
1995-2003	Associate Professor of Clinical Medicine, Department of Medicine, NYU SOM, NY.
2000-2003	Associate Professor of Clinical Pharmacology, Dept of Medicine, NYU SOM, NY.
2003-2010	Professor of Medicine and Clinical Pharmacology, Department of Medicine, NYUSOM, NY
2003-2007	Director, NYU Cancer Institute Clinical Trials Office
2005-2006	Ad Hoc Member, Clincal Oncololgy (CONC) study section NIH
2007-2011	Member, CONC study section
2009-2011	American Society of Clinical Oncology Scientific Program Committee member (colorectal track chair 2010)

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Jaffee, Elizabeth, M.	Professor of Oncology
eRA COMMONS USER NAME (credential, e.g., agency login) Ejaffee1	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Brandeis University	B.A.	1981	Biochem & Immunology
New York Medical College	M.D.	1985	Medicine

A. Personal Statement.

Dr. Jaffee is an internationally recognized expert in cancer immunology with specific expertise in the pre-clinical and early clinical development of immunotherapies for breast and pancreatic cancers. She also focuses on understanding the inflammatory responses that are associated with cancer development and progression in pre-clinical and clinical models of pancreatic cancer. She has developed novel vaccine approaches for the treatment of pancreatic and breast cancers and new methodologies for identifying vaccine induced T cell and antibody targets. She has mentored 21 post-doctoral fellows and 12 graduate students, has over 130 peer review publications, and is a nationally and internationally recognized guest lecturer. Dr. Jaffee holds 6 vaccine patents, and has been a Principal Investigator on many immunotherapy Clinical Studies.

Dr. Jaffee also serves as the Director of the Skip Viragh Pancreatic Cancer Center at Johns Hopkins, and as Co-Director of the Gastrointestinal Cancers Program and Associate Director for Translational Science in the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. She established and directs the Johns Hopkins Oncology Center Cell Processing and Gene Therapy cGMP Facility. In 2007, she was appointed as a Deputy Director for the Institute for Translational and Clinical Research at JHUSOM.

Dr. Jaffee has served on numerous NCI and national committees as an immunotherapy and translational research expert. She was a member of the old Experimental Immunology Study Section (1996-2000), a member of the Parent D Committee (PO1 translational grants), and recently completed service as a member of the NCI Board of Scientific Counselors. She also served on the RAID NCI Program Oversight Committee. Dr. Jaffee currently serves on the NCI NExT SEP Committee, is on the Board of Directors for AACR, is Chair of the AACR CIMM Steering Committee, and has served as a Co-Organizer for the AACR Special Conference on Cancer Immunology in 2010 and 2012. Dr. Jaffee was recently appointed by President Obama to serve on the National Cancer Advisory Board.

B. Positions and Honors.

Positions and Employment

1985-1988 Medical Resident, Presbyterian-University, Pittsburgh, PA
1988-1989 NIH Physician Investigator Research Fellow-University of Pittsburgh, Pittsburgh, PA
1989-1991 Senior Clinical Oncology Fellow, Johns Hopkins Oncology Center, Baltimore, MD
1992-1997 Assistant Professor of Oncology, Johns Hopkins University, Baltimore, MD
1997-2002 Associate Professor of Oncology, Johns Hopkins University, Baltimore, MD
2002-Present Professor of Oncology, Johns Hopkins University, Baltimore, MD

Other Experience and Professional Memberships

2001 Visiting Professor at the Ludwig Institute in Belgium
2001 Co-chair Lustgarten Foundation for Pancreatic Cancer Research Third Scientific Conference
2002 Established and direct the Johns Hopkins Oncology Center Cell Processing and Gene Therapy cGMP Facility
2004-2005 Chair, Clinical Research Committee, Sidney Kimmel Cancer Center at Johns Hopkins
2005-2010 Member NCI Board of Scientific Counselors
2006-2010 Member RAID NCI Program Oversight Committee

2006-present Deputy Director, Clinical and Translational Research Institute, Johns Hopkins School of Medicine
2006-2011 Co-Director, Immunology, Sidney Kimmel Cancer Center at Johns Hopkins
2007 Chair of Symposium on Cancer Vaccines, American Association for Cancer Research National Meeting
2007-present Co-Director, Gastrointestinal and Cancers Program, SKCC at Johns Hopkins
2007-present Deputy Director, the Johns Hopkins Institute for Clinical and Translational Research
2008-2011 Board of Directors, International Society for Biological Therapy of Cancer
2008-2010 AACR/ASCO Workshop on Methods in Clinical Research. Faculty and Symposium Chair. Vail, Colorado
2008-2010 AACR Biostatistics Workshop. Faculty and Scientific Program Committee. Sonoma, CA
2007-present Member ASCO YIA and CDA Review Committee, Chair 2011
2011-present Associate Director for Translational Research, the Sidney Kimmel Cancer Center at Johns Hopkins
2012-present Member, NCI NEXT SEP Committee
2012-present Member, National Cancer Advisory Board
2013 Member, Board of Directors, American Association for Cancer Research

Honors

1981 Brandeis University, Graduated Magna cum laude with highest honors in Biology/Immunology
1989 American Cancer Society Clinical Fellow - $10,000
1992 Stetler Award
1992 American Cancer Society Research Award
1992 Physician, Scientist Award NIH
1992 Clinical Investigator Award, Johns Hopkins University School of Medicine
2002-present The Dana and Albert Broccoli Professorship in Oncology
2006 Outstanding NCI SPORE Investigator
2012 Vice Dean's Award for the Advancement of Women Faculty, Johns Hopkins University

C. Selected peer-reviewed publications from over 133

1. **Jaffee EM**, Hruban RH, Biedrzycki B, Laheru D, Schepers K, Sauter PR, Goemann M, Coleman J, Grochow L, Donehower RC, Lillemoe KD, O'Reilly S, Abrams RA, Pardoll DM, Cameron JL, Yeo CJ. A novel allogeneic GM-CSF-secreting tumor vaccine for pancreatic cancer: A phase I trial of safety and immune activation. *Journal of Clinical Oncology*,19(1):145-156 2001.
2. Thomas AM, Santarsiero LM, Lutz ER, Armstrong, TD, Chen YC, Huang LQ, Laheru DA, Goggins M, Hruban RH, **Jaffee EM**: Mesothelin-specific cd8(+) t cell responses provide evidence of in vivo cross priming by antigen-presenting cells in vaccinated pancreatic cancer patients. The Journal of Experimental Medicine 2004;200:297-306.
3. Ercolini AM, Ladle BH, Manning EA, Pfannenstiel LW, Armstrong TD, Machiels JP, Bieler JG, Emens LA, Reillty RT, **Jaffee, EM**: Recruitment of latent pools of high-avidity cd8(+) t cells to the antitumor immune response. The Jounral of Experimental Medicine 2005:201:1591-1602.
4. Laheru D, Lutz E, Burke J, Biedrzycki B, Solt S, Onners B, Tartakovsky I, Nemunaitis J, Le D, Sugar E, Hege K, **Jaffee EM**. Allogeneic granulocyte macrophage colony-stimulating factor-secreting tumor immunotherapy alone or in sequence with cyclophosphamide for metastatic pancreatic cancer: a pilot study of safety, feasibility, and immune activation. Cancer Therapy: Clin Can Res 2008 Mar l:14(5):1455-1463. PMID: 18316569 PMCID: 2879140
5. Jones S, Zhang X, Parsons DW, Lin JC, Leary RJ, Angenendt P, Mankoo P, Carter H, Kamiyama H, Jimeno A, Hong SM, Fu B, Lin MT, Calhoun ES, Kamiyama M, Walter K, Nikolskaya T, Nikolsky Y, Hartigan J, Smith DR, Hidalgo M, Leach SD, Klein AP, **Jaffee EM**, Goggins M, Maitra A, Iacobuzio-Donahue C, Eshleman JR, Kern SE, Hruban RH, Karchin R, Papadopoulos N, Parmigiani G, Vogelstein B, Velculescu VE, Kinzler KW. Core signaling pathways in human pancreatic cancers revealed by global genomic analyses. Science. 2008;321(5897):1801-6. PMCID: 2848990.
6. Kim PS, Armstrong TD, Song H, Wolpoe ME, Weiss V, Manning EA, Huang LQ, Murata S, Sgouros G, Emens LA, Reilly RT, **Jaffee EM**. Antibody association with HER-2/neu-targeted vaccine enhances

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Kenneth J. Pienta, M.D.	Professor of Internal Medicine and Urology
eRA COMMONS USER NAME (credential, e.g., agency login) kpienta	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
The Johns Hopkins University, Baltimore, MD	B.A.	1983	
The Johns Hopkins University School of Medicine, Baltimore, MD	M.D.	1986	Medicine
University of Chicago Hospitals & Clinics, Chicago, IL	Intern	1986-1987	Internal Medicine
University of Chicago Hospitals & Clinics, Chicago, IL	Resident	1987-1988	Internal Medicine
The Johns Hopkins University School of Medicine, Baltimore, MD	Clinical Fellow	1988-1989	Oncology

A. Personal Statement

I am a Professor of Internal Medicine and Urology, a two-time American Cancer Society Clinical Research Professor Award recipient. Since 1995, I have been the Director of the Prostate Specialized Program of Research Excellence (SPORE) at The University of Michigan, with a proven, peer-reviewed track record in organizing and administering a translational research program that successfully incorporates bench research, agent development, and clinical application. I am the Director of Experimental Therapeutics at the Michigan Center for Translational Pathology. Currently, I am involved in research to define the tumor microenvironment of prostate cancer metastases, as well as developing new therapies for prostate cancer. I see advanced prostate cancer patients ½ day per week. I also direct the Rapid Autopsy Program of the University of Michigan Comprehensive Cancer Center.

B. Position and Honors

Positions

1991-1993 Assistant Professor of Medicine, Division of Hematology and Oncology, Department of Internal Medicine and Assistant Professor of Molecular Biology and Genetics, Wayne State University School of Medicine, Detroit, MI
1991-1994 Adjunct Assistant Member, The Michigan Cancer Foundation, Detroit, MI
1991-1994 Staff Physician, Harper Hospital, Detroit, MI
1991-1994 Deputy Director of the Urologic Oncology Program, Meyer L. Prentis Comprehensive Cancer Center of Metropolitan Detroit, Detroit, MI
1992-1994 Faculty, The Cancer Biology Graduate Program, Wayne State University School of Medicine, Detroit, MI
1994 Associate Professor of Medicine, Division of Hematology and Oncology, Department of Internal Medicine and Associate Professor of Molecular Biology and Genetics, Wayne State University School of Medicine, Detroit, MI
1994-1998 Associate Professor of Internal Medicine, Division of Hematology/Oncology and Associate Professor of Surgery, Section of Urology, University of Michigan Medical School, Ann Arbor, MI
1995-2010 Director, Urologic Oncology, University of Michigan Comprehensive Cancer Center
1998- Professor of Internal Medicine, Division of Hematology/Oncology, University of Michigan Medical School, Ann Arbor, MI
1998-2001 Professor of Surgery, Section of Urology, University of Michigan Medical School, Ann Arbor, MI
2001- Professor of Urology, Dept. of Urology, University of Michigan Medical School, Ann Arbor, MI
2006-2008 Chairman, Translational Medicine Committee, Southwest Oncology Group

2008-2011 Associate Dean for Clinical and Translational Research, University of Michigan Medical School, Ann Arbor, MI
2008-2011 Director, Michigan Institute for Clinical & Health Research
2008- Director, Experimental Therapeutics, Michigan Center for Translational Pathology
2012- Associate Vice President for Research, Health Sciences

Federal Government Public Advisory Committee

2009 - The Genitourinary Concept Evaluation Panel – National Cancer Institute
2009 - SPORE Study Section - National Cancer Institute

Honors

1988 Alpha Omega Alpha
1988-1992 Clinical Investigator, The American Board of Internal Medicine
2003 American Cancer Society Clinical Research Professorship
2005 American Society of Clinical Investigators
2007 Amer. Assoc. for Cancer Research Team Science Award
2009 American Urological Association Distinguished Mentor Award
2011 Johns Hopkins Society of Scholars
2011 Taubman Research Scholar, University of Michigan

C. Selected Peer-review Publications (Selected from peer-reviewed publications)

1. Kalikin LM, Schneider A, Thakur MA, Fridman Y, Griffin LB, Dunn R, Rosol TJ, Shah RB, Rehemtulla A, McCauley LK, PIENTA KJ. In vivo visualization of metastatic prostate cancer and quantitation of disease progression in immunocompromised mice. Cancer Biol Ther. 6:656-660, 2003. *PMID:14688471 NIHMS183513*
2. Shah RB, Mehra R, Chinnaiyan AM, Shen R, Zhou M, MacVicar GR, Varambally S, Harwood J, Bismar TA, Kim R, Rubin MA, PIENTA KJ. Androgen Independent Prostate Cancer is a Heterogeneous Group of Diseases: Lessons from a Rapid Autopsy Program. Cancer Res 64(24): 9209-16, 2004. *PMID:15604294*
3. PIENTA KJ, Loberg RD. The emigration, migration, and immigration of prostate cancer. Clin Prostate Cancer. 4(1):24-30, 2005. *PMID:15992458*
4. Wang X, Yu J, Sreekumar A, Varambally S, Shen R, Giacherio D, Mehra R, Montie JE, PIENTA KJ, Sanda MG, Kantoff PW, Rubin MA, Wei JT, Ghosh D, Chinnaiyan AM. Autoantibody signatures in prostate cancer. N Engl J Med. 353(12):1224-1235, 2005. *PMID:16177248*
5. Tomlins SA, Rhodes DR, Perner S, Dhanasekaran SM, Mehra R, Sun XW, Varambally S, Cao X, Tchinda J, Kuefer R, Lee C, Montie JE, Shah R, PIENTA KJ, Rubin MA, Chinnaiyan AM. Recurrent fusion of TMPRSS2 and ETS transcription factor genes in prostate cancer. Science 310(5748):644-648, 2005. *PMID:16254181*
6. Loberg RD, Logothetis CJ, Keller ET, PIENTA KJ. Pathogenesis and treatment of prostate cancer bone metastasis: targeting the lethal phenotype. J Clin Oncol 23(32):8232-8241, 2005. *PMID:16278478*
7. Loberg RD, St. John LN, Day LL, Neeley CK, PIENTA KJ. Development of the VCaP androgen independent model of prostate cancer. Urol Oncol. 24(2):161-168, 2006. *PMID:1557359 PMCID: PMC48699*
8. Axelrod R, Axelrod DE, PIENTA KJ. Evolution of cooperation among tumor cells. Proc Natl Acad Sci U S A 103(36):13474-13479, 2006. *PMID:1557388 PMCID:PMC48753*
9. Loberg RD, Ying C, Craig M, Day LL, Sargent E, Neeley C, Wojno K, Snyder LA, Yan L, PIENTA KJ. Targeting CCL2 with systemic delivery of neutralizing antibodies induces prostate cancer tumor regression in vivo. Cancer Res 67(19):9417-24, 2007. *PMID:17909051*
10. Meng Y, Tang W, Dai Y, Wu X, Liu M, Ji Q, Ji M, PIENTA K, Lawrence T, Xu L. Natural BH3 mimetic (-)-gossypol chemosensitizes human prostate cancer via Bcl-xL inhibition accompanied by increase of Puma and Noxa. Mol Cancer Ther. Jul: 7(7):2192-202, 2008. *PMID18645028 PMCID:PMC2515935 NIHMS58672*
11. Roca H, Varsos Z, PIENTA KJ. CCL2 protects prostate cancer PC3 cells from autophagic death via P13K/AKT-dependent surviving up-regulation. J Biol Chem. Sep 5;283(36):25057-73, 2008. *PMID:18611860 PMCID:PMC2529129*
12. Mizutani, K., Sud, S., McGregor, N. A., Martinovski, G., Rice, B. T., Craig, M.J., Varsos, Z.S., H. Roca, and PIENTA K. The chemokine CCL2 increases prostate tumor growth and bone metastasis through

Imagining Technology and Informatics
Sanjiv “Sam” Gambhir, Chair

Peer Review Panel Members for Approval

1. Daphne Haas-Kogan, M.D.
2. Jason Lewis, Ph.D.
3. Martin Pomper, M.D.

BIOGRAPHICAL SKETCH

NAME Haas-Kogan, Daphne Adele	POSITION TITLE Professor, Vice-Chair for Research & Program Director Department of Radiation Oncology Comprehensive Cancer Center
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Harvard University, Cambridge, MA	A.B.	1986	Biochemical Sciences
University of California, San Francisco	M.D.	1991	Medicine
University of California, San Francisco	Postdoctorate	1993	Neuro-oncology
University of California, San Francisco	Residency	1997	Radiation Oncology

A. Personal Statement

I have been the PI on clinical trials testing radiotherapy approaches in pediatric cancers and hold leadership positions in the Children's Oncology Group and Pacific Pediatric Neuro-Oncology Consortium (PNOC). As a translational scientist I have taken findings from my laboratory and used them to design clinical trials for adults and children with cancer. As PI or co-Investigator on several previous university- and NIH-funded grants, I have laid the groundwork for the proposed research by developing model systems to test experimental therapeutics and by establishing robust collaborations in order to advance this work. In addition, I have successfully carried out laboratory research, designed clinical trials, and established a robust clinical practice in radiation oncology, focusing on brain tumors and pediatric malignancies. I am pleased to serve on the CPRIT Imaging Technology and Informatics Scientific Peer Review Panel, which builds logically on my prior work and experience.

