



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting

AGENDA

Friday, November 1, 2013 - 9:00 AM

**Capitol Extension, Committee Room E1.012
1400 N. Congress Avenue, Austin, Texas**

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. Oath of Office
4. Election of Officers **TAB 1**
5. Adoption of Minutes from February 25, 2013 meeting **TAB 2**
6. Executive Director Report **TAB 3**
 - Legislative Wrap-up
 - Audit Implementation Plan
 - Summary of CPRIT Activities During Moratorium
 - 2014 Conference
 - Strategic Communications contract process - assign issue to a subcommittee
 - HUB Report
 - Other issues
7. Consideration of Changes to Oversight Committee Bylaws **TAB 4**
8. Consideration of Changes to Code of Conduct and Ethic **TAB 5**
9. Subcommittee assignments **TAB 6**
10. Proposed Changes to *Texas Administrative Code* Title 25, Chapters 701, 702, 703 and 704 **TAB 7**
11. Restarting grant review process **TAB 8**
 - Authorization to re-start grant review process for frozen applications
 - Authorization to move forward with release of RFAs
12. Appointments to Scientific Research and Prevention Programs Committees **TAB 9**
13. Honoraria Policy **TAB 10**
14. Chief Operating Officer Report **TAB 11**
 - FY 2013 Year End Financial and Performance Reports
 - Adoption of FY 2014 Operating Budget

- CPRIT Debt Issuance Update
- Authorization of 2014-15 Request for Financing to Texas Public Finance Authority
- Internal Audit Annual Report for FY 2013 and Internal Audit Plan for FY 2014

15. Compliance Report

TAB 12

16. Personnel Matters

TAB 13

- Executive Director/Chief Executive Officer
- Product Development Officer
- Chief Compliance Officer
- Internal Auditor

17. Foundation Settlement

TAB 14

18. Consultation with General Counsel

19. Future Meeting Dates and Agenda Items

20. Public Comment

Anyone wishing to make public comments is required to notify the Executive Director in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

21. Adjourn



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: OFFICER ELECTIONS
DATE: OCTOBER 28, 2013

Summary and Recommendation:

Article 5 of the Oversight Committee Bylaws requires the Oversight Committee to elect officers at its first meeting following the adoption of the bylaws. The interim presiding officer should call for a vote of the Oversight Committee to elect the chair, the vice chair and secretary from among its members. Alternatively, the chair may appoint the secretary from among the Oversight Committee members.

Discussion:

The Oversight Committee adopted Bylaws at its most recent open meeting, held February 25, 2013. Section 5.2 "Election, Term of Service, and Removal" provides in part:

"At the first regular Oversight Committee meeting following the adoption of these bylaws, the members of the Oversight Committee shall elect the Chairperson and Vice Chairperson by a vote of a simple majority as set forth in Section 3.13..."

The chairperson and vice chairperson will serve until the next election, which will be held in 2015 at the last regular meeting during the state fiscal year (September 1 – August 31). The Bylaws prevent a member from holding the position of chairperson or vice chairperson for two consecutive terms.

An election to fill the position of secretary of the Oversight Committee is also needed because certain agreements between CPRIT and Texas Public Finance Authority (TPFA) must be countersigned by the secretary of the Oversight Committee. TPFA is the state agency that issues debt on behalf of CPRIT.

The position of secretary is not specifically mentioned as an officer position in the Bylaws. Section 5.1 of the Bylaws has been amended to permit the Oversight Committee to elect additional officers from among its members by a vote of a simple majority. Alternatively, the secretarial position may be appointed by the presiding officer of the Oversight Committee.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: ADOPTION OF FEBRUARY 25, 2013 OVERSIGHT COMMITTEE MEETING MINUTES
DATE: OCTOBER 28, 2013

Summary and Recommendation:

State law requires CPRIT to prepare and keep minutes of each open meeting. Oversight Committee members should vote to approve the draft meeting minutes of the most recent open meeting.

Discussion:

Government Code § 551.021 requires governmental bodies to prepare and keep minutes of each open meeting of the body. CPRIT senior staff that attended the February meeting have reviewed the draft meeting minutes and confirm that the minutes accurately depict the discussion and deliberations at the meeting. An audio recording of the meeting is also available at: http://www.cprit.state.tx.us/cprit_oc_meeting_02-25-2013.html

MINUTES
Oversight Committee Quarterly Meeting
Cancer Prevention and Research Institute of Texas

Thompson Auditorium, 1st Floor
Texas Medical Association
401 W 15th Street, Austin, Texas

February 25, 2013
11:30 a.m.

Call to Order

Chairman James Mansour, announced a quorum and called the Oversight Committee Meeting of the Cancer Prevention and Research Institute of Texas (Institute) to order at 11:35 a.m. Chairman Mansour noted for the record that he received a letter from Walker Moody, notifying the Board he would not be attending the meeting because of a family matter.

Members Present

James Mansour, Chairman
Dr. Joseph Bailes, Vice Chairman
Barbara Canales
The Honorable Faith Johnson
Tom Luce
Alex Meade
Charles Tate
Mark E. Watson, Jr.

Members Absent

Walker N. Moody
Jay Dyer, Attorney General Designee
Whitney Blanton, Comptroller Designee

Legal Counsel

Kristen Doyle

Staff Present

Wayne Roberts, Interim Executive Director
Billy Hamilton, Senior Advisor to the
Oversight Committee and Executive Director
Heidi McConnell, Chief Operating Officer
Patricia Vojack, Compliance Officer
Ramona Magid, Prevention Program Director
Diego Alejos, Information Technology
Robert Gonzales, Information Technology
Therry Simien, Information Technology
Officer

Sandra Balderrama, Senior Advisor to the
Executive Director
Yvette Jimenez, Administrative Assistant
Ellen Read, Information Specialist
Alfonso Royal, Finance Manager
Lisa Nelson, Operations Manager
Michelle Frerich, Program Manager
Sandra Reyes, Executive Assistant

Minutes

December 5, 2012

December 21, 2012

Tom Luce moved to adopt the minutes of the CPRIT Oversight Committee Meetings held December 5, 2012, and December 21, 2012. Joseph Bailes seconded. None opposed. Motion carried.

Interim Executive Director's Report

Since commencing as Interim Executive Director on December 27, 2012, Mr. Roberts' first order of business was to work with Billy Hamilton, Senior Advisor to the Oversight Committee and Executive Director, to review the awards announced at the August and December 2012 meetings. Mr. Hamilton would be giving the Board a detailed report on those particular awards.

Mr. Roberts and Mr. Hamilton noted that based on the discussions at legislative hearings, they decided it would be prudent to review all 498 grants awarded by CPRIT. This will be done to ensure that the process used at the time of the awards was followed. He does not believe there are any problems with the awards, but they feel it would provide additional comfort to legislators.

Mr. Roberts reported that during his first week at CPRIT he was presented with a request from CTNeT, one of CPRIT's grant recipients, for an advance of funds totaling nearly \$780,000. He spent considerable time trying to reach a resolution that would allow CTNeT to continue operations but was unsuccessful. The issue has been well covered in the media and the State Auditor's report.

Mr. Roberts also coordinated development of a lengthy management response to the State Auditor's Report. CPRIT committed to implementing all 41 of the recommendations. The implementation plan has been posted on CPRIT's website and will be updated regularly as CPRIT takes action to implement each recommendation. For example, the Oversight Committee's consideration of the proposed administrative rule changes and adoption of Bylaws at this meeting are part of the implementation plan and the action taken today will be updated on the chart.

Mr. Roberts informed the Oversight Committee that staff continues to receive and respond to numerous public information requests. The staff time utilized to respond to the information requests limits CPRIT's ability to address some of CPRIT's pressing issues and purposes for which CPRIT was created as quickly and efficiently as he would like.

Per instruction from the Oversight Committee, Mr. Roberts reported that a request for proposals for media communications had been issued. CPRIT received 10 proposals. Four firms moved forward for further consideration. The two final firms were each interviewed three times by staff with some Oversight Committee involvement. The contract was awarded to Hahn, Texas two weeks ago and work started immediately.

Mr. Roberts and Mr. Hamilton and occasionally other senior staff have participated in numerous meetings with legislators and their staff. They have discussed revisions to CPRIT's enabling statutes and agency efforts to address concerns in the state audit report, the media, and elsewhere. Bills related to CPRIT have been introduced by Senator Nelson, Representative Keffer, Senator

Eltime, and Senator Davis, among others. He also met with staff of the Legislative Budget Board concerning the details and intent behind the introduced budget as they relate to CPRIT.

Mr. Roberts stated that staff has prepared for Oversight Committee consideration a lengthy list of draft amendments to CPRIT rules and regulations to implement the State Auditor's report. The implementation chart that was referenced earlier includes a list of initial items in proposed legislation and internal suggestions. Staff has created a list of what can be done now instead of waiting for further instruction from the Legislature. Staff wants CPRIT to address the problems that it can address now without further delay.

The grant management system contract was modified to enhance our post award contract performance monitoring. This was a concern for the State Auditor, Mr. Hamilton, and Mr. Roberts.

At the suggestion of Hahn, Texas and to improve our operational visibility, Mr. Roberts reported that he has initiated media calls to keep the media apprised of our actions and to respond to specific questions they may have. Also, several meetings have been held with various advocacy groups to provide updates on CPRIT activities.

Mr. Roberts has conducted approximately 31 meetings with Legislators, and will continue to schedule more meetings in the weeks ahead. He stated that staff, Mr. Hamilton and he have prepared for and given some 7.5 hours of testimony to 5 legislative committees concerning the State Auditor's report, agency operations, and proposed 2014-15 appropriations.

He met with nine vendors concerning unsolicited proposals to assist in operations and help CPRIT with the Legislature. He also met with numerous presidents of institutions of higher education, their representatives and others concerning various subjects, particularly the legislative leadership moratorium.

With respect to the bills before the Legislature, Mr. Roberts informed the Oversight Committee that SB 149 by Senator Nelson is not yet set for the Senate Floor. Senator Nelson hopes it will come up within the first two weeks of March subject to Senate rules.

Also, the Senate Finance Subcommittee pended CPRIT's budget to the full committee. There are no changes made at this time. CPRIT has been made a "priority 2". The House Appropriations subcommittee has also pended CPRIT budget to the full House committee with no changes.

Senate Bill 150 by Nelson is to be heard Tuesday, February 26, 2013, at the Senate Health and Human Services Committee. This is similar to legislation from last session that did not pass. SB 150 allows money to be deposited to our dedicated account in the treasury to pay for debt service on bonds and other statutory purposes.

Mr. Roberts ended his report by stating that the 21 employees that remain at the agency are dedicated professionals and were not the cause of the problems reported publicly in the past few months. He stated that many of the problems that have been revealed were identified first by CPRIT employees. He emphasized that through these public servants CPRIT can and will emerge reinvigorated and rededicated in the effort to mitigate cancer in our children's life time. He asked that all Oversight Committee members in attendance thank staff on their way out after the meeting.

Comments:

The Oversight Committee, led by Mr. Luce, also expressed their support of the statement and gave the staff an ovation. The Oversight Committee expressed its support for strengthening the integrity and transparency of agency grant award decisions and operations.

Senior Advisor to Oversight Committee Report

Billy Hamilton reported on the grant awards verifications process. He pointed out that overall the process has been slow due to staff's limited access to detailed data that are currently maintained by SRA and the limited number of staff within the agency.

Mr. Hamilton described the three phases of the verification process he is undertaking:

Phase 1: Verification of the "frozen grant awards", slates approved on August 2 and December 5. This was completed on January 31, 2013.

Phase 2: Verification of all past awards to identify any potential issues. This phase is ongoing at this time.

Phase I3: A "crosswalk" between the grant awards and contributions to the CPRIT Foundation. This phase remains to be done.

Verification that appropriate process was used for the "frozen grants" required building an individual grant profile for each of the grants to ensure that each step in the approval process as outlined in statute and agency rules had been met and then evaluating each grant. This process was carried out by Patricia Vojack, Compliance Officer, with assistance from Dr. Becky Garcia, Chief Prevention Officer, Dr. Margaret Kripke, Chief Scientific Officer, and Kristen Doyle, General Counsel.

129 research and prevention grant awards were reviewed as part of this phase, as well as 31 Recruitment awards.

The final conclusion of the review was that all but one of 160 grants ratified by the Oversight Committee on August 2, 2012, and December 5, 2012, followed appropriate processes laid out in the RFAs as well as CPRIT statute, rules, and guidelines. This information has been shared with Governor Perry and legislative leadership to inform their decision on how and when to lift the moratorium on CPRIT awards.

Due to legislative concerns, designated staff is proceeding with a review of all prior CPRIT grant awards to provide assurance that there are no additional awards that bypassed any applicable rules or state law.

Mr. Hamilton explained that the one grant recommendation which did not follow the rules was an individual investigator award that was originally part of a Multi-Investigator Research Award application that included eight individual proposed projects. The overall MIRA did not receive a favorable score, which meant it was not discussed before the full review committee. The individual project was brought to the attention of the chief scientific officer after peer review was completed and subsequently was added to the August 2, 2012, slate and ratified by the Oversight Committee. Mr. Hamilton said this was presumably done because the individual project had a good score on its own merits. However, this was a deviation from the process in the rules and the process used at the

time. He emphasized that nothing was wrong with the project award; it simply had the misfortune of being approved outside of the process that should have been followed.

He informed the Committee that there was no evidence in the written record or in interviews that any manipulation of the grant process occurred for either the August 2nd or December 5th awards. He added that the overall process is sound, particularly with the addition of monitoring by the outside monitor, Grant Thornton, and with the hiring of the chief compliance officer. These grant awards should move to contract finalization. This has been communicated and recommended to the leadership and to key legislative members and legislative committees.

Mr. Hamilton updated the Oversight Committee on the second phase of the review. He said SRA, CPRIT's third-party grant administrator, is developing profiles for the 300 CPRIT grants that have not already been reviewed in the first phase. This is a separate process from the one used for the frozen grants because the approval process has changed over time. All the profiles will be completed soon for phase II. Reports to the Committee and leadership will be given at that time.

Phase III involves making a cross walk of the grants awarded with the donors to the CPRIT Foundation and will begin soon. Reports to the Committee and leadership will be given when completed.

He added that it is vital that more resources be devoted to compliance and to post-award grant monitoring.

He also stated that he and Mr. Roberts have communicated to the Legislature that the process for grant approval is outstanding and has been markedly improved in recent months. He believes there should be confidence in the process. There are checks and balances that were in place, have been added, or will be added under Senate Bill 149 or by rule changes to be presented to the Oversight Committee shortly.

Comments:

Member Tom Luce agreed that more staff is needed to strengthen the process and resources. Mr. Luce requested that the Interim Executive Director itemize CPRIT's resource needs and report at the next Oversight Committee meeting.

Chairman Mansour also asked that it be on record that more full time employees are needed.

Member Charles Tate asked that Chairman Mansour seek a motion that reflected these comments.

Chairman Mansour called for a motion affirming Mr. Hamilton's findings regarding the review of the August and December 2012 slates as described in the Senior Advisor's report.

A motion was made by Charles Tate to support the Senior Advisor's report and findings. The motion was seconded by Tom Luce. None opposed. Motion carried.

Discussion continued on the slates approved at the August and December 2012 meeting. Member Tom Luce stated he understood why the moratorium was established. However, after hearing the Senior Advisor to the Oversight Committee indicate that there is no evidence of deviation of the grant process for either slate, he felt confident in recommending that the contracts be negotiated.

Member Charles Tate stated that many recruitment grants are part of the moratorium and the recruiting institutions have concern that additional delay may result in losses to Texas. He said everything that can be done short of signing the contract should occur.

Member Tom Luce agreed with Mr. Tate, and said it is important to affirm and preserve these grants. He suggested beginning negotiations to keep the grants alive so they would not expire from inaction.

Chairman Mansour clarified that at both August and December 2012 meetings these grants were ratified and the Committee approved delegating authority to negotiate and sign contracts to the executive director and general counsel.

General Counsel Kristen Doyle stated that once the moratorium is lifted CPRIT should be ready to move forward quickly to execute the contracts.

Member Faith Johnson expressed a concern with moving forward with negotiating contracts. She wanted a confirmation that the Committee is not in violation of the moratorium by moving forward with negotiating but not executing.

Ms. Doyle responded that a grant award is not considered final under CPRIT's statute until a contract is executed.

Member Barbara Canales agreed with Faith Johnson, saying that she favors Mr. Luce's use of the word "preservation" in describing what we want to do with the grants during the moratorium. She supported lifting the moratorium.

Ms. Canales requested a clarification from Mr. Hamilton regarding the findings on the MIRA grant. She asked if he found anything sinister or malicious in his review that caused the process to not be followed.

Mr. Hamilton responded that the individual investigator grant that was pulled out from the MIRA for approval simply had the misfortune of being approved outside of the process that should have been followed. This was not something the Oversight Committee could have known had happened. He then stated that the other grants reviewed had no problematic issues and it was a fair competition. The procedures were followed.

Member Charles Tate asked that Chairman Mansour seek a motion to instruct staff not to execute contracts, but preserve these announced awards by negotiating the contracts to be ready to be executed once the moratorium is lifted.

Chairman Mansour called for a motion to instruct staff not to execute contracts, but nevertheless preserve the announced awards by negotiating terms to be ready to execute once the moratorium is lifted.

A motion was made by Faith Johnson to instruct staff not to execute contracts, but nevertheless preserve the announced awards by negotiating terms and be ready execute once the moratorium is lifted. The motion was seconded by Tom Luce. None opposed. Motion carried.

Governance Committee Report

Barbara Canales, Board Governance Committee Chair, gave an overview of the Governance Committee's report.

Bylaws and Policies

Ms. Canales began by reminding members that at the December 5th meeting, the Board Governance Committee presented several recommendations to be included in the Board Bylaws and the Oversight Committee approved these recommendations. Each of the recommendations has been included in the proposed bylaws provided to the Oversight Committee for their consideration. Ms. Canales noted that some of the bylaws address recommendations made by the auditor.

Approved Recommendations and Proposed Bylaw Provisions

No.	Recommendation	Bylaw Section
1	Adopt a process for electing Board Chair and Vice Chair	5.1, 5.2
2	Adopt a succession policy in event of vacancy	5.2
3	Establish two-year term limits for Board Chair, Vice Chair	5.2
4	Defines roles/responsibilities for Chair, Vice Chair	5.3, 5.4
5	Approve/delegate approval of strategic partnerships, alliances and coalitions	3.8
6	Scientific Research subcommittee and Prevention subcommittee join the existing Development Subcommittee (formerly the "Economic Development and Commercialization Subcommittee")	4.8, 4.9
7	Board Governance and Ethics Subcommittee responsibilities	4.5
8	Audit Subcommittee responsibilities	4.4
9	Executive Committee membership	4.3
10	Executive Committee conducts the Executive Director's annual performance review	4.3
11	General Counsel provides new board member and training updates	3.15
12	Board Governance develops delegation of authority policy	4.5
13	ED reports on grant progress and allocation of funds quarterly	6.5
14	Compliance Officer reports on best practices for grant review and monitoring	7.2
15	Program chiefs and program subcommittees develop process for feedback to triaged grant applicants	4.7, 4.8, 4.9
16	ED reports on CPRIT Foundation governance and CPRIT/CPRIT Foundation relationship	6.6
17	CPRIT Foundation ED reports annually to the OC on Foundation	6.6
18	OC Chair and CPRIT Foundation Chair held by different people	5.3

Chairman Mansour suggested an amendment to the text of Section 5.2 “Selection, Term of Office and Removal.” Chairman Mansour proposed adding the following text as the first sentence in Section 5.2: *“At the first regular Oversight Committee meeting following the adoption of these bylaws, the members of the Oversight Committee shall select the Chairperson and Vice Chairperson by a vote of a simple majority as set forth in Section 3.13.”*

Subcommittees

Ms. Canales reported that the Board Governance Committee also worked to reconstitute board subcommittees and create new subcommittees as called for by the bylaws. All board members were consulted on committee assignments. Ms. Canales concluded by saying that the work of these subcommittees will strengthen the Oversight Committee and the role it plays in governing CPRIT.

Executive Committee

- Jimmy Mansour (Chair)
- Joe Bailes (Vice Chair)
- Charles Tate (Chair of Development Subcommittee)
- Barbara Canales (Chair of Prevention Subcommittee)
- Mark Watson (Chair of Scientific Research Subcommittee)

Nominations Subcommittee

- Joe Bailes (Chair)
- Alex Meade
- Charles Tate

Development Subcommittee

- Charles Tate (Chair)
- Walker Moody
- Tom Luce

Audit Subcommittee

- Mark Watson (Chair)
- Walker Moody
- Faith Johnson
- Jimmy Mansour
- Joe Bailes

Scientific Research Subcommittee

- Mark Watson (Chair)
- Jimmy Mansour
- Alex Meade

Board Governance and Ethics Subcommittee

- Walker Moody (Chair)
- Barbara Canales
- Tom Luce
- Jimmy Mansour
- Joe Bailes

Prevention Subcommittee

- Barbara Canales (Chair)
- Faith Johnson
- Joe Bailes

Diversity Subcommittee

- Faith Johnson (Chair)
- Alex Meade
- Barbara Canales

Chairman Mansour called for a motion to approve the subcommittee assignments.

A motion was made by Faith Johnson to approve the subcommittee assignments. The motion was seconded by Barbara Canales. None opposed. Motion carried.

Code of Ethics and Conduct Policy

Ms. Canales reported on the Code of Ethics and Conduct Policy that the Board Governance subcommittee reviewed. As noted in the proposed bylaws, the Code of Ethics and Conduct will be incorporated by reference as part of the Board Bylaws.

The Code of Ethics and Conduct Policy brings together into one document all of the statutory provisions and administrative rules already adopted by the Oversight Committee regarding the ethical conduct of the board and the agency.

While the Committee has always operated pursuant to the guidance in the Code of Conduct and Ethics, the Board Governance subcommittee believes this document supports CPRIT's commitment to increased transparency.

Ms. Canales invited Patricia Vojack, Compliance Officer, to give the Committee a brief overview of the policy.

Ms. Vojack introduced the proposed Code of Ethics and Conduct Policy. An important part of the compliance program is the Code of Ethics and Conduct Policy. This sets forth values, ethical principles and ethical standards to which the agency aspires and by which our actions can be judged. She indicated that the Code is the central guide and reference for the Oversight Committee and CPRIT employees in support of day-to-day decision making. Ms. Vojack reviewed key sections of the policy.

Comments:

The Board discussed changes to the proposed Code of Conduct:

Subchapter A. General Provisions

Sec. 1.02. Definitions. In this Code:

(7) "Pecuniary interest"

(A) ownership of five percent or more of the stock or shares of the business entity; or.....

The members discussed adding text so that it would refer to shares held prior to joining the Oversight Committee or becoming a CPRIT employee. In the event there is a pecuniary interest, the member should recuse him or herself. Mr. Tate and Mr. Luce asked staff to prepare proposed wording changes to reflect the discussion and bring those changes back to the Committee for consideration at a future meeting.

Sec. 1.08. General Standards of Conduct for Members and Employees

Mr. Luce recommended removing the text "might reasonably" from (1) – (5).

Subchapter B. Conflicts of Interest

Sec. 2.08. Procedures for Employee's Disclosure of Conflict of Interest.

Ms. Vojack recommended replacing the word "financial" with "annual."

Chairman Mansour thanked the Board Governance and Ethics Subcommittee for its work. He also reported that, with the amendment to the Bylaws that is currently pending, officer elections will take place at the next meeting on March 21, 2013. He said he was appreciative of all members' support for the past four years.

Chairman Mansour called for a motion to approve the proposed Board Bylaws and Policies and Code of Ethics and Conduct Policy with changes recommended by the Committee and have these changes reflected in the minutes.

A motion was made by Tom Luce to approve the proposed Board Bylaws and Policies and Code of Ethics and Conduct Policy with changes recommended by the Committee and reflected changes in the minutes. The motion was seconded by Charles Tate. None opposed. Motion carried.

CPRIT Foundation Structure and Relationship to CPRIT

Member Tom Luce led the discussion by saying that the Committee needs to look at the pros and cons of maintaining these as two separate entities.

He suggested that the Board officially adopt the State Auditors recommendations.

Chairman Mansour agreed that the Committee endorse all audit recommendations. He then called for a motion to adopt the State Auditor's report and implement recommendations as reflected in the report.

A motion was made by Tom Luce to adopt and endorse the State Auditor's report and implement recommendation as reflected in the report. The motion was seconded by Faith Johnson. None opposed. Motion carried.

Proposed Changes to Texas Administrative Code Title 25, Chapters 702 & 703

General Counsel Kristen Doyle presented proposed rule changes on behalf of the Board Governance Committee. She gave an overview of CPRIT's Administrative Rules and the changes made to implement state audit report recommendations and to codify some of CPRIT's current practices. Ms. Doyle explained the timeline for rulemaking, including the public comment period. As part of the rulemaking process, CPRIT will provide the proposed rules to the Lieutenant Governor and Speaker of the House for legislative input.

Ms. Doyle reported some of the proposed rule change highlights:

Chapter 702 – Institute Standards on Ethics and Conflicts

- Expands Code of Conduct applicability to CPRIT's peer reviewers
- Defines "business or professional activity" to include serving on the board of directors
- Requires adopting a Code of Conduct and Ethics
- Includes certain relationships with foundations affiliated with grant applicants as part of the professional conflict check
- Retains supporting documentation for the Conflict Of Interest policy

Chapter 703 – Grants for Cancer Prevention and Research

- Requires applications be submitted via CARS by the proposal deadline to be eligible
- Adds certification that an applicant has not contributed to the CPRIT Foundation and to identify all sources of funding
- Provides for written explanations when recommendations do not follow score order

- Adopts independent third-party observer as part of grant review to document processes followed
- Incorporates compliance activities and mandates compliance certification as part of the final decision on grant awards
- Enhances award contract provisions, including close-out requirements and right of termination
- Clarifies audit requirements for grant recipients

Proposed New Rule Highlights:

703.21 – Monitoring Grant Award Performance

- Requires annual submission of progress report
- Reviewed for sufficient progress with process for modifying/terminating the contract if progress is not being made
- Progress report results will be presented to the Oversight Committee

703.25 – Compliance and Ethics Program

- Compliance Officer will oversee and report on compliance activities

703.26 – Complaint, Reporting and Investigation of Compliance Violations

- Establishes an Ethics Hotline
- Requires prompt investigation following receipt of report

Comments:

Member Barbara Canales requested clarification on how the proposed rules affect the matching funds requirement.

Ms. Doyle responded that the matching funds requirement is an issue that is being considered by the Legislature and expects to return to the Committee with additional changes to the matching funds requirement. Some changes have been proposed to the rule for matching funds. Additional changes may be made by the Legislature.

Member Tom Luce thanked the General Counsel for her dedication to this project.

The Committee discussed changes to the proposed rules. Mr. Tate suggested adding text clarifying that § 702.9(12) applied to governing boards, not advisory committees.

Chairman Mansour called for a motion to instruct staff to publish the proposed rule amendments to Texas Administrative Code Title 25, Chapter 702 & 703, with the changes recommended by the Committee, in the “Rules Proposed” section of the *Texas Register* in accordance with the requirements of the Administrative Procedure Act.

A motion was made by Faith Johnson to instruct staff to publish the proposed rule amendments to Texas Administrative Code Title 25, Chapter 702 & 703, with the changes recommended by the Committee in the “Rules Proposed” section of the Texas Register in accordance with the requirements of the Administrative Procedure Act. The motion was seconded by Joseph Bailes. None opposed. Motion carried.

Subsequent to the vote on the motion, Ms. Doyle noted that based on the previous discussion related to the changes to the bylaws it would be appropriate to instruct staff to make any necessary changes to the proposed rules so that the proposed rules were consistent with the bylaw changes.

Chairman Mansour called for a motion to direct general counsel to make changes in the proposed rules consistent with the changes to the bylaws that apply to CPRIT employees.

A motion was made by Tom Luce to direct the general counsel to make changes in the proposed rules consistent with the changes in the bylaws that apply to CPRIT employees. The motion was seconded by Faith Johnson. None opposed. Motion carried.

CPRIT Annual Conference

Mr. Roberts expressed concern about having an October 2013 CPRIT conference. His primary concern is not knowing CPRIT's future make it difficult to plan for the conference. Also, booking a conference for October may send a message to the Legislature that CPRIT is not sufficiently concerned about its current situation. Mr. Roberts would like to focus first on making sure that CPRIT grant programs operate effectively and implement legislative changes and the State Auditor's recommendations. If the Committee wants to proceed with the October conference, contracts would need to be executed quickly but he suggested a much scaled down event.

His recommendation is not to hold a 2013 conference. He suggested planning a biennial conference to coincide with legislative sessions to give legislators the opportunity to attend. Mr. Roberts asked the Committee for further direction.

Board Members Faith Johnson, Mark Watson, Joseph Bailes, Barbara Canales, and Chairman Mansour all spoke in favor of Mr. Roberts' points for not holding the conference in October 2013.

The members also emphasized that the event is important for CPRIT so that the scientific community and grant awardees can see learn from other's work and for networking purposes. They also suggested considering retaining a conference contractor to plan these events.

No member advocated for holding the conference this year. CPRIT will proceed with planning a biennial event.

Change of Venue for Oversight Committee Meetings

Mr. Roberts suggested moving Committee meetings to one of the Capitol Extension hearing rooms. This change would occur after the Legislature adjourns. This move would improve transparency and openness, provide easier access for the general public, legislators, and their staff to access meetings. The Extension offers webcasting so one does not need to come to Austin to watch a CPRIT meeting; there is no cost for using Extension rooms.

All members agreed with Mr. Roberts' proposal.

Chief Operating Officer Report

Reports presented by Heidi McConnell, Chief Operating Officer:

- Financial Report
- FY 2013 First Quarter Performance Report
- General Obligation Bond Issuance Update

Comments:

Member Charles Tate requested that the interest rates be added to the general obligation bond issuance report.

Member Barbara Canales reported that at one of the committee hearings Senator West asked about the agency's HUB report. She said Heidi McConnell responded to the question. However, she would like the Committee to instruct the chief operating officer to address the report to the Committee, including reasons for low numbers. Interim Executive Director Roberts said that at the next Committee meeting he will provide the material given to Senator West explaining the CPRIT's use of HUBs.

Compliance Officer Report

Patricia Vojack, Compliance Officer, reported on compliance program activities including:

- Code of Ethics and Conduct policy
- Verification of grant awards – application pedigree
- Process documentation of the grant applications from online application submission to presentation to the Oversight Committee for ratification
- Verified 129 prior approved grant awards
- In process of verifying all past awards
- Ensuring the Institute is in compliance with the General Appropriations Act and donations to CPRIT Foundation
- Delineated the process of verification and certification of grant applicants
- Report on NIH grant application and management process and best practices recommendations. Also NCI grant management processes
- Met with Governor's staff in the Compliance and Oversight Division and discuss their process for grant monitoring.
- Best practices in a grant program include
 - Internal controls;
 - Performance measures;
 - A well defined pre-award process;
 - Managing performance through regular reviews—monitoring and qualitative measures; and
 - Assessing and using results to demonstrate program success.

Consultation with Counsel

No discussion or action taken regarding this item.

Future Meetings Dates and Agenda Items

Mr. Roberts reported that the next meetings are scheduled for March 21, 2013, May 22, 2013, and August 15, 2013.

He asked the Committee to consider changing the scheduled May 22, 2013, meeting to April 29th at 11:30 a.m. This would allow staff time to respond to comments received from the March 15 *Texas Register* posting and appropriate adoption of rules and regulations. In addition, it would allow for more staff and Oversight Committee flexibility during the closing days of the current legislative sessions.

All members agreed. The May 22nd meeting was replaced with the April 29, 2013, date.

Chairman Mansour announced that Oversight Committee members Barbara Canales, Walker Moody and Alex Meade have terms that expired in January. They will remain as Committee members until they are replaced. The Committee thanked them for their dedication and service.

Mr. Roberts reported that one new gubernatorial Oversight Committee member had been appointed but not confirmed.

Public Comment

Chairman Mansour called for public comments. None were submitted.

Adjournment

There being no further business, Chairman Mansour called for a motion to adjourn.

Motion was made by Mark Watson to adjourn the meeting. The motion was seconded by Faith Johnson. None opposed. Motion carried.

Meeting adjourned at 3:30 p.m.

Signature

Date

All of the items in this section are elements that will be discussed in the Executive Director's Report to the Oversight Committee.



**CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS**

MEMORANDUM

TO: OVERSIGHT COMMITTEE
FROM: WAYNE ROBERTS, INTERIM EXECUTIVE DIRECTOR
SUBJECT: LEGISLATIVE WRAP-UP
DATE: OCTOBER 28, 2013

The two items in this portion of the agenda provide a high level overview of significant actions by the 83rd Legislature affecting CPRIT. These include:

- “Summary of Legislation Related to CPRIT”—summarizes key legislation with special emphasis on Senate Bill 149, the bill containing major revisions to CPRIT’s enabling legislation. Also summarizes legislation creating a new interest and sinking fund for royalties, equity and other revenue payments (although enacted, not implemented in FY2014-15 due to another bill related to funds consolidation); public information requirement changes; reporting and posting of agency executive staff compensation and salary supplementations; and reporting and posting of all audits.
- Memorandum to the Oversight Committee on “Major New Biennial Legislative Spending Restrictions”, October 23, 2013—this transmittal summarizes new appropriations-related constraints that are unique to CPRIT.

Summary of Legislation Related to CPRIT

SB 149 by Senator Nelson

CPRIT Governance

This bill restructures CPRIT governance by renaming the Executive Director as the Chief Executive Officer (CEO) and enhancing the position's pre-requisite qualifications to include “a demonstrated ability to lead and develop academic, commercial, and governmental partnerships and coalitions.” It directs the CEO to hire a Chief Scientific Officer, Chief Product Development Officer, Chief Prevention Officer, and Chief Operating Officer, clarifying that these positions report directly to the CEO. The bill also directs the CEO to hire a Compliance Officer to oversee the program to ensure that all applicable laws, rules and procedures are followed in the grant award process and post-award administration under the newly established compliance program.

The bill removes the Attorney General and Comptroller of Public Accounts from the Oversight Committee. The bill ends the terms of the currently appointed Oversight Committee members on the date that the bill takes effect and directs the Governor, Lieutenant Governor, and Speaker to each appoint one member with a term expiring January 31, 2015, another with a term expiring on January 31, 2017, and another with a term expiring on January 31, 2019 as soon as possible. The purpose of ending the terms of the Oversight Committee in this manner is to allow the appointing offices to comply with another new provision of the law and include among their three appointments at least one member who is a physician or scientist with experience in oncology. It requires the Oversight Committee to elect a presiding officer and assistant presiding officer every two years, with a limit on the length of service in those positions to one term (two years). The bill also allows the Oversight Committee to elect other officers in addition those listed above. Oversight Committee members serve at the pleasure of the official who appointed them. It also requires that the Oversight Committee adopt duties and responsibilities for officer positions and the Oversight Committee to distinguish the positions from the responsibilities of the CEO and other CPRIT staff.

Oversight Committee members will be required to report to the Institute any political contributions of \$1,000 or more to candidates for state or federal office in the five years preceding their appointment and each year after their appointment through the end of their terms as members. CPRIT will be required to compile a report of this information and post it on the agency’s website.

Grant Approval

The bill makes changes in the grant approval process. It requires the Oversight Committee, according to legislative direction, to establish priorities for each grant program as well as the different types of research. The bill changes the authority of the Oversight Committee from current law that allows the two-thirds of the members to override award recommendations to a two-thirds vote affirmatively approving award recommendations. It also requires scoring and documentation of factors considered in making each award. The bill adds trained patient advocates to peer review committees.

The bill reduces the authority of the Executive Director (Chief Executive Officer) by establishing a Program Integration Committee (PIC) to review all grants after initial reviews by the various peer review committees and prepare a list of recommendations to the oversight committee. The PIC

would be composed of five members including the CEO, Chief Scientific Officer, Chief Product Development Officer, Chief Prevention Officer, and Commissioner of Health. The Compliance Officer would not serve on the PIC but would be required to observe PIC meetings as part of the officer's duties.

The CEO will be required to submit to the Oversight Committee a written affidavit for each grant award recommendation containing information about the peer review process, score, and any applicable due diligence or intellectual property reviews.

The bill requires grant recipients to dedicate an amount of matching funds equal to one-half of the amount of the grant awarded and specify the amount of matching funds to be dedicated to project, the period of the award and the specific deliverables of the research that is subject the subject of the grant proposal. The bill allows public and private institutions of higher education to use the difference between their allowed federal indirect cost rate (generally over 50 percent) and the 5 percent limitation on indirect costs in CPRIT grants towards the dedicated matching funds requirement.

The bill directs CPRIT to establish a system to document and justify increases in peer reviewer honorarium and implement a policy on in-state or out-of-state residency requirements for peer reviewers. It also directs CPRIT to implement a policy on advance payments to grant recipients.

Conflicts of Interest and Ethics

The bill establishes conflict of interest policies requiring recusal from the consideration of a grant award and standards of conduct policies for Oversight Committee members, PIC members, peer reviewers and CPRIT employees. It establishes a process to investigate unreported conflicts of interest by the general counsel and outlines the disposition of an investigation by the CEO or presiding officer of the Oversight Committee, as appropriate. The bill also provides a process for waiving the conflict of interest requirements for exceptional circumstances. ***It requires that all reported conflicts as well as any unreported conflicts confirmed by an investigation be listed on the agency's website.***

The bill requires the Oversight Committee to adopt a code of conduct to apply to the Oversight Committee, CPRIT employees, and PIC members. The bill strengthens rules prohibiting business relationships among grantees and CPRIT employees, Oversight Committee members, and peer reviewers. It prohibits members of the Oversight Committee, peer reviewers, and CPRIT employees from serving on a grantee's board of directors. The bill does not allow salary supplementation from any sources other than a legislative appropriation for the Chief Scientific Officer.

The bill prohibits CPRIT employees from having offices located at facilities owned by entities receiving or applying to receive funding from CPRIT.

Compliance Program

The bill directs the Compliance Officer to track and monitor grant recipient reporting, and to verify grant recipients' matching funds annually. It also requires the Compliance Officer to notify the general counsel and oversight committee of any grant recipients that have not maintained compliance with reporting requirements or matching funds provisions of the contract so that CPRIT

may initiate contract suspension or termination activities. The bill provides for procedures to confidentially report and investigate compliance violations.

CPRIT Fund

The bill incorporates language that was in SB 150 by Nelson to require royalty, equity and other revenue payments collected from CPRIT grant recipients with successfully commercialized discoveries to be deposited into a new sinking fund and applied toward paying the debt service on the bonds issued for grant awards.

The Senate still has to concur with the changes made to the bill in the House, and then it will be sent to the Governor for consideration. Because this bill passed both chambers with a two-thirds affirmative vote, it can take immediate effect once signed by the Governor.

Bill Status: ***Senate Concurs with House Amendments (31-0), May 24, 2013***
Voted out of the House (140-3) May 20, 2013.
Voted out of the Senate (31-0) on April 3, 2013

SB 895 by Senators Davis, Ellis, Nelson

SB 895 clarifies that the documents and records of the CPRIT Foundation are public information. This bill passed both chambers with a two-thirds affirmative vote and can take immediate effect once signed by the Governor.

Bill Status: ***Voted out of the House (146-0) on May 20, 2013.***
Voted out of the Senate (29-0) on April 16, 2013

HB 12 by Representative Flynn

HB 12 requires that for a state agency to accept a salary supplement for one of its employees, the amount of the salary supplement, methodology for determining the supplement, and the origination of the funding for the supplement, including the names of donors who provide \$10,000 or more in gifts to support a foundation created to support the agency, must be posted on the agency's website. The State Auditor will determine the format and schedule to report this information, and will compile a report of this information for the legislature.

The bill also incorporates language that was previously in HB 9 by Flynn which requires all agencies to post on their websites the amount of compensation being paid to each member of an agency's executive staff along with the methodology, including any employment market analysis, for determining the compensation. Compensation includes any salary supplement or other salary enhancement paid to a member of an agency's executive staff.

This bill passed both chambers with a two-thirds affirmative vote and can take immediate effect once signed by the Governor.

Bill Status: *Passed out of the Senate (Unanimous on Local Calendar) on May 21, 2013*
Voted out of the House (140-0) on May 10, 2013

HB 16 by Representative Flynn

HB 16 requires all agencies to post all agency audits, including internal audits and risk assessments, on their websites. The State Auditor will determine the format and schedule that agencies will use to report this information.

This bill passed both chambers with a two-thirds affirmative vote and can take immediate effect once signed by the Governor.

Bill Status: *Passed out of the Senate (Unanimous on Local Calendar) on May 21, 2013*
Voted out of the House (140-0) on May 10, 2013



**CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS**

MEMORANDUM

TO: OVERSIGHT COMMITTEE
FROM: WAYNE ROBERTS, INTERIM EXECUTIVE DIRECTOR
SUBJECT: MAJOR NEW BIENNIAL LEGISLATIVE SPENDING RESTRICTIONS
DATE: OCTOBER 23, 2013

The enacted 2014-15 biennial appropriations for the Cancer Prevention and Research Institute of Texas (CPRIT) provided the full historical level of \$300 million per year from general revenue obligation bond proceeds with five notable new restrictions. Such restrictions frequently appear after a state agency experiences operational or fiscal difficulties. The new restrictions are:

1. In prior biennia CPRIT had been authorized to carryforward issued but unused bond proceed balances from one biennia to the next. This authority was removed for 2014-15, resulting in a sum certain appropriation of \$300 million per year for the agency and leaving \$181.2 million in the treasury for future appropriation by the Legislature.

~~**6. Unexpended Balances of Bond Proceeds.** Included in amounts appropriated above are unexpended and unobligated balances of General Obligation Bond Proceeds remaining as of August 31, 2011, (estimated to be \$0) for the Cancer Prevention and Research Institute for the 2012-13 biennium in Strategies A.1.1, Award Cancer Research Grants, A.1.2, Award Cancer Prevention Grants, A.1.3, Grant Review and Award Operations, and B.1.1, Indirect Administration for purposes authorized by Health and Safety Code Chapter 102. Any unexpended balances in General Obligation Bond Proceeds described herein and remaining as of August 31, 2012, are hereby appropriated for the same purposes for the fiscal year beginning September 1, 2012.~~

2. Authority to carryforward balances from the first year of the biennium (2014) to the second year (2015) was eliminated. Again, resulting in a sum certain appropriation of \$300.0 million for FY 2015. The FY 2014 lapse is unknown at this time.

~~**3. Unexpended Balances Within the Biennium.** Any unexpended balances remaining as of August 31, 2012, in the appropriations made above are hereby appropriated for the fiscal year beginning September 1, 2012~~

3. Transfers between line items of appropriations without approval by the Legislative Budget Board (LBB) were prohibited. The amounts allocated between line items for 2014-15 were not adjusted for several decisions by the budget conferees. On July 17, 2013, CPRIT requested transfers between line items to accommodate CPRIT's funding needs for 2014 and to reflect legislatively approved adjustments (Attachment 1). Approval of this request was made on August 28, 2013 (Attachment 2). Future requests, certainly for FY 2015, may be necessary depending upon other developments.

5. Transfer Authority. Notwithstanding Article IX, Section 14.01, Appropriation Transfers, no appropriations or unexpended balances may be transferred out of Strategy A.1.1, Award Cancer Research Grants or Strategy A.1.2, Award Cancer Prevention Grants, unless the Cancer Prevention and Research Institute of Texas submits a written request to the Legislative Budget Board, in a format prescribed by the Legislative Budget Board, that provides information regarding the purposes for the transfer; and the Legislative Budget Board issues written approval.

4. CPRIT is now prohibited from entering into contracts in excess of \$100,000 without approval by the LBB. CPRIT issues numerous contracts in excess of \$100,000, which require Oversight Committee approval, so contract approval requests may be frequent.

9. Limitation on Expenditure for Contracts. Without the prior approval of the Legislative Budget Board, the Cancer Prevention and Research Institute of Texas shall not use funds appropriated above to enter into any contract, excluding grant awards under Health and Safety Code Chapter 102, Subchapter F, in excess of \$100,000. Additional information requested by the Legislative Budget Board related to this approval shall be provided in a timely manner and shall be prepared in a format specified by the Legislative Budget Board.

5. CPRIT is required to work with the Texas Facilities Commission (TFC) to find state-owned space in lieu of lease facilities by December 31, 2013. Minimizing lease space is a longstanding goal of the the Legislature and a good business practice. CPRIT's current lease expires February 28, 2014. The only state-owned space available by December 31 is a former warehouse that technically meets CPRIT's space needs. Due to the likely disruption in resuming CPRIT's award process and implementing the provisions of Senate Bill 149 and state audit findings, CPRIT requested removal of the December 31 deadline on September 25, 2013, to allow the agency and TFC additional time to find suitable state-owned space (Attachment 3). As of this writing, LBB's response has not been received.

7. Limit on Expenditures. Contingent on the passage of Senate Bill 149, House Bill 951, or similar legislation, by the Eighty-third Legislature, Regular Session, 2013, relating to the administration of the Cancer Prevention and Research Institute of Texas, the agency may expend an amount not to exceed \$150,623 out of General Obligation Bond Proceeds appropriated above in Strategies A.1.3, Grant Review and Award Operations and B.1.1, Indirect Administration, to close out lease

expenses and costs related to moving the agency into state-owned space. The Cancer Prevention and Research Institute of Texas shall work with the Texas Facilities Commission to relocate into state-owned space no later than December 31, 2013.

If the agency is unable to move into state-owned space by this date, they must submit a letter to the Legislative Budget Board no later than 45 days prior to this date providing information regarding why the agency is unable to meet this deadline and any request for additional appropriation authority related to continuing lease payments. The agency may expend additional General Obligation Bond Proceeds out of Strategy B.1.1, Indirect administration if the agency is provided written approval by the Legislative Budget Board.

**CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS**

July 17, 2013

Ms. Ursula Parks
Director
Legislative Budget Board
P.O. Box 12666
Austin, Texas 78711-2666

Dear Ms. ^{Ursula}~~Parks~~:

Pursuant to Senate Bill 1, 83rd Legislature, R.S., page I-16, Rider 5 (General Appropriations Act), Cancer Prevention and Research Institute of Texas (CPRIT), I request approval of two transfers for FY 2014 totaling \$4,947,676 from Strategy A.1.1 Award Cancer Research Grants. The first is for \$4,486,861 to Strategy A.1.3. Grant Review and Award Operations. The second is for \$460,815 to Strategy B.1.1. Indirect Administration.

This transfer is necessary to fund legislative priorities including sustaining contracted support services for pre- and post-award grants management, sustaining legal services for award contracts, funding eight new full-time equivalent salaries, and full state support for two exempt positions, among other expenses.

The Legislature provided total funding in the 2014-15 biennium for CPRIT with the expectation that historical program operating levels should continue. A reduction of administration and operations to the level specified in Senate Bill 1 would seriously erode our ability to meet legislative intent to continue current operating levels, prevent full implementation of Senate Bill 149 (CPRIT "reform" legislation), and prevent expected increased operational accountability.

Our proposed FY 2014 operating budget is based on the original FY 2013 budget assuming no moratorium had occurred that suspended our grant review and award process. Although new grant awards were stopped, agency operations continued with little reduction resulting from the moratorium. New grant award expenses were reduced but those "savings" were "realized" through cost avoidance since no additional bonds were issued to cover the delayed expenses. Basic agency operations, such as grant and fiscal oversight, in-house legal services, and compliance reviews, continued unabated, and in some instances increased.

CPRIT must maintain contracted support services for pre- and post-award grants management. These services augment CPRIT's limited state staff capabilities with scientific, technical, and information system resources to be able to receive and manage grant applications through a massive online portal; manage multiple in-person, telephonic, and videoconference peer review meetings throughout the year; and evaluate grant award performance and compliance through an electronic system. These computer systems are essential to maintain and access quickly all grant application and award data. CPRIT must also address findings in the State Auditor's January

2013 management report incorporated into Senate Bill 149, as well as extensive reporting and data requirements of a new strict compliance program.

CPRIT must retain contracted legal services to conduct intellectual property due diligence reviews on product development grant applications that move forward for funding recommendations. Each due diligence review costs around \$25,000. Contracted legal services will be needed to structure appropriate revenue sharing agreements, e.g., equity investments, in product development grant award contracts.

This request allows the agency to fill eight new fiscal/program compliance and internal audit staff authorized by the Legislature to help assure that the problems of 2012 never occur again. Since CPRIT must pay all employee benefits from its appropriations, all salary costs herein include the associated benefit costs calculated at a rate of 29.74 percent. The mandated 1 percent cost-of-living-adjustment is provided for all eligible employees on board in FY 2013. In addition, we are realigning \$658,562 of salaries and related benefit costs from Indirect Administration to Grant Review and Award Operations. This reallocation of half of the salaries of six positions—the Chief Executive Officer, Chief Operating Officer, General Counsel, Finance Manager, Accountant, and Operations Manager—recognizes the documented portion of time that these individuals spend directly supporting the pre-award grants process and post-award grants contracting, reporting, and overall management.

Finally, this request fully funds the salaries of the chief scientific officer and the newly renamed position of chief executive officer. Prior to FY 2014 these salaries were heavily supplemented by the now defunct CPRIT Foundation. General law now prohibits salary supplementation for these positions. In recognition of this prohibition, the Legislature authorized paying the full amount of these salaries from state funds (bond proceeds). This additional salary cost is \$364,000 plus benefits.

Attached are documents providing detailed information concerning this request. If you need additional information, please contact me at 512-305-8416 or our chief operating officer, Heidi McConnell, at 512-305-8487.

I appreciate the time you and others may take in considering this request.

Sincerely,



Wayne R. Roberts
Interim Executive Director

cc: Heidi McConnell

Attachments: 2014 Budget Comparison
New CPRIT Personnel Costs

**Cancer Prevention and Research Institute of Texas
2014 Budget Comparison**

Institution Operations (Indirect)									
	2014 Budgeted	Indirect Costs Reallocation	Increase CEO to Authorized Salary	Increase CSO to Authorized Salary	Prorated Share of Additional FTEs	1% COLA (Legislative Salary Increase)	2014 Revised Budget	2014 Appropriated	Difference Budget / Appropriated
Salaries and Wages	\$ 1,832,506	\$ (658,562)	\$ 46,706	\$ -	\$ 149,149	\$ 16,397	\$ 1,386,197		
Other Personnel Costs	50,000						50,000		
Professional Fees and Services	928,321						928,321		
Consumable Supplies	22,500						22,500		
Utilities	63,648						63,648		
Travel	34,874						34,874		
Rent - Building	415,450						415,450		
Rent-Machine and Other	24,150						24,150		
Other Operating Expenses	342,551						342,551		
Subtotal - Institution Operations	\$ 3,714,000	\$ (658,562)	\$ 46,706	\$ -	\$ 149,149	\$ 16,397	\$ 3,267,690	\$ 2,806,875	\$ (460,815)
Grant Review and Award Operations									
	2014 Budgeted	Indirect Costs Reallocation	Increase CEO to Authorized Salary	Increase CSO to Authorized Salary	Prorated Share of Additional FTEs	1% COLA (Legislative Salary Increase)	2014 Revised Budget	2014 Appropriated	Difference Budget / Appropriated
Salaries and Wages	\$ 1,110,014	\$ 658,562	\$ -	\$ 425,547	\$ 405,639	\$ 27,320	\$ 2,627,082		
Other Personnel Costs	100,000						100,000		
Professional Fees and Services:									
SRA International	7,131,457						7,131,457		
Virtual Management Company (VMC)	-						-		
Peer Review Committee Chair Honoraria	1,177,351						1,177,351		
Contracted Legal Services	300,000						300,000		
Travel	35,430						35,430		
Rent - Building (Houston Office)	32,400						32,400		
Rent-Machine and Other (Houston Office)	7,500						7,500		
Subtotal - Grant Operations	\$ 9,894,152	\$ 658,562	\$ -	\$ 425,547	\$ 405,639	\$ 27,320	\$ 11,411,220	\$ 6,924,359	\$ (4,486,861)
Grants									
	2014 Budgeted	Indirect Costs Reallocation	Increase CEO to Authorized Salary	Increase CSO to Authorized Salary	Prorated Share of Additional FTEs	1% COLA (Legislative Salary Increase)	2014 Revised Budget	2014 Appropriated	Difference Budget / Appropriated
Grants - Prevention	\$ 29,022,567	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 29,022,567	\$ 29,022,567	\$ -
Grants - Research	257,385,281	-	-	-	-	-	256,314,523	261,262,199	4,947,676
Subtotal - Grants	\$ 286,407,848	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 285,337,090	\$ 290,284,766	\$ 4,947,676
Grand Totals	\$ 300,016,000	\$ -	\$ 46,706	\$ 425,547	\$ 554,788	\$ 43,717	\$ 300,016,000	\$ 300,016,000	\$ (0)

* Virtual Management Company (VMC) will be re-evaluated and bid.
CPRI, Rider 5 Request

New CPRIT Personnel Costs

Position Title	Annual Salary ¹	Job Description
Internal Auditor ³	\$79,630	Performs advanced work to plan, conduct, schedule, coordinate, and review audits and report results.
Attorney ³	\$56,775	Assists the general counsel by drafting legal documents and responses to PIRs, advising staff on grant contract issues and legal matters, and interpreting agency policy and state/federal laws.
Grant Accountant	\$53,061	Performs complex grant accounting concerning examination of accounting records for reliability, adequacy, accuracy, efficiency, and regulatory compliance.
Accountant ³	\$53,061	Performs complex accounting work including preparing financial documents, purchasing, and travel vouchers.
Grant Compliance	\$49,590	Performs compliance monitoring by conducting on-site visits of grant recipients, reviewing implementation progress, verifying progress report information, evaluating performance outcomes, examining fiscal records, and providing technical assistance.
Grant Compliance	\$49,590	Performs compliance monitoring by conducting on-site visits of grant recipients, reviewing implementation progress, verifying progress report information, evaluating performance outcomes, examining fiscal records, and providing technical assistance.
Reimbursement Specialist	\$45,454	Performs moderately complex accounting work including analyzing, preparing, and processing requests for grant reimbursements; determines accuracy and budget compliance of grant invoices; performs data entry of information into the accounting system.
Legal Assistant ³	\$40,454	Assists the general counsel and staff attorney with research, analysis and preparation of legal correspondence and other official documents.
Salary Subtotal	\$427,615	
Benefit Subtotal²	\$127,173	
Salary and Benefit Total	\$554,788	

¹Average salary range for classification.

²Employee benefits calculated at 29.74%.

³Salary and benefits are apportioned at 50% between the two operations strategies.



LEGISLATIVE BUDGET BOARD

Robert E. Johnson Bldg.
1501 N. Congress Ave. - 5th Floor
Austin, TX 78701

512/463-1200
Fax: 512/475-2902
<http://www.lbb.state.tx.us>

August 28, 2013

Mr. Wayne R. Roberts
Interim Executive Director
Cancer Prevention and Research Institute of Texas
P.O. Box 12097
Austin, Texas 78711

Dear Mr. Roberts:

Pursuant to Rider 5, Transfer Authority in the Cancer Prevention and Research Institute of Texas's (CPRIT) bill pattern in the General Appropriations Act for the 2014-15 biennium, with approval from the Legislative Budget Board, the agency may transfer funds out of Strategies A.1.1, Award Cancer Research Grants and A.1.2, Award Cancer Prevention Grants into Strategies A.1.3, Grant Review and Award Operations and B.1.1, Indirect Administration.

