Cancer Prevention & Research Institute of Texas

Oversight Committee Meeting

August 17, 2016

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

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

August 17, 2016
10:00 a.m.

The Oversight Committee may discuss or take action regarding any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purpose permitted by the Act. Anyone wishing to offer public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the May 18 and May 19 meetings **TAB 1**
4. Public Comment*
5. Chief Executive Officer Report **TAB 2**
6. Chief Scientific Officer Report and Grant Award Recommendations **TAB 3**
7. Chief Prevention and Communications Officer Report and Grant Award Recommendations **TAB 4**
8. Chief Product Development Officer Report **TAB 5**
9. Scientific Research and Prevention Program Committee Appointments **TAB 6**
10. FY 2017 Honoraria Policy **TAB 7**
11. Health & Safety Code Section 102.1062 Waivers **TAB 8**
12. Proposed Amendments to 25 T.A.C. Chapters 701 - 703 **TAB 9**
13. Internal Auditor Report **TAB 10**
    - Internal Audit Follow-Up Procedures Over Prior Year Grant Management Findings
    - Internal Audit Report Over Commodity and Service Contract
14. Chief Operating Officer Report **TAB 11**
15. Contract Approvals **TAB 12**
    - Economic Assessment of Cost of Cancer in Texas
    - Due Diligence Services
    - Strategic Communications
    - Outside Legal Services
16. Subcommittee Business **TAB 13**
    - Diversity Subcommittee
    - Charter Amendments for Prevention, Product Development, Scientific Research, and Audit Subcommittees
17. Chief Compliance Officer Report **TAB 14**
18. FY 2017 Program Priorities Process **TAB 15**
19. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
20. Consultation with General Counsel
21. Future Meeting Dates and Agenda Items **TAB 16**
22. Adjourn

Summary Overview of the August 17, 2016, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the August 17, 2016, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including a personnel update, 2017 Oversight Committee Program Priorities, the upcoming September 14 special meeting, American Cancer Society Cancer Action Networks events, and a report on the grant funds available for FY 2016.

Chief Scientific Officer Report and Grant Award Recommendations
Dr. James Willson will provide an update on the Academic Research Program and present the Program Integration Committee's award recommendations for Core Facilities, Multi Investigator, and First-Time, Tenure-Track Faculty recruitment grants.

Information related to the Academic Research grant applications recommended for funding will not be publicly disclosed until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention and Communications Officer Report and Grant Award Recommendations
Dr. Becky Garcia will give a report regarding the Prevention Program activities as well as an update on the agency's communications activities. Dr. Garcia will also present the Program Integration Committee's award recommendations for Prevention Program grants.

Information related to the Prevention grant applications recommended for funding will not be publicly disclosed until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Product Development Officer Report
Michael Lang will provide a Product Development Research Program update.

Scientific Research and Prevention Programs Committee Appointments
The Chief Executive Officer has provisionally appointed 17 new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendations before the appointment is final. Biographical sketches for the appointees are included in the board packet.

Health and Safety Code § 102.1062 FY 2017 Waivers
Health & Safety Code § 102.1062 "Exceptional Circumstances Requiring Participation" provides a process for the Oversight Committee to consider and approve a waiver of statutory conflicts of

interest for individuals involved in the grant review or award process. The waivers may be renewed annually. Mr. Roberts proposes a waiver for FY 2017 for the following individuals: Donald Brandy, CPRIT Purchaser and HUB Coordinator; Dr. Becky Garcia, CPRIT's Chief Prevention Officer; Dr. John Hellerstedt, Program Integration Committee member; Amy Mitchell, Oversight Committee member; and Will Montgomery, Oversight Committee member. In order to approve the waivers, the Oversight Committee must find that exceptional circumstances justify the conflicted individual's participation in the review process. The proposed waivers include limitations and other protections in place to mitigate the opportunity for the award of grant funds to be affected by anything other than merit and established criteria.

Proposed Changes to Agency Administrative Rules
Ms. Doyle will present proposed changes to the agency's administrative rules. Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. A summary is provided for the 53 proposed changes affecting 27 administrative rules. These rule changes will be brought back to the Oversight Committee for final approval in November after the public has an opportunity to comment on the proposed rule changes.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide a status report on CPRIT's outsourced internal audit services and present an internal audit report on commodity and service contracts and a report on follow up procedures over prior year grant management findings.

Chief Operating Officer Report
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the third quarter of FY 2016. Ms. McConnell will also present a status update on CPRIT's Legislative Appropriations Request for the FY 2018 – 2019 biennium, which was submitted to the Texas Legislature and the Governor on August 5, 2016.

Contract Approvals
Ms. McConnell will present a recommendation for the approval of the following four service contracts for FY 2017:

- Due Diligence Services with ICON Clinical Research
- Economic Assessment of the Cost of Cancer in Texas with The Perryman Group
- Outside Legal Services with Yudell Isidore
- Strategic Communication Program Services with Hahn Public Communications

Subcommittee Business
Dr. Cynthia Mulrow will present the Diversity Subcommittee's recommendation to consider transferring the responsibilities of the Diversity Subcommittee to other standing subcommittees. Should the Oversight Committee approve the recommendation, the Oversight Committee will consider amendments to the charters for the Prevention, Product Development Research, Scientific Research and Audit subcommittees that recognize the new responsibilities.

Chief Compliance Officer Report
Vince Burgess will report on the status of required grantee reports, financial status report reviews, annual grantee certifications, desk reviews and site visits as well as grantee training and technical assistance.

FY 2017 Program Priorities Process
Health and Safety Code Chapter 102 requires CPRIT's Oversight Committee to establish program priorities on an annual basis. Mr. Roberts and Dr. Garcia will lead the discussion regarding the steps and timeline of activities necessary for the review and approval of the 2017 Program Priorities.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting
May 18, 2016

1. Call to Order

A quorum being present, Presiding Officer Geren called the Oversight Committee to order at 10:07 a.m.

2. Roll Call/Excused Absences

Committee Members Present:
Pete Geren
Ned Holmes
Donald (Dee) Margo
Will Montgomery
Cynthia Mulrow, M.D.
Amy Mitchell
Bill Rice, M.D.
Craig Rosenfeld, M.D.

Committee Members Absent:
Angelos Angelou

3. Adoption of Minutes from the February 17, 2016, meeting (Tab 1)

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the minutes of the February 18, 2016, Oversight Committee meeting.

4. Public Comment

Presiding Officer Geren noted there were no requests for public comment.

5. Chief Executive Officer Report (Tab 2)

Mr. Wayne Roberts, Chief Executive Officer, introduced new CPRIT staff: Gerald Green, Grant Accountant and Adriane Natal, Executive Assistant.

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Mr. Roberts stated that action items from the February 2016 Oversight Committee meeting are discussed in his memo in the meeting materials. Additionally the Oversight Committee Workshop to discuss program priorities is scheduled for May 19, 2016.

Each year in September, the Texas Tribune hosts Tribfest to explore and discuss issues regarding state and national politics. This year, Dr. James Willson, Chief Scientific Officer, has been invited to participate on a panel discussion on cancer, along with Lance Armstrong and Dr. Ronald DePinho, President of The University of Texas M.D. Anderson Cancer Center. It will be an opportunity to promote CPRIT's work.

Mr. Roberts briefly discussed CPRIT's 2016 Customer Service Survey results compared to 2014. He noted that survey results show CPRIT has improved in all service areas.

In response to a question from the Oversight Committee regarding who the agency's customers are, Mr. Roberts stated the citizens of Texas, who created the agency and the Legislature who represents them. However, CPRIT grantees and grant applicants are the people that CPRIT interacts with on a daily basis and are the ones the surveys were sent to for the Customer Service Survey.

Mr. Roberts noted that the information presented in his report on Grant Funds Available includes reference to awards in the Academic Research Program which have been deferred by the Program Integration Committee to the August 2016 Oversight Committee meeting in anticipation of receiving additional recruitment awards.

Presiding Officer Geren thanked Dr. Bill Rice for committing an extraordinary amount of time, in addition to his other duties as an Oversight Committee member, in helping to prepare strategic planning information for the Oversight Committee to consider at the workshop on May 19, 2016.

6. Chief Scientific Officer Report and Grant Award Recommendations (Tab 3)

Dr. James Willson, Chief Scientific Officer, reported on the 220 applications reviewed by the Scientific Review Council panels over the past quarter, stating that 27 grant proposals and 6 recruitment awards were before the Oversight Committee for approval. The mechanisms included in the recommendations are: Core Facilities Support Awards (CFSAs); High-Impact/High-Risk Research Awards (HIHRs); Multi-Investigator Research Awards (MIRAs); and Recruitment of First-Time, Tenure-Track Faculty Members (RFTs). The recommendations address a broad range of Oversight Committee priorities, which are shown in the tables below.

Core Facilities awards are instrumental in providing enabling resources technology for modern cancer research as well as access to innovative therapeutics The awards can be up $6 million over a five-year period. Four CFSAs are recommended today.

In response to an Oversight Committee member question, Dr. Willson stated that all CFSAs presented are strong examples of cross utilization and leveraging of core resources for

investigators in other institutions, which shows these awards will not just impact one individual institution but several. When asked if that could be measured, Dr. Willson responded in the affirmative saying the metrics would be subsequent publications and peer reviewed grants.

An Oversight Committee member asked if the monies given to core facilities could be used to support other research activities of the facility. Dr. Willson stated that the applicants reviewed by the Scientific Review Council are asked to document precisely the percent of utilization on cancer and the direct benefit on the cancer community. The information is carried forward in the annual reports submitted by the grantees.

When asked if core facilities are limited to university investigators or is open to industry investigators, Dr. Willson stated that the resources presented are directed primarily to the academic community and do not specifically propose interactions with industry at this time. He said, in his experience, when other CPRIT grantees asked to use core facilities, the requests were handled on a case-by-case basis with consideration given to the mutual benefit derived by each entity.

Dr. Willson then presented the High-Impact/High-Risk awards, stating they are a maximum of $200,000 over two years for creative ideas that are thoughtful ideas but require preliminary data prior to getting more conventional support from other resources. Of the 151 applications that were reviewed by peer review panels, 21 are being recommended for funding. Two-thirds of HIHRs recommended today are to applicants' institutions that are not in the top five of CPRIT grantees historically, showing the impact this mechanism is having in encouraging applications for institutions that have been less successful in receiving CPRIT awards. Eleven of the 21 applications specifically address Oversight Committee priorities, including computational biology and pediatric cancers.

Multi-investigator research awards are a maximum of $7,500,000 over five years and bring together investigators with complementary expertise, within an institution and/or across Texas institutions. Criteria for these projects include both the expectation of making a significant paradigm shift in addressing a particular cancer problem and the demonstration that there is real integration across the investigators involved. Of the 31 applications reviewed, two are recommended for approval today. Both address lung cancer and are led by investigators at The University of Texas M.D. Anderson Cancer Center as well as involving investigators across institutions.

An Oversight Committee member asked which four awards that were referred to in the meeting materials as addressing the priority "cancers of particular importance to Texas." Dr. Willson responded that the two multi-investigator awards led by M.D. Anderson Cancer Center and two core facility awards coming from The University of Texas at Austin and The University of Texas at San Antonio Health Science Center. In response to a question regarding how the applications are scored, Dr. Willson responded that on a scale of 1 to 9, a score of 1 was exceptional and a score of 9 was unacceptable.

Dr. Willson stated that six individuals are being recruited as First-Time, Tenure-Track Faculty Members. Their areas of study include: childhood brain cancer, pancreatic cancer, the relationship between the microbial environment and cancer in human bodies, melanoma, and advanced microscopy for examining cancer cells.

In summary, the Program Integration Committee recommended 33 applications totaling $45,346,968:

	Grant Type	Total
4	Core Facilities	$19,743,232
21	High Impact/High Risk	$ 4,193,354
2	Multi-Investigator	$10,587,315
6	First Time Tenure Track Faculty Recruitment	$10,823,067
33	**Total**	**$45,346,968**

#	Program Priorities Addressed by Grant Recommendations*
21	A broad range of innovative, investigator-initiated research projects
3	Prevention and early detection
2	Computational biology and analytic methods
9	Rare and intractable cancers, including childhood cancers
4	Population disparities and cancers of importance in Texas
6	Recruit outstanding cancer researchers to Texas
4	Enhance Texas' research capacity and life science infrastructure (priority across programs)

* One recommendation may address more than one program priority

FY 2016 Academic Research funding to date (does not include May awards) – $109,410,850

Special Notes: The PIC elected to defer seven grant award recommendations totaling $37,801,614 for consideration at the August 17 Oversight Committee meeting.

Academic Research Grant Award Recommendations

App ID	Mechanism	Organization/ Company	Application Title	Budget
RP160657	CFSA	The University of Texas at Austin	Targeted Therapeutic Drug Discovery & Development Program	$4,982,636
RP160716	CFSA	The University of Texas Health Science Center at San Antonio	Texas Pediatric Patient Derived Xenograft Facility	$5,079,843

App ID	Mechanism	Organization/ Company	Application Title	Budget
RP160732	CFSA	The University of Texas Health Science Center at San Antonio	UTHSCSA Cancer Genome Sequencing and Computation Core	$3,680,756
RP160805	CFSA	Baylor College of Medicine	Preclinical Candidate Discovery Core	$5,999,997
RP160704	HIHR	The University of Texas at Austin	High affinity therapeutic mimotope antibodies to the oncogenic Epidermal Growth Factor Receptor	$200,000
RP160713	HIHR	The University of Texas Southwestern Medical Center	Amino Acid Sensing: Directing Cell Growth through mTORC1	$198,983
RP160739	HIHR	The University of Texas M. D. Anderson Cancer Center	Targeting Histone Acetylation Readers in MLL-translocated Leukemias	$200,000
RP160763	HIHR	The University of Texas Health Science Center at Houston	Targeting multiple myeloma stem cell niche	$200,000
RP160765	HIHR	Texas A&M University System Health Science Center	An unlikely therapeutic target for malignant bone disease: Dkk-1 activates a stress resistance mechanism in bone tumor cells	$200,000
RP160770	HIHR	The University of Texas at Dallas	Optical opening of blood-brain barrier for brain tumor drug delivery by plasmonic nanobubbles	$200,000
RP160775	HIHR	The University of Texas Health Science Center at Houston	Becoming fatter to survive: cancer cells increase lipid storage to counter metabolic stress	$200,000
RP160776	HIHR	The University of Texas at Austin	Rapid Molecular Diagnosis of Lung Cancer Biopsies by Ambient Ionization Mass Spectrometry	$200,000
RP160795	HIHR	Baylor College of Medicine	A “Pap smear” for ovarian cancer	$200,000
RP160806	HIHR	Texas Tech University	Development of high throughput technology to identify drugs for muscle wasting during cancer	$199,995

App ID	Mechanism	Organization/ Company	Application Title	Budget
RP160813	HIHR	Acelerox	Nanoparticle Prophylaxis for Protection from Chemotherapy Ototoxicity	$195,665
RP160819	HIHR	Texas AgriLife Research	Quantitative mapping of intracellular protein- protein interactomes in healthy and cancerous cells	$198,753
RP160822	HIHR	Texas AgriLife Research	Exploring Geminivirus-encoded suppressor of histone methyltransferases as an anti-cancer drug	$199,958
RP160827	HIHR	Texas A&M University System Health Science Center	A platform technology for the isolation of anti- cancer monoclonal antibodies from chickens	$200,000
RP160834	HIHR	Texas A&M University	Integrated-cavity-enhanced pre-screening for lung cancer	$200,000
RP160841	HIHR	The University of Texas Health Science Center at San Antonio	Targeting EWS-FLI-1 for degradation	$200,000
RP160842	HIHR	Texas A&M University System Health Science Center	Novel roles for NIK in high-grade glioma: regulation of mitochondrial dynamics to control cell migration and invasion	$200,000
RP160847	HIHR	Texas A&M Engineering Experiment Station	A Body Coil for MR Imaging and Spectroscopy of Cancer at 7 Tesla	$200,000
RP160852	HIHR	Texas State University - San Marcos	Chemo-preventive Approach to Cancer Exploiting a Presumptive Link between Genomic Instability and Structural Stability of non-B DNA Sequences	$200,000
RP160866	HIHR	The University of Texas at Dallas	Renal Clearable Nanodelivery System for Triple Negative Breast Cancer Therapy	$200,000
RP160884	HIHR	Baylor College of Medicine	RNA processing stress: a new therapeutic entry point in triple-negative breast cancer	$200,000

App ID	Mechanism	Organization/ Company	Application Title	Budget
RP160652	MIRA	The University of Texas M. D. Anderson Cancer Center	Defining and Defeating Mechanistic Subtypes of KRAS-mutant Lung Cancers	$5,981,040**
RP160668	MIRA	The University of Texas M. D. Anderson Cancer Center	Pathogenesis and Early Progression of Lung Cancer	$4,606,275*

*RP160668 - The peer review panel recommended the deletion of Project 4 from the MIRA application. As a result, the funds dedicated to that project were removed from the budget for a revised total of $5,757,844. The final score was based on revised scope with the deletion of Project 4. The PIC further reduced the budget of this application by 20%, which is reflected in the above table.
**RP160652 - The PIC reduced the budget of this application by 20%, which is reflected in the above table.