B. Positions and Honors

Positions

1997-2002 Assistant Professor in Residence Department of Radiation Oncology, University of California, San Francisco
2002-2008 Associate Professor, Department of Radiation Oncology, University of California, San Francisco
Department of Radiation Oncology, University of California, San Francisco
2008-present Professor, Department of Radiation Oncology, University of California, San Francisco

Honors

1985 Joseph L. Barrett Award for Teaching, Harvard University
1986 Phi Beta Kappa, Harvard University
1986 Thomas T. Hoopes Prize awarded to Senior Honors Thesis
1986 *Summa cum laude* awarded to Senior Honors Thesis
1991 Alpha Omega Alpha, University of California, San Francisco
1995 ASTRO Basic Scientist Research Award
1995 Junior Scientist Travel Award, 10th International Congress of Radiation Research
1995 American Cancer Society Clinical Oncology Fellowship
1997 Radiological Society of North America Scholar Award
1998 UCSF Dean representative to Association of American Medical Colleges Professional Development Seminar for Junior Women Faculty, Santa Fe, New Mexico
1999 Pfizer Scholars Grant for New Faculty
1999 First place: CAP competition, General Clinical Research Center National Meeting; Arlington, VA
1999 UCSF-Mount Zion Clinical Investigator Award
2000 American Society of Clinical Oncology Career Development Award
2002 Henry J. Kaiser Award for Excellence in Teaching, UCSF School of Medicine
2002 UCSF Nominee, Assoc of American Medical Colleges (AAMC) Humanism in Medicine Award.
2003 Nominated for Teaching Award, UCSF School of Medicine

2004 Nominee: Henry J. Kaiser Award for Excellence in Teaching, UCSF School of Medicine
2005 Selected one of Best San Francisco Doctors for San Francisco Magazine, January 2005
2006 Alpha Omega Alpha, nominated by Medical Student Class of 2007
2010 Nominee: UCSF Medical Center's Exceptional Physician Award
2011 *Best Doctors* Marin Magazine
2012 Caring Tree Award of the UCSF Benioff Children's Hospital; From Families to Caregivers
2012 US News and World Report's "Top Doctors"
2007-present *Best Doctors in America®*
2010-present *America's Top Oncologists®*

C. Selected peer-reviewed publications most relevant to current application

1. **Haas-Kogan DA**, Prados MD, Tihan T, Eberhard DA, Jelluma N, Arvold ND, Baumber R, Lamborn KR, Kapadia A, Malec M, Berger MS, and Stokoe D. Epidermal Growth Factor Receptor, Protein Kinase B/Akt, and Glioma Response to Erlotinib. J Natl Cancer Inst, 2005; 97(12):880-887; PMID: 15956649.
2. **Haas-Kogan DA**, Prados MD, Lamborn KR, Tihan T, Berger MS, and Stokoe D. Biomarkers to predict response to Epidermal Growth Factor Receptor inhibitors. Cell Cycle, 2005; 4(10):95-98; PMID: 16177570.
3. Mishra KK, Puri DR, Missett BT, Lamborn KR, Prados MD, Berger MS, Banerjee A, Gupta N, Wara MW and **Haas-Kogan DA**. The role of up-front radiation therapy for incompletely resected pediatric WHO grade II low-grade gliomas. Neuro-oncol. 2006, 8(2):166-74; PMID: 16495375. PMCID: PMC1871938
4. Entin-Meer M, Yang X, Vandenberg, SR, Lambron KR, Nudelman A, Rephaeli A, and **Haas-Kogan DA**. *In vivo* efficacy of a novel histone deacetylase inhibitor in combination with radiation for the treatment of gliomas. Neuro-Oncol. 2007, 9(2):82-88; PMID: 17347490. PMCID: PMC1871664
5. Chen JS, Zhou LJ, Entin-Meer M, Yang X, Donker M, Knight Z, Weiss W, Shokat K, **Haas-Kogan DA**, and Stokoe D. Characterization of structurally distinct, isoform-selective PI3-kinase inhibitors as radiosensitizing agents in the treatment of human gliomas. Mol Can Therap, 2008, 7(4):841-850. PMID: 18413797
6. **Haas-Kogan DA** and Stokoe D. PTEN in Brain Tumors. Expert Review of Neurotherapeutics, 2008, 8(4):599-610. PMID: 18416662
7. Ermoian RP, Kaprealian T, Lamborn KR, Jelluma N, Arvold ND, Zeidman R, Berger MS, Stokoe D, and **Haas-Kogan DA**. Signal Transduction Molecules in Gliomas of all Grades. J Neurooncol. 2009, 91(1):19-26. PMCID: PMC2879130
8. McBride SM, Perez DA, Polley MY, Vandenberg SR, Smith JS, Zheng S, Lamborn KR, Wiencke JK, Chang SM, Prados MD, Berger MS, David Stokoe D, and **Haas-Kogan DA**. Activation of PI3K/mTOR pathway occurs in most adult low-grade gliomas and predicts patient survival. J Neurooncol. 2010, 97:33-40. PMCID: PMC2814032
9. Fan QW, Cheng CK, Hackett C, Feldman M, Houseman BT, **Haas-Kogan DA**, Nicolaides T, James, CD, Debnath J, Shokat KM, and Weiss WA. Akt and autophagy cooperate to promote survival in glioma. Science Signaling, 2010, 9;3(147):ra81. PMCID: PMC3001107
10. Mishra KK, Squire S, Lamborn K, Banerjee A, Gupta N, Wara WM, Prados MD, Berger MS, **Haas-Kogan DA**. Phase II TPDCV protocol for pediatric low-grade hypothalamic/chiasmatic gliomas: 15-year update. J Neurooncol. 2010, 100(1):121-127. PMCID: PMC2951507
11. **Haas-Kogan DA**, Banerjee A, Poussaint TY, Kocak M, Prados MD, Geyer JR, Fouladi M, Broniscer A, Minturn JE, Pollack IF, Packer RJ, Boyett JM, and Kun LE. Phase II Trial of Tipifarnib and Radiation in Children with Newly Diagnosed Diffuse Intrinsic Pontine Gliomas. Neuro-Oncology, 2011, 13(3):298-306. PMCID: PMC3064607
12. Prasad G, Sottero T, yang X, Mueller S, James CD, Weiss WA, Polley MY, Ozawa T, Berger M, Aftab DT, Prados MD, **Haas-Kogan DA**. Inhibition of PI3K/mTOR pathways in glioblastoma and implications for combination therapy with temozolomide. Neuro-Oncology, 2011 Apr;13(4):384-92. Epub 2011 Feb 11. PMCID: PMC3064692
13. Zheng S, Houseman EA, Morrison Z, Wrensch MR, Patoka JS, Ramos C, **Haas-Kogan DA**, McBride S, Marsit CJ, Christensen BC, Nelson HH, Stokoe D, Wiemels JL, Chang SM, Prados MD, Tihan T, Vandenberg SR, Kelsey KT, Berger MS, Wiencke JK. DNA hypermethylation profiles associated with glioma subtypes and EZH2 and IGFBP2 mRNA expression. Neuro-Oncology, 2011, 13(3):280-9. PMCID: PMC3064601

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
LEWIS, Jason S.	Emily Tow Jackson Chair
eRA COMMONS USER NAME (credential, e.g., agency login) LEWISJAS	

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Essex, UK	B.S.	1992	Chemistry
University of Essex, UK	M.S.	1993	Chemistry
University of Kent, Canterbury, UK	Ph.D.	1996	Biochemistry
Washington University, St. Louis, MO	Postdoctoral	1996-1999	Radiochemistry

A. Personal Statement

Dr. Lewis is a Radiochemist with more than 15 years of experience in the design and application of novel radiopharmaceuticals for the imaging of disease. His personal research program includes radiochemistry, molecular imaging, nuclear targetry, chemistry and imaging the tumor microenvironment. In his role as Chief Attending of the Radiochemistry & Imaging Science Service and Director of the Radiochemistry & Molecular Imaging Probe Core, he is responsible for overseeing all PET nuclide production and supply as well as clinical PET radiopharmaceutical manufacturing at MSKCC. His lab has worked on the development of small molecules targeting cancer, as well as radiolabeled peptides and antibodies targeting the over-expression of receptors and antigens on tumors.

B. Positions and Honors

Positions and Employment

2000-2002	Research Instructor, Radiology, Washington University School of Medicine, St. Louis, MO
2003-2008	Assistant Professor, Radiology, Washington University School of Medicine, St. Louis, MO
2008-2010	Associate Member, Memorial Sloan Kettering Cancer Center, New York, NY
2008-2010	Chief and Associate Attending Radiochemist, Memorial Hospital for Cancer and Allied Diseases, New York, NY
2008-2010	Associate Professor, Gerstner Sloan-Kettering Graduate School of Biomedical Sciences
2008-present	Laboratory Head, Molecular Pharmacology and Chemistry, Sloan-Kettering Institute, New York, NY
2008-present	Director, Cyclotron Core, Memorial Sloan-Kettering Cancer Center, New York, NY
2008-present	Vice Chair of Research, Department of Radiology, Memorial Hospital for Cancer and Allied Diseases, New York, NY
2009-present	Associate Professor of Radiochemistry and Radiopharmacy in Radiology, Weill Cornell Medical College, Cornell University
2010-present	Professor, Gerstner Sloan-Kettering Graduate School of Biomedical Sciences
2010-present	Chief Attending Radiochemist, Memorial Hospital for Cancer and Allied Diseases, New York, NY
2010-present	Member (with Tenure), Memorial Sloan Kettering Cancer Center, New York, NY
2013-present	Professor of Radiochemistry and Radiopharmacy in Radiology, Weill Cornell Medical College, Cornell University
2013-present	Emily Tow Jackson Chair in Oncology (Endowed Chair)

Honors, Memberships, Editorial, Review

1993-96, Biotechnology and Biological Sciences Research Council (BBSRC) Case Award; **1996**, Society Chemical Industry (SCI) Messel Fund Award; **2004-2007**, PCRP New Investigator Award, Department of

Defense; **2006-2009**, Sub-Chair Radiopharmaceutical Chemistry Track, SNM; **2009-present,** Chair, MICoE Task Force; MICoE Board of Directors; **2006**, Cover feature of Bone Journal (August). **2009**, Cover Side-Bar, Cancer Research (May); **Memberships,** The Royal Society of Chemistry (Chartered Member, 1/1995-12/1999); The American Chemical Society (1/1998-12/2002); Society of Nuclear Medicine (1/1998-present); Society of Radiopharmaceutical Sciences (10/2001-present); American Association of Cancer Research (1/2001- present). **Editorial,** Current Radiopharmaceuticals (Editorial Board, 2007-present); Cancer Research (AACR Journal) (Associate Editor, 10/2007- present); Journal of Nuclear Medicine (2010- present); Peer-reviewed journal reviewer (n=6). **Reviewer (selected),** Hematologic Malignancies P01 Cluster Review (Ad Hoc); Microenvironment P01 Cluster Review (Ad Hoc); NIH Special Emphasis Panel, Clinical Cluster Review; NIH Special Emphasis Panel, SPORE in Brain Tumor and Lymphoma; NIH Special Emphasis Panel, ONC-R (11) SBIR/STTR; NIH Oncological Sciences Fellowship Study Section (ZRG F09 20); NIH Special Emphasis Panel, ONC-P (02); NIH Clinical Molecular Imaging and Probe Development (CMIP) (Standing).

C. Selected peer-reviewed publications (out of >120).

Most relevant to the current application

1. Vāvere AL, Biddlecombe GB, Spees WM, Garbow JR, Wijesinghe D, Andreev OA, Engelman DM, Reshetnyak YK, **Lewis JS**. A Novel Technology for the Imaging of Acidic Prostate Tumors by Positron Emission Tomography. Cancer Research, 69:4510-4516, 2009. PMID: 19417132.

2. Daumar P*, Wanger-Baumann CA*, Pillarsetty NVP, Fabrizio L, Carlin SD, Reshetnyak YK, Andreev OA, **Lewis JS**. Efficient ^{18}F-Labeling of Large 37-Amino Acid pHLIP Peptide Analogues and their Biological Evaluation. Bioconjugate Chemistry, 2012. 1557-1566. PMID:22784215.

3. Zeglis BM, Mohindra P, Weissmann GI, Divilov V, Hilderbrand SA, Weissleder R, **Lewis JS**. Modular Strategy for the Construction of Radiometalated Antibodies for Positron Emission Tomography Based on Inverse Electron Demand Diels-Alder Click Chemistry. Bioconjugate Chemistry, 22, 2048-2059, 2011. PMCID:PMC3197258

4. Holland JP, Sheh Y, **Lewis JS.** Standardized methods for the production of high specific-activity zirconium-89. Nuclear Medicine and Biology 36, 729-739, 2009. PMCID:PMC2827875

5. Holland JP, Evans MJ, Rice SL, Wongvipat J, Sawyers CL, **Lewis JS**. Annotating MYC oncogene status with ^{89}Zr-transferrin imaging. Nature Medicine, 18, 586–1591, 2012. PMC Journal – In Process

Additional recent publications of importance to the field (in Chronological order)

1. **Lewis JS**, Laforest R, Lewis MR, Anderson CJ. Comparative dosimetry of copper-64 and yttrium-90-Labeled somatostatin analogs in a tumor-bearing rat model. Cancer Biotherapy and Radiopharmaceuticals 15:593-604, 2000. PMID: 11190491.

2. **Lewis JS**, Wang M, Laforest R, Wang F, Erion JL, Bugaj JE, Srinivasan A, Anderson CJ. Toxicity and dosimetry of ^{177}Lu-DOTA-Y3-octreotate in a rat model. International Journal of Cancer, 94: 873-877, 2001. PMID: 11745491.

3. **Lewis JS,** Connett JM, Garbow JR, Buettner TL, Fujibayashi Y, Fleshman JW, Welch MJ Copper-64-pyruvaldehyde-bis(N^4-methylthiosemicarbazone) for the Prevention of Tumor Growth at Wound Sites following Laparoscopic Surgery: Monitoring Therapy Response with microPET and Magnetic Resonance Imaging. Cancer Research, 62: 445-449, 2002. PMID: 11809694.

4. Parry R, Schneider D, Hudson D, Parkes D, Xuan J-A, Newton A, Toy P, Lin R, Harkins R, Alicke B, Biroc S, Kretschmer PJ, Halks-Miller M, Klocker H, Zhu Y, Larsen B, Cobb RR, Bringmann P, Roth G, **Lewis JS**, Dinter H, Parry G. Identification of a Novel Prostate Tumor Target, Mindin/RG-1, for Antibody-Based Radiotherapy of Prostate Cancer. Cancer Research 65:8397-8405, 2005. PMID: 16166318.