In a letter dated July 17, 2013, CPRIT requested approval to transfer \$4,486,861 in General Obligation Bond Proceeds from Strategy A.1.1, Award Cancer Research Grants into Strategy A.1.3, Grant Review and Award Operations and \$460,815 in General Obligation Bond Proceeds into Strategy B.1.1, Indirect Administration to maintain an existing contract with SRA International and to fund salaries and wages for eight new FTEs.

The LBB has reviewed the agency's request, and approves the transfer of \$4,497,676 in General Obligation Bond Proceeds out of Strategy A.1.1, Award Cancer Research Grants, into Strategies A.1.3, Grant Review and Award Operations and B.1.1, Indirect Administration in the amounts of \$4,486,861 and \$460,815, respectively

If you need additional information regarding this matter, please contact Emily Morganti, the LBB Analyst assigned to your agency at (512) 463-5311 or emily.morganti@lbb.state.tx.us.

Sincerely,

A handwritten signature in black ink, appearing to read "Ursula Parks".

Ursula Parks
Director

/em

August 28, 2013

Page 2

cc: John Opperman
Sarah Hicks
Rob Orr
John McGeady
Central Files

Andrew Blifford
Keith Yawn
Brady Vaughn
Wayne Pulver
Elizabeth Prado

**CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS**

September 25, 2013

Ms. Ursula Parks
Director
Legislative Budget Board
P.O. Box 12666
Austin, Texas 78711-2666

Ursula
Dear ~~Ms.~~ Parks:

Pursuant to Senate Bill 1, 83rd Legislature, R.S., page I-16, Rider 7 (2014-15 General Appropriations Act), I request removal of the December 31, 2013, deadline for moving the Cancer Prevention and Research Institute of Texas (CPRIT) from its current leased facilities to state-owned space and approval to exceed Rider 7's expenditure cap of \$150,623 for lease costs. Removing the impending relocation provides time for CPRIT and the Texas Facilities Commission (TFC) to devise a plan under established requirements and processes to achieve the goal of Rider 7 without interrupting CPRIT operations.

In an effort to comply with legislative intent I requested the TFC to locate adequate state-owned space suitable for CPRIT's purposes. Unfortunately, the only state-owned space available at this time that meets CPRIT's square footage requirements is a warehouse in an industrial park partially renovated for administrative technical support activities. Costs associated with the move are not inconsequential; TFC estimates that the 2014-15 cost to CPRIT will be \$266,037.

I appreciate and endorse the rationale for the Rider 7 directive; however, I believe that implementing the move by December 31, 2013, will be highly disruptive to CPRIT's operations and will endanger our ability to implement effectively the provisions of Senate Bill 149 (CPRIT modifying legislation). Please consider that CPRIT enters a new stage as soon as the Oversight Committee members are appointed by the Governor, Lieutenant Governor, and Speaker of the House. Between now and December 31, CPRIT must, among other activities:

1. fully inform and orient nine new board members to the complex cancer mitigation and abatement community and educate them on the intricate out-of-state peer review process to a sufficient degree for them to adopt statutorily required programmatic priorities between prevention, research, and commercialization activities;
2. adopt and implement an expansion from 40 to over 120 pages of CPRIT administrative rules and rules changes;
3. modify CPRIT's massive on-line pre-and post-award grants management system to fulfill new statutory requirements and address state audit recommendations;
4. recruit and train twelve specialized professional employees including the chief executive officer;
5. implement a statutorily required compliance program;

6. authorize issuance of \$300 million in general obligation bonds;
7. issue new requests for applications to restart and ramp up the grant award process;
8. develop and inaugurate a strategic communication program to assist in conducting a major national cancer conference for some 800 attendees; and
9. complete a required and expanded annual report statutorily due by January 31, 2014.

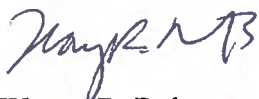
Furthermore, it appears that the impetus for Rider 7 was related to CPRIT's operational issues in 2012 and a presumed end to CPRIT activities due to drastic reduction of funding or legislative termination. Information posted on the Facilities Commission website indicates 27 state agency leases in the Austin area are up for renewal by September 30, 2014, but the only agency affected by a rider truncating the natural end of its lease is CPRIT. However, with the near unanimous passage of Senate Bill 149, CPRIT's mission was renewed and its full funding level restored. Given that the urgent need to end prematurely CPRIT's lease is no longer present, it is appropriate to provide additional time for CPRIT and TFC to effectuate a change to state-owned space. Although this will likely require an extension to CPRIT's lease, CPRIT's lease expenses will be less than previous years. CPRIT reduced its footprint last summer to provide space to the Texas Cancer Registry when that office was displaced for construction at the Department of State Health Services campus. When the Texas Cancer Registry moves out in April, CPRIT expects lease savings to result from its reduced space requirements.

CPRIT's enabling legislation establishes a ten year period to award \$3 billion in general obligation bonds for cancer research and prevention. CPRIT is currently operating under a moratorium on new awards and related activities instituted by state leadership last December. As a result, CPRIT effectively lost 10 percent of its life during fiscal year 2013 while the Legislature determined if and how it wanted CPRIT to exist. I am concerned that if the requirement driving the impending move is not eliminated, then CPRIT's attention for the remainder of the calendar year must be dominated by the move. Reorganizing in a new location will add to the delay in 2014. The time and resources consumed with relocating CPRIT operations at this time will add an additional five to six months delay before CPRIT can resume its grant making activities. The benefit of moving CPRIT to state-owned facilities by December 31 versus the cost of another five to six months in renewing CPRIT's constitutional mission should be carefully weighed.

If you need additional information concerning this request please contact me at 512-305-8416 or our chief operating officer, Heidi McConnell, at 512-305-8487.

I appreciate the time you and others may take in considering this request.

Sincerely,



Wayne R. Roberts
Interim Executive Director

cc: Heidi McConnell



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS
SUBJECT: AUDIT IMPLEMENTATION PLAN
DATE: OCTOBER 28, 2013

The State Auditor issued a report in January regarding CPRIT's grant management processes. The State Auditor's overall conclusion was that CPRIT should significantly improve the transparency and accountability of its grant management processes. The report included 41 specific recommendations to strengthen CPRIT's grant management program. CPRIT immediately and unequivocally agreed to implement all recommendations. SB 149, which was passed with near unanimous support from the House and Senate, incorporated most of the auditor's recommendations.

Stronger administrative controls and policies resulting from changes made to CPRIT's processes following the audit report will increase transparency of the agency's processes and improve the integrity of CPRIT's grant award system, both of which are crucial for restoring the legislature's and public's trust in CPRIT's ability to carry out its mission. The process to implement the State Auditor's recommendations will accelerate with the approval of the administrative rules proposed for the Oversight Committee's consideration at the November 1, 2013 meeting. As reflected on CPRIT's Audit Implementation Plan included in this section, a majority of the audit recommendations are addressed by making changes to CPRIT's administrative rules, including adopting new rules.

No Oversight Committee action is required at this time with regard to the Audit Implementation Plan itself. I will continue to update the Oversight Committee on CPRIT's progress to fulfill every audit recommendation.

CPRIT's IMPLEMENTATION PLAN - STATE AUDITOR'S RECOMMENDATIONS

Statutory and Rule Changes

All SAO recommendations include the page number of the SAO report

Rec. #	Recommendations	Statute	Admin Rule
01 SAO pg 8	Establish and implement rules that prohibit the executive director from discussing grant recommendations with individual members of the oversight committee before presenting those recommendations to the full Oversight Committee.	102.251(d)	702.19(f)
02 SAO pg 2	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.	102.057	702.9(16)
03 SAO pg 8	Revise its rules to prohibit members of the oversight committee, peer reviewers, and employees from engaging in business activities with grant applicants and grantees.	102.109 (b)(2), 102.156(c)	702.9(2), 703.5(h)
04 SAO pg 9	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).	102.251(e)	703.3(h)(1)
05 SAO pg 9	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.	102.251(a)(3)	703.3(h)(4), 703.8(1)(C)
06 SAO pg 9	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.		702.13(c)
07 SAO pg 9	Consistently maintain documentation to show that it identifies and takes action to address its peer reviewers' conflicts of interests.	102.0535(a)(4)	703.3(i) 703.4(1)(C)

08 SAO pg 9	Establish and implement a documented policy on residency requirements for members of its commercialization review council.	102.151(b)	701.17
09 SAO pg 16	Update and consistently follow agency policies and procedures for reviewing grant applications.	102.051(d)(1)	703.8(1)(A)
10 SAO pg 16	Require the executive director 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.	102.251(c)	703.7(7)
11 SAO pg 16	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.	102.251	703.4(1)(A)
12 SAO pg 16	Maintain and secure data that supports why grant applications are withdrawn from the peer review process.	102.0535(a)(1)	703.4
13 SAO pg 16	Require peer review councils to document how applications recommended for grants meet one or more of the recommendation standards.	102.251(a)(1)(B)	703.6(d)(2)(A)
14 SAO pg 16	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.	102.251(a)(2)(A) and (B)	703.7(3)(A) and (C)
15 SAO pg 16	Maintain documentation that supports how recommended grant amounts are determined by the peer review councils and the executive director.	102.0535(a)(1)	703.6(d)(2)(C) 703.7(3)(E) 703.4(1)(B)
16 SAO pg 20	Obtain documentation to verify the amount and availability of matching funds that grantees report.	102.255(c)(3)(A) & (C),(6),(d)(8),(9)	703.11(g), (j) 703.10(c)(21), 703.21(b)(3)(A)(x)

17 SAO pg 20	Require grantees to comply with matching fund requirements in statute and CPRIT rules.	102.255(c)(2), 102.255(c)(3)(A) & (C), 102.260(d), (f)	703.7(3)(c) 703.10(c)(21) 703.21(b)(3)(A)(i), (x)
18 SAO pg 24	Adopt and implement a policy regarding advance payments to grantees.	102.255(e)	701.19, 703.10(c)(14)
19 SAO pg 24	Obtain sufficient documentation to support the appropriateness of all payments it makes to grantees.	102.0535(a)(2), 102.260(a)	703.21(b)(1)
20 SAO pg 27	Retain documentation of all financial and progress reports received and all reviews of those reports.	102.0535(a)(3), (5)	703.4(1)(E)
21 SAO pg 27	Establish and implement a process to track the dates on which grantees' reports are due and received, and follow up on all missing reports.	102.051(a)(5), 102.260(e)	703.4(1)(F)
22 SAO pg 27	Follow the process established by CPRIT to perform desk reviews of financial reports that grantees submit.		703.21(b)(4)
23 SAO pg 27	Establish criteria for peer reviewers to follow when evaluating and documenting reviews of grantees' progress reports.		703.21(3)(C)
24 SAO pg 27	Ensure that public higher education institutions obtain and submit reports from required audits.		703.13
25 SAO pg 31	Develop, document, and implement a process for closing out grants and renewing grants, as well as develop, document, and implement procedures for extending grants.		703.14(c)
26 SAO pg 31	Ensure that all grant agreements include all reporting requirements.	102.260(d)	703.10(c)(8), (9), (15)
27 SAO pg 35	Refrain from involvement in CTNeT's business decisions.	102.109(b)(2)	702.9(2), (8)

28 SAO pg 35	Prohibit CPRIT employees from serving on CTNeT's board of directors.	102.109((b)(8)(9)	702.9(2),(8), (11)
29 SAO pg 35	Prohibit CTNeT board members from serving on CPRIT's commercialization review council.	102.156(c)	703.5(h)
30 SAO pg 35	Ensure that all payments to CTNeT comply with the terms of the grant.	102.260(b), 102.051(a)(5), 102.260(d)	703.21(b)(1)(e)
31 SAO pg 35	Withhold payments to CTNeT until after CPRIT has recovered the advanced funds that CTNeT spent on unallowable costs.	102.260(b)	701.19(3),(4),(5), 703.10(c)(14)
32 SAO pg 35	Require CTNeT to comply with requirements regarding matching funds and annual progress reporting.	102.255(d)(9), (i)	703.7(3)(c), 703.11(g), (j), 703.10(c)(21) 703.21(b)(3)(A)(i), (x)
33 SAO pg 40	Ensure that it properly identifies and defines its services needs and the associated costs prior to executing service contracts.		
34 SAO pg 40	Prohibit the awarding of contracts to parties that assist in the needs assessment process for the contracted services.		
35 SAO pg 40	Require vendor invoices to include specific information that clarifies the work products and services the vendors provided during the billing cycle.		
36 SAO pg 40	Competitively procure all contracted services, and require its contractors to competitively procure all subcontracted services.		
37 SAO pg 43	Establish minimum requirements for documentation that must be submitted for payments to reviewers for their services.	102.151(e)	701.15(4)
38 SAO pg 43	Implement a documented process to support and justify all changes in the amount of honorarium paid to reviewers.	102.151(e)	701.15(1)
39 SAO pg 43	Ensure that honorarium payment rates are reasonable and competitive for the value CPRIT receives.	102.151(e)	701.15(3)

40 SAO pg 46	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.	102.0535(b)	703.4(3)
41 SAO pg 46	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.	102.0535(a)(1)	703.4(1)(B),(C)
42 SAO pg 49	Allow peer reviewers to provide their grant recommendations to the executive director and members of the CPRIT oversight committee at the same time.	102.251(a)(1)	703.6(f)
43 SAO pg 49	Clarify what funds can be used and the intended use of matching funds reported by grantees.	102.255(d)(2)(B) & (d)(4)	703.11
44 SAO pg 49	Clarify whether contributions made by non-profit foundations affiliated with grantees are appropriate.	102.251(a)(3), (e)	703.3(h)(1)
45 SAO pg 49	Prohibit an interlocking directorate between CPRIT and the CPRIT Foundation.		701.5(1)(F)
46 SAO pg 49	Prohibit CPRIT employees from serving on grantee's board of directors and related foundations.	102.109((b)(8)(9)	702.9(2), (11)
47 SAO pg 9	Clarify the positions of the oversight committee's presiding officer and other officers, including the responsibilities and specific term of service for those positions.	102.104(c)(1)(2)	701.5(1)(C)(D)
48 SAO pg 49	Allow members of the oversight committee to affirmatively vote to approve the executive director's recommendations.	102.252	703.8(1)
49 SAO pg 49	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.	102.101(b)(4),(5)	
50 SAO pg 49	Allow the executive director to provide CPRIT's oversight committee, along with grant recommendations, documentation of the other factors that the executive director considered for making grant recommendations.	102.251(c)	703.7(6)
51 SAO pg 49	Require the CPRIT Foundation to make its records, books, and reports available to the public.	102.262(c), (d)	701.27(13)



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS
SUBJECT: SUMMARY OF CPRIT ACTIVITIES DURING THE MORATORIUM
DATE: OCTOBER 28, 2013

CPRIT has started several major initiatives since the most recent Oversight Committee meeting on February 25, 2013. Many of the activities were undertaken to address issues arising because of the moratorium instituted on grant review and awards. The documents included in this section provide an overview of these activities, such as:

- **Issuing CPRIT's 2012 Annual Report.** CPRIT is statutorily required to issue an annual report outlining CPRIT's activities. CPRIT released its 2012 report on June 27, 2013. The report includes an economic assessment of the agency, grant award information, highlights of the CPRIT's three program areas, and a financial summary. The report is included in the information for this section.
- **Withdrawing and returning grant proposals** to grant applicants because CPRIT was unable to move forward with grant review in a timely manner. Grant applications from three review cycles (FY2013 Cycle 2 Research, FY2013 Cycle 3 Commercialization, and FY2012 Cycle 3 Commercialization) were affected. The applications in both FY2013 cycles were withdrawn by CPRIT in April and returned because the application submission date was close to the initiation of the moratorium and CPRIT had not yet begun the review process. (Correspondence notifying grant applicants of the decision to withdrawal the applications is included in the information for this section.)

On the other end of the spectrum, the five remaining FY2012 Cycle 3 commercialization grant proposals were withdrawn due to concerns about the "freshness" of the applications' business and research plans. (See my June 14th email to Oversight Committee members and senior staff.) These applications were submitted to CPRIT in March 2012; by the time they were withdrawn by CPRIT the proposals had been pending in the CPRIT review process for more than one year. One of the five applications had been recommended for funding by the Commercialization Review Council but not yet presented to the Oversight Committee. I made the decision in June to exercise my statutory discretion not to recommend the application for funding consideration by the Oversight Committee because of the long delay between application submission and a final decision. The applicants may resubmit the

updated applications once CPRIT resumes its grant review. (June 17th correspondence sent to grant applicants of the decision to withdrawal the applications is included in the information for this section.)

- **Instituting a Reconciliation Process** to allow grant recipients delinquent in reporting obligations the opportunity to catch up and achieve 100% reporting compliance. The project, which began in late March, was initially expected to last through May 31, 2013. However, due to the overwhelming response from grant recipients, CPRIT extended the reconciliation period through the end of July. See Kristen Doyle's July 1, 2013 memorandum and notices sent to grant recipients.)

CPRIT program and financial staff report that the reconciliation process was successful in bringing most grant recipients into full compliance with financial and progress reporting requirements. To maintain the current high level of compliance with reporting requirements, CPRIT's new administrative rules propose other methods such as waiving reimbursement for late financial status reports and preventing grant recipients from applying for new CPRIT grants if they have not submitted final progress reports.

- **Executing Review Council Honoraria Contracts.** CPRIT's Review Council members have been actively engaged in the work necessary to restart the grant review process. As explained in Kristen Doyle's September 1, 2013 memorandum, executing the honoraria contracts on September 1st was necessary to avoid an interruption in the services provided by the Review Council members. An unusual issue presented itself because the appointments for seven Review Council members have not been approved by the Oversight Committee. In the event that the Oversight Committee does not approve the appointments, the honoraria contracts may be terminated by CPRIT.

A large, stylized graphic in the background features a DNA double helix in shades of orange and yellow, with a five-pointed star at the top. The entire graphic is set against a light yellow background that is framed by a dark red border.

ANNUAL REPORT

2012



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS OVERSIGHT COMMITTEE • FISCAL YEAR 2012

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Joseph S. Bailes, M.D., Vice Chairman

Barbara Canales

The Honorable Faith Johnson

Tom Luce

Alexander Meade

Walker Moody

Charles Tate

Mark E. Watson Jr.

The Honorable Greg Abbott

The Honorable Susan Combs

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LETTER FROM THE INTERIM EXECUTIVE DIRECTOR

The Honorable Rick Perry, *Governor*

The Honorable David Dewhurst, *Lieutenant Governor*

The Honorable Joe Straus, *Speaker of the House of Representatives*

Pursuant to V.T.C.A., Health and Safety Code Sec. 102.052 please accept this annual report from the Cancer Prevention & Research Institute of Texas (CPRIT). The following pages summarize how CPRIT is fulfilling its mission of reducing the burden of cancer in Texas.

Cancer is the leading cause of death among Texans younger than 85 years of age. On average, more than 100 Texans die from cancer every day. The tragic emotional and physical toll of cancer is incalculable, but in purely economic terms, Texas cancer deaths translate into a daily cost to the state of about **\$77 million** in medical expenses and lost productivity.

But Texas is rising to the challenge. Through August 2012, CPRIT has announced **423** awards for research, prevention and product development grants totaling **\$749,114,873**. Together with matching funds obligated by grant recipients, more than **\$902 million** has been invested in Texas' extraordinary commitment to the war against cancer.

Recipients of CPRIT awards include Texas academic institutions, non-profit organizations, and private companies. These awardees are advancing the health of Texans, expanding research in the state, building Texas' life-science infrastructure, and benefiting the Texas economy. In addition, CPRIT recruitment grants have helped bring research superiority to Texas through **26** outstanding researchers who, over the course of their careers, should attract significant follow-on funding to the state.

CPRIT-funded projects and programs reach Texans in all 254 counties. In addition to providing education and training to **620,000** people, CPRIT has funded clinical services for more than **230,000** Texans, including **38,000** who have never before been screened for cancer.

State law specifies several elements for annual reports. 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.

On behalf of the CPRIT Oversight Committee and the agency's staff, I thank you for this opportunity to highlight the contributions CPRIT has made in 2012. We look forward to the future and new opportunities to fulfill our mission to improve the health and lives of our fellow Texans.

Sincerely,

Wayne R. Roberts
Interim Executive Director

IMPACT OF CANCER

Age-Adjusted Invasive Cancer Incidence Rates in Texas

All Sites, 2005-2009

By County

Age-Adjusted to the 2000 U.S. Standard Population

Texas Rate: 451.0

Rate per 100,000

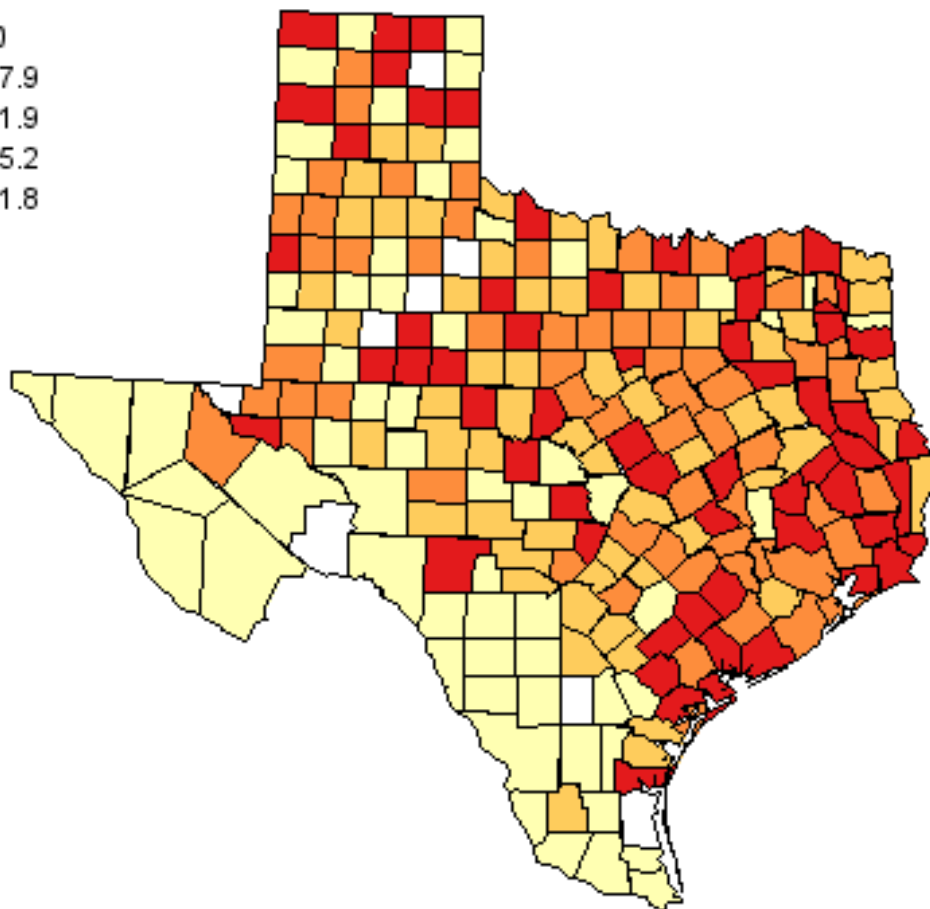
269.0 - 417.9

418.7 - 451.9

452.2 - 485.2

485.8 - 601.8

Risk Population
less than 1000



Source: Texas Cancer Registry, Cancer Incidence File, JANUARY 2012.

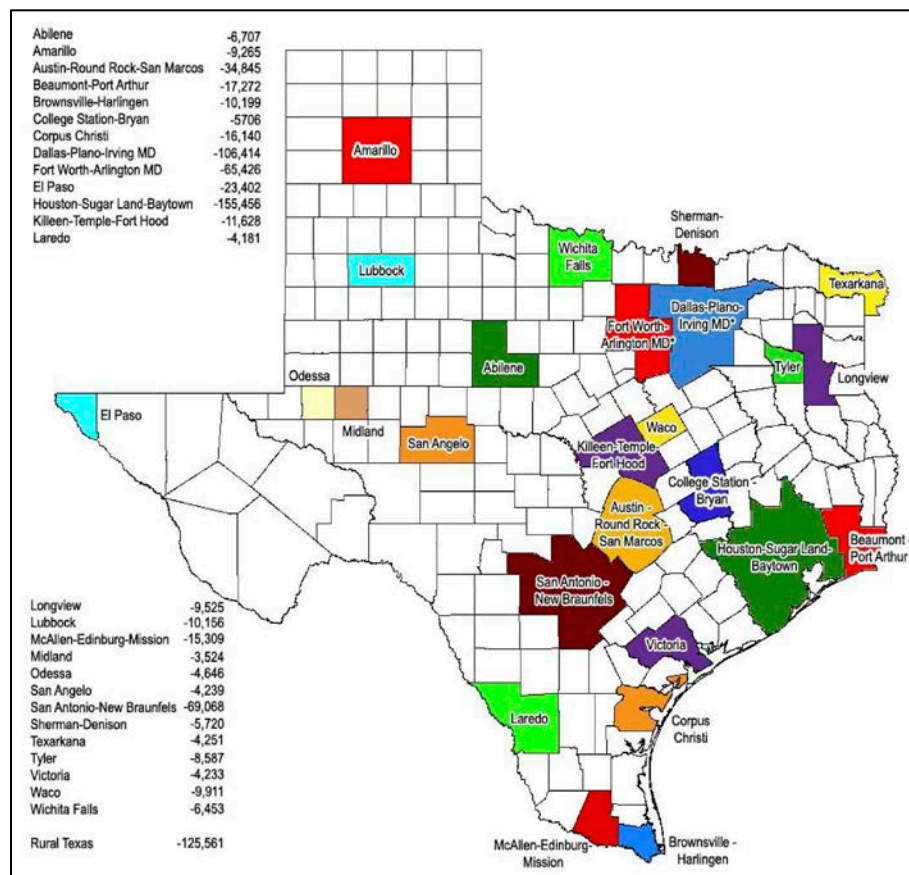
ECONOMIC IMPACT OF CANCER

On behalf of CPRIT, The Perryman Group studied the economic burden of cancer in Texas as well as the economic benefits of the agency's investments in the war against cancer. Some of the key findings:

- Cancer costs the Texas economy:
 - **\$146.5 billion** in reduced annual spending;
 - **\$72.4 billion** in output losses annually; and
 - **747,825 lost jobs** from cancer treatment, morbidity and mortality, and the associated spillover effects.
- Estimated returns on CPRIT investments in 2012 (totaling \$342.8 million in awards) include:
 - **\$2.9 billion** in economic activity (total expenditures) in 2012
 - **33,431 jobs** created through direct and indirect economic activity
 - **\$159.7 million** in state tax receipts and **\$73.5 million** in local government tax receipts

CPRIT's efforts not only decrease the costs of cancer (both human and economic) but also, by establishing Texas as a center for cancer research, enhance the economic development of the state.

Economic Cost of Cancer to Texas Metropolitan Areas: Estimated Job Losses Stemming from the Economic Cost of Treatment, Morbidity, and Mortality Associated with Cancer as of 2012



Source: The Perryman Group

TEXAS ADDRESSING CANCER: AWARDS THROUGH AUGUST 31, 2012

Investments in Cancer Prevention	
Angelo State University	\$ 1,120,825
Asian American Health Coalition of Greater Houston (dba Hope Clinic)	\$ 1,450,887
Asian Breast Health Outreach Project at Methodist Richardson Medical Center	\$ 535,540
Baylor College of Dentistry-TAMU Health Science Center	\$ 203,244
Baylor College of Medicine	\$ 5,066,713
Cancer and Chronic Disease Consortium	\$ 2,177,340
Cancer Foundation for Life	\$ 100,000
Cancer Services Network	\$ 99,581
Centro San Vicente	\$ 1,937,461
City of Laredo Health Department	\$ 2,497,500
Daughters of Charity Health Services of Austin (dba SETON Healthcare Network)	\$ 128,640
Texas Department of State Health Services	\$ 335,271
Funding Solutions	\$ 157,494
Healthy Tarrant County Collaboration	\$ 212,535
LIVESTRONG	\$ 600,000
Light and Salt Association	\$ 329,933
LRGV Community Health Management Corporation, Inc. (dba El Milagro Clinic)	\$ 149,100
Mercy Ministries of Laredo	\$ 608,579
Methodist Dallas Medical Center	\$ 599,574
MHMR of Tarrant County	\$ 2,397,784
Migrant Clinicians Network	\$ 473,405
National Center for Farmworker Health, Inc.	\$ 551,221

Investments in Cancer Prevention	
SETON Family of Hospitals	\$ 562,004
Shannon Business Services	\$ 255,198
South Texas Rural Health Services, Inc.	\$ 149,971
Texas A&M University	\$ 839,227
Texas A&M University System Health Science Center	\$ 3,830,498
Texas A&M University System HSC Research Foundation	\$ 339,932
Texas Agrilife Extension Service	\$ 3,410,830
Texas Department of State Health Services	\$ 2,936,382
Texas Medical Association	\$ 967,425
Texas Nurses Foundation	\$ 2,107,901
Texas Tech University	\$ 592,546
Texas Tech University Health Sciences Center	\$ 4,831,994
The Bridge Breast Network	\$ 977,603
The Cooper Institute	\$ 591,384
The Rose	\$ 3,845,471
The University of North Texas Health Science Center at Fort Worth	\$ 4,504,995
The University of Texas at Austin	\$ 266,920
The University of Texas Health Science Center at Houston	\$ 4,983,062
The University of Texas Health Science Center at San Antonio	\$ 6,741,439
The University of Texas MD Anderson Cancer Center	\$ 4,151,419
The University of Texas Medical Branch at Galveston	\$ 1,239,025
The University of Texas Southwestern Medical Center at Dallas	\$ 9,549,709
University Health System	\$ 6,218,267
University of Houston	\$ 272,753

AWARDS THROUGH AUGUST 31, 2012 CONTINUED

Investments in Company and Academic Research	
Apollo Endosurgery	\$ 5,001,063
Asuragen, Inc.	\$ 6,837,265
Baylor College of Medicine	\$ 80,385,033
Baylor Research Institute (MIRA Sub Award)	\$ 2,108,180
Baylor University	\$ 200,000
Baylor University Medical Center at Dallas	\$ 2,500,000
Bellicum Pharmaceuticals, Inc.	\$ 5,680,310
Caliber Biotherapeutics	\$ 12,808,151
Cell Medica	\$ 15,571,303
Clinical Trials Network (CTNeT) ¹	\$ 25,213,675
Gradalis, Inc. (MIRA Sub Award)	\$ 748,905
Ingeneron, Inc.	\$ 198,111
Kalon Biotherapeutics, LLC ²	\$ 7,901,420
Mirna Therapeutics, Inc.	\$ 10,297,454
Molecular Templates, Inc.	\$ 10,600,000
Peloton Therapeutics, Inc. ³	\$ 11,044,931
Pulmotect, Inc.	\$ 7,126,398
Rice University	\$ 23,472,111
Rules-Based Medicine	\$ 3,024,432
Scott & White Healthcare	\$ 3,584,521
Texas A&M University	\$ 1,577,777
Texas A&M University System Health Science Center	\$ 3,201,312

Investments in Company and Academic Research	
Texas A&M University System Health Science Center - Institute of Biosciences and Technology	\$ 12,614,927
Texas Life Science Foundation	\$ 7,745
Texas Tech University	\$ 2,899,790
Texas Tech University Health Sciences Center	\$ 12,153,955
The Methodist Hospital Research Institute	\$ 25,283,225
The University of North Texas Health Science Center at Fort Worth	\$ 179,834
The University of Texas at Arlington	\$ 2,285,375
The University of Texas at Austin	\$ 33,083,678
The University of Texas at Dallas	\$ 5,909,898
The University of Texas at El Paso (MIRA Sub Award)	\$ 999,992
The University of Texas at San Antonio	\$ 898,026
The University of Texas Health Science Center at Houston	\$ 7,827,104
The University of Texas Health Science Center at San Antonio	\$ 17,561,348
The University of Texas MD Anderson Cancer Center	\$ 124,537,092
The University of Texas Medical Branch at Galveston	\$ 6,512,077
The University of Texas Southwestern Medical Center at Dallas	\$ 164,030,876
The University of Texas System	\$ 5,000,000
University of Houston	\$ 6,597,188
University of North Texas	\$ 200,000
Visualase, Inc.	\$ 2,151,776

¹ Project terminated January, 2013; final amount expended was \$8.7 million.

² In contract negotiation

³ Project suspended; grant funds expended to date is \$3.2 million.

RESEARCH

The goal of CPRIT's research investments is to transform new and promising ideas into positive outcomes for cancer patients. The value that CPRIT adds to the fight against cancer goes well beyond the substantial dollars invested by the people of Texas. CPRIT's research programs are designed to challenge the brightest and most innovative scientists to pursue the most worthy research objectives that will help reduce the burden of cancer in Texas and throughout the world.

Research proposals submitted to CPRIT are reviewed by peer review committees comprised of some of the most outstanding cancer researchers and clinicians in the nation. These individuals bring a wealth of knowledge and experience to ensure that the funds invested are awarded to programs and projects that can make a real difference. Peer review committees are charged to follow their own independent and objective judgment, free from political or geographic influences or conflicts of interest, in providing a thorough evaluation of programs.

CPRIT's goal is to support a collection of the most creative ideas from the finest cancer researchers in Texas, and as such, there are no pre-determined quotas for the types of cancer research to be funded. CPRIT aims to support the most meritorious and promising programs and projects across the research spectrum — from basic science to translational research and clinical applications, and from short-term individual projects to complex, multi-year research programs.

CPRIT'S CANCER RESEARCH AWARDS

CPRIT Scholars in Cancer Research awards recruit superior cancer researchers at various stages of their careers to Texas academic institutions to establish laboratories or clinical research programs that add research talent to the state.

High Impact-High Risk Research Awards provide seed money for investigators to try out new ideas at the cutting edge of cancer research.

Individual Investigator Research Awards support innovative research projects directed by one scientist that can significantly advance knowledge of the causes, prevention, diagnosis, and/or treatment of cancer.

Multi-Investigator Research Awards fund large-scale cross-disciplinary research projects that promise to deliver significant advances through innovation and collaboration.

Research Training Awards support programs designed to educate the next generation of cancer researchers. Individuals from underrepresented racial and ethnic groups or disadvantaged backgrounds, as well as persons with disabilities, are encouraged to participate in these training programs.

Shared Instrumentation Awards underwrite the cost of major research equipment at Texas institutions to support the work of multiple investigators and the goals of scientifically significant projects.

Core Facilities Support Awards support centralized laboratories performing widely used technologies that serve the needs of multiple researchers.

Early Translational Research Awards support 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.

Through August 2012, the CPRIT research program has announced awards totaling \$565 million for 305 programs and projects across 26 academic institutions. Funding has allowed for not only academic advancement in research, but has had an economic impact by creating hundreds of new jobs in the state.

RESEARCH HIGHLIGHTS — GROUNDBREAKING DISCOVERIES TODAY

1. Developing new ways to predict and block metastasis



Sean Morrison, Ph.D.

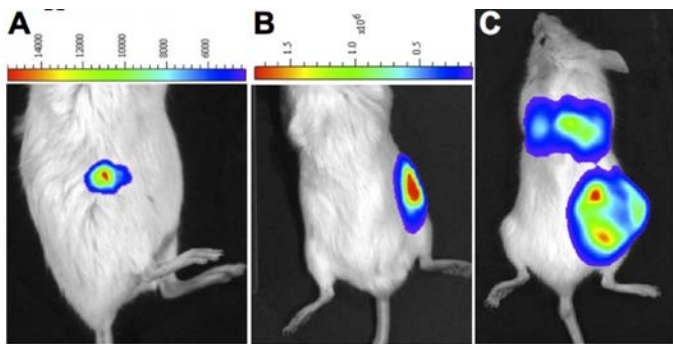
Children's Medical Center Research Institute at UT Southwestern

Human melanoma — the most severe form of skin cancer — is curable through surgery to remove the tumor unless the cancer has spread elsewhere in the body (what's known as metastasis). Knowing how to predict and prevent metastasis makes a substantial difference in the effectiveness of melanoma treatment and patient outcomes. However, it has proven difficult to reproduce in the laboratory the ways in which melanoma cells actually form and spread in human patients. CPRIT Scholar Dr. Sean Morrison's laboratory at UT Southwestern has developed a specialized mouse model that promises to overcome this challenge.

The Morrison laboratory's "xenograft" model allows small numbers of melanoma cells (even single cells) obtained directly from patients to be transplanted into specially bred laboratory mice (known as NSG mice), forming human melanomas. The mice are then used to study the biology of human melanomas, to identify new biomarkers, and to test new therapies.

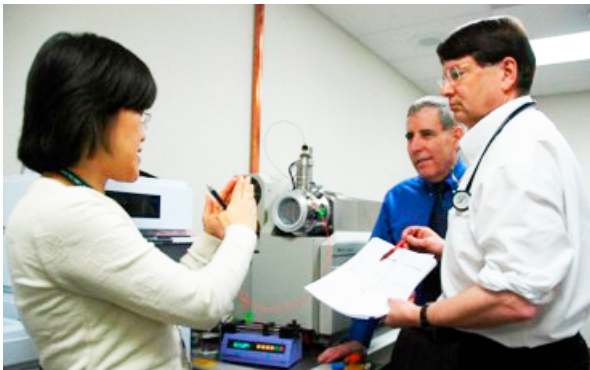
The Morrison laboratory recently showed that Stage III melanoma cells did, in fact, metastasize in these mice in the same ways they did in the patients from which the cells came — with some spreading rapidly and widely ("efficient") and others more slowly ("inefficient"). These differences correlated with the frequency of circulating melanoma cells in the blood of the mice, suggesting that the rate of entry into the blood is one factor that governs how quickly and widely melanomas spread.

The Morrison laboratory is currently testing new potential therapies to block the growth and spread of melanoma, as well as exploring genetic approaches to compare “efficient” and “inefficient” melanomas and identify the molecular mechanisms that regulate metastasis. New potential small molecule therapies are being tested now for their ability to cure or to prevent the spread of human melanoma in mice. The therapies that prove most promising in mice will ultimately be tested in clinical trials in patients.



The Morrison lab has used these mice to study the mechanisms that regulate metastasis.

2. A novel target for cancer chemotherapy: the building blocks of cell membranes



C. Patrick Reynolds, M.D., Ph.D., Barry Maurer, M.D., Ph.D., and Min Kang, PharmD, Texas Tech University Health Sciences Center (TTUHSC) School of Medicine Cancer Center

Many new cancer chemotherapy drugs focus on precise targets, often related to changes (mutations) in cancer cell DNA that produce molecules that can be attacked by new drugs. This new generation of targeted drugs is less toxic to a patient’s healthy cells than traditional chemotherapy, but cancer cells can rapidly overcome these narrowly targeted drugs by additional mutations. A team of CPRIT-funded investigators at the Texas Tech University Health Sciences Center (TTUHSC) School of Medicine Cancer Center developed a novel way of targeting cancer cells that could overcome some of the limitations of both traditional chemotherapy and the new targeted drugs.

The starting point for the work of Drs. Reynolds, Maurer and Kang is a well-tolerated drug, derived from vitamin A, called fenretinide. This drug tricks cancer cells — but not normal cells — into overproducing ceramides, one of the building blocks of cell membranes. This is highly toxic to many cancer cells. This approach was initially developed to treat neuroblastoma, the most common type of cancer in infants, but was soon found to be effective against certain adult lymphomas (cancer of lymph nodes). The TTUHSC investigators were able to move their research forward much faster by carrying out simultaneous clinical trials in both pediatric and adult patients.

Fenretinide has achieved complete remissions in children with neuroblastoma and adults with T-cell lymphoma, but many cancers do not respond to fenretinide alone. Therefore, Drs. Reynolds, Maurer, and Kang are developing next-generation drugs to combine with fenretinide and amplify its effects. Laboratory work with one such drug, safingol, has been promising, with a phase I clinical trial at UT Southwestern being ramped up for use on patients. A CPRIT grant to Dr. Reynolds provides partial support for this clinical trial as well as for other ongoing fenretinide trials in both adults and children.

Drs. Maurer and Kang have identified another drug (called PPMP) that also enhances the effect of fenretinide and safingol. With support from a CPRIT Early Translational Grant, critical manufacturing, formulation, and toxicity studies are under way to bring PPMP to early-phase clinical trials.

3. Exploring the Origins of Liver Cancer in Children

Gail Tomlinson, MD, PhD, lead investigator

Greehey Children's Cancer Research Institute, UT Health Science Center at San Antonio

In 2012, about 1,300 children were diagnosed with cancer in Texas, and about 200 children died of cancer. Pediatric cancer is different from adult cancer and requires different treatment strategies. Whereas the genetic damage that leads to adult cancers can accumulate over decades of aging and exposure to carcinogens, cancer in young children is thought to stem from a handful of acquired genetic alterations at specific stages of development.

As a result, pediatric cancer is rare, affecting only a few thousand patients in the U.S. each year. To ensure that pediatric cancers are not left behind in the ongoing revolution in targeted therapy, it is critical that researchers from different institutions work together to share their knowledge and focus their energies and expertise. CPRIT's multi-investigator research awards (MIRAs) are designed precisely to support this crucial collaboration; since 2009, CPRIT has awarded three MIRAs that focus on specific types of pediatric cancer.

One of these is hepatoblastoma, a rare type of liver cancer that almost always occurs in children under 5; the average age of onset is 20 months. This type of cancer is occasionally associated with both very low birth weight (as in premature birth) and unusually high birth weight. It is thought that genes involved in early growth and development of the prenatal liver contribute to the disease.

Hepatoblastoma exemplifies all of the challenges of treating cancer in young children. Current therapies involve standard chemotherapy, which is toxic to the entire body and can result in life-long damage to vital organs. There is a clear need for targeted therapies, as well as for markers that predict whether children with hepatoblastoma need the most intensive and potentially damaging therapies.

Dr. Gail Tomlinson, a physician-scientist at the Greehey Children's Cancer Research Institute, is an expert in hepatoblastoma biology and genetics and leads this MIRA project. Her collaborators include:

- Dr. D. Will Parsons at the Baylor College of Medicine Human Genome Center, who has directed genetic analysis of 35 hepatoblastoma tumors, the first such study of pediatric liver cancer;
- Dr. Dolores Lopez-Terrada, director of the Molecular Oncology Laboratory at Texas Children's Hospital, whose work allows distinct groups of tumors to be categorized based on gene expression;
- Dr. Milton Finegold, a world leader in liver pathology at Texas Children's Hospital, who analyzes tumor pathology;
- Dr. Dinesh Rakheja, a pediatric anatomic pathologist at UT Southwestern, who is pursuing additional

studies of genes on tumor tissues;

- Drs. Sarah Comerford and Robert Hammer at UT Southwestern, who are constructing the first mouse model of hepatoblastoma to use to study the role of developmental genes in the liver;
- Dr. Yidong Chen and his team at the Greehey Children's Cancer Research Institute, who are compiling a complete integrated genomic profile out of the data collected throughout the MIRA.

The end result of this project will be the most comprehensive knowledge to date of the genetic factors contributing to hepatoblastoma, which will allow for the development of targeted therapies that improve patient outcomes.

CPRIT SCHOLARS

The CPRIT Scholars in Cancer Research program recruits exceptional researchers to Texas academic and research institutions. These awards support the work and the laboratories of promising outstanding established investigators, first-time tenure-track faculty, missing links, and rising stars, and are a key component of CPRIT's strategic investment in building Texas' research infrastructure. For full biographies go to <http://www.cprit.state.tx.us/funded-grants/cprit-scholars/>.

ESTABLISHED INVESTIGATOR AWARDS

Lynda Chin

Institution: The University of Texas MD Anderson Cancer Center

Recruited from: Harvard Medical School

Degrees and positions held:

- M.D., Albert Einstein College of Medicine
- Chief Resident of Dermatology, Columbia Presbyterian Medical Center
- Professor of Dermatology, Harvard Medical School
- Senior Associate Member of the Broad Institute of MIT and Harvard
- Scientific Director, Belfer Institute for Applied Cancer Science at the Dana-Farber Cancer Institute
- Co-Leader, Dana-Farber Cancer Institute/Harvard Cancer Center's Melanoma Program
- Chair, Department of Genomic Medicine, MD Anderson Cancer Center
- Scientific Director, Institute for Applied Cancer Science, MD Anderson Cancer Center
- Founder, AVEO Pharmaceuticals and Metamark Genetic

Honors: The Cancer Genome Atlas (TCGA) Executive Subcommittee, GBM and Melanoma Disease Working Groups, Scientific Steering Committee of the International Cancer Genome Consortium, Member, Institute of Medicine

Research interests: Transcription, telomere biology, mouse models of human cancer, oncogenomics, and personalized cancer medicine

Neal Copeland

Institution: The Methodist Hospital Research Institute

Recruited from: Institute of Molecular and Cell Biology, Singapore

Degrees and positions held:

- Ph.D., Biochemistry, University of Utah, Harvard Medical School
- Director, Mouse Cancer Genetics, National Cancer Institute
- Director, Institute of Molecular and Cell Biology, Singapore
- Co-director, Methodist Hospital Research Institute

Honors: National Academy of Sciences

Research interests: Modeling human cancer in mice; molecular biology of retroviruses; identifying candidate cancer genes in hematopoietic tumors; transposon-based insertional mutagenesis to identify drug resistant genes.

Nancy Jenkins

Institution: The Methodist Hospital Research Institute

Recruited from: Institute of Molecular and Cell Biology, Singapore

Degrees and positions held:

- Ph.D., Molecular and Cellular Biology, Indiana University
- Postdoctoral Fellow, Dana-Farber Cancer Institute, Harvard Medical School
- Head, Molecular Genetics of Development, National Cancer Institute
- Deputy Director, Institute of Molecular and Cell Biology, Singapore
- Co-director, Methodist Hospital Research Institute

Honors: National Academy of Sciences
Research interests: Molecular biology of retroviruses; retroviruses as insertional mutagens in mice; transposon screening; lung and ovarian cancer

David Johnson

Institution: The University of Texas Southwestern Medical Center
Recruited from: Vanderbilt University

Degrees and positions held:

- M.D., Medical College of Georgia, Vanderbilt University
- Director, Division of Hematology and Medical Oncology, Vanderbilt University
- Deputy Director, Vanderbilt-Ingram Cancer Center
- Distinguished Chair, Department of Internal Medicine, UT Southwestern

Honors: Chair-Elect, American Board of Internal Medicine
Research interests: Biology of lung cancer

Herbert Levine

Institution: Rice University
Recruited from: University of California, San Diego

Degrees and positions held:

- Ph.D., Physics, Princeton University, Harvard University
- Distinguished Professor, University of California, San Diego
- Professor, Bioengineering and Physics, Rice University
- Co-director, Center for Theoretical Biological Physics

Honors: Fellow of the American Physical Society, National Academy of Sciences
Research interests: Application of non-equilibrium physics to cancer

Sean Morrison

Institution: The University of Texas Southwestern Medical Center
Recruited from: University of Michigan

Degrees and positions held:

- Ph.D., Immunology, Stanford University, California Institute of Technology
- Director, Center for Stem Cell Biology, University of Michigan
- Director, Children's Research Institute, UT Southwestern

Honors: Searle Scholar; Presidential Early Career Award for Scientists and Engineers; McCulloch and Till Award; Harland Mossman Award; National Institute on Aging

Research interests: Stem cell aging and self-renewal

Jose Onuchic

Institution: Rice University
Recruited from: University of California, San Diego

Degrees and positions held:

- Ph.D., Physics, California Institute of Technology
- Professor, University of California, San Diego
- Professor, Physics and Astronomy, Chemistry and Biochemistry, Rice University
- Co-director, Center for Theoretical Biological Physics

Honors: International Center for Theoretical Physics Prize; Fellow of the American Physical Society, National Academy of Sciences; Fellow of the American Academy of Arts and Sciences; Brazilian Academy of Sciences; Fellow of the Biophysical Society

Research interests: Theoretical and computational methods for molecular biophysics

Jeffrey Chang

Institution: The University of Texas Medical School at Houston
Recruited from: Duke University
Degrees: Ph.D., Biomedical Informatics, Stanford University
Research interests: Genomics-based investigation of cancer

Guangbin Dong

Institution: The University of Texas at Austin
Recruited from: California Institute of Technology
Degrees: Ph.D., Chemistry, Stanford University
Research interests: Synthetic technology to construct small molecule agents for cancer research

Lauren Ehrlich

Institution: The University of Texas at Austin
Recruited from: University of California, San Francisco
Degrees: Ph.D., Immunology, Stanford University
Research interests: T-cell lymphomas and leukemias

Dmitri Ivanov

Institution: The University of Texas Health Science Center at San Antonio
Recruited from: Harvard Medical School
Degrees: Ph.D., Biophysics and Structural Biology, Brandeis University
Research interests: HIV-related cancers

Ning Jiang

Institution: The University of Texas at Austin
Recruited from: Stanford University
Degrees: Ph.D., Biology, Georgia Institute of Technology
Research interests: Metrics for cancer progression prediction and monitoring

Ralf Kittler

Institution: The University of Texas Southwestern Medical Center
Recruited from: University of Chicago
Degrees: Ph.D., Dresden University of Technology and Max Planck Institute
Research interests: New targets for detection and treatment of prostate and lung cancer

Li Ma

Institution: The University of Texas MD Anderson Cancer Center
Recruited from: Massachusetts Institute of Technology
Degrees: Ph.D., Cornell University
Research interests: Roles and mechanisms of microRNAs

Kyle Miller

Institution: The University of Texas at Austin
Recruited from: Cambridge University
Degrees: Ph.D., University College London
Research interests: Chromatin and DNA repair in human cells

Daisuke Nakada

Institution: Baylor College of Medicine
Recruited from: University of Michigan
Degrees: Ph.D., Nagoya University
Research interests: Stem cell maintenance and mutation

Kathryn O'Donnell

Institution: The University of Texas Southwestern Medical Center
Recruited from: Johns Hopkins University
Degrees: Ph.D., Human Genetics and Molecular Biology, Johns Hopkins University
Research interests: Genetic mechanisms in cancer

Patrick Potts

Institution: The University of Texas Southwestern Medical Center
Recruited from: The University of Texas Southwestern Medical Center
Degrees: Ph.D., Biochemistry, UT Southwestern
Research interests: Biochemical and molecular mechanisms behind cellular processes

Lidong Qin

Institution: The Methodist Hospital Research Institute
Recruited from: California Institute of Technology
Degrees: Ph.D., Chemistry, Northwestern University
Research interests: Nanomedicine, prostate cancer

Jin Wang

Institution: Baylor College of Medicine
Recruited from: University of North Carolina at Chapel Hill
Degrees: Ph.D., Chemistry, The Ohio State University
Research interests: Nanotechnology in cancer research

Yonghao Yu

Institution: The University of Texas Southwestern Medical Center
Recruited from: Harvard Medical School
Degrees: Ph.D., Chemistry, University of California, Berkeley
Research interests: Mass spectrometric technologies in signal transduction networks

MISSING LINKS AWARDS**Robert Lenkinski**

Institution: The University of Texas Southwestern Medical Center
Recruited from: Harvard Medical School
Degrees and positions held:

- Ph.D., Chemistry, University of Houston, Weizmann Institute of Science
- Professor, Radiology, University of Pennsylvania
- Professor, Radiology, Harvard Medical School

Research interests: Molecular imaging

Hamid Mirzaei

Institution: The University of Texas Southwestern Medical Center
Recruited from: Institute for Systems Biology, Seattle
Degrees: Ph.D., Analytical Chemistry, Purdue University
Research interests: Development of new technologies for purification of proteins involved in gene regulatory complexes.

Carol Nilsson

Institution: The University of Texas Medical Branch at Galveston
Recruited from: Pfizer Global Research and Development, San Diego
Degrees and positions held:

- M.D., Ph.D., Clinical Neurochemistry, Goteborg University
- Associate Professor, Goteborg University
- Director, Ion Cyclotron Resonance User Program, National High Magnetic Field Laboratory
- Senior Principal Scientist, Pfizer Global Research and Development

Research interests: Use of quantitative phosphoproteomics and related systems biological techniques in neuro-oncology

RISING STAR AWARDS

Taiping Chen

Institution: The University of Texas MD Anderson Cancer Center
Recruited from: Harvard Medical School
Degrees: Ph.D., Molecular and Cell Biology, McGill University
Research interests: Role of epigenetic modifications in cancer

Joshua Mendell

Institution: The University of Texas Southwestern Medical Center
Recruited from: Johns Hopkins University
Degrees: M.D., Ph.D., Johns Hopkins University
B.A., Biology, Cornell University
Research interests: Activity of microRNAs

Jessica Tyler

Institution: The University of Texas MD Anderson Cancer Center
Recruited from: University of Colorado School of Medicine
Degrees: Ph.D., Virology, University of Glasgow
B.A., Biochemistry, University of Sheffield
Research interests: Chromatin and DNA repair

PRODUCT DEVELOPMENT

Groundbreaking science matters most when it is translated into products that help patients. CPRIT fulfills its mission by accelerating the progression of new cancer drugs, diagnostics, and therapies from the laboratory into clinical practice. In addition to improving patient care, CPRIT's Product Development Initiative fosters economic development in Texas' emerging life sciences industry and, through intellectual property and revenue sharing, provides a direct return on the investments made by the people of Texas.

CPRIT funds product development projects based upon both scientific merit and significant commercial potential. In addition to the scientific peer review process used by all CPRIT initiatives, product development proposals are subjected to a thorough due-diligence analysis to evaluate commercial prospects for new oncology products and services.

In addition to projects funded through grant awards, CPRIT's Product Development Initiative includes support programs such as the CPRIT Accelerator Program and the Entrepreneur in Residence Program. The CPRIT Accelerator Program attracts industry partners to work with CPRIT grantees on promising oncology products and services whose development has been funded by CPRIT. The Entrepreneur in Residence Program is designed to attract venture partners and strong management teams to Texas.

CPRIT'S PRODUCT DEVELOPMENT AWARDS

Company Awards support Texas-based companies with at least one round of professional institutional investment in developing marketable oncology products or services.

Company Formation Awards help underwrite new start-up companies, with no previous rounds of professional institutional investment, seeking to develop marketable oncology products or services. Companies must either be currently based in Texas or be willing to relocate to Texas.

Company Relocation Awards supports non-Texas-based companies with at least one round of professional institutional investment that are willing to relocate to Texas to develop commercially oriented oncology products or services.

CPRIT'S PRODUCT DEVELOPMENT PORTFOLIO

- CPRIT has announced awards totaling \$98 million in product development grants.
- More than 150 companies applied for CPRIT funding; 13 Texas-based companies were selected for funding (two companies were selected by the research program prior to launch of CPRIT's commercialization program).
- To date these 13 companies have leveraged CPRIT's investment to attract \$200 million in additional capital to Texas, both in matching funds and in subsequent financing.
- Commitments as of 2011 are projected to create or maintain approximately 140 life science-specific jobs in Texas over the next 3 years.
- Combined CPRIT and private capital of \$260 million could result in more than 3,380 new jobs in Texas over the next three years.
- CPRIT-funded company projects include promising drugs, diagnostics, and devices targeting a variety of

cancers, including cancers of the blood (leukemia, lymphoma, and myeloma), colon and rectum, esophagus, stomach, lung, and prostate. In addition, some companies are developing approaches applicable to multiple cancer types.