CFSA = Core Facilities Support Awards
HIHR = High-Impact/High-Risk Research Awards
MIRA = Multi-Investigator Research Awards

Academic Research Recruitment Grant Award Recommendations Cycle 16.8

App ID	Mechanism	Candidate	Organization	Budget
RR160047	RFT	Omid Veiseh	Rice University	$2,000,000
RR160048	RFT	Lydia Finley	The University of Texas Southwestern Medical Center	$2,000,000
RR160053	RFT	Mark Pellegrino	The University of Texas at Arlington	$823,067

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

Academic Research Recruitment Grant Award Recommendations Cycle 16.9

App ID	Mechanism	Candidate	Organization	Budget
RR160055	RFT	Charles Kaufman	The University of Texas Southwestern Medical Center	$ 2,000,000
RR160057	RFT	Reto Fiolka	The University of Texas Southwestern Medical Center	$ 2,000,000
RR160062	RFT	Myron Ignatius	The University of Texas Health Science Center at San Antonio	$ 2,000,000

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

COMPLIANCE CERTIFICATION

Mr. Vince Burgess, Chief Compliance Officer, presented his certification report on the review process for the all proposed grant awards being recommended to the Oversight Committee at this meeting, including: Recruitment of First-Time, Tenure-Track Faculty Members; Core Facilities Support Awards; High-Impact, High-Risk Awards; Multi-Investigator Research Awards; and New Company Product Development Awards.

A prohibition against communications begins when an application is submitted until the final determination of the award. Pursuant to Texas Administrative Code, Section 702.19, Mr. Roberts granted Michael Lang, Chief Product Development Officer, a waiver from the general prohibition against communicating with grant applicants for two product development awards being considered today. The waiver allowed Mr. Lang to discuss possible reductions in the applicants' budgets and neither applicant was given an unfair advantage because they had already been recommended by the Product Development Review Council to the Program Integration Committee.

Mr. Burgess certified that the review process for the applications being recommended awards complied with applicable statutory and administrative requirements for the four academic research award slates and the one product development research award slate being presented for approval at this meeting.

CONFLICT OF INTEREST NOTIFICATIONS

Presiding Officer Geren noted that there were no reported conflicts of interest for the members present. However, Mr. Angelou, who was not present, had reported a conflict of interest with applications RP160657, RP160704, and RP160776 submitted by The University of Texas at Austin.

MOTION:

On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendation for four Core Facility Support grant awards.

MOTION:

On a motion made by Mr. Montgomery and seconded by Dr. Mulrow, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendation for twenty-one High-Impact/High-Risk grant awards.

MOTION:

On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendation for two Multi-Investigator Research awards submitted by The University of Texas M.D. Anderson Cancer Center.

MOTION:

On a motion made by Mr. Montgomery and seconded by Ms. Mitchell, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations for First Time-Tenure Track-Recruitment Awards submitted by:

- Rice University;
- The University of Texas Southwestern Medical Center;
- The University of Texas at Arlington; and
- The University of Texas Health Science Center at San Antonio.

An Oversight Committee member asked what the chances are of the recruitments actually accepting the offer, and Dr. Willson responded that historically 25 percent would decline for various reasons. Among the First-Time, Tenure-Track recruits, there is historically a higher percentage of acceptance.

MOTION:

On a motion made by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the delegation of contract negotiation authority to the Chief Executive Officer and CPRIT staff, and authorized the Chief Executive Officer to sign the contracts on behalf of CPRIT.

7. Chief Product Development Officer Report, Grant Award Recommendations (Tab 4)

Mr. Michael Lang, Chief Product Development Officer, presented his program review:

- **Review Cycle 16.1** – 25 applications were received and reviewed, 12 were selected for presentation, and ultimately 2 were selected by the Product Development Review Committee and were recommended for approval.
- **Review Cycle 16.2** – 32 applications were received and reviewed, 13 were selected for presentation at the May 10-12 Peer Review meeting, and recommendations are expected to be presented at the Oversight Committee in August, 2016.
- **Peer Review Process** – the Product Development Review Council made recommendations for improving the due diligence process and staff is working with CPRIT's third-party due diligence provider to improve some specific information they provide.
- **Requests for Application (RFAs)** – the Product Development RFA is being updated to incorporate Product Development Review Council and Oversight Committee changes:
    - Highlighting CPRIT interest in funding all sectors that impact cancer care (therapeutics, diagnostics, devices, etc);
    - Objective criteria defining Texas location;
    - Streamlining investment policy to focus on preclinical and Phase I and IIA stages of development; and
    - Trying an investment policy to avoid multiple awards to the same firms.

When asked why the emphasis on locating in Texas, Mr. Lang stated that while there had been no problems, it was sometimes difficult to determine where employees were based if a company needed to maintain a presence in their original location after moving to Texas or when employees were classified as telecommuting. He also stated that occasionally a company needed a service that could not be procured in Texas. Ensuring that actual employees are physically located in Texas is important.

When asked why a firm might ask for another grant from CPRIT, he stated it could be to produce a drug for which CPRIT had previously provided development funding; or after receiving funding to develop a drug for one disease, the company wants funding to develop another drug for a different disease.

Mr. Lang presented the two Product Development Research grant award recommendations.

- Salarius Pharmaceuticals is developing a small molecule targeted at two cancers: Ewing's Sarcoma, a rare pediatric bone cancer, and prostate cancer. The company will be relocating to Houston upon award.
- Pelican Therapeutics is continuing to develop a drug for several types of cancer, including lymphoma, lung, prostate, pancreatic and ovarian cancer.

Mr. Lang noted that Mr. Roberts granted him a waiver so he could engage with Salarius Pharmaceuticals and Pelican Therapeutics regarding their budgets. In both cases, budget reductions were made based on the progress the companies had achieved since submission of their applications, which reduced the funding needed.

The Product Development Review Council also required a pre-contract contingency for both companies regarding their Freedom to Operate opinions, a legal opinion by a third party on whether their technologies infringe upon other technologies. They currently have clean opinions, but the opinions are several years old and need to be updated before grant approval. These updates are being addressed.

Mr. Lang stated that Dr. Rosenfeld is recommending another pre-contract contingency to confirm that the Product Development Review Council has reviewed the companies' pharmacokinetics reports and is accepting of them.

In response to questioning, Mr. Lang stated that Salarius is planning to relocate to Houston and Pelican is relocating to Austin.

In response to another question, Mr. Lang stated that, if approved, Salarius and Pelican would have standard revenue sharing terms based on a royalty return. Ms. Doyle clarified that all CPRIT award contracts, whether academic research or product development, include a standard revenue sharing agreement revenue sharing agreement appropriate to the program. Any revenue sharing agreement other than the standard agreement must be approved by the Oversight Committee.

Mr. Lang responded to a question about the reason for reducing the budgets by stating that because a significant amount of time had passed between the submission of the companies' applications and their review, each project had accomplished some activities that were originally included in the grant request amounts, resulting in a decreased need for funding. For Salarius the reduction is approximately $200,000, and for Pelican the reduction is approximately $2.7 million.

Product Development Research Grant Award Recommendations

App ID	Company Name	Project	Maximum Requested Budget
DP160014	Salarius Pharmaceuticals	Developing Epigenetic Drugs that treat Rare Pediatric Cancers	$18,893,395 REVISED BY OC: $18,688,144
DP160012	Pelican Therapeutics	Developing Killer T cell therapy for multiple cancers	$17,940,143 REVISED BY OC: $15,245,222

These recommendations are subject to the company's acceptance of certain contract contingencies and/or additional goals and objectives. Presiding Officer Geren noted that Mr. Burgess had previously certified these awards, and that no Oversight Committee members reported conflicts of interest.

MOTION:

On a motion made by Dr. Mulrow and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations for Salarius Pharmaceuticals and Pelican Therapeutics with revised budget amounts as recommended by the Chief Product Development Officer. The revised budget amount for Salarius is $18,688,144. The revised budget amount for Pelican is $15,245,222.

MOTION:

On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the delegation of contract negotiation authority to the Chief Executive Officer and CPRIT staff, and authorized the Chief Executive Officer to sign the contracts on behalf of CPRIT.

MOTION:

On a motion made by Mr. Margo and seconded by Mr. Holmes, the Oversight Committee unanimously voted, pursuant to the General Appropriations Act, Article IX, Section 4.03(a), to authorize CPRIT to disburse grant funds via advance payments to Salarius Pharmaceuticals and Pelican Therapeutics upon execution of the award contract and the successful completion of tranches.

8. Chief Prevention and Communications Officer Report (Tab 5)

Dr. Rebecca Garcia, Chief Prevention and Communications Officer, gave a report of the following items.

Prevention Update

- **FY 2016 Cycle 2 Prevention Applications under Review** – 6 Requests for Applications were released on September 24, 2015. Forty-four applications were received by March 3, 2016, more than doubling the number of applications received the previous cycle, which was a direct result of staff visits to several parts of the state to encourage applications. Assignments to peer reviewers have been made and the review meeting will be held May 23-25 in Dallas.
- **FY 2017 Cycle 1 Requests for Prevention Applications** – Requests for Applications will be released in May 2016, with applications due by August 30. Recommendations are expected to go before the Oversight Committee for consideration in February 2017.
- **Other Activities** - As a result of the March quarterly reports, this is the first time the Prevention Program can claim that at some point in the program's history, people in every county have had a direct service. A complete redesign of the grantee quarterly reports is underway with SRA, CPRIT's grant management contractor. Also, staff can now run reports about projects in individual counties.

An Oversight Committee member requested that a report on projects by legislative district by county be sent to legislators at least once a year.

Communications Update

- **Halfway Point Press Briefing** – Held on May 17, 2106 and resulted in an interview with the Houston Chronicle and other key publications.
- **Grants Awards Announcements** – Resulted in 5 articles featuring CPRIT and 47 additional articles mentioning CPRIT.
- **Significance Project Survey** – After testing the survey on a small number of grantees, a revised survey was sent to a larger group of grantees with a May 5 deadline for responses.
- **2017 Conference** – Planning has begun with the selection of Swift Solutions to provide meeting planning services.
- **Website Redesign** – Request for Proposal was issued and responses are being considered.

9. Scientific Research and Prevention Program Committee Appointments (Tab 6)

Mr. Roberts presented the appointments to the Scientific Research and the Prevention Program Review Committees. He stated that 2 appointments were for the Product Development peer review panels, 7 to the Prevention peer review panels, and 6 to the Academic Research peer review panels.

MOTION:

On a motion made by Mr. Holmes and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the Scientific Research and Prevention Program Committee appointments.

10. Health & Safety Code Section 102.1062 Waiver (Tab 7)

Mr. Roberts presented a conflict of interest waiver for Dr. Rebecca Garcia, pursuant to Texas Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Dr. Garcia has accepted an appointment to the advisory committee serving the Texas Health Improvement Network (THIN), a statutorily created program that is administratively attached to The University of Texas System. The waiver is necessary for Dr. Garcia to participate in the Program Integration Committee review process. The waiver will stipulate that Dr. Garcia must recuse herself from any discussion, review or vote if:

- THIN submits an application for a CPRIT grant award; or
- A principal investigator applying for CPRIT funds has also received funds from THIN for the same project.

MOTION:

On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the proposed Health & Safety Code Section 102.1062 waiver for Dr. Rebecca Garcia.

11. Chief Operating Officer Report (Tab 8)

Ms. Heidi McConnell, Chief Operating Officer, presented a report on the agency's draft state Strategic Plan for 2018-19 biennium. She stated there are no major changes being requested in the current budget structure but changes are being requested to the performance measures. In addition to a revision to one of the prevention measures, staff is requesting that one of the compliance performance measures be struck because of the difficulty of collecting the data and replaced with a new compliance measure. These changes have been submitted for approval to the Legislative Budget Board and Governor's Office of Budget, Planning and Policy. The Oversight Committee will not have to approve the final Strategic Plan, but the plan will require an approval signature from the Presiding Officer.

Ms. McConnell then presented information regarding the agency's Legislative Appropriations Request for the 2018-19 biennium. While instructions for preparing the request have not yet been released by the Legislative Budget Board, staff anticipates having to submit the document in early August prior to the next quarterly Oversight Committee meeting. Ms. McConnell requested provisional approval from the Oversight Committee of the appropriations request based on the information presented in the meeting book. Possible requested changes would be:

- An increase of three full-time equivalent (FTE) positions to provide additional support in compliance and grant accounting.
- Addition of a new rider to appropriate any bond premiums earned above the bond proceed amounts to pay issuance costs of the bonds.
- Deletion of Rider 5, which transfers funds to the Department of State Health Services to fund the Texas Cancer Registry.
- Deletion of Rider 7, which requires Legislative Budget Board approval for all contracts in excess of $250,000.
- An increase in the cap on the Chief Executive Officer's exempt salary amount.
- An Interest & Sinking Fund exemption from funds consolidation.

Ms. McConnell was asked whether the increase in FTEs was in addition to the personnel provided through the CohnReznick contract to assist in the compliance function. She responded that if the three FTEs were approved, the grantee desk review and on-site monitoring functions performed by CohnReznick would be transitioned to CPRIT employees when the positions were filled.

Ms. McConnell clarified that if the Audit Subcommittee's review of the final draft indicates a material inconsistency with what has been discussed today, the Legislative Appropriations Request would be added to the agenda of a special Oversight Committee meeting.

MOTION:

On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to authorize the Presiding Officer to sign a final draft of the Strategic Plan and approval transmittal to the appropriate offices.

MOTION:

On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to provisionally approve the draft Legislative Appropriations Request, subject to final review for consistency by the Audit Subcommittee of the CPRIT Oversight Committee.

12. Grant Management Support Services Contract (Tab 9)

Ms. McConnell presented the staff recommendation that the Oversight Committee provisionally approve a contract of up to $10 million for grant management support services. The estimated cost of the contract is based on an existing contract providing a similar scope of services. The contract costs will be based on time and materials provided by the chosen vendor so CPRIT would only pay for actual services received from the vendor. The posted Request for Proposal allows for four one-year renewal options which would bring the total value of the contract to approximately $50 million, should they all be exercised.

Since the contract will need to be effective September 1, 2016, to have continuity of services, staff is requesting provisional Oversight Committee approval of the contract pending final review for consistency by the Audit Subcommittee. Ms. McConnell clarified

that if the Audit Subcommittee's review of contract indicates a material inconsistency with what has been discussed today, the contract would be added to the agenda of a special Oversight Committee meeting.

MOTION:

On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to provisionally approve a contract of up to $10 million for grant management support services subject to final review by the Audit Subcommittee of the CPRIT Oversight Committee.

13. FY 2017 Bond Issuance Resolution (Tab 10)

Ms. McConnell presented the staff recommendation that the Oversight Committee approve the resolution found in the Oversight Committee meeting materials requesting the Texas Public Finance Authority to issue debt on behalf of CPRIT in fiscal year 2017. The amount to be financed is $300 million in bond proceeds appropriated to CPRIT for its operations and prevention and research grant awards.