5. Holland JP, Caldos-Lopes E, Divilov V, Longo VA, Taldone T, Zatorska D, Chiosis G, **Lewis JS**. Measuring the pharmacodynamic effects of a novel Hsp90 inhibitor on HER2/neu expression in mice using ^{89}Zr-DFO-trastuzumab, PLoS One, 5, e8859, 2010. PMCID:PMC2810330.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Martin G. Pomper	POSITION TITLE Professor of Radiology, Pharmacology, Oncology, Radiation Oncology, Psychiatry, Environmental Health Sciences, Pathobiology
eRA COMMONS USER NAME mpomper1	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing,*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Illinois at Urbana-Champaign	B.S.	1979-82	biochemistry
University of Illinois at Urbana-Champaign	Ph.D.	1982-89	chemistry (organic)
University of Illinois at Urbana-Champaign	M.D.	1982-90	medicine

A. Personal Statement

For the past 18 years my group has been dedicated to the development and application of new imaging agents, with a focus on cancer. We currently consist of about 25 individuals, including graduate students, technicians, postdoctoral fellows, junior faculty, rotating students, residents and clinicians. Most of our work involves chemical and radiochemical synthesis, but we have several projects involving molecular-genetic imaging as well as nanotechnology, and we adapt and generate our own biological assays and translate quantitative imaging techniques to the clinic.

B. Positions and Honors.

Positions and Employment

1990—1991 Intern in Medicine, Johns Hopkins Hospital, Baltimore, MD (Osler Service)
1991—1995 Resident in Radiology, Johns Hopkins Hospital, Baltimore, MD
1994—1995 Resident in Nuclear Medicine, Johns Hopkins Hospital, Baltimore, MD
1994—1996 Fellow in Neuroradiology, Johns Hopkins Hospital, Baltimore, MD
1996—2002 Assistant Professor, Department of Radiology, Johns Hopkins University, Baltimore, MD
2002—2007 Associate Professor, Department of Radiology, (2003) Pharmacology and Molecular Sciences, Oncology, Johns Hopkins University, Baltimore, MD; (2006) Department of Environmental Health Sciences, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
2007—present Professor, Radiology, Pharmacology and Molecular Sciences, Oncology, and Environmental Health Sciences; (2008) Psychiatry; (2013) Pathobiology, Johns Hopkins University, Baltimore, MD
2011—present William R. Brody Professor of Radiology (inaugural)

Other Experiences and Professional Memberships

2000—present Associate Director, Johns Hopkins *In Vivo* Cellular and Molecular Imaging Center (ICMIC)
2001—present Director, Johns Hopkins Small Animal Imaging Resource Program (SAIRP)
2001—present Ad Hoc Reviewer, National Institutes of Health
2005—2006 Treasurer, Society for Molecular Imaging
2005—present Steering Committee, Johns Hopkins Institute for NanoBioTechnology
2006—2008 President, Society of Nuclear Medicine's Molecular Imaging Center of Excellence
2007—2012 Board of Scientific Counselors, NIH Clinical Center
2007—2012 Editor-in-Chief, *Molecular Imaging*
2009—2013 Member, Clinical Molecular Imaging and Probes Study Section (NIH)
2009—present Co-Director, Johns Hopkins PET Center
2009—2012 CPRIT Scientific Review Panel (Imaging Technology and Informatics)
2010—present Co-Director, Johns Hopkins Center for Cancer Nanotechnology Excellence

2010—present Director, Johns Hopkins Center for Translational Molecular Imaging

Honors

1982-1990	Medical Scholars Program, University of Illinois at Urbana-Champaign
1988	Berson-Yalow Award, Society of Nuclear Medicine (first author)
1988	R.C. Fuson Award for Excellence in Organic Chemistry, University of Illinois
1995	William Gatewood Award (Department of Radiology, Johns Hopkins Hospital)
1996-1998	Radiological Society of North America, Scholar's Award
1997-1999	NARSAD Young Investigator Award – Marcia Simon Investigator
2007	Berson-Yalow Award, Society of Nuclear Medicine (co-author)
2008	Distinguished Service Award, Society of Nuclear Medicine
2011	Berson-Yalow Award, Society of Nuclear Medicine (senior author)
2012	Distinguished Investigator of the Academy of Radiology Research

Specialty Certifications and Licenses

1995	American Board of Radiology, Diagnostic Radiology
1995, 2005	American Board of Nuclear Medicine
Medical Licenses:	Maryland, New York

C. Selected Peer-reviewed Publications (from appx. 180 and 50 issued or pending patents)

1. Zhou J, Neale JH, Pomper MG, Kozikowski AP. NAAG Peptidase inhibitors and their potential for diagnosis and therapy. Nat Rev Drug Discov 2005; 4:1015-1026.
2. Bettegowda C, Foss CA, Wang Y, Fox J, Zhou S, Kinzler K, Vogelstein B, Pomper MG. Imaging bacterial infection in live animals with radiolabeled FIAU. Proc Natl Acad Sci USA 2005; 102:1145-51150.
3. Diaz LA, Foss CA, Thornton K, Nimmagadda S, Endres CJ, Uzuner O, Seyler TM, Ulrich SD, Conway J, Bettegowda C, Agrawal N, Cheong I, Zhang X, Ladenson PW, Vogelstein BN, Mont MA, Zhou S, Kinzler KW, Vogelstein B, Pomper MG. Imaging of musculoskeletal bacterial infections by [^{124}I]FIAU-PET/CT. PLoS One 2007; 2:e1007.
4. Fu D-X, Tanhehco YC, Chen J, Foss CA, Fox J, Lemas V, Chong J-M, Ambinder RF, Pomper MG. Tumor imaging by induction of integrated viral gene expression. Clin Cancer Res 2007; 13:1453-1458.
5. Fu D, Tanhehco Y, Chen J, Foss CA, Fox JJ, Chong J-M, Fukayama M, Sgouros G, Kowalski J, Pomper MG, Ambinder RF. Bortezomib-induced enzyme-targeted radiotherapy in herpesvirus-associated tumors. Nat Med 2008; 14:1118-1122. PMC2709824.
6. Banerjee SR, Foss CA, Castanares M, Mease RC, Byun Y, Fox JJ, Hilton J, Lupold S, Kozikowski AP, Pomper MG. Synthesis and evaluation of technetium-99m- and rhenium-labeled inhibitors of the prostate-specific membrane antigen (PSMA). J Med Chem 2008; 51:4504-4517. PMC3336105.
7. Wang H, Byun Y, Barinka C, Pullambhatla M, Bhang HE, Fox JJ, Lubkowski J, Mease RC, Pomper MG. Bioisosterism of urea-based GCPII inhibitors: Synthesis and structure-activity relationship studies. Bioorg Med Chem Lett 2010; 20:392-397. PMC2818328.
8. Zhang Y, Byun Y, Ren YR, Liu JO, Laterra J, Pomper MG. Identification of Inhibitors of ABCG2 by A Bioluminescence Imaging-based High-throughput Assay. Cancer Res 2009; 69:5867-75. PMC2711991.
9. Banerjee SR, Pullambhatla M, Byun Y, Nimmagadda S, Green G, Fox JJ, Horti A, Mease RC, Pomper MG. 68Ga-labeled inhibitors of prostate-specific membrane antigen (PSMA) for imaging prostate cancer. J Med Chem 2010; 53:5333-5341. PMC3341619.
10. Bhang H-E, Gabrielson KL, Laterra J, Fisher PB, Pomper MG. Tumor-Specific Imaging through Progression Elevated Gene-3 Promoter-Driven Gene Expression. Nat Med 2011; 17:123-129. PMC3057477.
11. Chen Y, Pullambhatla M, Byun Y, Foss CA, Nimmagadda S, Senthamizhchelvan S, Sgouros G, Mease RC, Pomper MG. 2-(3-{1-Carboxy-5-[(6-[18F]fluoro-pyridine-3-carbonyl)-amino]-pentyl}-ureido)-pentanedioic acid, [18F]DCFPyL, a PSMA-based PET Imaging Agent for Prostate Cancer. Clin Cancer Res 2011; 17(24):7645-53. PMC3243762.
12. Banerjee SR, Pullambhatla M, Byun Y, Nimmagadda S, Foss CA, Green G, Fox JJ, Lupold SE, Mease RC, Pomper MG. Sequential SPECT and optical imaging of experimental models of prostate cancer with a dual modality inhibitor of the prostate-specific membrane antigen. Angew Chem Int Ed Engl 2011; 50:9167-70. PMC3192196.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: CYNTHIA MULROW, INTERIM CHAIR, DIVERSITY SUBCOMMITTEE
SUBJECT: DIVERSITY SUBCOMMITTEE REPORT
DATE: JANUARY 20, 2014

CPRIT staff provided a historical overview to the subcommittee at its January 15th meeting about the origination of the subcommittee. It was created by the former members of the Oversight Committee to develop outreach to encourage minority researchers to apply for CPRIT grant awards. The issue that the former subcommittee found was that the number of racial, ethnic and women minorities in the scientific field who hold faculty positions that would qualify them as a principal investigator to apply for CPRIT grant funds is small. This is a result of a much larger issue in the U.S. educational system which has a limited pipeline of people who choose to focus on sciences from primary school through graduate and professional schools. While CPRIT alone cannot address the pipeline from the beginning, the former subcommittee's efforts resulted in the development of the Research Training Awards which fund fellowships at academic institutions for undergraduate and graduate students in oncology programs. CPRIT has seven of these training awards at institutions around Texas, and it is believed that a large number of the students in the programs are minorities.

The Diversity Subcommittee discussed the diversity issue both as it relates to the agency and grantee procurement processes to support the state's goal of increasing the number of Historically Underutilized Business (HUB) entities that are successful at receiving state contracts and as it relates to increasing the number of minorities who receive CPRIT grants. In addition to the agency actively increasing its procurement of services from HUB entities, the subcommittee discussed the possibility of impacting grantee HUB procurement practices by incenting grant awardees to meeting institutional or organizational goals for procuring services from HUB entities.

The ideas that the subcommittee discussed to increase the number of minorities who receive CPRIT grants include:

1) Developing a set aside or target for successful minority applications; and
2) Giving extra points to applicants who demonstrate they have made efforts to hire as and train minorities that put them on a path toward a tenured faculty position.

Both of these approaches may be controversial for differing reasons. For instance, state HUB programs use "goals" instead of set-asides for agencies to work towards in their contracting and purchasing activities. However, these suggestions can serve as vehicles for expanded discussion.

State law requires CPRIT to establish standards to ensure that grant recipients purchase goods and services from HUBs (Health & Safety Code Section 102.259). As a result CPRIT's standard contract language includes a requirement that grantees use reasonable efforts to purchase materials, supplies or services from a HUB.

Grantees report compliance to CPRIT but verification and quality of compliance is done only superficially on an individual grantee basis. Aggregation of data suitable for analysis requires additional software programming by SRA, Inc., CPRIT's third party grant award application and review administrator. CPRIT staff will discuss HUB data aggregation with SRA to see how this project can be integrated into other workload requirements of SRA.

Recommendations and Action Items

To provide more analysis around the HUB procurement issue, the subcommittee requested that CPRIT staff provide aggregated information on the HUB data from CPRIT grantees, provide a copy of the HUB form for review, and incorporate the importance of the HUB procurement program in the compliance training that the agency will provide to grantees. CPRIT staff will address these requests immediately but will have to discuss HUB data aggregation with SRA to see how this project can be integrated into its other workload requirements.

The subcommittee also requests that the University Advisory Committee be tasked with providing the subcommittee and the Oversight Committee information about their institutional HUB programs, including purchasing statistics and efforts to increase HUB purchasing. The subcommittee would like to receive this information by April 18th to be able to prepare for the May 21st Oversight Committee meeting.

The possibility of folding the Diversity Subcommittee's charge on increasing the number of applications from diverse populations into the three program subcommittees and the other charge on improving HUB procurement practices among CPRIT grantees into the Governance subcommittee was discussed since these are issues common to all CPRIT activities. However, the subcommittee chose not to pursue this recommendation at this time to keep this as a priority in front of the agency at least for the duration of this fiscal year if not longer.

In that vein, the subcommittee recommends that diversity issues be included in the Oversight Committee's priority setting process. To prepare for that discussion, the subcommittee has requested that CPRIT staff provide the subcommittee and Oversight Committee with a summary of the minority and gender status from the past year's grant application and award data as well as basic statistics about Texas population and cancer demographics. The subcommittee would also like to task the University Advisory Committee with providing information from the academic institutions about the demographics of the general population of their faculty, medical students, and post-doctoral students and, if available, those who are or might be focused on oncology-related

prevention or treatment areas. Similar to the other request to the advisory committee, the subcommittee would like to receive this information by April 18th.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT: CPRIT FINANCIAL OVERVIEW FOR FISCAL YEAR 2014, QUARTER 1
DATE: JANUARY 20, 2014

FY 2014, Quarter 1 Operating Budget

CPRIT expended or obligated approximately $1 million in Indirect Administration in the first quarter. The expenditures in the Professional Fees and Services category are to provide outsourced legal, audit and communications services to the agency. The agency has also expended in Grant Review and Award Operations $1.5 million. The expenditures in the Professional Fees and Services category are to provide grants management support services through SRA International.

Debt Issuance History

Through the Texas Public Finance Authority (TPFA), CPRIT issued $55.2 million in commercial paper notes at the end of November 2013, bringing the total debt issued to date to almost $441.5 million. The November issuance provides $7.4 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 $46.3 million allows CPRIT to make reimbursements payments due to grant recipients for expenses on their awards.

Cancer Prevention and Research Institute of Texas
LBB Summary
As of December 31, 2013

Indirect Administration (B.1.1.)

		2014 Appropriated	12/01/2013 thru 12/31/2013	% of Total Budget	AY 13 Year to Date as of 12/31/2013	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,559,830	$ 1,386,196		$ 326,508	1,059,688	24%	$ 979,524	$ 406,672
1002	Other Personnel Costs	21,400	50,000		12,621	37,379	25%	37,862	12,138
2001	Professional Fees and Services	350,500	928,321		447,265	481,056	48%	1,341,794	(413,473)
2003	Consumable Supplies	25,332	22,500		3,904	18,596	17%	11,712	10,788
2004	Utilities	32,600	-		38,131	(38,131)	#DIV/0!	114,393	(114,393)
2005	Travel	24,176	-		1,972	(1,972)	#DIV/0!	5,917	(5,917)
2006	Rent - Building	427,450	415,450		126,549	288,901	30%	379,647	35,803
2007	Rent-Machine and Other	16,763	24,150		4,805	19,345	20%	14,416	9,734
2009	Other Operating Expenses	348,824	342,551		49,879	292,672	15%	149,637	192,914
	Subtotal - Indirect Administration (B.1.1.)	**$ 2,806,875**	**$ 3,169,168**	**1.07%**	**$ 1,011,634**	**$ 2,157,534**	**32%**	**$ 3,034,901**	**$ 134,267**

Grant Review and Award Operations (A.1.3.)

		2014 Appropriated	12/01/2013 thru 12/31/2013	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,026,701	$ 2,627,082		$ 499,482	$ 2,127,600	19%	$ 1,498,447	$ 1,128,635
1002	Other Personnel Costs	3,600	100,000		5,521	94,479	0%	16,564	83,436
	Professional Fees and Services	4,285,471	8,608,808		992,592	7,616,216	12%	2,977,777	5,631,031
lance, 1	Consumable Supplies	27,324	-		-	-	0%	-	-
2005	Travel	24,400	35,430		2	35,428	0%	6	35,424
2006	Rent - Building	4,867	32,400		14,476	17,924	45%	43,427	(11,027)
2007	Rent-Machine and Other	-	7,500		693	6,807	9%	2,080	5,420
2009	Other Operating Expenses	1,551,996	-		-	-	0%	-	-
	Subtotal - Grant Operations (A.1.3.)	**$ 6,924,359**	**$ 11,411,220**	**3.84%**	**$ 1,512,767**	**$ 9,898,453**	**13%**	**$ 4,538,302**	**$ 6,872,918**

Grants

		2014 Appropriated	12/01/2013 thru 12/31/2013	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 29,022,567	$ 29,022,567		$ 10,778,222	$ 18,244,345	37%	$ 32,334,666	$ (3,312,099)
4000	Grants - Research (A.1.1.)	261,262,199	253,344,969		-	$ 253,344,969	0%	-	253,344,969
	Subtotal - Grants	**$ 290,284,766**	**$ 282,367,536**	**95.09%**	**$ 10,778,222**	**$ 271,589,314**	**4%**	**$ 32,334,666**	**$ 250,032,870**
	Grand Totals	**$ 300,016,000**	**$ 296,947,924**	**100.00%**	**$ 13,302,623**	**$ 283,645,301**	**4%**	**$ 39,907,869**	**$ 257,040,055**

* 2014 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 December 31, 2013

	12/01/2013 thru 12/31/2013	AY 13 Year to Date as of 12/31/2013
Beginning Balance : 09/01/2013		**499,412**
Increases:		
(1) License Plate Revenue Received	$ 0.00	$ 3,109
(2) Revenue Sharing / Royalties	-	34,817
Total Increases	**$ 0.00**	**$ 37,926**
Reductions:		
Expenditures - Appropriated	$ 0.00	$ 0.00
Estimated Transfers for Employee Benefits	-	-
Benefit Replacement Pay	-	-
Total Reductions	**$ 0.00**	**$ 0.00**
Ending Balance, 12/31/2013		**$ 537,339**

Note: 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.