PRODUCT DEVELOPMENT HIGHLIGHTS

Company	CPRIT Investment	Potential ROI (up to 5 years post marketing)	Follow-on Capital Attracted	Jobs Created and Maintained
Apollo Endosurgery, Inc. <i>Austin</i>	\$5,001,063	\$15 million	\$52 million	43
Asuragen, Inc. <i>Austin</i>	\$6,837,265	(to be determined)	\$6.8 million	none reported
Bellicum Pharmaceuticals, Inc. <i>Houston</i>	\$5,680,310	\$18 million	\$22 million	14
Caliber Biotherapeutics, Inc. <i>College Station</i>	\$12,808,151	(to be determined)	\$6.4 million	none reported
Cell Medica, Inc. <i>Houston</i>	\$15,571,303	\$80 million	\$11 million	none reported
InGeneron, Inc. <i>Houston</i>	\$198,111	\$221,000	\$0.2 million	4
*Kalon Biotherapeutics, LLC <i>College Station</i>	\$7,901,420	\$10 million	\$3.95 million	none reported
Mirna Therapeutics, Inc. <i>Austin</i>	\$10,297,454	\$15 million	\$39.6 million	5
Molecular Templates, Inc. <i>Georgetown</i>	\$10,600,000	\$42 million	\$5.3 million	none reported
**Peloton Therapeutics, Inc. <i>Dallas</i>	\$11,044,931	\$113 million	\$18 million	21
Pulmotect, Inc. <i>Houston</i>	\$7,126,398	(to be determined)	\$3.56 million	none reported
Rules-Based Medicine, Inc. <i>Austin</i>	\$3,024,432	\$25 million	\$1 million + \$80 million (acquisition)	4
Visualase, Inc. <i>Houston</i>	\$2,151,776	\$2.4 million	\$1.8 million	5

* Pending contract negotiation.

** Project suspended; grant funds expended to date is \$3.2 million.

In addition to creating new and improved tools and treatments for fighting cancer, CPRIT's investments are helping to build Texas' life-science industry. While bringing a product to market can take time, jobs and economic activity are generated throughout the process. Projects funded by CPRIT are expected to create approximately 140 direct jobs — highly skilled, high-wage positions in life sciences — in Texas over the three-year term of CPRIT's grant awards. In addition, using standard multipliers for the life science industry, the \$260 million in combined CPRIT and private capital associated with these projects should generate approximately 3,380 indirect jobs in Texas over the same period.

Every CPRIT award includes an **intellectual property agreement** that specifies a revenue return to the State of Texas from the successful development of CPRIT-funded drugs, devices, diagnostics, or services. These revenue-sharing standards provide a fair return on Texas' investments without impeding the ability to attract future commercial ventures. Like any interested investor, CPRIT is an engaged partner who can help bridge the gap between early stage discoveries and product development and hold award recipients accountable for their efforts to bring products to market.

PREVENTION

Ten percent of CPRIT's annual funding supports cancer prevention programs and services in Texas. These grants make it possible for proven services and interventions to reach many more Texans and decrease the burden of cancer statewide.

There are diverse and complex cancer prevention and control needs across the state, and CPRIT only funds projects that are results-oriented, evidence-based, non-duplicative, and innovative in delivery. These projects include:

- Primary prevention efforts, from vaccination to healthy lifestyle and obesity prevention initiatives, tobacco control, and sun protection;
- Early detection, screening, and diagnostic services primarily for breast, cervical, and colorectal cancers; and
- Survivor services, including physical rehabilitation and therapy, behavioral health, and support services.

CPRIT's Prevention Initiative focuses on the delivery of proven programs and services for people of Texas in the greatest need – those who are uninsured or underinsured, those in medically underserved areas of the state, or those at highest risk of cancer.

CPRIT'S PREVENTION AWARDS

Cancer Prevention Microgrant Awards focus on policy or systems change for tobacco cessation and increasing access to prevention services

Evidence-Based Cancer Prevention Services Awards provide for the delivery of evidence-based prevention services (e.g., prevention vaccine, screening, diagnostic, survivorship services)

Health Behavior Change Through Public and Professional Education and Training Awards focus on public health promotion, education, and outreach programs and/or professional education and training programs

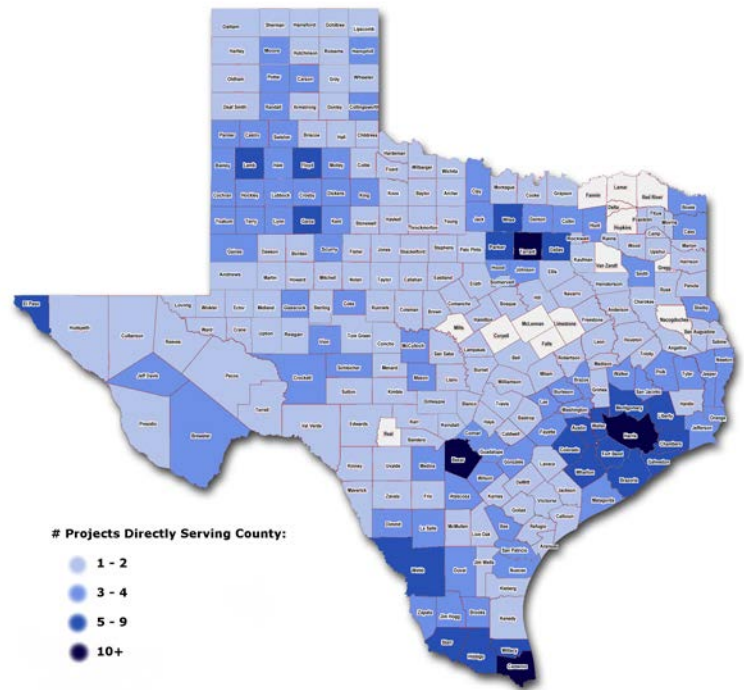
CPRIT'S PREVENTION PORTFOLIO

CPRIT's prevention work spans across Texas; the vast majority of counties have targeted projects serving their area of the state. Through August 2012, the prevention program has announced 105 awards totaling over \$85 million. To date, these projects have served over 850,000 Texans:

- o More than 620,000 people have received education, outreach, support services, and training
- o More than 230,000 people have received direct clinical services, including vaccination, screening and diagnosis, and survivor services. These include:
 - More than 31,000 tobacco-cessation clients
 - Almost 7,000 preventive vaccinations

- More than 184,000 people screened for colorectal, cervical, or breast cancer. Of these, more than 38,000 — 21 percent — had never before been screened. These screenings have detected at least 1,145 cancer precursors and 534 actual cancers.

Counties Served: Active Prevention Projects (75)
13 Projects Serve ALL Counties



PREVENTION HIGHLIGHTS

1. Moncrief Cancer Center



Faith Walker lives on a small ranch in Johnson County, south of Fort Worth. Through a CPRIT-funded project at UT Southwestern Medical Center's Moncrief Cancer Institute, Faith and other uninsured or underinsured women from Denton, Wise, Parker, Hood and Johnson Counties are now able to access state-of-the art breast cancer screening services close to home. These services are brought to patients' communities through mobile mammography and navigation services. Moncrief was able to diagnose Faith's cancer quickly, and because of Moncrief's excellent patient navigation services, Faith found out that she qualified for treatment under Medicaid. Better yet, she was able to get her surgery, chemotherapy, and radiation in her home county.

"It was a miracle for me to get treatment, a godsend to me, really. I can't thank them enough for all their help, and I'll never forget it." – Faith Walker

2. A Healthier San Antonio: Salud San Antonio!

Salud San Antonio!, a program led by the Institute for Health Promotion Research at the UT Health Science Center, is creating a healthier San Antonio. Often facing low income and little education on how to fight cancer, Latinas have few options for support, which means that breast or cervical cancer is often not detected until it has reached an advanced stage. One such woman attended a Salud event and shared that she had been diagnosed with precancerous cells in her cervix but could not afford to pursue treatment. With the assistance of Salud, the woman was shown how to receive the help she needed.

3. HOPE Where Hope is Scarce: The Asian American Health Coalition

A 44-year old Vietnamese man with a low income and no healthcare felt lost in Houston's 200,000-strong Asian American population. Like many in this demographic, financial and cultural limitations left him with limited access to cancer education and prevention programs. He had never been to a doctor. Through a friend, he learned about and attended a HOPE Clinic and Asian American Health Coalition program that incorporates a variety of activities to promote cancer awareness in the community. Through this program, he was able to register for a multitude of cancer and chronic disease screenings and to gain access to the care he needed.

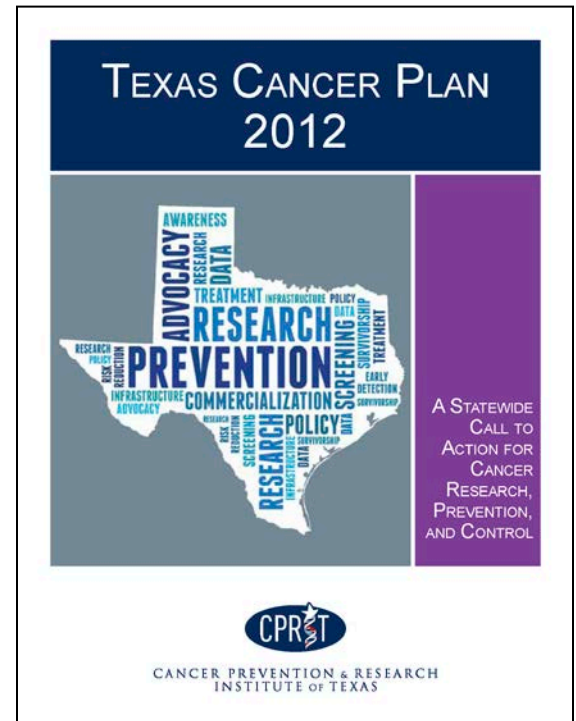
SAVING MONEY WHILE SAVING LIVES

Early detection of breast, cervical and colorectal cancer reduces the cost of patient care by as much as 50 percent, according to Texas Cancer Registry data. This allows scarce health care dollars to go farther to meet the needs of Texans. In addition, CPRIT's Prevention Initiative has helped providers to leverage federal, state and local resources to build the most effective programs. For example, Dr. Samir Gupta of The University of Texas Southwestern Medical Center and his colleagues used preliminary data from a CPRIT-funded prevention program to obtain more than \$6 million in funding from the National Cancer Institute. "It is notable that our site is one of only three colorectal cancer sites nationwide, the only site in Texas, and the only site exclusively focused on improving colorectal cancer screening for the uninsured," Dr. Gupta writes. "Receiving this prestigious NCI grant will allow Texas to be at the forefront of efforts to optimize colorectal cancer screening for the underserved, and could not have been possible without CPRIT support."

TEXAS CANCER PLAN

By state statute, CPRIT is charged with facilitating the development and implementation of the *Texas Cancer Plan*. As the statewide action plan for cancer prevention and control, the *Plan* identifies the challenges and issues that affect our state and presents a set of goals, objectives, and strategies to help inform and guide communities in the fight against cancer. The 2012 revision of the plan includes:

- Sixteen specific goals
- Measureable objectives, baselines, and targets for change
- Strategic actions for implementation
- Research and Commercialization section
- *Call to Action* section – What Can YOU Do?



ANNUAL CONFERENCE



Researchers, health professionals, and advocates from throughout Texas and the nation flocked to Austin in October 2012 for CPRIT's third annual *Innovations in Cancer Prevention and Research Conference*. The most up-to-date trends, debates, topics, and issues related to cancer research, prevention, and product development were presented during the 3-day conference. Speakers, CPRIT grantees, sponsors, and guests discussed experiences, current challenges, and goals for the future in the ongoing fight against cancer.

Dr. Brian J. Druker, the renowned leukemia specialist whose research led to the development of the drug Gleevec, keynoted the conference and gave attendees insight into the process of turning scientific breakthroughs into patient-ready treatments. Governor Rick Perry and Lieutenant Governor David Dewhurst both made unannounced appearances during the conference, thanking the attendees for their work as well as sharing their support and encouragement for CPRIT's future impact on Texas.

ADVISORY COMMITTEES

In carrying out CPRIT's mission, the Oversight Committee benefits from advice and input from four standing committees that are external to the governing body. These committees meet at least semi-annually and report to the CPRIT executive director and Oversight Committee executive leadership. Committee updates and reports are presented to the Oversight Committee at its quarterly meetings.

Advisory Committee on Childhood Cancers

The Advisory Committee on Childhood Cancers (ACCC) was created by statute to provide input and advice to CPRIT regarding the prevention, control and cure of childhood cancers. ACCC membership includes childhood cancer advocates and scientists whose research focus targets issues in pediatric oncology.

Product Development Strategy Committee

The Product Development Strategy Committee was created by the Oversight Committee to provide tactical advice regarding CPRIT's product development efforts and enhancing Texas' ability to move innovative products from the laboratory into clinical practice.

Scientific and Prevention Advisory Committee

The Scientific and Prevention Advisory Committee (SPAC) was created by the Oversight Committee to provide advice and support services to the Oversight Committee. The 22 SPAC members represent cancer-related fields including research, clinical trials, health care delivery, prevention programs, advocacy, and cancer survivorship.

University Advisory Committee

The University Advisory Committee was created by statute to advise the Oversight Committee regarding the role of institutions of higher education in cancer research. Membership is comprised of representation from the following university systems or institutions:

- University of Texas
- Texas A&M University
- Texas Tech University Health Sciences Center
- University of Houston
- Texas State University
- University of North Texas
- Baylor College of Medicine
- Rice University

FINANCIALS

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS FINANCIAL SUMMARY (UNAUDITED) For the Year Ended August 31, 2012

REVENUES		
Legislative Appropriations	\$	297,072,446
License, fees and permits		76,896
Interest income		1,345
Other		64,728
Total Revenues	\$	297,251,415
EXPENSES		
Salaries and Wages	\$	2,400,734
Other Personnel Cost		26,200
Professional Fees and Services		9,583,665
Consumable Supplies		19,070
Utilities		50,663
Travel		59,224
Rent – Building		462,813
Rent – Machine and Other		20,923
Other Operating Expenses		341,642
Grant		281,565,685
Capital Expenditures		–
Total Expenses	\$	294,530,619
EXCESS OF REVENUES OVER EXPENSES	\$	2,684,796

Financial Position of the Cancer Prevention and Research Institute of Texas

Management of the Cancer Prevention and Research Institute of Texas (CPRIT) is responsible for establishing and maintaining adequate internal control over financial reporting and compliance with certain provisions of laws, regulations, contracts, and grant agreements and other matters.

Clifton Larsen Allen LLP, an independent public accounting firm, has audited CPRIT's internal control over

financial reporting and compliance for the year ended August 31, 2012. As a result of the audit, Clifton Larsen Allen LLP has ascertained that the financial statements of CPRIT “present fairly, in all material respects, the respective financial position of the governmental activities and governmental funds of CPRIT as of August 31, 2012, and the respective changes in financial position and the discretely presented component unit for the year then ended in conformity with accounting principles generally accepted in the United States of America.”



2013 Executive Team

Wayne R. Roberts

Interim Executive Director

Margaret Kripke, Ph.D.

Chief Scientific Officer

Rebecca Garcia, Ph.D.

Chief Prevention Officer

Heidi McConnell

Chief Operating Officer

Kristen Pauling Doyle

General Counsel

Patricia Vojack

Chief Compliance Officer

Sandra Balderrama

Senior Advisor to the Executive Director

Laurie Baker

Receptionist

Ellen Read

Information Specialist

Michael Brown

Research Program Director

Sandra Reyes

Executive Assistant

Michelle Frerich

Prevention Program Manager

Alfonso Royal

Finance Manager

Michelle Huddleston

Accountant

Therry Simien

Information Technology Officer

Yvette Jimenez

Administrative Assistant

Ramona Magid

Prevention Program Director

Lisa Nelson

Operations Manager

**CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
FISCAL YEAR 2013 CYCLE 2**

**APPLICATION REVIEW STATEMENT
(PRIVILEGED COMMUNICATION)**

Principal Investigator: <<PI Full Name>>
Application ID: <<Display ID>>
Application Title: <<Application Title>>
Award Mechanism: <<Award Mechanism Full Name>>

Dear Dr. <<PI Last Name>>:

As you are aware, in a letter dated December 18, 2012 to CPRIT's Oversight Committee, Gov. Rick Perry, Lt. Gov. David Dewhurst, and Speaker Joe Straus called for a moratorium on new CPRIT grant awards. This affected all aspects of CPRIT's grants review and award processes. On February 1, 2013, you were notified that, in light of this directive, CPRIT could not proceed with the review of your submission, as scheduled.

At this time, a decision to lift the moratorium has not been reached. It is possible a decision may be reached by the end of May. Given the current restrictions, and to be respectful of your options regarding the work proposed in this submission, CPRIT has decided to administratively withdraw your application from this review cycle (FY 2013 Cycle 2).

When CPRIT's peer review activities resume, a new Request for Applications (RFA) will be issued for this award mechanism. We hope you will consider submitting an application at that time. This may be the same application you submitted for this review cycle, or an updated version that includes developments that may have occurred in the intervening months. (This withdrawn application does not count towards the application submission limit.)

Please note that your FY 2013 Cycle 2 application has not undergone any stage of review, including assessment of eligibility or responsiveness to the award mechanism. If you have any questions regarding either of these aspects, kindly contact the CPRIT Scientific Review Office, (512) 463-3190, prior to your subsequent submission.

CPRIT is aware of the hardship this has created for its cancer research applicant community in Texas and regret that it has no other course of action at this time.

Again, we thank you very much for your submission and for your patience and support.

Sincerely,

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

April 26, 2013

**CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
FISCAL YEAR 2013 CYCLE 3**

**APPLICATION REVIEW STATEMENT
(PRIVILEGED COMMUNICATION)**

Principal Investigator: <<PI Full Name>>
Application ID: <<Display ID>>
Application Title: <<Application Title>>
Award Mechanism: <<Award Mechanism Full Name>>

Dear Dr. <<PI Last Name>>:

As you are aware, in a letter dated December 18, 2012 to CPRIT's Oversight Committee, Gov. Rick Perry, Lt. Gov. David Dewhurst, and Speaker Joe Straus called for a moratorium on new CPRIT grant awards. This affected all aspects of CPRIT's grants review and award processes. On February 1, 2013, you were notified that, in light of this directive, CPRIT could not proceed with the review of your submission, as scheduled.

At this time, a decision to lift the moratorium has not been reached. It is possible a decision may be reached by the end of May. Given the current restrictions, and to be respectful of your options regarding the work proposed in this submission, CPRIT has decided to administratively withdraw your application from this review cycle (FY 2013 Cycle 3).

When CPRIT's peer review activities resume, a new Request for Applications (RFA) will be issued for this award mechanism. We hope you will consider submitting an application at that time. This may be the same application you submitted for this review cycle, or an updated version that includes developments that may have occurred in the intervening months. (This withdrawn application does not count towards the application submission limit.)

Please note that your FY 2013 Cycle 3 application has not undergone any stage of review, including assessment of eligibility or responsiveness to the award mechanism. If you have any questions regarding either of these aspects, kindly contact the CPRIT, (512) 463-3190, prior to your subsequent submission.

CPRIT is aware of the hardship this has created for its cancer research applicant community in Texas and regret that it has no other course of action at this time.

Again, we thank you very much for your submission and for your patience and support.

Sincerely,

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

April 26, 2013

Kristen Doyle

From: Wayne Roberts
Sent: Friday, June 14, 2013 8:55 AM
To: Sandra Balderrama
Cc: CPRIT Senior Staff
Subject: Withdrawing Stale Applications
Attachments: oth130610kpd FY2012 Cycle 3 Timeline of Events.pdf; mmo130610kpd FY2012 C3 comm grants rec.pdf

As we look toward restarting efforts to issue cancer prevention and research grants, I am working through an issue that remains unresolved from a past award cycle. This concerns five commercialization applications that were submitted in March 2012 in response to CPRIT's request for commercialization applications.

Through no fault of the applicants, these five proposals have been pending a final decision for well over a year. Due to the length of time between submission and final decision, I have concerns about the "freshness" of both the business and research plans in the pending proposals as well as the expert reviewers' input. As a result, I have made the decision to withdraw these applications from further consideration and review at this time.

One of these five applications has been recommended for funding by the Commercialization Review Council. I am exercising my statutory discretion not to recommend this application for funding consideration by the Oversight Committee. This decision is not a reflection upon the underlying merit of the application or because I disagree with the expert reviewers' recommendations regarding the application. Instead, because of the unusual circumstances and long delay between the application and a final decision, I will not bring this to you for a vote. I will contact the applicant and encourage the company to resubmit an updated application when CPRIT restarts its product development program.

I plan to notify the applicants on Monday that CPRIT will be withdrawing the applications from further consideration. The applicants may resubmit their proposals when CPRIT issues a request for applications. Although it will not be what the applicants want to hear after waiting so long, this past legislative session has made it clear that when we are investing taxpayer dollars CPRIT's award decisions must be based on the best and most recent information possible.

I have attached a memo from Kristen Doyle providing legal advice regarding these applications.

Please let me know if you have any questions or need more information.

Wayne R. Roberts
Interim Executive Director
Cancer Prevention & Research Institute of Texas
P.O. Box 12097
Austin, Texas 78711
wroberts@cpriti.state.tx.us
512-305-8416

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**CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
FISCAL YEAR 2012 CYCLE 3**

**APPLICATION REVIEW STATEMENT
(PRIVILEGED COMMUNICATION)**

Principal Investigator: <<PI Full Name>>
Application ID: <<Display ID>>
Application Title: <<Application Title>>
Award Mechanism: <<Award Mechanism Full Name>>

Dear Dr. <<PI Last Name>>:

This notifies you that CPRIT regretfully withdraws from further review all applications submitted in March 2012 in response to CPRIT's FY2012 Cycle 3 request for commercialization applications. You receive this notice because your company has a commercialization application pending in the FY 2012 Cycle 3. **Should you wish to re-submit your application at a later time pursuant to an appropriate and applicable request for applications, CPRIT will not count the withdrawn application towards the application submission limit and you will not be required to pay the commercialization application fee.**

The decision to withdraw the applications was not made lightly. Last December the members of CPRIT's Oversight Committee received a letter from Gov. Rick Perry, Lt. Gov. David Dewhurst, and Speaker Joe Straus calling for a moratorium on new CPRIT grant awards. This affected all aspects of CPRIT's grants review and award processes, including the review of FY 2012 Cycle 3 CPRIT commercialization applications. The moratorium was initiated due to questions raised about the CPRIT grant award process. CPRIT governance, operations, and award review issues received a great deal of attention during the recently-concluded Texas regular legislative session, culminating in the adoption of extensive reforms to CPRIT's statute. The reform legislation was just signed into law by the governor. As a result, CPRIT's governing body - the Oversight Committee - will be reset with new members.

CPRIT is unable to project when it will be able to move forward with commercialization recommendations, if any, from this review cycle. At this time, a decision to lift the moratorium has not been reached. Furthermore, CPRIT is operating without a commercialization officer and it will take time to fill this important position. It is likely that by the time CPRIT is able to take action, the business and research plans submitted by you will be nearly two years old. To be respectful of your options regarding the work proposed in this submission and to provide you with the best possible opportunity to receive CPRIT funding, CPRIT has decided to administratively withdraw your application from this review cycle (FY 2012 Cycle 3).

A new request for commercialization applications will be issued for company awards when CPRIT's grant application and peer review activities resume. We hope you will consider submitting an application at that time. This may be the same application you submitted for this review cycle updated with current information that includes developments that may have occurred in the intervening months. A final copy of the business operations due diligence report conducted as part of this review cycle will be provided to you in the event that information presented in the report helps you in preparing a submission to CPRIT or for other business purposes.

CPRIT is aware of the hardship this has created for its cancer research applicant community in Texas and regrets that it has no other course of action at this time. Again, we thank you for your submission and for your patience and support.

Sincerely,

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

June 17, 2013

MEMORANDUM

TO: WAYNE R. ROBERTS, INTERIM EXECUTIVE DIRECTOR
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: OVERVIEW OF GRANT REPORTING RECONCILIATION PROJECT
DATE: JULY 1, 2013
ATTACHMENTS: NOTICE SENT TO OVERSIGHT COMMITTEE, NOTICES SENT TO GRANT RECIPIENTS

Summary

CPRIT initiated the reconciliation project in March 25, 2013 to provide grant recipients the opportunity to become current on outstanding reporting obligations. The goal of the reconciliation project is to assist grant recipients in achieving 100% reporting compliance for all required reports before standards and penalties become effective with the implementation of new administrative rules. Maximizing the number of current reports also increases the accuracy of projected bond issuance schedules and enhances CPRIT's grant monitoring responsibilities. Financial and programmatic staff resources have been dedicated to reviewing and reconciling all outstanding reports submitted during the reconciliation period. The reconciliation period was originally set to end May 31, 2013, but was extended until July 31, 2013 to accommodate the number of reports submitted.

Background

CPRIT's grant award contract requires the submission of reports to CPRIT on a regular basis. Required reports include quarterly financial status reports (FSRs), quarterly, annual, and final progress reports, equipment inventory reports, HUB reports, and single audit determination reports. The grant recipient submits a quarterly FSR documenting the expenses made in the previous fiscal quarter in order to receive a grant payment. Pursuant to the grant contract terms, a grant recipient has 90 days following the end of the fiscal quarter to submit a FSR to CPRIT. The agency's financial staff reviews each FSR to ensure that expenses proposed for reimbursement are consistent with the contract requirements and other state standards, such as the Comptroller's Uniform Grant Management Standards (UGMS). The financial review typically takes 10 days, but may take longer if non-reimbursable expenses are included. Once the FSR is reviewed and approved by CPRIT's financial department, it is signed by the Chief Operating Officer and the expenses listed on the FSR are reimbursed via a transfer through USAS. Most CPRIT grant award contracts are paid on a reimbursable basis; however grant

recipients receiving grant funds via approved advances are also required to submit quarterly FSRs.

Until September, 2012, FSRs and other required reports associated with the grant award contract were submitted to CPRIT via an interim grant management system that relied primarily upon the exchange of .pdf documents. CPRIT's fully electronic grant management system (CGMS) was put into place late last year to enhance CPRIT's grant monitoring efforts and implement several audit recommendations. The new system facilitates the exchange and review of financial documents and other reports associated with the grant award, as well as automatically notifying the grant recipient of reporting deadlines and "locking down" any grant award that is late in submitting a required report. Until CGMS was brought online, all of the cross-checking work was done manually and consumed staff time and resources.

As with most major technology infrastructure projects, there were some early challenges for users navigating the new fully electronic CGMS. In addition to reporting delays associated with learning CGMS, some grant recipients have fallen behind on reporting for other reasons and have missed submission deadlines for required reports.

Discussion

A grant recipient's failure to timely submit a required FSR impacts CPRIT's ability to effectively manage its bond issuance. CPRIT must coordinate the timing of bond issuances with Texas Public Finance Authority (TPFA). The Chief Operating Officer creates a detailed bond issuance plan by relying upon the grant project budgets that are approved when awards are announced. CPRIT uses the bond issuance plan to notify TPFA of the anticipated need for bond funding. However, because most grant funds are distributed on a reimbursable basis, if a grant recipient does not timely submit the FSR then CPRIT retains the grant funds until a reimbursement request is made and approved. Some grant recipients are delinquent in submitting reports for several quarters. Failure to submit FSRs on time is particularly problematic when it occurs at institutions that receive many grant awards. As a result of the number and amount of delinquent reports, CPRIT's projected near-term bond issuance needs are overstated.

Inaccurate projections that overstate the need for bond funds in the early years may impact the ability of CPRIT to issue bonds in the later years. The natural consequence of a grant recipient's overstating the need for grant funds in the early years of the funded project is that the reimbursement obligations are pushed off into later years. CPRIT's statute prohibits TPFA from issuing and selling more than \$300 million in general obligation bonds in a state fiscal year. (See Tex. Health & Safety Code § 102.202(b)).

CPRIT's grant contract permits the agency to terminate the grant award if the recipient fails to fully comply, in any material aspect, with contract terms. Although this provision provides CPRIT the grounds to terminate a grant contract for delinquent reports, termination may not be the appropriate response. The termination process requires additional administrative steps and may subject the agency to litigation, both of which will consume staff resources. In order to create a more effective tool to ensure compliance, CPRIT will propose a new administrative rule that makes it clear that if grant recipient fails to submit the FSR within the required 90 days following the close of the quarter (and does not request a 30 day extension) then the recipient waives the right to reimbursement for that quarter. This remedy is proportional to problem and is likely ensure that FSRs are submitted by the due date. CPRIT is using the reconciliation process in order to provide grant recipients the opportunity to come into compliance before the proposed rule change becomes effective.

Although this memo discusses the reconciliation period primarily in relation to delinquent FSRs, it should be noted that the reconciliation period covers all required reports, including quarterly, annual and final progress reports, matching certification forms, equipment inventory reports, historically underutilized business reports, and single audit determination reports. Timely submission of these reports is an important component of CPRIT's grant monitoring responsibilities.

Actions Taken By CPRIT

CPRIT Oversight Committee members were notified about the reconciliation project on March 22, 2013, via email from interim Executive Director, Wayne Roberts.

All CPRIT grant recipients were notified about the reconciliation period via a message sent to individual CGMS accounts on March 25, 2013.

The original term of the reconciliation period began March 25, 2013, lasting through May 31, 2013.

The volume of past due reports submitted for review increased steadily in the period leading up to the original May 31st deadline. CPRIT received several requests from grant recipients seeking expedited treatment of submitted reports, including moving some reports to the front of the line for review. CPRIT processes reports in the order the reports are received to be fair to everyone. However, to give grant recipients every opportunity to become compliant, CPRIT extended the reconciliation period for submitting delinquent required reports until July 31, 2013.

From: help@cpritgrants.org
To: [Lisa Nelson](#)
Subject: Reconciliation EXTENSION Notice
Date: Tuesday, May 28, 2013 12:07:20 PM

Dear Grantee,

This notice is being sent to all grantees.

To give grant recipients every opportunity to become compliant, CPRIT extends the reconciliation period for submitting delinquent required reports until July 31, 2013. Once this reconciliation period ends, CPRIT intends to enforce fully its available contractual rights, such as withholding reimbursement or early termination, for missed reporting deadlines.

CPRIT began this reconciliation project in late March to give grant recipients that were delinquent in reporting obligations the opportunity to become current. The goal is to assist grant recipients in achieving 100% reporting compliance before new, stricter standards become effective. This reconciliation period covers all required reports, including financial status reports, quarterly, annual and final progress reports, matching certification, equipment inventory reports, historically underutilized business reports, and single audit determination reports.

CPRIT has dedicated financial and programmatic staff resources to review submitted reports as quickly as possible during the reconciliation period. During the reconciliation period, CPRIT has approved more than 750 financial status reports in addition to other required reports. As expected, the volume of past due reports to be reviewed has increased in the period leading up to the original May 31st deadline. Several requests have been made seeking expedited treatment of submitted reports, including moving some reports to the front of the line for review. To be fair to everyone, CPRIT is processing the reports in the order they are received. CPRIT asks that you consider the impact of your institution's summer schedules when planning the submission of your reports by the July 31, 2013, deadline.

If your grant award contract is scheduled to end this summer and you are considering seeking a no cost extension (NCE), you must submit the NCE request to CPRIT **before** the contract terminates. The NCE request may be granted only if your grant is in good fiscal and programmatic standing. If you are delinquent in submitting required reports to CPRIT, the NCE request will be denied. However, do not wait to submit the NCE request even though required reports may be delinquent. During this reconciliation period, the grantee may resubmit the NCE request for reconsideration once the delinquencies have been addressed as long as the original request was submitted to CPRIT prior to the termination date of the grant contract.

Sincerely,

Wayne R. Roberts
Interim Executive Director
Cancer Prevention & Research Institute of Texas

From: Help@CPRITGrants.org
Sent: Friday, March 22, 2013 3:46 PM
Subject: Reconciliation Period

Dear Grantee:

CPRIT is sending this notice to all grantees. If you are delinquent in your reporting obligations, you have this opportunity to become current. During this reconciliation period CGMS will be available to accept past due reports. **Please bring this opportunity to the attention of your finance office so your grant funding is not affected.**

Commencing March 25, 2013 and ending on May 31, 2013, financial status reports, progress reports, and all other required reports (Matching Certification, Equipment Inventory, Historically Underutilized Business, and Single Audit Determination Report) that would otherwise be considered late may be submitted to CPRIT for review. CPRIT will dedicate financial and programmatic staff resources to review and reconcile all reports that are submitted.

Additionally, no-cost extensions may be requested and will be considered by CPRIT following the standards and procedures applicable to no-cost extension requests.

The goal of this project is to assist grant recipients in achieving 100% reporting compliance. Please allow yourself sufficient time for submission, review, correction (if required) and approval of your report(s) within the reconciliation period. **Once this reconciliation period ends, CPRIT will fully enforce its available contractual rights for missed reporting deadlines which include withholding payments or grant termination.**

Should you have any questions concerning this reconciliation period or the required reports, please do not hesitate to contact:

- Program Questions—Grant Manager
- Finance Questions—Finance Manager
- CGMS Questions—Help Desk

All communication must be through CGMS correspondence. We are looking forward to mutually meeting all reporting expectations and requirements.

Sincerely,

Wayne Roberts
Interim Executive Director
Cancer Prevention & Research Institute of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: WAYNE R. ROBERTS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: REVIEW COUNCIL CONTRACTS FOR FY 2014
DATE: SEPTEMBER 1, 2013

Summary and Recommendation:

The FY 2014 Review Council contracts, effective September 1, 2013, reflect changes made pursuant to CPRIT's new honoraria policy. Although Oversight Committee approval is not required to execute these honoraria contracts, the statute requires that the Oversight Committee approve Review Council member appointments and some Review Council members have not yet been approved. CPRIT's Review Councils are actively working with CPRIT staff to prepare for resumption in grant activities. To avoid an interruption in their service, all Review Council contracts should be executed at this time, including contracts for those members whose appointments have not yet been approved by the Oversight Committee. In the event that the Oversight Committee does not approve a Review Council member's appointment, the honoraria contract may be terminated by CPRIT.

Discussion:

CPRIT relies upon three Review Councils, one for each grant program. Review Council members are Scientific Research and Prevention Program (SRPP) Committee members that have been designated as chairpersons of the peer review panels. The Oversight Committee is responsible for approving the Chief Executive Officer's SRPP appointments, including those individuals appointed to the Review Council. Eight of the 14 Review Council members have been approved by the Oversight Committee.

Review Council members are paid honoraria pursuant to a written contract. Typically, the honoraria contract term is for the fiscal year. A new statutory provision requires the Chief Executive Officer to establish a written policy for honoraria paid to SRPP Committee members.¹ CPRIT has established a written policy consistent with the statutory requirement and has updated the honoraria contract to follow the new policy.² Neither the statute nor CPRIT's administrative rules require Oversight Committee approval for an honoraria contract. Under normal circumstances, execution of honoraria contracts would occur following approval of the Review Council member's appointment. However,

¹ The new statutory provision, Section 102.151(e), is consistent with a recommendation made by the State Auditor.

² The honoraria policy will be formally presented at the next Oversight Committee meeting and will be available on CPRIT's website.

new Oversight Committee member appointments have not been announced and it is not yet clear when an Oversight Committee meeting will be held.

Review Council members for all three of CPRIT's programs have been working to prepare for a resumption of grant making activity, as well as advising CPRIT regarding current funded grants. To avoid an interruption in service, the Review Council contracts should be executed at this time. Should the Oversight Committee not approve a Review Council member appointment, the honoraria contract includes a provision that the contract may be immediately terminated by CPRIT. Executing the contracts now subject to final approval of the Review Council member by the Oversight Committee at its next meeting appropriately balances the need to continue Review Council work without nullifying the Oversight Committee's role in the Review Council member appointment process.

The Appropriations Act passed during the last legislative session includes a rider requiring Legislative Budget Board approval for CPRIT contracts that are for \$100,000 or more. Although the honoraria paid to a Review Council member varies by position and by program, no honoraria contract exceeds \$100,000.

Recommendation:

The FY 2014 honoraria contracts for Review Council members should be executed at this time in order to avoid an interruption in service. Consideration and approval of new Review Council member appointments will be an agenda item for the next Oversight Committee meeting. If the Oversight Committee does not approve one or more of the Chief Executive Officer's Review Council member appointments, the honoraria contract will be terminated.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: WAYNE R. ROBERTS, INTERIM EXECUTIVE DIRECTOR
FROM: REBECCA GARCIA, PH.D., CHIEF PREVENTION OFFICER
SUBJECT: CPRIT 2014 CONFERENCE
DATE: OCTOBER 28, 2013

Summary and Recommendation:

CPRIT has held conferences over the last three years and a decision is needed on whether to proceed with a conference in 2014. CPRIT staff recommends that discussion of the purpose and goals for a 2014 conference be assigned to the Governance subcommittee and, if a conference is deemed appropriate, any necessary RFPs or actions be prepared under its guidance. Any proposed contract resulting from the selection process must be approved by the Oversight Committee in an open meeting. In addition, any final decision concerning a conference will be brought to the Oversight Committee as will any significant financial decisions.

Discussion:

CPRIT's annual conference has been designed to provide educational and networking opportunities for grantees, highlight the accomplishments of CPRIT grantees, and communicate to the public how CPRIT uses its state appropriations. CPRIT has held three conferences in the fall of 2010, 2011 and 2012. Due to the moratorium and other issues, CPRIT did not hold a conference in 2013.

As CPRIT emerges from the moratorium, the conference could be an excellent venue to communicate to grantees and the public that CPRIT is resuming full operations and to convey future directions.

Audience

Each conference has attracted about 850 registrants. The primary audience for the conference has been CPRIT grantees with about two-thirds being researchers and one-third being public and community health professionals. CPRIT grantees are encouraged to attend and may use grant funds to register up to two people involved in a funded project.

Program Structure

Previous conferences have been 2.5 days in length. The format included keynote speakers in plenary sessions, grantee presentations, and abstract and poster presentations in concurrent breakout

sessions. Afternoons were comprised of three tracks, one for each program--prevention, research and product development. The first two conferences were held at the Austin Convention Center and the third at the Austin Renaissance Hotel.

Costs and Funding for the Conference

The cost for the 2012 conference was about \$450,000. The largest expenses were food and beverage and audio visual equipment. In prior years, CPRIT partnered with the CPRIT Foundation to put on the conference. The first year the Foundation supported all the conference costs and in the last two years, CPRIT and the Foundation shared costs. CPRIT's share for the 2012 conference was about \$190,000. The Foundation solicited sponsorships for the conference and hosted a dinner the night before the conference. Registration fees ranged from \$295-\$355 and covered some of the conference costs.

New Challenges with 2014 Conference

Funding

Without the CPRIT Foundation subsidies and due to certain state funding restrictions, CPRIT must reevaluate how to structure and fund a conference. Options currently being explored include sponsorships, restructuring the conference to a smaller scale and exploring whether all conference costs can be covered by a registration fee that would not be cost prohibitive for attendees.

Venue and date

Although the conferences have been held annually, in February 2013 the Oversight Committee discussed transitioning to biennial conferences. If a conference is held in 2014, staff recommends holding the conference in November or December prior to the 2015 legislative session. Once the session starts the agency will be focused on legislative activities. If a conference is to be held, requests for bids/proposals must be prepared quickly. The bidding process will allow us to outline our needs based on a scaled back budget (lower than in previous years). Suitable conference space is difficult to come by in Austin during the popular fall season. We are targeting the last quarter in the calendar year in the hopes that this is a slower time for the venues and that they find our conference an attractive opportunity. Other steps CPRIT is taking include exploring venues in cities other than Austin and sites other than hotels.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: WAYNE R. ROBERTS, INTERIM EXECUTIVE DIRECTOR
FROM: REBECCA GARCIA, PH.D., CHIEF PREVENTION OFFICER
SUBJECT: STRATEGIC COMMUNICATIONS CONTRACT
DATE: OCTOBER 28, 2013

Summary and Recommendation:

An effective, coordinated, strategic communications program is needed to inform the public, legislature, media, health professionals, and partner organizations about CPRIT's activities. CPRIT has historically relied on contractors to meet its communications needs. The current communications contract expires February 28, 2014. CPRIT staff recommends that the needs assessment for communications services be reviewed by the Governance subcommittee and if deemed appropriate, an RFP be prepared under its guidance. If an RFP is released, it should be reviewed by the Governance subcommittee. Any proposed contract resulting from the selection process must be approved by the Oversight Committee in an open meeting.

Discussion:

Created to make a difference in the lives of Texans affected by cancer, CPRIT has a responsibility to inform the public, legislature, media, health professionals, and partner organizations about its activities. An effective, coordinated, strategic communications program is needed to provide this service.

Components of a strategic communications program include:

- **Communications Strategy Planning** - determining objectives, audiences, messages, and strategies for important communications initiatives. Identifying channels and activities to reach particular audiences and evaluating the results of the communications activities undertaken to assist in planning and future initiatives.
- **Public Outreach** –communications activities to inform and educate the public about CPRIT activities and accomplishments. Promoting, disseminating, and reinforcing messages about programs and goals both internally and externally. Examples include the CPRIT Conference and outreach events (e.g. town hall, check presentations).

- **Public Affairs** –developing messaging and providing access to CPRIT staff in arranging press interviews on Institute activities including cancer-related topics. Preparing draft public statements for the Oversight Committee and staff as appropriate.
- **CPRIT Publications Support** -consultation on content, printing, graphic design, and publications layout of CPRIT’s required and other reports.
- **Web Site Content Development** -consultation on message development for agency information, health/cancer content as well as website design and layout.

CPRIT has minimal staff to support the agency’s communication needs, and historically has relied on contractors to assist with many of the above communications activities. Since 2010, CPRIT has contracted with communications firms, based in Austin, to provide strategy and support to ensure successful CPRIT communications. With increasing demand for immediate information in the ever-changing information age, providing a coordinated and comprehensive communications strategy could require 3-4 full time staff members.

After a difficult year played out in the media across the state, CPRIT communications hopes to build on new relationships and trust earned with key media outlets. The services provided by CPRIT’s current communications contractors were crucial to improved relations.

To continue to build on these efforts, CPRIT needs continued support from a professional communications firm to develop and oversee a strategic communications plan. This service should reach internal and external audiences while generating positive publicity for the agency through both traditional and digital media avenues that advance CPRIT priorities and goals. Other activities that a strategic communications contract can provide include but are not limited to:

1. Providing ongoing counsel and strategic direction, including daily media monitoring.
2. Drafting informational releases, talking points and other key communications pieces related to CPRIT and its initiatives.
3. Developing key messages and talking points for CPRIT staff and Oversight Committee members.
4. Ensuring consistent messaging and branding across all communications vehicles: annual report, website, social media, legislative requests, and advocacy groups.
5. Developing and implementing external communication strategies to promote the opportunities, work and successes of CPRIT and its funded initiatives not only in Texas but nationally.
6. Serving as a point of contact for media inquiries and managing interview preparation, messaging and execution.
7. Assisting staff in planning and execution of potential CPRIT conferences; e.g., conference overarching themes and brand, promotion, media relations, developing collateral materials (brochures, program books, etc.).
8. Performing environmental scanning to determine emerging communications opportunities and threats.

The current communications contract expires February 28, 2014. As CPRIT prepares to resume activities under the leadership of a new Oversight Committee, there will be considerable attention paid to the agency's activities. To meet expected and unexpected communications needs in the future, CPRIT will continue to need the services of a qualified communications contractor.

Possible Next steps

Steps for Communications Services RFP	Time frame
Staff develop needs assessment/scope of work & RFP	1-2 weeks
Discuss scope and draft RFP with OC subcommittee	1-2 weeks
Make changes to draft RFP based on OC input	1 week
Submit to Comptroller for processing; incorporate Comptroller changes	2-3 months
Release RFP and receipt of proposals	2 weeks minimum, up to 4 weeks is norm
Evaluate candidates; make selection	1 week
Inform OC	Via memo or at OC meeting depending on timing
Submit to LBB for approval of contract	No set timetable for review and approval
Contract with firm	Up to six months from beginning of process



**CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS**

MEMORANDUM

TO: OVERSIGHT COMMITTEE
FROM: WAYNE ROBERTS, INTERIM EXECUTIVE DIRECTOR
SUBJECT: HUB REPORT TO SENATOR ROYCE WEST, FEBRUARY 13, 2013
DATE: OCTOBER 27, 2013

Summary and Recommendation:

This transmittal provides information requested at the last Oversight Committee (OC) on February 25, 2013, concerning CPRIT's Historically Underutilized Businesses (HUB) report. To improve the agency's and awardees' use of HUB vendors the OC Diversity Subcommittee should direct staff to monitor and improve conformity with state goals for all CPRIT-related HUB procurement activities.

Discussion:

During the Chief Operating Officer Report at the February 25, 2013, OC meeting, Member Barbara Canales reported that at the first Senate Finance Committee hearing Senator Royce West asked about CPRIT's HUB report. Member Canales requested an explanation at the next Oversight Committee meeting (November 1, 2013) for CPRIT's comparatively low percentages and a copy of the follow-up information provided to Senator West.

HUB programs facilitate the use of minority and women-owned business for state agency operations. The state contract procurement goal for "other services" which is highly applicable to CPRIT procurement contracts is 24.6 percent. CPRIT's 2012 percent for "other services" was 5 percent. The state goal for "commodities" procurements is 21.0 percent. CPRIT's 2012 percent for "commodities" was 20.0 percent.

These figures are from the memo to Wayne Roberts from Alfonso Royal (finance manager) that was provided to Senator West (attachment).

CPRIT's 2013 HUB report is not yet available.

The major reason for the low percentage of HUB awards in "other services" is due to the size of the SRA International contract which is CPRIT's massive online grant application, review, and monitoring portal which constitutes 55 percent of CPRIT's 2012 contracts. CPRIT recently added a HUB contractor to provide financial audit services for FY 2014. However, CPRIT has discontinued use of a woman-owned contractor (JHL Company) which provided planning and management services for community and stakeholder outreach events.

Recommendation:

I recommend that the Diversity Subcommittee review and discuss CPRIT's procurement practices to identify ways to improve conformity with legislative intent for state agency HUB goals. Perhaps more significantly, CPRIT could begin tracking awardees' compliance with individual institutional HUB requirements (each university has one) with the goal of making sure that CPRIT awards (which contain CPRIT's significant expenditures) maximize HUB vendors and minority/woman relationships.



CANCER PREVENTION &
RESEARCH INSTITUTE OF TEXAS

TO: Wayne Roberts, Interim Executive Director

CC: Heidi McConnell, Chief Operating Officer

FROM: Alfonso Royal, Finance Manager

DATE: February 13, 2013

SUBJECT: Historical Underutilized Business Expenditure Information

Wayne,

The statewide Historical Underutilized Business (HUB) Program facilitates the use of HUBs in state procurement and provides information on the state's procurement process to minority and woman-owned businesses.

Each state agency is required to make a good faith effort to use HUBs in contracts for construction, other services (including professional and consulting services), and commodity purchases. The State has developed the following HUB procurement goals for agencies:

- 11.2% - Heavy Construction
- 21.1% - Building Construction
- 32.7% - Special Trade
- 23.6% - Professional Services
- 24.6% - Other Services, and
- 21.0% - Commodity Purchasing

CPRIT's purchaser uses a variety of purchasing options including statewide term and managed contracts (many through TxSmartBuy), Texas Multiple Award Schedules (TXMAS) contracts, Department of Information Resources contracts, Texas Correctional Industries, TIBH Industries, Inc., TIBH Central Store, and Council on Competitive Government (CCG) contracts to procure all goods and services for the Institute focusing on maximizing best value, efficiencies, and costs savings. Certified HUB vendors are incorporated in all of these procurement options for standard goods and services purchased by state agencies, such as computer equipment, office supplies, and

temporary staff services. HUB vendors are also maintained on a centralized bidders list maintained by the Comptroller of Public Accounts (CPA) for goods and services that a state agency may procure specific to an agency's mission.

When CPRIT procures these types of goods or services, the purchaser searches for HUB vendors on the HUB directory to notify them of CPRIT procurement opportunities that are open for bid. The purchaser also encourages all vendors who come into contact with the Institute directly to become HUB certified, if qualified, with the CPA. In fiscal year 2012, the Institutes overall HUB percentage was five percent and we attained one of the HUB procurement goals (commodities). Below is a summary of HUB expenditures from FY 2010 through 2012.

Fiscal Year 2010 - 2012 HUB Expenditure Information			
<u>Procurement Category</u>	FY 2010 Expenditures		
	<u>HUB</u>	<u>Non- HUB</u>	<u>HUB %</u>
Other Services	48,910	4,662,284	1%
Commodities	112,003	619,274	18%
Totals	160,913	5,281,558	3.0%
<u>Procurement Category</u>	FY 2011 Expenditures		
	<u>HUB</u>	<u>Non- HUB</u>	<u>HUB %</u>
Other Services	188,163	6,314,225	3%
Commodities	26,357	65,052	41%
Totals	214,520	6,379,277	3.4%
<u>Procurement Category</u>	FY 2012 Expenditures		
	<u>HUB</u>	<u>Non- HUB</u>	<u>HUB %</u>
Other Services	483,264	9,954,559	5%
Commodities	34,113	169,660	20%
Totals	517,377	10,124,219	5.1%

Additionally, CPRIT grant award recipients are strongly encouraged to make a good faith effort to use the services, products, or materials provided by certified HUB vendors. The CPRIT grant contract and policy guide includes a requirement that grant recipient submit an annual HUB report that identifies the goods or services purchased through HUBs with CPRIT grant awarded funds. The data collected from the grant recipients are not included in the Institute's HUB expenditure information.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: PROPOSED CHANGES TO OVERSIGHT COMMITTEE BYLAWS
DATE: OCTOBER 28, 2013

Summary and Recommendation:

Statutory changes enacted by the 2013 Texas Legislature impact some provisions of the Oversight Committee Bylaws ("Bylaws"). Revisions to the Bylaws are required to ensure consistency with applicable Texas law. The Oversight Committee should vote to adopt the proposed Bylaw changes.

Discussion:

In September, 2012, the Oversight Committee created the Board Governance subcommittee and charged the subcommittee with creating a set of bylaws to govern the Oversight Committee. The Board Governance subcommittee solicited input from all Oversight Committee members. The Oversight Committee approved the proposed Bylaws at its February 25, 2013 open meeting. Section 4.5 of the Bylaws provides that the Board Governance Committee shall review and recommend proposed bylaw changes to the Oversight Committee for adoption.

Senate Bill 149 was signed into law by Governor Perry on June 14, 2013, taking effect immediately. The legislation enacted changes to CPRIT's enabling legislation, Chapter 102 of the Texas Health & Safety Code. It also ended the terms of the Oversight Committee members serving at the time the legislation took effect.

The recent legislative changes impact some provisions of the Bylaws, including the number of Oversight Committee members, membership and qualifications requirements, and the title for the head of the agency. Proposed revisions to the text are noted by strikethroughs (suggested deletions) and underscoring (new text). There are no sitting members of the Board Governance Committee to review and recommend these proposed revisions; in their absence, I recommend that the Oversight Committee adopt the proposed changes at its November 1, 2013 meeting in order to conform to state law.

There may be other changes the Oversight Committee desires to make to Bylaw provisions. Those changes may be considered by the Board Governance Subcommittee, as set forth in the Bylaws, and recommended to the Oversight Committee at a future meeting.



THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

OVERSIGHT COMMITTEE BYLAWS

**DRAFT VERSION REFLECTING PROPOSED REVISIONS
TO BYLAWS ADOPTED FEBRUARY 25, 2013**

Proposed Revisions will be considered at the October Oversight Committee Meeting

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CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS OVERSIGHT COMMITTEE BYLAWS

ARTICLE 1 ESTABLISHMENT AND PURPOSES

Section 1.1 Establishment. The Cancer Prevention and Research Institute of Texas (the “Institute”) was established by the Texas Legislature in 2007, as authorized by Article 3, Section 67 of the Constitution of the State of Texas. The statutory provisions establishing the Institute are set forth in Chapter 102 of the Health and Safety Code of the State of Texas (the “Health and Safety Code”). Administrative rules governing the Institute are set forth in Title 25, Chapters 701–704, of the Texas Administrative Code.

Section 1.2 Purposes. The Institute is established to:

- (a) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- (b) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
- (c) develop and implement the Texas Cancer Plan.

ARTICLE 2 AUTHORITY, AMENDMENT, AND INTERPRETATION

Section 2.1 Rulemaking Authority. These Bylaws (“Bylaws”) have been adopted by the Oversight Committee (as defined herein) pursuant to the authority granted to the Oversight Committee in Section 102.108 of the Health and Safety Code.

Section 2.2 Amendment. These Bylaws may be amended or modified only with the approval of a simple majority of the members of the Oversight Committee as set forth in Section 3.13; provided, that no amendment or modification to these Bylaws may be made if such amendment or modification would cause these Bylaws to conflict with applicable law. All approved amendments or modifications shall be noted in a “Statement of Revisions” at the end of these Bylaws.

Section 2.3 Interpretation. These Bylaws are adopted subject to any applicable law, including, but not limited to, Chapter 102 of the Health and Safety Code and Title 25, Chapters 701–704, of the Texas Administrative Code. Whenever these Bylaws may conflict with applicable law, the conflict will be resolved in favor of the applicable law. If at any time the Oversight Committee determines that these Bylaws conflict with applicable law, then the Oversight Committee shall promptly act to amend these Bylaws to cause them to conform to applicable law.

ARTICLE 3 THE OVERSIGHT COMMITTEE

Section 3.1 General Powers. The Oversight Committee of the Institute (the “Oversight Committee”) is the governing body of the Institute. The Oversight Committee may adopt such policies and practices, consistent with applicable law, as it may deem proper for the conduct of its meetings and the management of the Institute.

Section 3.2 Number. The Oversight Committee is composed of the following nine ~~(9)44~~ members:

- (a) three members appointed by the Governor of the State of Texas;
- (b) three members appointed by the Lieutenant Governor of the State of Texas; and
- (c) three members appointed by the Speaker of the House of Representatives of the State of Texas;
- ~~(d) the Comptroller of Public Accounts of the State of Texas or its designee;~~
- and
- ~~(e) the Attorney General of the State of Texas or its designee.~~

Section 3.3 Composition; Disqualification.

(a) The members of the Oversight Committee must represent the geographic and cultural diversity of the State of Texas. In making appointments to the Oversight Committee, the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas shall each appoint at least one person who is a physician or a scientist with extensive experience in the field of oncology or public health and should attempt to include cancer survivors and family members of cancer patients if possible.

(b) A person may not be a member of the Oversight Committee if the person or the person’s spouse: (i) is employed by or participates in the management of a business entity or other organization receiving money from the Institute; (ii) owns or controls, directly or indirectly, an more than a five percent interest in a business entity or other organization receiving money from the Institute; or (iii) uses or receives a substantial amount of tangible goods, services, or money from the Institute, other than reimbursement authorized by law for Oversight Committee membership, attendance, or expenses.

Section 3.4 Term. Each member of the Oversight Committee will hold office for such member’s term or until such member’s earlier death, resignation, disqualification, or removal. Members of the Oversight Committee appointed by the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas serve at the pleasure of the appointing office for staggered six-year terms, with the terms of three members expiring on January 31 of each odd-numbered year. Not later than the 30th day after the date an Oversight Committee member’s term expires, the appropriate appointing authority shall appoint a replacement. ~~Members of the Oversight Committee who are designated by the Comptroller of~~

~~Public Accounts or the Attorney General of the State of Texas serve in accordance with such designation.~~

Section 3.5 Vacancy. If a vacancy occurs on the Oversight Committee, then the appropriate appointing authority shall appoint a successor, in the same manner as the original appointment, to serve for the remainder of the unexpired term. The appropriate appointing authority shall appoint the successor not later than the 30th day after the date the vacancy occurs.

Section 3.6 Resignation. Any appointed or designated member of the Oversight Committee may resign at any time by notice given in writing to the appropriate appointing authority and to the Chair of the Oversight Committee or to the Vice Chair if the Chairman is resigning. The resigning member will continue to serve until such time that the appropriate appointing authority appoints a successor.