Ms. McConnell and Mr. Roberts responded to a question about how monies would need to be expended in the final years of CPRIT operation. Ms. McConnell stated that since the Legislature did not appropriate $300 million in bond proceeds during the first two years of operation and because there was a moratorium on grant awards in 2013, the agency will have money to expend for operations during the sunset process. Also, the agency cannot make grants during the final year before sunset, as set by statute. Mr. Roberts added that the sunset legislation would make provisions for any grants still in progress at the time of sunset, either by transferring the responsibilities to another entity yet to be identified, or retaining a small CPRIT staff for the purpose of grant monitoring and compliance.

MOTION:

On a motion made by Mr. Montgomery and seconded by Dr. Mulrow, the Oversight Committee unanimously voted to approve the fiscal year 2017 request for financing resolution.

14. Chief Compliance Officer Report (Tab 11)

Mr. Vince Burgess, Chief Compliance Officer, presented his report, including:

- Delinquent/Missing Reports have continued to decrease.
  - 6,800 reports are submitted annually, averaging 570 reports per month. The number of delinquent/missing reports typically averages about 5 – 15 during any given week.

- Training/Technical Assistance – staff conducted the following training:
  - New grantee training for Coastal Bend Wellness Center in Corpus Christi
  - Grantee training interactive webinar for more than 300 grantee staff

- Presented "Being a CPRIT Grantee: What You Need to Know" at the National Council of University Research Administrators (NCURA) Region V meeting in Dallas.

15. Compliance Support Services Contract (Tab 12)

Mr. Burgess presented the staff recommendation to exercise the second, one-year renewal option on the contract with CohnReznik for $500,800 to provide compliance monitoring support services in FY 2017. In CPRIT's 2017 compliance monitoring plan, CohnReznick will perform approximately 100 desk reviews and 30 on-site monitoring reviews of grant recipients. They also support the annual risk assessment process and development of the annual grant compliance monitoring plan.

The contract will require approval from the Legislative Budget Board.

MOTION:

On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve a contract renewal with CohnReznick for compliance monitoring services in fiscal year 2017.

16. Internal Auditor Report (Tab 13)

Ms. Alyssa Martin from Weaver and Tidwell, LLP, external providers of internal audit services to CPRIT, presented the planned timing of the audits and follow up procedures included in the 2016 Internal Audit Plan approved by the Oversight Committee in November 2015.

2016 Audits to Be Performed

- Commodity and Services Contracts, May 2-18
- Revenue, June 20-July 1
- Information Security, July 11-22
- Cash Management, July 25-August 5

2016 Follow-up Procedures of Prior Audit Findings

- Information Technology, May 30-June 3
- Pre-Award Grant Management, Post Award Grant Management, Grant Contracting, June 1-10

2016 Annual Internal Audit Requirement

- Project Management, Ongoing
- Risk Assessment Update, Late August
- Annual and Quarterly Oversight Committee Reports, Ongoing

17. Final Orders Approving Amendments to 25 T.A.C. Chapters 702 and 703 (Tab 14)

Ms. Kristen Doyle presented the proposed administrative rule changes to Chapters 702 and 703, originally considered by the Oversight Committee in February 2016, for final adoption. CPRIT received comments from one grantee institution regarding the proposed changes after publication of the proposed rule changes in the *Texas Register*. The comment inquired about the process for requesting an appeal of funds in which reimbursement was waived. This question is procedural and will be explained through instructions to all grantees; therefore, CPRIT legal staff recommended that the Oversight Committee adopt the rule changes as originally proposed. Once the Oversight Committee approves the final orders, CPRIT will submit the proposed rule changes to the Secretary of State and the changes will be finally adopted 20 days after that date.

- Rule § 702.11 "Conflicts of Interest Requiring Recusal" - The proposed amendment clarifies that serving as a consultant or contractor for a grant applicant constitutes a professional conflict of interest. This additional description fills a gap that currently exists.

- Rule § 703.12(b)(1) "Limitation on Use of Funds" – The change adds visa fees to the expenses that are not authorized to be reimbursed by CPRIT grant funds.

- Rule § 703.21(b)(2) – The amendment adds an appeal process if a grantee's reimbursement of project expenses is waived by CPRIT. A grantee waives reimbursement for otherwise allowable expenses incurred in a fiscal quarter if the grantee fails to submit a financial status report within 120 days after the end of the fiscal quarter. The proposed process allows the grantee to appeal the waiver of reimbursement. The grantee's appeal must be in writing and submitted to the CEO through CPRIT's electronic grant management system. The CEO's decision to approve the appeal and reverse the waiver is final. However, after discussion with the Board Governance subcommittee, the proposed rule reflects the grantee's option to seek reconsideration from the Oversight Committee if the CEO denies the grantee's appeal. The grantee must submit a written request to the CEO within 10 days. If at least three Oversight Committee members agree, the Oversight Committee will consider the grantee's appeal at an open meeting. The Oversight Committee's decision is final.

MOTION:

On a motion made by Mr. Montgomery and seconded by Dr. Mulrow, the Oversight Committee unanimously voted to approve the final order adopting CPRIT's rule changes and to direct staff to file the order with the Secretary of State.

18. Subcommittee Business (Tab 15) *(Agenda Item 19 – taken out of order)*

Mr. Roberts stated that the subcommittee report was in the Oversight Committee meeting book. One significant item for Oversight Committee consideration was that of transferring the responsibilities of the Diversity Subcommittee to the Academic Research, Product

Development Research, Prevention, and Audit subcommittees. CPRIT staff recommends, and Diversity Subcommittee members concur, that Diversity issues are important and could best be considered by all Oversight Committee members through their participation in one or more of the three main program subcommittees. These issues include increasing participation by individuals from groups historically underrepresented in science and medicine, geographic and population services and dispersion of awards, agency employment practices, and state-mandated Historically Underutilized Business vendor requirements. The Diversity Subcommittee members have requested feedback for consideration at the subcommittee's August meeting.

Mr. Roberts responded to a question about the process for making and implementing this change by saying that he will be directing the Chief Operating Officer, Chief Scientific Officer, Chief Product Development Officer and Chief Prevention and Communication Officer to discuss this issue with the subcommittee they each support.

A question was asked whether there will still be a cohesive element if diversity issues are spread among the subcommittees. Mr. Roberts said it will require some changes to the charges to the individual subcommittees, but each one of the subcommittees has a main staff liaison. To emphasize the importance of the issue, Mr. Roberts himself was the liaison for the Diversity Subcommittee. However, Mr. Roberts also participates in each of the individual subcommittees and will continue to be the lead spokesperson on these issues.

Closed Session

Presiding Officer Geren announced the Oversight Committee would go into closed session to take up Agenda Item 18, Personnel – Chief Executive Officer in closed session. He noted for the record that standing Agenda Item 20 – Compliance Investigation Pursuant to Health & Safety Code § 102.2631, and Agenda Item 21 – Consultation with General Counsel, would not be taken up as there was nothing to discuss.

Pursuant to Texas Open Meetings Act Section 551.074, the Oversight Committee went into closed session to discuss personnel matters related to the Chief Executive Officer evaluation. The following CPRIT staff were asked to join the Oversight Committee in the closed session: Kristen Doyle, General Counsel.

Presiding Officer Geren convened in closed session at 12:53 p.m.

Presiding Officer Geren reconvened the open meeting at 2:40 p.m.

19. Personnel – Chief Executive Officer *(Agenda Item 18 – taken out of order)*

MOTION:

On a motion made by Dr. Rice and seconded by Mr. Holmes, the Oversight Committee unanimously voted to authorize an increase in the base salary of the Chief Executive Officer's annual salary to the legislative authorized amount of $256,250.

Presiding Officer Geren stated that in Agenda Item 11, in the discussion of the Legislative Appropriations Request, there was a request for an increase in the Chief Executive Officer's exempt salary in the Administrator's Statement. He requested a motion to insert in that statement a specific percentage increase.

MOTION:

On a motion made by Mr. Montgomery and seconded by Mr. Holmes, the Oversight Committee unanimously voted to amend the language in the Legislative Appropriations Request Administrator's Statement to say "an increase of 10 percent in the Chief Executive Officer's exempt salary."

20. Future Meeting Dates and Agenda Items *(Agenda Item 22)*

Presiding Officer Geren announced the next regular Oversight Committee meeting is August 17, 2016, at 10:00 a.m. He noted that a meeting on September 14, 2016, has been added to the Oversight Committee Meeting schedule.

21. Adjourn *(Agenda Item 23)*

MOTION:

There being no further business, the Oversight Committee unanimously approved a motion to adjourn made by Presiding Officer Geren and seconded by Mr. Montgomery.

Meeting adjourned at 2:43 p.m.

_____ _____

Signature Date

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Workshop Meeting
May 19, 2016

1. Call to Order

A quorum being present, Presiding Officer Geren, called the Oversight Committee Workshop to order at 9:00 a.m.

2. Roll Call/Excused Absences

Committee Members Present:
Angelos Angelou
Pete Geren
Ned Holmes
Donald (Dee) Margo
Amy Mitchell
Will Montgomery
Bill Rice, M.D.
Craig Rosenfeld, M.D.

Committee Members Absent:
Cynthia Mulrow, M.D.

MOTION:
On a motion made by Ms. Mitchell and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to excuse the absence of Dr. Mulrow from the May 19, 2016, Oversight Committee Workshop meeting.

3. Work Session Overview

Mr. Wayne Roberts, Chief Executive Officer opened the work session stating that the discussion would provide the basis for more in-depth discussions by the Oversight Committee subcommittees during the upcoming months. Some of the discussions may the groundwork for future Oversight Committee meetings. Topics for the work session are:

- The draft Strategic Plan and receive Oversight Committee guidance for future planning;
- Investment options for the two research programs; and
- Priorities across the three programs.

4. Strategic Planning

Dr. Bill Rice presented a draft agency strategic plan outlining the proposed path of the agency, programmatically and operationally, over the next five years and in preparation for the statutory Sunset process. This plan is distinct from the strategic plan the agency is required to submit as part of the state budget planning process.

After discussion, Presiding Officer Geren asked that the revised draft be presented to the Oversight Committee at a future meeting.

5. Oversight Committee Program Priorities and Program Funding

Mr. Michael Lang, Chief Product Development Officer presented an overview of the Texas research and development landscape, current program funding, and the Program Priorities.

After discussion of the program priorities, Presiding Officer Geren asked that the discussion be incorporated into the priorities document and be presented to the Oversight Committee for approval.

Presiding Officer Geren also asked that staff develop a funding plan based on the work shop discussion, which could then be approved by the Oversight Committee at a future meeting.

6. Adjourn

Presiding Officer Geren adjourned the meeting at 12:00 pm.

_____ _____

Signature Date

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 5, CHIEF EXECUTIVE OFFICER REPORT
DATE:	AUGUST 10, 2016

As of this writing the Chief Executive Officer Report for the August 17, 2016, Oversight Committee (OC) will consist of the following items:

- Personnel update, including introduction of new staff
- 2017 OC Program Priorities
- September 14, 2016, Special Oversight Committee Meeting
- American Cancer Society Cancer Action Network Events
- Report on "FY 2016 Grant Award Funds Available" (see following attachment)

In addition, for your reference, copies of the CPRIT Activities Updates for June and July previously provided to you are included at the end of this tab. These are the reports provided to you in months in which the Oversight Committee does not meet.

Other topics may be added as warranted.

*****

CPRIT has awarded **1,033** grants totaling **$1.575 billion**

- 158 prevention awards totaling $155.4 million
- 875 academic research and product development research awards totaling $1.420 billion

Of the $1.420 billion in academic research and product development awards,

- 30.1% of the funding ($427.1 million) supports clinical research projects
- 27.3% of the funding ($387.4 million) supports translational research projects
- 24.3% of funding ($345.0 million) supports recruitment awards
- 15.2% of the funding ($216.4 million) supports discovery stage research projects
- 3.1% of funding ($44.4 million) supports training programs.

CPRIT has 13 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Academic Research
- 2 Product Development Research
- 5 Prevention

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FY 2016 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / PD Research	Prevention Percentage Based on Available Award Appropriations	Operating Budget	Total Appropriations
Available Appropriated Funds	**$ 28,325,035**	**$ 254,925,317**		**$ 16,749,648**	**$ 300,000,000**
Unexpended Bond Proceeds Carry Forward		**$ -**			**$ -**
Unexpended Balance Carry Forward		**$ -**			
Approved Adjustment to Operating Costs		**$ (621,952)**		**$ 621,952**	
Appropriations Transfer to DSHS		**$ (2,969,554)**		**$ 2,969,554**	
Adjusted Appropriations	**$ 28,325,035**	**$ 251,333,811**		**$ 20,341,154**	**$ 300,000,000**
Total Available for All Grants			**$ 279,658,846**		
Calculated 10% for Prevention Grants of Total Available Grant Funding			**$ 27,965,885**		
Adjustment for 10% Prevention Grants Limit	**(359,150)**	**$ 359,150**			
Adjustment to Address Avg Prev Historical Limi	**(924,530)**	**$ 924,530**			
Revised Adjusted Appropriations	**$ 27,041,355**	**$ 252,617,491**		**$ 20,341,154**	**$ 300,000,000**
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	**$ 27,041,355**	**$ 252,617,491**			**$ 279,658,846**
Announced Grant Awards					
9/10/15 Rsch Recruitment Awards		$ 17,700,000			
11/19/15 Rsch Recruitment Awards		$ 16,000,000			
11/19/15 Rsch Awards-IIRA		$ 34,744,442			
11/19/15 Rsch Training		$ 14,966,408			
11/19/15 PD Awards		$ 20,000,000			
11/19/15 Prevention Awards	$ 13,247,742				
2/17/16 Rsch Recruitment Awards (w/withdrawals)		$ 26,000,000			
5/18/2016 Rsch Core Facility Awards	$ -	$ 19,743,232			
5/18/16 Rsch Awards-HIHR	$ -	$ 4,193,354			
5/18/16 Rsch Awards-MIRA	$ -	$ 10,587,315			
5/18/16 Rsch Recruitment Awards	$ -	$ 10,823,067			
5/18/16 PD Rsch Awards		$ 33,913,939			
Announced Grant Award Subtotal	**$ 13,247,742**	**$ 208,671,757**	$ -		**$ 221,919,499**
Grant Award Adjustments					
Declined Recruit Award (UTSW) 2/2016 Slate		$ (2,000,000)			$ (2,000,000)
Declined Recruit Award (UTSW) 5/2016 Slate		$ (2,000,000)			$ (2,000,000)
Adjustment to IIRA Grant (UTMDA) 2/2016 Slate		$ (10,292)			$ (10,292)
Revised Grant Award Subtotal	**$ 13,247,742**	**$ 204,661,465**			**$ 217,909,207**
Adjusted Available Funds Post May 2016	**$ 13,793,613**	**$ 47,956,026**			**$ 61,749,639**
Prevention Grants	$ 13,690,454				
Academic Research Grants		$ 47,801,615			
Pending Award Subtotal	**$ 13,690,454**	**$ 47,801,615**			**$ 61,492,069**
Total Potential Grant Funding Committed	**$ 26,938,196**	**$ 252,463,080**			**$ 279,401,276**
Available Funds as of June 15, 2016	**$ 103,159**	**$ 154,411**			**$ 257,570**

Operating Budget Detail	
Indirect Administration	$ 3,003,133
Grant Review & Award Operations	$ 14,368,467
Subtotal, CPRIT Operating Costs	$ 17,371,600
Cancer Registry Operating Cost Transfer	$ 2,969,554
Total, Operating Costs	20,341,154