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of December 31, 2013

		12/01/2013 thru 12/31/2013	AY 13 Year to Date as of 12/31/2013
Beginning Balance : 09/01/2013			**0**
Increases:			
(1)	Product Development Application Fees Received	$ 0.00	$ 0.00
(2)	Appropriated Receipts applied to payments	-	-
Total Increases		**$ 0.00**	**$ 0.00**
Reductions:			
	Expenditures - Appropriated	$ 0.00	$ 0.00
	Estimated Transfers for Employee Benefits	-	-
	Benefit Replacement Pay	-	-
Total Reductions		**$ 0.00**	**$ 0.00**
Ending Balance, 12/31/2013			**$ 0.00**

(1) CPRIT has not collected any product development application fees because it did not have any active Product Development Requests for Application.

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	92,700	N/A	N/A	N/A	92,700	23.18%
Number of Entities Relocating to TX for Cancer Research Related Projects	7.00	0.00	N/A	N/A	N/A	0.00	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
N/A
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.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount 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		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
				$ 55,200,000				
TOTAL ISSUED TO DATE				**$ 441,475,000**				

[1]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 = 0.22% (12/31/13).

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT: CPRIT FINANCIAL AUDIT FOR FISCAL YEAR 2013
DATE: JANUARY 17, 2014

CPRIT is required by Health and Safety Code, Sec. 102.053 to audit its financial statements every year. For a state agency the financial statement is the Annual Financial Report (AFR). The format and content of the AFR is prescribed by the Comptroller's Office which consolidates the financial statements of every state agency into the Comprehensive Annual Financial Report (CAFR) for the state.

On December 20, 2013, McConnell & Jones LLP issued an opinion that CPRIT's basic financial statements "present fairly, in all respects, the respective financial position of the governmental activities and governmental funds information of CPRIT as of August 31, 2013" in accordance with U.S. generally accepted accounting principles (GAAP). They reviewed CPRIT's internal control over financial reporting and tested its compliance with certain provisions of laws, regulations, contracts, grant agreements, and other matters, but do not provide an opinion about CPRIT's internal controls over financial reporting or compliance.

In their testing of CPRIT's internal financial controls and compliance, McConnell & Jones identified three material weaknesses (findings 2013-01, 2013-02, and 2013-03) and another item (finding 2013-04) that they must report according *Government Auditing Standards* but do not provide an opinion on these items because they were not within the scope of the audit. The detailed explanation of the four findings begins on page 24 of the audit report. Below is a summary of the findings, recommendations, and corrective actions:

1) Finding No. 2013-01: Deficiencies in Internal Control Over Financial Reporting
   CPRIT's year-end procedures did not capture subsequent grant expense transactions, did not record one vendor payment in the proper expenditure account, and overstated the prior year's balances by $5.3 million, and the CPRIT Foundation did not make available supporting documents for testing and provided no support for salary supplements paid to the CPRIT Executive Director and Chief Scientific Officer

   McConnell & Jones recommends that CPRIT establish a responsibility matrix for its general ledger functions and year end closeout processes to ensure timely and accurate completion of

financial reporting, review, and reconciliation and that CPRIT assemble an inventory of financial spreadsheets to support the preparation of the required financial statements. There was no recommendation related to the CPRIT Foundation.

CPRIT management agrees with the recommendation and will incorporate the recommended processes and documentation for general ledger closeout into finance staff job responsibilities once CPRIT hires additional finance staff to support the agency's financial operations.

2) Finding No. 2013-02: Ineffective Review of Grantee's Compliance with Grant Agreements
Grantees did not provide enough supporting documents with their financial status reports (reimbursement requests) for CPRIT to be able to verify allowability, reasonableness and use of funds, and CPRIT is not verifying grantee compliance with the 50 percent matching fund requirement.

McConnell & Jones recommends that CPRIT expedite its implementation of the adopted administrative rule for grantee compliance with matching fund requirements and strengthen its review of grant reimbursements to ensure only allowable costs are paid to grantees.

CPRIT management agrees with the recommendation on matching funds verification and has developed and implemented as of December 6, 2013, a process that requires grantees to submit documentation verifying the amount and availability of matching funds. There was also a similar finding in the January 2013 State Audit. CPRIT implemented the new verification process in response to that finding.

CPRIT management believes that the standard of required supporting documentation for processing grantee reimbursement payments is higher than that required for other similar types of grant programs at the federal and state level. We are looking at the documentation standard of other grant making organizations and will make a recommendation related to this issue, including implementation as necessary.

3) Finding No. 2013-03: Inadequate Process to Monitor Revenue Sharing Requirements
CPRIT lacks a process for determining the accuracy and completeness of the revenue sharing receipts (royalty or equity payments, license fees, etc.) from grantees, relying on self-reported amounts from them.

McConnell & Jones recommends that CPRIT develop processes and procedures to ensure completeness and accuracy of self-reported receipts by grantees with revenue sharing requirements and develop an administrative policy around this issue.

CPRIT management agrees with the recommendation and has established a process in the proposed administrative rules that requires grantees to submit in the annual grant progress report all financial information necessary to support the calculation of CPRIT's share of the revenues resulting from the funded project. The proposed administrative rule is expected to be adopted on January 24, 2014.

4) Finding No. 2013-04: Noncompliance with Laws and Regulations
The Oversight Committee did not hold quarterly public meetings between February 26, 2013, and August 31, 2013.

McConnell & Jones recommends that CPRIT's General Counsel monitor CPRIT's compliance with the state law requiring quarterly Oversight Committee meetings now that the new Oversight Committee members have been appointed (subsequent to the fiscal year-end).

CPRIT management agrees with the recommendation. During the identified time period agency management worked with the legislature and state leadership to address statutorily the January 2013 State Auditor's management report findings and other legislative concerns. Oversight Committee meetings during this period would have impeded the legislative engagement. Since no award making activities were necessary due to the state leadership imposed moratorium on grant making, agency activities were not impacted negatively by the lack of Oversight Committee meetings. Furthermore, the meeting schedule was well known among members of the legislature and state leadership. With the appointment of the new Oversight Committee members, CPRIT is meeting the requirement to hold quarterly meetings.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

FINANCIAL STATEMENTS

AUGUST 31, 2013

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

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August 31, 2013

MJ McCONNELL & JONES LLP
CERTIFIED PUBLIC ACCOUNTANTS

INDEPENDENT AUDITORS' REPORT

To the Honorable Rick Perry, Governor,
and the Oversight Committee of
Cancer Prevention and Research Institute of Texas

We have audited the accompanying financial statements of the governmental activities and governmental funds of Cancer Prevention and Research Institute of Texas (CPRIT) as of and for the year ended August 31, 2013, and the related notes to the financial statements, which collectively comprise CPRIT's basic financial statements as listed in the table of contents.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these basic financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP); this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of basic financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express opinions on these basic financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America (U.S. GAAS) and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the basic financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the basic financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the basic financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the basic financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the basic financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions.

Opinions

In our opinions, the basic financial statements referred to above present fairly, in all material respects, the respective financial position of the governmental activities and governmental

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funds information of CPRIT as of August 31, 2013, and the respective changes in financial position for the year then ended in accordance with U.S. GAAP.

Other Matters

Required Supplementary Information

U.S. GAAP requires that the management's discussion and analysis and budgetary comparison schedule, as listed in the table of contents, be presented to supplement the basic financial statements. Such information, although not a part of the basic financial statements, is required by the Governmental Accounting Standards Board (GASB), who considers it to be an essential part of financial reporting for placing the basic financial statements in an appropriate operational, economic, or historical context. We have applied certain limited procedures to the required supplementary information in accordance with U.S. GAAS, which consisted of inquiries of management about the methods of preparing the information and comparing the information for consistency with management's responses to our inquiries, the basic financial statements, and other knowledge we obtained during our audit of the basic financial statements. We do not express an opinion or provide any assurance on the information because the limited procedures do not provide us with sufficient evidence to express an opinion or provide any assurance.

Other Reporting Required by *Government Auditing Standards*

In accordance with *Government Auditing Standards*, we have also issued our report dated December 20, 2013, on our consideration of CPRIT's internal control over financial reporting and on our tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements and other matters. The purpose of that report is to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on the internal control over financial reporting or on compliance. That report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering CPRIT's internal control over financial reporting and compliance.

Houston, Texas
December 20, 2013

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

Management's Discussion and Analysis

August 31, 2013

Introduction

This section of the Cancer Prevention and Research Institute of Texas (CPRIT) annual financial report presents management's discussion and analysis of CPRIT's financial performance during the fiscal year that ended on August 31, 2013. Please read it in conjunction with the CPRIT's financial statements, which follow this section.

The State of Texas established the CPRIT 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, thereby 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
- 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.

The CPRIT is governed by an Oversight Committee, composed of 9 members which are appointed by the Governor, Lieutenant Governor, and Speaker of the House.

Overview of the Financial Statements

This discussion and analysis is intended to serve as an introduction to CPRIT's basic financial statements, comprised of three components: 1) management's discussion and analysis, 2) basic financial statements, and 3) notes to the financial statements. The basic financial statements are presented in a combined format including the Combined Balance Sheet/Statement of Net Assets and Combined Statement of Revenue, Expenditures and Changes in Fund Balance/Statement of Activities for the governmental funds.

- The Statement of Net Assets and Statement of Activities provide information about the CPRIT's overall financial position and results. These statements are presented on an accrual basis.
- The basic financial statements also include a "Notes to Financial Statement" section which explains some of the information presented in the combined financial statements and provides additional detailed data.
- The fund financial statements (Balance Sheet and Statement of Revenue, Expenditures and Changes in Fund Balance) provide information about the CPRIT's governmental fund activities funded primarily through state appropriation of bond proceeds for which CPRIT follows a modified accrual basis of accounting.

The remainder of this overview section of the management's discussion and analysis explains the structure and contents of each of these statements.

Government-Wide Financial Statements

The Statement of Net Position shows Governmental Activities consolidated on a full accrual basis. The Statement of Activities presents a government wide format of expenses, operating grants and contributions and net expenses by Governmental activities.

Schedule of Net Position

The following table reflects condensed information on the CPRIT's accumulated net assets and deficit at August 31, 2013 and 2012:

ASSETS	2013	2012	Change	%
CURRENT ASSETS				
Cash and cash equivalents				
Cash in state treasury	$ 492,564	$ 284,474	$ 208,090	73%
Cash in bank	316,461	934,521	(618,060)	-66%
Due from other agencies	25,192,133	13,972,470	11,219,663	80%
Other current assets	-	17,140	(17,140)	-100%
Consumable inventories	7,900	8,581	(681)	-8%
Total current assets	26,009,058	15,217,186	10,791,872	71%
CAPITAL ASSETS				
Furniture and equipment	401,124	573,733	(172,609)	-30%
Less: Accumulated depreciation	(304,823)	(233,297)	(71,526)	31%
TOTAL ASSETS	$ 26,105,359	$ 15,557,622	$ 10,547,737	68%
LIABILITIES AND NET ASSETS				
CURRENT LIABILITIES				
Accounts payable	$ 9,131,545	$ 19,406,531	$ (10,274,986)	-53%
Accrued Payroll	188,363	208,969	(20,606)	-10%
Due to other agencies	16,026,181	7,749,491	8,276,690	107%
Deferred Revenues	-	226,302	(226,302)	-100%
Employees' compensable leave	263,160	273,035	(9,875)	-4%
Total current liabilities	25,609,249	27,864,328	(2,255,079)	-8%
LONG-TERM LIABILITIES				
Employees' compensable leave	313,745	161,190	152,555	95%
TOTAL LIABILITIES	25,922,994	28,025,518	(2,102,524)	-8%
NET ASSETS (DEFICIT)				
Invested in capital assets	$ 96,301	$ 167,827	$ (71,526)	-43%
Restricted	316,461	771,964	(455,503)	-59%
Unrestricted	(230,397)	(8,225,004)	7,994,607	-97%
TOTAL NET ASSETS (DEFICIT)	$ 182,365	$ (7,285,213)	$ 7,467,578	-103%

In Fiscal Year 2013, the CPRIT received legislative appropriations that provided for annual funding for staff and associated on-going operations cost as well as funding to award cancer prevention, research, and product development projects. Included in Other Liabilities is the current and non-current portion of Employees' Compensable Leave. It represents the growing unpaid balances of employees' accumulated annual leave.

In comparison to fiscal year 2012, current assets increased significantly as a result of increased grant payment activity which resulted in increases to the amount due from other State organizations, license and royalty agreements with grantees despite a reduction in revenue from the activities of the CPRIT Foundation which ceased outreach activities mid-year in fiscal 2013. Liabilities decreased slightly overall, but accounts payable decreased sharply as a result of the state leadership imposed moratorium on grant making which reduced expenses for contracted pre- and post-award grants management support services as well as other operational costs for grant review and award operations. Conversely, the due to amount other agencies increased as grantees improved fiscal compliance by submitting resulting in submission of fiscal reports for which reimbursement occurred.

In Fiscal Year 2013, the CPRIT received full funding by the Legislature. Funding in Fiscal Year 2013 provided for annual funding for staff and associated on-going operations cost as well as funds to award cancer prevention and research projects.

Included in Other Liabilities is the current and non-current portion of Employees' Compensable Leave. It represents unpaid balances of employees' accumulated annual leave.

Schedule of Activities

The Schedule of Activities reflects the sources of the CPRIT's changes in net assets as they arise through its various programs and functions. CPRIT operations and prevention grants are shown as governmental activities.

A condensed Schedule of Activities for the fiscal year ended August 31, 2013 and 2012 is shown below. The table shows operating revenues for the CPRIT's governmental activities totaled $81.6 million and were primarily received through Legislative appropriations of bond proceeds that were transferred to the Institute by the Texas Public Finance Authority. Funding in Fiscal Year 2013 provided for full funding for staff (24 FTEs), office space and fixtures, and grant award operations in relation to FY 2013.

	2013	2012	Increase/Decrease Amount	%
REVENUES				
License, fees and permits	$ 558,547	$ 337,018	$ 221,529	66%
Interest and investment income	1,923	2,771	(848)	-31%
Other	482,153	642,693	(160,540)	-25%
	1,042,623	982,482	60,141	6%
EXPENDITURES				
Grants	147,044,669	105,877,463	41,167,206	39%
Operations	16,365,446	16,103,353	262,093	2%
Deficiency of Revenues over Expenditures	(162,367,492)	(120,998,334)	(41,369,158)	34%
OTHER				
Transfer out to other entities	438,846,405	242,120,768	196,725,637	81%
Transfer in from other entities	(269,011,335)	(131,036,219)	(137,975,116)	105%
Total other	169,835,070	111,084,549	(58,750,521)	-53%
CHANGE IN NET ASSETS	7,467,578	(9,913,785)		
BEGINNING NET ASSETS,	(7,285,213)	(2,554,111)		
RESTATEMENTS	-	5,182,683		
ENDING NET ASSETS	$ 182,365	$ (7,285,213)		

The license, fees, and permits revenue reflects a significant increase in fiscal year 2013 due to CPRIT's receipt of additional income from license and royalty agreements from grantees. The increase in these license and royalty payments reflect the maturation of some company research projects funded in fiscal year 2010, the first year CPRIT made awards. The increase in the license, fees, and permits revenue is also due to additional income collected by the CPRIT Foundation from either the 2012 conference or donations.