Section 3.7 Removal. It is a ground for removal from the Oversight Committee that a member: (a) is ineligible for membership of the Oversight Committee under Section 3.3(b) of these Bylaws; (b) cannot, because of illness or disability, discharge the member's duties for a substantial part of the member's term; or (c) is absent from more than half of the regularly scheduled Oversight Committee meetings that the member is eligible to attend during a calendar year without an excuse approved by a majority vote of the Oversight Committee. If the ~~Chief Executive Officer~~~~Director~~ has knowledge that a potential ground for removal exists, then the ~~Executive Director~~Chief Executive Officer shall notify the Chairperson of the potential ground. The Chairperson shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. If the potential ground for removal involves the Chairperson, then the ~~Executive Director~~Chief Executive Officer shall notify the next highest ranking officer of the Oversight Committee, who shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. Notwithstanding, the foregoing, the validity of an action of the Oversight Committee is not affected by the fact that it is taken when a ground for removal of a committee member exists.

Section 3.8 Strategic Partnerships. To the fullest extent permitted by applicable law, the Oversight Committee retains the authority and power to approve strategic partnerships, alliances, and coalitions of the Institute subject to vote of the simple majority of the members of the Oversight Committee as set forth in Section 3.13.

Section 3.9 Regular Meetings. The Oversight Committee shall hold a public meeting at least once in each quarter of the calendar year, with appropriate notice and with a formal public comment period.

Section 3.10 Special Meetings. Special meetings of the Oversight Committee may be held upon the call of the Chairperson of the Oversight Committee, or the Vice Chairperson of the Oversight Committee when performing the duties of the Chairperson, as he or she may deem necessary, with appropriate notice and with a formal public comment period. Emergency meetings and telephonic meetings may be held only as provided under applicable law.

Section 3.11 Notice of Open Meetings. All meetings of the Oversight Committee are subject to the terms of the Open Meetings Act, Chapter 551 of the Texas Government Code (the "Open Meetings Act"). The Open Meetings Act provides that the public must be given notice of

the time, place, and subject matter of meetings of governmental bodies. In absence of an emergency, notice of a meeting must be posted at a place that is readily accessible to the public at all times at least seven (7) days preceding the scheduled time of the meeting. In case of an emergency of urgent public necessity, which shall be clearly identified in the notice, it shall be sufficient if the notice is posted two hours before the meeting is convened.

Section 3.12 Quorum. The presence of a simple majority of the members of the Oversight Committee present is necessary and sufficient to constitute a quorum for the transaction of business at any meeting of the Oversight Committee.

Section 3.13 Action By Simple Majority Vote. Except as otherwise provided by these Bylaws or applicable law, the vote of a simple majority of the members of the Oversight Committee present at a meeting at which a quorum is present will be the prevailing action of the Oversight Committee.

Section 3.14 Expenses. A member of the Oversight Committee is not entitled to compensation, but is entitled to reimbursement for actual and necessary expenses incurred in attending meetings of the Oversight Committee or performing other official duties authorized by the Chairperson.

Section 3.15 Training. The Institute's General Counsel and Chief Compliance Officer of the Institute shall provide training to all new members of the Oversight Committee and shall provide ongoing or continuing training to all members of the Oversight Committee not less than once a year. The form and substance of such training will be in the discretion of the Institute's General Counsel and Chief Compliance Officer of the Institute. Each new member of the Oversight Committee shall also complete a course of training regarding his or her responsibilities under the Open Meetings Act within 90 days of becoming a member of the Oversight Committee.

ARTICLE 4 SUBCOMMITTEES OF THE OVERSIGHT COMMITTEE

Section 4.1 Generally. The Oversight Committee may designate one or more subcommittees of the Oversight Committee, each subcommittee to consist of three or more of the members of the Oversight Committee. The Oversight Committee shall appoint and approve members of the subcommittees specifically listed in Section 4.2, except for the members of the Executive Committee, which shall be comprised of the designated members as set forth below in Section 4.3. The Oversight Committee may designate one or more members of the Oversight Committee as alternate members of any subcommittee, who may replace any absent or disqualified member at any meeting of the subcommittee. If a member of a subcommittee is absent from any meeting, or disqualified from voting thereat, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of a subcommittee, a majority of the then authorized members of the subcommittee will constitute a quorum, and the vote of a majority of the members of the subcommittee present at any meeting at which there is a quorum will be the act of the subcommittee. Unless the Oversight Committee

provides otherwise, each subcommittee designated by the Oversight Committee shall adopt a subcommittee charter and may make, alter, and repeal rules and procedures for the conduct of its business. The Subcommittee charter shall be approved by a vote of a simple majority as set forth in Section 3.13. In the absence of ~~a subcommittee chartersuch rules and procedures~~, each subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business. Each subcommittee will have a chairperson, who will be selected by the Oversight Committee at large.

Section 4.2 Certain Subcommittees. Without limiting in any way the previous Section, the following are subcommittees of the Oversight Committee (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):

- (a) Executive Subcommittee;
- (b) Audit Subcommittee;
- (c) Board Governance and Ethics Subcommittee;
- (d) Nominations Subcommittee;
- (e) Product Development Subcommittee;
- (f) Scientific Research Subcommittee;
- (g) Prevention Subcommittee; and
- (h) Diversity Subcommittee.

Section 4.3 Executive Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Executive Subcommittee (the “Executive Subcommittee”).

(a) The purpose of the Executive Subcommittee is to transact all normal business referred to it by the Oversight Committee and to conduct the ~~Executive Director~~Chief Executive Officer’s annual performance review.

(b) The Executive Subcommittee will be composed of ~~five no more than four~~ (4) members of the Oversight Committee, ~~and such five persons will be (i) the Chairperson, (ii) the Vice Chairperson, (iii) the chairperson of the Prevention Subcommittee, (iv) the chairperson of the Scientific Research Subcommittee, and (v) the chairperson of the Development Subcommittee.~~ Members of the Executive Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal from their positions by action of the Oversight Committee.

(c) The Executive Subcommittee shall meet as often as the Chair deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

(d) Meetings of the Executive Subcommittee shall be conducted in accordance with the Texas Open Meetings Act.

Section 4.4 Audit Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Audit Subcommittee (the “Audit Subcommittee”).

(a) The purpose of the Audit Subcommittee is to review and make recommendations to the Oversight Committee with respect to the following:

- (i) The annual operating budget and strategic plan;
- (ii) The ~~Executive—Director~~Chief Executive Officer’s ~~recommendations for~~ senior staff hires or dismissals and related compensation;
- (iii) Policies for monitoring grant performance;
- (iv) Variances in the operating budget of the Institute of more than 5% or \$25,000;
- (v) Non-grant contracts exceeding \$100,000; and
- (vi) Any variance of more than 10% in any announced grant award.

(b) The members of the Audit Subcommittee will be appointed by the Oversight Committee. The Audit Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Audit Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Audit Subcommittee.

(c) The Audit Subcommittee shall meet as often as the Chairperson of the Audit Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.5 Board Governance and Ethics Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Board Governance and Ethics Subcommittee (the “Board Governance and Ethics Subcommittee”).

(a) The purpose of the Board Governance and Ethics Subcommittee is to review, and recommend proposed changes for approval to the Oversight Committee with respect to the following:

- (i) These Bylaws;
- (ii) Any policies or administrative rules of the Institute;
- (iii) Legislation regarding or affecting the Institute;
- (iv) The delegation of authority to the ~~Executive—Director~~Chief Executive Officer;
- (v) The ethics policies of the Institute and their administration; and
- (vi) An annual review of the internal policies and processes of the Oversight Committee.

(b) The members of the Board Governance and Ethics Subcommittee will be appointed by the Oversight Committee. The Board Governance and Ethics Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Board Governance and Ethics Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Board Governance and Ethics Subcommittee.

(c) The Board Governance and Ethics Subcommittee shall meet as often as the Chairperson of the Board Governance and Ethics Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.6 Nominations Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Nominations Subcommittee (the “Nominations Subcommittee”).

(a) The purpose of the Nominations Subcommittee is to identify members for the Institute’s advisory committees.

(b) The members of the Nominations Subcommittee will be appointed by the Oversight Committee. The Nominations Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Nominations Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Nominations Subcommittee.

(c) The Nominations Subcommittee shall meet as often as the Chairperson of the Nominations Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.7 Product Development Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Product Development Subcommittee (the “Product Development Subcommittee”).

(a) The purpose of the Product Development Subcommittee is to develop policies for the Oversight Committee’s adoption that will ensure that the Institute properly exercises its duty to award grants ~~to develop products and treatments for patient use from basic cancer research and to properly balance basic research and the realization of opportunities for commercialized treatment and prevention.~~ for research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer. In addition, the Product Development Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT ~~research-product development research grants.~~ research-product development research grants. ~~The purpose of the Development Subcommittee is to develop policies for the Oversight Committee’s adoption that will ensure that the Institute properly exercises its duty to award grants to develop and to properly balance basic research and the realization of opportunities for commercialized treatment and prevention.~~

(b) The members of the Product Development Subcommittee will be appointed by the Oversight Committee. The Product Development Subcommittee will be composed of not less than three members of the Oversight Committee; ~~provided that the~~

~~Comptroller of Public Accounts of the State of Texas (or its designee) and the Attorney General of the State of Texas (or its designee) may participate on an ad-hoc basis in all meetings and actions of the Development Subcommittee.~~ Members of the Product Development Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Product Development Subcommittee.

(c) The Product Development Subcommittee shall meet as often as the Chairperson of the Product Development Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.8 Scientific Research Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Scientific Research Subcommittee (the “Scientific Research Subcommittee”).

(a) The purpose of the Scientific Research Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT scientific research grants. The purpose of the Scientific Research Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants ~~to develop and to balance basic research and the realization of opportunities for commercialized treatment and prevention of cancer~~ for research into the causes of and cures for all types of cancer in humans and to create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT research grants.

(b) The members of the Scientific Research Subcommittee will be appointed by the Oversight Committee. The Scientific Research Subcommittee will be composed of not less than three members of the Oversight Committee; ~~provided that the Comptroller of Public Accounts of the State of Texas (or its designee) and the Attorney General of the State of Texas (or its designee) may participate on an ad-hoc basis in all meetings and actions of the Scientific Research Subcommittee.~~ Members of the Scientific Research Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Scientific Research Subcommittee.

(c) The Scientific Research Subcommittee shall meet as often as the Chairperson of the Scientific Research Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.9 Prevention Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Prevention Subcommittee (the “Prevention Subcommittee”).

(a) The purpose of the Prevention Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants. The purpose of the Prevention Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for cancer prevention and control programs to mitigate the incidence of all types of cancers in humans and to implement the Texas Cancer Plan to develop and to balance basic research and the realization of opportunities for commercialized treatment and prevention of cancer. ~~In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants.~~

(b) The members of the Prevention Subcommittee will be appointed by the Oversight Committee. The Prevention Subcommittee will be composed of not less than three members of the Oversight Committee; ~~provided that the Comptroller of Public Accounts of the State of Texas (or its designee) and the Attorney General of the State of Texas (or its designee) may participate on an ad-hoc basis in all meetings and actions of the Prevention Subcommittee.~~ Members of the Prevention Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Prevention Subcommittee.

(c) The Prevention Subcommittee shall meet as often as the Chairperson of the Prevention Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.10 Diversity Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Diversity Subcommittee (the "Diversity Subcommittee").

(a) The purpose of the Diversity Subcommittee is to ensure that the Institute makes every effort to outreach to all communities about the cancer research and prevention funding opportunities in the State of Texas.

(b) The members of the Diversity Subcommittee will be appointed by the Oversight Committee. The Diversity Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Diversity Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Diversity Subcommittee.

(c) The Diversity Subcommittee shall meet as often as the Chairperson of the Diversity Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

ARTICLE 5 CHAIRPERSON AND VICE CHAIRPERSON

Section 5.1 E~~S~~election. The Oversight Committee shall ~~s~~elect from among its members a Chairperson and a Vice Chairperson in accordance with the selection provisions of

these Bylaws. Nothing herein restricts the ability of the Oversight Committee to elect additional officers from among its members by a vote of a simple majority of the members of the Oversight Committee.

Section 5.2 ESelection, Term of Office and Removal. At the first regular Oversight Committee meeting following the adoption of these bylaws, the members of the Oversight Committee shall ~~select~~ the Chairperson and Vice Chairperson by a vote of a simple majority as set forth in Section 3.13. Thereafter, the members of the Oversight Committee shall ~~select~~ the Chairperson and Vice Chairperson by a vote of a simple majority of as set forth in Section 3.13 at the last regular Oversight Committee meeting of the state fiscal year in each odd-numbered year. The Chairperson and the Vice Chairperson will hold office until death, resignation, or removal from office, or the ~~selection~~ and qualification of a successor, whichever occurs first; provided, however, that neither the Chairperson nor the Vice Chairperson may hold office for ~~more than two consecutive terms~~years. If the person holding the office of Chairperson or Vice Chairperson holds office for ~~one term~~two years, and a successor has not been ~~selected~~ by the Oversight Committee to take office at the expiration of the ~~two-year term limit~~, then the person holding the office of Chairperson or Vice Chairperson, as applicable, shall continue to hold the office until such time that a quorum of the Oversight Committee can meet and ~~select~~ a successor. The Chairperson or the Vice Chairperson may be removed at any time, with or without cause, by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13. If the office of the Chairperson or the Vice Chairperson becomes vacant for any reason, including by the expiration of the ~~two-year term limit~~, then the vacancy must be filled by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13.

Section 5.3 Chairperson. The Chairperson is the presiding officer of the Oversight Committee. The Chairperson shall preside at each meeting of the Oversight Committee. The Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by applicable law or recommended by the Board Governance and Ethics Subcommittee and approved by the Oversight Committee. The Chairperson may authorize official duties of members of the Oversight Committee, the University Advisory Committee, or any Ad Hoc Advisory Committee in accordance with applicable law. The ~~office of the Chairperson and the office of the CPRIT Foundation Chair or may not serve as the presiding officer for~~ any other foundation or organization created to specifically benefit ~~CPRIT may not be held by the same person~~ the Institute.

Section 5.4 Vice Chairperson. The Vice Chairperson shall, in the absence of the Chairperson, preside at each meeting of the Oversight Committee. The Vice Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by the Board Governance and Ethics Subcommittee or applicable law and approved by the Oversight Committee.

Section 5.5 Presiding Officers in the Absence of the Chairperson and Vice Chairperson. In the absence of the Chairperson and Vice Chairperson, the Chairperson of the Scientific Research Subcommittee shall preside at each meeting of the Oversight Committee. In the absence of Scientific Research Subcommittee Chairperson, then the Chairperson of the Product Development Subcommittee shall preside. In the absence of the Chairpersons of the

Scientific Research and Product Development Subcommittees, then the Chairperson of the Prevention Subcommittee shall preside.

ARTICLE 6

THE ~~EXECUTIVE DIRECTOR~~CHIEF EXECUTIVE OFFICER

Section 6.1 General Powers. There will be one ~~executive director~~Chief Executive Officer of the Institute (the "~~Executive Director~~Chief Executive Officer"). The ~~Executive Director~~Chief Executive Officer has such powers as are delegated to the ~~Executive Director~~Chief Executive Officer by the Oversight Committee and such powers as are vested in the ~~Executive Director~~Chief Executive Officer pursuant to applicable law.

Section 6.2 Selection by the Oversight Committee. The Oversight Committee shall hire the ~~Executive Director~~Chief Executive Officer.

Section 6.3 Performance of Duties. The ~~Executive Director~~Chief Executive Officer shall perform the duties of the ~~Executive Director~~Chief Executive Officer as provided by these Bylaws, applicable law, or the Oversight Committee.

Section 6.4 Grant Review. The ~~Executive Director~~Chief Executive Officer shall oversee the grant review process and may terminate grants that do not meet contractual obligations.

Section 6.5 Quarterly Report. Each quarter, the ~~Executive Director~~Chief Executive Officer shall report to the Oversight Committee on any new grant awards and the progress and continued merit of scientific research and prevention programs previously awarded funding. The report must include a summary of the allocation of funding among scientific research and prevention programs and details regarding the final results of completed projects under these programs.

Section 6.6 Duties Regarding ~~the CPRIT Foundation or Other~~ Foundations or Organizations Created to Specifically Benefit CPRIT. The ~~Executive Director~~Chief Executive Officer shall annually report to the Oversight Committee on guidelines for the governance of ~~the Cancer Prevention and Research Institute of Texas Foundation (the "CPRIT Foundation") or any other~~ foundation or organization created specifically to benefit CPRIT and the relationship between the Institute and the ~~foundation or CPRIT Foundation or similar~~ organization. The ~~Executive Director~~Chief Executive Officer shall also annually solicit a report from the ~~executive director~~foundation or ~~of the CPRIT Foundation or similar~~ organization created specifically to benefit ~~the Institute~~ regarding the funds ~~the foundation or organization~~ holds, the pledges it has received, and the identities of contributors.

ARTICLE 7

OTHER OFFICERS OF THE INSTITUTE

Section 7.1 Creation and Selection of Other Officers of the Institute. The Oversight Committee may direct the ~~Executive Director~~Chief Executive Officer to create other officer positions of the Institute and to hire individuals to fill such positions.

Section 7.2 Certain Officers. Without limiting in any way the previous Section, the following officer positions of the Institute have been created (each of which has the duties and authority set forth in this Article in addition to any other duties and authority as may be delegated to such officer by the Oversight Committee):

(a) Chief Operating Officer, whose duties include oversight of the Institute's daily operations, including financial administration, grants management administration, communications, governmental relations, and information technology services;

(b) Chief Compliance Officer, whose duties include reporting to the Oversight Committee on ~~the agency's compliance with applicable law, administrative rules, and policies, the best practices for grant review and post-award grant monitoring used by the National Institutes of Health and other similar organizations,~~ and building, developing, and maintaining a compliance program that fosters ethical business behavior and includes requirements for risk assessments, program governance, metrics, and reporting;

(c) Chief Scientific Officer, whose duties include oversight of the scientific research application submission process, coordinating the review of research proposals, monitoring grant progress, and fostering collaboration among the cancer and disease scientific research community to maximize the Institute's impact

(d) Chief ~~Product~~ Development Officer, whose duties include oversight of the cancer research development application submission process, coordinating review of the cancer research ~~product~~ development proposals, monitoring grant progress and fostering collaboration among the bioscience community to maximize the Institute's impact;

(e) Chief Prevention Officer, whose duties include oversight of the prevention application submission process, coordinating the review of prevention proposals, monitoring grant progress, and fostering collaboration among the cancer and disease prevention community to maximize the Institute's impact; and

(f) General Counsel, whose duties include oversight of the legal issues that arise as part of the Institute's operations.

ARTICLE 8 COMMITTEES OF THE INSTITUTE

Section 8.1 Creation of Committees of the Institute. Pursuant to applicable law and in accordance with this Article, the Oversight Committee may create Committees of the Institute and appoint and approve members of such committees.

Section 8.2 Scientific Research and Prevention Programs Committee. There will be one or more scientific research and prevention programs committees of the Institute (each, a "Scientific Research and Prevention Programs Committee"). Each Scientific Research and Prevention Programs Committee has such powers as are vested in it pursuant to applicable law. The ~~Executive Director~~ **Chief Executive Officer**, with approval by simple majority of the members of the Oversight Committee as set forth in Section 3.13, shall appoint as members of one or more Scientific Research and Prevention Programs Committees experts in the field of cancer research, ~~and prevention,~~ **and patient advocacy** to serve for terms as determined by the

~~Executive Director~~Chief Executive Officer. Individuals appointed to a Scientific Research and Prevention Programs Committee may be residents of another state. A member of a Scientific Research and Prevention Programs Committee may receive an honorarium according to a policy developed by the Chief Executive Officer in consultation with the Oversight Committee.

Section 8.3 University Advisory Committee. There will be one university advisory committee of the Institute (the “University Advisory Committee”). The University Advisory Committee has such powers as are vested in it pursuant to applicable law. The University Advisory Committee shall advise the Oversight Committee and each Scientific Research and Prevention Programs Committee regarding the role of institutions of higher education in cancer research. The University Advisory Committee is composed of the following members to serve for the term as determined by the appropriate appointing authority appointing such member:

(a) two members appointed by the chancellor of The University of Texas System to represent:

- (i) The University of Texas Southwestern Medical Center at Dallas;
- (ii) The University of Texas Medical Branch at Galveston;
- (iii) The University of Texas Health Science Center at Houston;
- (iv) The University of Texas Health Science Center at San Antonio;
- (v) The University of Texas Health Center at Tyler; or
- (vi) The University of Texas M. D. Anderson Cancer Center;

(b) one member appointed by the chancellor of The Texas A&M University System to represent:

- (i) The Texas A&M University System Health Science Center; or
- (ii) the teaching hospital for The Texas A&M Health Science Center College of Medicine;

(c) one member appointed by the chancellor of the Texas Tech University System to represent the Texas Tech University Health Sciences Center;

(d) one member appointed by the chancellor of the University of Houston System to represent the system;

(e) one member appointed by the chancellor of the Texas State University System to represent the system;

(f) one member appointed by the chancellor of the University of North Texas System to represent the system;

(g) one member appointed by the president of Baylor College of Medicine;

(h) one member appointed by the president of Rice University; and

(i) members appointed at the ~~Executive Director~~Chief Executive Officer's discretion by the chancellors of other institutions.

Section 8.4 Ad Hoc Advisory Committee on Childhood Cancers. The Oversight Committee shall create an ad hoc committee of experts to address childhood cancers. Members of the Ad Hoc Advisory Committee on Childhood Cancers shall be appointed by the Oversight Committee and serve for terms determined by the Oversight Committee. The Ad Hoc Advisory Committee on Childhood Cancers has the duties and authority set forth in the advisory committee's charter in addition to any other duties and authority as may be delegated ~~to such officer~~ by the Oversight Committee.

Section 8.5 Other Ad Hoc Advisory Committees of the Institute. The Oversight Committee, as necessary, may create additional ad hoc committees of experts to advise the Oversight Committee on issues relating to cancer. The number of members of each Ad Hoc Committee will be determined by the Oversight Committee. Ad Hoc Advisory Committee members are appointed by the Oversight Committee and serve for terms determined by the Oversight Committee.

Section 8.6 Certain Ad Hoc Advisory Committees of the Institute. Without limiting in any way the previous Section, the following are the Ad Hoc Advisory Committees of the Institute (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):

- (a) Scientific and Prevention Advisory Council; and
- (b) Commercialization Advisory Committee;

Section 8.7 Annual Report to the Oversight Committee. Each Committee of the Institute shall report to the Oversight Committee at least annually regarding the work undertaken by such committee pursuant to a schedule and format dictated by the Oversight Committee.

ARTICLE 9 CODE OF ~~ETHICS AND CONDUCT~~ AND ETHICS POLICY

Section 9.1 Adopted by Reference. The Oversight Committee herein by reference incorporates the *Code of ~~Ethics and Conduct~~ and Ethics Policy* as approved by the Oversight Committee on February 25, 2013 and all approved amendments.

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STATEMENT OF REVISIONS

Approved October **, 2013

Changes made to Sections 3.2, 3.3(a) and (b), 3.4, 3.7, 3.15, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 7.1, 7.2(b) and (d), 8.2, 8.3(i), 8.4, 9.1, Article 6 (title), and Article 9 (title) and text.

Reason for change(s): Revisions made to reflect statutory changes adopted in 2013 legislative session.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: PROPOSED CHANGES TO THE CODE OF CONDUCT AND ETHICS
DATE: OCTOBER 28, 2013

Summary and Recommendation:

Statutory changes enacted by the 2013 Texas Legislature require the code of conduct adopted by the Oversight Committee to include, at minimum, provisions that specifically prohibit certain activities. The Oversight Committee previously adopted a Code of Conduct and Ethics; however, due to the extensive revisions required by the statute, the Oversight Committee should vote to adopt the proposed Code of Conduct and Ethics, replacing the previous version in its entirety.

Discussion:

Section 572.051(c) of the Texas Government Code requires state agencies to adopt a code of ethics. The Board Governance Committee created a Code of Conduct and Ethics that was adopted by the Oversight Committee at its February 25, 2013 meeting. The Code of Conduct and Ethics was modeled extensively upon the Code of Ethics adopted by University of Texas Investment Management Company (UTIMCO).

Senate Bill 149 was signed into law by Governor Perry on June 14, 2013, taking effect immediately. The legislation enacted changes to CPRIT's enabling legislation, Chapter 102 of the Texas Health & Safety Code, including a new provision, Section 102.109 "Code of Conduct". The newly enacted statutory requirement adds to the obligations set forth in CPRIT's current Code of Conduct and Ethics. In some cases, the statutory requirements are more restrictive than the existing guidance. The proposed Code of Conduct is based upon the Office of the Attorney General's model ethics policy, revised to incorporate the additional prohibitions or requirements applicable to Oversight Committee members, CPRIT employees, and Program Integration Committee members.

Section 4.5 of the Oversight Committee Bylaws provides that the Board Governance Committee shall review and recommend proposed Code of Conduct and Ethics changes to the Oversight Committee for adoption. However, there are no sitting members of the Board Governance Committee to review and recommend these proposed revisions. In their absence, I recommend that the Oversight Committee adopt the proposed Code of Conduct and Ethics at the November 1, 2013 meeting in order to conform to state law.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CODE OF CONDUCT and ETHICS

I. OVERVIEW

A. Authority

Pursuant to Section 572.051(c) of the Government Code and Section 102.109 of the Health & Safety Code, the Cancer Prevention and Research Institute of Texas (CPRIT) promulgates the following Code of Conduct and Ethics (Code).

B. General Principles

(1) This Code recognizes CPRIT's unique role as the steward of taxpayer funds in furtherance of CPRIT's mission and the ultimate beneficiaries of the funds, the citizens of the State of Texas and sets forth the basic principles and guidelines for Oversight Committee Members, PIC Members, and Employees.

(2) Oversight Committee Members, PIC Members, and Employees are expected to discharge their duties in a manner that promotes and preserves public trust, proper stewardship, and confidence in the integrity of CPRIT and be guided by the basic principles of loyalty, prudence, honesty and fairness in conducting CPRIT's affairs.

C. Definitions

In this Code:

(1) "Audit Subcommittee" means the standing Audit Subcommittee of the Oversight Committee established by CPRIT bylaws.

(2) "Business entity" means any entity recognized by law through which business for profit is conducted, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership, or trust. Tex. Gov't Code Ann. § 572.002(2).

(3) "CPRIT" means the Cancer Prevention and Research Institute of Texas.

(4) "CEO" means the Chief Executive Officer of CPRIT.

(5) “Employee” means a person working for CPRIT in an employer-employee relationship.

(6) “Grant Applicant” means the public or private institution of higher education, as defined by §61.003, Education Code, research institution, government organization, non-governmental organization, non-profit organization, other public entity, private company, individual, or consortia, including any combination of the aforementioned, that submits a grant application to CPRIT. Unless otherwise indicated, this term includes the Principal Investigator or Program Director.

(7) “Grant Recipient” means the entire legal entity responsible for the performance or administration of the CPRIT grant. Unless otherwise indicated, this term includes the Principal Investigator, Program Director, or Company Representative.

(8) “Oversight Committee Member” means a member of the CPRIT Oversight Committee.

(9) “Oversight Committee” means CPRIT’s governing body, composed of the nine individuals appointed by the Governor, Lieutenant Governor, and the Speaker of the House of Representatives.

(10) “Program Integration Committee” (PIC) means the group composed of the Chief Executive Officer, the Chief Scientific Officer, the Chief Product Development Officer, the Commissioner of State Health Services, and the Chief Prevention Officer that is responsible for submitting to the Oversight Committee the list of grant applications the PIC recommends for grant awards.

(11) “PIC Member” means a member of the PIC.

(12) “Relative” means a person related within the second degree by consanguinity or affinity determined in accordance with Sections 573.021 – 573.025, *Government Code*. For purposes of this definition:

(A) examples of an individual within the second degree by consanguinity are a child, grandchild, parent, grandparent, brother, sister, uncle, aunt, niece, or nephew;

(B) examples of an individual within the second degree by affinity are a spouse, a person related to a spouse within the second degree by consanguinity, or a spouse of such a person;

(C) an individual adopted into a family is considered a Relative on the same basis as a natural born family member; and

(D) an individual is considered a spouse even if the marriage has been dissolved by death or divorce if there are surviving children of that marriage.

D. Enforcement

(1) The Oversight Committee shall enforce this Code with respect to Employees through the CEO. The CEO is responsible for implementing this Code with respect to Employees and PIC Members. An Employee who violates any provision of the Code is subject to termination of the employee's employment or another employment-related sanction.

(2) The Oversight Committee shall enforce this Code with respect to individual Oversight Committee Members through resolutions of reprimand, censure, or other appropriate parliamentary measures, including requests for resignation.

(3) An Oversight Committee Member, PIC Member, or Employee who violates any applicable federal or Texas law or rule may be subject to civil or criminal penalties in addition to any employment-related sanction.

II. STANDARDS OF CONDUCT

A. Expected Conduct of Oversight Committee Members, PIC Members, and Employees

All Oversight Committee Members, PIC Members, and Employees shall:

(1) familiarize themselves with the Code and should be specifically knowledgeable of Chapter 102, *Health & Safety Code*, Chapter 572, *Government Code*, and Sections 36.02 (Bribery), 36.07 (Acceptance of Honorarium), 36.08 (Gift to Public Servant), 39.02 (Abuse of Official Capacity), and 39.06 (Misuse of Official Information), *Penal Code*;

(2) abide by all applicable federal and Texas laws, administrative rules, and CPRIT conduct policies, including this Code. The Code does not supersede any applicable federal or Texas law or administrative rule;

(3) perform his or her official duties in a lawful, professional, and ethical manner;

(4) practice responsible stewardship of CPRIT resources; and

(5) report any conduct or activity that the employee believes to be in violation of this Code of Conduct policy to the Chief Compliance Officer or the General Counsel, as may be appropriate. Retaliatory action may not be taken against a person who makes a good faith report of a violation involving another person.

B. Prohibited Conduct

An Oversight Committee Member, a PIC Member, an Employee, or the spouse of an Oversight Committee Member, a PIC Member, or an Employee shall not:

- (1) accept or solicit any gift, favor, or service that could reasonably tend to influence member or employee in the discharge of official duties, or that the member, employee, or spouse of the member or employee knows or should know is being offered with the intent to influence the member's or employee's official conduct;
- (2) intentionally or knowingly solicit, accept, or agree to accept any benefit for exercising the member's official powers or performing the member's or employee's official duties in favor or another;
- (3) disclose confidential information, information that is excepted from public disclosure under the Texas Public Information Act, or information that has been ordered sealed by a court, that was acquired by reason of the member's or employee's official position, or accept other employment, including self-employment, or engage in a business, charity, nonprofit organization, or professional activity that the member or employee might reasonably expect would require or induce the member or employee to disclose confidential information, information that is excepted from public disclosure under the Texas Public Information Act, or information that has been ordered sealed by a court, that was acquired by reason of the employee's official position;
- (4) accept other employment, including self-employment, or compensation that could reasonably impair the member's or employee's independent judgment in the performance of the official duties;
- (5) make personal investments or have a financial interest that could reasonably create a substantial conflict between the member's or employee's private interest and the member's or employee's official duties;
- (6) utilize state time, property, facilities, or equipment for any purpose other than official state business, unless such use is reasonable and incidental and does not result in any direct cost to the state or CPRIT, interfere with the member's or employee's official duties, and interfere with CPRIT functions;
- (7) utilize the member's or employee's official position, or state issued items, such as a badge, indicating such position for financial gain, obtaining privileges, or avoiding consequences of illegal acts;
- (8) knowingly make misleading statements, either oral or written, or provide false information, in the course of official state business;
- (9) engage in any political activity while on state time or utilize state resources for any political activity.

(10) lease, directly or indirectly, any property, capital equipment, employee or service to a Grant Recipient;

(11) submit a grant application to CPRIT;

(12) participate in a matter before CPRIT that involves a business, contract, property, or investment held by the person if it is reasonably foreseeable that CPRIT action on the matter would confer a benefit to the person by or through the business, contract, property, or investment;

(13) recommend or cause discretionary CPRIT business to be transacted with or for the benefit of a Relative;

(14) represent any person in any action or proceeding before or involving the interests of CPRIT except as a duly authorized representative or agent of CPRIT;

(15) serve on a CPRIT Grant Recipient's board of directors or similar committee that exercises governing powers over the Grant Recipient. This prohibition also applies to serving on the board of directors or similar committee of a non-profit foundation established to benefit the Grant Recipient;

(16) use confidential information, or knowledge of non-public decisions related to CPRIT Grant Applicants, received by virtue of the individual's employment or official duties associated with CPRIT, to make an investment or take some other action to realize a personal financial benefit; or

(17) copyright or patent any work produced or developed as part of the individual's service to or employment with CPRIT when the work is related to a CPRIT goal, project, or concern.

C. Special Provisions

(1) An Oversight Committee Member, an Employee, or the spouse of an Oversight Committee Member shall not be employed by or participate in the management of a business entity or other organization receiving money from CPRIT.

(2) An Oversight Committee Member, an Employee, or the spouse of an Oversight Committee Member shall not own or control, directly or indirectly, an interest in a business or entity or other organization receiving money from CPRIT, except that the prohibition does not apply to ownership of shares in a publicly traded mutual fund or similar investment vehicle in which the person does not exercise any discretion regarding the investment of the assets of the fund or other investment vehicle.

(3) An Oversight Committee Member or Employee shall not have an office in a facility

owned by a business entity or other organization receiving or applying to receive money from CPRIT.

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

(5) An Oversight Committee Member or the spouse of an Oversight Committee Member shall not use or receive a substantial amount of tangible goods, services, or money from CPRIT other than reimbursement authorized for Oversight Committee Members attendance or expenses.

(6) A former Oversight Committee Member or former CEO may not make any communication to or appearance before a current Oversight Committee Member or Employee before the second anniversary of the date the former Oversight Committee Member or former CEO ceased to be an Oversight Committee Member or CEO if the communication is made:

(a) with the intent to influence a decision or with intent to cause any action or inaction; and

(b) on behalf of any person or business entity in connection with any matter on which the former Oversight Committee Member or former CEO seeks action by CPRIT.

(7) A former Oversight Committee Member or former Employee may not represent any person or entity, or receive compensation for services rendered on behalf of any person or entity, regarding a particular matter in which the former Oversight Committee Member or Employee participated during the period of state service or employment, either through personal involvement or because the case or proceeding was a matter within the Oversight Committee Member's or Employee's official responsibility.

(a) This subsection applies to an Employee who is compensated, as of the last date of state employment, at or above the amount prescribed by the General Appropriations Act for step 1, salary group 17, of the position classification salary schedule, including an employee who is exempt from the state's position classification plan.

(b) For purposes of this subsection, the term "participated" means to have taken action through decision, approval, disapproval, recommendation, giving advice, investigation, or similar action.

(c) For purposes of this subsection, the term "particular matter" means a specific investigation, application, request for a ruling or determination, rulemaking proceeding, contract, claim, accusation, charge, arrest, or judicial or other proceeding, except that the

prohibition of this subsection does not apply to a rulemaking proceeding that was conducted before the Oversight Committee Member's or Employee's service or employment ceased.

(8) CPRIT may not enter into an agreement or transaction with a former Oversight Committee Member or former Employee, or a business entity or other organization in which a former Oversight Committee Member or former Employee owns or controls an interest or serves on the governing board, on or before the first anniversary of the date the person ceased to be an Oversight Committee Member or Employee. Nothing herein prevents a business entity or organization that would otherwise be prohibited from entering into an agreement or transacting with CPRIT under this subsection from applying for or receiving grant funds.

D. Nepotism

(1) Except as provided in subsection (2), CPRIT may not employ a person who is a Relative of an Oversight Committee Member or Employee. For purposes of this section, the prohibition on employment includes employment as a consultant to CPRIT.

(2) This subsection does not prohibit the continued employment of a person who has been working for CPRIT for at least 90 consecutive days before the date of the related Oversight Committee Member's appointment.

E. Outside Employment or Business Activity

(1) An Employee may not engage in outside employment, business, or other activities that detract from the individual's ability to reasonably fulfill responsibilities to CPRIT.

(2) An Employee (other than the CEO) must obtain advance written approval from the CEO for any outside employment or business activity, including service on the board of directors of a business or non-profit organization. The CEO shall notify the Audit Subcommittee in writing concerning any approval given for outside employment or other business activity by Employees, including the nature of the employment or other business activity.

(3) The CEO must obtain advance approval from the Oversight Committee if the CEO intends to engage in outside employment or other business activities, including service on the board of directors for a business or non-profit organization.

(4) The CEO shall report to the Oversight Committee annually all approved outside employment or business activities of Employees.

III. CONFLICTS OF INTEREST

A. Decision-Making Based on Merit.

Oversight Committee Members, PIC Members, and Employees shall base CPRIT business transactions on professional integrity and competence, financial merit and benefit to CPRIT, and, as required, in accordance with procurement laws for state agencies.

B. Conflict of Interest Requirements.

(1) The Oversight Committee adopts herein by reference the statutory requirements regarding conflicts of interest, Sections 102.106 – 102.1064, *Health & Safety Code*, and CPRIT's administrative rules, Section 702.11 – 702.17, and any updates thereto.

(2) The conflict of interest statutory and administrative rule provisions apply to any decision to commit CPRIT funds, whether or not the commitment is part of the grant award process or to a Grant Applicant.

IV. GIFTS AND ENTERTAINMENT

A. Prohibition Against Acceptance of Gifts or Consideration

Except as provided herein, Oversight Committee Members, PIC Members, and Employees may not accept gifts, consideration or anything reasonably regarded as a financial gain or advantage.

B. Exceptions

The prohibition against acceptance of a gift or consideration does not apply to the following items so long as the acceptance of such an item does not violate Section II(B)(1) or any other applicable law and the Oversight Committee, PIC Member, or Employee has no reason to believe that a gift or consideration that would otherwise be prohibited is being offered through an intermediary:

- (1) a non-cash item with a value less than \$50;
- (2) gifts or consideration of any value provided to the Oversight Committee Member, PIC Member, or Employee by a Relative;
- (3) gifts or consideration of any value provided to the Oversight Committee Member, PIC Member, or Employee by a personal friend or colleague, so long as:
 - (a) The gift or consideration is given based solely on an existing personal, professional, or business relationship independent of the Oversight Committee Member's, PIC

Member's, or Employee's official status;

(b) The personal friend or colleague, or a Relative of the personal friend or colleague, is not an employee or the member of the governing board of an entity receiving or applying to receive money from CPRIT; and

(c) The Oversight Committee Member, the PIC Member, or the Employee has no reason to believe that the gift or consideration is being offered through the personal friend or colleague as an intermediary; and

(4) payments to which the Oversight Committee Member, PIC Member, or Employee is lawfully entitled in a capacity other than the individual's official status;

(5) political contributions;

(6) items issued by CPRIT or other governmental entities to the Oversight Committee Member, PIC Member, or Employee that allow the use of property or facilities owned, leased, or operated by CPRIT or other governmental entity;

(7) food, lodging, transportation, or entertainment accepted as a guest with the donor present;

(8) food, lodging, transportation, and/or a speaker gift of nominal intrinsic value (less than \$50) in connection with a speech given by the Oversight Committee Member, PIC Member, or Employee in the individual's official capacity, so long as the speech is not merely perfunctory;

(9) books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of an Oversight Committee Member, Employee, or PIC Member and that are accepted by the individual on behalf of CPRIT for use in performing the individual's job duties; and

(10) registration or admittance fees for seminars, conferences, or other sponsored events that may involve entertainment or recreation. If the seminar, conference, or other sponsored event is hosted or paid for by a business entity or organization applying for or receiving CPRIT funds, prior written approval to attend the event is required and the entity sponsoring or paying for the event must attend. For Oversight Committee Members, approval may be provided by the Oversight Committee chair (or vice chair if the chair is seeking approval). For a PIC Member or Employee, approval may be provided by the CEO (or the Oversight Committee chair if the CEO is seeking approval.)

C. Gifts or Consideration from Lobbyists

An Oversight Committee Member, PIC Member, or Employee shall immediately report to the

Chief Compliance Officer any gift or consideration if the gift or consideration is provided by a registered lobbyist.

D. Return of Prohibited Gifts or Consideration

An Oversight Committee Member, PIC Member, or Employee who receives a prohibited gift or other prohibited consideration shall make every effort to return the gift or consideration to its source or, if that is not possible or feasible, donate the gift or consideration to a recognized tax-exempt charitable organization formed for educational, religious, or scientific purposes.

E. Reporting Requirements

An Oversight Committee Member, PIC Member, or Employee shall report to CPRIT's Chief Compliance Officer any gift, grant, or consideration provided to the individual as soon as possible, but no later than thirty (30) days after receipt of the gift, grant or consideration.

- (1) The individual shall provide the name of the donor, the date of receipt, and amount of the gift, grant, or consideration.
- (2) The reporting requirement applies to any gifts, grants, or other consideration provided to an Oversight Committee Member, PIC Member, or Employee, except for those specified in subsection (B).
- (3) Notwithstanding the foregoing, information related to subsections (B)(7) and (9) shall be reported to the Chief Compliance Officer.

V. FINANCIAL DISCLOSURE AND COMPLIANCE STATEMENTS

Unless otherwise directed, the following statements and certifications shall be completed and returned to the Chief Compliance Officer. Unless otherwise specified, the statements and certifications shall be filed with the Chief Compliance Officer no later than 30 days following the date of the member's or employee's appointment or employment and then annually thereafter on or before September 30th. The CEO may postpone a filing deadline for not more than 60 days on the written request of an Oversight Committee Member, PIC Member, or Employee, or for an additional period for good cause.

A. Financial Disclosure Statements.

- (1) An Oversight Committee Member and the CEO shall file a financial disclosure statement with the Chief Compliance Officer not later than the 30th day after the date of appointment or employment, and not later than April 30 of each year thereafter.
- (2) CPRIT must maintain a financial disclosure statement for at least five years after the date

it is filed.

(3) Oversight Committee Members who are required to file disclosure statements with the Texas Ethics Commission shall file those statements in the form and time prescribed by law.

B. Ethics Compliance Statements.

An Oversight Committee Member, PIC Member, or Employee, including an interim Employee, must sign, date, and file an ethics compliance statement acknowledging that the individual has received and read this Code, that the individual will comply with its provisions, and that it is the individual's duty to report knowledge of any act or failure to act that is a violation of this Code.

C. Conflict of Interest Compliance Statements.

An Oversight Committee Member, PIC Member, or Employee, including an interim Employee, must sign, date, and file a conflict of interest compliance statement acknowledging that the individual has received and read the statutory and administrative rules related to conflicts of interest, that they will comply with its provisions, and that it is their duty to report when they have knowledge of any act or failure to act that is a violation of the conflict of interest statutes or rules.

D. Non-Disclosure Agreements

An Oversight Committee Member, PIC Member, or Employee, including an interim Employee, must sign, date, and file a non-disclosure agreement.

E. Certification of No Financial Interest.

(1) Before the Oversight Committee votes on proposed grant awards, each Oversight Committee Member shall certify that he or she does not have a financial interest in a business entity or other organization applying for or receiving CPRIT funds.

(2) For purposes of this certification, "financial interest" means:

- (a) ownership of stock or shares of the business entity; or
- (b) ownership of any sum of the fair market value of the business entity; or
- (c) receipt of any sum of the person's gross income for the preceding calendar year from the business entity; or
- (d) any private investment in the business entity, such as debt obligation or equity interest that is not a publicly traded security.

(3) Oversight Committee Members shall sign, date, and file the certification not later than the day preceding the date of the Oversight Committee meeting scheduled to consider the proposed grant awards.

(4) An Oversight Committee Member is prohibited from participating in any action taken regarding the proposed grant awards if the member fails to file the required certification prior to the day preceding the Oversight Committee meeting. However, upon a showing of good cause, the Oversight Committee may vote to allow the Oversight Committee Member to participate in action taken related to the proposed grant awards, so long as the member certifies for the record in the open meeting that the member does not have a financial interest in a business entity or other organization applying for or receiving grant funds. Immediately following the meeting, the Oversight Committee Member must complete the certification.

F. Statement of No Communication.

(1) Before the Oversight Committee awards a grant, each Oversight Committee Member and PIC Member shall certify that he or she has not communicated with any Grant Applicant for CPRIT funds regarding the substance of a pending application. The period of the restricted communication begins on the first day that grant applications are accepted by CPRIT until the Grant Applicant receives notice regarding a final decision on the grant application.

(2) In addition to the certification required in subsection (1), each PIC Member must also certify that the PIC Member did not communicate individually with one or more Oversight Committee members about a pending grant recommendation prior to the time that the PIC submits its list of recommendations to the Oversight Committee and the CEO has submitted the affidavits required by statute. Communication that involves one or more PIC members responding to a question raised by an Oversight Committee Member does not constitute a prohibited communication so long as the question and the response is provided in writing to all Oversight Committee Members contemporaneously.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: RECONSTITUTING OVERSIGHT COMMITTEE SUBCOMMITTEES
DATE: OCTOBER 28, 2013

Summary and Recommendation:

The Oversight Committee Bylaws designate eight subcommittees, composed of Oversight Committee members, to provide input and advice to the Oversight Committee related to policies, operations and management of the Institute. Due to the Oversight Committee transition, there are no current members of any subcommittee. With the exception of the Executive Committee, all subcommittee appointments should be approved by a vote of the Oversight Committee at the November 1, 2013 open meeting.

The appropriate number of Executive Committee members and whether the members should be appointed from the at-large membership or based upon other criteria should be referred to the Board Governance Subcommittee for a recommendation to be presented at a future Oversight Committee meeting.

Discussion:

The Oversight Committee approved Bylaws at its February 25, 2013 open meeting. Section 4.2 "Certain Subcommittees" designates eight subcommittees of the Oversight Committee:

- Executive
- Audit
- Board Governance
- Diversity
- Nominations
- Prevention
- Product Development
- Scientific Research

Subcommittees play an important role in the Oversight Committee's policy development and fiduciary management of the agency. Subcommittees generally have more flexibility in terms of the conduct of meetings and the depth of analysis that can be undertaken due to the subcommittee size

(usually three members) and advisory role. Section 4.1 of the Bylaws directs the Oversight Committee to appoint members to the subcommittees, with the exception of the Executive Committee. With regard to Executive Committee membership, Section 4.3 provides that the committee is comprised of five members: the Oversight Committee Chair, Vice Chair, and the chairs of the Prevention, Product Development and Research subcommittees.

Proposed charters for all subcommittees, with the exception of the Executive Committee, have been distributed to new Oversight Committee members as part of the agency orientation process. The proposed charters are for informational purposes only; Oversight Committee members may review the proposed charters when deciding preferred subcommittee appointments. Once subcommittee members are appointed, each subcommittee must take action to approve its proposed charter, including any changes, at that time.

Special consideration is necessary for issues related to the Executive Committee. Pursuant to the Bylaws, the Executive Committee's role is to transact all normal business referred to it by the Oversight Committee and to conduct the Chief Executive Officer's annual performance review. Because the Executive Committee is authorized to take action on behalf of the Oversight Committee on referred issues, it is subject to the Open Meetings Act. However, due to the statutory reduction in the number of Oversight Committee members from 11 members to nine members, the five-member Executive Committee currently specified by the Bylaws is no longer feasible. No action should be taken on constituting the Executive Committee until the issue of membership is addressed and conforming changes to the Bylaws are adopted by the Oversight Committee. The Board Governance subcommittee is the designated committee to consider changes to the Bylaws such as Executive Committee membership.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHARTER OF THE AUDIT SUBCOMMITTEE FOR THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas (“CPRIT” or “Institute”) established an Audit Subcommittee (the “Subcommittee”) on June 18, 2010. This Charter, adopted by the Oversight Committee on _____, supersedes any other documents relating to the Audit Subcommittee.

PURPOSE

The primary purpose of the Subcommittee is to assist the Oversight Committee in fulfilling its responsibilities for monitoring the audit, financial and compliance functions of the Institute to assure the transparency and integrity of Institute’s operations and use of taxpayer funds. Specifically, the Subcommittee is to assist the Oversight Committee by monitoring the following activities and making recommendations to the Oversight Committee regarding:

- The Institute’s annual operating budget and strategic plan, including variances in the operating budget of more than five percent (5%) or \$25,000;
- The integrity of the financial reporting process, the system of internal controls, the audit process and policies, and the process for monitoring compliance with laws and regulations;
- The performance of the Institute’s independent auditors;
- Internal audit functions performed by the CPRIT finance office and grant management staff;
- Audits of the Institute performed by the Texas State Auditor’s Office;
- The Institute’s enterprise risk management;
- The Institute’s compliance program; including the Institute’s adherence to state law, and administrative and regulatory requirements and internal policies for

monitoring the performance of cancer research and prevention grants awarded by the Institute;

- Certain financial decisions of the Institute, including the employment of senior staff (Chief Scientific Officer, Chief Prevention Officer, Chief Product Development Officer, Chief Operating Officer, Chief Compliance Officer, and General Counsel) and related compensation, approval of certain non-grant contracts and variances of more than ten percent (10%) in any announced grant award.

The Subcommittee will take all appropriate actions to set the overall tone at the Institute for quality financial reporting, sound risk practices, and ethical behavior. The Subcommittee is responsible for maintaining free and open communication as well as effective working relationships among the Subcommittee members, Institute staff responsible for the grant review and administration, the Chief Compliance Officer, independent external auditors, the CPRIT finance office, the Texas State Auditor's Office, and senior management of the Institute.

SCOPE

This Audit Subcommittee Charter sets forth the Subcommittee's monitoring responsibilities with respect to the Institute and its use of state funds, including the awarding of grant funds for cancer research and prevention. As such, the role and purpose of the Subcommittee includes monitoring the functions and processes of the Institute and the funds issued on behalf of the State of Texas for cancer research and prevention grant awards.

COMPOSITION

The Subcommittee shall be composed of at least three members of the Oversight Committee; such members to be appointed from time to time by a majority vote of the Oversight Committee at a meeting at which a quorum is present and approved by the Oversight Committee. The Oversight Committee shall designate a Chairperson of the Subcommittee from among its members. Members of the Subcommittee must meet the independence and, to the extent possible, the financial literacy requirements as defined below. To perform their role effectively, each Subcommittee member will need to develop and maintain his or her skills and knowledge, including an understanding of the Subcommittee's responsibilities and of the Institute's activities, operations and risks. A member of the Subcommittee will serve until his or her successor is duly appointed and qualified unless the member resigns or is removed from the Subcommittee. The Oversight Committee may replace any member of the Subcommittee by a majority vote of the Oversight Committee.

INDEPENDENCE REQUIREMENTS

The Oversight Committee shall determine that all members of the Subcommittee are independent. A person is “independent” who has no relationship with the Institute which would interfere with the exercise of independence from management. In addition, Subcommittee members would not be “independent” if during the three years prior to their appointment or at any time during their service on the Subcommittee they accepted, directly or indirectly, any consulting, advisory, or other compensatory fee from the Institute apart from travel and expense reimbursements they may receive as members of the Oversight Committee and its Committees.

FINANCIAL LITERACY

The Oversight Committee, based on its business judgment, shall determine that each member of the Subcommittee is financially literate.

FINANCIAL MANAGEMENT EXPERTISE

To the extent possible, the Oversight Committee, based on its business judgment, shall determine that at least one member of the Subcommittee is a “financial expert.” A financial expert possesses the following attributes:

- An understanding of generally accepted accounting principles (GAAP) and financial statements;
- An ability to assess the application of GAAP in connection with accounting for estimates, accruals and reserves;
- An understanding of audit committee functions;
- Experience preparing, auditing, analyzing or evaluating financial statements, or experience actively supervising persons engaged in such activities; and
- An understanding of internal controls and procedures for financial reporting as specifically related to Texas state agencies.

MEETINGS AND QUORUM

The Subcommittee shall meet as often as the Chairperson of the Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under the Bylaws. The Subcommittee shall keep regular minutes of its meetings and cause such minutes to be

recorded in books kept for that purpose in the principal office of the Institute, and report the same to the Oversight Committee at its next regular meeting.

If a member of the Subcommittee is absent from any meeting, or disqualified from voting at that meeting, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of the Subcommittee, a majority of the then authorized members of the Subcommittee will constitute a quorum, and the vote of a majority of the members of the Subcommittee present at any meeting at which there is a quorum will be the act of the Subcommittee.

Unless the Oversight Committee provides otherwise, the Subcommittee may make, alter, and repeal rules and procedures for the conduct of its business. In the absence of such rules and procedures, the Subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business, except that meetings of the Subcommittee are not required to be conducted pursuant to the Open Meetings Act.

FUNCTIONS, DUTIES AND RESPONSIBILITIES

Review Financial Statements for Quality Considerations

The Subcommittee has the following duties and responsibilities with respect to the financial statements of the Institute and the grant award funds managed on behalf of the State of Texas:

- Review the annual audited financial statements with management and the independent auditor, including significant issues regarding adequacy of internal controls and accounting principles and practices;
- Review an analysis prepared by management and the independent auditor of significant financial reporting issues and judgments made in connection with the preparation of the financial statements;
- Discuss with the independent auditor the matters required to be communicated by AU 380, *The Auditor's Communication with Those Charged with Governance*, as amended, relating to an audit of financial statements;
- Discuss with the independent auditor any fraud of which the independent auditor becomes aware that involves senior staff and/or which causes a material misstatement of the financial statements; and

- Receive and review periodic reports from the independent auditor regarding the auditor's independence and discuss such reports with the auditor.

Monitor Management's Handling of Internal Controls

The Subcommittee has the following duties and responsibilities with respect to its monitoring of the integrity of the financial reporting process and internal controls of the Institute and the grant award funds managed on behalf of the State of Texas:

- Review with the independent auditor all significant deficiencies and material weaknesses identified during the audit as required by AU 325, *Communicating Internal Control related Matters Identified in an Audit*, as amended.
- Review with the independent auditor any problems or difficulties the auditor may have encountered during its audit and any management letter provided by the auditor and the Institute's response to that letter, such review to include:
 - any restrictions on the scope of activities or access to required information; and
 - any changes required in the planned scope of the audit;
- Obtain reports from management, the independent auditor, the Chief Compliance Officer and CPRIT finance office and grant accountants with respect to the Institute's policies and procedures regarding compliance with applicable laws, regulations and grant policies;
- When considered necessary, meet with the independent auditor and the senior personnel of the CPRIT finance office and grant accountants without management participation;
- Meet periodically with management to review the major financial risk exposures and the steps management has taken to monitor and control such exposures;
- Review significant changes to internal controls and accounting principles and practices as suggested by the independent auditor, internal auditors or management;
- Review the significant reports to management prepared by the State Auditor's

Office and the Comptroller of Public Accounts and management's responses; and

- Review with the Institute's legal counsel legal matters that may have a material impact on the financial statements, the Institute's compliance policies and any material reports or inquiries received from regulators or governmental agencies.

Manage the Relationship with the External Auditors

The external auditors for the Institute are selected by and report to the Oversight Committee. The Oversight Committee directs the external auditors to have dual reporting responsibilities to the Oversight Committee and to the Subcommittee. The Subcommittee may approve additional audit and non-audit services provided by the external auditor related to the Institute and grant award funds as long as the work does not impair auditor independence.

The Subcommittee has the following specific duties and responsibilities with respect to the Institute's independent auditors:

- Recommend to the Oversight Committee the appointment of the independent auditor, which firm is ultimately accountable to the Subcommittee and the Oversight Committee.
- Approve the fee arrangement of the independent auditor;
- After interviewing members of the Institute's staff, evaluate together with the Oversight Committee the performance of the independent auditor and, if so determined by the Subcommittee, recommend that the Oversight Committee replace the independent auditor; and
- If determined by the Subcommittee to be necessary or advisable, recommend that the Oversight Committee take appropriate action to satisfy itself of the independence of the auditor.