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2016

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	5		77			6			36				124	
New Grant Contracts Signed	8	0	1	4	25	31	10	5	4	0	22		110	
New Grant Contracts In Negotiation			43			24			27				94	
Grant Reimbursements Processed	31	7	266	208	529	245	294	129	96	311	139		2,255	
Grant Reimbursements Processed	$ 2,897,094	$ 23,414,469	$ 19,906,130	$ 21,102,375	$ 41,408,221	$ 19,447,324	$ 23,751,614	$ 12,000,762	$ 8,771,030	$ 26,088,909	$ 13,760,393		$ 212,548,321	
Revenue Sharing Payments	$ -	$ 10,117	$ 4,959	$ -	$ 21,122	$ -	$ -	$ 9,358	$ 5,745	$ -	$ 865,236		$ 916,536	$ 3,130,053
Total Value of Grants Contracted	$ 49,662,860	$ -	$2,000,000	$ 9,202,957	$ 42,908,491	$ 40,857,638	$ 14,512,920	$ 6,058,940	$ 9,645,064	$ -	$ 51,572,468		$ 226,421,338	
Grants Awarded (#)/ Applications Rec'd (#)	12%	11%	13%	13%	13%	13%	12%	12%	11%	11%	11%			
Debt Issued ($)/Funding Awarded	62%	62%	58%	58%	62%	61%	61%	61%	64%	64%	64%			
Grantee Compliance Trainings/Monitoring Visits	3	2	2	0	3	0	3	0	1	4	5		23	
Awards with Delinquent Reimbursement Submission (FSR)			5			3			0					
Awards with Delinquent Matching Funds Verification			10			3			0					
Awards with Delinquent Progress Report Submission			4			3			1					
IA Agency Operational Recommendations Implemented	0	6	6	6	6	6	6	6	9	9	9			
IA Agency Operational Recommendations In Progress	13	7	7	7	7	7	7	7	2	2	2			
Open RFAs	17	14	9	9	11	11	15	9	8	10	10			
Prevention Applications Received	0	0	0	0	0	0	44	0	0	0	0		44	549
Product Development Applications Received	25	0	0	0	0	32	0	0	0	0	0		57	309
Research Applications Received	4	212	2	6	5	5	9	13	488	8	1		753	4,536
Help Desk Calls/Emails	193	289	231	159	143	323	191	300	422	198	189		2,638	
MISSION														
RESEARCH PROGRAM														
Number of Research Grants Awarded (Annual)			55			6			34				95	
Recruited Scientists Announced														143
Recruited Scientists Accepted														113
Recruited Scientists Contracted														104
Published Articles on CPRIT-Funded Projects (#)														
Jobs Created & Maintained (#)														
Trainees in CPRIT-Funded Training Programs (#)														
Open Clinical Trials (#)														53
Number of Patents Resulting from Research														
Number of Patent Applications														

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2016

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Investigational New Drugs														
PRODUCT DEVELOPMENT PROGRAM														
Number of Product Development Grant Awarded (Annual)			1			0			2				3	
Life Science Companies Recruited (in TX)														7
Published Articles on CPRIT-Funded Projects														
Number of Jobs Created & Maintained														
Open Clinical Trials (#)														7
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)			12			0			0				12	
People Served by CPRIT-Funded Prevention and Control Activities			120,112			130,335			158,329				408,776	
People Served through CPRIT-Funded Education and Training			58,126			55,377			72,564				186,067	
People Served through CPRIT-Funded Clinical Services			61,986			74,958			85,765				222,709	
TRANSPARENCY														
Total Website Hits (Sessions)	8,560	7,901	8,581	4,617	5,993	7,458	7,031	7,001	9,533	5,819	6,848		79,342	
Total Unique Visitors to Website (Users)	5,778	5,472	5,679	3,376	4,435	5,251	4,916	4,789	6,171	4,332	5,134		55,333	

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE – JULY 2016
DATE:	JULY 29, 2016

Topics in the memo include: recent milestones in our fight against cancer; CPRIT staffing; legislative and related briefings; Compliance, Program, and Operations updates; and staff presentations and meetings.

Please note: in addition to the August 17 Oversight Committee and upcoming subcommittee meetings we have three important CPRIT-related events in August:

- August 2 – American Cancer Society Cancer Action Network Texas Cancer Policy Forum (Austin), 2:00-3:30 pm, Texas Medical Center Association, 401 W. 15th Street

- August 4 - American Cancer Society Cancer Action Network Texas Cancer Policy Forum (Houston), 2:00-3:30 pm, Greater Houston United Way Community Resource Center, 50 Waugh Dr.

- August 30 - American Cancer Society Cancer Action Network Texas Cancer Policy Forum (Dallas), 2:00-3:30 pm, Texas Health Presbyterian Hospital Dallas, 8200 Walnut Hill Lane

These forums will bring together key leaders and decision-makers in business, health care, and government to discuss the present and future impact of CPRIT. If you are able to attend, please register using the information provided to you previously via email. I will be attending each session along with several other staff members.

In addition, the American Cancer Society Cancer Action Network is hosting a breakfast on August 16 at 8:00 a.m. in Austin to discuss community perspectives on the National Cancer Moonshot Initiative. The breakfast will be held at their information center, 11701 Stonehollow Dr., Austin. Registration is required. I will attend.

Preparation for the August Oversight Committee Meeting

The Oversight Committee will meet August 17 at 10:00 a.m. in the Capitol Extension. The final agenda for the Oversight Committee meeting will be posted by August 9; a tentative agenda is attached. The Academic Research and Prevention programs will have award recommendations

to be considered by the Oversight Committee. Other major agenda items include several proposed rule and subcommittee charter changes, internal auditor report presentations, service contract approvals, and a discussion of the FY 2017 program priorities process.

You will receive an email from CPRIT by August 4 with a link and password to access the PIC's recommendations via the grant award portal. The portal has supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, and grant pedigree. A summary of the award slate will also be available through the portal. There will be a large number of recommended awards, please allow time to complete the individual conflict of interest checks and review the supporting material.

Oversight Committee members should receive an electronic copy of the agenda packet by COB August 10. Hard copies of the agenda packet will be available at the meeting.

Please also remember that there will be a special Oversight Committee meeting on September 14, 10:00 a.m. primarily to review recruitment award recommendations.

Recent Milestones in the Fight against Cancer (Academic Research, Product Development Research, Prevention)

- Mirna Therapeutics (2010 and 2014 Product Development grantee) presented new clinical data at the American Society of Clinical Oncology. Their novel micro RNA therapy demonstrated a good safety profile and was shown to reduce tumor size in both melanoma and renal cell carcinoma patients. Additional clinical studies are planned.

- Cell Medica (2012 Product Development grantee) has received European Commission orphan drug designations for its treatment for extranodal NK/T-cell lymphoma, nasal type, and post-transplant lymphoproliferative disorder. The EU orphan designation makes regulatory and financial incentives for developing and marketing Cell Medica's treatment, along with a ten-year period of marketing exclusivity within the EU after product approval. Cell Medica has also received orphan drug designation from the U.S. Food and Drug Administration for treating all oncogenic Epstein Barr virus-associated non-Hodgkin lymphomas.

- DNAtrix (2013 Product Development grantee) announced successful intra-tumoral administration of their novel oncolytic adenovirus therapy in recurrent glioblastoma patients. The therapy has already demonstrated a good safety profile, a strong tumor-killing potential, and is now shown to be deliverable directly into brain tumors. Clinical studies are ongoing. The company also reports that the European Medicines Agency granted DNAtrix' therapy a PRIority MEdicines (PRIME) designation as a promising new treatment for recurrent glioblastoma. Currently, there are no cures or adequate treatments for recurrent glioblastoma. The PRIME designation provides patients with few treatment options with early access to priority medicines that could provide significant benefit.

- AERase (2014 Product Development grantee) initiated a Phase I clinical trial for patients with acute myelogenous leukemia.

- Pulmotect (2012 Product Development grantee) completed their second Phase I clinical study and an IND filing with the FDA.

- On June 29, Vice President Joe Biden convened the Cancer Moonshot Summit at Howard University to accelerate progress toward "ending cancer as we know it". The four Texas NCI Designated Cancer Centers - MD Anderson, UT Southwestern, UT San Antonio and Baylor College of Medicine - hosted satellite summits in Houston, Dallas, and San Antonio, that included the Vice President's remarks and local presentations and panel discussions on how to double the rate of progress in our understanding, prevention, diagnosis, treatment, and care of cancer. A "blue ribbon" panel of experts was announced to assist in implementing the Cancer Moonshot. Texans on the Moonshot advisory panel include CPRIT grantees: James Allison, Alfred Yung and Ernie Hawk from MD Anderson and Will Parson from Texas Children's Cancer Center. More details on the "Cancer Moonshot" can be found at http://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative.

- Jane Johnson (2013 and 2015 CPRIT grantee), Professor of Pharmacology at UT Southwestern, has identified a new and promising therapeutic target for small cell lung cancer. The discovery, published this month in the journal *Cell Reports*, is important because small cell lung cancer is a recalcitrant cancer with a five-year survival rate of less than 7 percent. This discovery would not have happened without CPRIT. Dr. Johnson, a renowned neuroscientist, has been studying the roles of a protein called ASCL1 in the nervous system for many years. When she found that ASCL1 was present in most small cell lung cancers, she turned to CPRIT and received a CPRIT individual investigator award to investigate small cell lung cancer. She found that small cell lung cancers are dependent on ASCL1 and that targeting ASCL1 caused the cancers to die. She is now working with colleagues at UT Southwestern to develop entirely new types of targeted therapies for small cell lung cancer.

Personnel Changes and Job Openings

CPRIT has 32 authorized full-time equivalent (FTE) positions, of which 31 are filled as of August 1, 2016.

- Ralph Azeez starts work on August 1 as a Grant Accountant.

- Jodi Garza has accepted the position as Grant Compliance Specialist effective August 15, 2016.

- The vacant Communications Specialist position is posted through August 12, 2016.

Legislative Briefings and CPRIT Outreach

- Kristen Doyle, Heidi McConnell and I met on July 7 with staff from the Senate Finance Committee to discuss legislative issues and CPRIT's likely request for legislative appropriations.

- Several CPRIT staff members met with Asuragen, an Austin-based provider of cancer diagnostic tests on July 7. The lab tour was informative and discussions included how to expand the biotech ecosystem in Texas.

- On July 8 Dr. Garcia participated in the first meeting of the Texas Health Improvement Network (THIN) as a member of its advisory board. The network was established to address urgent health care challenges and improve the health care system in Texas.

- On July 13 Dr. Willson, Kristen Doyle, and I met with a delegation from the Houston Methodist Hospital Research Institute (HMRI) led by Dr. Mauro Ferrari, the Institute's President and CEO, and Dr. Jenny Chang, Methodist Hospital Cancer Center Director. Drs. Ferrari and Chang discussed a $50 million commitment to new recruitments with a goal of becoming a National Cancer Institute Designated Cancer Center. Dr. Ferrari discussed HMRI's product development capabilities. As a follow up, Jim Willson and Michael Lang plan an onsite meeting with the Houston Methodist leadership and faculty. The meeting will be hosted by Houston Methodist Hospital and open to all researchers in the Texas Medical Center.

- I met with Troy Alexander, Associate Director of Legislative Affairs of the Texas Medical Association on July 14 to discuss legislative issues.

- Kristen Doyle, Heidi McConnell and I met on July 19 with Representative Drew Darby to update him on CPRIT activities.

- On July 25 I met with Senator Charles Perry to update him on CPRIT activities.

- I met with Senator Kirk Watson's legislative director on July 26 to discuss legislative issues.

- I met with staff of the Speaker's Office on July 26 to discuss legislative issues and CPRIT's request for legislative appropriations.

- Dr. Willson met with Dr. David Lakey, Senior Vice President for Population Health and Dean, School of Community Health and Health Professions and Joe Woelkers, Executive Vice President and Chief Operating Officer UT Northeast (UT Tyler). Dr. Lakey provided an overview of the extreme cancer burden in northeast Texas and discussed his plans to recruit 10 population health experts to address this burden. Mr. Woelkers reported on new clinical and research affiliations between UT Northeast and UT MD Anderson. Dr. Willson discussed current and planned opportunities, such as CPRIT

request for applications, available to support these new initiatives and he will visit Tyler in the early fall.

- Dr. Willson met with Dr. Clay Johnston, Dean, Dell Medical School and Dr. Michael Pignone, Chair, Internal Medicine, at UT Austin. This introductory meeting gave Dr. Willson the opportunity to learn about the Dell Medical School and Livestrong Cancer Center and to discuss current and planned CPRIT request for applications that might stimulate cancer research at UT Austin.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

A delinquent report is produced by CPRIT's grant management system (CGMS) each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 550+ grants that are either active or wrapping up grant activities and gets about 570 grantee reports each month.

As of the most recent CGMS report (July 25, 2016), five required grantee reports from four entities have not been filed in the system by the set due date. Of the five delinquent reports, three (60%) are Prevention grants, one (20%) is an Academic Research grant, and one (20%) is a Product Development grant. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to promptly resolve filing issues.

Financial Status Reports (FSRs)

CPRIT's Grant Compliance Specialists performed 153 second level reviews of grantee FSRs during July. Nine required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Nineteen desk reviews were performed during the month of July, bringing the FY 2016 year-to-date total to 248 desk reviews performed. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission. Grant compliance specialists are working with two grantees to remediate desk review findings.

On-site Reviews

Grant compliance staff performed five on-site reviews during July covering Prevention and Product Development Research grants. On-site reviews typically include an examination of the grantee's financial and administrative operations, procurement and inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Grant compliance specialists are working with two grantees to remediate on-site review findings.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $500,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year.

There are currently 10 grantees with outstanding audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Grant compliance specialists are also working with two grantees regarding delinquent audit reports and one grantee regarding a delinquent Corrective Action Plan (CAP). Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless a request for additional time was submitted on or before the due date of the required audit and subsequently approved by me.

Training & Support

As a result of the grantee training webinars conducted in March and June, CPRIT staff drafted a Frequently Asked Questions (FAQ) document for our website as a resource for grantees. The FAQ document covers post-award topics such as required reporting timelines, financial status report supporting documentation, matching funds certification, travel expenses and documentation, and progress reports.

CPRIT staff is scheduled to present at UT Southwestern Medical Center's Research Administration Demonstration Training Series on August 26. This interactive training will cover recent administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process and is open to all North Texas CPRIT grantees.

Academic Research Program Update

FY 2016 Review Cycle 2 Core Facilities and Multi-Investigator Research Awards

At its May meeting, the Program Integration Committee (PIC) deferred final award recommendations for seven applications recommended by the Scientific Review Council (SRC). The PIC is expected to consider the five deferred Multi-Investigator Research Award

applications and two deferred Core Facilities applications at the August 2 PIC meeting. Any recommendations will be presented to the Oversight Committee for final approval on August 17.

FY 2016 Review Cycle 10 Recruitment Applications

The SRC received thirty nominations for CPRIT recruitment awards during the final quarter of FY 2016 (Cycles 16.10 – 12). These include nominations for 20 "First-Time, Tenure-Track" faculty members; two "Rising Star" candidates; and eight "Established Investigators" candidates. The total funding amount requested for the nominations is $96 million.

The SRC presented its final recommendations for five First-Time, Tenure Track Faculty Recruitment awards in Cycle 16.10 totaling $10 million to the presiding officers for the PIC and Oversight Committee on July 22, 2016. The PIC will consider the recommendations at its meeting on August 2.

Funds available in FY 2016 will not be sufficient to support the remaining expected recommendations. The SRC will defer making additional recommendations to the PIC and the Oversight Committee related to the remaining nominations until after the September 1 start of FY 2017. The award recommendations are expected to be considered at a special Oversight Committee meeting on September 14, 2016.

FY 2017 Cycle 17.1 Research Applications – Under Review

CPRIT released six Requests for Applications (RFAs) in February 2016 resulting in 479 applications. The table below shows the breakdown of applications received by RFA mechanism.

MECHANISM	# Submitted	Funds Requested
Early Translational Research Awards	54	$52,963,977
Individual Investigator Research Awards (IIRA)	292	$249,869,280
IIRA- Cancers in Children and Adolescents	45	$53,187,597
IIRA - Computational Biology	44	$34,103,086
IIRA - Prevention and Early Detection	35	$ 34,759,426
Research Training Awards	9	$29,134,072
TOTAL	**479**	**$454,017,438**

Seven review panels are reviewing the applications and will finalize their recommendations at peer review meetings scheduled for September 21-29 in Dallas. The review panels will forward decisions from the peer review meetings to the SRC. Award recommendations are expected to be considered at the November 2016 Oversight Committee meeting.