In fiscal year 2013, CPRIT processed a higher volume of grantee reimbursement payments accounting for some of the $196.7 million increase in transfers out to other entities. Related to this is the decrease in transfers in from other entities which reflects the timing of general obligation debt issuance and when actual grantee reimbursement payments are made. For fiscal year 2010 and certain fiscal year 2011 grant awards, CPRIT was required to have all of the debt issued for those multi-year awards at the time of the award. Because those awards were still active and CPRIT was processing reimbursement requests for them in fiscal year 2013, there was no corresponding transfer in from the issuance of debt as the debt proceeds were already deposited in the state treasury.

General Fund Budgetary Highlights

The original budget appropriated by the legislature was amended through authority provided in the General Appropriations Act that allows agencies to transfer funds between strategies. The transfers were made from the research grant strategy to the grant review and award operations strategies to cover the pre- and post-award management of CPRIT's grants. Variances between final budget and actual are the result of increased resources–additional in-flows from increased appropriated receipts (product development fees), license and royalty agreements with grantees, and transfers in of encumbered award balances from prior years for grantee payments. Transitioning to the uses of resources, variances are attributable to decreased grant award activity due to the state leadership imposed moratorium on grant making. See page 19 for a budgetary comparison schedule.

Future Outlook

CPRIT anticipates continuing to process a high volume of grantee reimbursement payments with the implementation of currently proposed administrative rules which include provisions designed to address grantee compliance with reporting requirements. With respect to reimbursement payments, grantees must correctly submit the financial status report after the end of a fiscal quarter or forego the reimbursement of grant expenses for that quarter. In conjunction with the implementation of these rules, CPRIT is designing a compliance program with more grantee education about CPRIT's grant administration policies and procedures. With continued high volume in grantee reimbursements, CPRIT anticipates issuing more debt to support the reimbursement payments for grants made since fiscal year 2011 which will impact our transfers in.

Request for Information

This financial report is designed to provide a general overview of the Cancer Prevention and Research Institute of Texas' operations for all parties interested in the government's finances. Questions concerning any of the information provided in this report or request for additional financial information should be addressed to the Cancer Prevention and Research Institute of Texas, Finance Manager, P.O. Box 12097, Austin, Texas 78711.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

Statement of Net Position and Governmental Funds Balance Sheet

August 31, 2013

	General Fund	Special Revenue Fund	Governmental Funds Total	Capital Assets Adjustments	Long-Term Liabilities Adjustment	Other Adjustments	Statement of Net Position
ASSETS							
CURRENT ASSETS							
Cash and cash equivalents							
In state treasury	$ 492,564	$ -	$ 492,564	$ -	$ -	$ -	$ 492,564
In bank		316,461	316,461	-	-	-	316,461
Due from other agencies	25,192,133	-	25,192,133	-	-	-	25,192,133
Consumable inventories	7,900,	-	7,900	-	-	-	7,900
Contribution receivable, net of allowance $36,000	-	-	-	-	-	-	-
Total current assets	25,692,597	316,461	26,009,058	-	-	-	26,009,058
Capital Assets							
Depreciable							
Furniture and equipment	-	-	-	401,124	-	-	401,124
Accumulated depreciation	-	-	-	(304,823)	-	-	(304,823)
TOTAL ASSETS	$ 25,692,597	$ 316,461	$ 26,009,058	$ 96,301	$ -	$ -	$ 26,105,359
LIABILITIES AND FUND BALANCES							
CURRENT LIABILITIES							
Payables from:							
Accounts payable	$ 9,131,545	$ -	$ 9,131,545	$ -	$ -	$ -	$ 9,131,545
Payroll	188,363	-	188,363	-	-	-	188,363
Due to other agencies	16,026,181	-	16,026,181	-	-	-	16,026,181
Employees' compensable leave-current portion	-	-	-	-	263,160	-	263,160
Total current liabilities	25,346,089	-	25,346,089	-	263,160	-	25,609,249
LONG-TERM LIABILITIES							
Employees' compensable leave	-	-	-	-	313,745	-	313,745
TOTAL LIABILITIES	25,346,089	-	25,346,089	-	576,905	-	25,922,994
FUND BALANCES/(DEFICIT)							
Nonspendable	7,900	-	7,900			(7,900)	-
Restricted	-	316,461	316,461			(316,461)	-
Committed	492,564	-	492,564			(492,564)	-
Unassigned	(153,956)	-	(153,956)			153,956	-
Total fund balances	346,508	316,461	662,969			(662,969)	-
TOTAL LIABILITIES AND FUND BALANCES	$ 25,692,597	$ 316,461	$ 26,009,058				
Government-Wide Statement of Net Position							
NET POSITION							
Invested in capital assets, net of related debt				$ 96,301	$ -	$ -	$ 96,301
Restricted				-	-	316,461	316,461
Unrestricted				-	(576,905)	346,508	(230,397)
Total net position				$ 96,301	$ (576,905)	$ 662,969	$ 182,365
TOTAL LIABILITIES AND NET POSITION							$ 26,105,359

The accompanying notes are an integral part of these financial statements.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

Statement of Activities and Governmental Fund Revenues, Expenditures, and Changes in Fund Balances

Year Ended August 31, 2013

	General Fund	Special Revenue Fund	Total Governmental Funds	Capital Assets Adjustments	Long-Term Liabilities Adjustment	Statement of Activities
REVENUES						
Interest income	$ 1,516	$ 407	$ 1,923	$ -	$ -	$ 1,923
License fees and permits	235,910	322,637	558,547	-	-	558,547
Other	34,052	448,101	482,153	-	-	482,153
Total revenues	271,478	771,145	1,042,623	-	-	1,042,623
EXPENDITURES						
Salaries and Wages	2,055,287	305,507	2,360,794	-	142,680	2,503,474
Payroll related costs	363,332	-	363,332	-	-	363,332
Professional fees and services	11,255,715	-	11,255,715	-	-	11,255,715
Travel	62,397	-	62,397	-	-	62,397
Materials and supplies	17,727	-	17,727	-	-	17,727
Communication and utilities	107,920	-	107,920	-	-	107,920
Repairs and maintenance	88,581	-	88,581	-	-	88,581
Rentals and leases	533,981	-	533,981	-	-	533,981
Printing and reproduction	9,542	-	9,542	-	-	9,542
State grant payment-pass-thru	100,195,286	-	100,195,286	-	-	100,195,286
Public assistance payments	46,849,383	-	46,849,383	-	-	46,849,383
Other expenditures	430,110	885,141	1,315,251	-	-	1,315,251
Bad debt expenses	-	36,000	36,000	-	-	36,000
Depreciation Expense	-	-	-	71,526	-	71,526
Total expenditures	161,969,261	1,226,648	163,195,909	71,526	142,680	163,410,115
DEFICIENCY OF REVENUES OVER EXPENDITURES	(161,697,783)	(455,503)	(162,153,286)	(71,526)	(142,680)	(162,367,492)
OTHER FINANCING SOURCES						
Transfer in	438,846,405	-	438,846,405	-	-	438,846,405
Transfer out	(269,011,335)	-	(269,011,335)	-	-	(269,011,335)
Net Transfers	169,835,070	-	169,835,070	-	-	169,835,070
Net change in fund balances/net position	(8,137,287)	(455,503)	7,681,784	(71,526)	(142,680)	7,467,578
FUND BALANCES						
Fund balances (deficit), September 1, 2012	(13,098,071)	723,964	(12,374,107)	340,436	(434,224)	(12,467,896)
Restatements (see note 13)	5,307,292	48,000	5,355,292	(172,609)	-	5,182,683
Fund balances/(deficit). September 1, 2012, as restated	(7,790,779)	771,963	(7,018,815)	167,827	(434,224)	(7,285,213)
Fund balances, August 31. 2013	$ 346,508	$ 316,461	$ 662,96			

Government-Wide Statement of Activities	
Net Position, September 1, 2012, previously stated	$ 12,467,896
Restatements (see note 13)	5,182,683
Net Position, September 1, 2012, as restated	(7,285,213)
Net Position, August 31, 2013	$ 182,365

The accompanying notes are an integral part of these financial statements.

NOTE 1 — NATURE OF OPERATIONS

The Cancer Prevention and Research Institute of Texas (CPRIT) is an agency of the State of Texas (State) and its financial records comply with state statutes and regulations. This includes compliance with the Texas Comptroller of Public Accounts' (Comptroller) *Reporting Requirements for Annual Financial Reports of State Agencies and Universities*.

In 2007, Texans overwhelmingly approved a constitutional amendment to create CPRIT and fund $3 billion in grants to support cancer research and prevention efforts in Texas. For the next decade, CPRIT will work on behalf of all Texans to: (1) 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; (2) 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.

CPRIT is primarily funded through State appropriations financed through sale of general obligation debt provided by the Texas Public Finance Authority (TPFA).

CPRIT is also supported by the CPRIT Foundation (Foundation), which augmented CPRIT's activities in the form of public outreach and marketing activities designed to provide Texans with information about the health benefits of screening and lifestyle choices (such as weight management, smoking avoidance, healthy eating, etc.) to prevent cancer. Additionally, the Foundation works with Texas business and community leaders to create and promote cancer prevention programs in the workforce, thereby enhancing CPRIT's goal for early diagnosis and treatment across the state. The Foundation also supplemented CPRIT's efforts to attract and employ high caliber executives, necessary to effectively distribute cancer prevention and research grants annually. The Foundation is a legally separate, tax-exempt 501(c)3 organization. The five-member board was appointed by the CPRIT Oversight Committee, which could also remove board members at any time with or without cause. Effective, August 31, 2013 the Foundation terminated its operation in May 2013 but a final financial close out is not expected to occur until fiscal year 2014 because the settlement terms regarding use of proceeds is still in negotiation between CPRIT and the Foundation.

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying financial statements of CPRIT have been prepared in conformity with accounting principles generally accepted in the United States of America as applied to governmental units. The Governmental Accounting Standards Board (GASB) is the accepted primary standard-setting body for establishing governmental accounting and financial reporting principles. CPRIT's significant accounting policies are described below.

A. Reporting Entity

Considerations regarding the potential for inclusion of other entities, organizations, or functions in the financial reporting entity are based on the criteria prescribed by accounting principles generally accepted in the United States of America (U.S. GAAP). These same criteria are evaluated in considering whether CPRIT is a part of any other governmental or other type of reporting entity. The overriding elements associated with the prescribed criteria considered in determining that CPRIT's financial reporting entity status is that of a component unit are: that it does not have a separately elected governing body; and it is not fiscally independent of other state and local governments.

Based on criteria prescribed by U.S. GAAP, CPRIT is considered a component unit of the State of Texas. The primary criterion for this is that of financial accountability. The State appoints voting Oversight Committee members and approves CPRIT's budget.

The Foundation, although a legally separate, not for profit corporation, is considered a blended component unit of CPRIT as of August 31, 2013. The financial statement activities of the Foundation were included as a special revenue fund of CPRIT.

B. Basis of Presentation

The government-wide financial statements (i.e., the statement of net position and the statement of activities) report information on all of the non-fiduciary activities of CPRIT. Under the GASB Statement No. 34, *Basic Financial Statements - and Management's Discussion and Analysis - for State and Local Governments*, CPRIT qualifies as a special purpose government with one program, to support cancer research and prevention efforts in the State of Texas. All activities of CPRIT are considered governmental activities, as defined by GASB. GASB Statement No. 34 allows such entities to combine the presentation of the fund financial statements and the government-wide financial statements, rather than present separate statements. Adjustments are provided to reconcile the government-wide statements to the fund statements. Explanations for reconciling items in the "Adjustments" column are provided on the face of the financial statements.

C. Measurement Focus and Basis of Accounting

Fund Financial Statements

The accounting and financial reporting treatment applied to a fund is determined by its measurement focus. Governmental fund financial statements are presented using "current financial resources measurement focus" and "modified accrual basis of accounting." With this measurement focus, only current assets and current liabilities generally are included on the balance sheet. The operating statements of these funds present increases and decreases in net current assets. Under the modified accrual basis of accounting, revenues are recognized when they become susceptible to accrual - that is, when they become both measurable and available to finance expenditures of the fiscal period. "Measurable" means the amount of the transaction can

be determined and "available" means collectible within the current period or soon enough thereafter to be used to pay liabilities of the current period. CPRIT considers all revenues as available if it is collected within 60 days after the year end. Expenditures are generally recognized under the modified accrual basis of accounting when the related fund liability is incurred.

General Fund

The following sub-funds collectively comprise the general fund.

a) TPFA G.O. Commercial Paper Series A&B Cancer Project Fund (fund 7639) is the principal operating fund used to account for all of CPRITs general activities. It accounts for all financial resources except those required to be accounted for in another fund.

b) Cancer Prevention and Research Fund (fund 5136) is used to receive and account for fees charged for the specialty license plates in addition to motor vehicle registration fees. In addition, the fund is used to receive all miscellaneous revenues of CPRIT.

Special Revenue Fund

The special revenue fund represents the activities of the Foundation.

Government-wide Adjustment Fund Types

The statement of net position and statement of activities display information about CPRIT as a whole. The statement of net position and statement of activities were prepared using the "economic resources measurement focus" and the "accrual basis of accounting." Revenues, expenditures, gains, losses, assets, and liabilities are recognized when the underlying transactions take place. This includes unpaid employee compensable leave, capital assets and accumulated depreciation.

Budget and Budgetary Accounting

The budget is prepared biennially and represents appropriations authorized by the legislature and approved by the State's Governor (the General Appropriations Act). The State monitors its statewide budget by establishing the legal level of control at the agency level to ensure that expenditures are not made in excess of budgetary authority. Within CPRIT, procedures are used to ensure that expenditures do not exceed the total budget, but the Comptroller ultimately ensures that each total authorized agency budget is not exceeded.

Unencumbered appropriations are generally lapse 60 days after the end of the fiscal year for which they have been appropriated.

Fund Balances/Net Position

The difference between fund assets and liabilities is "Net Position" on the government-wide statements and the "Fund Balance" is the difference between fund assets and liabilities on the governmental fund statements.

a) *Non-spendable Fund Balance:* This classification includes amounts that cannot be spent because they are either (a) not in spendable form or (b) legally or contractually required to be maintained intact. The "not in spendable form" criterion includes items that are not expected to be converted to cash, for example, inventories and prepaid amounts if any. It also includes the long-term amounts of loans and notes receivable, as well as property acquired for resale. However, if the use of the proceeds from the collection of those receivables or from the sale of those properties is restricted, committed, or assigned, then they should be included in the appropriate fund balance classification (restricted, committed, or assigned), rather than nonspendable fund balance. The corpus (or principal) of a permanent fund is an example of an amount that is legally or contractually required to be maintained intact.

b) *Restricted Fund Balance:* These are amounts that are restricted for specific purposes. Fund balance is reported as restricted when constraints placed on the use of resources are either (a) externally imposed by creditors (such as through debt covenants), grantors, contributors, or laws or regulations of other governments, or (b) imposed by law through constitutional provisions or enabling legislation.

c) *Committed Fund Balance*: These are amounts that can only be used for specific purposes pursuant to constraints imposed by a formal action of the government's highest level of decision-making authority. Those committed amounts cannot be used for any other purpose unless the government removes or changes the specified use by taking the same type of action (for example, legislation, resolution, ordinance) it employed to previously commit those amounts. Committed fund balances also incorporate contractual obligations to the extent that existing resources in the fund have been specifically committed for use in satisfying those contractual requirements. Compliance with constraints imposed by the government that commit amounts to specific purposes is not considered to be legally enforceable and may be redeployed for other purposes with appropriate due process. Amounts used only for specific purposes pursuant to constraints imposed by a formal action of the Texas Legislature, the state's highest level of decision making authority.

d) *Assigned Fund Balance:* Amounts constrained by the state's intent to be used for specific purposes, but are neither restricted nor committed. Intent is expressed by: (1) the Texas Legislature or (2) a body (for example, a budget or finance committee) or official to which the governing body has delegated the CPRIT to assign amounts to be used for specific purposes.

e) *Unassigned Fund Balance:* The residual classification for the general fund and represents fund balances that were not assigned to other funds, and was not restricted, committed or assigned to specific purposes within the general fund.

f) *Net Assets:* Invested in capital assets, consists of capital assets, including restricted capital assets, net of accumulated depreciation. Unrestricted net assets consist of net assets that do not meet the definition of invested in capital assets or restricted net assets.