Auditor Independence

In connection with the selection of external auditors, the Subcommittee shall determine that:

- The public accounting firm engaged to perform the annual audit does not provide non-audit services contemporaneously with the audit;
- The lead audit partner and reviewing partner rotate off of the audit every 3 years,

unless the Subcommittee adopts a resolution affirmatively determining that such rotation is not required; and

- The Institute's Chief Executive Officer, Grant Accountant, Finance Officer, or person in an equivalent position shall not have been employed by the public accounting firm during the one year period preceding the audit.

Work with the Internal Audit Function

The Institute uses a third-party auditor to perform internal audit functions hereunder with respect to the Institute and grant award funds. The third-party auditor reports directly to the Subcommittee. The Subcommittee has the following duties and responsibilities with respect to internal audit:

- Review the independence, qualifications, activities, resources and structure of the internal audit function;
- Review significant findings and recommendations made by the internal auditor and management's response and proposed implementation plan;
- Review the proposed internal audit plan for the coming year to determine that it addresses key areas of risk and that there is appropriate coordination with the external auditor;
- Review completed internal audits and the status of management's implementation of related recommendations;
- Receive a progress report on the internal audit plan with explanations for any deviations from the original plan; and
- Review procedures for the receipt, retention and treatment of complaints about accounting, internal accounting controls or auditing matters.

Oversee Regulatory Compliance

The Subcommittee is responsible for overseeing the effectiveness of the system for assuring Institute compliance with laws and regulations, particularly with the award of cancer research and prevention grant funds; as such, the Subcommittee has the following duties and responsibilities:

- Review the effectiveness of the system for monitoring compliance with laws and regulations and the results of management’s investigation and follow-up of any fraudulent acts or non-compliance;
- Obtain regular updates from management, the Chief Compliance Officer, and the Institute’s legal counsel regarding compliance matters that may have a material impact on the Institute’s financial statements, grant awards or compliance policies;
- Obtain regular updates from management and the Chief Compliance Officer regarding their consideration of all regulatory compliance matters in connection with the preparation of the financial statements; and
- Review the findings of any examinations by regulatory agencies, including the Texas State Auditor’s Office.

Oversee the Institute’s Enterprise Risk Management

Without limiting any of the foregoing, the Subcommittee, along with management and other personnel, as directed by the Oversight Committee, is responsible for the Institute’s enterprise risk management. Enterprise risk management assists management in achieving the Institute’s performance goals and prevents loss of resources, helps ensure effective reporting and compliance with laws and regulations, and helps avoid damage to the Institute’s reputation and associated consequences. Enterprise risk management enables management to deal effectively with uncertainty and associated risk and opportunity, enhancing the capacity to build value. The Subcommittee has the following responsibilities related to enterprise risk management:

- Evaluate the overall effectiveness of the Institute’s achievement of its objectives, as set forth in four categories:
 - 1) Strategic – high-level goals, aligned with and supporting its mission;
 - 2) Operations – effective and efficient use of its resources;
 - 3) Reporting – reliability and timeliness of reporting; and
 - 4) Compliance with applicable laws and regulations and with Oversight Committee policies such as the Code of Conduct and Ethics and Delegation of Authority.
- Evaluate whether management is setting the appropriate tone at the top by communicating the importance of enterprise risk; and

- Inquire of management, the Chief Compliance Officer, and the independent external auditor about significant enterprise risks or exposures to the Institute and how these are being managed.

Review the Overall Duties and Responsibilities of the Chief Compliance Officer

The Chief Compliance Officer will report functionally to the Subcommittee and administratively to the CPRIT Chief Executive Officer. The Chief Compliance Officer will report compliance activities of the Institute to the Chief Executive Officer and directly to the Subcommittee at its regular meetings and to the chair between meetings. The Chief Executive Officer will direct day-to-day responsibilities of the Chief Compliance Officer with oversight by the Subcommittee.

Other Duties

The Subcommittee has the following additional duties and responsibilities:

- Review and make recommendations to the Oversight Committee regarding:
 - 1) The Chief Executive Officer's recommendations for senior staff hires or dismissals and related compensation;
 - 2) Variances in the operating budget of the Institute of more than 5% or \$25,000;
 - 3) Non-grant contracts exceeding \$100,000;
 - 4) Variance of more than ten percent (10%) in any announced grant award; and
 - 5) The adequacy of this Audit Subcommittee Charter periodically and any proposed changes.
- Make regular reports (at least twice each calendar year) to the Oversight Committee regarding the Subcommittee's activities and such other reports as may be requested by the Oversight Committee;
- Perform such additional special functions, duties or responsibilities as may from time to time be designated by the Oversight Committee; and

- Evaluate the Subcommittee's own performance, both of individual members and collectively, on a regular basis.

POWERS AND LIMITATIONS

The Subcommittee shall have the authority to retain special legal, accounting or other consultants to advise the Subcommittee, subject to state laws and regulations regarding retention of professional services. The Subcommittee may request any employee of the Institute, consultant, or independent auditor to attend any meeting of the Subcommittee or to meet with any members of, or consultants to, the Subcommittee.

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CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CHARTER OF THE BOARD GOVERNANCE AND ETHICS
SUBCOMMITTEE
FOR THE CANCER PREVENTION AND RESEARCH INSTITUTE OF
TEXAS**

BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas (“CPRIT” or “Institute”) established a Board Governance and Ethics Subcommittee (the “Subcommittee”) on September 5, 2012. This Charter, adopted by the Oversight Committee on _____, 2013, supersedes any other documents relating to the Board Governance and Ethics Subcommittee.

PURPOSE

The primary purpose of the Subcommittee is to review and recommend proposed changes for approval to the Oversight Committee with respect to the following:

- Oversight Committee Bylaws and other organizational documents as may be necessary;
- Institute Policies;
- Administrative Rules;
- Legislation regarding or affecting the Institute;
- The delegation of authority to the Chief Executive Officer;
- The Institute’s Code of Conduct and Ethics, including the administration thereof; and
- An annual review of the internal policies and processes of the Oversight Committee.

COMPOSITION

The Subcommittee shall be composed of at least three members of the Oversight Committee; such members to be appointed from time to time by a majority vote of the Oversight Committee at a meeting at which a quorum is present and approved by the Oversight Committee. The

Oversight Committee shall designate the Chairperson of the Subcommittee from among its members. A member of the Board Governance Subcommittee will serve until his or her successor is duly appointed and qualified unless the member resigns or is removed from the Board Governance Subcommittee. The Oversight Committee may replace any member of the Subcommittee by a majority vote of the Oversight Committee.

MEETINGS AND QUORUM

The Subcommittee shall meet as often as the Chairperson of the Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under the Bylaws and as set forth in this Subcommittee charter. The Subcommittee shall keep regular minutes of its meetings and cause such minutes to be recorded in books kept for that purpose in the principal office of the Institute, and report the same to the Oversight Committee at its next regular meeting.

If a member of the Subcommittee is absent from any meeting, or disqualified from voting at that meeting, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of the Subcommittee, a majority of the then authorized members of the Subcommittee will constitute a quorum, and the vote of a majority of the members of the Subcommittee present at any meeting at which there is a quorum will be the act of the Subcommittee.

Unless the Oversight Committee provides otherwise, the Subcommittee may make, alter, and repeal rules and procedures for the conduct of its business. In the absence of such rules and procedures, the Subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business, except that meetings of the Subcommittee are not required to be conducted pursuant to the Open Meetings Act.

DUTIES AND RESPONSIBILITIES

The Subcommittee has the following duties and responsibilities:

- Review and recommend changes to the Oversight Committee Bylaws for approval by the Oversight Committee;
- Propose and provide guidance regarding any additional organizational documents for approval by the Oversight Committee;

- Review and recommend changes to the Institute’s administrative rules for approval by the Oversight Committee;
- Review, provide input and recommend approval, if necessary, changes to Institute policies;
- Review and provide input regarding proposed legislative changes related to or affecting the Institute;
- Propose and recommend for approval a policy regarding the delegation of authority to the Chief Executive Officer, including any recommended changes;
- Review and recommend changes to the Institute’s Code of Conduct and Ethics for approval by the Oversight Committee;
- Monitor compliance with the Code of Conduct and Ethics;
- Report to the Oversight Committee annually, or upon a more frequent schedule as established by the Oversight Committee Chair, regarding the Oversight Committee’s internal policies and processes, including any recommended changes.

OTHER DUTIES

The Subcommittee will submit this Charter to the Oversight Committee for its approval, evaluate the Subcommittee’s performance on a periodic basis, periodically review the adequacy of this Charter and perform any other activities consistent with this Charter, the Bylaws, and applicable laws as the Subcommittee or the Oversight Committee deems necessary or appropriate.

In addition to its duties and responsibilities, the Subcommittee shall perform such additional special functions, duties or responsibilities related thereto as may from time to time be designated to it by the Oversight Committee Chair.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHARTER OF THE DIVERSITY SUBCOMMITTEE FOR THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas (“CPRIT” or “Institute”) established a Diversity Subcommittee (the “Subcommittee”) on February 25, 2013 to succeed the Diversity Workgroup established January 20, 2010. This Charter, adopted by the Oversight Committee on _____, supersedes any other documents relating to the Diversity Subcommittee.

PURPOSE

The primary purpose of the Subcommittee is to advise the Oversight Committee on the effectiveness of policies, procedures, and outreach efforts that address diversity related to increasing high-quality jobs and opportunities to participate in and benefit from Institute-funded cancer research and prevention programs.

COMPOSITION

The Subcommittee shall be composed of at least three members of the Oversight Committee; such members to be appointed from time to time by a majority vote of the Oversight Committee at a meeting at which a quorum is present and approved by the Oversight Committee. The Oversight Committee shall designate the Chairperson of the Subcommittee from among its members. A member of the Diversity Subcommittee will serve until his or her successor is duly appointed and qualified unless the member resigns or is removed from the Diversity Subcommittee. The Oversight Committee may replace any member of the Subcommittee by a majority vote of the Oversight Committee.

MEETINGS AND QUORUM

The Subcommittee shall meet as often as the Chairperson of the Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under the Bylaws. The Subcommittee shall keep regular minutes of its meetings and cause such minutes to be recorded in books kept for that purpose in the principal office of the Institute, and report the same to the Oversight Committee at its next regular meeting.

If a member of the Subcommittee is absent from any meeting, or disqualified from voting at that meeting, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous

vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of the Subcommittee, a majority of the then authorized members of the Subcommittee will constitute a quorum, and the vote of a majority of the members of the Subcommittee present at any meeting at which there is a quorum will be the act of the Subcommittee.

Unless the Oversight Committee provides otherwise, the Subcommittee may make, alter, and repeal rules and procedures for the conduct of its business. In the absence of such rules and procedures, the Subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business, except that meetings of the Subcommittee are not required to be conducted pursuant to the Open Meetings Act.

DUTIES AND RESPONSIBILITIES

The Subcommittee has the following duties and responsibilities:

- Annually review and report to the Oversight Committee regarding the effectiveness of policies and procedures that may impact grant applicant diversity and outreach efforts in the Institute's cancer research and prevention funding opportunities; and
- Advise the Oversight Committee regarding policies, programs and outreach efforts that address diversity related to increasing high-quality jobs and opportunities to participate in and benefit from Institute-funded cancer research and prevention funding programs.

OTHER DUTIES

The Subcommittee will submit this Charter to the Oversight Committee for its approval; evaluate the Subcommittee's performance on a periodic basis, periodically review the adequacy of this Charter and perform any other activities consistent with this Charter, the Bylaws, and applicable laws as the Subcommittee or the Oversight Committee deems necessary or appropriate.

In addition to its duties and responsibilities, the Subcommittee shall perform such additional special functions, duties or responsibilities related thereto as may from time to time be designated to it by the Oversight Committee Chair.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHARTER OF THE NOMINATIONS SUBCOMMITTEE FOR THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas (“CPRIT” or “Institute”) established a Nominations Subcommittee (the “Subcommittee”) on November 19, 2008. This Charter, adopted by the Oversight Committee on _____, supersedes any other documents relating to the Nominations Subcommittee.

PURPOSE

The primary purpose of the Subcommittee is to advise the Oversight Committee on the composition and effectiveness of the Institute advisory committees, including identifying and nominating qualified candidates for appointment to Institute’s advisory committees.

COMPOSITION

The Subcommittee shall be composed of at least three members of the Oversight Committee; such members to be appointed from time to time by a majority vote of the Oversight Committee at a meeting at which a quorum is present and approved by the Oversight Committee. The Oversight Committee shall designate the Chairperson of the Subcommittee from among its members. A member of the Nominations Subcommittee will serve until his or her successor is duly appointed and qualified unless the member resigns or is removed from the Nominations Subcommittee. The Oversight Committee may replace any member of the Subcommittee by a majority vote of the Oversight Committee.

MEETINGS AND QUORUM

The Subcommittee shall meet as often as the Chairperson of the Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under the Bylaws. The Subcommittee shall keep regular minutes of its meetings and cause such minutes to be recorded in books kept for that purpose in the principal office of the Institute, and report the same to the Oversight Committee at its next regular meeting.

If a member of the Subcommittee is absent from any meeting, or disqualified from voting at that meeting, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at

all meetings of the Subcommittee, a majority of the then authorized members of the Subcommittee will constitute a quorum, and the vote of a majority of the members of the Subcommittee present at any meeting at which there is a quorum will be the act of the Subcommittee.

Unless the Oversight Committee provides otherwise, the Subcommittee may make, alter, and repeal rules and procedures for the conduct of its business. In the absence of such rules and procedures, the Subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business, except that meetings of the Subcommittee are not required to be conducted pursuant to the Open Meetings Act.

DUTIES AND RESPONSIBILITIES

The Subcommittee has the following duties and responsibilities:

- Annually review and report to the Oversight Committee regarding the composition and effectiveness of the Institute's advisory committees;
- Identify qualified individuals for appointment as members of advisory committees; and
- 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.

OTHER DUTIES

The Subcommittee will submit this Charter to the Oversight Committee for its approval; evaluate the Subcommittee's performance on a periodic basis, periodically review the adequacy of this Charter and perform any other activities consistent with this Charter, the Bylaws, and applicable laws as the Subcommittee or the Oversight Committee deems necessary or appropriate.

In addition to its duties and responsibilities, the Subcommittee shall perform such additional special functions, duties or responsibilities related thereto as may from time to time be designated to it by the Oversight Committee Chair.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHARTER OF THE PREVENTION SUBCOMMITTEE FOR THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas (“CPRIT” or “Institute”) established a Prevention Subcommittee (the “Subcommittee”) on February 25, 2013. This Charter, adopted by the Oversight Committee on _____, supersedes any other documents relating to the Prevention Subcommittee.

PURPOSE

The primary purpose of the Subcommittee is to assist the Oversight Committee in fulfilling its responsibility to oversee the prevention grants program. The Subcommittee assists the Oversight Committee by monitoring the direction, processes and outcomes of the prevention grants program to ensure that the Institute properly exercises its duty to award prevention grants with transparency and integrity and the appropriate deployment of taxpayer funds.

Specifically, the Subcommittee will monitor the following activities and make recommendations to the Oversight Committee regarding the following:

- The direction and priorities of the prevention grants program;
- The processes underlying the solicitation, review, award, and monitoring of CPRIT prevention grants,
- The success of the prevention grants program in achieving its goals and priorities,
- The implementation, monitoring, and revision of the Texas Cancer Plan, and
- The balance between the Institute’s investments in cancer prevention grants program and investment and activities directed toward cancer research and product development activities.

COMPOSITION

The Subcommittee shall be composed of at least three members of the Oversight Committee; such members to be appointed from time to time by a majority vote of the Oversight Committee at a meeting at which a quorum is present and approved by the Oversight Committee. To perform their role effectively, each Subcommittee member will need to develop and maintain his or her skills and knowledge, including an understanding of the Subcommittee’s responsibilities

and of the Institute's activities and operations. The Oversight Committee shall designate Chairperson of the Subcommittee from among its members. A member of the Prevention Subcommittee will serve until his or her successor is duly appointed and qualified unless the member resigns or is removed from the Prevention Subcommittee. The Oversight Committee may replace any member of the Subcommittee by a majority vote of the Oversight Committee.

MEETINGS AND QUORUM

The Subcommittee shall meet as often as the Chairperson of the Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under the Bylaws. The Subcommittee shall keep regular minutes of its meetings and cause such minutes to be recorded in books kept for that purpose in the principal office of the Institute, and report the same to the Oversight Committee at its next regular meeting.

If a member of the Subcommittee is absent from any meeting, or disqualified from voting at that meeting, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of the Subcommittee, a majority of the then authorized members of the Subcommittee will constitute a quorum, and the vote of a majority of the members of the Subcommittee present at any meeting at which there is a quorum will be the act of the Subcommittee. The Chief Prevention Officer will attend Subcommittee meetings and act as staff liaison to the Subcommittee.

Unless the Oversight Committee provides otherwise, the Subcommittee may make, alter, and repeal rules and procedures for the conduct of its business. In the absence of such rules and procedures, the Subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business, except that meetings of the Subcommittee are not required to be conducted pursuant to the Open Meetings Act.

DUTIES AND RESPONSIBILITIES

The Subcommittee has the following duties and responsibilities with respect to:

- **The direction and priorities of the prevention grants program**

Annually review and recommend program priorities to the Oversight Committee in consultation with the Chief Prevention Officer. Review the prevention program portfolio, including the number and types of proposals received and awarded, to determine whether the program is meeting its stated priorities.

- **The processes for award and monitoring of prevention grants**

Review processes for the solicitation, review, award, and monitoring of prevention grants and make recommendations for improvement as needed. Review appointments to the peer review panels and the composition of the panels as needed; review any changes in the honorarium policy for prevention peer reviewers.

- **The success of the prevention grants program in achieving its goals and priorities**

Review summaries of prevention grantee reported metrics and other measures of success, including the degree to which the program addresses the Texas Cancer Plan. Annually monitor the balance of funding among the prevention programs and recommend adjustments as needed.

- **Implementation, monitoring, and revision of the Texas Cancer Plan**

Review the current Texas Cancer Plan and discuss monitoring its implementation in consultation with the Chief Prevention Officer. Provide input on plans for revision and review drafts prior to presentation to the full Oversight Committee.

OTHER DUTIES

The Subcommittee will submit this Charter to the Oversight Committee for its approval, evaluate the Subcommittee's performance on a periodic basis, periodically review the adequacy of this Charter and perform any other activities consistent with this Charter, the Bylaws, and applicable laws as the Subcommittee or the Oversight Committee deems necessary or appropriate.

In addition to its duties and responsibilities, the Subcommittee shall perform such additional special functions, duties or responsibilities related thereto as may from time to time be designated to it by the Oversight Committee Chair.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHARTER OF THE PRODUCT DEVELOPMENT SUBCOMMITTEE FOR THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas (“CPRIT” or “Institute”) established a Product Development Subcommittee (the “Subcommittee”) on February 25, 2013, to succeed the Economic Development and Commercialization Subcommittee established on November 19, 2008. This Charter, adopted by the Oversight Committee on _____, supersedes any other documents relating to the Product Development Subcommittee.

PURPOSE

The primary purpose of the Subcommittee is to assist the Oversight Committee in fulfilling its responsibilities for overseeing the product development grants program. The Subcommittee assists the Oversight Committee by monitoring the direction, outcomes, and processes of the grants program for the product development of cancer research to ensure that the Institute properly exercises its duty to award product development grants with transparency and integrity and the appropriate deployment of taxpayer funds.

Specifically, the Subcommittee will monitor the following activities and make recommendations to the Oversight Committee regarding the following:

- The direction and priorities of the grants program for the product development of cancer research;
- Processes underlying the solicitation, review, award, and monitoring of CPRIT grants for product development of cancer research;
- The success of the grants program for product development of cancer research in achieving its goals and priorities;
- The degree to which the grants program for product development of cancer research addresses the Texas Cancer Plan and the priorities set by statute;
- The return on investment from the grants program for product development of cancer research in terms of jobs created and retained, products moved forward toward development, and additional funding generated; and

- The balance between the Institute's investments in the grants program for product development of cancer research and investment and activities in cancer prevention interventions and scientific research.

COMPOSITION

The Subcommittee shall be composed of at least three members of the Oversight Committee; such members to be appointed from time to time by a majority vote of the Oversight Committee at a meeting at which a quorum is present and approved by the Oversight Committee. To perform their role effectively, each Subcommittee member will need to develop and maintain his or her skills and knowledge, including an understanding of the Subcommittee's responsibilities and of the Institute's activities and operations. The Oversight Committee shall designate the Chairperson of the Subcommittee from among its members. A member of the Product Development Subcommittee will serve until his or her successor is duly appointed and qualified unless the member resigns or is removed from the Product Development Subcommittee. The Oversight Committee may replace any member of the Subcommittee by a majority vote of the Oversight Committee.

MEETINGS AND QUORUM

The Subcommittee shall meet as often as the Chairperson of the Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under the Bylaws. The Subcommittee shall keep regular minutes of its meetings and cause such minutes to be recorded in books kept for that purpose in the principal office of the Institute, and report the same to the Oversight Committee at its next regular meeting.

If a member of the Subcommittee is absent from any meeting, or disqualified from voting at that meeting, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of the Subcommittee, a majority of the then authorized members of the Subcommittee will constitute a quorum, and the vote of a majority of the members of the Subcommittee present at any meeting at which there is a quorum will be the act of the Subcommittee. The Chief Product Development Officer will attend Subcommittee meetings and act as staff liaison to the Subcommittee.

Unless the Oversight Committee provides otherwise, the Subcommittee may make, alter, and repeal rules and procedures for the conduct of its business. In the absence of such rules and procedures, the Subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business, except that meetings of the Subcommittee are not required to be conducted pursuant to the Open Meetings Act.

DUTIES AND RESPONSIBILITIES

The Subcommittee has the following duties and responsibilities with respect to the grants program for product development of cancer research:

- **The direction and priorities of the product development grants program**

Annually recommend to the Oversight Committee priorities for the grants program for product development of cancer research in consultation with CPRIT's Chief Product Development Officer. Review the portfolio for the grants program for product development of cancer research, including the number and types of proposals received and recommended during each review cycle, to determine whether the program is meeting its stated priorities.

- **The processes for award and monitoring of product development grants**

Review processes for the solicitation, review, award, and monitoring of grants for product development of cancer research and make recommendations for improvement. Review appointments to the peer review panels and the composition of the panels as needed; review any changes in the honorarium policy for product development peer reviewers. Assist the Institute in developing a needs-assessment for support services for product development initiatives and regularly monitoring the efforts of any contracted service providers related to the support and growth of the Institute's product development portfolio.

- **The success of the product development grants program in achieving its goals and priorities**

Track measures of success for the grants program for product development of cancer research, including measures of the return on the State's investment in the program, the degree to which the program addresses the Texas Cancer Plan, and adherence of the program to the research priorities set by statute. Annually monitor the balance of funding among the product development of cancer research programs and recommend adjustments where necessary.

OTHER DUTIES

The Subcommittee will submit this Charter to the Oversight Committee for its approval, evaluate the Subcommittee's performance on a periodic basis, periodically review the adequacy of this Charter and perform any other activities consistent with this Charter, the Bylaws, and applicable laws as the Subcommittee or the Oversight Committee deems necessary or appropriate.

In addition to its duties and responsibilities, the Subcommittee shall perform such additional special functions, duties or responsibilities related thereto as may from time to time be designated to it by the Oversight Committee Chair.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHARTER OF THE SCIENTIFIC RESEARCH SUBCOMMITTEE FOR THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas (“CPRIT” or “Institute”) established a Scientific Research Subcommittee (the “Subcommittee”) on February 25, 2013. This Charter, adopted by the Oversight Committee on _____, supersedes any other documents relating to the Scientific Research Subcommittee.

PURPOSE

The primary purpose of the Subcommittee is to assist the Oversight Committee in fulfilling its responsibilities for overseeing the scientific research grants program. The Subcommittee assists the Oversight Committee by monitoring the direction, processes, and outcomes of the scientific research grants program to ensure that the Institute properly exercises its duty to award scientific research grants with transparency and integrity and the appropriate deployment of taxpayer funds.

Specifically, the Subcommittee will monitor the following activities and make recommendations to the Oversight Committee regarding the following:

- The direction and priorities of the scientific research grants program;
- The processes underlying the solicitation, review, award, and monitoring of CPRIT scientific research grants;
- The success of the scientific research grants program in achieving its goals and priorities;
- The degree to which the scientific research grants program addresses the Texas Cancer Plan and the priorities set by statute;
- The return on investment from the scientific research grants program in terms of jobs created and retained, products moved forward toward development, and additional funding generated; and
- The balance between the Institute’s investments in the scientific research grants program and investment and activities in cancer prevention interventions and product development of cancer research.

COMPOSITION

The Subcommittee shall be composed of at least three members of the Oversight Committee; such members to be appointed from time to time by a majority vote of the Oversight Committee at a meeting at which a quorum is present and approved by the Oversight Committee. To perform their role effectively, each Subcommittee member will need to develop and maintain his or her skills and knowledge, including an understanding of the Subcommittee's responsibilities and of the Institute's activities and operations. The Oversight Committee shall designate the Chairperson of the Subcommittee from among its members. A member of the Scientific Research Subcommittee will serve until his or her successor is duly appointed and qualified unless the member resigns or is removed from the Scientific Research Subcommittee. The Oversight Committee may replace any member of the Subcommittee by a majority vote of the Oversight Committee.

MEETINGS AND QUORUM

The Subcommittee shall meet as often as the Chairperson of the Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under the Bylaws. The Subcommittee shall keep regular minutes of its meetings and cause such minutes to be recorded in books kept for that purpose in the principal office of the Institute, and report the same to the Oversight Committee at its next regular meeting.

If a member of the Subcommittee is absent from any meeting, or disqualified from voting at that meeting, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of the Subcommittee, a majority of the then authorized members of the Subcommittee will constitute a quorum, and the vote of a majority of the members of the Subcommittee present at any meeting at which there is a quorum will be the act of the Subcommittee. The Chief Scientific Officer will attend Subcommittee meetings and act as staff liaison to the Subcommittee.

Unless the Oversight Committee provides otherwise, the Subcommittee may make, alter, and repeal rules and procedures for the conduct of its business. In the absence of such rules and procedures, the Subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business, except that meetings of the Subcommittee are not required to be conducted pursuant to the Open Meetings Act.

DUTIES AND RESPONSIBILITIES

The Subcommittee has the following duties and responsibilities with respect to the research grants program:

- **The direction and priorities of the scientific research grants program**

Annually recommend to the Oversight Committee priorities for the scientific research grants program in consultation with the Chief Scientific Officer. Review the scientific research grants program portfolio, including the number and types of proposals received and awarded, to determine whether the program is meeting its stated priorities.

- **The processes for award and monitoring of scientific research grants**

Review processes for the solicitation, review, award, and monitoring of scientific research grants and make recommendations for improvement. Review appointments to the peer review panels and the composition of the panels as needed; review any changes in the honorarium policy for scientific research peer reviewers.

- **The success of the scientific research grants program in achieving its goals and priorities**

Track measures of success for the scientific research grants program, including measures of the return on the State's investment in the program, the degree to which the program addresses the Texas Cancer Plan, and adherence of the program to the research priorities set by statute. Annually monitor the balance of funding among the scientific research programs and recommend adjustments where necessary.

OTHER DUTIES

The Subcommittee will submit this Charter to the Oversight Committee for its approval, evaluate the Subcommittee's performance on a periodic basis, periodically review the adequacy of this Charter and perform any other activities consistent with this Charter, the Bylaws, and applicable laws as the Subcommittee or the Oversight Committee deems necessary or appropriate.

In addition to its duties and responsibilities, the Subcommittee shall perform such additional special functions, duties or responsibilities related thereto as may from time to time be designated to it by the Oversight Committee Chair.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: APPROVAL OF PROPOSED ADMINISTRATIVE RULE CHANGES
DATE: OCTOBER 28, 2013

Summary and Recommendation:

Significant revisions to CPRIT's administrative rules are necessary to address recently enacted legislative changes and to implement the State Auditor's recommendations. The Oversight Committee should approve the proposed amendments to the administrative rules found in Chapters 701, 702, and 703. Once approved, the proposed rule amendments will be published in the *Texas Register* for public comment. Final rules that incorporate changes recommended by the public should be ready for the Committee's consideration at an Oversight Committee meeting held in January, 2014.

Discussion:

CPRIT must revise its existing administrative rules to conform agency practices to newly-enacted legislative requirements. In addition, the revisions will 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*.

Proposed changes made to the administrative rules, including several new provisions, are extensive. Credibility and public confidence are vital throughout the grant making process. The new rules and rule changes stand for the commitment that CPRIT is making to Texans to operate its grant award program with integrity while also serving its important mission. The changes made will increase transparency in CPRIT's major operations.

CPRIT's activities are addressed by three chapters 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, and Chapter 703 - Grants for Cancer Research and Prevention. A fourth chapter, Chapter 704, governs the Texans Conquer Cancer Program, but this chapter should be repealed because the statutory authority has been revised. A chapter-by-chapter overview of the proposed changes is included at the end of this memorandum.

The Oversight Committee's consideration and approval for publishing the proposed rules in the next edition of the *Texas Register* (likely to be the November 15th edition) is the first step in the process

to adopt final rules. Once the proposed rules are published, the public has 30 days to submit written comments to CPRIT before the rules can be brought back to the Oversight Committee for final approval. The rules, along with a summary of the input received from the public and any recommended changes, will be brought to the Oversight Committee for final approval and adoption at an open meeting held in January, 2014.

In the rules proposed for your consideration, new text is denoted by underscoring while proposed deletions are struck-through.

Chapter 701 - Policies and Procedures

Chapter 701 addresses policies and procedures for the Institute, including several policies referenced by CPRIT's statute, Chapter 102 of the Texas Health and Safety Code. Many of the overarching issues of transparency 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. Notable issues include:

- Adoption of Oversight Committee Bylaws to govern its operation and management of the Institute, and the new requirement that the Oversight Committee establish grant program requirements annually.
- Implementation of the Compliance and Ethics Program mandated by CPRIT's statute and a system for the complaint, reporting, and investigation of suspected compliance violations.
- Framework for the development, implementation, continual monitoring, and revisions to the Texas Cancer Plan.
- Appointment and reporting requirements for CPRIT's Advisory Committees.
- Scientific Research and Prevention Program Committee Members (the formal name for CPRIT's peer reviewers) honoraria and residency standards.
- Guidelines regarding advance payment of grant funds, as well as CPRIT's policy on electronic signatures for executing and approving changes to the grant contract, and the preference for Texas Suppliers and HUBs when expending grant funds.
- A comprehensive list of documents and information that CPRIT commits to make publicly available to increase transparency on agency actions and operations.
- Policies related to Open Records, including CPRIT's policy for implementing the statutory protection for 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

A special responsibility is imposed on everyone entrusted with the disposition of state funds. Maintaining CPRIT's integrity and credibility 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. This chapter defines personal, professional, and financial interests that may conflict with an individual's objective review of a grant application. Given that the community of high-level, highly respected, well-established cancer research, product development, and prevention experts that CPRIT relies upon for peer review is relatively exclusive, it is expected that there will be conflicts of interest. Guidelines are provided for recusing individuals with conflicts of interest and for ensuring transparency. This chapter also addresses CPRIT's Code of Conduct and Ethics, which will be a central tenet guiding Oversight Committee and CPRIT employee actions going forward. Notable issues include:

- Guidelines regarding the acceptance and public disclosure of gifts and donations to the agency, specifying the agency's commitment that no CPRIT employee's salary will be supplemented with gifts or donations.
- Adoption of a Code of Conduct and Ethics.
- Minimum standards, including disclosure of gifts and consideration received by Oversight Committee members and CPRIT employees.
- A comprehensive system of identifying, disclosing, recusing, and monitoring conflicts of interest in the awarding of CPRIT funds.
- The process for reporting and investigating undisclosed conflicts of interest.
- A procedure for granting a waiver for a person to participate in the grant review process upon a showing of exceptional circumstances.
- A restriction on communication about grant applications between individual Oversight Committee members and Program Integration Committee members while grant award decisions are being made. Communication between a grant applicant and anyone involved in the grant award process is also restricted during grant review.

Chapter 703 - Grants for Cancer Research and Prevention

Recognizing that any grant selection process relies to some extent upon subjective decision-making, CPRIT's grant review process is designed to provide applicants a fair, timely, transparent evaluation free from professional, financial or personal bias. It is also 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. It also delineates the grant contracting process, including comprehensive monitoring of financial and programmatic contractual obligations, revenue sharing requirements and contract termination. Notable issues include:

- The components of CPRIT's Request for Applications, such as the evaluation criteria and scoring guidance, as well as the various cancer research and prevention areas the Institute may fund. Includes mandatory eligibility requirements for applicants such as submission by the posted deadline to the designated electronic portal, as well as certification that the grant application has not made and will not make a donation to CPRIT or to any foundation established to benefit CPRIT. Requires disclosure of all sources of a grant applicant's funding for purposes of identifying conflicts of interest.
- Establishes CPRIT's electronic grant management system as the repository to maintain complete grant records for the application submission, review, award, contracting, and monitoring processes implemented by the agency.
- Adds guidance for peer reviewers related to refraining from 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 the 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.
- Provides for the Oversight Committee's process to approve grant award recommendations, including consideration of Compliance Officer reports, as well as the affidavits submitted by the Chief Executive Officer for every grant recommendation.
- Clarifies the limitation on reconsidering grant application decisions unless an undisclosed conflict of interest is found.
- Delineates the required grant contract provisions, including a certification that the grant recipient has not made and will not make a contribution to CPRIT or to a foundation established to benefit CPRIT and repayment provisions if the grant recipient fails to live up to the grant contract.
- Guidelines for the matching funds obligation for grant recipients, including a description of appropriate sources of matching funds, reporting requirements, and penalty provisions.

- Explains various limitations on the use of grant award funds, including a list of expenses that are not authorized to be made with grant funds.
- Makes clear audit requirements for grant recipients, and provides explicit penalties for the failure to submit required audits to CPRIT in a timely manner.
- Spells out the process for terminating, extended, and closing out grant contracts.
- Describes obligations specific to multi-year contracts, such as a limitation on the grant award amounts that may be carried forward from year to year without specific justification and approval.
- 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, and provides explicit penalties for failure to timely submit required reports to CPRIT.

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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.

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.

(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.

(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

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

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 102.2003(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

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, biologics, 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

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.

(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

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.

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

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.

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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.

(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.

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.

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.

(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.

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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.

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.

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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.

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 purchase products and materials produced in the State of Texas 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.

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.

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.

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;

(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*.

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

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.

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.

(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.

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.

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.

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RULE §702.3 Definitions

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

(1) ~~Ad hoc committee means a committee of experts created by the Oversight Committee to advise the Oversight Committee on issues related to cancer.~~

(2) ~~Applicant means the public or private institution of higher education, as defined by §61.003, Education Code, research institution, government organization, non-governmental organization, non-profit organization, other public entity, private company, individual, or consortia, including any combination of the aforementioned, that submits an application to the Institute for a grant funded by the Cancer Prevention and Research Fund. Unless otherwise indicated, this term includes the principal investigator.~~

(3) ~~Application means the written proposal submitted to the Institute by an applicant that, if successful, will result in an award of money from the Cancer Prevention and Research Fund. An application may be submitted in response to a published Request for Applications or unsolicited by the Institute.~~

(4) ~~Cancer Prevention and Research Fund means the dedicated account in the general revenue fund consisting of patent, royalty, and license fees and other income received under a contract with a CPRIT funding award recipient, legislative appropriations, gifts, grants, and other donations, and earned interest.~~

(5) ~~Close relative means a parent, spouse, domestic partner, or son or daughter.~~

(6) ~~Entity means any organization recognized by law, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership, or trust, as well as any program, enterprise, non-profit corporation public or private research or academic institution.~~

(7) ~~Executive Director means the Executive Director of the CPRIT and any other official or employee of the CPRIT to whom the authority involved has been delegated.~~

(8) ~~Funding Award means any award of money from the Cancer Prevention and Research Fund made by the Institute to an applicant in response to a solicited or unsolicited application. A funding award must be in the form of an executed contract between the Institute and the Recipient.~~

(9) ~~Institute means the Cancer Prevention and Research Institute of Texas or CPRIT.~~

(10) ~~Institute employee means any individual within the employ of the Institute, including any individuals performing duties for the Institute pursuant to a contract of employment.~~

~~(11) Oversight Committee member means any person appointed to and serving on the Oversight Committee of the Institute, or any person who sits on that board by operation of statute or by designation.~~

~~(12) Principal investigator means a single individual designated by the grantee in the grant application and approved by the Institute, who is responsible for the scientific and technical direction of the project.~~

~~(13) Professional associate of the reviewer means any colleague, scientific mentor, or student with whom the peer reviewer is currently conducting research or other significant professional activities or with whom the member has conducted such activities within three years before the date of the review.~~

~~(14) Recipient means the public or private institution of higher education, as defined by §61.003, Education Code, research institution, government organization, non-governmental organization, non-profit organization, other public entity, private company, individual, or consortia, including any combination of the aforementioned, who is awarded money from the Cancer Prevention and Research Fund. Unless otherwise indicated, this term includes the principal investigator.~~

~~(15) Scientific Research and Prevention Program committee means one or more groups of experts in the field of cancer research, prevention or commercialization appointed by the Executive Director and approved by the Oversight Committee for the purpose of reviewing grants applications and making recommendations to the Executive Director regarding the award of cancer research and prevention grants.~~

~~(16) University Advisory Committee means the committee created by the Texas Health and Safety Code, §102.154 to advise the Oversight Committee regarding the role of institutions of higher education in cancer research.~~

RULE §702.5 Intent

It is the intent of the Institute that the ~~Institute's~~ ~~Grant~~ ~~Review and funding award~~ process be provide ~~Grant~~ ~~Applicants~~ a fair, and unbiased merit-based assessment and 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.

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. ~~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.~~

(b) ~~An Oversight Committee m~~Member or an ~~employee of the 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 ~~Director~~ 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 ~~Director~~ Officer that includes the following information:

- (A) Name and biographical data regarding the individual or organization making the gift;

(B) A description of the gift;

(C) A list of conditions or requirements to be imposed on the Institute as a result of accepting the gift;

(D) If one of the conditions is naming, then include a description of the object to be named and whether there is a time limit on continuing the name;

(E) If the gift is real property, an evaluation of the gift by the General Land Office;

(F) If the gift is stock or other investments, a description of how they will be sold and the expected net proceeds; and

(G) A description of how the gift will be used.

(5) All funds received from donations to the Institute will be deposited to the state treasury and used for the purpose specified by the donor or for general Institute programs when no purpose is specified.

(d) The Institute encourages the offer of gifts of additional revenue and real and personal property through naming.

(1) Naming can be given to both real objects and inanimate objects, such as gGrant programs 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 (~~will the Institute will have discretion in the use of the real or personal property or will it be limited to certain uses~~).

(3) The Oversight Committee must approve the recommendation to name an object or program by a majority vote of its members.

(e) The Oversight Committee may refuse a gift to the Institute for any reason, including:

(1) The gift requires an initial and/or on-going expenditure that will likely equal or exceed the value of the gift.

(2) The gift is from an institution, entity, ~~or organization or individual~~, 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 has received funding from the Institute at any time in the past two years.~~ This limitation applies to donations in excess of \$1,000 by a director, officer, or executive of an institution, entity, organization, or individual 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 ~~shall~~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 ~~contributor~~donor subsequently submits an 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 ~~the following institution, entity, organization, or individual:~~

(A) ~~A not-for-profit 503(c)(3) corporation that is a separate legal entity from the associated institution, entity, organization, or individual.~~

(B) ~~Aa donation that would be otherwise unacceptable pursuant to paragraph (2) of this subsection that is made as the result of the final bequeathal.~~

(f) ~~At each meeting of the Oversight Committee, a list of all gifts that have been accepted by the Executive Director and by the Executive Committee since the last meeting will be presented as an information item on the public agenda. The list will include the identity of the contributor, unless the contributor has requested anonymity, the type of gift (unrestricted general support, restricted programmatic support, endowed/restricted funds, or other), and the amount of the gift. The Institute shall maintain a list of gifts received, including the identity of contributor, unless the contributor has requested anonymity, the type of gift, and the amount of the gift.~~ 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:

(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 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;

(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.

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

~~Pursuant to the provisions of Texas Government Code Chapter 572 and Texas Health and Safety Code Chapter 102-~~(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 ~~employee of the Institute~~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 ~~might could~~ reasonably ~~tend to~~ 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 ~~his or her~~ the member or employee's official conduct.

(2) A member of the Oversight Committee, Institute Employee, or ~~employee of the Institute~~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, ~~which he or she might that would~~ reasonably ~~expect would~~ require or induce that person to disclose confidential information acquired by reason of ~~his or her~~ the member or employee's official position.

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

(4) A member of the Oversight Committee, Institute Employee, or ~~employee of the Institute~~Program Integration Committee Member, or the spouse of an individual governed by this provision shall not make personal investments or have a financial interest ~~which that~~ could reasonably ~~be expected to~~ create a substantial conflict between his or her private

interest and the ~~individual's member or employee's~~ official duties ~~as a member of the Oversight Committee or employee of the Institute.~~

(5) A member of the Oversight Committee, Institute Employee, or ~~employee of the Institute~~ 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 ~~having exercised~~ his or her official powers or performed ~~his or her the member or employee's~~ official duties in favor of another.

(6) An Oversight Committee Member, Institute Employee, or ~~employee of the Institute~~ 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 ~~any program, business, enterprise or institution that receives a grant from the Institute~~ a Grant Recipient.

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

(8) A member of the Oversight Committee, ~~or 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, ~~more than five percent~~ 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.

(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.

(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.

RULE §702.11 Conflicts of Interest Requiring Recusal

(a) For purposes of this chapter, a ~~e~~Conflict of ~~i~~Interest exists when an individual subject to this rule has an interest in the outcome of ~~a~~ Grant ~~a~~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 ~~g~~Grant proposal Application. Individuals subject to this rule are:

(1) Oversight Committee Members;

(2) ~~University Advisory Committee members;~~

(3) ~~Ad hoc committee(s) members;~~

(4) Institute ~~e~~Employees; ~~and~~

(5) ~~Scientific Research and Prevention Programs e~~Committee ~~m~~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 conflict of interest with respect to an application, 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 on the application related to the entity.

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

(1) Owns or controls, directly or indirectly, an ownership interest ~~of five percent (5%) or more in an~~ business entity or other organization 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 eConflict of iInterest 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 eCommittee, the Program Integration Committee, the Institute, or its Oversight Committee related to an entity receiving or applying to receive money from the Institute could result in a financial benefit to the individual ~~of 100% or more.~~

(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 eConflict of iInterest exists if the individual subject to this rule or a ~~close r~~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 ~~other~~ of a foundation or similar organization affiliated with an entity receiving or applying to receive money from the Institute during the same gGrant Review eCycle;

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

(5) Is a ~~professional associate~~ colleague, scientific mentor, or student of a primary m Senior Member or Key Personnel of the research/ or prevention program applicant's 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 ~~primary~~ Senior mMember or Key Personnel of the research/ or prevention program applicant's 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 ~~primary Senior~~ Member or Key Personnel of the research/or prevention program applicant's team listed on the Grant Application; or

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

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

(f) Nothing herein shall prevent ~~the Oversight Committee members, Institute employees, or Scientific Research and Prevention Program committee members~~ from adopting more stringent standards with regard to prohibited conflicts of interest.

(g) The ~~Executive Director~~ General Counsel and Chief Compliance Officer may provide guidance to ~~the members of the Oversight Committee, Institute employees, and Scientific Research and Prevention Program Committee Members~~ individuals subject to this section on what interests would constitute a ~~e~~Conflict of interest or an appearance of a ~~e~~Conflict of interest.

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 eConflict of iInterest 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 ~~m~~Member shall:

(1) ~~Notify~~ Provide written notice of the Conflict of Interest to the Chief Executive Director/Officer and the presiding officer of the Oversight Committee ~~of the conflict of interest~~ (or the next ranking member of the Oversight Committee if the presiding officer has the ~~eConflict of iInterest~~);

(2) Disclose the eConflict of iInterest 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 a 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 eCommittee mMember has a eConflict of iInterest as described in this chapter with respect to an Grant aApplication that comes before the individual for review or other action, the member shall:

(1) ~~Notify the Scientific Research and Prevention Program committee chair and the CPRIT Chief Scientific Officer, Chief Prevention Officer, or the Chief Commercialization Officer as may be applicable,~~ Provide written notice of the eConflict of iInterest 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 aApplication, including access to information regarding the matter to be decided; ~~and,~~ unless a waiver has been granted pursuant to Section 702.15

(3) ~~Submit a signed certification post review statement at the conclusion of the peer review process that he/she did not participate in the discussion or review of any application for which he/she had a conflict of interest.~~

(c) ~~If a University Advisory Committee member or a member of an ad hoc committee has a conflict of interest as described in this chapter with respect to an application that comes before the individual for review, or other action, the member shall:~~ 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) ~~Notify the Executive Director of the conflict of interest; and~~ The individual subject to this provision is an employee of a Grant Applicant;

(2) ~~Recuse himself/herself from participation in the review, discussion, scoring, deliberation, and vote on the application, including access to information regarding the matter to be decided.~~ 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;

(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 ~~eEmployee other than the Executive Director~~ or independent contractor involved in the Grant Review Process has a ~~eConflict of iInterest~~ as described in this chapter with respect to an ~~Grant a~~Application that comes before the individual for review or other action, the ~~Institute eEmployee or independent contractor~~ shall:

(1) ~~Notify~~ Provide written notice to the ~~Chief Executive Director~~Officer of the ~~eConflict of iInterest~~; and

(2) Recuse himself/ or herself from participation in the review of the ~~Grant a~~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) ~~If the Executive Director has a conflict of interest as described in this chapter with respect to an application that comes before the Executive Director for review or other action, the employee shall.~~ 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) ~~Notify the presiding officer of the Oversight Committee of the conflict of interest; and~~ The supporting documentation retained by the Institute may be stored by the Institute's electronic Grant Management System.

(2) ~~Disclose the conflict of interest in an open meeting of the Oversight Committee; and~~ 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) ~~Recuse himself/herself from participation in the review of the application and be prevented from accessing information regarding the matter to be decided.~~ 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 eConflict of iInterest 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 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 gGrant rReview pProcess.

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

(a) ~~A person subject to this chapter~~ 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 Director/Officer of a the potential eConflict of iInterest. 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. A grant applicant seeking an investigation regarding whether an individual subject to this chapter failed to report a prohibited conflict of interest shall file a written request with the Institute's Executive Director. The request for investigation shall provide all facts regarding the alleged conflict of interest known to the grant applicant requesting the investigation. Upon notification, Tthe Chief Executive Director/Officer willmust notify the presiding officer of the Oversight Committee and the General Counsel who shall immediately determine the nature and extent of the unreported conflict, if any.

(b) ~~The request for investigation shall be submitted no later than 30 days after the date that the Executive Director presents the final funding recommendations for the affected grant cycle to the Oversight Committee.~~ 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 Director/Officer. The request for investigation 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), Tthe General Counsel shall:

(1) iInvestigate the matter; and shall

(2) pProvide an opinion to the Chief Executive Director/Officer and presiding officer of the Oversight Committee an opinion regarding whether a conflict of interest exists and any appropriate course of action. 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~~A statement of the facts giving rise to the ~~potential~~alleged conflict ~~and shall provide an opinion;~~
- (B) A determination of whether a ~~e~~Conflict of ~~i~~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. ~~If the conflict is held by the presiding officer, the General Counsel shall provide the opinion to the next ranking member of the Oversight Committee who has no conflict.~~
- (d) After receiving the General Counsel's opinion and consulting with the presiding officer (or, if appropriate, the next highest ranking Oversight Committee m~~Member)~~, the Chief Executive Director~~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 ~~e~~Conflict of ~~i~~Interest is held by the Chief Executive Director~~Officer~~, the presiding officer of Oversight Committee shall take actions regarding recusal.
- (e) A ~~final~~ determination regarding the existence of a ~~e~~Conflict of ~~i~~Interest, involving an individual subject to this chapter shall be made by the Chief Executive Director~~Officer~~, or by the presiding officer of the Oversight Committee if the alleged ~~e~~Conflict of ~~i~~Interest is held by the Chief Executive Director~~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 Executive Director's determination will~~must include actions to be taken, if any, to address the ~~e~~Conflict of ~~i~~Interest, impropriety, or self-dealing, including:
- (1) ~~r~~Reconsideration of the Grant a~~Application;~~ ~~or and~~
 - (2) ~~r~~Rereferral of the Grant a~~Application~~ to a different Scientific Research and Prevention Programs ~~e~~Committee for review. ~~The Executive Director's decision will be considered final unless three or more Oversight Committee members request that the issue be added to the agenda of the Oversight Committee.~~
- (f) The Chief Executive Officer or, if applicable, the presiding officer of the Oversight Committee must provide ~~W~~ritten notice of the final ~~decision~~determination ~~will be provided~~ to the person requesting ~~an~~the investigation, including a description of further actions to be taken, if any.
- (g) Unless specifically ~~determined by the Executive Director or the Oversight Committee~~stated in the final determination, the validity of an action taken with regard to a ~~g~~Grant ~~a~~Application is not affected by the fact that an individual that failed to report a ~~e~~Conflict of ~~i~~Interest participated in the action.

RULE §702.17 Exceptional Circumstances Requiring Participation

(a) ~~In exceptional cases, as determined by the CPRIT Executive Director a vote of the simple majority of the Oversight Committee present and voting, the need for participation of the an Oversight Committee mMember, Institute eEmployee, ad hoc committee member, University Advisory Committee member~~ Program Integration Committee Member, independent contractor, or Scientific Research and Prevention Programs eCommittee mMember in the Grant Review Process, the Grant Contract process, or the monitoring of the Grant Award outweighs the potential bias posed by a eConflict of iInterest held by the individual and a waiver will from recusal required by Section 702.13 may be granted by the Oversight Committee, unless otherwise prohibited by state or federal law.

(b1) ~~To issue a waiver, tThe Chief Executive Director must find that it would be difficult or impractical to carry out the review or action otherwise,~~ 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 and the integrity of the Grant rReview pProcess, the Grant Contract process, the monitoring of Grant Awards, or committee action would not be impaired by the memberindividual's participation; and The waiver may

(D) any proposed limits on certain activities to be taken by the individual, such as voting on the application.

(e2) ~~The interest in the application held by the Oversight Committee member, Institute employee, ad hoc committee member, University Advisory Committee member or Scientific Research and Prevention Programs committee member and the reason for issuing the waiver shall be disclosed in writing by the Executive Director and~~ The written proposal for a waiver must be submitted to the presiding officer of the 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 slate of Grant aApplications 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.

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RULE §702.19 Restriction on Communication Regarding Pending Grant Application

(a) Communication regarding the substance of a pending Grant aApplication between the Grant aApplicant and an Oversight Committee ~~mMember~~, ~~the Executive Director~~ a Program Integration Committee Member, or a Scientific Research and Prevention Programs ~~eCommittee mMember~~ is prohibited, ~~except for communication with an applicant for the purpose of resolving a question raised by the grant application.~~

(b) The prohibition on communication begins on the first day that Grant aApplications for the ~~particular funding award~~ Grant Mechanism are accepted by the Institute and extends until the Grant aApplicant receives notice regarding a final decision on the Grant aApplication.

(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 aApplicant from further consideration for a ~~CPRIT funding~~ Grant Award.

(d) This rule is not intended to prohibit open dialogue between the public and the Chief Executive Director ~~Officer~~, a Program Integration Committee Member, or a member of the Oversight Committee regarding the general status or nature of pending Grant aApplications.

(e) The Chief Executive Director ~~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 aApplicants 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.

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.

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CHAPTER 703 – GRANTS FOR CANCER RESEARCH AND PREVENTION

RULE §703.1 Purpose and Application

(a) Grant ~~a~~ Awards from the Institute shall fund:

(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~~Research into the causes of and cures for all types of cancer in humans;

(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~~Facilities for use in research into the causes and cures for cancer; and

(3) ~~Develop and implement the Texas Cancer Plan~~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) ~~This chapter applies to all grant proposals considered by the Institute for initial funding on or after September 1, 2009.~~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.

RULE §703.2 Definitions

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

~~(1) 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 an application to the Institute for a grant funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute. Unless otherwise indicated, this term includes the principal investigator.~~

~~(2) Authorized expenses—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, except as otherwise provided by this chapter.~~

~~(3) 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.~~

~~(4) Cancer prevention and control program—cancer prevention programs designed to mitigate the incidence of all types of cancer in humans.~~

~~(5) Cancer Prevention and Research Fund—the dedicated account in the general revenue fund consisting of patent, royalty, and license fees and other income received under a contract with a grant recipient, legislative appropriations, gifts, grants, and other donations, and earned interest.~~

~~(6) Cancer research—research into the causes, detection, treatments, and cures for all types of cancer in humans, including pre-clinical studies, animal studies, translational research, and clinical research to develop therapies, protocols, medical pharmaceuticals, medical devices or procedures for the detection, treatment, cure or substantial mitigation of all types of cancer in humans.~~

~~(7) Chief Commercialization Officer—the individual employed by the Institute to oversee the review and evaluation of commercial prospects of the grant applications for cancer research and prevention activities.~~

~~(8) Chief Prevention Officer—the individual employed by the Institute to oversee the scientific and program review and evaluation of the grant applications for cancer prevention activities.~~

~~(9) Chief Scientific Officer—the individual employed by the Institute to oversee the scientific review and evaluation of the grant applications for cancer research activities.~~

~~(10) Commercialization Review Council—the group of individuals designated to review the commercial prospects of cancer research and prevention program applications.~~

~~(11) Commercial prospects—the potential for development of commercial products or services or the development of infrastructure to support these efforts, including but not limited to pre-clinical, clinical, manufacturing, and scale up activities.~~

~~(12) Encumbered funds—funds that are designated by a recipient for a specific purpose.~~

~~(13) Grant—a funding mechanism, including a direct company investment, awarded by the Institute providing money to the recipient to carry out the research or prevention program objectives.~~

~~(14) Indirect costs—the expenses of doing business that are not readily identified with a particular grant, contract, project, function, or activity, but are necessary for the general operation of the organization or the performance of the organization's activities.~~

~~(15) Institute—the Cancer Prevention and Research Institute of Texas.~~

~~(16) 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 awarded by the Institute:~~

~~(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 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.~~

~~(17) 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.~~

~~(18) 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.~~

~~(19) Prevention Review Council—the group of individuals designated as chairs of the prevention program committees created to review cancer prevention program applications.~~

~~(20) Project Results—any and all technology and associated intellectual property Rights.~~

~~(21) Recipient—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, or any combination of the aforementioned that is awarded a grant funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute.~~

~~(22) Scientific research and prevention program committee—one or more groups of experts in the field of cancer research, prevention or commercialization appointed by the Executive Director and approved by the Oversight Committee for the purpose of reviewing grant applications and making recommendations to the Executive Director regarding the award of cancer research and prevention grants.~~

~~(23) Scientific Review Council—the group of individuals designated as chairs of the scientific research and prevention program committees created to review cancer research applications.~~

~~(24) Technology—any and all of the following resulting or arising from work funded by the grant:~~

~~(A) inventions;~~

~~(B) proprietary and confidential 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 limited to therapeutics, drugs, drug delivery systems, drug formulations, devices, diagnostics, biomarkers, reagents and research tools.~~

RULE §703.3 Grant Applications

(a) The Institute ~~will~~shall accept ~~g~~Grant aApplications for ~~e~~Cancer rResearch and ~~Cancer~~Cancer ~~p~~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 ~~r~~Requests for aApplications that ~~will be publicly~~ issued by the Institute ~~at least annually~~. The ~~requests for applications will be announced in the *Texas Register* and available through the Institute's public website.~~

(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 ~~r~~Requests for aApplications from time to time. Notice of modifications will be announced ~~in the *Texas Register* and available through the Institute's public~~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 eCancer rResearch-grant applications and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:

(1) ~~Short-term, high-impact programs~~Basic research;

(2) ~~Individual investigator awards~~Translational research, including proof of concept, preclinical, and Product Development activities;

(3) ~~Multiple investigator awards, including collaborative projects, centers, core facilities, shared instrumentation, and infrastructure~~Clinical research;

(4) ~~Recruitment to the state of new, emerging, and established investigators~~Population based research;

(5) Training;

~~(6) Translational research, including proof of concept, preclinical, and clinical trials~~
Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;

~~(7) Commercialization investment grant awards, including cancer-related infrastructure and services to support development of commercializable products~~
Infrastructure, including centers, core facilities, and shared instrumentation; and

~~(8) Implementation of the Texas Cancer Plan-;~~ and

~~(9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.~~

~~(d) Requests for cancer prevention grant applications issued by the Institute may address, but are not limited to, the following areas:~~

~~(1) Innovation awards;~~

~~(2) Education, outreach and training;~~

~~(3) Evidence based prevention programs and services;~~

~~(4) Collaborative projects;~~

~~(5) Infrastructure/capacity building grants; and~~

~~(6) Implementation of the *Texas Cancer Plan*.~~

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 a~~Applications for Cancer Research projects shall seek information from Grant a~~Applicants regarding whether the proposed project has commercial-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 r~~Request for a~~Applications may serve as grounds for disqualification from further consideration of the g~~Grant a~~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) The Institute will undertake reasonable efforts to protect information submitted to the agency by third parties from unauthorized disclosure, consistent with the need for objective review of the application and the requirements of state law, including the establishment of procedures to be followed by Oversight Committee members, Institute employees, and scientific research and~~

~~prevention program committee members.~~ 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 following information is public information and may be disclosed under Chapter 552, Government Code:~~

~~(1) The applicant's name and address;~~

~~(2) The amount of funding applied for;~~

~~(3) The type of cancer to be addressed under the proposal; and~~

~~(4) Any other information designated by the Institute with the consent of the grant applicant.~~

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 Relatives of the following individuals:

(A) the Principal Investigator, Program Director, or Company Representative;

(B) a Senior Member or Key Personnel listed on the Grant Application;

(C) an officer or director of the Grant Applicant.