FY 2017 Cycle 17.1 Recruitment Awards

CPRIT released three recruitment RFAs for Cycle 17.1 on June 21, 2016. These RFAs continue CPRIT's commitment to recruiting outstanding cancer researchers to Texas and include the following: Recruitment of First-Time, Tenure-Track Faculty Members; Recruitment of Rising Stars; and Recruitment of Established Investigators.

FY 2017 Cycle 17.2 Request for Academic Research Applications

CPRIT released two RFAs July 25 for the High Impact/High Risk Awards and Core Facility Resource Support Awards. Applications are due by January 16, 2017. Grant award recommendations will be presented to the Oversight Committee for approval in August 2017.

- High Impact/High-Risk Research Awards (RFA R-17.2-HIHR)
  Provides short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Award: Up to $200,000 (total costs); Maximum duration: 2 years

- Core Facilities Support Awards (RFA R-17.2- CFSA)
  Solicits applications from institutions to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer. Award: Up to $3 million (total costs) for the first 2 years and up to $1 million (total costs) for each subsequent year; Maximum duration: 5 years

Product Development Research Program Update

Product Development Awards

Contracting is underway for the three most recent grant awards: Salarius Pharmaceuticals LLC, Pelican Therapeutics and Ruga. All are developing novel cancer therapeutics.

Product Development Review Cycle 16.2

This is one of the Product Development's program largest submission pool with 32 applications. Following the screening review panel meetings and the in-person presentations, seven applications are undergoing due diligence. Award recommendations will be presented at the November Oversight Committee meeting for final approval.

Product Development Review Cycle 17.1

The Cycle 17.1 Request for Applications opened on June 30 and will close on August 11. The applications will begin peer review in September; recommended applications will be presented at the February 2017 Oversight Committee meeting.

Increasing Academic Commercialization

Michael Lang has had initial discussions with several Texas academic institutions to evaluate interest in collaborating to increase academic commercialization. All expressed interest and additional meetings are planned. To date Mr. Lang has met with UT Southwestern, Baylor College of Medicine and Dell Medical School at UT Austin. Many institutions have well-developed commercialization initiatives within their technology transfer offices. A comprehensive recommendation will be developed over the next several months.

Revenue Sharing

As you know, all CPRIT awards require revenue sharing terms. For product development this is typically in the form of royalty on net sales. We are reviewing all grants to assess if royalties due to CPRIT are in fact being paid. A refined monitoring process is being developed to insure compliance now that many of CPRIT's companies are maturing.

Prevention Program Update

FY 2016 Cycle 16.2 Prevention Applications

The Program Integration Committee (PIC) will consider the recommendations August 2 and the Oversight Committee will review the PIC's recommendations August 17. Six Requests for Applications (RFAs) in Cycle 16.2 were released on September 24, 2015. Forty-four applications were received by March 3, more than doubling the number of applications received the previous cycle. Two reviews panel met May 23-25 in Dallas and the results forwarded to the Prevention Review Council (PRC). The PRC met July 1 to conduct a programmatic review.

FY 2017 Cycle 1 Request for Prevention Applications

Five RFAs for Cycle 17.1 were released in May 2016. Applications are due August 30 and will go to the Oversight Committee for consideration in February 2017.

Other activities

- The project to list the grants in each of the 254 counties was completed. We are working on ways to format and display the data.

- A complete redesign of the grantee quarterly reports is underway with SRA, CPRIT's grant management contractor. The revised report will be tested with a few grantees prior to its release.

Communications Update

- The website redesign project kicked off with a meeting CPRIT staff and TradeMark Media (CPRIT's selected vendor) on July 6. The redesign will take approximately 6 months.

- Approximately one-third of the summaries of the closed grants have been completed for the Significance Project. A freelance writer will assist with the remaining summaries.

- CPRIT's request for proposals (RFP) seeking a hotel venue for the 2017 CPRIT Conference is being reviewed by the Comptroller's Office. We hope to release the RFP next week and present the hotel contract to the Oversight Committee in September for approval.

- Staff continues to prepare legislative briefing materials as needed.

Social Media

Communications staff continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources.

Operations and Finance (Contracts, RFPs, Audit)

Contracts

Heidi McConnell presented the staff recommendation for SRA International, Inc. (a CSRA Company), the only respondent to the Request for Proposal (RFP), to provide grant management support services for FY 2017 to the Audit Subcommittee at a specially called meeting on July 12, 2016. The subcommittee verified consistency with the Oversight Committee's provisional approval on May 18. I have submitted a letter to the Legislative Budget Board (LBB) requesting approval of a proposed $7,038,659 contract for FY 2017, about 27 percent less than the current FY 2016 contract for $9,693,907.

Request for Proposals

On July 8, 2016, Grant Thornton LLP, the vendor that provides third-party observer services at all CPRIT peer review meetings, notified us that it does not intend to renew its contract with us in FY 2017. However, it will extend its FY 2016 contract to provide these services for scheduled peer review meetings in September and October 2016 to allow us time to issue a competitive Request for Proposal for these services.

Legislative Appropriations Request

On June 30 the Governor's Office and LBB issued instructions for the Legislative Appropriations Request (LAR) for the 2018-19 biennium. CPRIT's LAR is due August 5, 2016. Heidi McConnell presented the summary information for the LAR to the Audit Subcommittee at the specially called meeting on July 12, 2016, and the subcommittee verified consistency with the Oversight Committee's provisional approval on May 18**.**

The statutorily required joint hearing of the Governor's Office and LBB on CPRIT's LAR is scheduled for Wednesday, September 14, 2016, at 4:00 p.m. in the Capitol Extension, E2.026.

FY 2017 Request for Financing

On June 30, 2016, the Bond Review Board considered CPRIT's Request for Financing of General Obligation Commercial Paper Notes for FY 2017 and approved the request with a vote of 2 to 1, with the Comptroller's representative dissenting.

Upcoming Subcommittee Meetings

The dates and times for the upcoming August subcommittee meetings are listed below.

Subcommittee	Date & Time
Board Governance	August 3 at 10:00 am
Diversity	August 5 at 10:30 am
Audit	August 8 at 10:00 am
Prevention	August 9 at 10:00 am
Scientific Research	August 10 at 10:00 am
Product Development	August 11 at 10:00 am
Nominations	August 12 at 10:30 am

An agenda, call-in information and supporting material will be sent to the subcommittees one week prior to the meeting date.

September Oversight Committee Meeting

As mentioned in the opening, a special Oversight Committee meeting is set for September 14, 2016, primarily to review recruitment award recommendations.

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CPRIT has awarded **1,033** grants totaling **$1.575 billion**

- 158 prevention awards totaling $155.4 million
- 875 academic research and product development research awards totaling $1.420 billion

Of the $1.420 billion in academic research and product development awards,

- 30.1% of the funding ($427.1 million) supports clinical research projects
- 27.3% of the funding ($387.4 million) supports translational research projects
- 24.3% of funding ($345.0 million) supports recruitment awards
- 15.2% of the funding ($216.4 million) supports discovery stage research projects
- 3.1% of funding ($44.4 million) supports training programs.

CPRIT has 13 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Academic Research
- 2 Product Development Research
- 5 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE – JUNE 2016
DATE:	JULY 1, 2016

Topics in the memo include: recent noteworthy events in our fight against cancer; CPRIT staffing; legislative briefings and staff outreach; executive management training; Compliance, Program, and Operations updates.

CPRIT Grantees in the News

- Cell Medica, a CPRIT funded company, announced a major strategic partnership with Baylor College of Medicine (BCM) to develop next-generation cellular immunotherapy products for the treatment of solid tumors. The collaboration provides Cell Medica with an exclusive license over several Baylor cell and gene technologies and an option to license new products introduced into the co-development partnership by Baylor's leading research teams in the field of genetically engineered immune cells. This agreement accelerates the work of Dr. Leonid Metelitsa, BCM Professor of Pediatrics – Oncology. CPRIT has funded several of Dr. Metelitsa's research projects focused on functionally enhanced CAR-modified "natural killer" T cells (NKT cells). As part of the collaboration, Cell Medica will fund BCM research teams developing new technologies that may be utilized to create therapeutic products using modified NKT cells and other immune cells or to improve manufacturing systems. Cell Medica expects the collaboration to generate a significant number of new products for its cellular immunotherapy pipeline.

- Representatives of UT Health Northeast (Tyler) were recognized at a conference hosted by The University of Texas System for ongoing efforts to increase the number of people screened in East Texas for colorectal cancer and for pain management education. Thanks to a $1.23 million state grant awarded by CPRIT, about 2,000 uninsured and underserved Northeast Texans are receiving potentially life-saving colorectal cancer screenings.

- While immune therapy has shown significant impact against intractable cancers, most fail to respond. Cassian Yee, M.D., CPRIT Scholar and professor in the Departments of Melanoma Medical Oncology and Immunology at UT MD Anderson Cancer Center, reported in the June 6, 2016, issue of the *Journal of Clinical Oncology* that patients with metastatic melanoma who had not responded to an immune therapy had significant responses when treated with a combination of an immune check-point inhibitor and the

patient's own T-cells. This trial builds on Yee's pioneering work in developing cellular therapy for metastatic melanoma and promises to be an important step toward expanding the impact of immune therapies. He plans to extend this combination immune therapy approach to patients with other solid tumors that have proven resistant to immune checkpoint therapy alone.

- Dr. Matthew Ellis, CPRIT Scholar and director of the Smith Breast Center at BCM reported in the May issue of *Nature* results of a landmark study to characterize all proteins expressed in breast cancers. The cancer research community will use the findings from this multi-institutional study to identify new predictive markers and new therapeutic targets for breast cancer.

- Dr. Marc Cox, CPRIT grantee and associate professor in The University of Texas at El Paso's Department of Biological Sciences, was selected as the 2016 Texas Inventor of the Year by the Intellectual Property Committee of the State Bar of Texas for his discoveries related to treatments for breast and prostate cancers.

- Dr. Kent Osborne, CPRIT University Advisory Committee Member and Director, Dan L Duncan Comprehensive Cancer Center Cancer Center at BCM was presented with the 2016 Gianni Bonadonna Breast Cancer Award at the 2016 Annual Meeting of the American Society of Clinical Oncology on June 4 in recognition of his outstanding contributions to translational research in breast cancer and exceptional mentoring abilities.

- Dr. Peter Jones, a member of CPRIT's Scientific Review Council, was elected to the National Academy of Sciences this spring in recognition of his role in pioneering the field of epigenetics and its role in cancer. Dr. Jones is the Research Director and Chief Scientific Officer at the Van Andel Research Institute, Grand Rapids, Michigan.

Personnel Changes and Job Openings

CPRIT has 32 authorized full-time equivalent (FTE) positions, of which 30 are filled as of June 30, 2016.

- The posting closed for the vacant Grant Compliance Specialist position and interviews are in progress.

- A candidate has been identified for the vacant Grant Accountant position.

- Program Manager for Academic Research, Patricia "Patty" Moore, Ph.D., started work on June 27. Patty's Ph.D. is in Health Services Research from Texas A&M Health Science Center School of Public Health. Prior to joining CPRIT she held director level positions in the Texas Department of State Health Services and the Office of Sponsored Research Administration at Scott & White Memorial Hospital. She replaces Michael

Brown who resigned in April to take a position at M.D. Anderson, and she will work with Jim Willson in managing CPRIT's academic research program portfolio.

- Communications Specialist Jeff Hillery has accepted a position as Deputy Press Secretary with Attorney General Ken Paxton effective July 5. A posting to fill the position is being prepared.

Grantee Compliance Training

CPRIT staff conducted a grantee training webinar on June 15, 2016, with approximately 140 grantee staff in attendance. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process. Grantees also had the opportunity to ask questions during the two-hour training webinar. This was the second webinar conducted for grantees this fiscal year in support of the new annual compliance training requirement, which states that the Authorized Signing Official (ASO) and at least one other employee from each grantee organization must attend an annual compliance training by November 1 of each year. A third grantee training webinar is planned for October 12, 2016.

CPRIT Staff Compliance and Ethics Training

Vince Burgess, Chief Compliance Officer, and Cameron Eckel, Staff Attorney, conducted compliance and ethics training for all CPRIT employees during the month of June. The interactive training included an overview of CPRIT's Code of Conduct and Ethics, Conflict of Interest Policy, Non-Disclosure Agreement, and relevant sections from Health and Safety Code § 102 and Texas Administrative Code §§ 701-703.

Executive Management Training

In consultation with Oversight Committee members Ned Holmes and Dee Margo, CPRIT contracted with the Governor's Executive Development Program operated by the LBJ School of Public Affairs at The University of Texas at Austin for team building and executive management training. All CPRIT senior staff participated in the training on June 29. Separate specific sessions for me will be scheduled later this summer. Additional information concerning the training will be provided later.

Legislative Briefings and CPRIT Outreach

- Kristen Doyle, Jim Willson and I met with staff of the Governor's Office on June 1 to discuss CPRIT's halfway point metrics and to report on CPRIT's activities.

- Representative Jim Keffer and I met with former Lieutenant Governor Ben Barnes on June 2 to discuss CPRIT activities.

- Michael Lang, Kristen Doyle and I attended the BIO International Convention June 6 – 9 in San Francisco. A reported 17,000 biotechnology and pharmaceutical leaders interested in life science partnerships attended. CPRIT was part of a coalition representing Texas.

We met with about 30 company and governmental life science representatives. In addition, we met with representatives of the California Institute of Regenerative Medicine (CIRM) to discuss topics of common interest.

- On June 6, Heidi McConnell attended the Texas Public Finance Authority (TPFA) Board meeting and provided a brief update about CPRIT's progress. The TPFA Board approved CPRIT's FY 2017 request for financing of $300 million in bond proceeds.

- Heidi McConnell, Kristen Doyle and I met with our new assigned analyst from the Legislative Budget Board. Our previous analyst is no longer with the LBB.

- I represented CPRIT at the grand opening of the MCA Cardwell Collaboration facility in El Paso on June 17. This facility houses significant economic development activities for the El Paso region with incubator space and dry/wet lab facilities. Texas Tech University Health Sciences Center is a major leaseholder in the building.

- On June 21 Heidi McConnell, Kristen Doyle, and I attended the Bond Review Board (BRB) planning session. I provided an update on CPRIT's progress as they considered CPRIT's FY 2017 request for financing. The BRB met on June 30 and voted without discussion to approve CPRIT's request for financing. Comptroller Hegar dissented.

- Heidi McConnell, Kristen Doyle and I met with Senator Nelson's legislative director, Travis Broussard, on June 22 to discuss the upcoming 2017 legislative session.

- Jim Willson and I visited the Texas Tech University Health Sciences Center El Paso and The University of Texas El Paso on June 28. Meetings were held with institutional leadership at both sites and with CPRIT grantees and cancer investigators. The overarching goal of the visits was to build communication between CPRIT and the academic cancer research community in El Paso. The sessions provided us with an overview of cancer research ongoing in El Paso and an opportunity to communicate current and planned CPRIT RFA opportunities available to support this research. A special focus was on the status of clinical cancer research in El Paso and what is needed to build additional capacity in clinical cancer research and thereby extend access to cancer clinical trials for this region of Texas.

Compliance Program Update

<u>Submission Status of Required Grant Recipient Reports</u>

A delinquent report is produced by CPRIT's grant management system (CGMS) each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 530+ grants that are either active or wrapping up grant activities and receives approximately 570 grantee reports each month.

As of the most recent CGMS report (June 24, 2016), 10 required grantee reports from 9 entities have not been filed in the system by the set due date. In most cases, CPRIT does not disburse

grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to promptly resolve filing issues.

Financial Status Report (FSR) Reviews

CPRIT's Grant Compliance Specialists performed 226 second level reviews of grantee Financial Status Reports (FSRs) during the month of June. Only six FSRs required resubmission due to insufficient documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Thirteen desk reviews were performed during the month of June, bringing the FY 2016 year-to-date total to 222 desk reviews performed. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission.

On-Site Reviews

Grant compliance staff performed one on-site review during the month of June covering a Product Development Research grant. On-site reviews typically include an examination of the grantee's financial and administrative operations, procurement and inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. There were three findings identified during this review. Grant Compliance Specialists are working closely with the grantee to fully remediate these findings.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $500,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year.