Cash and Cash Equivalents

Short-term, highly liquid investments with an original maturity of three months or less are considered cash equivalents. Cash held in the State's Treasury are derived from the sale of specialty license plates "Texans Conquer Cancer" and fees from company product development applications. These funds are utilized, subject to legislative appropriations, for additional cancer prevention grants and to defray the cost of CPRIT's due diligence reviews.

Consumable Inventories

Consumable inventories consist of items purchased by CPRIT for (a) reissue/reuse, which CPRIT controls as part of its ongoing operations (e.g., hardware items, or maintenance parts that have a long shelf life and are stocked by CPRIT). Inventories are valued at cost, generally using the last-in, first-out method. The consumption method of accounting is used to account for inventories and prepaid items that appear in the governmental and proprietary fund types. The cost of these items is expensed when the items are consumed.

Due from/to Other Agencies

Amount due from other agencies are appropriations due to CPRIT that have not been received at year end. Amount due to other agencies are grant funds payable to other state agencies.

Capital Assets

Assets with an initial, individual cost of more than $5,000 and an estimated useful life in excess of one year are capitalized. These assets are capitalized at cost or, if donated, at appraisal fair value as of the date of acquisition. Purchases of assets by governmental funds are reported as expenditures. Depreciation is reported on all "exhaustible" assets in the entity-wide financial statements. Maintenance and repairs are charged to operations when incurred.

Assets are depreciated over the estimated useful life of the asset (5 years for both Furniture & Equipment) using the straight-line method.

Accounts Payable

Accounts payable represents the liability for the value of assets or services received at the balance sheet date for which payment is pending.

Employees' Compensable Leave Balances

Employees' compensable leave balances represent the liability that becomes "due" upon the occurrence of relevant events such as resignations, retirements, and uses of leave balances by covered employees. Liabilities are reported separately, either as current or noncurrent, in the statement of net position. These obligations are normally paid from the same funding source from which each employee's salary or wage compensation was paid.

Administrative Expenses

Administrative expenses include agency operation costs and grant payments to organizations for cancer research and prevention projects authorized by the CPRIT's Oversight Committee.

Inter-fund Transactions and Balances

CPRIT may have the following types of transactions among funds: (1) Transfers - Legally required transfers that are reported when incurred as "Transfers In" by the recipient fund and as "Transfers Out" by the disbursing fund. (2) Legislative Sources/Uses — Budget transfers between agencies within a fund. In this particular instance, CPRIT is required to transfer funds to the Texas Department of State Health for the Texas Cancer Registry.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires managements to make estimates and assumptions that affect certain reported amounts and disclosures. Actual results could differ from those estimates. There were no significant estimates included in the financial statements.

NOTE 3 — LIQUIDITY

CPRIT's net deficit results from timing of the receipt of the proceeds through sale of general obligation commercial paper provided by the TPFA. The deficit will be funded by proceeds to be received after August 31, 2013.

NOTE 4 — DEPOSITS

As of August 31, 2013, the carrying amount of deposits for CPRIT was $492,564. CPRIT's cash is held in the State's Treasury and has no interest rate risk or credit risk. As of August 31, 2013, the carrying amount of deposits for the Foundation was $316,461. The Foundation's cash is held in a cash account with Merrill Lynch.

Custodial Credit Risk – Deposits

In the case of deposits, this is the risk that in the event of a bank failure, the deposits may not be returned to the government or its component unit. All of CPRIT's deposits are held by the Comptroller, in the State's Treasury. Deposits of the State of Texas are normally managed by the Comptroller. Deposits that

exceed the $250,000 of insurance by the Federal Deposit Insurance Corporation (FDIC) are collateralized in accordance with Comptroller's policy. As of August 31, 2013, cash balances for the Foundation exceeded federally insured limits by approximately $116,400. The Foundation has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk to cash due to the perceived financial stability of the financial institutions where deposits are maintained.

NOTE 5 — CAPITAL ASSETS

A summary of Capital Assets for the year ended August 31, 2013 is presented below:

Governmental Activities	Balance September 1, 2012	Additions	Retirements	Transfers	Balance August 31, 2013
Capital assets, being depreciated:					
Furniture and equipment, restated	$ 401,124	$ -	$ -	$ -	$ 401,124
Total	401,124	-	-	-	401,124
Less accumulated depreciation for:					
Furniture and equipment	(233,297)	(71,526)	-	-	(304,823)
Total	(233,297)	(71,526)	-	-	(304,823)
Governmental activities capital assets, net	$ 167,827	$ (71,526)	$ -	$ -	$ 96,301

Depreciation expense for the year ended August 31, 2003 was $71,526.

NOTE 6 — SUMMARY OF LONG TERM LIABILITIES

Changes in Long-Term Liabilities

During the year ended August 31, 2013, the following changes occurred:

Governmental Activities	Balance 09/01/2012	Additions	Reductions	Balance 09/01/2013	Amount Due within One Year	Amount Due Thereafter
Compensable leave	$ 434,225	$ 384,114	$ (241,434)	$ 576,905	$ 263,160	$ 313,745

Employees' Compensable Leave

A State employee is entitled to be paid for all unused vacation time accrued, in the event of the employee's resignation, dismissal, or separation from State employment, provided the employee has had continuous employment with the State for six months. Expenditures for accumulated annual leave balances are recognized in the period paid or taken in governmental fund types. For these fund types, the

liability for unpaid benefits is recorded in the Statement of Net Assets. No liability is recorded for non-vesting accumulating rights to receive sick pay benefits.

NOTE 7 — OPERATING LEASE OBLIGATIONS

CPRIT leases certain office spaces and the lease is expiring August 2014. Rental expenses have been included in the expenditures reported in the financial statements are the following amounts of rent paid or due under operating leases:

Fund Type	Amount
Bond Proceed – General Obligation Bonds	$ 403,707

Future minimum lease rental payments under non-cancelable operating leases having an initial term in excess of one year are as follows:

Year Ending August 31,	Amount
2014	$ 390,783

NOTE 8 — EMPLOYEE BENEFITS

CPRIT contributes to the Employee Retirement System of Texas (the System), a cost-sharing, multiple-employer, defined benefit plan. The System provides service retirement, disability retirement benefits, and death benefits to plan members and beneficiaries. The System operates under the authority of provisions contained primarily in Texas Government Code, Title 8, Subtitle B, which is subject to amendment by the Texas Legislature. Under provisions in state law, plan members are required to contribute 6% of their annual salary. The System's annual financial report and other required disclosure information are available by writing the Employees Retirement System of Texas, P.O. Box 13207, Austin, Texas, 78711-3207. CPRIT contributed the state's share of benefits totaling $208,170 during the fiscal year ended August 31, 2013.

NOTE 9 — BOND ISSUANCE

As provided by statute, CPRIT requests TPFA to issue and sell general obligation commercial paper of the state as authorized by Section 67, Article III, Texas Constitution. TPFA is not authorized to issue or sell more than $300 million in general obligation debt in a single state fiscal year. Proceeds of the debt are required to be deposited into the state treasury, and may be only used for 1) making grant payments, 2) purchasing laboratory facilities, 3) paying operating cost of CPRIT, or 4) paying the cost of issuing the debt and related administrative cost of TPFA. As of August 31, 2013, $386,454,128 has been disbursed by TPFA. The commercial paper is a general obligation of the State of Texas and is not specific obligation of CPRIT.

For the year ended August 31, 2013, CPRIT received proceeds from the sale of debt of approximately $23,000,000, which are included in "Transfers In" from other entities on the Statement of Activity.

NOTE 10 — CANCER PREVENTION AND RESEARCH AWARDS

CPRIT has entered into various grant contract awards with third party grant recipients to perform cancer prevention and research activities through 2013. The outstanding value of these grant awards as of August 31, 2013, totals approximately $580,000,000. Payments will be made from bond proceeds issued by TPFA and provided to CPRIT under annual appropriation.

NOTE 11 — RELATED PARTY TRANSACTIONS

The executive director of the Foundation is also the President of JHL Enterprises, a vendor of the Foundation which provided project management and fundraising services to the Foundation. Total amounts paid and included in the expenditures during the year ended August 31, 2013, approximated $303,000.

NOTE 12 — RISKS AND UNCERTAINTIES

In January 2013, the State of Texas Auditor's Office issued a report that identified several areas of concerns related to CPRIT's evaluation of grant applications, making award decisions, managing contract agreements with grantees, processing payments to grantees, monitoring grant expenditures, assessing and measuring progress on awarded grants. Additionally, specific concerns were noted related to the structure of the Oversight Committee, conflicts of interest issues in awarding grants and expending grant funds in a manner that may have violated certain of the restrictive provisions of the related grants, including verification of compliance with matching fund requirements. CPRIT generally agreed with all the findings and recommendations reported by the State Auditor. Implementation of recommendations by CPRIT is in various stages and management expects to fully implement all recommendations by the end of fiscal year 2014. The possible outcome of these matters is uncertain and cannot presently be determined. However, management believes that no provision for any liability is necessary that may result in a significant impact on the basic financial statements.

NOTE 13 — PRIOR PERIOD ADJUSTMENTS

During the current year, CPRIT's management identified errors in accounts payable and capital assets that resulted in prior period adjustments. It was noted that accruals for grant reimbursement requests for approximately $5.3 million recorded in the prior years was not reversed. Also, capital assets amounting to approximately $176 thousand were recorded in error that did not meet the capitalization threshold followed by CPRIT. The effect of these errors resulted in an overstatement of prior year's fund balance/net position and accounts payable. Additionally, the Foundation's management identified an error in recording contributions for the fiscal year ended August 31, 2012 that resulted in an understatement of revenue and fund balance/net position of approximately $48 thousand that are reported as a special revenue fund in CPRIT's basic financial statements. The effect of all these restatements in governmental funds and statement of activities are presented on the face of the financial statements.

NOTE 14 — SUBSEQUENT EVENTS

On December 6, 2013, the Travis County District Attorney released a statement about the criminal investigation of three CPRIT grant awards and possible conflicts of interest related to CPRIT Oversight Committee members and their business interests and investments and to the Foundation. The grand jury issued one indictment against a former CPRIT executive for securing execution of a document by deception but did not issue indictments on the other matters. The District Attorney communicated in the statement that the investigation into CPRIT is concluded. With the results of the investigation now final, CPRIT can move forward with the review and consideration of the grant application of Peloton Therapeutics, one of the three grant awards under investigation, to continue the award made in fiscal year 2010.

While the Foundation ceased operations in May 2013 and agreed to a settlement with CPRIT, CPRIT and the Foundation are still in negotiation on the settlement's financial terms regarding the use of proceeds.

The Governor, Lieutenant Governor, and the Speaker of the House notified CPRIT on October 30, 2013, that the moratorium on finalizing announced grant awards or making new grant awards could be ended and CPRIT could proceed with finalizing 118 prevention and research awards announced in August and December 2012 and resume grant operations. The joint letter noted that their concerns about processes and operations for awarding grants outlined in their December 18, 2012, letter had been addressed through the passage of Senate Bill 149, 83rd Legislature, appointment of new Oversight Committee members pursuant to Senate Bill 149, and CPRIT's continued progress in addressing the concerns raised in December 2012.

Management has evaluated these subsequent events through December 20, 2013; and concluded that no changes were made, or are necessary to be made, to the financial statements, as a result of this evaluation.

REQUIRED SUPPLEMENTARY INFORMATION

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

BUDGETARY COMPARISON SCHEDULE (Unaudited)

For the Year Ended August 31, 2013

	Original Budget	Final Budget	Actual (Budgetary Basis)	Variance with Budget Positive/ (Negative)
Budgetary Deficit, Sep 1, 2012 restated	$ (7,790,779)	$ (7,790,779)	$ (7,790,779)	$ -
Resources (Inflows):				
Appropriated Receipts	20,000	20,000	35,568	(15,568)
Other	12,000	12,000	235,910	(223,910)
Transfer in-Legislative Appropriations	300,000,000	300,000,000	438,846,405	(138,085,405)
Total Resources	292,241,221	292,241,221	431,327,104	(139,085,883)
Uses of Resources (Outflows):				
Operations	9,954,328	16,641,091	14,924,592	1,716,502
Grants	287,108,118	280,409,352	147,044,669	133,376,683
Transfer out-Legislative Requirements	2,969,554	2,969,554	269,011,335	(266,041,781)
Total Uses of Resources	300,032,000	300,032,000	430,980,596	(130,948,596)
Budgetary Fund Balance(Deficit), August 30, 2013	$ (7,790,779)	$ (7,790,779)	$ 346,508	$ (8,137,287)

(Continued)

Explanation of Differences Between Budgetary Inflows and GAAP Revenues:

Sources/Inflows of Resources	$ 431,327,104
Differences – budget to GAAP:	
The deficit at the beginning of the year as restated is a budgetary item but is not current year revenue for financial reporting purposes.	7,790,779
The transfer in is a budgetary resource but is not current year revenue for financial reporting purposes.	(438,846,405)
Total revenue as reported on the statement of activities and governmental fund revenues, expenditures, and changes in fund balances	$ 271,478

Explanation of Differences Between Budgetary Outflows and GAAP Expenditures:

Uses/Outflows of Resources	$ 430,980,596
Differences – budget to GAAP:	
Governmental funds report capital outlays as expenditures. However, in the statement of activities, the cost of those assets is allocated over their estimated useful lives and reported as depreciation expense.	71,526
The transfer out is a budgetary uses but is not current year expenditures for financial reporting purposes.	(269,011,335)
Long-term liabilities are not available to pay current period expenditures and therefore, are not reported in the governmental funds.	142,680
Total expenditure as reported on the statement of governmental fund revenues, expenditures, and changes in fund balances	$ 161,969,261

COMPLIANCE SECTION

McCONNELL & JONES LLP
CERTIFIED PUBLIC ACCOUNTANTS

INDEPENDENT AUDITORS' REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING AND ON COMPLIANCE AND OTHER MATTERS BASED ON AN AUDIT OF FINANCIAL STATEMENTS PERFORMED IN ACCORDANCE WITH *GOVERNMENT AUDITING STANDARDS*

To the Oversight Committee and Management of
Cancer Prevention and Research Institute of Texas

We have audited, in accordance with the auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States, the financial statements of the governmental activities and the governmental funds information of Cancer Prevention and Research Institute of Texas (CPRIT), as of and for the year ended August 31, 2013, and the related notes to the financial statements, which collectively comprise CPRIT's basic finance statements, and have issued our report thereon dated December 19, 2013.

Internal Control Over Financial Reporting

In planning and performing our audit of the financial statements, we considered CPRIT's internal control over financial reporting (internal control) to determine the audit procedures that are appropriate in the circumstances for the purpose of expressing our opinions on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of CPRIT's internal control. Accordingly, we do not express an opinion on the effectiveness of CPRIT's internal control.

Our consideration of internal control was for the limited purpose described in the preceding paragraph and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies and therefore, material weaknesses or significant deficiencies may exist that were not identified. However, as described in the accompanying schedule of findings and responses, we identified certain deficiencies in internal control that we collectively consider to be a material weakness.

A *deficiency in internal control* exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. A *material weakness* is a deficiency, or a combination of deficiencies, in internal control such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected on a timely basis. A *significant deficiency* is a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance. We collectively consider the deficiencies described in the accompanying schedule of findings and responses as item numbers 2013-01, 2013-02, and 2013-03 to be a material weakness.

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Compliance and Other Matters

As part of obtaining reasonable assurance about whether CPRIT's financial statements are free from material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the determination of financial statement amounts. However, providing an opinion on compliance with those provisions was not an objective of our audit, and accordingly, we do not express such an opinion. The results of our tests disclosed instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards* and which are described in the accompanying schedule of findings and responses as items 2013-02, 2013-03, and 2013-04.

CPRIT's Response to Findings

CPRIT's responses to the findings identified in our audit are described in the accompanying schedule of findings and responses. CPRIT's response was not subjected to the auditing procedures applied in the audit of the financial statements and, accordingly, we express no opinion on it.

Purpose of this Report

The purpose of this report is solely to describe the scope of our testing of internal control and compliance and the results of that testing, and not to provide an opinion on the effectiveness of CPRIT's internal control or on compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering CPRIT's internal control and compliance. Accordingly, this communication is not suitable for any other purpose.