(3) Notwithstanding the foregoing, one or more donations exceeding \$500 by an employee or Relative of 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) ~~To assist the Institute in identifying and protecting the confidentiality of information submitted to the agency, the applicant shall identify all confidential and proprietary information on the application or other documents provided to the Institute. However, the applicant's failure to identify information as confidential and proprietary does not constitute a waiver of the designation for purposes of Chapter 552 of the Government Code, or other applicable federal or state law or regulation.~~ 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.

(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.

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RULE §703.4 Grants Management System

The Institute may engage third-party grants management services. ~~to assist in some or all aspects of the grant application process, as determined by an agreement with the Institute.~~ 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.

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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 Director/Officer, with approval of a by simple majority of the Oversight Committee, will is responsible for appointing experts in the fields of Cancer Research, Prevention or commercialization, life science Product Development, and patient advocacy to serve as members of sScientific rResearch and pPrevention pPrograms eCommittee members for terms designated by the Chief Executive Director/Officer.

(b) An individual appointed to serve as a member of a scientific research and prevention programs committee may be a resident of another state. 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 rResearch and pPrevention pPrograms eCommittee mMembers is are responsible for conducting Peer rReviewing of the scientific research and prevention programs gGrant aApplications assigned to the individual member's committeePeer Review Panel.

(d) A Scientific rResearch and pPrevention pPrograms eCommittee mMembers 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 sScientific rResearch and pPrevention pPrograms eCommittee 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 sScientific rResearch and pPrevention pPrograms eCommittee 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 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:

(A) Represent an organization or other community of people

(B) Demonstrate prior community involvement or other work on behalf of cancer patients

(C) Possess good communication and writing skills, including the ability to analyze information and make judgments with consideration of patient impact

- (D) Express interest in and fundamental knowledge of the medical research process, including basic and translational scientific research and prevention concepts
- (E) Reside outside of the state of Texas
- (F) 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:

- (A) 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;
- (B) Current resume or curriculum vitae
- (C) 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.

RULE §703.6 Grants Review Process

(a) ~~The Institute will use the grants review process to identify the most creative, and innovative projects representing the best science and, if appropriate, commercial prospects. To the extent possible, priority for funding for cancer research and cancer prevention applications will be given to proposals that:~~

- ~~(1) Could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;~~
- ~~(2) Strengthen and enhance fundamental science in cancer research;~~
- ~~(3) Ensure a comprehensive coordinated approach to cancer research and prevention;~~
- ~~(4) Are interdisciplinary or interinstitutional;~~
- ~~(5) Address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention, or cures for cancer;~~
- ~~(6) Are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;~~
- ~~(7) Use money from the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute to obtain additional cancer research and prevention funding from other sources;~~
- ~~(8) 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;~~
- ~~(9) Have a demonstrable economic development benefit to this state;~~
- ~~(10) Enhance research superiority at institutions of higher education or in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources; and~~
- ~~(11) 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.~~

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) Based upon the number of applications received and the resources available for the scientific research and prevention program committees, the Institute reserves the option to conduct an initial evaluation of the grant applications by one or more scientific research and prevention program committees. An application determined to be incomplete or otherwise noncompetitive during the initial evaluation will not be considered for further review. 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) Grant applications that are not eliminated in the initial peer review evaluation will undergo a rigorous peer review process supervised by the Institute in coordination with the Scientific Review Council, the Prevention Review Council and the Commercialization Review Council, as may be appropriate to the subject matter of the applications. 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 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) Based upon the results of the peer review process and in consideration of the standards described in subsection (a) of this section, as applicable, each scientific research and prevention program committee shall submit to the Scientific Review Council, Prevention Review Council or the Commercialization Review Council the grant applications that the committee recommends~~

~~should be considered for funding awards.~~ The Review Council's prioritization process for Grant Award recommendations encompasses the following actions, which will be consistently applied:

(1) The Review Council prioritizes the Grant Application recommendations across all the Peer Review Panels by assigning a Numerical Ranking Score to each Grant Application that was discussed by a Peer Review Panel. The Numerical Ranking Score is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

(2) The Review Council's recommendations are submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. The recommendations, listed in order by Numerical Ranking Score shall include:

(A) An explanation describing how the Grant Application meets the Review Council's standards for Grant Award funding;

(B) The final Overall Evaluation Score assigned to the Grant Application by the Peer Review Panel, including an explanation for ranking one or more Grant Applications ahead of another Grant Application with a more favorable final Overall Evaluation Score; and

(C) The specified amount of the Grant Award funding for each Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline.

~~(e) Grant funding recommendations made by individual research and prevention program committees will be evaluated by the Scientific Review Council, the Prevention Review Council and the Commercialization Review Council as may be appropriate to the subject area of the applications.~~ 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.

(2) The Institute shall assign all Grant Applications submitted for recruitment of researchers and clinicians to the Scientific Review Council.

(A) The Scientific Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the proposed recruitment.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one recruitment Grant Application is reviewed by the Scientific Review Council during the Grant Review Cycle, then the Scientific Review Council shall assign a Numerical Ranking Score to each Grant Application to convey its prioritization ranking.

(D) If the Scientific Review Council recommends a change to the Grant Award funds requested by the Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Scientific Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this Section.

(3) The Institute may assign continuation Grant Applications to the appropriate Review Council.

(A) The Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an

individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the progress and continued funding.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one continuation Grant Application is reviewed by the Review Council during the Grant Review Cycle, then the Review Council shall assign a Numerical Ranking Score to each continuation Grant Application to convey its prioritization ranking.

(D) If the Review Council recommends a change to the Grant Award funds or to the scope of work or timeline requested by the continuation Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this Section.

(4) The Institute's Peer Review process described in subsections (c) and (d) of this Section may include the following additional process steps for Product Development of Cancer Research Grant Applications:

(A) A Grant Applicant may be invited to deliver an in-person presentation to the Peer Review Panel. The Product Development Review Council chairperson is responsible for deciding which Grant Applicants will make in-person presentations. The decision is based upon the initial Overall Evaluation Scores of the primary reviewers following a discussion with Peer Review Panel members, as well as explicit criteria published in the Request for Applications.

(i) Peer Review Panel members may submit questions to be addressed by the Grant Applicant at the in-person presentation.

(ii) A Grant Application that is not presented in-person will not be considered further. The average of the primary reviewers' initial Overall Evaluation Scores will be the final Overall Evaluation Score for the Grant Application.

(iii) Following the in-person presentation, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(B) A Grant Application may undergo business operations and management due diligence review and an intellectual property review conducted by third parties. The Peer Review Panel decides which Grant Applications will undergo business operations and management due diligence and intellectual property review. The decision is based upon the Grant Application's final Overall Evaluation Score, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications. A Grant Application that is not recommended for due diligence and intellectual property review will not be considered further.

(C) After receipt of the business operations and management due diligence and intellectual property reviews for a Grant Application, the Product Development Review Council and the Primary Reviewers meet to determine whether to recommend the Grant Application for a Grant Award based upon the information set forth in the due diligence and intellectual property reviews. The Product Development Review Council may recommend changes to the Grant Award budget and goals and objectives or timeline.

(D) The Product Development Review Council assigns a Numerical Ranking Score to each Grant Application recommended for a Grant Award.

~~(f) Pursuant to a schedule developed by the Executive Director, the Scientific Review Council, the Prevention Review Council, and the Commercialization Review Council will submit a prioritized list of grant funding recommendations to the Executive Director. The list of grant funding recommendations will include a statement of how the grant applications recommended for funding meet one or more standards of subsection (a) of this section. 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 decision to recommend a grant application for funding is entirely within the purview of the scientific research and prevention programs committee(s) evaluating the grant application. 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) A grant applicant shall not contact a scientific research and prevention programs committee member regarding the status or substance of any grant application. 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 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) Prior to receiving access to confidential and proprietary information submitted by a grant applicant, all individuals, including scientific research and prevention programs committee members, CPRIT employees, Oversight Committee members, and grants management system employees shall certify that confidential and proprietary information will not be disclosed or used in any way other than for the purposes of evaluating and awarding grants. The certification may be accomplished by signing a non-disclosure agreement. The Institute will retain the signed certifications on file. 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**

~~The Executive Director shall submit to the Oversight Committee a prioritized list of applications to be awarded cancer research grants and cancer prevention program grants substantially based upon the lists submitted by the Scientific Review Council, the Prevention Review Council and the Commercialization Review Council.~~(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;

(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

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.

(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.

RULE §703.8 ~~Overriding the Executive Director's~~ Oversight Committee Consideration of the Program Integration Committee's Funding Recommendation

The Oversight Committee ~~shall consider~~ must vote to approve the Executive Director's funding each Grant Award recommendation submitted by the Program Integration Committee. as a comprehensive slate

(1) The Executive Director's slate of funding recommendations is approved unless two-thirds of the members of the Oversight Committee vote to disregard the slate of recommendations. 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) If the Oversight Committee votes to disregard the slate of funding recommendations, the Executive Director may re-submit recommendations for consideration by the Oversight Committee pursuant to a process and time table established by the Oversight Committee. The Oversight Committee may request the appropriate review council to conduct further investigation into issues specified by the Oversight Committee. 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.

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RULE §703.9 Limitation on Review of Grant Process

(a) The decision to recommend a Grant aApplication for funding is based upon the sufficiency, ~~scientific merit~~, and, if applicable, ~~commercial~~ Product Development prospects of the Grant aApplication, as determined ~~through the application's~~ by the Institute's ~~p~~Peer r~~Review and~~ Program Review processes as described in the Chapter~~conducted by the scientific research and prevention program committee(s).~~

(b) By submitting a Grant Application, the Grant Applicant understands and accepts that ~~G~~rounds for reconsideration of the Institute's final decision regarding a Grant aApplication are limited to an undisclosed ~~e~~Conflict of ~~i~~Interest ~~concerns~~ 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 aApplicant shall file a request with the Chief Executive Director ~~Officer~~ for a review of the ~~g~~Grant Review p~~Process~~ based on the undisclosed ~~e~~Conflict of ~~i~~Interest pursuant to the process and timeline set forth in Chapter 702 of this title.

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 ~~g~~Grant ~~¶~~Recipient.

(b) The Oversight Committee may delegate ~~Grant e~~Contract negotiation duties to the Chief Executive Director~~Officer~~ and the General Counsel for the Institute. The Chief Executive Director~~Officer~~ may enter into a written contract with the ~~g~~Grant ~~¶~~Recipient on behalf of the Oversight Committee.

(c) The ~~Grant e~~Contract ~~between the Institute and the grant recipient may~~ shall include the following provisions:

(1) If any portion of the ~~Grant e~~Contract has been approved by the Oversight Committee to be used to build a capital improvement, the ~~Grant e~~Contract shall specify that:

(A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the ~~g~~Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the ~~g~~Grant ~~¶~~Recipient agrees to repay to the state the ~~g~~Grant Award ~~money~~ 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 ~~i~~Intellectual ~~p~~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 ~~g~~Grant Award funds or related to the Cancer ¶Research or Cancer Prevention project~~program~~ that is the subject of the gGrant Contract ~~funds~~, including an acknowledgement of Institute funding and copyright ownership, if applicable;

(4) Repayment terms, including interest rates, to be enforced if the ~~g~~Grant ~~¶~~Recipient has not used ~~g~~Grant ~~money~~ Award funds for the purposes for which the ~~g~~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~~or prevention program~~, 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~~or prevention program~~ is conducted with full consideration for the ethical and medical implications of the ~~research~~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 sStandards established by the Oversight Committee in Chapter 701 pursuant to §102.258 and §102.259, Health and Safety Code, to ensure that gGrant rRecipients, to the extent reasonably possible, in a demonstrate good faith effort to achieve a goal of more than 50 percent of such purchases, purchase goods and services for the Grant Award project funded by the Institute from suppliers in this state and purchase goods and services from historically underutilized businesses as defined by Chapter 2161, Government Code, and any other state law;

(8) An agreement by the gGrant rRecipient to submit to regular inspection reviews of the gGrant 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 gGrant rRecipient to present-submit Grant Pprogress rReports to the Executive Director Institute on a schedule specified by the gGrant eContract that include information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Cancer Prevention and Research Institute funding;

(10) An agreement that, to the extent possible, the gGrant rRecipient will evaluate whether any new or expanded preclinical testing, clinical trials, commercializationProduct 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 gGrant rRecipient 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 gGrant rRecipient is under a continuing obligation to notify the Executive Director Institute of any adverse conditions that materially impact milestones and objectives included in the Grant eContract;

(13) An agreement that the design, conduct, and reporting of the Cancer rResearch or pPrevention programproject will not be biased by conflicting financial interest of the applicant-Grant Recipient or any individuals associated with the gGrant Award. This duty is fulfilled by certifying that an appropriate written, enforced eConflict of iInterest policy governs the gGrant rRecipient.

(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;

(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.

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Requirement to Demonstrate Available Funds for Cancer Research Grants

(a) ~~At the time of award, a cancer research grant recipient must certify that encumbered funds equal to one-half of the amount of the total grant are available and not yet expended for research that is the subject of the grant.~~ 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 gGrant aAwards may provide certification at the institutional level.

(b) For purposes of the certification required by subsection (a) of this section, a ~~Grant Recipient may use the following categories to classify encumbered funds that are dedicated to cancer research:~~ 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 102.2003(c), Texas Health and Safety Code, subject to the following requirements:

(1) ~~Cancer biology and genetics, including oncogenesis and collection and characterization of tumors (genomics, proteomics, and other "omics");~~ 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) ~~Cancer immunology, including vaccines;~~ 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.

(3) ~~Cancer imaging and diagnostics;~~

(4) ~~Cancer epidemiology and outcomes research; and~~

(5) ~~Cancer treatment, including drug discovery and development and clinical trials.~~

(c) For purposes of the certification required by subsection (a) of this section, ~~e~~Encumbered ~~f~~Funds may include ~~but are not necessarily limited to~~:

(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 (NCI) or other similar programs);~~

(2) State of Texas funds;

(3) ~~Other States'~~ funds of other states;

(4) Non-governmental funds, ~~(including private funds, foundation grants, gifts and donations);~~ and

(5) Unrecovered Indirect Costs not to exceed ~~10~~ ten percent (10%) of the ~~g~~Grant ~~a~~Award amount, subject to the following conditions:

(A) These costs are not otherwise charged against the ~~g~~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 ~~Institution or Grant~~ ~~f~~Recipient must have a documented federal indirect cost rate or an indirect cost rate certified by an independent accounting firm; ~~and~~

(C) The allowance for unrecovered ~~i~~Indirect ~~e~~Costs must be specifically approved by the Chief Executive ~~Director~~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 ~~e~~Encumbered ~~f~~Funds:

(1) In-kind costs;

(2) Volunteer services furnished to the ~~g~~Grant ~~f~~Recipient;

(3) Noncash contributions;

(4) Income earned by the Grant Recipient that is not available at the time of ~~Grant~~ ~~a~~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) For awards to investigators representing more than one institution or organization, the certification required by subsection (a) of this section may be made on a grant award level by one or more of the participating institutions or organizations. 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) The recipient of a multiyear grant award may demonstrate available funds on a year-by-year basis. In no event shall Grant Award funds for a Project Year be advanced or reimbursed, as may be appropriate for the Grant Award and specified in the Grant Contract, until the certification required by subsection (a) of this section is filed and approved by the Institute.

(g) No later than 60 days from the anniversary of the Effective Date of the Grant Contract, the Grant Recipient shall file a form with the Institute reporting the amount of Matching Funds spent for the preceding Project Year.

(h) If the Grant Recipient failed to expend Matching Funds equal to one-half of the actual amount of Grant Award funds distributed to the Grant Recipient for the same period, the Institute shall:

(1) Carry forward and add to the Matching Fund requirement for the next Project Year the dollar amount equal to the deficiency between the actual amount of Grant Award funds distributed and the actual Matching Funds expended, so long as the deficiency is equal to or less than twenty percent (20%) of the total Matching Funds required for the same period and the Grant Recipient has not previously had a Matching Funds deficiency for the project;

(2) Suspend distributing Grant Award funds for the project to the Grant Recipient if the deficiency between the actual amount of Grant Funds distributed and the Matching Funds expended is greater than twenty percent (20 %) but less than fifty percent (50%) of the total Matching Funds required for the period.

(A) The Grant Recipient will have no less than eight months from the anniversary of the Grant Contract's effective date to demonstrate that it has expended Encumbered Funds sufficient to fulfill the Matching Funds deficiency for the project.

(B) If the Grant Recipient fails to fulfill the Matching Funds deficiency within the specified period, then the Grant Contract shall be considered in default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract;

(3) Declare the Grant Contract in default if the deficiency between the actual amount of Grant Award funds distributed and the Matching Funds expended is greater than fifty percent

(50%) of the total Matching Funds required for the period. The Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract; or

(4) Take appropriate action, including withholding reimbursement, requiring repayment of the deficiency, or terminating the Grant Contract if a deficiency exists between the actual amount of Grant Award funds distributed and the Matching Funds expended and it is the last year of the Grant Contract;

(i) Nothing herein shall preclude the Institute from taking action other than described in subsection (h) 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.

(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.

(a) ~~A gGrant rRecipient may use the money~~ Grant Award funds only for eCancer rResearch and Cancer pPrevention programs projects consistent with the purpose of the Act, and in accordance with the Grant eContract. 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) ~~Money Grant Award funds awarded from the Cancer Prevention and Research Fund or from the proceeds of bonds issued on behalf of the Institute must be used for aAuthorized eExpenses.~~

(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.

(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 ~~a~~Authorized ~~e~~Expenses for a specific program may be provided by the terms of the Grant ~~e~~Contract ~~between the gGrant rRecipient and the Institute~~ 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 R~~ecipient of ~~Grant Award~~ funds for a ~~a~~eCancer ~~r~~Research project may not spend more than five percent (5%) of the ~~money awarded~~ Grant Award funds for ~~i~~ndirect ~~e~~Costs.

(d) ~~The Institute may n~~Not award more than five percent (5%) of the total Grant Award funds for each fiscal year ~~money awarded from the Cancer Prevention and Research Fund or from the proceeds of bonds issued on behalf of the Institute may~~ to be used for facility purchase, construction, remodel, or renovation purposes during any year. Any Grant Award funds awarded 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 Director~~Officer to be spent on facility purchase, construction, remodel, or renovation purposes~~ with notification to the Oversight Committee; ~~and~~

(2) ~~Money~~ Grant Award funds spent on facility purchase, construction, remodel, or renovation projects must benefit ~~e~~Cancer ~~p~~revention and ~~r~~esearch;

(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 10 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 may to be used for eCancer pPrevention and eControl 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.

~~(f) Grant funds may not be used for purposes other than those purposes for which the grant was awarded.~~

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~~The Institute shall have the right to request in writing and receive from the recipient in a reasonable timeframe any and all documents and other information related to the grant at any time during or for four years after the term of the grant expires. This right includes, but is not limited to, the right to review all financial books and records of the recipient related to the grant and to perform an audit or other accounting procedures of all expenses related directly or indirectly to the grant. To the extent that confidential information must be disclosed during the course of the audit, the Institute and its employees will execute a non-disclosure agreement with the grant recipient.~~

(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 four (4) year period following the termination of the Grant Contract.

(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.

(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.

(a) ~~The Executive Director may terminate a grant prior to the expiration of the contract between the Institute and the grant recipient on the grounds that~~ The termination date of a Grant Contract shall be the date stated in the Grant Contract, except:

(1) ~~The recipient has failed to meet contractual obligations; or~~ 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 Ffunds allocated to the gGrant Award are reduced, depleted, or unavailable during the award period, and CPRIT-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, The Executive Director then the Chief Executive Officer shall notify the gGrant rRecipient 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 notice shall state the reasons for termination, the procedure, and the time period for seeking reconsideration of the decision to terminate.~~ 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) Nothing in this section prohibits termination of the grant by mutual agreement of the parties prior to expiration of the contract. Mutual agreement is not required for termination as provided by subsection (a) of this section. 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 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.

- (a) ~~The Oversight Committee may approve gGrant Award funds for a multiyear project subject to the requirement that all funds for the multiyear project are awarded in the state fiscal year that the project is approved by the Oversight Committee. 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) ~~Only those funds to be expended during the fiscal year will be distributed to the multiyear grant recipient. 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) ~~Funds approved by the Oversight Committee for multiyear projects not expended during the fiscal year shall be maintained in an escrow account until such time as the funds are distributed for subsequent years of the project. 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 gGrant Award for a multiyear project may fulfill the certification requirements set forth in §703.11 of this chapter (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants) on a year-by-year basis at the time of the annual progress review or upon a schedule established by the contract between the Institute and the recipient 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.~~

(a) To the extent that there is a conflict between this chapter and the ~~award~~ Grant eContract between the Institute and the ~~gGrant~~ Recipient, the Grant eContract terms will control.

(b) The ~~gGrant~~ Recipient may retain, assign or transfer all or a portion of any of the ~~iIntellectual~~ pProperty ~~Rights~~ relating to the project results. Any such assignment or transfer to a third party is subject to the following requirements:

(1) The ~~gGrant~~ Recipient shall notify the Institute of the proposed transfer or assignment;

(2) The ~~gGrant~~ 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 eContract 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 ~~gGrant~~ Recipient related to the proposed transfer or assignment of rights, which the ~~gGrant~~ 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, ~~gGrant~~ Award proceeds shall not be used to pay the costs or expenses associated with the efforts to protect the ~~iIntellectual~~ pProperty ~~Rights~~ or to pay the costs or expenses associated with commercialization activities.

(d) As a condition of accepting ~~gGrant~~ Award funding from the Institute, the ~~gGrant~~ Recipient agrees to the following required commitments as defined in the Grant eContract 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 ~~pProject~~ RResults, as set forth in the Grant eContract.

(3) To notify the Institute in writing prior to declining to pursue, abandoning, waiving or disclaiming some or all ~~iIntellectual~~ pProperty ~~Rights~~ related to the ~~pProject~~ RResults. 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 ~~iIntellectual~~ pProperty ~~Rights~~ to the fullest extent permitted by law.

(4) To keep the Institute promptly and reasonably informed regarding the activities undertaken by the ~~g~~Grant ~~r~~Recipient to protect and/or commercialize the ~~p~~Project ~~r~~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 ~~l~~License ~~a~~Agreements.

(5) To allow access to the books and records of the ~~g~~Grant ~~r~~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 ~~g~~Grant ~~r~~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 ~~p~~Project ~~r~~Results in a manner and form to be prescribed by the Institute.

- (a) The Institute shall share in the financial benefit received by the ~~g~~Grant ~~r~~Recipient resulting from the patents, royalties, assignments, sales, conveyances, licenses and/or other benefits associated with the ~~p~~Project ~~r~~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 ~~g~~Grant ~~e~~Contract.
- (c) Unless otherwise provided by the Grant eContract between the Institute and the ~~g~~Grant ~~r~~Recipient, payments to the Institute required by this section shall be made no less than annually pursuant to a schedule set forth in the ~~g~~Grant ~~e~~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.

- (a) The gGrant rRecipient bears the responsibility for licensing activities including identification of potential licensees, negotiation of lLicense aAgreements, documentation of the progress and development under a lLicense aAgreement, monitoring the performance of the licensee, and taking commercially reasonable actions to enforce the terms of the lLicense aAgreements.
- (b) Each lLicense aAgreement for pProject rResults entered into by the gGrant rRecipient shall include an acknowledgement by the licensee that such lLicense aAgreement is subject to the Institute's licenses, interests and other rights, if any.
- (c) Nothing herein prohibits the gGrant rRecipient from negotiating an exclusive lLicense aAgreement for pProject rResults if exclusivity is reasonably believed by the gGrant rRecipient to provide an economic incentive necessary for achieving commercial development and availability of the pProject rResults. The gGrant rRecipient 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 gGrant rRecipient negotiating exclusive or non-exclusive lLicense aAgreements shall seek to retain the right to exploit the use of its pProject rResults and utilize the same for its non-commercial purposes.

(a) The Institute shall have the option, but not the obligation, to pursue protection of the applicable ~~i~~Intellectual ~~p~~Property ~~r~~Rights and/or to commercialize or otherwise bring to practical application the applicable ~~p~~Project ~~r~~Results either directly or through one or more licensees, in the event of the following:

(1) Upon receipt of ~~g~~Grant ~~r~~Recipient's notice of its election to abandon, waive or disclaim any ~~i~~Intellectual ~~p~~Property ~~r~~Rights or to cease its efforts to commercialize or otherwise bring to practical application any particular ~~p~~Project ~~r~~Results; or

(2) Grant ~~r~~Recipient 's failure to materially comply with its obligations to protect the ~~i~~Intellectual ~~p~~Property ~~r~~Rights or to use diligent and commercially reasonable efforts to commercialize or otherwise bring to practical application the ~~p~~Project ~~r~~Results in accordance with the ~~g~~Grant ~~r~~Recipient's commercial development plan(s), and ~~g~~Grant ~~r~~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 ~~g~~Grant ~~r~~Recipient in writing of such election. Upon receipt of notification, the ~~g~~Grant ~~r~~Recipient shall:

(1) Fully cooperate with the Institute's efforts to protect, commercialize or otherwise bring to practical application the applicable ~~p~~Project ~~r~~Results at the Institute's cost, including but not limited to the transfer to the Institute or the Institute's designee of the ~~g~~Grant ~~r~~Recipient 's rights, title and interest in and to the applicable ~~p~~Project ~~r~~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 ~~p~~Project ~~r~~Results.

(c) If the Institute exercises its option under this section, the ~~g~~Grant ~~r~~Recipient shall have no further claim to or interest in ~~or~~ to the applicable ~~p~~Project ~~r~~Results and shall not be entitled to any share of the revenue or other compensation with respect to such ~~p~~Project ~~r~~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.

**RULE §703.20 Certification of Tobacco-Free Policy for ~~Entities Receiving CPRIT~~
FundsGrant Recipients**

~~(a) The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.~~

~~(1) CPRIT-funded entity—An institution, organization or company that receives grant funding from CPRIT equal to or more than \$25,000 during the applicable fiscal year. All references to the CPRIT-funded entity include the entity's faculty, staff, employees, and students.~~

~~(2) 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.~~

~~(b) To be eligible to receive CPRIT funding a Grant Award, a CPRIT-funded entity Grant Recipient shall certify that the entity has adopted and enforces a Tobacco-free workplace policy.~~

~~(e1) A Tobacco-free workplace policy will comply with the certification required by this section if the policy is adopted by the CPRIT-funded entity's Grant Recipient's board of directors, governing body, or similar; and, at a minimum, includes provisions:~~

~~(1A) Prohibiting the use of all Tobacco products by all employees and visitors to the property owned, operated, leased, occupied, or controlled by the CPRIT-funded entityGrant Recipient. For purposes of the Tobacco-free workplace policy, the CPRIT-funded entity Grant Recipient may designate the property to which the policy applies, so long as the workplace policy encompasses all buildings and structures where the CPRIT 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 CPRIT-funded entityGrant Recipient owns, leases or controls the building, sidewalks, parking lots and parking structures.~~

~~(2B) Providing for and/or referring to Tobacco use cessation services for employees.~~

~~(d2) Exceptions—Upon request by a CPRIT-funded entityGrant Recipient, the CPRIT Chief eExecutive director Officer may grant authorize a waiver of compliance with this section. If grantedapproved, the waiver is effective only for the State fiscal year during which it was grantedapproved.~~

~~(eb) Provisions in this section apply to all grant proposals submitted to the Institute in response to a request for proposals issued by the Institute on or after March 1, 2012. All other CPRIT-funded entities must certify compliance with this rule by August 31, 2012 or the first anniversary of the CPRIT-funded entity's grant award, whichever is later.~~

(3) The certification and waiver requests addressed herein shall be submitted by the Grant Recipient via the Institute's electronic Grant Management System.

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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;

- (ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;
- (iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;
- (iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;
- (v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;
- (vi) A Historically Underutilized Businesses report;
- (vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;
- (viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;
- (ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;
- (x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report;
- (xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and
- (xii) A single audit determination form.

(C) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

(D) The Grant Progress Report will be evaluated by a grant manager pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific

Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff.

(E) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in 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.

(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.

~~RULE §704.1 Texans Conquer Cancer Advisory Committee~~

~~(a) Advisory Committee.~~

- ~~(1) The advisory committee shall be appointed under and governed by this section.~~
- ~~(2) The name of the advisory committee is Texans Conquer Cancer Advisory Committee (TCCAC).~~
- ~~(3) The council is authorized by Health and Safety Code, §102.018 to appoint a seven-member advisory committee.~~

~~(b) Purpose. The purpose of the TCCAC is to assist and advise the council regarding the Texans Conquer Cancer program.~~

~~(c) Tasks. The TCCAC shall:~~

- ~~(1) assist the council in establishing guidelines for spending money credited to the Texas Conquer Cancer Account (TCCA); and~~
- ~~(2) review and make recommendations to the council on applications submitted to the council for grants funded with money credited to the TCCA.~~

~~(d) Terms of TCCAC members.~~

- ~~(1) The terms of office for each member shall be four years, with the terms of three or four members expiring on January 31st of each odd-numbered year. The term of office of Group A, made up of three of the original members expired on January 31, 2007. The term of office of the Group B, consisting of the remaining four original members, will expire on January 31, 2009. Thereafter, the terms of the Group members and the terms of Group B members will expire on alternate odd-numbered years, beginning with Group A in 2011, resulting in a four-year term for each group.~~
- ~~(2) Members serve without compensation and are not entitled to reimbursement for expenses.~~
- ~~(3) If a vacancy occurs, the council shall appoint a person to serve the unexpired portion of that term.~~
- ~~(4) The TCCAC shall select from among its members a presiding officer every odd-numbered year at the first committee meeting held during that calendar year.~~

~~(e) Meetings.~~

- ~~(1) The TCCAC shall meet at least 30 days prior to a council board meeting or when directed by the council or Executive Director to conduct TCCAC business.~~

~~(2) Members shall attend meetings as scheduled. A TCCAC member who is unable to attend a meeting shall inform the presiding officer prior to the date of the meeting. Meetings may be held via teleconference.~~

~~(3) Meeting arrangements shall be made by the presiding officer in consultation with council staff.~~

~~(4) The TCCAC is not a governmental body as defined in the Open Meetings Act, therefore meetings need not comply with the requirements of the Open Meetings Act.~~

~~(5) Four members of the TCCAC shall constitute a quorum.~~

~~(6) The TCCAC shall report to council staff and a committee of the council regarding its reviews of applications submitted. The report should include a description of the review process and recommendations for awards. The recommendation shall be determined by a simple majority vote of the TCCAC.~~

~~RULE §704.3 Texans Conquer Cancer Account~~

~~(a) The TCCA is an account in the Dedicated General Revenue Fund as authorized by the Health and Safety Code §102.017.~~

~~(b) Money, gifts, grants and donations may be deposited in the TCCA from any source for the benefit of the TCCA.~~

~~(c) The council may spend these funds only~~

~~(1) to make grants to non-profit organizations that provide support services for cancer patients and their families, and~~

~~(2) to defray the cost of administering the TCCA.~~

~~RULE §704.5 Guidelines for Expenditures~~

~~(a) The council, with advice from the TCCAC, shall establish guidelines for awarding the funds in the TCCA. The guidelines shall be referred to as the "Guidelines for Awarding Support Services Funds."~~

~~(b) As described in §704.7 of this chapter, the "Guidelines for Awarding Support Services Funds" are to assist applicants by clarifying guidelines and procedures related to the Texans Conquer Cancer awards. The document is published by and available from the Texas Cancer Council, P.O. Box 12097, Austin, TX 78711 and when funds are available on the agency website at www.tcc.state.tx.us.~~

~~RULE §704.7 Guidelines for Awarding Support Services Funds~~

~~(a) This section governs the submission and review of grant applications, and the award, amendment, and termination of grants.~~

~~(b) The intent of these grants is to provide support services to cancer patients and their families.~~

~~(c) Funds from the TCCA will be used to award grants to non-profit organizations that provide a range of support services needed by cancer patients and their families.~~

~~(d) When the amount of funds in the TCCA becomes substantial, a notification of available funds will be published in the *Texas Register*, and the council will issue a Request For Applications (RFA).~~

~~(1) Funds may be used to provide the following allowable services, which include but are not limited to:~~

~~(A) Transportation~~

~~(B) Childcare~~

~~(C) Medical equipment~~

~~(D) Consumable supplies for cancer care~~

~~(E) Lodging for patients and/or family during active treatment~~

~~(F) Medications and equipment required for symptom control~~

~~(G) Rent assistance during active treatment~~

~~(H) Food assistance during active treatment~~

~~(2) Because other resources may cover these costs, funds shall not be used to provide the following unallowable services, which include but are not limited to:~~

~~(A) Expenses associated with cancer treatment such as:~~

~~(i) Hospitalization~~

~~(ii) Surgery~~

~~(iii) Outpatient care, including laboratory tests and physician visits~~

~~(iv) Chemotherapy~~

~~(v) Radiation~~

~~(vi) Health insurance deductibles~~

~~(B) Operating expenses for the grantee such as utilities, salaries, office equipment, entertainment~~

~~(3) Items not listed in paragraphs (1) and (2) of this subsection are not necessarily allowable.~~

~~(e) Scope. The council will award grants taking into consideration recommendations from the TCCAC.~~

~~(f) Application Requirements.~~

~~(1) The council adopts by reference an application form entitled "Texans Conquer Cancer Patient Support Services Application (2008)". This form is available from the council office.~~

~~(2) Applicants must follow the format of the "Patient Support Services Application (2008)" form.~~

~~(3) Applications that are incomplete, are not in the proper format, or are marked as received by the council after the posted deadline shall be automatically disqualified and shall not be forwarded to the TCCAC for review or recommendation for award.~~

~~(g) Application Submission.~~

~~(1) The grant application must be submitted to the council staff in accordance with instructions contained in the applicable RFA.~~

~~(2) Upon receipt, staff will review the proposals for completeness.~~

~~(3) All questions regarding submission and review process may be directed to council staff. The council staff shall not answer questions or provide advice to applicants regarding the merits of any application during the application process.~~

~~(4) The Texans Conquer Cancer Advisory Committee will review applications for merit and will make funding recommendations to the TCC for final funding approval. Funding availability will be announced in the *Texas Register* and on the TCC website at www.tcc.state.tx.us at least 45 days prior to the deadline for receipt of applications. The grant application amount will be identified in the funding announcement. The application must be submitted in writing (Texas Cancer Council, P.O. Box 12097, Austin, Texas 78711) or through e-mail to applications@tcc.state.tx.us using the application form referenced in subsection (f)(1) of this section. Council decisions will be made during Council meetings, and the awardees will be contacted approximately 15 days after the meeting and will be sent a contract that must be signed as a condition to receiving the grant funds.~~

~~(h) Review Process.~~

~~(1) Applications will be collected by the council staff and forwarded to the TCCAC. Council staff will be available to the TCCAC to answer questions concerning applicable statutes, council rules, requirements, and procedures.~~

~~(2) The TCCAC will review and evaluate each eligible application using appropriate selection criteria established in the RFA.~~

~~(3) All applications that the TCCAC reviews will be submitted to a committee of the council for additional technical review.~~

~~(4) The TCCAC shall make recommendations to the council committee regarding the applications.~~

~~(5) A report from the council committee will be submitted to the full council before a final funding decision is made. The report shall include the TCCAC recommendation, the committee recommendation, and the basis for the committee's recommendation. The council will review recommendations from TCCAC at the next scheduled meeting of the council.~~

~~(6) Council members may review an application in its entirety prior to making a funding decision.~~

~~(7) Council approval is based on the requirements identified in the RFA.~~

~~(8) The council will set funding caps for all awards.~~

~~(i) Approval.~~

~~(1) The council staff will notify applicants of the final decision.~~

~~(2) If an applicant's application is approved by the council, grant money will not be disbursed until the grantee signs a contract with the council.~~

~~(3) All council funding decisions are final and are not subject to reconsideration, appeal, or administrative or judicial review.~~

~~(j) Reporting. Grantees must submit reports to the council as described in the Guidelines for Awarding Support Services Funds.~~

~~(k) Expense Reimbursement.~~

~~(1) Funding for this program will be on a reimbursement basis only. Once organizations are selected to receive funding under this program they will be provided a Financial Status Report Form 269A, which will be used to request reimbursement and report financial actions. Claims for reimbursement of actual expenses of services delivered can be submitted once a month or quarterly.~~

~~(2) TCC grantees are required to collect performance data and report performance accomplished with funding from this program. A report indicating the number of people directly served by the grant and a report indicating the provided services must be submitted with the Reimbursement Request.~~

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~~RULE §704.9 Termination of Contract with Grantee~~

~~Termination~~

~~(1) The council may terminate the contract of any grantee prior to the expiration of the contract term upon finding that the grantee has defaulted or has not substantially performed under the contract. The council shall notify the grantee in writing of its intent to terminate no later than 30 days before the intended termination date. The written notice shall state the reasons for the termination and the procedure for requesting reconsideration.~~

~~(2) The grantee shall have the opportunity to request that the council's contract management committee reconsider the proposed termination. The grantee must file a written request for reconsideration with the Executive Director, Texas Cancer Council, P.O. Box 12097, Austin, Texas 78711-2097, prior to the termination date; otherwise, the grantee will be deemed to have waived the review, and the contract will be terminated.~~

~~(3) During the time between the notice of the proposed termination and the final decision of the council contract management committee, the council may withhold further funding. In the event the contract management committee's decision is favorable to the grantee, the funds shall be promptly distributed to the grantee.~~

~~(4) The council hereby delegates to the contract management committee full authority to terminate grant contracts awarded under this chapter for reasons the committee deems appropriate. Any such decision of the council contract management committee shall be final and shall not be subject to reconsideration, appeal, or administrative or judicial review.~~

~~(5) The contract shall be subject to automatic termination by the council if the council's funds are reduced or upon mutual agreement of the grantee and the council.~~

~~RULE §704.11~~ — ~~Confidentiality of Records~~

~~(a) A grantee who provides direct services must have a system to protect client and patient records from inappropriate disclosure. Disclosure of confidential information must be in accordance with applicable law.~~

~~(b) As required by §5.04 of the Human Immunodeficiency Virus Services Act, Article 4419b-4, Texas Revised Civil Statutes, a grantee who receives funds for residential or direct client services or programs shall develop and implement guidelines regarding confidentiality of medical information regarding Acquired Immune Deficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) infection.~~

~~(1) The guidelines shall apply to all employees of the grantee and clients, patients, and residents served by the grantee.~~

~~(2) The guidelines shall be consistent with guidelines published by the Texas Department of State Health Services and with state and federal regulations.~~

~~(3) A grantee that does not adopt confidentiality guidelines as required by this section is not eligible to receive state funds until the guidelines are adopted and implemented.~~

~~RULE §704.13~~ — **Grantee Performance**

~~The grantee shall perform in accordance with the terms of the contract signed with the council.~~

DRAFT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, INTERIM EXECUTIVE DIRECTOR
SUBJECT: RESTARTING THE GRANT REVIEW PROCESS
DATE: OCTOBER 28, 2013

Summary and Recommendation:

CPRIT is undertaking several initiatives to restart the grant review process once the moratorium is lifted, including reconstituting peer review committees, executing grant award contracts, and preparing to release new requests for grant applications. Although Oversight Committee action is not required, a vote supporting CPRIT's plan to restart grant review is appropriate.

Discussion:

Since January, CPRIT has taken purposeful strides to strengthen agency governance and restore trust in its commitment to the fight against cancer in Texas. The end of the moratorium imposed on CPRIT's grant processes is a critical milestone for the agency. CPRIT will move forward with deliberate purpose, accountability, and transparency to identify and fund ground-breaking cancer prevention and research projects, including support for early stage companies in Texas developing cancer therapeutics, devices and diagnostics.

When it is fully functioning, CPRIT's review process involves CPRIT staff, specialized service providers and more than 150 peer reviewers. Restarting the grant process will be accomplished in stages. Actions to be taken over the next three months, reflected in chronological order, include:

- **Appointment of Scientific Research and Prevention Programs Committees** to conduct peer review of grant applications (on-going). CPRIT expects that when it restarts its grant review processes, 100 - 110 individuals who previously served as CPRIT peer reviewers for the scientific research, prevention and product development programs will continue to do so. CPRIT is actively recruiting about 60 – 70 additional members, primarily for the scientific research review panels. Peer reviewers must be appointed by CPRIT's Chief Executive Officer and approved by the Oversight Committee. New appointments are scheduled for approval at the November 1, 2013 meeting. CPRIT expects that approval of peer review appointments will remain an agenda item for the next several Oversight Committee meetings.

- **Execution of award contracts** for grant recommendations ratified at the August 2, 2012 and December 5, 2012 Oversight Committee meetings. These awards have been reviewed for compliance. No further Oversight Committee action is necessary to proceed with finalizing the award contracts; authority to negotiate and execute the award contracts has been delegated to the executive director. Grant recipients have been notified regarding the contract execution protocol. Requests to change the contract end date by six months (for December 5, 2012 awards) and one year (for August 2, 2012 awards) will be honored in order to accommodate the delay caused by the moratorium. Because these grant awards were recommended in FY 2013, bond authority from FY2013 will be used.
- **Release of new Requests for Applications (RFAs).** CPRIT solicits proposals for grant awards pursuant to published RFAs. Due to the moratorium, there are no “open” RFAs. Program staff will meet with the new Scientific Research, Prevention and Product Development subcommittees to discuss issuing proposed RFAs on or before November 15. The first RFAs to be released are expected to be similar to RFAs issued previously; however, as the Oversight Committee establishes its program priorities, the RFAs may change accordingly.
- **Preparation of grant award recommendations** for applications frozen in the review process. Ten prevention grant applications and seven product development applications have been left pending in the review process during the moratorium. Because of the delay caused by the moratorium, applicants have been contacted and provided an opportunity to update their applications with any progress that has been made in the interim. Grant award recommendations for the pending prevention applications may be presented to the Oversight Committee for consideration as early as the next Oversight Committee meeting following the November 1st meeting. Product development award recommendations will follow closely behind, with consideration by the Oversight Committee expected in December or January.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: APPROVAL OF THE EXECUTIVE DIRECTOR'S APPOINTMENTS TO THE
SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE: OCTOBER 28, 2013

Summary and Recommendation:

The Interim Executive Director has appointed seven individuals to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the appointments to be approved by Oversight Committee. The Oversight Committee should vote to approve these appointments, including the appointment of the late Dr. Patricia Buffler. Approval of Dr. Buffler's appointment is necessary in order to reimburse travel expenses and pay a pro-rated honorarium to her estate.

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 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 appointments to be considered by the Oversight Committee at its November 1, 2013 meeting will serve as the chairs of the seven scientific research peer review panels. These men and women are all highly distinguished in their respective fields and bring enormous stature to the peer review process. Unlike chairs of other review processes, CPRIT's chairs are responsible for recruiting peer reviewers for their panel. In addition, they serve as strategic advisors for CPRIT's grant programs. These responsibilities are unique to CPRIT review panel chairs and

require considerably more effort and expertise than simply chairing a committee. Having panel chairs of this caliber distinguishes CPRIT's peer review process from all others.

Dr. Margaret Kripke, CPRIT's Chief Scientific Officer, has been working with these appointments in preparation for re-starting CPRIT's grant review process. One appointment, Dr. Patricia Buffler, was recruited because of her significant expertise in the field of cancer prevention research. Her appointment was effective August 20, 2013, pursuant to a signed honorarium contract. She traveled to Texas to meet with Dr. Kripke and Dr. Becky Garcia, CPRIT's Chief Prevention Officer, in the course of her work with CPRIT, as well as other preparatory activities. Unfortunately, Dr. Buffler died unexpectedly on September 27, 2013. I bring this to your attention because, pursuant to the terms of the honorarium contract, her appointment is not final until approved by the Oversight Committee. In order for CPRIT to reimburse her estate for the travel costs and pay a pro-rated honorarium for the work performed consistent with her CPRIT contract, the Oversight Committee must approve her appointment.

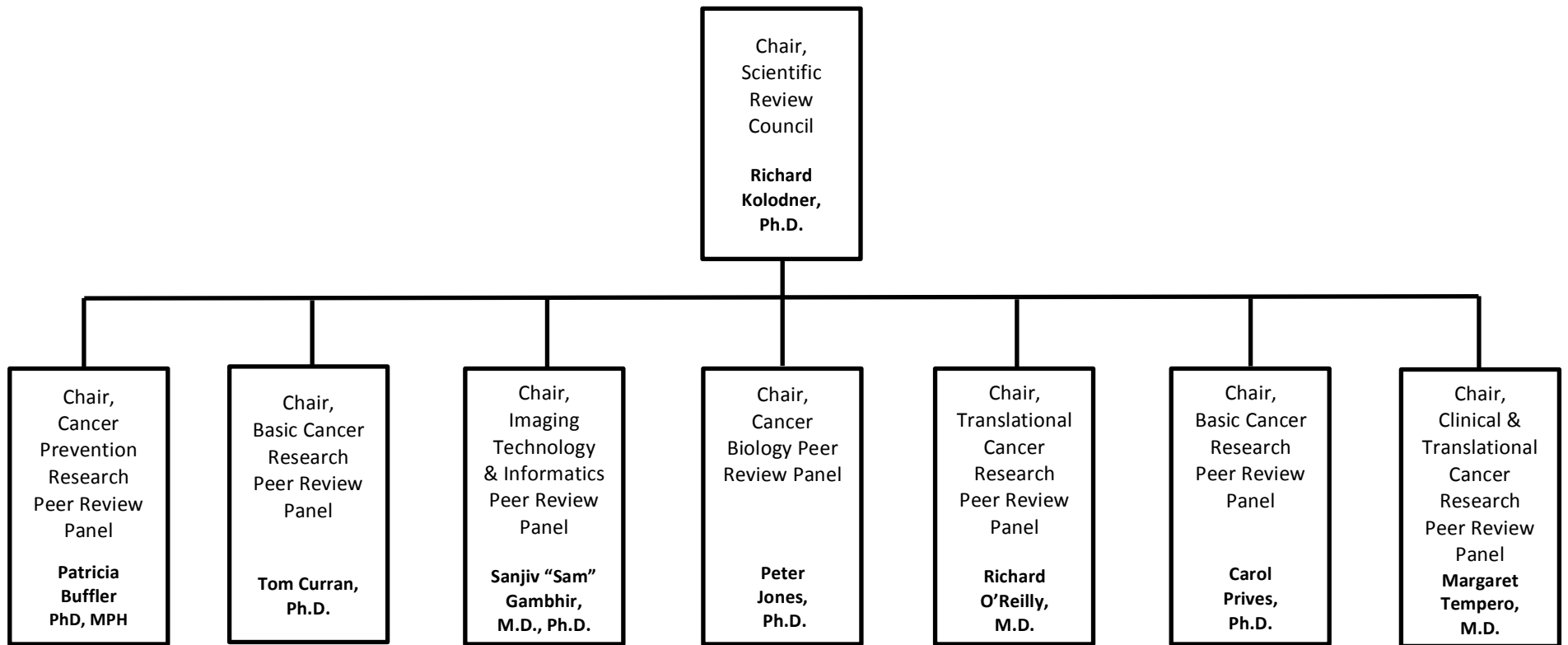
Dr. Kripke will be available at the Oversight Committee meeting to speak to the qualifications of the chairperson appointments. She is working to recruit a new chair to replace Dr. Buffler.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CPRIT Scientific Peer Review Council
Biographies and Research Interests**

CPRIT Scientific Review Council



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

Current Positions

Head, Academic Affairs, Ludwig Institute for Cancer Research, New York Offices

Member, Ludwig Institute for Cancer Research San Diego Branch and Head of the Laboratory of Cancer Genetics
Distinguished Professor of Medicine and of Cellular and Molecular Medicine, UCSD School of Medicine

Previous Positions

Assistant, Harvard Medical School Department of Biological Chemistry and the Dana-Farber Cancer Institute

Associate, Harvard Medical School Department of Biological Chemistry (Renamed Department of Biological Chemistry and Molecular Pharmacology, 1987) and the Dana-Farber Cancer Institute

Full Professor, Harvard Medical School Department of Biological Chemistry and Molecular Pharmacology and the Dana-Farber Cancer Institute Division of Cellular and Molecular Biology and Division of Human Cancer Genetics

Education

University of California, Irvine, B.S.

University of California, Irvine, Ph.D., Biological Sciences

Postdoctoral Fellow at Harvard Medical School

Other Experience

Member, American Society for Microbiology

Member, American Society of Biochemistry and Molecular Biology

Member, Genetics Society of America

Member, American Association for Cancer Research

Co-editor-in-chief of PLASMID

Associate Editor, Cancer Research

Associate Editor, Cell

Editorial Board Member, Molecular and Cellular Biology

Editorial Board Member, Journal of Biological Chemistry

Advisory Committee, National Institute of Health Consortium of Familial Colon Cancer Registries

National Cancer Institute Board of Scientific Counselors

Scientific Review Board, Howard Hughes Medical Institute

Scientific Advisory Committee, American Association for Cancer Research-Stand Up to Cancer Foundation

Selected Honors

ACS Junior Faculty Research Award

ACS Faculty Research Award

NIH MERIT Award

Sandoz Pharmaceuticals Inc. Special Scientific Achievement Award

Dana-Farber Cancer Institute Morse Research Award

Dana-Farber Cancer Institute Charles A. Dana Senior Investigator Chair

Charles S. Mott Prize of the General Motors Cancer Research Foundation

Kirk A. Landon-American Association for Cancer Research Award for Basic Cancer Research

Fellow, American Academy of Arts and Sciences

Member, National Academy of Sciences (USA)

Member, Institute of Medicine (USA)

Research Focus

The major research interest of Dr. Kolodner's laboratory is using *Saccharomyces cerevisiae* as a model organism to study the molecular mechanisms by which cells maintain the stability of their genome and prevent the accumulation of mutations and genome rearrangements. The laboratory also works on inherited defects in human recombination and repair genes to understand how such defects cause cancer susceptibility and to understand the

basic human genetics of these genes. These studies have involved the routine use of techniques in *S. cerevisiae* genetics, protein purification, genomics and human genetics.

Research in Dr. Kolodner's laboratory is focused on two major projects. In the first project, the laboratory is using *S. cerevisiae* to study the genes and proteins that function in DNA Mismatch Repair (MMR), a pathway that prevents mutations from accumulating as a result of errors during DNA Replication. The majority of ongoing work on this project is directed at the purification and study of MMR proteins, the reconstitution of MMR using purified proteins and the biochemical analysis of the mechanism of MMR. As part of Dr. Kolodner's work on MMR, his laboratory has made a number of important contributions to the discovery that a common cancer susceptibility syndrome, hereditary non-polyposis colon cancer (HNPCC) sometimes called Lynch Syndrome, is caused by inherited defects in MMR genes. The laboratory also discovered that the majority of sporadic MMR defective cancers occur as the result of epigenetic silencing of MMR genes. In a second project on DNA repair in *S. cerevisiae*, Dr. Kolodner's laboratory identified a new class of genes that prevent the accumulation of deletion mutations and chromosomal translocations like the chromosomal rearrangements seen in human cancer cells. The majority of ongoing work on this project is directed at identifying the genes and pathways that suppress genome rearrangements, identifying the mechanisms by which genome rearrangements are formed and prevented, and determining if defects in genome rearrangement suppressing pathways play a role in the development of cancer.

Patricia A. Buffler, Ph.D., MPH

Chair, Cancer Prevention Research Peer Review Committee

Current Position

Professor of Epidemiology, University of California, Berkeley, School of Public Health, Division of Epidemiology

Previous Positions

Assistant Professor of Epidemiology, School of Public Health, UTHSC at Houston
Lecturer, WAMI Experiment in Regional Medical Education, Alaska Methodist University, Anchorage, and University of Washington School of Medicine, Seattle; Assistant Professor University of Alaska, Fairbanks
Assistant Professor, Dept. of Preventative Medicine and Community Health, UTMB - Galveston
Associate Professor of Epidemiology and Associate Dean for Research, School of Public Health, UTHSC
Occupational Epidemiologist, National Center for Health Statistics, Washington, DC
Professor of Epidemiology, School of Public Health, UTHSC at Houston
Director, Epidemiology Research Unit & Director of Southwest Center for Occupational Health and Safety
Educational Resource Center UTHSC & Texas A&M University
Professor of Epidemiology (Dean 1991-1998), School of Public Health, University of California
Visiting Scientist, International Agency for Research on Cancer, Lyon, France (Sabbatical)

Education

Catholic University of America, B.S.N., Biology, Nursing
University of California, Berkeley, M.P.H., Epidemiology
University of California, Berkeley, Ph.D., Epidemiology

Other Experience

Society for Epidemiologic Research (Past-President)
Fellow, Board of Directors, American College of Epidemiology (Past-President)
International Commission on Occupational Health
Founding Member, International Society for Environmental Epidemiology (Past-President)
Scientific Committee on Epidemiology in Occupational Health
Full Member, Society of Toxicology
Member, Brain Tumor Epidemiology Consortium
Founding member, Childhood Leukemia International Consortium

Selected Honors

Harriet Cunningham Citation for Meritorious Scientific Writing, Editorial Committee of Texas Medicine
Dean's Teaching Excellence List, School of Public Health, UTHSC
Awardee for Outstanding Woman in Science from Association of American Women in Science
Texas Women's Hall of Fame, Science & Technology, Texas Governor's Commission on Women
Ashbel Smith Professorship, UTHSC at Houston, honoring the First President of the University of Texas
Fellow, American Association for the Advancement of Science
Member, Institute of Medicine/National Academy of Science
Lilienfield Award, American College of Epidemiology
Honorary Fellow, American College of Epidemiology
James D. Bruce Award in Preventive Medicine, American College of Physicians/American Society for Internal Med.
Visiting Scientist Award, International Agency for Research on Cancer
Kenneth and Marjorie Kaiser Endowed Chair
Fellow, American Association for the Advancement of Science
Member, Institute of Medicine of the National Academies

Research Focus

Dr. Buffler is a highly accomplished epidemiologist with a primary interest in cancer and tobacco related malignancies. She has conducted research on active smoking and respiratory cancer, and passive exposures to tobacco smoke and lung cancer in nonsmokers. Dr. Buffler's research has shaped public health policy in several arenas. Her analysis of the effects of cigarette smoking on lung cancer risk in women helped target more smoking cessation programs towards women. The US and California governments used information from her study of lung cancer in women exposed to second hand smoke during the development of their environmental and workplace tobacco regulations.