There are currently 12 grantees with outstanding audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Grant compliance specialists are also working with two grantees regarding delinquent audit reports and two grantees regarding delinquent Corrective Action Plans (CAPs). Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit

and corrective action plan, unless a request for additional time was submitted on or before the due date of the required audit and subsequently approved by CPRIT's CEO.

Academic Research Program Update

FY 2016 Recruitment Applications – Under Review

The Scientific Review Council (SRC) received thirty nominations for CPRIT recruitment awards during the final quarter of FY 2016. These include nominations for 20 "First-Time, Tenure-Track" faculty members; two "Rising Star" candidates; and eight "Established Investigators" candidates. The total funding amount requested for the nominations is $96 million.

The SRC meets monthly to review the nominations submitted the previous month. However, because funds available in FY 2016 will not be sufficient to support the expected recommendations, the SRC will defer making recommendations to the Program Integration Committee and the Oversight Committee on these nominations until after the September 1 start of FY 2017. The SRC's recommendations will be made in early September and award recommendations are expected to be considered at a special Oversight Committee meeting on September 14, 2016.

FY 2017 Cycle 1 Research Applications – Under Review

CPRIT released six Requests for Applications (RFAs) in February 2016 resulting in 479 applications. The table below shows the breakdown of applications received by RFA mechanism.

MECHANISM	No. Submitted	Funds Requested
Early Translational Research Awards	54	$52,963,977
Individual Investigator Research Awards (IIRA)	292	$249,869,280
IIRA- Cancers in Children and Adolescents	45	$53,187,597
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TOTAL	**479**	**$454,017,438**

Seven review panels are reviewing the applications and will finalize their recommendations at peer review meetings scheduled for September 21-29 in Dallas. The review panels will forward decisions from the peer review meetings to the SRC. Award recommendations are expected to be considered at the November 2016 Oversight Committee meeting.

FY 2017 Request for Academic Research Applications released in June

CPRIT released three recruitment RFAs for Cycle 17.1 on June 21, 2016. These RFAs continue CPRIT's commitment to recruiting outstanding cancer researchers to Texas and include the following: Recruitment of First-Time, Tenure-Track Faculty Members; Recruitment of Rising Stars; and Recruitment of Established Investigators.

FY 2017 Cycle 17.2 Request for Academic Research Applications to be released in July

CPRIT is developing RFAs for Cycle 17.2 in consultation with the University Advisory and Childhood and Adolescent Cancer Committees. We anticipate release of RFAs for High Impact/ High Risk Awards and Core Facility Resource Support Awards in July. Additional RFAs for Cycle 17.2 with a focus on clinical research support are in development.

Advisory Committee Meetings

The University Advisory Committee (UAC**)** met on June 17, 2016, at the University of Houston. The meeting was chaired by Dr. Mary Ann Ottinger, Associate Vice Chancellor for Research, University of Houston System. Dr. Willson provided an update on the FY 2016 grant programs and presented concepts for new requests for applications. The UAC recommended the development of a new RFA for an Individual Investigator Award for Clinical Research that would stimulate applications focused on assessment of biomarkers and/or imaging studies that would inform interpretation of early phase clinical trials. The UAC noted that this is an important area of cancer research that is not well supported by the National Cancer Institute or industry sponsors. The UAC discussed other RFA concepts including strategies for building clinical research capacity at academic research centers in Texas that do not have NCI designated cancer centers. The UAC was updated on the CPRIT "significance project" and discussed ways the members and their affiliated institutions could contribute to this effort. The UAC members plan to meet in Austin in October 2016.

Product Development Research Program Update

Product Development Review Cycle 16.1

Contract negotiations are underway for the two grant awards, Salarius Pharmaceuticals LLC and Pelican Therapeutics, approved at the May Oversight Committee meeting. Salarius will develop a first in class drug to treat Ewing's Sarcoma and certain prostate cancers. Pelican will develop a first in class immunotherapy to activate killer T-cells for use in multiple cancers.

Product Development Review Cycle 16.2

Thirty-two applications were submitted in Cycle 16.2, making this among our largest application pools. Following the in-person presentations by thirteen companies to the product development peer review panels in early May, due diligence is underway for seven projects recommended by the review panels. Although the grant recommendations from this cycle were originally scheduled to be presented at the August 2016 Oversight Committee meeting, CPRIT moved the consideration of the Cycle 16.2 recommendations to the November 2016 meeting due to the

unavailability of funds for FY 2016. The Product Development Review Council will finalize award recommendations in October when due diligence is complete. The seven projects are requesting $106,864,758 in grant funds.

Product Development Review Cycle 17.1

CPRIT released two RFAs for review cycle 17.1 on June 24. The RFAs were updated to reflect eligibility requirements, development stage focus and enhanced data submission requirements. Applications will be accepted June 30 through August 11. Award recommendations are expected to be presented at the February 2017 Oversight Committee meeting.

Early Translational Research Awards (ETRA) – Business Plan Review

The Oversight Committee approved 20 ETRA grants in November 2014 to "bridge the gap between promising new discoveries achieved in the research laboratory and commercial development." In addition to other reporting requirements, the principal investigators for these ETRA grants are required to develop and submit a business plan defining commercial opportunities. CPRIT recruited four Product Development peer review panel members with business expertise to individually review the business plans and provide specific feedback to the individual ETRA grantees. The business plan reviews and post-review conferences were completed earlier this month.

Equity Ownership Policy

CPRIT staff has met with the Texas Treasury Safekeeping Trust Company (TTSTC), a division of the Office of the Comptroller that manages state assets. We discussed TTSTC managing CPRIT's equity portfolio and other opportunities for investment management. TTSTC will draft a management proposal for CPRIT and Oversight Committee review. Additional information will be provided as discussions develop.

Increase Academic Commercialization

CPRIT has had initial discussion with several Texas health-related institutions to evaluate interest in collaborating to increase academic commercialization. All expressed interest and follow-on meetings are expected.

Prevention Program Update

FY 2016 Review Cycle 2 Prevention Applications – Under Review

CPRIT released six Requests for Applications (RFAs) on September 24, 2015, and received 44 applications by the March 3 deadline. The number of applications more than doubled the number received in the previous cycle. Two review panels met May 23-25 in Dallas and the results were forwarded to the Prevention Review Council (PRC.) The PRC meets today (July 1) to conduct a programmatic review of the scored applications. The Program Integration Committee (PIC) will consider the recommendations August 2 and the Oversight Committee is expected to vote on the PICs recommendations August 17.

FY 2017 Cycle 1 Request for Prevention Applications - Released May 26

CPRIT released five RFAs for Cycle 17.1 on May 26, 2016. Applications are due August 30 and will go to the Oversight Committee for consideration in February 2017.

Other activities

- The project to list the grants in each of the 254 counties is complete. CPRIT staff is working on ways to format and display the data.

- Quarterly reports were due June 15 and are being reviewed.

- A complete redesign of the grantee quarterly reports is underway with CSRA, CPRIT's grant management contractor. The revised report will be tested with a few grantees prior to its release.

Communications Update

CPRIT Messages

- Half -Way Point Event: An event celebrating CPRIT's half-way point in awarding the $3 billion entrusted to it to fight cancer was held May 17 at the Capitol Extension Auditorium. Will Montgomery, CPRIT Assistant Presiding Officer and I provided introductory comments and each of the three Chief Program Officers reported on the state of their programs including key metrics and achievements to date. Coverage of the event included Xconomy, Houston Chronicle, San Antonio Business Journal, Strategic Partnerships Inc. and Livestrong.

- Significance Project: Due to the low response rate to the significance project survey, communications staff is taking a different approach to the project. The final reports from closed grants are being mined for key accomplishments.

- 2017 CPRIT Conference: The RFP for a hotel venue and a preliminary budget are being drafted. The plan is to present the hotel contract to the Oversight Committee in August or September for consideration.

- Website: TradeMark Media was selected as the vendor to redesign the website. The project will kick off July 6 and take approximately 6 months.

- Other: Staff continues to prepare legislative briefing materials as needed.

Social Media

Communications staff continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources.

Operations and Finance (Contracts, RFPs, Audit)

Contracts

As previously mentioned, CPRIT staff selected TradeMark Media Corporation, located in Austin, Texas to redesign CPRIT's website. The contract is for a not to exceed amount of $68,442. All of the redesign work will be completed in six months, and the contract includes a 12-month maintenance period following the deployment of the redesigned website to address any issues that arise as a result of the redesign.

Request for Proposals

The Request for Offer (RFO) for Grant Management Support Services closed on June 16, 2016. One vendor submitted a proposal to CPRIT. CPRIT staff reviewed and evaluated the proposal and held an in-person presentation by the vendor on June 30, 2016. As you will remember, the Oversight Committee provisionally approved a contract for these services up to $10 million at its May meeting. Heidi McConnell will be presenting a summary of the proposed contract to the Audit Subcommittee at a specially called meeting on July 12, 2016, and the subcommittee will verify consistency with the Oversight Committee's provisional approval.

State Agency Strategic Planning

CPRIT submitted the Agency Strategic Plan to the Governor's Office and Legislative Budget Board (LBB) on June 24, 2016, the due date. With the approval of both of those offices, performance measure changes include revising a prevention program performance measure, deleting an existing compliance program performance measure and adding one compliance program performance measure in lieu of the one deleted. The submission of the strategic plan is the first step in the state budget process for the 2018-19 biennium that will be considered by the 85th Texas Legislature when it convenes in January 2017.

As of this writing, the Governor's Office and LBB have not issued instructions for the Legislative Appropriations Request for the 2018-19 biennium.

Regular Oversight Committee Meeting

The Oversight Committee will hold its next meeting on August 17, 2016, at 10:00 a.m. in the Capitol Extension.

Upcoming Subcommittee Meetings

A special Audit Subcommittee meeting will be held July 12, 2016, to review material related to CPRIT's request for legislative appropriations for the biennium beginning September 1, 2017. An agenda, call-in information and supporting material will be sent to the subcommittee members one week prior to the meeting date.

The dates and times for the upcoming August subcommittee meetings are listed below.

Subcommittee	Date & Time
Board Governance	August 4 at 10:00 am
Diversity	August 5 at 10:30 am
Audit	August 8 at 10:00 am
Prevention	August 9 at 10:00 am
Scientific Research	August 10 at 10:00 am
Product Development	August 11 at 10:00 am
Nominations	August 12 at 10:30 am

An agenda, call-in information and supporting material will be sent to the subcommittees one week prior to the meeting date.

September Oversight Committee Meeting

A special Oversight Committee meeting is set for September 14, 2016, to review recruitment award recommendations.

*****

Updated 6-24-16

CPRIT has awarded **1,033** grants totaling **$1.575 billion**

- 158 prevention awards totaling $155.4 million
- 875 academic research and product development research awards totaling $1.420 billion

Of the $1.420 billion in academic research and product development awards

- 30.1% of the funding ($427.1 million) supports clinical research projects
- 27.3% of the funding ($387.4 million) supports translational research projects
- 24.3% of funding ($345.0 million) supports recruitment awards
- 15.2% of the funding ($216.4 million) supports discovery stage research projects
- 3.1% of funding ($44.4 million) supports training programs

CPRIT has 10 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 2 Product Development Research
- 5 Prevention

Return to agenda

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: JAMES WILLSON, MD, CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH UPDATE

DATE: AUGUST 5, 2016

Summary
This memo provides an overview of Academic Research program activities since the last Oversight Committee meeting in May. Subjects include a summary of the research awards and recruitment nominations in FY2106, an update on applications currently under review, and notification of recently released Requests for Applications (RFAs) for FY2017.

Academic Research Awards in 2016
Academic Research Funding in FY2016 to date (not including August awards) totals $198,549,131. Research Applications were reviewed by six research panels led by the members of the CPRIT Scientific Review Council. A total of 138 reviewers participated in the review of research applications during 2016. The distribution of the number of applications received, number of awards, and total funding by RFA mechanism are shown in the following table.

Academic Research Awards by RFA Mechanism through May 2016			
Funding Mechanism	**Applications Received**	**Applications Awarded**	**Total Funding**
Individual Investigator Research Awards (IIRA)	351	39	$34,740,000
IIRA Cancer in Children and Adolescents	45	5	$6,110,000
IIRA Computational Biology	50	1	$390,000
IIRA Prevention and Early Detection	45	6	$6,550,000
Multiple Investigator Research Awards	31	2 (5 deferred)*	$37,792,887
Core Facilities Support Awards	18	4 (2 deferred)*	$30.338,728
High-Impact/High-Risk Research Awards	153	21	$4,193,364
Research Training Awards	13	4	$14,970,000

*At the May 3, 2016 Program Integration Committee (PIC) meeting, the PIC approved the use of the award deferral process set by CPRIT administrative rule § 703.7(d) to defer the decision to recommend awards for seven academic research applications until a future FY 2016 meeting. Two Core Facility Support Awards and five Multi-Investigator Research Awards (MIRA) were deferred due to CPRIT budget limitations for the remainder of FY 2016 and these applications will be considered at the August 17, 2016, meeting of the Oversight Committee.

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Academic Research Recruitment Nominations in 2016

2016 Academic Research Recruitment Nominations through May 2016				
Funding Mechanism	**Applications Submitted**	**Applications Funded**	**Funding**	**Success Rate**
Established Investigators Award	14	5	$30,000,000	35.7%
Rising Stars	9	4	$15,700,000	44.4%
First Time -Tenure-Track Faculty	33	13	$24,820,000	39.4%
Total	**56**	**22**	**$70,520,000**	**39.3%**

Fifty-six recruitment nominations were received in 2016 (through May 2016) to three recruitment RFAs: Established Investigators, Rising Stars, and First-Time, Tenure Track Faculty Members.

During the fourth quarter of FY 2016, an additional 15 Recruitment Awards (Established Investigators- 3; Rising Stars -1; and First-Time Tenure Track Members -11) were received and are currently under review. A subset of these submitted to the 16.10 cycle will be considered at the August meeting of the Oversight Committee and the remaining recruitment awards received during the last quarter of the fiscal year will be deferred to FY17 because sufficient funds are not available to support all recommended recruitment awards. The deferred award recommendations will be considered at a special Oversight Committee meeting on September 14, 2016.

FY 2017 Cycle 17.1 Research Applications – Under Review

CPRIT released six Requests for Applications (RFAs) in February 2016 resulting in 479 applications. The table below shows the breakdown of applications received by RFA mechanism. The six review panels have begun their evaluations of these applications and will meet September 21 – 28, 2016, to finalize their recommendations to the Scientific Review Council (SRC). The SRC and Program Integration Committee recommendations for funding will be considered at the November 2016 Oversight Committee meeting.

FY17 Cycle 17.1 Research Applications – Under Review			
Funding Mechanism	**Applications Submitted**	**Applications Under Review**	**Funds Requested**
Individual Investigator Research Awards (IIRA)	292	287	$245,379,218
IIRA Cancer in Children and Adolescents	45	42	$49,806,122
IIRA Computational Biology	44	42	$33,206,014
IIRA Prevention and Early Detection	35	33	$33,274,172
Early Translational Research Awards	54	54	$52,963,977
Research Training Awards	9	9	$27,374,487
Total Cycle 17.1 Research	**479**	**472**	**$442,003,990**

2017 Recruitment RFAs – Under Review
CPRIT released three recruitment RFAs for 2017 on June 21, 2016. These RFAs continue CPRIT's commitment to recruiting outstanding cancer researchers to Texas and include the following: Recruitment of First-Time, Tenure-Track Faculty Members; Recruitment of Rising Stars; and Recruitment of Established Investigators.

FY17 Cycle 17.1 Recruitment Applications – Under Review			
Funding Mechanism	**Applications Submitted**	**Applications Under Review**	**Funds Requested**
Established Investigators Award	0	0	0
Rising Stars	0	0	0
First-Time Tenure-Track Faculty Members	1	1	$2,000,000
Total Cycle 17.1 Recruitment Awards	**1**	**1**	**$2,000,000**

FY 2017 Cycle 17.2 Request for Academic Research Applications
CPRIT released two RFAs July 25, 2016 for the High Impact/High Risk Awards and Core Facility Resource Support Awards. Applications are due by January 17, 2017. Grant award recommendations will be presented to the Oversight Committee for approval in August 2017.