Houston, Texas
December 20, 2013

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

SCHEDULE OF FINDINGS AND RESPONSES
FOR THE YEAR ENDED AUGUST 31, 2013

SECTION 1:

SUMMARY OF AUDITORS' RESULTS

Financial Statements:

1.	Type of auditors' report issued:	Unmodified
2.	Internal control over financial reporting:	
	a) Material weakness identified?	Yes
	b) Significant deficiencies identified that are not considered to be material weaknesses?	No
	c) Noncompliance material to financial statements noted?	Yes

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

SCHEDULE OF FINDINGS AND RESPONSES
FOR THE YEAR ENDED AUGUST 31, 2013

FINDINGS – FINANCIAL STATEMENT AUDIT

Finding No. 2013–01: Deficiencies in Internal Control Over Financial Reporting

***Condition*:** During the course of our audit procedures, we considered CPRIT's internal controls over financial reporting and noted deficiencies in those controls. The following instances were noted:

(1) Year-end cut-off procedures did not capture certain significant subsequent grant expense transactions that should have been accrued per U.S. GAAP requirements resulting in an understatement of accounts payable and due to other agencies for approximately $14.7 million.

(2) Payable to vendors for approximately $1.7 million were accrued but not recorded in the proper expenditure accounts that resulted in audit adjusting entries.

(3) In the current year, management identified prior period adjustment amounting to approximately $5.3 million that indicated overstatement of prior year's fund balance/net position and accounts payable. Additionally, prior year's net position was restated to reverse the previously capitalized assets for $176 thousand. All these adjustments were not caught by management personnel on a timely basis to correct the reported amounts in the proper period.

(4) For 9 out of the 11 samples we selected to test expenditures for the CPRIT Foundation, supporting documents were not made available for our review. Additionally, no support was provided for salary supplements paid to the CPRIT's executive director and Chief Scientific Officer.

***Criteria*:** Effective internal controls over financial reporting include process and procedures for proper recording of transactions, timely reconciliation of general ledger account details to control accounts, proper cut-off procedures and effective supervision, review and approval processes to ensure preparation of financial statements in conformity with U.S. GAAP.

***Effect*:** Deficiencies in internal control over financial reporting could result in a material misstatement of CPRIT's financial statements or omission of required disclosures under U.S. GAAP. However, necessary adjustments have been made in the financial statements to correct identified misstatements.

***Cause*:** CPRIT has a weak system of internal controls, processes and procedures with respect to its year-end accounting close process. Also, the processes and procedures performed do not reliably and consistently generate financial statements prepared in accordance with U.S. GAAP on a timely basis.

Although the financial activities of CPRIT Foundation are included in CPRIT's financial statements as a blended component unit, management of CPRIT Foundation is usually responsible for providing supporting documents for any financial transactions. The Foundation ceased its operations in May 2013 and supporting documents for expense transactions that were selected for testwork were not provided to us as of the date of our report.

***Recommendation*:** We recommend that CPRIT establish a more efficient and effective responsibilities matrix for its general ledger functions and closing process to provide timely and accurate completion of

financial reporting as well as timely review and approval of all reconciliations and account balances. It is recommended that CPRIT assemble an inventory of financial spreadsheets used to support the preparation of the financial statements and assign the responsibility for reviewing such spreadsheets for accuracy of calculations.

Views of Responsible Official and Planned Corrective Action**:** *CPRIT agrees that there should be processes and procedures to streamline the end of year financial closeout. As CPRIT hires additional finance staff to support the agency's financial operations, the Chief Operating Officer and Finance Manager will determine how to incorporate the recommended processes and documentation to address efficient and effective general ledger closeout into job responsibilities by August 31, 2014*.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

SCHEDULE OF FINDINGS AND RESPONSES
FOR THE YEAR ENDED AUGUST 31, 2013

Finding No. 2013–02: Ineffective Review of Grantee's Compliance with Grant Agreements

***Condition*:** During the course of the audit, we reviewed grant expenditures recorded by CPRIT and noted the following matters related to CPRIT's review of grantees' reimbursement reports that underlies CPRIT's grant expenditures:

(1) Out of 47 of the 50 samples we tested, grantees did not provide, in our judgment, enough supporting documents with their financial status reports that would enable CPRIT to verify allowability, reasonableness and use of funds per the terms of their grant agreements.

(2) For 27 samples we tested for research awards, a verification of 50% matching funds per the terms of grant agreements was not made, indicating that CPRIT relies on self-reporting by grantees and may not know, on a timely basis, occurrences of non-compliance by grantees to enable them to take the necessary steps to address such non-compliance.

***Criteria*:** CPRIT's adopted policies and procedures in November 2009 and are required to follow the term of grant awards whereby grantees' and CPRIT must ensure compliance with Uniform Grant Management Standards. Additionally, CPRIT's adopted administrative rule 703.11 in November 2009 to interpret the State of Texas law requiring grant recipients to comply with the 50% matching funds requirement for all research awards.

***Effect*:** Lack of adequate supporting documents and review of compliance with 50% matching fund requirements increases the potential of processing grant disbursements to grantees which they are not entitled to per the terms of grant agreements. Additionally, CPRIT has not implemented its adopted administrative rule mentioned in the "Criteria" section above.

***Cause*:** Ineffective review of grantees' reimbursement requests.

***Recommendation*:** We recommend that CPRIT expedite its implementation of the adopted administrative rule for 50% matching fund requirements and strengthen its review of grant reimbursement requests to ensure only allowable costs are paid to grantees per the terms of the agreement.

***Views of Responsible Official and Planned Corrective Action*:** *CPRIT agrees with the recommendation on verifying matching funds and has developed and implemented as of December 6, 2013, a process that requires grantees to submit documentation verifying the amount and availability of matching funds. In addition to the certification of available matching funds that the grantee must submit at the beginning of the grant award and each grant award year (if the grant recipient is demonstrating matching funds on a year-by-year basis), the grantee must submit documentation that supports the certification of available funds to be used as match. If the grantee is an academic institution, the grantee may provide a letter from the U.S. government approving the federal indirect cost rate for the institution to serve as confirmation of available matching funds. As part of the certification, grantees must also provide information about the actual expenditures of funds counted as match toward grants with the documentation at the end of each award year.*

CPRIT management believes that the standard of required supporting documentation for processing grantee reimbursement payments is higher than that required for other similar types of grant programs at

the federal and state level. The Chief Operating Officer and Finance Manager will investigate further the documentation standard of other grant making organizations and develop a proposal by February 2014 to address this recommendation, taking into consideration CPRIT's personnel resources and the necessary grantee compliance education on this issue.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

SCHEDULE OF FINDINGS AND RESPONSES
FOR THE YEAR ENDED AUGUST 31, 2013

Finding No. 2013–03: Inadequate Process to Monitor Revenue Sharing Requirements

***Condition*:** During the course of our audit, we reviewed the process for reviewing Revenue Sharing receipts from grantees and noted that CPRIT lacks a process for determining the accuracy and completeness for those receipts and relies on the self-reported amounts from grantees.

***Criteria*:** Texas Administrative Code Title 25 Part II Chapter 703 Rule §703.17 specifies that CPRIT shall share in the financial benefit received by the grant recipients resulting from the patents, royalties, assignments, sales, conveyances, licenses and/or other benefits associated with the project results. Such payments may include royalties, income, milestone payments, or other financial interest in an existing company or other entity. To comply with this administrative Code, CPRIT requires grant recipients to pay an academic research or prevention grantee receives from licensing or royalty payments from the results of a research or prevention activity funded by CPRIT. CPRIT receives revenue from a company grantee based on the negotiated amount of any licensing, royalty, or equity payment that results from the research activity funded by CPRIT.

***Effect*:** In addition to the ineffective implementation of the requirements mentioned in the "Criteria" section above, reliance on self-reporting by grantees may result in fewer receipts to CPRIT which may have a potential of under reporting of revenue in the financial statements.

***Cause*:** CPRIT has relied on self-reporting from grantees and lacks an administrative policy that would provide guidance and an administrative process to verify accuracy and completeness of the self-reported receipts by grantees.

***Recommendation*:** We recommend that CPRIT develop processes and procedures to ensure completeness and accuracy of self-reported receipts by grantees under Revenue Sharing requirements. An administrative policy should be developed and implemented to aid in this process.

***Views of Responsible Official and Planned Corrective Action*:** *CPRIT agrees with the recommendation and its grant award contract provides specific instructions and guidance regarding revenue-sharing payments described in T.A.C. § 703.17. For example, Section D4.03 specifies the timing of payments and the information that shall accompany each payment. The contract also expressly requires the grant recipient to maintain complete and accurate revenue-related records until the fourth anniversary of the date of the last revenue-sharing payment owed pursuant to the contract. The documentation must be maintained with sufficient detail to permit CPRIT to confirm the accuracy of the supporting information accompanying the revenue-sharing payment. The contract explicitly permits CPRIT the right to examine the revenue-sharing records of the grant recipient for the purpose of verifying compliance with the contractual revenue-sharing requirements and provides a notification and process for doing so. CPRIT requires grant recipients to provide information on revenue sharing in the annual progress report submitted by the grant recipients.*

CPRIT has established a process, set forth in the proposed administrative rule, § 703.21 "Monitoring Grant Performance and Expenditures" that requires the grant recipient to submit in the annual grant progress report all financial information necessary to support the calculation of the CPRIT's share of revenues resulting from the funded project. This information, along with other required financial information shall be reviewed by CPRIT's financial staff. If the grant recipient fails to provide the

required information, CPRIT's financial staff is required to notify CPRIT's CEO and General Counsel for further action, including contract termination. The proposed administrative rule implementing this process is expected to be adopted January 2014.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

SCHEDULE OF FINDINGS AND RESPONSES
FOR THE YEAR ENDED AUGUST 31, 2013

Finding No. 2013–04: Noncompliance with laws and regulations

***Condition*:** During the course of our audit, we noted that quarterly meetings of CPRIT's Oversight Committee were not held between February 26, 2013 through August 31, 2013.

***Criteria*:** Per state statute, Texas Health and Safety Code, Chapter 102.055, the Oversight Committee is required to hold a public meeting at least once each quarter of the calendar year.

***Effect*:** Non compliance with state laws.

***Cause*:** In fiscal year 2013, the Oversight Committee had only two meetings to select an interim executive director and to address governance issues as a result of findings and recommendations by the State Auditor's Office in its January 2013 report to CPRIT. As a result of that review, a substantial change in the structure of the Oversight Committee members was legislatively mandated in State Bill 149 in May 2013.

***Recommendation*:** With the new Oversight Committee members now in place (subsequent to the fiscal year-end), it is recommended that CPRIT's legal counsel monitor's compliance with the state law mentioned in the "Criteria" section above.

***Views of Responsible Official and Planned Corrective Action*:** *CPRIT agrees with the recommendation. During the identified time period, agency management was working with the legislature and state leadership to address statutorily the findings of the State Auditor's January 2013 Management Report on CPRIT as well as other legislative and agency management concerns. Oversight Committee meetings during this period would have impeded this legislative engagement. Since no award making activities were necessary due to the state leadership imposed moratorium on grant making, agency activities were not impacted negatively by the lack of Oversight Committee meetings. The meeting schedule was well known by interested members of the legislature and state leadership. In the opinion of the agency management, the lack of quarterly meetings during this period was appropriate and facilitated addressing larger and more pressing concerns of the legislature and state leadership. Agency staff could and did continue appropriate compliance monitoring of all outstanding awards during this period.*

The Governor, Lieutenant Governor, and Speaker of the House appointed new members to the Oversight Committee in October and November 2013. The Oversight Committee held two meetings in November 2013 and is implementing a quarterly meeting schedule with future meetings set in 2014 for January, February, May and August.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Austin, Texas

SCHEDULE OF PRIOR YEAR FINDINGS AND RESPONSES
FOR THE YEAR ENDED AUGUST 31, 2013

Prior year Findings:

There were no audit findings reported in the fiscal year ended August 31, 2012 Schedule of Findings and Responses.

Fiscal Year 2013 Annual Internal Audit Report

January 20, 2014

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Cancer Prevention and Research Institute of Texas
Annual Report for the year ended August 31, 2013

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I. Compliance with House Bill 16

House Bill 16 requires state agencies and higher education institutions, as defined in the bill, to post their Internal Audit Plan, Internal Audit Annual Report, and other audit information on the Internet.

The CPRIT Oversight Committee will review and approve the agency's internal audit plan and internal audit annual report at the recommendation of the Audit Subcommittee. Once the Oversight Committee has approved these reports at an open meeting, the reports will be posted to the agency's website in a section designated for audit reports within 30 days of approval. In addition, the agency will post to the website the individual internal audit reports related to the internal audit annual report.

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II. Internal Audit Plan for Fiscal Year 2013

The internal audits planned for fiscal year 2013 were selected to address the agency's highest risk areas, based on the risk assessment process conducted during the summer of 2012, which included input from CPRIT management. The audits conducted during fiscal year 2013 are listed below, along with a brief description of each.

Audit Name & Description	Report #	Report Date	Status
Grants Management – this audit consisted of a review of the grants management processes and controls to determine whether controls are in place to help validate that the grant application process and the subsequent review of programmatic and financial activities are operating effectively. The audit will also review whether grantee activity is adequately monitored periodically and throughout the duration of grant programs.	2013 – 01	7/19/13	Completed
Expenditures – this review took into consideration whether controls are in place to help validate that the Agency's expenditure process and controls are operating effectively to mitigate the risk of fraudulent activity.	2013 – 02	7/19/13	Completed
Information Technology – this audit considered whether controls are in place to help validate that the Agency's IT environment is compliant with Texas Administrative Code. The internal audit will also consider whether general computer controls are in place and operating effectively.	2013 – 03	8/9/13	Completed

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Audit Name & Description	Report #	Report Date	Status
Grantee Field Audit – Cooper – this audit validated if the grantee had a clear understanding of CPRIT's policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2013 – 04	7/18/13	Completed
Grantee Field Audit – Baylor College of Medicine – this audit validated if the grantee had a clear understanding of CPRIT's policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2013 – 05	8/29/13	Completed
Grantee Field Audit – Texas Tech – this audit validated if the grantee had a clear understanding of CPRIT's policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2013 – 06	8/5/13	Completed
Grantee Field Audit – MD Anderson – this audit validated if the grantee had a clear understanding of CPRIT's policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2013 – 07	8/28/13	Completed
Grantee Field Audit – University of Houston – this audit validated if the grantee had a clear understanding of CPRIT's policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2013 – 08	8/30/13	Completed
Grantee Field Audit – Caliber Biotherapeutics, LLC – this audit validated if the grantee had a clear understanding of CPRIT's policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2013 – 09	8/29/13	Completed

There were no deviations from the audit plan that was previously submitted in the fiscal year 2012 annual internal audit report.

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III. Consulting Services & Non-Audit Services Completed

As defined in the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing and the Government Auditing Standards, 2011 Revision, Sections 3.33 – 3.58, CPRIT completed the following consulting and non-audit services for FY 2013:

- CPRIT engaged Grant Thornton as the third party to observe each in-person and telephone conference peer review meeting. The following meetings were attended:

Review Panel	Report #	Report Date	Status
Peer Review – Scientific Basic Cancer Review Committee 1A/2A	2013 – 10	9/11/12	Completed
Peer Review – Scientific Basic Cancer Review Committee 3A	2013 – 11	9/18/12	Completed
Scientific Translational and Clinical Cancer Review Committee 3A	2013 – 12	9/20/12	Completed
Peer Review – Interfaces Review Committee A	2013 – 13	9/26/12	Completed
Peer Review – Basic Cancer Review Committee 1A	2013 – 14	9/26/12	Completed
Peer Review – Basic Cancer Review Committee 2A	2013 – 15	9/28/12	Completed
Peer Review – Commercialization Panel A, FY 13 Cycle 1 Screening	2013 – 16	9/27/12	Completed
Peer Review – Commercialization FY 13 Cycle 1	2013 – 17	9/30/12	Completed
Peer Review – Prevention Peer Review Panel – FY13 Cycle 1	2013 – 18	11/13/12	Completed
Peer Review – Prevention Program Peer Review FY13 Cycle 1	2013 – 19	11/15/12	Completed

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Review Panel	Report #	Report Date	Status
Peer Review – Commercialization Panel B, FY13 Cycle 2 Screening Teleconference	2013 – 20	12/3/12	Completed
Peer Review – Commercialization Program Peer Review FY13 Cycle 2	2013 – 21	12/17/12	Completed
Peer Review – Prevention Peer Review Council Meeting	2013 – 22	12/18/12	Completed

  - The purpose of the peer review panel observations was to document that:
    - Procedures on conflict of interest are followed during peer review sessions (e.g., reviewers leave room or do not participate in the telephone conference if they are conflicted on a certain proposal, etc.);
    - CPRIT program staff participation is appropriate, offering points of information when asked by the peer review panel and not engaging in the panel's discussion on the merits of applications; and
    - The discussion by the peer review panel is appropriately focused on the merits of each application.