Dr. Buffler's current research focuses on the genetic, environmental, and infectious exposures associated with childhood leukemia and brain tumors. She has successfully conducted the California Childhood Leukemia Study (CCLS) since 1995. The CCLS is a NIEHS-funded, multi-institutional comprehensive molecular epidemiology study of childhood leukemia that pioneered the use of a multidisciplinary approach to study the molecular, toxicologic, genetic, environmental and epidemiologic factors related to the development of childhood leukemia.

Tom Curran, Ph.D., FRS

Chair, Basic Cancer Research Peer Review Panel

Current Positions

Mai and Harry F. West Chair in Pediatric Research
Deputy Scientific Director, The Children's Hospital of Philadelphia Research Institute
Professor of Pathology and Laboratory Medicine, Cell & Developmental Biology, Perelman School of Medicine
Associate Director Translational Genomics, University of Pennsylvania

Previous Positions

Senior Scientist, Assistant Member, Associate Member, Full Member, Associate Director, Roche Institute of Molecular Biology
Adjunct Professor, Columbia University
Affiliated Professor, the University of Tennessee, College of Medicine
Member and Founding Chairman, Department of Developmental Neurobiology, St. Jude Children's Research Hospital

Education

University of Edinburgh (Scotland), B.Sc. (Honors), Biological Sciences
Imperial Cancer Research Fund & University College (London), Ph.D., Zoology and Anatomy
Salk Institute, Postdoctoral, Molecular Oncology

Other Experience

Member, NIH Study Section Cellular Biology and Physiology 2
Member, Scientific Review Board, Hoffmann La Roche, Inc.
Member, NCI Initial Review Group Committee Subcommittee C
President, American Association for Cancer Research
National Cancer Institute Board of Scientific Advisors

Selected Honors

Passano Foundation Young Scientist Award
Rita Levi Montalcini Award in Neurosciences
Tenovus-Scotland Medal, Glasgow University, Scotland
American Association for Cancer Research, for Outstanding Achievement in Cancer Research Award
Golgi Award, Italian Academy of Neuroscience and the Camillo Golgi Foundation, Brescia, Italy
Fellow of the American Association for the Advancement of Science
Fellow of the American Society of Microbiology
Highly Cited Scientist by Institute for Scientific Information (ISI) in three categories; Neuroscience, Molecular Biology & Genetics, and Microbiology
Javitz Neuroscience Investigator Award, National Institute of Neurological Disorders and Stroke, NIH
Peter M. Steck Memorial Award for Brain Tumor research
LIMA International Award for Excellence in Pediatric Brain Tumor Research, Pediatric Brain Tumor FD
Fellow of the Royal Society
Member, Institute of Medicine of the National Academies
American Association for Cancer Research Academy

Research Focus

Dr. Curran discovered the Fos oncogene and its binding partner, p39, which he later showed was the product of the Jun oncogene. His laboratory demonstrated that Fos and Jun function as inducible transcription factors that regulate gene expression in response to extracellular stimuli associated with proliferation, differentiation, cell death and neuronal activation. This work elucidated the signal transduction pathways that go awry in cancer cells and has initiated the use of Fos as a marker for activity-dependent changes in the nervous system.

His laboratory also uncovered redox regulation of mammalian transcription factors by Ref-1, which also functions as a DNA repair protein. In addition, he identified the gene Reelin and elaborated a signaling pathway that controls neuronal positioning in the developing brain.

Dr. Curran recently developed a high-incidence model of pediatric medulloblastoma with which he demonstrated that orally-bioavailable, small molecule inhibitors of Hedgehog signaling rapidly eliminate even large tumors in mice. This work led to clinical development of inhibitors for the treatment of basal cell carcinoma and medulloblastoma.

Sanjiv “Sam” Gambhir, M.D., Ph.D.

Chair, Imaging Technology and Informatics Peer Review Panel

Current Positions

Chair, Department of Radiology, Stanford University School of Medicine
Director, Canary Center at Stanford for Cancer Early Detection
Director, Molecular Imaging Program at Stanford (MIPS)
Professor, Department of Radiology and Bio-X Program, Stanford University
Professor, Department of Bioengineering, Stanford University

Previous Positions

Head, Nuclear Medicine, Stanford University School of Medicine
Vice Chair, Department of Molecular and Medical Pharmacology, UCLA

Director, Crump Institute for Molecular Imaging, UCLA
Chief, Division of Molecular Medicine, Laboratory of Structural Biology and Molecular Medicine (LSBMM), Department of Energy (DoE) Labs, UCLA
Associate Professor, Department of Molecular & Medical Pharmacology, Crump Institute for Molecular Imaging & Department of Biomathematics, UCLA
Principal Investigator, DOE Laboratory of Structural Biology and Molecular Medicine, UCLA
Clinical Attending, Nuclear Medicine, Center for Health Sciences, UCLA School of Medicine
Director, Computational & Communication Sciences Division, Crump Institute for Biological Imaging, UCLA School of Medicine
Assistant Professor, Department of Molecular & Medical Pharmacology, Crump Institute for Biological Imaging & Department of Biomathematics, UCLA
Nuclear Medicine Fellow, UCLA Center for Health Sciences

Education

Arizona State University, B.S., Physics
University of California Los Angeles, M.D. (MSTP)
University of California Los Angeles, Ph.D., Biomathematics (MSTP)

Selected Honors

Distinguished Basic Scientist of the Year Award, Academy of Molecular Imaging
Doris Duke Distinguished Clinical Scientist Award
Scientific Achievement Award, Society of Molecular Imaging
Fellow of the American Institute for Medical and Biological Engineering
Hounsfield Medal, Imperial College London
Paul C. Aebersold Award, Society of Nuclear Medicine
Nobel Conference – Organized and co-chaired Nobel symposium, “Watching Life Through Molecular Imaging,” Stockholm, Sweden
Tesla Medal, United Kingdom Royal College of Radiologists
American Society of Clinical Investigation
Member, Institute of Medicine of the National Academies
Virginia and D.K. Ludwig Endowed Professorship
George Charles de Hevesy Nuclear Pioneer Award, Society of Nuclear Medicine

Research Focus

Dr. Gambhir’s research focuses on imaging assays to monitor fundamental cellular/molecular events in living subjects with an emphasis on cancer. Technologies being utilized include micro-positron emission tomography (microPET), bioluminescence imaging, fluorescence optical imaging, Raman optical imaging, ultrasound, and photoacoustics in small animal models. Particular interest of his research and lab is early cancer detection including combining *in vivo* and *in vitro* diagnostics.

Peter Jones, Ph.D.

Chair, Cancer Biology Peer Review Panel

Current Positions

Mark A., J. Ruth, and Stillman F. Sawyer Chair in Cancer Research, Keck School of Medicine of USC, USC Norris Comprehensive Cancer Center
Professor of Biochemistry & Molecular Biology and Urology, Keck School of Medicine USC

Previous Positions

Director, USC Norris Comprehensive Cancer Center
Associate Director for Basic Research, USC Norris Comprehensive Cancer Center
Associate Professor of Biochemistry and Pediatrics, USC
Assistant Professor of Pediatrics and Biochemistry, USC, Division of Hematology-Oncology, Childrens Hospital LA

Chief Research Officer of Medical Biochemistry, University of Stellenbosch Medical School, South Africa
Research Fellow of Hematology-Oncology, Childrens Hospital Los Angeles

Education

University College of Rhodesia, B.Sc., Biochemistry
University of London, Ph.D., Biochemistry

Other Experience

Member, Cellular Biology and Physiology Study Section
Member, Cancer Center Support Review Committee, NCI
Member, Integration Panel, US Army Medical Research and Development Command Breast Cancer Research
Co-Chair, NCI Progress Review Group, Kidney and Bladder Cancers
President, American Association for Cancer Research

Selected Honors

Outstanding Investigator Grant, National Cancer Institute
Distinguished Professor of Biochemistry and Molecular Biology at USC
Greenfield Lecturer, University of Nebraska Medical Center
Nakahara Memorial Lecture, Tokyo, Japan
Simon M. Shubitz Award, University of Chicago
Willet Whitmore Lecture, American Urological Association
Distinguished Speaker, American Society of Human Genetics
Firkin Oratory, Australian Society for Medical Research
William Wallace Scott Memorial Lecture, The Johns Hopkins University
Donald S. Coffey Lecture, Society for Basic Urologic Research
Oettlé Award, Cancer Association of South Africa
Workman Award, Samuel Waxman Foundation, New York, NY (shared with S. Baylin)
Kirk A. Landon Prize for Basic Cancer Research (shared with S. Baylin)
Meyenburg Lecturer, German Cancer Research Center
MERIT Award, National Cancer Institute
Fellow, American Association for the Advancement of Science
Distinguished Service Award, University of Miami, Winter Symposium
American Cancer Society, Medal of Honor for Basic Research (shared with S. Baylin)
Lattimer Lecturer, American Urological Association
Fellow, American Association for Cancer Research Academy

Research Focus

A pioneer in the field of epigenetics, Dr. Jones has uncovered basic mechanisms of DNA methylation and its role in cancer. He discovered that 5-azacytidine can induce changes in gene expression and act as a powerful DNA methylation inhibitor, which led to the isolation of the first mammalian determination gene and to the discovery of tumor suppressor genes that are epigenetically silenced in human cancer. The drug 5-azacytidine has been approved for use in treatment of myelodysplastic syndrome.

Dr. Jones' collaborative research has led to delineating molecular pathways in the development of bladder cancer and to the realization that DNA methylation sites are hotspots for cancer-causing mutations and that epigenetic silencing plays a major role in carcinogenesis. He helped establish the International Human Epigenome consortium and co-directs a Stand-Up-to-Cancer dream team developing new cancer treatments.

Richard J. O'Reilly, M.D.

Chair, Translational Cancer Research Peer Review Panel

Current Positions

Chair, Department of Pediatrics and Director of the Bone Marrow Transplantation Program, Memorial Sloan-Kettering Cancer Center

Previous Positions

Chief, Marrow Transplantation Services, Department of Pediatrics/Medicine, Memorial Hospital, NY, NY
Associate Attending Pediatrician, Clinical Immunology Service, Department of Medicine Memorial Hospital & Hematology/Lymphoma Service
Associate Attending Pediatrician, Department of Pediatrics, Memorial Hospital
Associate Attending Pediatrician, New York Hospital
Assistant Attending Physician, Hematology/Lymphoma Service, Memorial Hospital
Director, Marrow Transplantation Program, Memorial Hospital
Assistant Attending Pediatrician, Department of Pediatrics, Memorial Hospital
Fellow, Infectious Diseases, Children's Hospital Medical Center/Beth Israel Hospital
Resident, Pediatrics, Children's Hospital Medical Center/Beth Israel Hospital
Intern, Department of Pediatrics, University of Minnesota Hospital

Education

College of the Holy Cross, B.S., Pre-Medicine
University of Rochester School of Medicine, M.D.

Other Experience

Member, Sloan-Kettering Institute for Cancer Research
Professor of Pediatrics, Cornell University Medical Center
Lila Acheson Wallace Professor of Pediatric Research, Cornell University Medical Center
Associate Professor of Pediatrics, Cornell University Medical Center
Assistant Professor of Biology, Sloan-Kettering Division of Graduate School of Medical Science, Cornell University Medical Center
Associate, Sloan-Kettering Institute for Cancer Research
Head, Laboratory of Microbial Immunology, Sloan-Kettering Institute
Instructor of Pediatrics, Harvard Medical School

Selected Honors

John P. McGovern Compleat Physician Award, Houston Academy of Medicine
Bob Pinedo Cancer Care Prize, Society of Translational Oncology
Sanctae Crucis Award, Holy Cross College
Lifetime Achievement Award, American Society for Blood and Marrow Transplantation
Pediatric Oncology Award, American Society of Clinical Oncology
Distinguished Alumnus Award, Memorial Sloan-Kettering Cancer Center
Pediatric Oncology Award, American Society of Clinical Oncology
Lifetime Achievement Award – Society for Blood and Marrow Transplantation
Timothy Gee Humanity in Medicine Award – Lauri Strauss Leukemia Foundation
Claire L. Tow Chair in Pediatric Oncology Research
Herman Boerhaave Medal, Leiden University
Board of Scientific Counselors, National Cancer Institute
Mary Jane Keller Visiting Professorship, Yale University
Vincent Astor Chair in Clinical Research, Memorial Sloan Kettering Cancer Center
Visiting Woodruff Professor, Emory University School of Medicine
Louise and Allston Boyer-Young Investigator Award - Clinical Research

Research Focus

Dr. Richard J. O'Reilly has been engaged in clinical research and experimental therapeutics focused on allogeneic hematopoietic cell transplantation. He pioneered the development of curative marrow transplantation approaches for the treatment of children with severe combined immune deficiency who lack an HLA matched sibling donor. He introduced the use of matched unrelated donors and T-cell depleted transplants from HLA half matched donors in order to provide a normal blood system without graft vs host disease (GvHD) to patients afflicted with lethal immune deficiencies and leukemia, and subsequently performed the first successful transplants of unrelated marrow for the treatment of leukemia. He and his colleagues developed an approach employing soy bean lectin agglutination and E-rosette depletion for elimination of T lymphocytes from bone marrow allografts. Thereafter, they verified the potential of allogeneic T cell-depleted transplants to prevent GvHD in primate models. Beginning in 1980, they introduced trials of transplants from haplotype matched parents depleted of T-cells by this technique as a treatment for children with severe combined immune deficiency. This experience, which is now one of the world's largest, clearly demonstrates that such transplants can reconstitute immunity and abrogate GvHD. Indeed, 70% of the patients in the entire series are surviving with immune reconstitution and without GvHD.

Over subsequent years, his research focused on the application of T-cell depleted transplants in patients with leukemia and demonstrated that adequately depleted bone marrow or cytokine mobilized blood progenitor cells can be transplanted both in matched and HLA disparate recipients without GvHD. In 1994, he introduced the use of adoptive T-cell therapy for treatment of EBV+ lymphomas. Currently, he is developing new approaches for adoptive cell therapy for leukemias and conducting Phase I and II trials testing adoptive transfer of virus-specific and tumor-specific T-cells as a therapeutic approach for EBV+ lymphoproliferative disease, drug resistant CMV infections, and leukemic relapse in post-transplant patients.

Carol Prives, Ph.D.

Chair, Basic Cancer Research Peer Review Panel

Current Position

De Costa Professor, Department of Biological Sciences, Columbia University

Previous Positions

Chair, Department of Biological Sciences, Columbia University

Associate Professor Department of Biological Sciences, Columbia University

Visiting Expert, National Institutes of Health

Associate Professor, Weizmann Institute, Rehovoth, Israel

Assistant Professor, Weizmann Institute, Rehovoth, Israel

Education

McGill University, B.S., Biochemistry

McGill University, Ph.D., Biochemistry

Albert Einstein College of Medicine, Postdoc Fellow, Biochemistry

Weizmann Institute, Senior Postdoctoral Fellow, Biochemistry

Other Experience

NIH Virology Study Section

Chair, NIH Experimental Virology Study Section

Damon Runyon Advisory Committee

NICHD Scientific Advisory Board

Damon Runyon Scholars Panel

Alberta Heritage Foundation SAC

Howard Hughes Medical Institute Review

NCI Board of Scientific Councilors

MGH Cancer Center Advisory Board
Dana Farber Cancer Center Advisory Board
Memorial Sloan Kettering Scientific Advisory Board
General Motors Awards Council
AACR Board of Directors
Chair, CAMP Study Section

Selected Honors

NIH MERIT Award
American Cancer Society Research Professor
American Academy of Arts and Sciences
American Academy of Microbiology
Member, Institute of Medicine of the National Academies
Member, National Academy of Sciences
NCI Rosalind E Franklin Award for Women in Science
Paul Jansen Prize in Advanced Biotechnology and Medicine
AACR-Women in Cancer Research Charlotte Friend Memorial Lectureship Award

Research Focus

Dr. Prives's research has focused on the p53 tumor suppressor since the late 1980's when she established conditions for purifying and characterizing the p53 protein biochemically and was among the first to show that p53 is a sequence specific transcriptional activator. Her research found that tumor derived mutant forms of p53, especially those that are mutated with high frequency, are defective in such transactivation. Dr. Prives continued to study p53 as a DNA binding transactivator, with special focus on mechanisms by which p53 selects its target genes; and she also provided the first model for stabilization of p53 by genotoxic stress when her group showed that p53 becomes phosphorylated after DNA damage at sites that weaken its interaction with its negative regulator Mdm2. They have continued to study the structure and functional regulation of Mdm2 and its relationship to p53. After the p53 homologues, p63 and p73, were identified, she developed and tested the hypothesis that one of the modes by which some tumor derived mutant forms of p53 elicit pro-oncogenic activities is through down-regulation of the apoptotic functions of p63/p73. Since then, her work has focused on many aspects of the p53 family and on mutant p53. Recently, she has examined mutant p53 pro-oncogenic activities in breast cancer cell lines using the "3D" culture protocol.

Margaret A. Tempero, M.D.

Chair, Clinical and Translational Cancer Research Peer Review Panel

Current Positions

Director, Pancreas Center, Helen Diller Family Comprehensive Cancer Center, University of California San Francisco, School of Medicine
Rombauer Family Distinguished Professorship in Pancreas Cancer Clinical and Translational Science

Previous Positions

Deputy Director and Director of Research Programs, UCSF Helen Diller Family Comprehensive Cancer Center, Professor of Medicine, UCSF School of Medicine
Chief of Medical Oncology, UCSF School of Medicine
Deputy Director, UNMC/Eppley Cancer Center
Interim Director, UNMC/Eppley Cancer Center
Chief of Oncology/Hematology, V.A. Medical Center
Professor of Medicine, Department of Internal Medicine, University of Nebraska Medical Center (UNMC)
Assistant Professor (Courtesy), Eppley Institute for Cancer Research
Associate Professor of Medicine, Department of Internal Medicine, UNMC
Assistant Professor of Medicine, Department of Internal Medicine, UNMC

Education

Creighton University, B.S., Medical Technology
University of Nebraska Medical Center, M.S., Clinical Pathology
University of Nebraska Medical Center, M.D., Medicine
University of Nebraska Medical Center, Residency, Internal Medicine
University of Nebraska Medical Center, Fellowship, Oncology

Other Experience

President, American Society of Clinical Oncology
Member, Board of Directors, American Society of Clinical Oncology
Organizer, Pancreas Cancer Think Tank
Co-Lead, NCI sponsored Progress Review Group on Pancreatic Cancer
Chair, NCCN Guidelines Panel on Pancreatic Cancer
Co-Chair, NCI Pancreas Task Force Tissue Acquisition Working Group
Co-Director, AACR/ASCO Methods in Clinical Cancer Research
Chair, NCI Clinical Oncology Study Section (CONC)
Member and Chair, NCI Board of Scientific Counselors
External Advisory Board, Pancreas SPORE, University of Alabama-Birmingham/University of Minnesota/Mayo Clinic
Scientific Advisory Board, Lustgarten Foundation; Pancreatic Cancer Action Network; The V Foundation; The Alberta Canada Cancer Board; EORTC
Oncology Drug Advisory Committee, FDA
Member, Clinical Advisory Board and Scientific Advisory Board, Raven Biotechnologies, Inc.
Member, Scientific Advisory Board at Ras Therapeutics, Inc.
Chairperson, Oncology Scientific Advisory Board at Rexahn Pharmaceuticals, Inc.
Member, Clinical Trial Advisory Board of Oxigene Inc.

Selected Honors

Doris & Donald Fisher Distinguished Professor in Clinical Cancer Research; University of California, San Francisco

Research Focus

Dr. Tempero's research career has focused on pancreatic ductal adenocarcinoma, especially in the area of investigational therapeutics. She was a pioneer in the use of antibody-based therapies and helped develop the fixed dose rate concept for gemcitabine. Her group has developed effective gemcitabine combinations and provided a foundation for using CA19-9 as a surrogate for survival in clinical trials, and currently is assessing molecular subtypes and molecular enrichment for selecting new drugs for clinical evaluation.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, INTERIM EXECUTIVE DIRECTOR
SUBJECT: HONORARIA POLICY
DATE: OCTOBER 28, 2013

Summary and Recommendation:

A newly adopted provision of CPRIT's enabling legislation requires CPRIT's Chief Executive Officer, in consultation with the Oversight Committee, to adopt a policy regarding honoraria paid by CPRIT for peer review services. The Oversight Committee should vote to approve the proposed honoraria policy for FY 2014.

Discussion:

CPRIT's 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. State law authorizes CPRIT to pay honoraria to individuals appointed to CPRIT's Scientific Research and Prevention Programs committees (Health and Safety Code § 102.151(d)). The ability to pay honoraria is essential to retaining individuals with the expertise and experience to carry out the complex review process required by statute and CPRIT's administrative rules.

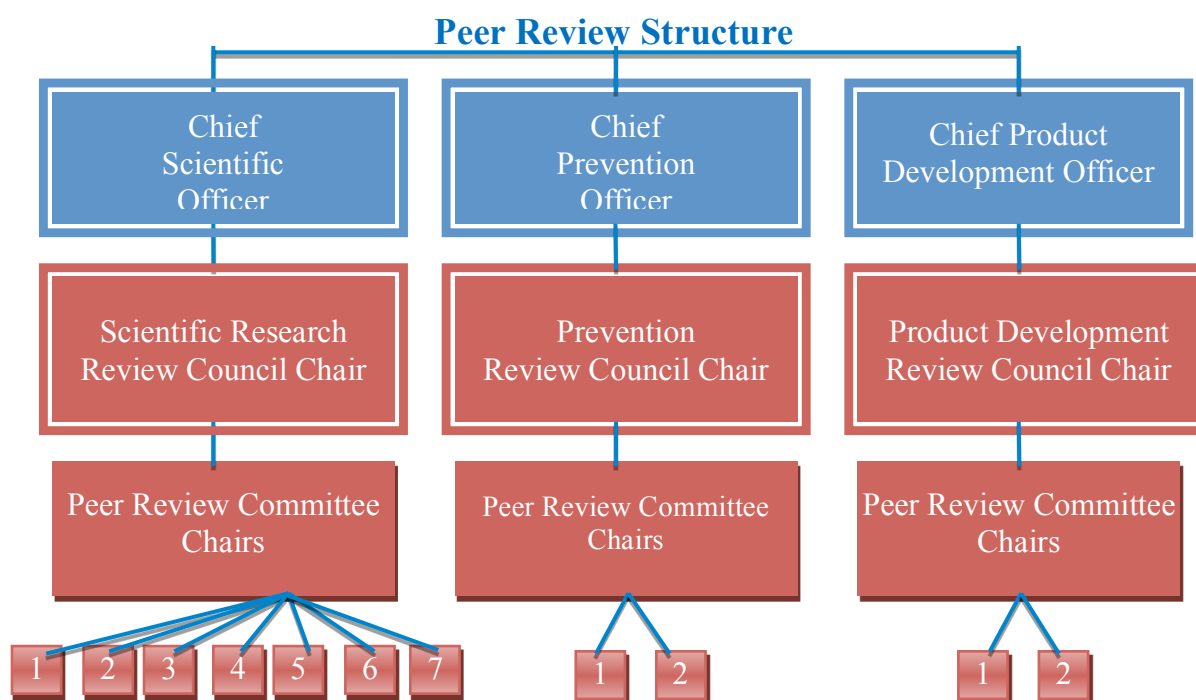
In his January report, the State Auditor recommended that CPRIT implement a process to support the amount of honorarium it pays, to justify any changes, and to ensure that the honoraria are reasonable and competitive for the value CPRIT receives. Adopting documentation and process requirements for honoraria payments was also recommended. This guidance was codified in Section 102.151(e) of the Health and Safety Code.

As reflected in the comprehensive honoraria policy proposed for your approval, CPRIT's program staff relied upon historical information as well as anticipated workload projections to perform a detailed analysis of the activities, hours, and units for peer reviewer workload. The proposed policy incorporates the different roles and responsibilities assigned to Review Council chairs, Peer Review panel chairs, and peer review panel members and justifies the FY 2014 honorarium amount paid for each role. In the event that honoraria rates are not standard across the prevention, scientific research, and product development programs, the policy justifies the reasons for paying different amounts. The approved policy fully implements the statutory mandate and the State Audit recommendations.

CPRIT PEER REVIEW HONORARIA POLICY¹

Adopted September 1, 2013

Peer review of prevention and research applications is the evaluation process conducted by qualified experts for feasibility, significance, and potential for impact. Like many funding agencies, CPRIT has implemented a tiered peer review process designed to identify the best projects based on excellence, program-specific objectives, and organizational priorities.² Maximizing the success of CPRIT's scientific research, product development, and prevention programs is dependent upon the quality of the peer reviewers CPRIT recruits. Therefore the peer reviewers must be exceptionally qualified, highly respected, well-established members of the cancer research, product development, and prevention communities.



CPRIT relies upon a pool of approximately 170 expert peer reviewers to evaluate, score and rank grant applications based upon significance and merit. As reflected above, the general peer review structure is the same for CPRIT's three grant programs. Reviewers are assigned to peer review committees based upon their expertise and background. The evaluations conducted by the peer review committees are used to develop the list of grant applications recommended for CPRIT grant awards.³

¹ Adopted pursuant to TEX. HEALTH & SAFETY CODE Section 102.151(e).

² A tiered approach to peer review has been recommended by the National Academies of Sciences.

³ For more information about the grant review process undertaken by the peer review committees, please see CPRIT's administrative rules, 25 T.A.C. Part 11, Sections 703.6 and 703.7.

All of CPRIT's expert peer reviewers live and work outside Texas, which is an uncommon requirement among grant-making organizations. CPRIT implemented this peer reviewer qualification to ensure an impartial review, minimize conflicts of interest and provide the opportunity to select the best projects without regard for self-interest.

Honoraria

In recognition of the work undertaken by CPRIT peer reviewers, state law authorizes CPRIT to pay honoraria to its peer reviewers.⁴ CPRIT's ability to pay honoraria is essential to retaining individuals with the expertise and experience to carry out the complex review process required by statute and CPRIT's administrative rules.

CPRIT recruits world-renowned experts who live and work outside of the state to be peer reviewers. CPRIT's residency policy is important to maintaining a review process that minimizes the potential for political and other outside influences, but it means that the CPRIT review process, by design, lacks non-monetary incentives common to other grant review processes that may otherwise justify the time commitment required of CPRIT peer reviewers in addition to their full-time jobs.

Specifically, CPRIT reviewers are not eligible to compete for CPRIT grants. This is different than other cancer grant-making organizations such as National Institutes of Health (NIH), Centers for Disease Control and Prevention, Department of Defense, American Cancer Society, and Susan G. Komen for the Cure. For example, NIH reviewers may review grant applications as well as compete for NIH grants. Familiarity with the NIH review process gained by serving as an NIH peer reviewer provides the individual a significant nonmonetary benefit since that understanding better positions the reviewer to compete for and secure NIH grant funds as an applicant. This benefit is not available to CPRIT's reviewers.

A second nonmonetary benefit from serving on a review panel is that such service is an indication of external recognition in one's field, which is essential for academic promotion. Using peer reviewers who are already well-established in their careers means that this is not an incentive for CPRIT peer reviewers to participate.

The Chairs of CPRIT review panels are all highly distinguished in their respective fields and bring enormous stature to the peer review process. Unlike chairs of other review processes, CPRIT's chairs are responsible for recruiting peer reviewers for their panel. In addition, they serve as strategic advisors for CPRIT's grant programs. These responsibilities are unique to CPRIT review panel chairs and require considerably more effort and expertise than simply chairing a committee. Having panel chairs of this caliber distinguishes CPRIT's peer review process from all others.

⁴ TEX. HEALTH & SAFETY CODE Section 102.151(d)

Honoraria Payment Process and Documentation

Review Council and Committee Chairs receive quarterly honoraria payments directly from CPRIT. The honoraria payment process for Review Council chairs and Committee chairs is as follows:

1. At the end of the fiscal quarter, the Review Council chairs and Committee chairs submit to CPRIT a written certification of the work performed and an estimate of hours* spent related to CPRIT's peer review activities for the quarter.
2. The CPRIT Program Officer reviews the certifications and confirms that the quarterly honoraria should be paid to the Review Council chair and Committee chairs.
3. CPRIT's financial staff authorizes payment of the honoraria and retains the documentation supporting the honoraria payment.
4. The Chief Compliance Officer and Internal Auditor may also review the certification submitted.

* NOTE: Honorarium is paid for the annual service of the Review Council chair or Committee chair. Payment is not based on an hourly wage structure; the estimated number of hours devoted to CPRIT activities by a Review Council or Committee chair may vary by quarter depending upon the timing of review cycle activities. The hourly estimate is used at the end of the year to set honoraria payment structures for the next fiscal year.

Peer reviewers are paid by CPRIT's third party grant administrator for each review cycle in which they participate. To document the work performed by a peer review committee member for the review cycle, CPRIT's third party grant administrator confirms that the reviewer attended the peer review meeting and submitted written comments and scores for the grants assigned to the reviewer for evaluation.

CPRIT also reimburses travel expenses and pays the Texas state per diem when peer reviewers and Review Council chairs and Committee chairs travel to attend peer review meetings. CPRIT relies upon standard travel documentation for travel reimbursements.

Peer Review Responsibilities

Review Council Chairs

The Council Chair works directly with the CPRIT Program Officer to coordinate the peer review activities for each CPRIT program. The CPRIT model for peer review is unique. Other grant-making programs typically use committee chairs only to preside at committee meetings; however, CPRIT engages preeminent experts in their field for the Council Chair and Committee Chair positions to advise CPRIT on program aspects, including the short-term and long-term direction of the program, the review process itself, and the award portfolio composition. This work is done in addition to the administrative tasks associated with chairing Review Council

meetings. Many of the Council Chair responsibilities are similar across the three CPRIT programs, including:

- advising on the selection of committee chairs
- assisting with peer reviewer selection
- reviewing all abstracts of projects that are to be discussed at Prevention, Research, and Product Development Review Council meetings
- chairing Review Council meetings
- chairing a peer review panel meeting if a chair has an unexpected conflict
- finalizing grant award recommendations to the Chief Executive Officer
- providing ongoing advice to CPRIT staff on programs, review processes, and future funding opportunities

Estimated Annual Time Commitment: Council Chairs are expected to commit approximately 240 hours to CPRIT-related activities in FY2014. This equates to 11.5% of a standard 2080 hour work year. **Table 1** provides a detailed analysis of the activities, hours, and units used to project the Council Chair workload. The information in Table 1 is based upon 2009 – 2012 review cycle information and the projected workload for FY2014.

NOTE: In addition to the regular Council Chair duties in FY 2014, CPRIT anticipates that the Product Development Review Council Chair will perform services totaling approximately 60 additional hours. This is due in part to the absence of a Chief Product Development Officer. The position has been vacant since November 2012, and as a result, the Product Development Council Chair, under the direction of CPRIT executive staff, has performed additional services related to monitoring the product development grant activities undertaken at CPRIT-funded early stage companies. The increased workload is expected to continue in FY 2014. Examples of the additional activities include coordinating the review of annual progress reports and milestone funding decisions and providing expert advice and assistance related to CPRIT's product development portfolio and substantive grant contract amendment requests.

Hourly Rate Proxy: Honorarium is paid for the annual service of the Review Council chair and is not based on an hourly wage structure. However for comparison, the honoraria paid to Review Council chairs equate to a \$250/hour rate. This is in line with hourly rates paid for skilled professional services in other industries and less than the \$500/hour rate paid for medical experts in malpractice cases.⁵ The hourly rate used by CPRIT is also likely to be less than rates used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is considerably greater than the \$60,000 - \$75,000 honoraria paid to CPRIT Review Council Chairs.

⁵ Data from *National Medical Consultants, P.C.*, a physician owned and operated company representing a panel of over 2700 medical experts who are distinguished specialists in all areas of medicine.

Peer Review Committee Chairs

Each peer review committee is led by a Committee Chair. The CPRIT model for peer review is unique. Other grant-making programs typically use committee chairs only to preside at committee meetings; CPRIT engages preeminent experts in their field for the Committee Chair positions to advise CPRIT on program aspects, including the short-term and long-term direction of the program, the review process itself, and the award portfolio composition. This work is done in addition to the administrative tasks associated with chairing peer review committee meetings. Committee Chairs are also members of the Review Council for the program. Duties of the committee chair include:

- recruiting reviewers for their review panels
- assigning applications to their panel members
- becoming familiar with the abstracts of all applications assigned to their panel
- determining order of review for applications for panel discussion
- chairing panel discussions
- reviewing full applications to participate in programmatic review meetings
- evaluating CPRIT Scholar recruitment grants (Scientific Review committee chairs)
- assessing due diligence and intellectual property reports for product development applications (Product Development committee chairs)
- ranking grant applications and developing a list of recommended grant awards and supporting information for consideration by the CPRIT Program Integration Committee
- reviewing annual progress reports and milestone funding decisions (Product Development committee chairs)
- participating in meetings with CPRIT staff to provide advice on future program directions, processes, evaluation criteria, and other related issues

Estimated Annual Time Commitment: The amount of time spent on committee chair activities varies depending on the program. Scientific Research and Product Development committee chairs are expected to commit approximately 200 hours to CPRIT-related activities in FY2014, and Prevention review committee chairs will commit 125 hours. **Table 2** provides a detailed analysis of the activities, hours, and units used to project the committee chair workload. The information in Table 2 is based upon 2009 – 2012 review cycle information and the projected workload for FY2014.

Hourly Rate Proxy: Honorarium is paid for the annual service of the Review Committee chair and is not based on an hourly wage structure. However for comparison, the honoraria paid to Committee chairs equates to a \$200/hour fee. This is in line with hourly rates paid for skilled professional services in other industries and less than the \$500/hour rate paid for medical experts in malpractice cases.⁶ The hourly rate used by CPRIT is also likely to be less than rates used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education

⁶ Data from *National Medical Consultants, P.C.*, a physician owned and operated company representing a panel of over 2700 medical experts who are distinguished specialists in all areas of medicine.

limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is considerably greater than the \$25,000 - \$40,000 honoraria paid to CPRIT Committee Chairs.

Peer Reviewers

The number of peer review committees varies by program, generally based on the volume of grant applications submitted. Peer reviewers are responsible for individually reviewing, scoring and critiquing 6-10 applications per cycle, as well as participating in panel discussions about grant applications assigned to the peer review committee. A full review of a single application generally takes a reviewer 6-8 hours, but substantially more time may be required for complex, highly technical applications. A typical CPRIT grant application averages about 40 pages in length with additional supporting documentation. Applications for multi-million dollar collaborative research projects and product development project may be much more extensive.

Estimated Time Commitment per Review Cycle: Peer reviewer activity varies by program and number of applications assigned. Scientific Research peer reviewers are expected to commit approximately 85 hours per review cycle. Prevention peer reviewers will commit 55-70 hours per cycle. Product Development peer reviewers will commit 100 hours per cycle. **Table 3** provides a detailed analysis of the activities, hours, and units used to project the peer review workload. The information in Table 3 is based upon 2009–2012 review cycle information and the projected workload for FY2014.

Hourly Rate Proxy: Honorarium is paid for the service of Scientific Research and Prevention peer reviewers for a given review cycle and is not based on an hourly wage structure. However for comparison, honoraria paid to Scientific Research and Prevention peer reviewers equates to a rate of \$50/hour. Honoraria paid to Product Development peer reviewers is \$65/hour. These reviewers must have both scientific and product development backgrounds and are more difficult to recruit. While the hourly rates are significantly less than those paid to professionals of this caliber, the rate is appropriate given the workload and responsibilities compared to Review Council and Committee chairs.

Comparison to other Grant Making Organizations

Grant-making organizations use various models and methods for compensating peer review committee members. A survey of 21 cancer granting organizations reported wide variation among programs such that an average compensation scheme for panel members was not possible. The disparity among organizations makes it difficult to devise a benchmark compensation method or amount. Reported compensation practices may fail to include intangible benefits available to reviewers in addition to monetary compensation, which further complicates the ability to make a meaningful comparison between CPRIT and other grant-making organizations. As discussed earlier, these non-monetary incentives are largely unavailable to CPRIT reviewers because of CPRIT's policy to use highly qualified, experienced, out-of-state reviewers.

- International Cancer Research Partners (ICRP) surveyed 31 of its partner organizations and 21 responded. The report found that organizations commonly paid different

honoraria depending on the role of the reviewer. Chairs often received more than committee members, and teleconference or online reviewers typically received less compensation than those members who participated in-person. An average could not be computed on the basis of the supplied data.⁷

- CPRIT's third party grant administrator reports that two other clients pay reviewers \$1,250 and \$2,000 per review meeting.
- NCI's website reports that NCI pays \$200 per day of review in addition to travel expenses.

⁷ The report did not include a range but when the survey sponsors were asked they indicated the range for compensation for panel members was \$150-\$3,000 per day.

Table 1. Council Chair Activities

Table 1 - Review Council Chair Activities, Hours, Units					
Research Council Chair		Prevention Council Chair		Product Development Council Chair	
Units	Activity	Units	Activity	Units	Activity
5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	5	Consult with staff on vision and direction for the program; bi-weekly calls with staff
2	Help select and recruit Committee Chairs	2	Help select and recruit Committee Chairs	2	Help select and recruit Committee Chairs
2	Advise on peer review and other processes as needed	2	Advise on peer review and other processes as needed	2	Advise on peer review and other processes as needed
4	Review draft RFAs, propose new ones, etc.	4	Review draft RFAs, propose new ones, etc.	6	Review draft RFAs, propose new ones, etc.
4	Communicate with Committee Chairs prior to peer review & programmatic mtg	1	Communicate with Committee Chairs prior to peer review & programmatic mtg	6	Communicate with Committee Chairs prior to peer review & programmatic mtg
4	Prepare for Programmatic meetings; review materials	2	Prepare for Programmatic meetings; review materials	4	Prepare for Programmatic meetings; review materials
2	Lead programmatic review	6	Lead programmatic review	5	Lead programmatic review
4	Prepare slate recommendations for ED	1	Prepare slate recommendations for ED	4	Prepare slate recommendations for ED
15	Review recruitment applications, become familiar with applications to be discussed	15	Review abstracts, attend portions of panel meetings, back up for panel Chair	12	Review abstracts, attend portions of panel meetings, back up for panel Chair
4	Lead quarterly discussion on recruitment awards	4	Collaborate on articles for publication	4	Analyze data for Product Development program
4	Analyze data for Research program	4	Analyze population and other data for Prevention program	12.5	Review annual and final progress reports, including milestone achievement reports, advise on activities of funded product development grants
50		4	Review Annual and Final progress reports	62.5	
\$ 1,200	Unit cost	50		\$1,200	Unit cost
\$ 250	Hourly rate	\$1,200	Unit cost	\$250	Hourly rate
\$60,000	Annual honoraria	\$250	Hourly rate	\$75,000	Annual honoraria
		\$60,000	Annual honoraria		

See Table 4 for an explanation of the correlation between units and hours.

Table 2. Committee Chair Activities

Table 2 - Committee Chair Activities, Hours, Units					
Research Committee Chair		Prevention Committee Chair		Product Development Committee Chair	
Units	Activity	Units	Activity	Units	Activity
2	Select/recruit committee members	1	Select/recruit committee members	2	Select/recruit committee members
2	Review draft RFAs and provide input (as needed)	1	Review draft RFAs and provide input (as needed)	1	Review draft RFAs and provide input (as needed)
10	Read abstracts; assign grants to reviewers	10	Read abstracts assigned to their committee	15	Read abstracts assigned to their committee
1	Assist with follow up of delinquent reviewers	1	Assist with follow up of delinquent reviewers	1	Assist with follow up of delinquent reviewers
6	Chair the assigned committee review process via conference call or in person meeting	6	Chair the assigned committee review process via conference call or in person meeting	3	Chair the assigned Screening Teleconference committee via conference call
2	Prepare for Programmatic meetings; review materials	2	Prepare for Programmatic meetings; review materials	10	Chair the assigned committee review process via 2-day, in-person peer review meeting
2	Participate in Chair's programmatic review meetings	6	Participate in Chair's programmatic review & debriefing meetings	2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs
2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs	2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs	11	Review annual and final progress reports, including milestone achievement reports, advise on activities of funded product development grants.
15	Review recruitment applications				
3	Participate in quarterly review of recruitment applications				
45		29		45	
\$875	Unit cost	\$875	Unit cost	\$875	Unit cost
\$200	Hourly	\$200	Hourly	\$200	Hourly
\$39,375	\$40 K Annual honoraria	\$25,375	\$25K Annual honoraria	\$39,375	\$40K Annual honoraria

See Table 4 for an explanation of the correlation between units and hours.

Table 3. Peer Reviewer Activities per Cycle

Table 3 - Peer Reviewers Activity by Program					
Product Development:~30 reviewers		Prevention:~ 33 reviewers		Research: ~ 105 reviewers	
Units	Activity	Units	Activity	Units	Activity
8	Preparation of full critiques	8	Preparation of full critiques	10	Preparation of critiques
2	Screening teleconference	3	one meeting by phone, one in- person	3	Travel to/from on-site meeting
3	Travel to/from on-site meeting	2	Participation at meeting	3	Participation at meeting
4	Participation at meeting	1	Post-meeting discussion	1	Post-meeting discussion
1	Post-meeting discussion				
1	Review of due diligence and intellectual property evaluations				
1	Teleconference discussion of due diligence and intellectual property evaluation				
	\$325 Unit cost \$65 avg. hourly rate \$6,500 per cycle		\$250 Unit cost \$50 avg. hourly rate \$2,750 teleconference \$3,500 in person per cycle		\$250 Unit cost \$50 avg. hourly rate \$4,250 per cycle

See Table 4 for an explanation of the correlation between units and hours.

NOTE: As reflected in the table, key activities are assigned a unit cost. Peer reviewers are paid only for activities in which they participate. For example, participation at an in-person research peer review meeting is 3 units (11-15 hours) and each unit is valued at \$250; thus, the amount paid to a research peer reviewer for attendance at an in-person meeting is \$750. If the reviewer was unable to attend the meeting, then \$750 would be subtracted from the honorarium paid to the reviewer.

Table 4. Hours and Units Calculation

PARTICIPATION (HOURS)	UNITS		Council Chairs	Committee Chairs	Peer reviewers
1-5	1		Unit Cost		
6-10	2		\$1200	\$875	\$250-\$325
11-15	3		Average Hourly Rate		
16-20	4		\$250	\$200	\$50-\$65
21-25	5		Honoraria		
26-30	6		\$60 - \$75K annually	\$25 - \$40K Annually	\$2,750 - \$6,500 per cycle
31-35	7				
36-40	8				
41-45	9				
46-50	10				
51-55	11				
56-60	12				
61-65	13				
66-70	14				
71-75	15				



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 2013 AND 2014
DATE: OCTOBER 28, 2013

FY 2013 Financial Summary

In fiscal year 2013 CPRIT's total expenditures for general agency administration, pre- and post-award administration, and prevention and research grant award encumbrances, including announced grants subject to the December 2012 moratorium, was almost \$119 million. This leaves \$181.2 million in the treasury for future appropriation by the Legislature.

FY 2014 Operating Budget

The Legislature appropriated \$300 million of general obligation bond proceeds, with a required transfer of almost \$3 million to the Department of State Health Services for the Texas Cancer Registry operations. There is also an appropriation for an estimated \$16,000 in general revenue from the sale of the Texans Conquer Cancer license plates to CPRIT for fiscal year 2014.

To be able to operate in fiscal year 2014, Wayne Roberts sent a request to the Legislative Budget Board on July 17, 2013, as required by CPRIT Appropriations Budget, Rider 5 (limiting the agency's transfer authority among budget line items) to transfer approximately \$5 million from the research grants line item among the agency's two administrative operations line items. The Legislative Budget Board approved this request on August 28, 2013. The request and approval are included in the packet of memos you received.

With the approval, CPRIT's operating budget is:

Institution Operations:	\$ 3,267,690 (1.10% of total budget)
Grant Review and Award Operations	\$ 11,411,220 (3.84% of total budget)
Prevention Grant Awards:	\$ 29,022,567
Research Grant Awards:	\$253,344,969

Debt Issuance History

Through the Texas Public Finance Authority (TPFA), CPRIT issued \$98.7 million in commercial paper notes during the fiscal years 2012 and 2013 for agency operations and to pay reimbursements

to grant recipients for expenses on their awards. In addition, TPFA has issued \$282.9 million in long-term general obligation bonds for debt CPRIT incurred in fiscal years 2010 and 2011. The bonds will yield \$287.8 million in proceeds to cover CPRIT's actual expenditures and outstanding grant award obligations.

Authorization for Fiscal Year 2014 Request for Financing

For TPFA to issue debt on behalf of CPRIT in fiscal year 2014, the Oversight Committee must authorize a request for financing for \$300 million in bond proceeds appropriated to CPRIT for its operations and prevention and research grant awards in fiscal year 2014. I estimate that CPRIT will need to request that TPFA issue \$145.5 million in commercial paper to pay for CPRIT administrative operations and pay reimbursements to grant recipients on grants awarded in fiscal years 2011, 2012, 2013, and 2014.

Cancer Prevention and Research Institute of Texas

Financial Summary (unaudited)

As of August 31, 2013
Oversight Committee

Method of Finance

	AY 2013
General Obligation Bonds	\$ 300,000,000
GAA Rider Transfer for Cancer Registry to Dept. of State Health Services	(2,969,554)
Company Application Fees	20,000
License Plate Revenue	12,000
Total Appropriated FY 2013	\$ 297,062,446

Appropriation Year 2013

	Total Expenses, Encumbrances, and Obligations thru				
	Budgeted	8/31/2013	Remaining Budget	Percent Expended	
Salaries and Wages	\$ 2,830,515	\$ 2,255,715	\$ 574,800	80%	
Other Personnel Costs	150,000	111,088	38,912	74%	
Professional Fees and Services	12,630,729	8,291,948	4,338,781	66%	
Consumable Supplies	22,500	19,163	3,337	85%	
Utilities	32,000	49,778	(17,778)	156%	
Travel	51,500	54,967	(3,467)	107%	
Rent - Building	451,850	421,586	30,264	93%	
Rent-Machine and Other	131,500	164,500	(33,000)	125%	
Other Operating Expenses	340,500	305,458	35,042	90%	
Grants	280,421,352	102,007,268	178,414,084	36%	
Grand Total	\$ 297,062,446	\$ 113,681,470	\$ 183,380,976	38%	

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				
TOTAL ISSUED TO DATE				\$ 386,275,000				

¹The 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%.

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
				\$ 9,600,000				
TOTAL ISSUED TO DATE				\$ 372,875,000				

¹The 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 (as of 2/28/13) - 0.21%.

CPRIT Commercial Paper and G.O. Bond Issuance

[illegible]

CPRIT Commercial Paper and G.O. Bond Issuance

[illegible]



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**A RESOLUTION
AUTHORIZING A REQUEST FOR FINANCING
AND THE EXECUTION AND DELIVERY OF DOCUMENTS
REQUIRED TO EFFECT SUCH FINANCING**

Whereas, the Texas Public Finance Authority (the "Authority") is authorized to issue bonds for the use and benefit of the Cancer Prevention & Research Institute of Texas (the "Institute"), to provide funds for grants for cancer research, prevention, and control and related purposes and for the operations of the Institute, (the "Program") pursuant to Article III, Section 67, Texas Constitution; Texas Health & Safety Code, Chapter 102, as amended; Texas Government Code, Chapter 1232, as amended; and provisions of the General Appropriations Act, 83rd Legislature, R.S. (2013), (collectively, the "Authorizing Law");

Whereas, the Institute desires and intends to request the Authority to finance its Program costs as permitted by the Authorizing Law;

Whereas, the Institute recognizes that in order to finance the cost of the Program, the Authority may issue public securities including short-term obligations, general obligation bonds, or other authorized obligations (collectively, "Obligations") in an aggregate principal amount not to exceed \$300,000,000 for authorized Program costs appropriated in the 2014 state fiscal year, and appropriated in previous state fiscal biennia (including the (i) \$225,000,000 appropriated in the 2010 state fiscal year, (ii) the \$225,000,000 appropriated in the 2011 state fiscal year, (iii) the \$300,000,000 appropriated in the 2012 state fiscal year and (iv) the \$300,000,000 appropriated in the 2013 state fiscal year), together with related costs of issuance and other ancillary costs to be determined at the time of issuance; provided that the total amount of Obligations issued in a year may never exceed \$300 million in accordance with the requirements of Authorizing Law;

Whereas, a Request for Financing, including a description of the Program and a proposed expenditure schedule is presently before the Cancer Prevention and Research Institute of Texas Oversight Committee ("Committee") and attached hereto as Exhibits A and B, respectively;

NOW THEREFORE BE IT RESOLVED by the Committee that:

Section 1. The Committee hereby ratifies and confirms that the purpose of the financing is to provide funds for the purposes in the Authorizing Law including grants for cancer research, prevention, and control and related purposes, and for the operations of the Institute and that financing thereof is appropriate at this time. Accordingly, the execution and delivery of the Request for Financing to the Authority pursuant to the Authorizing Law is hereby ratified, approved and confirmed.

Section 2. The Committee hereby empowers, authorizes and directs the Executive Director or designee of the Institute, for and on the behalf of the Board and the Institute, to negotiate, date, sign, and otherwise execute on behalf of the Institute (i) a Memorandum of Understanding (the "Memorandum of Understanding"), as necessary, between the Authority and the Institute and to deliver the Memorandum of Understanding; (ii) a financing Agreement (the "Agreement") between the Authority and the Institute and to deliver such Agreement; and (iii) such other documents (the "Other Documents") as are necessary or desirable to effect the issuance of the Obligations, to provide funds for the Program, and to deliver such Other Documents.

Upon execution by both parties thereto and delivery thereof, the Memorandum of Understanding, the Agreement, and the Other Documents shall be binding upon the Authority and the Institute in accordance with the terms and provisions thereof.

Section 3. The Committee recognizes that the Authority will proceed to issue the Obligations to provide the requested financing upon receipt of any necessary approvals from the Texas Bond Review Board ("BRB") and the Texas Attorney General of Public Finance Division ("OAG").

Section 4. The Executive Director or designee of the Institute is hereby authorized to cooperate with the Authority, and its consultants, to obtain approval from the BRB and OAG and to prepare an Official Statement or other offering documents in connection with the sale of the Obligations and to take any other action necessary to assist in such sale.

Section 5. All actions not inconsistent with provisions of this Resolution heretofore taken by the Institute and the Executive Director or designee thereof and the other officers of, or consultants to the Institute, directed toward the financing of the Program, and the issuance of the Obligations are hereby ratified, approved and confirmed.

Section 6. The officers of the Institute and the Executive Director or designee thereof shall take all action in conformity with the Authorizing Law to effect the issuance of the Obligations and complete the Program as provided in the Agreement and take all action necessary or desirable or in conformity with the Authorizing Law for carrying out, giving effect to, and consummating the transactions contemplated by the Memorandum of Understanding, the Agreement, the Obligations, and this Request for Financing, including without limitation, the execution and delivery of any closing documents in connection with the closing of the Obligations.

Section 7. If any section, paragraph, clause, or provision of this Resolution shall be held to be invalid or unenforceable, the invalidity or unenforceability of such section, paragraph, clause, or provision shall not affect any of the remaining portions of this Resolution.

Section 8. This Resolution was adopted at a meeting open to the public, and public notice of the time, place and purpose of said meeting was given, all as required by Ch. 551, Texas Government Code.

Adopted by the affirmative vote of a majority of the Cancer Prevention and Research Institute of Texas Oversight Committee present and voting on this ____ day of _____, 2013.

Cancer Prevention and Research Institute
of Texas Oversight Committee

Attested:

Chairman

Secretary



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Fiscal Year 2014 Request for Financing Program Description

Purpose

The Cancer Prevention and Research Institute of Texas (CPRIT) is the state agency mandated 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.

Powers and Duties

CPRIT will make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and make grants to institutions of learning and to advanced medical research facilities and collaborations in this state for:

- 1) research into the causes of and cures for all types of cancer in humans;
- 2) facilities for use in research into the causes of and cures for cancer;
- 3) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans; and
- 4) cancer prevention and control programs in this state to mitigate the incidence of all types of cancer in humans.

Implementation Plan

CPRIT estimates that \$145.5 million in bonds proceeds must be issued on an as-needed basis consistent with Texas Government Code, Chapter 1232 to cover grant award obligations from fiscal years 2011, 2012, and 2013; new grant award obligations made during fiscal year 2014; and operating costs for general agency administration and pre- and post-award grants management processes. During fiscal year 2014, CPRIT will use the bond proceeds to disburse grant funds for grants awarded by CPRIT during the last three months of fiscal year 2011 as well as during fiscal years 2012 and 2013. CPRIT is authorized to commit up to \$282.3 million in fiscal year 2014 of cancer prevention and research grant awards.

Based on its operating history, CPRIT usually announces grant awards for cancer prevention education and service programs and scientific and product development cancer research programs four times per year. In fiscal year 2014, CPRIT anticipates it may only announce grant awards two or three times as it restarts the grant pre-award peer review and decision-making processes following the moratorium instituted in December 2012, opens new opportunities for funding, and

implements additional review steps and certifications required by the passage of Senate Bill 149, 83rd Regular Legislature which made significant changes to Health and Safety Code, Chapter 102.

Grant funds are generally disbursed quarterly on a reimbursement basis to grant recipients. For certain types of grant awards, historically limited to product development and scientific recruitment awards, CPRIT advances funds in order to provide those specific types of recipients with working capital to meet their milestones or objectives.

CPRIT is authorized to use bond proceeds to fund its grant review and award operating and indirect administrative costs. At this time, the total of these two categories budgeted is \$14.7 million bond proceeds in fiscal year 2014. CPRIT must also transfer \$2.9 million in bond proceeds to the Texas Department of State Health Services (DSHS) for the operating costs associated with the Texas Cancer Registry. From the total of all of these operating costs, CPRIT requires half of the proceeds to be available at the beginning of the state fiscal year to be able to cover the operating expenses for six months. CPRIT also requires proceeds at the beginning of each state fiscal quarter to pay for award costs reimbursed to grant recipients for the previous state fiscal quarter.

The scientific research program provides awards in the following areas: cancer biology, cancer genetics, immunology, imaging, therapeutics, prevention/epidemiology, and informatics/computation. The product development research program focuses awards on the development of cancer drugs, diagnostics, and devices based on discoveries made in one of the seven areas described above. Prevention program grants are awarded for cancer prevention information and services, early detection and treatment, professional education and practice, cancer data acquisition and utilization, or survivorship (the areas of the Texas Cancer Plan). Awards for all programs are issued for multiple years, ranging from two years to five years.