- **High Impact/High-Risk Research Awards (RFA R-17.2-HIHR**)

Provides short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Award: Up to $200,000 (total costs); Maximum duration: 2 years.

- **Core Facilities Support Awards (RFA R-17.2- CFSA)**

Solicits applications from institutions to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer. Award: Up to $3 million (total costs) for the first 2 years and up to $1 million (total costs) for each subsequent year; Maximum duration: 5 years.

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CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	PREVENTION PROGRAM UPDATE
DATE:	AUGUST 8, 2016

FY 2016 Cycle 2

Fourteen grant applications are being presented to the Oversight Committee for approval on August 17. This is the culmination of the grants cycle that began with the release of 6 Requests for Applications (RFAs) on September 24, 2015. Forty-four applications were received by due date of March 3, 2016. Two reviews panel met May 23-25 and the Prevention Review Council (PRC) met July 1. The Program Integration Committee met on Aug. 2 and forwarded their recommendations to the Oversight Committee.

FY 2017 Cycle 1

Five RFAs for Cycle 17.1 were released in May 2016. Applications are due August 30 and will go to the Oversight Committee for consideration in February 2017.

Other activities

- The project to list the grants in each of the 254 counties was completed. We are working on ways to format and display the data.
- A complete redesign of the grantee quarterly reports is underway with SRA, CPRIT's grant management contractor. The revised report will be tested with a few grantees this month prior to its release.

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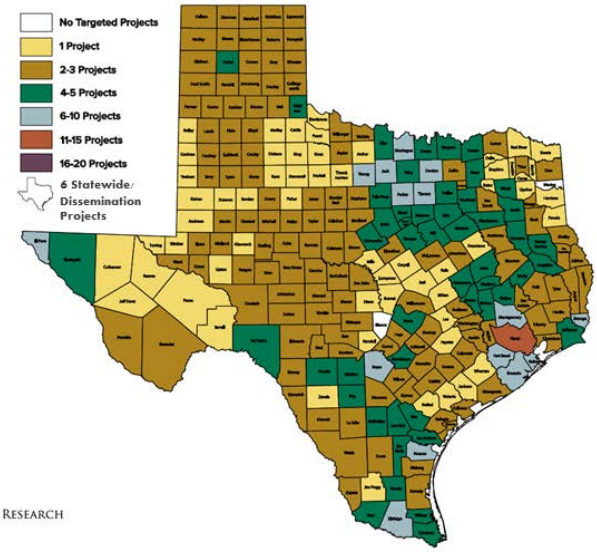
Geographic Coverage

Counties Served by CPRIT Prevention Projects
62 Active Projects – August 2016



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

1

Over 3,020,432 Prevention Services for Texans

Grantee Reports Through May 2016

Education and Training	Clinical Service Delivery
1,399,186	1,621,246

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

2

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	COMMUNICATIONS UPDATE
DATE:	AUGUST 17, 2016

The following report provides an overview of the agency's communications activities from May 17, 2016 through August 17, 2016.

Earned Media

The communications team worked with and pitched individual publications and reporters to secure positive coverage for CPRIT. Additionally, the communications team hosted a press conference and distributed a press release announcing CPRIT's halfway point in funding, resulting in several of the articles represented in the coverage highlights below.

Grant Awards Announcement: Following the Oversight Committee's approval, on May 18, 2016, CPRIT distributed a press release to and pitched local, regional and national media announcing the awarding of 33 academic research grants and two product development research grants which resulted in some of the coverage represented below.

Coverage: (May 3, 2016 – August 2, 2016)

- 12 articles featured CPRIT
- 84 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- May 12, 2016, *BioNews Texas*, CPRIT to Mark Halfway Point of Its Authorized Funding
- May 18, 2016, *Xconomy*, CPRIT Marks Midpoint in Texas Agency's 10-year Cancer-fighting Mandate
- May 19, 2016, *Austin Business Journal,* Austin Biopharma Startup Gets $15M CPRIT Grant
- May 20, 2016, *SPI Insights (Strategic Partnerships, Inc.)*, CPRIT Reaches Midway Point of 10-year Life Cycle
- May 25, 2016, *Houston Chronicle*, Pharma Company Developing Cancer Drug Moving to Houston

- May 26, 2016, *Houston Business Journal*, Houston Dominates Texas Cities for CPRIT Awards
- May 29, 2016, *Texas A&M AgriLife TODAY*, Cancer Research Boosted by $400K Grant to Texas A&M AgriLife Research
- June 3, 2016, *San Antonio Business Journal*, Cancer Money to Boost Local Pediatric Research
- July 1, 2016, *Fort Worth Star-Telegram*, We've Reached Some Major Milestones in North Texas' Fight Against Cancer

CPRIT Projects and Events

- Halfway Point Event: An event celebrating CPRIT's halfway point in awarding the $3 billion entrusted to it to fight cancer was held May 17 at the Capitol Extension Auditorium. Will Montgomery, CPRIT Assistant Presiding Officer and Wayne Roberts, CEO provided introductory comments and each of the three Chief Program Officers reported on the state of their programs including key metrics and achievements to date. Coverage of the event included Xconomy, Houston Chronicle, San Antonio Business Journal and Strategic Partnerships Inc.

- Website: The project began with a meeting on July 6 and will take approximately six months. TradeMark Media is the vendor we are working with to redesign the website.

- Significance Project: Approximately one third of the summaries of the closed grants have been completed. A freelance writer has been identified to help with the remaining summaries.

- 2017 Conference: The RFP for a hotel venue was released on August 1. It was sent to hotels in Austin, Houston, Dallas and San Antonio. Hotels have until August 22 to respond.

- Other: Staff continues to prepare legislative briefing materials as needed.

Social Media

Communications staff continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources.

CPRIT to Mark Halfway Point of its Authorized Funding

DANIELA SEMEDO, PHD

MAY 12TH, 2016

The Cancer Prevention and Research Institute of Texas (CPRIT) will hold a press conference on Tuesday, May 17, 2016, at the Capitol (1 to 3:30 p.m.) to mark the halfway point of the agency's authorized funding. CPRIT's leadership team will present some accomplishments in the agency's cancer prevention, academic research, and product development research programs.

According to a press release provided by CPRIT to *BioNews Texas*, participants in the May 17 event include CPRIT leadership, Dr. Susan Blaney, chair of CPRIT's Advisory Council on Childhood Cancer, advocates, along with an exceptional group of grantees from CPRIT's prevention, academic research, and product development programs, namely:

- NanoTx Therapeutics/Dr. Andrew Brenner, The University of Texas Health Science Center at San Antonio;
- Dr. Cassian Yee, The University of Texas MD Anderson Cancer Center;
- Dr. Keith Argenbright, director of the Moncrief Cancer Institute, The University of Texas Southwestern Medical Center;
- Asuragen/Dr. Gary Latham, vice president of research and technology;
- Mirna Therapeutics/Dr. Paul Lammers, president and CEO;
- Dr. Raghu Kalluri, The University of Texas MD Anderson Cancer Center.

At the press conference, CPRIT's Chief Executive Officer Wayne Roberts will be joined by Jim Willson, MD, CPRIT Chief Scientific Officer, Mike Lang, CPRIT Chief Product Development Research Officer, and Becky Garcia, PhD, CPRIT Chief Prevention and Communications Officer.

Texas voters overwhelmingly approved a constitutional amendment in 2007 establishing CPRIT, and authorizing the state to issue $3 billion to fund groundbreaking cancer research, prevention programs and services in Texas.

The goal of CPRIT's academic research program is to discover new information about cancer that can lead to prevention, early detection, and more effective treatments; translate new and existing discoveries into practical advances in cancer diagnosis, treatment, and survivorship; and increase the prominence and stature of Texas in the fight against cancer throughout the state.

Texas leads the nation in its commitment to the war on cancer. CPRIT has funded 998 awards for cancer research, product development, and prevention since 2010. The total amount awarded thus far is $1,496,398,115.

Recipients of CPRIT awards include 98 academic institutions, non-profit organizations, and private companies, all located in Texas. The research and prevention efforts funded by CPRIT advance the health of Texans, research superiority of the state, life science infrastructure, and the Texas economy. These projects are operating in virtually all regions of the state with Texas-based employees.

https://bionews-tx.com/news/2016/05/12/cprit-holds-press-conference-halfway-point-authorized-funding/

CPRIT Marks Midpoint in Texas Agency's 10-Year Cancer-Fighting Mandate

Angela Shah
May 18th, 2016

Xconomy Texas — *Austin*—Officials at the Cancer Prevention and Research Institute of Texas Tuesday marked the midpoint of the agency's mandate.

"Curing cancer takes 10 to 15 years and costs hundreds of millions of dollars, if not billions," said Wayne Roberts, CPRIT's executive director. "But preventions and cures are possible with every advance…Cancer is not cured now, but it is one discovery at a time."

To date, CPRIT has awarded 998 grants totaling $1,496,398,115. On Wednesday, the agency will announce additional awards, which it says will push that amount over $1.5 billion —the halfway mark of its $3 million mandate.

CPRIT, or "sip-rit," as the agency is known, was approved by Texas voters in a 2007 referendum to spend $3 billion in taxpayer money to help prevent, find cures for, and educate the public about cancer. The institute began giving out grants in 2011.

Among those investments are funds put into a number of notable young biotech and life sciences companies that have come through the agency's filters and received funding to help develop therapies, pay for clinical trials, and other needs of young biotech companies. These include **Apollo Endosurgery**, which has developed a flexible endoscope to remove early-stage cancer from the gastrointestinal tract instead of major invasive surgery, and Asuragen, which makes a kit and software to identify tumor mutations.

In total, CPRIT has invested in 13 companies. One of them, **Mirna Therapeutics**, filed for an IPO last August.

Michael Lang, the agency's chief product development officer, said CPRIT has given out 28 product development grants—funds that go directly to companies seeking to commercialize therapies, or devices—for a total of $200 million. The vast majority of the money has been allotted to drug companies, he added.

"But the real proof in the pudding is in the outputs; one of the outputs is follow-on funding," Lang said. "These companies have attracted over a billion dollars in follow-on funding, the vast majority from private interests. That's a very significant testament to our success."

Among the statistics Roberts recounted Tuesday were: 84 clinical trials, which have enrolled a combined 1,500 patients; 4,700 jobs created, none of which have left the state; and 110 "star" researchers brought to Texas. "We have brought 2,000 future years of research to Texas," he said. "They will be CPRIT's legacy and Texas' gift."

The briefing comes four years after the agency stumbled and had its operations **suspended** because of conflicts of interest allegations and improperly awarded grants. The agency was **reopened** in June 2013.

For Will Montgomery, assistant presiding officer on the agency's oversight board, having CPRIT in the state is personal. **Jim Allison** was recruited away from Memorial Sloan-Kettering Cancer Center in New York in 2010 to head the immunology department of the University of Texas MD Anderson Cancer Center in Houston. His work "saved the life of my great-uncle," Montgomery said. "He's free of lung cancer."

http://www.xconomy.com/texas/2016/05/18/cprit-marks-midpoint-in-texas-agencys-10-year-cancer-fighting-mandate/

AUSTIN BUSINESS JOURNAL

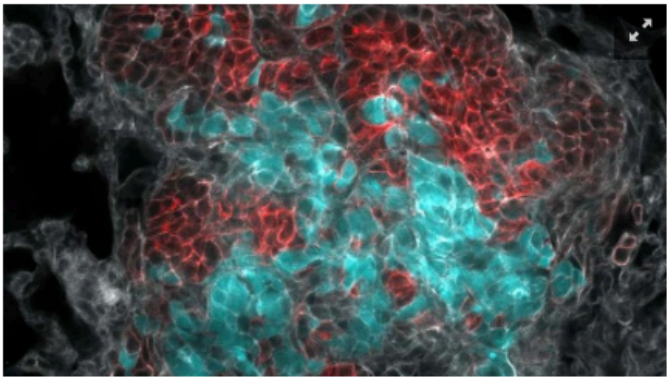
Austin biopharma startup gets $15M CPRIT grant

Will Anderson
Digital Editor
Austin Business Journal

May 19, 2016,

Pelican Therapeutics, an Austin-based biopharma startup fighting cancer, has received a $15.2 million grant from the Cancer Prevention and Research Institute of Texas.

Pelican has two employees: Dr. Taylor Schreiber is director and chairman of its scientific advisory board and Josiah Hornblower is CEO. Hornblower told Austin Business Journal the company plans to add 20 employees within three years.



An image of a lung metastasis showing two types of cancer cells. An Austin startup... more

FRED HUTCHINSON CANCER RESEARCH CENTER

Pelican develops therapies in the promising field of immunotherapy, which uses the body's own immune system to fight cancer. The company said the CPRIT grant will allow it to start a clinical trial with its lead antibody, called PTX-25, and set upits headquarters and labs in Austin.

The startup cash was part of a larger announcement by Austin-based CPRIT, which on Wednesday announced 35 new grants for $79.2 million. It has now given out $1.57 billion, or more than half of the $3 billion set aside in 2007 by the state to fight cancer.

In addition to Pelican Therapeutics, University of Texas at Austin faculty Kevin Dalby ($4.9 million), Livia Schiavinato Eberlin ($200,000) and Haley Tucker ($200,000) also received grants.

http://www.bizjournals.com/austin/news/2016/05/19/austin-biopharma-startup-gets-15m-cprit-grant.html

Strategic Partnerships, Inc.

by Peter Partheymuller May 20th 2016

CPRIT reaches midway point of 10-year life cycle

Cancer institute has awarded $1.5 billion for cancer research, product commercialization

The Texas Legislature passed legislation in the 2007 legislative session that led to the creation of the Cancer Prevention and Research Institute of Texas (CPRIT) as a source of funding for research and medical commercialization. Texas voters passed a constitutional amendment that established the institute and approved its funding with $3 billion in bond money in the November 2007 election, and CPRIT was authorized to use that money over a 10-year period.

This week, CPRIT's leaders awarded 35 grants worth $79.2 million to academic researchers and product development researchers. Those grants pushed the institute's total awards past two important health care milestones. There have been more than 1,000 grants awarded for just more than $1.5 billion now, pushing CPRIT over the midway point in terms of its authorized funding.

"Since we began awarding grants in 2010, we've taken Texas farther and faster in the fight against cancer," said Chief Executive Officer Wayne Roberts. "CPRIT has accelerated cancer research and prevention to get answers about cancer faster, push promising drugs into clinical trials sooner and prevent cancer or detect it earlier."

The grants are divided into three categories: academic research, prevention and product development.

About two-thirds of the grant funding already awarded, just shy of $1 billion, has gone to academic research programs. Among the mandates given to the institute was to bring nationally recognized cancer researchers and scholars to Texas so that the state's medical and educational institutions may benefit directly from their work. Since the first CPRIT grants were awarded in 2010, almost $335 million has been used to recruit 110 scientists to Texas institutions.

CPRIT's announcement of the milestones reached this week highlighted two doctors brought to The University of Texas MD Anderson Cancer Center through CPRIT grants. Raghu Kalluri has used the funding to do work toward the development of a blood test that may detect pancreatic cancers at an earlier stage than ever before. Cassian Yee's work in immunotherapy is headed to the clinical trial stage with a company that has benefited from a CPRIT product commercialization grant.

About 30 recipients have been awarded product development grants totaling about $275 million. Two of them have already reached the market. One has developed a kit and software used in labs and aids researchers in identifying mutations that power cancer cells. The other has built a flexible endoscope that removes early stage cancer from the gastrointestinal tract. That product has been used in 5,000 procedures in lieu of invasive surgery, which has historically been the method used to perform the operation.

The institute was forced to shut down funding operations for almost a year in 2013 amid a controversy over suspect methodology used in awarding several grants. Legislators devoted close attention to the institute, and CPRIT was in danger of being shuttered permanently. A legislative reform package passed in the 2013 session and, later that year, the institute was again allowed to continue its funding operations.

Jeff Hillery, a spokesman for CPRIT, says of the institute in the years since: "CPRIT implemented the reforms required by the legislature in the 83rd session. Those reforms included heightened conflict-of-interest standards, process improvements for developing and approving grants and more consistent and effective monitoring of grantees' performance that strengthen the agency's commitment to transparency and accountability in all of its operations."