- CPRIT engaged Mr. Billy Hamilton as a consultant to perform an operational review of the agency and provide independent findings and recommendations to the CPRIT Oversight Committee and Interim Executive Director. The services he performed related to the operational review consisted of:
  - Reviewing the agency's processes and past issues, interviewing key staff, and reviewing relevant documents;
  - Meeting with members of the Legislature, stakeholders, and others involved in the agency's work as necessary to complete the assignment;
  - Providing the CPRIT Oversight Committee with a written report of findings and recommendations; and
  - Testifying before the Legislature.

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IV. External Quality Assurance Review (Peer Review)

In accordance with professional standards, and to meet the requirements of the Texas Internal Auditing Act, Internal Audit is required to undergo an external quality assurance review a t least once every three years. CPRIT did not engage in an external quality assurance review during FY 2013.

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V. Internal Audit Plan for Fiscal Year 2014

The internal audits planned for fiscal year 2014 were selected to address the agency's highest risk areas, based on the agency's risk assessment. Although the Internal Audit Plan contains various audits, it is not intended to cover every risk, and it does not provide coverage for all CPRIT's activities. This internal audit plan may be adjusted if significant changes in risk occur. Additional projects, such as management requests, may be conducted or some of the audits included may not be performed. Adjustments in the audit plan will be communicated to the CPRIT Audit Subcommittee, as appropriate.

Internal Audit performed an enterprise risk assessment (ERA) of the agency in the summer of 2013. The assessment was performed in collaboration with agency management, using a combination of management interviews and a web-based survey. The ERA also included an evaluation of issues identified during prior audits and took into consideration the current risks within the Agency's environment.

Internal Audit combined the assessed risks identified in the ERA with additional information obtained from prior internal audits and other business risks, to identify the higher risk areas within the agency. These lists were presented to agency executives for review and agreement, combined into a comprehensive list, and then ranked in order to identify those areas that warrant focus by internal audit for the current fiscal year.

Internal Audit	Description	Budgeted Hours
Grants Management	An internal audit of grants management processes and controls will consider whether controls are in place to help validate that the grant application process and the subsequent review of programmatic and financial activities are operating effectively. The audit will also review whether grantee activity is adequately monitored periodically and throughout the duration of grant programs.	200

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Internal Audit	Description	Budgeted Hours
Expenditures	An internal audit of expenditures will consider whether controls are in place to help validate that the Agency's expenditure process and controls are operating effectively to mitigate the risk of fraudulent activity.	150
Information Technology	An internal audit of expenditures will consider whether controls are in place to help validate that the Agency's IT environment is compliant with Texas Administrative Code. The internal audit will also consider whether general computer controls are in place and operating effectively.	100
Governance	An internal audit of the Agency's governance will consider whether controls are in place to help ascertain if there is coordination of activities and communication of information among the board, external parties and management in order to promote appropriate ethics and values within the organization. Areas to review may include conflict of interest disclosures, on-boarding and training of Oversight Committee members, and understanding of policies and procedures.	200
Grantee Field Audits	Internal audits of various grantees will help validate if the grantees have a clear understanding of CPRIT's policies and procedures and will review whether CPRIT funds have been used in accordance with the established guidelines.	800
Special Projects	To be determined by Management or the Audit Subcommittee	TBD

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VI. External Audit Services Procured in Fiscal Year 2013

CPRIT engaged CliftonLarsonAllen, a certified public accounting and consulting firm, as their external auditors for FY 2013. CliftonLarsonAllen is registered with the Public Company Auditor Oversight Board (PCAOB) and is a member of the Government Audit Quality Center and the Employee Benefit Plan Audit Quality Center.

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VII. Reporting Suspected Fraud and Abuse

Reference	Description of Entity's Actions
Fraud Reporting (Article IX Section 7.09, 83rd Legislature, Conference Committee Report)	On the CPRIT website, the agency provides the State Auditor's Office toll free fraud, waste, and abuse hotline and website address for individuals to anonymously and directly report suspected fraud, waste, and abuse involving CPRIT or other state resources.
Coordination of Investigations (Chapter 321, Texas Government Code, §321.022)	The CPRIT Chief Compliance Officer is the designated staff member within the agency to receive written or verbal allegations of suspected fraud, waste, and abuse. The Compliance Officer has the authority to examine and investigate those allegations and turn over information of verified instances of fraud, waste, or abuse to the State Auditor's Office.

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CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: DAVID A. REISMAN, CHIEF COMPLIANCE OFFICER
SUBJECT: COMPLIANCE OFFICER REPORT
DATE: JANUARY 20, 2014

An Ethics and Compliance Program is a critical component of an organization's internal control processes and necessary when the organization is entrusted with taxpayer funds. Compliance activities have been a function of CPRIT operations since inception. Examples include ethical conduct policies, audit policies and conflict of interest policies and procedures. CPRIT created the position of Compliance Officer in August 2012 to ensure organizational compliance and to establish a formal compliance program that promotes a culture of ethical conduct and adherence to the law.

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 proposed 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.

CPRIT has recently implemented the CPRIT Grants Management System (CGMS). CGMS is an electronic portal system that facilitates CPRIT's execution of grant contracts and the ongoing monitoring and management of grant awards, including required grant recipient reports and submissions. Prior to CGMS, almost all of the paperwork associated with grant contracts and grant monitoring activities were exchanged between CPRIT and the grant recipients either as physical documents or as PDF applications, which made contract execution and grant monitoring a time-intensive process. CGMS not only allows for comprehensive status update review of all required reports, but it also automatically notifies grant recipients of upcoming deadlines. The automatic notices help grant recipients maintain full compliance.

A compliance program is constantly evolving to meet the current and continuing needs of the Institute. The compliance program, however, must assure the Oversight Committee that controls are in place to manage risk, be transparent, and ensure the public's trust.

Monitoring Submission Status of Required Grant Recipient Reports:

As of January 16, 2014, the date the report was run, information regarding delinquent grant recipient reports is as follows:

- 52 grant projects, at 15 separate entities, have not filed required quarterly financial status (FSR) reports by the deadline. An FSR is due to CPRIT within 90 days following the close of the fiscal quarter. Of the 52 delinquent reports, 0 are less than 30 days overdue. 49 are more than 30 days but less than 90 days overdue. 3 FSRs are currently 90+ days overdue. For purposes of this report, I have excluded grant projects where contract execution was affected by the moratorium on new CPRIT awards.
- 2 grant projects 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 2 delinquent progress reports, both are currently 90+ days overdue. One of the projects is on hold. The other project had contract issues that have been resolved. For purposes of this report, I have excluded grant projects where contract execution was affected by the moratorium on new CPRIT awards.

CPRIT staff will follow up with the grant projects that have delinquent reports. Currently, CPRIT may cease reimbursing or advancing grant proceeds if FSRs or other required reports such as progress reports are not on file for the grant project. The failure to timely submit required reports may also be considered an "event of default" under CPRIT's grant contract, which leads to grant termination unless the default event is cured to CPRIT's satisfaction. The Oversight Committee will be notified by the Chief Executive Officer and General Counsel in the event that the contract default option is pursued for any grant contract.

CPRIT's proposed administrative rules provide new options to address delinquent reports. For example, proposed rule 703.21(b)(2) provides, "…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 due date. The Chief Executive Officer may approve an extension of the submission deadline if, prior to the FSR due date, the grant recipient submits a written explanation for the grant recipient's inability to complete a timely submission of the FSR." (emphasis added)

The addition of new grant monitoring staff authorized by the legislature, together with the automatic notification features in CGMS, and additional tools in the proposed administrative rules should work together so that CPRIT can ensure that grant recipients are achieving full compliance with applicable rules, requirements and policies.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WILLIAM RICE, M.D., PRESIDING OFFICER
SUBJECT: AGENDA ITEM 13: AGENCY PLANNING & OPERATIONS
DATE: JANUARY 20, 2014

Three topics are to be discussed under Agenda Item 13: Agency Planning and Operations.

Baldrige Criteria for Performance Excellence

The Baldrige Program was established by Congress in 1987 and managed by the National Institute of Standards and Technologies (NIST), an agency of the U.S. Department of Commerce. The program helps organizations improve their performance and succeed in the competitive global marketplace. It provides organizations with:

- An integrated management framework;
- Organizational self-assessment tools;
- Analysis of organizational strengths and opportunities for improvement by a team of trained experts; and
- Educational presentations, conferences, and workshops on proven best management practices and on using the Baldrige criteria to improve.

The program promotes awareness of performance excellence as an increasingly important element in competitiveness. It also promotes the sharing of successful performance strategies and the benefits derived from using these strategies. To receive a Baldrige Award, an organization must have a role-model organizational management system that ensures continuous improvement in delivering products and/or services, demonstrates efficient and effective operations, and provides a way of engaging and responding to customers and other stakeholders. The award is not given for specific products or services.

Copies of *Criteria for Performance Excellence 2013-2014* describing the Baldrige Program will be provided to the Oversight Committee at the January 24, 2014, meeting.

An overview of the program and a discussion of interest in CPRIT engaging in the Baldrige process will occur at the meeting.

Required State Strategic Plan for CPRIT

The State of Texas budget system is formally named the Strategic Planning and Budget System. It is a nearly four-year continuous cycle that includes strategic planning, budgeting, implementation of the budget and strategic plan, and evaluation of how well that plan and budget is implemented.

The first step in the process is development of a statewide vision for the future of Texas government. The Governor, in cooperation with the Legislative Budget Board (LBB), is responsible for preparing a mission statement for Texas. This statement provides a framework for the development of agency strategic plans and establishes a mission for state government, core principles to guide decision-making, and goals and benchmarks for all state services and programs.

The second step is the development of individual agency strategic plans. These are long-term (6 year) plans that establish where an agency is and where the agency plans to go. These include a mission statement and identify goals for the agency, the population served by the agency, a description of the means by which the agency plans to achieve its goals, and the measures that will be used to assess the agency's success in achieving those goals. The Governor's Office and the LBB issue rigid instructions for developing strategic plans in the spring preceding a legislative session. After developing a strategic plan, the agency submits it to the Governor's Office and LBB for approval.

This strategic plan and its associated measures establish the budget structure that the agency must use in preparing its funding request for the next legislative session. Agencies have little flexibility in establishing new measures or modifying existing ones. There is even less flexibility in changing the strategic planning and budget structure.

Based on prior biennia, instructions for developing the agency strategic plans will be released by the Governor and LBB in March. Other key deadlines are:

- Mid-April: requesting additions, modifications, or deletion of budget structure elements (line items, measures, and measure definitions)
- May: Instructions for preparing budget requests released
- June 1: Report on customer service due
- Late June and early July: strategic plans due
- July-August: budget requests due
- August-September: public budget hearings conducted by the Governor's Office and LBB

Staff recommends that any additional planning processes or programs for organizational excellence accommodate and consider the restrictions, time, and resource demands of the statutorily required state strategic planning and budget system. Otherwise, finite staff resources could be shifted from the programmatic policy operations for which CPRIT was created to address towards administrative endeavors such as management programs and excellence pursuits.

Dashboard Metrics, Operational Measures, and Operational Presentations

In his CEO presentations, Wayne Roberts provides a few baseline measures: total awards made and amounts, RFAs open and submitted, and status of contracting of those awards that had been suspended due to the moratorium.

There is interest in adding to these and having the OC get monthly reports in addition to those at the open meetings on the agency's progress in achieving them both in terms of quantity and quality.

Other considerations include:

- Software platform use metrics, platform change requests and updates, usability, and functionality metrics from SRA
- Standard reports and customized reports from the SRA software platform, specifically the grant management program
- Number of applications that are received by week/month/year by RFA, what applications are incomplete, what applications are delinquent, what grants have missing updates
- Reports from SRA that list all grants with documentation updates that are overdue

Operationally, we need all kinds of visibility into SRA—grant management software—and knowledge of what reports and information we've gotten in the past, what we're getting now, what's available, and what we need.

The OC may like to see a "dashboard" report that highlights these aspects of the work of SRA to meet the OC's responsibility of knowing that CPRIT information is secure, usable, and can be acted upon efficiently.

Other meeting changes to consider include:

- Hearing three points of view on the balance of dollars devoted to research versus product development (could be part of the program priority setting process)
- Having 3 researchers come to each meeting to discuss their work and allow the OC to ask questions
- Operational updates on progress on the Baldrige process, if undertaken
- Receiving an ethics report at each OC meeting that shares progress in achieving a third party recognition as an ethical organization
- Report from a systems biology expert to highlight the need for new approaches in cancer research.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WILLIAM RICE, M.D., CHAIR
SUBJECT: AGENDA ITEM 14: ANNUAL PROGRAM PRIORITIES PURSUANT TO HEALTH & SAFETY CODE 102.107
DATE: JANUARY 20, 2014

This agenda item introduces a major Oversight Committee initiative, the Program Priorities Project. The undertaking is necessary to carry out a new statutory obligation set for the Oversight Committee as the policy-making entity for CPRIT. A change to Health & Safety Code Section 102.107 enacted by the 83rd Legislature requires the Oversight Committee to annually set priorities for each CPRIT grant program and consider the priorities in awarding cancer research and prevention grants.

This is an important undertaking. The priorities established by the Oversight Committee for the agency's three programs (scientific research, prevention, and product development) will be used to solicit cancer research and prevention projects and set goals and benchmarks that track the progress the agency is making towards its statutory mission.

The Oversight Committee should establish the process and timeline for the project on January 24th. The Program Priorities Project must be an Oversight Committee-driven process with staff assisting as expert advisors, information gatherers, and facilitators. I set out some programmatic and process topics for your consideration and discussion. I welcome your input. Additional discussion and refinement may be necessary at the February 19th Oversight Committee meeting.

Process and Timeline

I propose that the Oversight Committee plan to approve program priorities at its May 21st meeting, with a final report prepared for Oversight Committee approval in August. This schedule gives the subcommittees time to develop recommended priorities over the next five months through the process we establish.

We have a statutory requirement to fund prevention programs with 10% of available CPRIT funds. Within that limitation, perhaps the first discussion about program priorities is to explore the balance of funding across prevention, scientific research, and product development. In relation to this discussion, we could invite each of the respective subcommittees to suggest their own priorities. However, each conversation should begin and end with the disclaimer that we do not consider these as absolute targets, but rather directional emphasis given that high quality work is the first filter of all decisions.

Process issues and questions to be discussed include:

- The overall timeline to complete the Program Prioritization Project as required by SB 149.
- The timeline for program subcommittees to develop the recommended priorities for each program
- Whether a special subcommittee composed of the chairs of the three program subcommittees is needed and should be established
- Whether to solicit input from the public when considering program priorities, and if so, how to receive and assess the public response
- What role CPRIT's Ad Hoc Advisory Committees should play in the process

Programmatic

- How can CPRIT best leverage the $300 million in bond funds per year to maximize the impact of CPRIT programs?
- Should the amount of grant funding for each program be capped, and if so, what would be appropriate caps for each program?
- Should certain stages of research (discovery, translational, or clinical research) be prioritized over others as opposed to funding the most meritorious projects regardless of stage of research, and if so, what is the best way to achieve desired portfolio balance?
- Should some cancer prevention (primary, secondary, or tertiary) interventions be prioritized over others as opposed to funding other meritorious projects regardless of type prevention intervention, and if so, what is the best way to achieve desired portfolio balance?
- Should certain technology transfer or product development activities be emphasized?
- Should public or private research partnerships be considered and supported through grant funds?