CPRIT has established a grant process that allows grant proposals for cancer prevention, scientific research, and product development research to be submitted through requests for applications (RFA) issued throughout each fiscal year. All proposals are reviewed by multiple experts in the appropriate area. CPRIT has historically had approximately 200 national experts in cancer prevention, research and product development to review proposals and provide funding recommendations to CPRIT. While about 40% of the scientific reviewers resigned from the academic research peer committees during the fall of 2012, CPRIT has been able to recruit reviewers of the same caliber to fill out the committees and, in some cases, reviewers who resigned have returned to serve on committees.

The award recommendations developed by the peer review committees must now be forwarded to the Program Integration Committee (PIC) for consideration. The five members of the PIC are statutorily set as the Chief Executive Officer (CEO), Chief Scientific Officer, Chief Prevention Officer, Chief Product Development Officer, and the DSHS Commissioner. The PIC will finalize award recommendations across all programs for consideration by the Oversight Committee. When those proposed awards are forwarded to the Oversight Committee, each recommended award will be accompanied by an affidavit signed by the CEO to affirm that the award followed all required pre-award grant procedures. The Oversight Committee will consider each recommended award and vote to approve it for funding or not.

Cancer Prevention and Research Institute of Texas

Estimated Expenditure Schedule, Fiscal Year 2014

Fiscal Year 2014	September	October	November	December	January	February	March	April	May	June	July	August	Total
Bond proceeds for Indirect Administration	\$ -	\$ -	\$ -	\$ 1,633,845	\$ -	\$ -	\$ 1,633,845	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 3,267,690
Bond proceeds for Grant Review and Award Operations	\$ -	\$ -	\$ -	\$ 5,781,378	\$ -	\$ -	\$ 6,527,795	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 12,309,173
Bond proceeds for Texas Cancer Registry (GAA 2014-15, Art. I, CPRIT Rider 6)	\$ -	\$ -	\$ -	\$ 1,484,777	\$ -	\$ -	\$ 1,484,777	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 2,969,554
Bond proceeds for Prevention and Research Grants	\$ -	\$ -	\$ -	\$ 46,300,000	\$ -	\$ -	\$ 37,353,583	\$ -	\$ -	\$ 43,300,000	\$ -	\$ -	\$ 126,953,583
Cumulative Debt Total, Fiscal Year 2014	\$ -	\$ -	\$ -	\$ 55,200,000	\$ 55,200,000	\$ 55,200,000	\$ 102,200,000	\$ 102,200,000	\$ 102,200,000	\$ 145,500,000	\$ 145,500,000	\$ 145,500,000	\$ 145,500,000



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, INTERIM COMPLIANCE OFFICER
SUBJECT: COMPLIANCE REPORT
DATE: OCTOBER 28, 2013

CPRIT's Compliance Officer, Patricia Vojack, resigned effective September 30, 2013 to accept the position as Senior Advisor with the Health and Human Services Commission. CPRIT has posted a Chief Compliance Office job position seeking qualified applicants to fill the vacancy. Applications are due by the close of business on October 31, 2013. I will be serving as the interim Compliance Officer until the position is filled. I can answer any questions you may have related to the Compliance Program information included in this report.

The items in this portion of the agenda provide a high level overview of the significant actions undertaken by CPRIT's Compliance Program since the Oversight Committee meeting held on February 25, 2013. These include:

- **Compliance Program Reports to the Oversight Committee** – Ms. Vojack issued four program reports since the February 25, 2013 Oversight Committee meeting. Report dates are February 25, 2013; March 21, 2013; July 26, 2013; and September 30, 2013.
- **Crosscheck Review of the CPRIT Foundation Donor Funds** – One of Ms. Vojack's major projects was a comprehensive review of the CPRIT Foundation's donor list to identify any entities or institutions that may have received CPRIT grants. Information in this section includes Wayne Roberts' April 16, 2013 correspondence to David Erinakes, Chief of Staff to Representative Dan Flynn, responding to a House Transparency Committee request to identify any donors on a provided list that may have invested in any CPRIT grant awards. In addition, several pieces of communication document CPRIT's internal processes undertaken to identify any CPRIT Foundation donors that may be connected to an entity or organization receiving a CPRIT grant award. See Ms. Vojack's April 22, 2013 memorandum describing the CPRIT donor match process, Mr. Roberts' April 22, 2013 correspondence with Jennifer Stevens, CPRIT Foundation Executive Director, requesting the Foundation to return the donations made by five individuals that were employees, officers or directors of organizations that receive grant funds from CPRIT and Ms. Vojack's May 2, 2013 memorandum providing more information on her review and recommendation.

- **Compliance Review of All Awarded Grants** – Ms. Vojack and Billy Hamilton, Special Advisor to the Oversight Committee, undertook full compliance reviews of all grants awarded by CPRIT. The compliance review project was divided into two parts. The first review, described in Mr. Hamilton’s January 31, 2013 memorandum, examined each step of the grant application review and approval process for the grant awards subject to the moratorium. The second review, described in Ms. Vojack’s June 25, 2013 memorandum, verified compliance with the statutory grant award processes for all prior grant awards.

Cancer Prevention and Research Institute of Texas
Compliance Program Report
February 25, 2013

Section 1: Organizational Matters

- The Board Governance Committee continued to refine Oversight Committee organizational documents.

Section 2: Risk Assessment, Monitoring and Training

Identification of Critical Risks and Detailed Monitoring Plans

A limited risk assessment of the Institute was conducted by Internal Audit in August-September 2010. Because the Institute's operations were commenced in early 2010, the internal audit approach and assessment primarily focused on the organizational structure including the existence of policies and procedures. A more comprehensive risk assessment is being planned by Internal Audit that will lead to the identification of mission critical risks thereby enabling the development of monitoring plans, with responsible parties, appropriate controls and reporting to minimize risk.

Risk: Grant Application

Risk: Grant Management

On December 5, 2012, the Oversight Committee requested a report at its next regularly scheduled meeting on the NIH grant application and management process and best practice recommendations. The following is a very high-level summary of those processes. The majority of applications undergo the processes described below; however different programs and Institutes may have program and agency specific requirements.

NIH Grant Application Process:

- An application is submitted to the NIH in response to a Program Announcement.
- Most applications are submitted electronically.
- The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas.
 - A Scientific Review Officer (SRO) (staff scientist) is responsible for ensuring that each application receives a fair and impartial peer review.
 - The SRO recruits qualified reviewers based on scientific and technical qualifications and other considerations (including geographic distribution, gender, ethnicity, level of professor) and establishes SRGs.
 - The SRO assigns applications to reviewers for critique preparation and assignment of individual criterion scores.
 - The SRO convenes a peer review and attends and oversees administrative and regulatory aspects of peer review meetings.

- The SRG has a chair that serves as moderator for the peer review meeting and is also a peer reviewer for the meeting.
 - The reviewers declare conflicts of interest, receive grant applications approximately six (6) weeks before the meeting, prepare a written critique based on established review criteria, assign a numerical score (1 to 9), and make recommendations regarding scientific and technical merit.
 - An in-person Peer Review meeting is then convened where the applications are then reviewed based on established review criteria.
 - Assigned reviewers summarize their prepared critiques for the group.
 - An open discussion follows.
 - Final scoring of overall impact scores is conducted by private ballot.
 - At the conclusion of the peer review meeting, the SRO prepares a summary statement for each of the applications reviewed. The summary statement will also include the application's score.
- The second level of review is performed by the funding Institute (i.e., NCI) and their National Advisory Councils or Boards. Councils are composed of both scientific and public representatives chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council may be recommended for funding.
 - The Program Officer (PO) examines applications, their overall impact scores, and their summary statements and considers these against the funding Institute's needs.
 - The PO provides a grant-funding plan to the Advisory Board/Council.
 - The Advisory Board/Council also considers the funding Institute's goals and needs and advises the funding Institute director.
 - The funding Institute's director makes final funding decisions based on staff and Advisory Council/Board advice.
 - While an application may be recommended for funding, this does not guarantee that it will be funded. Some funding Institutions publish paylines that will guide applicants on the likelihood of funding. If the application is assigned to an IC that does not announce a payline, the PO may be able to provide guidance on the likelihood of funding.
 - After the Advisory Council meeting, if an application results in an award, the applicant works closely with the PO of the funding Institute on scientific and programmatic matters and a Grants Management Officer (GMO) on budgetary or administrative issues. The Grants Management Specialist contacts the applicant to collect information needed to prepare the award.
 - If the application is funded, a Notice of Award (NoA) is issued to the grantee. The NoA is the legal document containing all applicable terms and conditions of the award either by reference or specific statement.

NIH Grant Management

- Grant management takes place at the funding Institute level (i.e., NCI).
- Most grant management occurs electronically.
- Grantees are responsible for managing the day-to-day operations of their grant. To fulfill their role in regard to the stewardship of federal funds, NIH awarding offices monitor grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the grantee, audit reports, site visits, and other information available to NIH.
- Applicant organizations are required to have financial systems in place to monitor their grant expenditures. NIH monitors grantee expenditures under individual grants within each budget period and within the overall project period.
- The Grants Management Specialist (GMS) reviews grantee cash expenditure reports to determine whether they indicate a pattern of accelerated or delayed expenditures may seek additional information from the grantee and may make any necessary and appropriate actions.
- NIH requires grantees to submit a variety of reports which are due at specific times during the life cycle of a grant award. All reports must be accurate, complete, and submitted on time.
- There are standard research terms and conditions that are included in the contract as well as contained in the *Code of Federal Register*. These include required reports and a reporting schedule including remedies available to the funding Institute for failure to provide the required reports.
- Grantee progress reports are monitored by the PO and other staff.
- Grantees that expend \$500,000 or more in federal awards during the fiscal year are subject to an audit requirement.
- At the end of the project period, the grantee is required to timely submit closeout reports. Failure to submit timely and accurate final reports may affect future funding to the organization or awards with the same PD/PI.
- There are also record retention requirements.

CPRIT Grant Application

- The CPRIT peer review process is very similar to the NIH process described above. CPRIT deviates from the NIH in its process for the recruitment of peer reviewers. At the NIH recruitment is done at the staff level with geographic, gender and ethnicity requirements in addition to expertise considerations and limitations. CPRIT's program chiefs (Chief Science Officer, etc) recruit peer reviewers. Peer reviewers and CPRIT staff believe this creates a superior group of reviewers for CPRIT applicants.
- The NIH electronic application system appears to be similar to the CPRIT electronic system including access by peer reviewers only after a conflict of interest statement is executed.
- CPRIT also has a similar two-level review including in-person meeting and presentation by reviewers, review criteria, discussion and scoring with recommendation to a Council

for final funding recommendations. Similar post-review summaries are provided to the applicant.

- Unlike the NIH where the funding Institute's director makes the final funding decision, CPRIT Executive Director is required submit to the Oversight Committee a list of grant applications that is substantially based on the list submitted by the Council.

CPRIT Grant Management

- CPRIT's grant management differs from the NIH funding Institutes.
- CPRIT has an electronic grants management system (CGMS) that became operational in October 2012. Prior to that time, there was a modified electronic system.
- CPRIT and the grantee communicate via CGMS.
- Post award management includes required reports—progress, financial status, matching funds certification, equipment inventory, HUB report and single audit determination. Programmed notices are sent to grantees when reports are due. Notices are received by CPRIT staff when a grantee has submitted a document.
- In all programs, financial status reports are reviewed by the internal finance team against established criteria. A single audit is required for grantees receiving \$500,000 or more. The internal auditor does financial field audits of select grantees below \$500,000. The internal auditor will also begin desk audits on all grantees below \$500,000.
- In Prevention, quarterly program progress reports are reviewed by the Prevention Program Director based on established criteria. The grantee is notified when a progress report has been approved or rejected along with the reason(s). Annual progress reports are reviewed by the chair of the Prevention Review Council for progress in meeting goals and objectives. An approved progress report is required prior to processing financial status reports.
- In Commercialization, annual progress reports are reviewed by the commercialization peer reviewers.
- In Research, the procedure had the original peer reviewers of that application review the annual program progress reports. Challenges in obtaining progress reports from grantees and the availability of reviewers prevented this procedure from being fully implemented. Changes to this process are underway by the Chief Scientific Officer to have program progress reports reviewed by the grants contractor staff.
- Additionally, uniform progress report and review criteria are currently being drafted across all award mechanisms. This will be utilized by the grantee in reporting progress and by the reviewer to document progress report reviews.
- CPRIT has similar record retention, research subject and biosafety requirements, confidentiality requirements, among others, as the NIH.

Selected Grant Management Process Improvement

- Changes, as described above, are underway to enable the Institute to perform desk audits on all grantee's expending less than \$500,000 and engaging additional resources to review and report on research program progress reports.

- Drafting of uniform progress reporting and review criteria is underway.
- Documentation of reviews of prior progress reports in each of the award programs must be entered into CGMS.
- Better enforcement of rules and contract provisions should be implemented.
- Post award grant management monitoring and controls must be established and reported to the Audit Subcommittee and Oversight Committee.
- Reporting requirements, including financial status reports, are set forth in the contract. Generally, grantees are funded on a reimbursement basis. In the Commercialization program, funds are advanced to the company in tranches. There are some grantees that are delinquent in meeting their financial reporting obligations—quarterly and close-out reporting. This presents a challenge for the agency to forecast bond issuance requirements, may impact the agency's \$300 million cap on annual expenditures and most importantly, timely audit for the proper expenditure of funds. Although a rule permitting the Executive Director to terminate grants for failure to meet contractual obligations is available, consideration should be given to adding additional enforcement options including a bar to future grant awards if the sponsoring institution is not current with its reporting in other grant awards and a time limit following the end of a reporting period upon which reimbursements may be requested.

Best Practices

- In 2005, the Texas State Auditor's Office participated in a work group chaired by the Comptroller General of the United States to address common issues relating to how grant funds are used and the results achieved. The group identified a mutual concern regarding grant accountability. The following are areas of opportunity in grant accountability and promising practices identified by the group. (See <http://www.ignet.gov/randp/grantguide.pdf>) CPRIT has many of these practices implemented or is in the process of implementation. Best practices for the Institute must be tailored to meet the agency's needs. Further development of these best practices will occur in the Institute risk assessment and monitoring plan development.
 - Internal Control Systems
 - Preparing policies and procedures before issuing grants
 - Consolidating information systems to assist in managing grants
 - Providing grant management and training to staff and grantees
 - Coordinating programs with similar goals and purposes
 - Performance Measures
 - Linking activities with performance goals
 - Working with grantees to develop performance measures
 - Pre-Award Process
 - Assessing applicant capability to account for funds

- The RFA should include a requirement that the applying organization list any grant awards that were terminated early by the granting organizations and the reasons for this termination
 - Competing grants to facilitate accountability
 - Preparing work plans to provide framework for grant accountability
 - Including clear terms and conditions in grant award documents
- Managing Performance
 - Monitoring the financial status of grants
 - Ensuring results through performance monitoring
 - Adding a quantitative measure to all progress reports in all award programs (Prevention currently has a quantitative measure)
 - Using audits to provide valuable information about grantees
 - Monitoring subrecipients as a critical element of grant success
- Assessing and Using Results
 - Providing evidence of program success
 - Identifying ways to improve program performance

Risk: Conflict of Interest

- To increase transparency and improve identification of conflicts of interest, every Request for Application will collect detailed funding source information from the applicant so reviewers and Oversight Committee members can more easily identify potential conflicts of interest prior to review or taking action on the grant applications.
- At a minimum, the sources of funding will include a capitalization table that will include all parties, including private, who have investment, stock or rights in the project.
- Additionally, the applicant organization shall certify that it has not made a donation to the CPRIT Foundation.

Section 3: Monitoring and Assurance Activities (Performed by Compliance Officer)

Risk: Grant Application

Assurance Activities: CO reviewed 129 research and prevention grant awards, along with 22 recruitment awards presented to the Oversight Committee on August 2, 2012 and December 5, 2012 within the documentation available to certify compliance with CPRIT processes. CO will undertake a compliance review of all prior grant awards.

Significant Findings: CO was not able to certify one (1) Individual Investigator Award that did not follow CPRIT processes. Additionally, three (3) CTNet awards were presented to the Oversight Committee on August 2, 2012 that are not included in the CO's certification. These grant applications were submitted pursuant to an RFA developed and managed by CTNet—outside of CPRIT's processes.

Section 4: Action Plan Activities

- The collection of information is being undertaken to perform an agency risk assessment and develop monitoring plans.

- Rules have been drafted for a confidential mechanism to report non-compliance. An RFP is being developed.
- Respond to Legislative requests—including meetings, hearings, reports, legislative drafting and other needs.
- Continue implementation of audit recommendations, rule revisions, policy and procedure update, *Guideline* revisions.

Section 5: Confidential Reporting

- CPRIT will issue an RFP to establish a confidential reporting Hotline to receive and process complaints. An internal process will be developed for the handling of these calls. The types and numbers of calls will be reported to the Oversight Committee.

Cancer Prevention and Research Institute of Texas
Compliance Program Report
March 21, 2013

Section 1: Organizational Matters

- The Code of Ethics and Conduct was revised to reflect the Oversight Committee discussion at the February 25, 2013 meeting. The revised Code is discussed separately.

Section 2: Risk Assessment, Monitoring and Training

Identification of Critical Risks and Detailed Monitoring Plans

A limited risk assessment of the Institute was conducted by Internal Audit in August-September 2010. Because the Institute's operations were commenced in early 2010, the internal audit approach and assessment primarily focused on the organizational structure including the existence of policies and procedures. A more comprehensive risk assessment is being planned by Internal Audit that will lead to the identification of mission critical risks thereby enabling the development of monitoring plans, with responsible parties, appropriate controls and reporting to minimize risk. The proposed risk assessment is discussed separately.

Risk: Grant Management

- Agency staff and SRA are developing an annual progress report compliance review template to document review along with quantitative and qualitative measures of grant awards.
- Agency staff and SRA are developing a system that provides accurate and timely information regarding delinquent reports.
- Agency staff and SRA are developing a system that provides notice to the grantee of due dates for required reports.

Section 3: Monitoring and Assurance Activities (Performed by Compliance Officer)

Risk: Conflicts of Interest

Assurance Activities: CO has contacted the Signing Officials of each grantee institution to search for any matches to the CPRIT Foundation individual donor list and report to CPRIT.

Significant Findings: None at this time.

Risk: Grant Application

Assurance Activities: CO and designated staff are verifying, within the information available, that each prior grant award (excluding the August 2, 2012 and December 5, 2012 slates) underwent the grant review process as required by statute and rules. This should be completed by March 30, 2013.

Significant Findings: None at this time.

Section 4: Action Plan Activities

- Rules have been drafted for a confidential mechanism to report non-compliance. An RFP is being developed.
- Respond to Legislative requests—including meetings, hearings, reports, legislative drafting and other needs.
- Continue implementation of audit recommendations, rule revisions, policy and procedure update, *Guideline* revisions.

Section 5: Confidential Reporting

- CPRIT will issue an RFP to establish a confidential reporting Hotline to receive and process complaints. The scope of work has been defined and is under review by staff prior to issuing RFP.

Kristen Doyle

From: Patricia A. Vojack
Sent: Friday, July 26, 2013 1:01 PM
To: Sandra Balderrama
Cc: Wayne Roberts; Billy C Hamilton
Subject: Compliance Officer Update

Dear Oversight Committee Members:

I wanted to provide you with a brief update on compliance activities at CPRIT.

Risk Assessment

Grant Thornton issued a risk survey at the end of May to a select group of people (sampling of Oversight Committee members, agency staff, peer reviewers and grantees) as part of our enterprise risk management endeavor. We had very good participation—21 surveys were distributed with 16 responses. Participants were asked to select the top 15 risks for the agency out of a list of 44 risks. Additionally, participants were asked to propose actions that would minimize and control each of the 44 risks. The next steps in this project is to consider other factors that impact these risks to better inform us of the current risk environment. Thereafter, risk monitoring and control plans will be developed.

Internal Audit

Grant Thornton has begun our annual internal audit. They are currently in the field visiting select grantees. Other audit areas include grants management and expenditures, information technology and the Institute's electronic grants management system—CGMS. Data gathering will be complete mid-August with a report issued shortly thereafter.

Training & Education

During the general staff meeting held earlier this month, the Institute's Code of Ethics and Conduct was introduced to the agency staff. The meeting kicked off the *Training & Education* aspect of the Institute's compliance program. Kristen Doyle and I will provide monthly training to agency staff. Compliance tips on daily business operations are also shared with the staff as part of the training program.

Oversight Committee Orientation Manual

Kristen Doyle, Sandra Balderrama and I are updating the Orientation Manual to incorporate the many changes to CPIRT's statute from the 83rd Legislative Session. We will also be providing training in the near future.

Grant Monitoring Program

Senate Bill 149 requires the Institute to continuously monitor and ensure that each grant recipient complies with the terms and conditions of the grant contract. I am developing, along with the Program and Finance staff, a grant monitoring program that includes desk-reviews, on-site visits and programmatic reviews. CGMS, our electronic grants management system is being programmed to track the dates on which grant recipient reports are due and received by the Institute and provide notice to grantees of report due dates to assist in their planning. Additionally, we will be able to run a variety of reports to determine compliance with these requirements.

Reconciliation

Earlier this year we began a reconciliation period for all grantees to achieve compliance with all required reports. The reconciliation period will be wrapping up soon—however, we have had a tremendous response to this opportunity. I look forward to reporting the final tallies to you in the near future.

Grant Administration Guide

Finally, I am in the process of writing a grant administration guide for grantees. The intent of the guide is to simplify the grant administration process, ensure reporting requirements are met and for the grantees to have a successful experience with CPRIT. I believe this guide will be a very vital component of the Grant Monitoring Program.

This concludes my report. Please let me know if you have any questions or if I can provide you with additional information. I hope you are having a wonderful summer with family and friends.

Kindest regards,

Patricia

Patricia A. Vojack
Compliance Officer
Cancer Prevention and Research Institute of Texas
P.O. Box 12097
Austin, TX 78711
pvojack@cprit.state.tx.us

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Compliance Program Report to the Oversight Committee
September 30, 2013

Submitted by:
Patricia A. Vojack

February - September 2013

I. Legislature

a. Verification

Between February to May, the Compliance Program completed a number of special project requests for the 83rd Texas Legislature. At several hearings, the Cancer Prevention and Research Institute of Texas ("CPRIT" or "Institute") was asked about the previously awarded 498 grants' compliance with grant award processes and procedures. To respond to Legislative inquiries and provide compliance assurances with the Institute's statute and rules, a verification of each previously awarded grant was performed. Within the information that was available, the previously awarded grants followed agency processes and procedures.

With the December 2012 grant awards, the Compliance Officer created a "grant pedigree" detailing the CPRIT processes each grant application must follow. The "grant pedigree" documents and provides compliance assurances to the Oversight Committee that a grant award has met statutory, rule and Institute procedures. The "grant pedigree" should continue for the life of the grant and document the grant monitoring processes and contract terms and conditions for additional compliance assurances.

b. Donor Match

Another special project was matching donors of the CPRIT Foundation with any "employee, officer or director" of a grantee. The General Appropriations Act, 82nd Legislature, prohibits a donor to a foundation established to benefit the Cancer Prevention and Research Institute of Texas from receiving a grant. A list of donors was obtained from the CPRIT Foundation and was sent to each grantee requesting the grantee to perform a search identifying any employee, officer or director that matched the CPRIT Foundation donor list. The CPRIT Foundation was notified of any matches and funds were returned to the donor.

Senate Bill 149, 83rd Legislature requires the Institute's Chief Compliance Officer to compare each grant application submitted to the Institute to a list of donors from any nonprofit organization established to provide support to the Institute "before the application is submitted to a research and prevention programs committee for review and again before any grant is awarded to the applicant". This will ensure that grant awards are not made to any foundation donors.

II. Compliance Program

A compliance program was introduced to the Oversight Committee at the December 5, 2012 meeting. (See Compliance Officer report, December 5, 2012). Senate Bill 149 requires the Institute to establish a compliance program "to assess and ensure compliance by the Institute's committee members and employees with applicable laws,

rules, and policies". Implementation of the program has taken place over the past nine (9) months. A discussion of the implementation follows.

a. Risk Assessment

We worked with Grant Thornton to perform a top to bottom risk assessment of the Institute. A prior risk assessment was completed shortly after the agency was created. That risk assessment was limited in scope to the grant application process and early operational processes. Now that the agency has been in operation for several years and has over 400 grant awards, a more comprehensive risk assessment is required for enterprise risk management and the compliance program.

At the end of May an online risk survey was sent to a select group of people (sampling of Oversight Committee members, agency staff, peer reviewers and grantees). We had very good participation—21 surveys were distributed with 16 responses. Participants were asked to select the top 15 risks for the agency out of a list of 44 risks. Additionally, participants were asked to propose actions that would mitigate and control each of the 44 risks. Following the survey other factors impacting these risks were considered and weighted to better inform us of the current risk environment. At the end of September, risk owners and responsible parties were identified for the 19 highest risks.

Next steps in the risk assessment project are the development of risk mitigation, monitoring and management plans for the highest risks. These plans form the basis for the risk owner(s) to track, monitor and control and report on the status and effectiveness of each risk response action. The plans are a key component to the Monitoring, Compliance Reporting, and Auditing element of a comprehensive compliance program.

Follow-up risk assessment should be performed annually as the risk environment changes thereby ensuring current risks are carefully monitored and controlled.

i. Grant Monitoring Program

Within the risk areas for the Institute is grantee performance and grant monitoring. Senate Bill 149 requires the Institute to continuously monitor and ensure that each grant recipient complies with the terms and conditions of the grant contract. A brochure describing the compliance monitoring program was developed by the Compliance Officer. This brochure describes the grant monitoring program which includes desk-reviews, on-site visits and programmatic reviews. CGMS, the electronic grants management system is being programmed to notify the grantee of report due dates, track the dates on which grant recipient reports are due and received by the Institute, and provide the ability to generate reports to determine compliance with these requirements. Additionally, grantee progress reports have been revised to include compliance elements.

b. Training & Education

Another element of a comprehensive compliance program is training and education. During the general staff meeting held in July, the Institute's Code of Conduct and Ethics was introduced to the agency staff. Commencing on September 23, 2013, an agency wide monthly compliance training program began with an in depth discussion of the Code of Conduct and Ethics Policy. The training session was recorded therefore any Institute staff unable to attend can receive the training online. Additionally, the Compliance Officer drafted a policy for consideration by the Interim Executive Director to make the monthly 60 minute compliance training sessions mandatory for all staff. Moreover, monthly compliance training should become a performance measure in the employee's annual performance evaluation.

Finally, July also saw the start of weekly compliance tips to all Institute staff. These compliance tips focus on daily business operations and other important compliance information keeping the Compliance Program relevant and timely.

c. Other Compliance Program Elements

Other elements in a comprehensive compliance program include: Monitoring, Compliance Reporting, and Auditing, Enforcement and Discipline, Response and Prevention, and Effectiveness Evaluations. Monitoring, Compliance Reporting, and Auditing were briefly discussed in Risk Assessment above. Response and Prevention along with Enforcement and Discipline go hand-in-hand. Information has been obtained from various vendors to establish an anonymous reporting Hotline to encourage reporting of violations of Institute processes and procedures or the Code of Conduct and Ethics Policy and activate a response plan. Institute employees have signed annual certification of compliance statements. In addition, employee disclosure forms are available to report outside employment or charitable service or ownership/investment interest that could create a conflict of interest.

A compliance program is only effective if it is followed. Therefore Effectiveness Evaluations are critical to evaluating the success of the program. Effectiveness questions have been developed and provided to the Interim Executive Director to assess and report on the compliance program.

d. Compliance Manual

The Compliance Officer establishes the compliance structure and documents the policies and procedures that pertain to the compliance program. A manual provides implementation guidance and should detail the responsibilities of the Chief Compliance Officer to the Institute, include policies and procedures that pertain to the compliance program (including anonymous reporting policies and procedures), and include examples of monitoring and reporting plans. The manual is a compilation of relevant materials maintained in an electronic format. The structure of the Institute's compliance

manual has been created by the Compliance Officer along with the responsibilities of the Chief Compliance Officer. As monitoring plans are established and Institute policies and procedures revised, these should be incorporated into the compliance manual for implementation guidance. The Compliance Manual should be reviewed annually and updated as required.

III. Other Compliance Activities

a. Reconciliation

Earlier this year the Institute began a reconciliation period for all grantees to achieve compliance with all required reports. It was identified that grantees were behind in progress reports and financial status reports. Timely reports are critical for measuring the grantee performance and achieving financial certainty for the Institute. There was a tremendous response by grantees to this opportunity. The Chief Operating Officer will provide the details of the reconciliation.

b. RFA Development

The Compliance Officer has worked with the Chief Scientific Officer and the Chief Prevention officer to include additional financial disclosure requirements by the grant applicant including all sources of funding, as well as, loss of funding prior to the end of the award for any reason. The additional financial disclosure will enhance conflict of interest identification and financial stability of the applicant.

IV. Conclusion

This concludes my report to the Oversight Committee.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

April 16, 2013

Chief of Staff David Erinakes
Representative Dan Flynn
Texas Capitol, Room GN.7
Austin, Texas 78701

Dear David:

Thank you for allowing us to provide this additional information to your committee.

Question

On April 10, 2013, you provided us with a list of selected donors to the CPRIT Foundation (Attachment 1) and asked if any CPRIT award monies were 1) a direct award to any of the donors or 2) where the donor also invested in a project in which CPRIT gave an award.

Process

CPRIT staff reviewed the grant applications for 417 grant awards. A grant application (that can be upwards of 300 pages or more) consists of several parts. Two components are "budget and justification" and "current and pending support." In the "budget and justification" the applicant lists any sub-contractors and consultants that may be used in the project if known at the time of application. The "current and pending support" identifies other sources of funding supporting the principal investigator or collaborators. The applicant also states whether these sources of funding "overlap" with the application request to CPRIT. Planning Award (\$25,000) applications, which were offered in FY2010, requested only a general budget summary and justification. Product development award applications require a business plan that includes "current and pending support" and "budget and justification." It was determined that these areas of the application provide the most relevant information, if any, relating to the selected donors. Therefore, we reviewed those identified areas of the grant application for any "matches" with the selected donor list.

Results

The review documented that the researchers enjoy a wide variety of sources of funding for their laboratories and projects. Sources of funding include government organizations (National Institutes of Health; US Army/Department of Defense), private organizations (Juvenile Diabetes Research Foundation; Golfers Against Cancer) and corporate support (AstraZeneca; Circadian Technologies Limited) to identify a few. Following the process described above, none of the donors on the selected donor list provided by your office invested in a project in which CPRIT gave an award.

Additionally, CPRIT has not made any awards to the donors identified on the selected donor list.

Please let me know if you need any additional information or clarification.

Sincerely,

A handwritten signature in dark ink, appearing to read "Wayne R. Roberts". The signature is fluid and cursive, with a large initial "W" and a stylized "R".

Wayne R. Roberts
Interim Executive Director

Attachment

Donor	
O'Donnell Foundation	\$1,600,000
Eisai Inc.	200,000
Novartis Pharmaceuticals Corp.	185,000
Amgen USA	135,000
Genentech USA	135,000
Pfizer, Inc.	110,000
Charles Tate	60,000
Southwestern Medical Foundation	52,500
Eli Lilly and Company	50,000
Texas A&M University HSC Foundation	37,500
Vinson & Elkins LLP	37,000
Texas Tech University System - Foundation	35,000
Texas Tech University System Foundation	35,000
The Methodist Hospital System - Foundation	35,000
Barry G. Andrews	35,000
Daiichii Sankyo, Inc.	35,000
Mary Crowley Cancer Foundation	35,000
Astellas USA Foundation	30,000
Texas A&M Foundation	30,000
Serafy Foundation	30,000
Texas Tech System Admin. Foundation	30,000
Joseph S. Bailes	27,500
Thomas Kaplan	27,500
James M. Mansour (in kind)	27,323
University of Houston Foundation	25,000
Dee Kelly	25,000
UNT Health Science Center Foundation	22,500

MEMORANDUM

TO: Wayne Roberts
Billy Hamilton
Heidi McConnell
Kristen Doyle

FROM: Patricia Vojack

DATE: April 22, 2013

SUBJECT: CPRIT Foundation Donor Match

Introduction

The General Appropriations Act (GAA) permits salary supplements for exempt positions—the Executive Director and the Chief Scientific Officer of the CPRIT “because of the particular requirements of directing the administrative and scientific affairs of the Institute.” *See 82nd Leg., General Appropriations Act, Rider 4, page I-18.* However, the GAA prohibits “an individual, an organization, or an employee, officer or director of an organization that makes a contribution to the foundation, or person who is second-degree consanguinity or affinity to an employee of the Institute” from receiving a grant from the Institute. *Id.* CPRIT must ensure compliance with the law.

Process

An updated donor list was received from the CPRIT Foundation on January 17, 2013. *See* Appendix A. Institutional/corporate/foundation donors were matched against the grant award data contained in the CPRIT electronic grants management system (CGMS). Grantee assistance was required to determine compliance with the GAA and individual donors to the CPRIT Foundation. A list of all authorized signing officials (“ASO”) [the ASO has institutional authority to legally bind the institution in grants administration matters] for each grant awarded was obtained from SRA, International, the third-party grants manager for the Institute. Each ASO was contacted to verify email address, to introduce the donor match project and gain cooperation in the execution of the project. An email was sent to all ASOs with a spreadsheet of individual CPRIT Foundation donors. Each grantee organization was asked “to search (first and last name and address) for any matches to your institution’s officers, directors and employees” and report any matches to the Institute. Grantee organizations were asked to report “no matches” as well. *See* Appendix B.

Results

Sixty-six (66) ASOs were contacted and all have responded to this compliance request. Five (5) individual CPRIT Foundation donors were identified as an “employee, officer or director” of a grantee. *See* Appendix C. No institutional/corporate/foundation donors were matched with the data in CGMS.

Recommendation

To achieve compliance with the GAA, I recommend these individual donor matches be communicated to the CPRIT Foundation with a request that the Foundation return the donor’s money and confirm to CPRIT the return of the donations.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

April 22, 2013

Ms. Jennifer Stevens
Executive Director
CPRIT Foundation
P.O. Box 12631
Austin, TX 78711

RE: Foundation Donors

Dear Ms. Stevens :

Our review of individual CPRIT Foundation donors with grantee recipient organizations in compliance with the *General Appropriations Act, 82nd Leg.* (GAA) has concluded. The following individuals were identified by grantee recipient organizations as an officer, director or employee:

Malcolm Gillis
C.W. Duncan
Roger Staubach
Al Gilman
Bill Gimson

The GAA prohibits “an individual, an organization, or an employee, officer or director of an organization that makes a contribution to the foundation, or person who is second-degree consanguinity or affinity to an employee of the Institute” from receiving a grant from the Institute. To be in compliance with the rider requires the return of any identified donor’s money. We request that you return the donor’s money and copy us on the donor correspondence. Thank you for your immediate attention to this matter. Should you have any questions, please contact Patricia Vojack, Compliance Officer at 512-305-8453 or pvojack@cprit.state.tx.us.

Sincerely,

Wayne R. Roberts

cc: Patricia Vojack
Kristen Doyle

MEMORANDUM

TO: Wayne Roberts
Kristen Doyle

FROM: Patricia Vojack

DATE: May 2, 2013

SUBJECT: CPRIT Foundation Donor Funds

The following individuals gave donations to the CPRIT Foundation (Foundation):

Name	Donation Date	Organization	Amount
C.W. Duncan	10.16.2012	Methodist Hosp. Board	\$500.00
Malcolm Gillis	4.30.2009	Rice University	\$1,000.00
Alfred Gilman	8.22.2012	CTNet Board	\$3,000.00
Bill Gimson	10.16.2009	CTNet Board	\$3,000.00
Bill Gimson	12.30.2010	CTNet Board	\$3,000.00
Bill Gimson	12.10.2011	CTNet Board	\$3,000.00
Roger Staubach	12.19.2011	Cooper Institute Board	\$500.00
TOTAL:			\$14,000.00

It is assumed for the purposes of this memo that the donations are unrestricted donations.

The pertinent section of Rider 4, General Appropriations Act, 82nd Legislature states:

An individual, an organization, or an employee, officer or director of an organization that makes a contribution to the foundation...is not eligible to receive grants from the Institute.

A simple analysis is to match the individual donor to the organization receiving a grant award and if there is a relationship declare that to be a “match” for purposes of the rider.

Another analysis, slightly more laborious would be to match names and donation dates in relation to grant award dates. A donation to the Foundation made after the grant was awarded appears not to be prohibited by the rider. However, the organization would be precluded from receiving future awards as long as the matched donor remains associated with the organization.

Prior to CPRIT matching donors and organizations, the Foundation performed its own match and returned funds to the donors based on its findings. It is unknown whether the Foundation matched solely by organization affiliation or considered dates of donations and dates of grant awards.

The Institute's Code of Ethics and Conduct, currently under consideration by the Oversight Committee, requires the Institute to operate in "a manner that promotes and preserves public trust, proper stewardship, and confidence in the integrity of the Institute and be guided by the basic principles of loyalty, prudence, honesty and fairness in conducting CPRIT's affairs."

As a values-based ethical culture and in light of the controversy surrounding the CPRIT Foundation and its relationship with CPRIT, I recommend simply directing the Foundation to return the funds to the identified donors, regardless of donation or award dates. Going forward, and in proposed legislation pending before the 83rd Legislature, the Institute shall match donors at the time of application and at the times of award thereby addressing the concerns of impropriety.



CANCER PREVENTION &
RESEARCH INSTITUTE OF TEXAS

January 31, 2013

MEMORANDUM

TO: Wayne Roberts, Executive Director

FROM: Billy Hamilton

SUBJECT: Review of CPRIT Grants Subject to Current Moratorium

As part of my agreement with the Cancer Prevention and Research Institute of Texas (CPRIT), I have completed a review of the CPRIT grant applications currently subject to moratorium and am providing you with this report of the findings along with recommendations for action subject to the agency's review and approval.

Methodology

A total of 129 research and prevention grant applications were presented to the Oversight Committee in two slates during Oversight Committee meetings on August 2, 2012, and December 5, 2012. In addition, 31 recruitment grant applications were presented at the two meetings. The applications presented on the two slates are classified as follows:

	Aug. 2, 2012	Amount	Dec. 5, 2012	Amount
Research	8 (43 projects)	\$40,328,201	64 ¹	\$55,113,647
Prevention	14	\$16,202,596	0	\$0
Commercialization	0	\$0	0	\$0

¹ Since the December meeting, one grantee declined the award thereby reducing the total grants to 63 for the sum of \$54,983,859.

In addition there were 20 researcher recruitment proposals presented in August and 11 in December.

	Aug. 2, 2012	Amount	Dec. 5, 2012	Amount
Research Recruitment ²	20	\$53,392,800	11	\$29,946,750

These grant applications were reviewed by the Compliance Officer using detailed information on the process followed for each application based on information contained in the database maintained by SRA, the CPRIT grants contractor. This detailed information tracks each step in the grant application review and approval process. The cumulative information on the steps taken by the applicants and review committee at each point in the process forms what is known as the application's "pedigree" The methodology followed by the Compliance Officer was to check and verify each step in the grant process to determine whether all steps had been followed according to CPRIT applicable state law, agency rules, the applicable Request for Applications (RFA) and CPRIT's *Policy and Procedures Guide: CPRIT Applications and Funding Awards*. The Compliance Officer also reviewed backup documentation maintained either by CPRIT or SRA where necessary.

The recruitment grants presented a special issue, since they are designed to attract high-quality researchers to Texas. They have a special urgency because the individuals identified may be lost by further delays. The recruitment grants are a continuous review and award notification program. The Scientific Review Council considers these grant applications at their scheduled telephone conference and make recommendations to the Executive Director. There is not a written formal process for review of these grants applications.

In addition to the review by the Compliance Officer, Dr. Margaret Kripke, the Chief Scientific Officer, and Dr. Becky Garcia, the Chief Prevention Officer, reviewed their respective grant application program recommendations to identify any specific questions associated with each application. Dr. Kripke, of course, had no involvement in the grant application or scientific review process. Dr. Garcia oversaw the original grant application and review process for prevention grants, but in my judgment, the prevention grants program has been free of past problems identified by CPRIT or by the State Auditor's Office, and the slate presented on August 5 was no exception.

Validity of Process Followed

As part of the review, consideration was given to whether the results of the grant application review process had been subject to overt or unintended influence exerted either by individual members of the Review Committees or by CPRIT employees. This was evaluated using the best available information and information from staff who attended the meetings.

It is important to note that the process of using an independent outside observer was not implemented until May 2012. The observers monitor the face-to-face meetings and phone conferences of the peer review committees and report any anomalies. The independent observers were present for the May 14-17,

² Since the awards were announced in August and December, several Recruit recipients declined the award (other grant funding, decided not to relocate, etc.). The total recruit awards as of the date of this report are: 25 for the sum of: \$71,839,550.

2012 peer review of the Prevention grant applications. However, the process was not in place during the February peer review of the Research grant applications. The December 5 slate did include the use of the independent observers (Grant Thornton in this case). The observations of the independent monitors were presented to the Oversight Committee at its December meeting prior to ratification of the slates. The process of using external independent observers will be used for subsequent reviews.

Within the limits of the evidence available, we have tried to verify the integrity of the review process for both slates. Where the question of possible undue influence is concerned, there is nothing questionable to report based on the available record, from the monitor reports or from recollections of staff who were present at the meetings.

Results of the Review

Both Dr. Kripke and Dr. Garcia verify that, within the limits of their review, appropriate steps were taken in the grant process, and that the grants represent valid candidates for funding by CPRIT based on the priorities established by agency policy and state law.

In her attached report, the Compliance Officer concludes that each of the grant applications followed the CPRIT statute, rules, guidelines and applicable RFA with one exception—application RP120848.

RP120848 is a research project application that was part of a multi-investigator research application (MIRA) that was submitted in response to a MIRA RFA in FY 2012, Cycle 2. In general terms, this means that it was part of grant application specifically requesting applications from several researchers bundled in a single application.

The MIRA application in question, which incorporated a total of eight (8) individual proposed projects, did not receive a fundable score during the initial review stage, which involves a review by two or three reviewers. This means that the composite score assigned by the reviewers did not reach the level for funding consideration. As a result, neither the MIRA application nor the individual project was discussed at the face-to-face peer review committee and no peer review member advanced this application for discussion at the meeting on February 16-17, 2012. It has been the practice of the CPRIT Research Program to consider individual research projects that are part of a MIRA application for an Individual Investigator Research Award when an individual research project is deemed meritorious but contained within an otherwise weak MIRA application that would not otherwise be funded.

In the review of the MIRA applications for FY2012, Cycle 2, there were five (5) Individual Investigator Awards recommended in this manner. As the Scientific Review Council chair wrote, in recommendations to the Executive Director, “these were strong projects that were pulled out of otherwise weak Multi-Investigator Research Awards.” RP120848 was not one of those recommended awards. CPRIT rules, *Guidelines* and the MIRA RFA do not provide notice of this type of award consideration. The National Cancer Institute (NCI) has a similar process of identifying promising individual research projects, however, the NCI instructs the individual researcher to submit an application for an award during an open Individual Research Award program notice, and therefore the award and funding are tied to an appropriate award program.

Subsequent to the peer review meeting, the Scientific Review Council met to consider the recommendations from the peer review committees. Following the conclusion of the meeting by the

Scientific Review Council and its recommendations of grant awards to the CPRIT Executive Director, the principle investigator of an individual project in RP120848 made a request for individual funding consideration. In this regard, RP120848 was a clear deviation from prescribed CPRIT practices and presents concerns that should not be ignored.

Insofar as the available documentation shows, RP120848 was not discussed at the peer review meeting or at the Scientific Review Council meeting on March 16, 2012. There are no documents showing Scientific Review Committee recommendation to the Executive Director.

Further detailed review of CPRIT and SRA records reveals an email request for individual project consideration and funding by one of the project's principle investigators. The Chief Scientific Officer coordinated review and approval with a few scientific reviewers via email, but this was not consistent with the established peer review process. The project was included in the final slate presented to the Oversight Committee on August 2, 2012. The Oversight Committee approved the slate, and a contract was under negotiation at the time the moratorium was announced.

Findings

1. Both the slate presented on August 2, 2012, and the slate presented on December 5, 2012, followed the approved process with the exception of RF120848 described above.
2. There is no evidence of any effort to manipulate the grant process for either slate.
3. With the sole exception described above, the process worked as intended, and you can have reasonable confidence that both slates represent valid research and prevention projects that meet the standards for CPRIT funding.
4. Grant application RP120848 did not follow the approved grant process for reasons that cannot be definitely established.
5. Individual Investigator Research Awards were recommended from a MIRA RFA.
6. The overall process is sound but future problems could be avoided by implementing certain checks and balances that have not been applied to date.

Recruitment grant applications do not have a written formal process for review.

Recommendations

1. All of the individuals involved in this review recommend that all of the grant applications on the two slates of August 2, 2012, and December 5, 2012, be released from the moratorium and allowed to proceed to the development of final agreements with one exception—RP120848.
2. The approval of RP120848 did not follow the approved process and should be rejected. It should be emphasized that there is no apparent problem with this proposal, and it could be resubmitted in a future Request for Application and considered without prejudice.
3. The current monitoring of Review Committee meetings by an independent outside monitor should continue.

4. In the future, the Compliance Officer should certify that each grant application in a slate has followed all required steps in the application and approval process, and a slate should not be presented to the Oversight Committee without the Compliance Officer's certification. Slates lacking this certification should be rejected without exception.
5. MIRA grant proposals should not be separated into individual components for grant awards unless the rules and/or statutes governing the process are specifically amended to allow this process as a valid part of the approval process.
6. In Dr. Kripke's review of the Recruitment Award program, she should establish a transparent written review process and evaluation criteria for this award.

Again, there is no evidence that the two slates should not be released from the current hold and proceed normally through the process.

Prioritization

After consultation with the Compliance Officer, the Chief Scientific Officer and the Chief Prevention Officer, I believe prioritization of the frozen grants would present a particular problem and should be avoided if at all possible. It is very difficult to prioritize these projects in a way that is both meaningful and fair to the applicants. It is difficult, if not impossible, to prioritize which research projects, for example, have the greatest potential value to the State due to the nature of the research process itself. It is also difficult to decide which of the grants represent the greatest hardship to the institution or individual researchers based on the information available.

In the event that a prioritization of projects becomes necessary, the key guiding factors should be:

1. The priorities established in the Health and Safety Code provisions for CPRIT, which are specified in Section 102.252:

“(2) the executive director shall submit to the oversight committee a list of grant applications that is substantially based on the list submitted by the committee under Subdivision (1) and, to the extent possible, gives priority to proposals 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;

(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;

(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; and

(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.

2. A first-in-first out approach that recognizes that the August slate has been pending several months longer than the December slate.
3. Priority could be given to the recruitment grants, since they represent opportunities to bring outstanding cancer experts to Texas, and that opportunity may be lost due to unnecessary delay.

I would like to thank CPRIT's Compliance Officer, Patricia Vojack; Chief Scientific Officer, Dr. Margaret Kripke; and Chief Prevention Officer, Dr. Becky Garcia for the time and effort that went into this review within the allotted time frame. I also appreciate their review and input on this report. They did an exceptional job, and what we learned from this review will go a long way to insuring future grant application processes work effectively and equitably for all concerned.

If you have questions or need further information, please me know.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

TO: Wayne Roberts
Billy Hamilton

FROM: Patricia Vojack

DATE: June 25, 2013

SUBJECT: Verification of Process of Prior Grant Awards

Summary and Conclusion:

Following the certification of the August and December 2012 grant awards, I was directed to verify compliance of prior grant awards with statutory grant award processes. There is no complete single source of documentation to confirm review and recommendation for each of the grant awards. Therefore, a variety of documents and sources of documents were utilized. Within the limitations of the information available from a variety of sources and the fact this verification is occurring, with certain grant awards, at least three (3) years after the award has been made, the prior grant awards followed the statute for the procedure for making awards and the rules issued by the Oversight Committee regarding the procedure for awarding grants to an applicant.

Process

Verification of the previously awarded grants followed the requirements set forth in statute for the grant award procedure and the rules issued by the Oversight Committee regarding the procedure for awarding grants to an applicant. *See* Subchapter F. Procedure for Making Awards, 102.251 *et seq.* Health & Safety Code and 25 TAC 703. The verification spanned several months utilizing many resources including the Prevention program staff, SRA, our third-party grant manager, and IT staff for forensic email recovery. A pedigree for each program/award type was designed to document the statutory and rule required processes for grant awards. Subsequently, a process documentation pedigree was completed for each of the 399 grants. These pedigrees were initiated by SRA, the third party grant administrator and then provided to CPRIT for further process documentation. I reviewed every pedigree for compliance with statutory and rule requirements and to address any missing or conflicting information. A variety of sources of information were utilized to document processes including emails from current and former employees and peer reviewers, memos, spreadsheets, minutes, and PowerPoint presentations.

Brief Discussion

Since CPRIT's inception, processes have continued to evolve as the programs became more mature. Extensive legislative changes were enacted with the passage of SB 149 that will further impact the grant award process. The Institute has been working continuously to implement these changes. This memo does not discuss any recommendations as a result of this verification. Recommendations are being discussed with Institute staff in the implementation of SB 149. I do want to note, however, certain information relating to some of the grant award programs that I became aware of during this review that provides context to this verification process.

Recruits Awards

The Recruit grant award process consisted of a continuous request for application—meaning applications were accepted throughout the fiscal year and not limited to a certain period. A single notice was published in the Texas Register on September 11, 2009 announcing this continuous award. The application was submitted via the online application system and subsequently reviewed and discussed by the Scientific Review Council. There is no complete single source of documentation to confirm review and recommendation of the recruits therefore verification of review and recommendation is obtained from a variety of sources including meeting minutes, emails, and spreadsheets maintained by SRA, former employees and peer reviewers. Additionally, Recruits were either reviewed during regularly scheduled telephone conferences or via email communication.

MIRAs

MIRAs are submitted as a single collaborative proposal comprising several individual project components. Therefore, the verification of these grant awards is of the single collaborative proposal and not the individual project.

Prevention Grants

Matching funds are not required for Prevention Awards. The statute requires matching funds for cancer research awards.

The 13 earliest Prevention awards were “grandfathered” from the prior Texas Cancer Council. The awards were approved by the Oversight Committee approval at the August 14, 2008 meeting.

Pedigrees

As described above, a pedigree was completed for each of the 399 prior grant awards. Upon reviewing each of these pedigrees, where I noted information was missing or deviated from certain dates or deadlines, I created a spreadsheet of these grant awards and verified compliance with the statute and rules through further review of prior documentation. Attached is a spreadsheet of the grant awards requiring additional information and the resolution of my inquiry.

Attachment: Verification Questions



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHIEF COMPLIANCE OFFICER

General Position Summary

The Chief Compliance Officer (CCO) is responsible for performing highly advanced managerial work providing direction and guidance in compliance strategy and planning of a \$3 billion cancer research and prevention award program. The CCO should develop and implement a compliance program pursuant to V.T.C.A., Health and Safety Code, Section 102.263. The CCO will report directly to the Chief Executive Officer, but have independent reporting authority to the CPRIT Oversight Committee and relevant subcommittees.

The CCO must be able to work in a large mainframe grant award proprietary computer system. The CCO works under general supervision with significant latitude for use of initiative and independent judgment. The CCO must be customer service oriented and be able to interact professionally in a personable manner with individuals at all levels of state government and private companies.

Salary Range: \$109,601 - \$180,842/year

Closing Date: October 31, 2013, 5:00 p.m.

Agency Description

In November 2007, Texas voters approved Proposition 15, the constitutional amendment that allows the State of Texas to issue \$3 billion in general obligation bonds to fund grants for cancer research and prevention. HB 14 in 2007 created the Institute and authorized the agency to award grant funds to address its constitutional mission through August 31, 2020.

The vision for the Institute is to become a world-class leader in cancer research and prevention by collaborating with all who are committed to the war on cancer. The Institute invests in cancer research, product development, prevention and ancillary activities. The Institute will enhance the potential for medical and scientific breakthroughs in cancer prevention, detection and treatment, and develop high quality jobs in Texas. The investment of \$3 billion of state funds and any other funds received are strategically allocated to fund projects and research infrastructure that add value to current efforts and resources as well as spur new opportunities.

The Institute is governed by an Oversight Committee consisting of nine members who are appointed by the Governor, Lieutenant Governor, and the Speaker of the House.

The Institute presently occupies leased space in downtown Austin, Texas.

GENERAL QUALIFICATION REQUIREMENTS:

Experience

Seven (7) or more years of experience in Texas state government required. Demonstrated experience working with program compliance, policies and procedures at a State of Texas agency or institution of higher education, as defined by V.T.C.A., Education Code Section 61.003.

Education

Bachelor's degree is required. An advanced degree in business administration, public administration or law is required.

Knowledge and Abilities

Knowledge of local, state and federal laws and regulations relevant to compliance/quality assurance programs. Ability to direct and organize program activities; establish strategic compliance plan and goals and objectives; identify problems; evaluate alternatives; implement effective solutions; coordinate, develop and evaluate policies and procedures; prepare reports; communicate effectively; and supervise the work of others.

EXAMPLES OF WORK PERFORMED

Implement and direct the statutorily required compliance program.

Review, evaluate and monitor CPRIT's grant award policies and procedures for compliance and reports findings regularly to CPRIT leadership, including the Oversight Committee.

Publicly certify that the grant review process complies with agency statute and rules.

Train CPRIT employees and Oversight Committee members regarding compliance with the laws and rules governing the peer review process and conflicts of interest.

Monitor grant recipients' compliance with the terms of grant contracts, including the status of required reports.

Oversee CPRIT's activities related to the report and investigation of suspected compliance violations.

Attend and observe meetings of CPRIT grant review panels to document compliance with agency statute and regulations.

Identify potential areas of compliance vulnerability and risk; recommend corrective action plans for resolution of issues, and recommends general guidance on how to avoid or deal with similar situations in the future.

Develop, establish, and implement goals and objectives that are consistent with and support overall agency strategies; plans, develops, and approve schedules, priorities, and standards for achieving goals; and develop and implement techniques for evaluating compliance program activities.

May report to the state legislature regarding compliance program activities and recommend proposed legislation.

May represent the agency at business meetings, hearings, legislative sessions, conferences, and seminars or on boards, panels, and committees.

Review results of special investigations, internal audits, research studies, forecasts, and modeling exercises to provide direction and guidance.

Review all documents and other information that are relevant to compliance activities.

Develop and coordinate a multifaceted educational and training program for agency staff and the Oversight Committee that focuses on the elements of the compliance program, and seeks to ensure that all appropriate employees and management are knowledgeable of, and comply with, pertinent federal and state standards.

Develop quarterly performance status reports for the Chief Executive Officer and executive staff with findings and recommendations as necessary.

Develop process or performance improvement plan for all deficient performance elements.

Perform other duties as assigned.

Application Instructions

If you meet the qualifications, complete and submit a State of Texas application to Cancer Prevention and Research Institute of Texas, Human Resources, P.O. Box 12097, Austin, Texas 78711. State of Texas application may be obtained from <http://www.cprit.state.tx.us/about-cprit/cprit-employment-opportunities>.

All resumes must be accompanied by a fully completed state of Texas application. Incomplete applications may be disqualified at the agency's discretion.

Faxed and emailed applications will not be accepted.

Non-smoking office and building.

The Cancer Prevention & Research Institute of Texas is an equal opportunity employer.

Additional information regarding the Institute's history and operations can be found on the agency's web site at www.cprit.state.tx.us.

The Oversight Committee has been sent the Attorney-Client privileged communication related to this item separately.