He also stressed that the legislative reforms mandate that, "if an application is not recommended by the peer reviewers, then neither CPRIT's Program Integration Committee nor its Oversight Committee is able to consider that application."

Since the legislative moratorium was lifted, CPRIT has awarded about 400 grants worth $600 million.

The complete list of CPRIT grantees is available on the institute's website.

SPI's newsletters are excellent sources of information regarding state government news. Subscribe here.

http://www.spartnerships.com/cprit-reaches-midway-point-10-year-life-cycle/

HOUSTON CHRONICLE

By Jenny Deam May 25, 2016

Pharma company developing cancer drug moving to Houston

A Utah-based pharmaceutical company that has discovered a drug to battle a rare pediatric bone cancer is moving its operations to Houston after winning a coveted grant, the company's CEO said Wednesday.

Salarius Pharmaceuticals, formerly headquartered in Salt Lake City, has already begun setting up shop in the newly opened JLABS @ TMC, a business incubator formed in a partnership between Johnson & Johnson and the Texas Medical Center to provide lab space and support for biotech and medical startups.

"We are very excited about coming. This is a fabulous opportunity," Salarius CEO David Arthur said in an interview.

Although the company was also being wooed by another state, Arthur said he jumped at the chance to relocate to Houston after learning Salarius had been awarded an $18.69 million grant from the Cancer Prevention and Research Institute of Texas. One of the criteria for the award is being located in the state.

Arthur said he got word of the grant on May 18 and put his house on the market the next day.

He called Houston "a very attractive location to work in biotechnology." He is especially drawn to the JLABS@TMC location just down the street from not only the University of Texas M.D. Anderson Cancer Center but also Texas Children's Hospital.

Salarius is developing a drug to combat Ewings sarcoma, a rare bone cancer that strikes children. Currently there is no targeted therapy for the disease, only radiation, chemotherapy and surgery. The drug discovery was made about two years ago at the Huntsman Cancer Institute at the University of Utah based on research by Dr. Sunil Sharma.

Arthur said the company is working with the U.S. Food and Drug Administration to begin testing the still-unnamed drug on humans. "We will begin Phase I clinical trials by the end of the year," he said. Arthur said his company has two employees now but plans to hire about 18 more over the next few years as it hastens the march toward commercialization.

The Cancer Prevention and Research Institute of Texas is the state's $3 billion taxpayer-funded assault on cancer. Approved by voters in 2007 and launched in 2009, it allows the state to award up to $300 million annually in grant money, mostly for research into how to better treat the disease. To date, it has awarded 1,033 grants totaling more than $1.57 billion.

The Salarius grant is an example of the agency's recent shift to emphasize pediatric cancers and product development.

The program has weathered its share of controversy with critics alleging mismanaged funds and under-performance, but Arthur said that will have no impact on his grant.

http://www.houstonchronicle.com/business/medical/article/Pharma-company-developing-cancer-drug-moving-to-7945701.php

HOUSTON BUSINESS JOURNAL

Joe Martin
Reporter
Houston Business Journal

May 26, 2016,

Houston dominates Texas cities for CPRIT awards

The Bayou City and its cancer research institutions lead the way in state funding as Texas' cancer research program reaches its halfway point.

The Cancer Prevention and Research Institute of Texas has awarded just over $1.5 billion in funding since it began in 2009. In that time, the program has awarded more than $648 million to Houston institutions and given funding to 14 different companies that have set up shop or relocated to Houston.

Wayne Roberts, CEO, CPRIT

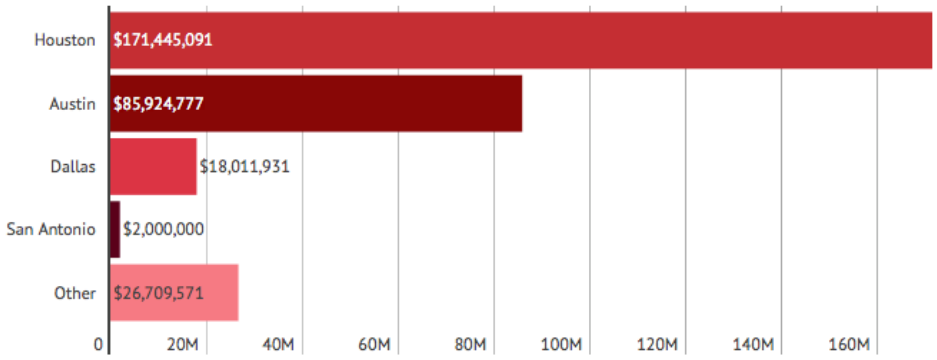
SUBMITTED PHOTO

A lot of that funding has gone to health care organizations such as the University of Texas M.D. Anderson Cancer Center and the Baylor College of Medicine. However, Rice University has been awarded more than $41 million, and the University of Houston has garnered more than $20 million, according to HBJ research. Some of these grants help recruit top minds in cancer research to Houston programs, like Rice's courting of Natasha Kirienko from Harvard in May 2015, while others help these institutions develop new ways to approach cancer.

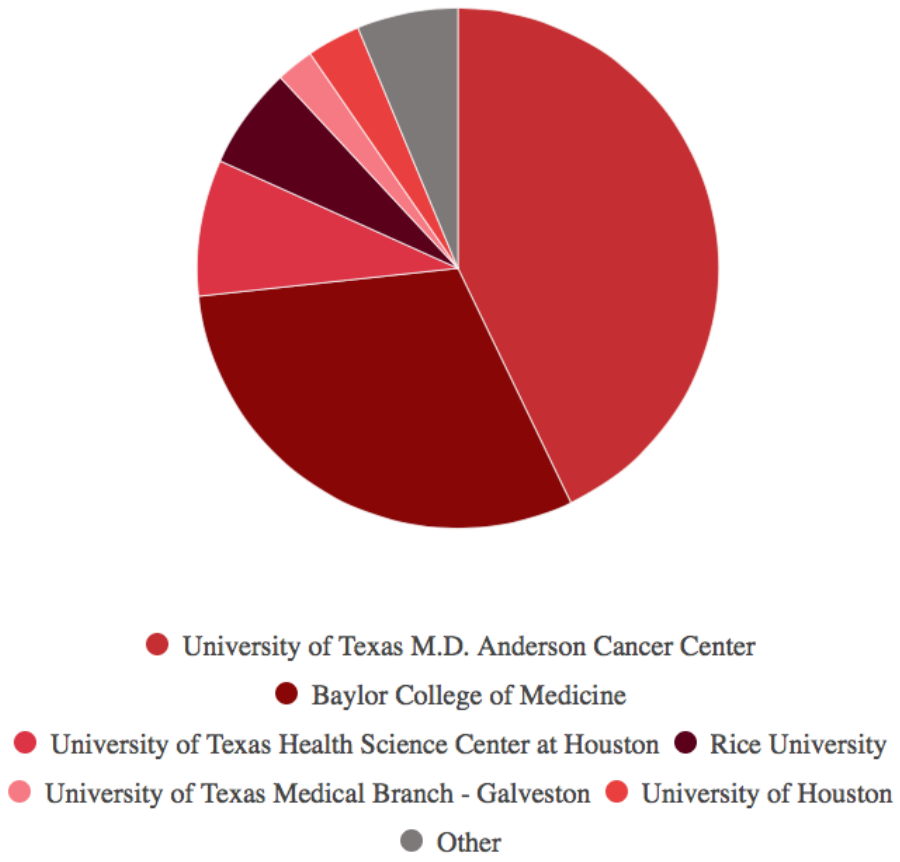
And as for courting new companies, Houston is well ahead of Austin and Dallas, as well. CPRIT grants have brought nine companies to Austin and three to Dallas, while San Antonio has only seen one new company set up shop there. David Arthur, the CEO of Salarius Pharmaceuticals LLC, which recently announced its plans to relocate to Houston, said the reason is because Houston and Texas' infrastructure is superior to others out there.

CPRIT to-date has awarded more than 1,000 grants. It will continue until it doles out $3 billion to fund cancer research, according to its website.

Amount of money CPRIT has awarded companies by city



Houston CPRIT grants by institution



http://www.bizjournals.com/houston/morning_call/2016/05/houston-dominates-texas-cities-for-cprit-awards.html

AgriLife TODAY

• Writer: Kathleen Phillips, 979-845-2872, ka-phillips@tamu.edu May 29, 2016

Cancer research boosted by $400K grant to Texas A&M AgriLife Research

COLLEGE STATION — Two scientists with Texas A&M AgriLife Research will share almost $400,000 for cancer research granted by the Cancer Prevention Research Institute of Texas.

The research institute was established in 2007 to "expedite innovation in cancer research and product development and to enhance access to evidence-based prevention programs throughout the state."

Dr. Xiuren Zhang's grant for $199,958 is for "Exploring Geminivirus-Encoded Suppressor of Histone Methyltransferases as an Anticancer Drug." Zhang is an AgriLife Research biochemist and geneticist in College Station.

Zhang said histone methyltransferases and demethylases are often altered in cancers, and countering these processes is an active area for therapeutic intervention.

Dr. Xiuren Zhang (Texas A&M AgriLife Research photo by Kathleen Phillips)

His laboratory recently discovered how a tiny viral protein enables the infection of a complex plant — a finding that could help understand how viral diseases such as cancer spread in animals and humans.

He said histone methyltransferases and demethylases are often altered in cancers, and countering these processes is an active area for therapeutic intervention.

Zhang will further explore and engineer the potent suppressor protein that specifically inhibits eukaryotic histone methyltransferases to control cell proliferation and the formation of tumors in human cells.

"The approach proposed in the study is innovative in that it applies a novel, biologically derived inhibitor, which may prove more effective than artificial inhibitors," he said. "With this funding, I hope to develop a new cell biology tool with the potential to facilitate our understanding of methyltransferases and histone methylation in gene regulation and cancer biology. The ultimate goal is to provide a powerful toolkit for studying and perhaps fixing epigenetic changes in cancer."

The grant to Dr. Jean-Philippe Pellois, for "Quantitative Mapping of Intracellular Protein-Protein Interactomes in Healthy and Cancerous Cells" totals $198,753. Pellois is an AgriLife Research biochemist in College Station.

"Cells can become cancerous when the function of certain proteins becomes dysregulated," Pellois said. "These proteins carried out their molecular function by binding to other intracellular partners. To date, understanding how this network of interactions change when proteins become dysregulated is a challenge, because we currently lack the technologies that would permit to probe interactions networks directly inside cells."

Dr. Jean-Philippe Pellois (Texas A&M AgriLife Research photo by Kathleen Phillips)

Pellois said the grant will help his team "develop a radically novel technology that addresses this challenge by delivering proteins modified with affinity labels directly inside cells. Affinity labels can leave a chemical trace on the protein's interaction partners and these partners can then be analyzed and quantified.

"This novel technology is only now feasible because of the recent progress we have made in finding efficient means of introducing proteins into live cells. Building on this success, we propose that our approach is plausible and of great potential impact," Pellois added. "In particular, by mapping protein interaction networks inside cells and by monitoring how these networks change under various stimuli, we expect that this new platform will lead to powerful ways of monitoring the molecular causes of cancers.

"In addition, we envision that this technology will be useful to decipher physiological versus pathological interaction networks, which in turn should contribute to the identification of new drug targets – by comparing non-cancerous and cancerous cells – and to a better understanding of how anti-cancer drugs impact intracellular protein-protein interactions – by comparing cells treated with or without drugs."

Pellois said it also should be useful as a prognosis tool by identifying protein-protein interactions that can be used as predictive markers for drug resistance.

-30-

http://today.agrilife.org/2016/05/29/cancer-research-boosted-by-400k-grant-to-texas-am-agrilife-research/

SAN ANTONIO BUSINESS JOURNAL

SBAILEY@BIZJOURNALS.COM June 3, 2016

CANCER RESEARCH

Cancer money to boost local pediatric research

The Cancer Prevention & Research Institute of Texas has awarded nearly $11 million to the University of Texas Health Science Center at San Antonio in its latest funding round. That award includes $5 million to help establish the Texas Pediatric Patient-Derived Xenograft Facility.

Peter Houghton, director of the Greehey Children's Cancer Research Institute at the Health Science Center, said the grant will be used to develop animal models that can be used to test new therapies in underserved pediatric populations, including minority groups who have not typically responded well to current treatments.

One of the challenges researchers now face is that existing pediatric cancer treatments can be as harmful as the disease.

"The therapies can be very toxic," Houghton said.

One way researchers can try to improve outcomes is to better understand what they are up against.

"That's what the CPRIT core grant is about – to try and generate models that create accurately the genetic defects we see in tumors in kids," Houghton said.

The funding will allow the Health Science Center to collaborate with the University of Texas Southwestern Medical Center in Dallas to develop and characterize new patient-derived xenograft models from children that will be made available to pediatric cancer researchers across Texas and elsewhere. The hope is that researchers can gain new insight that ultimately leads to better drug therapies for pediatric cancer patients.

"The more people who get engaged in the study of pediatric cancer, the more likely a breakthrough will occur," Houghton said.

▸ BY THE NUMBERS

HEALTH SCIENCE CENTER CPRIT FUNDING

Here is a breakdown of the balance of the $10.9 million awarded by CPRIT to the San Antonio institution:

$3.6 million

Awarded to the Greehey Children's Cancer Research Institute's Yidong Chen to update and expand existing infrastructure establishing a Cancer Genome Sequencing and Computational Core that will be available to South Texas researchers through the Health Science Center

$2 million

To enable the recruitment of pediatric cancer researcher Myron Ignatius from Massachusetts Hospital and Harvard Medical School

$200,000

To support a research program to study a novel approach to treating Ewing sarcoma, one of the most common bone and soft-tissue cancers found in children and young adults

SOURCE: UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

▸ NOTABLE NUMBER

$25.1 million

The amount Methodist Healthcare System co-owner Methodist Healthcare Ministries plans to award to some 80-plus organizations this year to support a variety of health-related initiatives

FILE PHOTO

Methodist Healthcare Ministries CEO Kevin Moriarty.

Star-Telegram
SUNDAY JULY 3 2016

We've reached some major milestones in North Texas' fight against cancer

BY KEITH E. ARGENBRIGHT
Special to the Star-Telegram

We are halfway through a $3 billion investment in cancer research and programs in Texas.

What do we have to show for it? Plenty! And a good chunk of it right here in North Texas.

Since 2009, the Cancer Prevention and Research Institute of Texas (CPRIT) has awarded more than $1.5 billion to fight cancer, after Texas voters overwhelmingly approved a 2007 bond issue.

Here are just a few programs this important agency funded at Moncrief Cancer Institute in Fort Worth and our partner UT Southwestern's Harold C. Simmons Comprehensive Cancer Center in Dallas:

- $4,800,000 for colorectal screening for the under-served, offering free tests for 165,000 qualifying residents in Tarrant and 20 surrounding counties. It's part of a multiyear research collaboration between JPS Health Network and Moncrief Cancer Institute. This is the largest CPRIT prevention grant awarded to date.
- 30,000 women have received mammograms and follow-up treatment as a result of CPRIT awards starting in 2010 at Moncrief/UT Southwestern. Since then we have detected 450 cancers, most at an early stage when cancer is most curable.
- $1,499,800 for enhanced genetic counseling and testing services for under-served populations in Fort Worth, Dallas and other rural counties. This grant enabled us to identify and help patients with DNA mutations that could lead to breast, ovarian or colon cancer.
- $803,800 for our Community Survivorship program. This initial grant allowed us to "prove the concept," showing that cancer survivors can thrive with exercise, nutrition and psychological counseling, along with visits to oncology-trained specialists and genetic counselors at no cost to the patient.

We used that initial Survivorship funding to secure a larger federal grant in partnership with UT Southwestern. The grant enabled Moncrief to design, build and deploy a first-of-its-kind Mobile Cancer Survivor Clinic, which travels to reach cancer survivors in their home communities in Tarrant and eight nearby counties.

Before CPRIT, MD Anderson in Houston was the only National Cancer Institute-designated Comprehensive Cancer Center in Texas. Now, UT Southwestern's Simmons Comprehensive Cancer Center has achieved NCI top-tier status, considered the gold standard in cancer care.

Without CPRIT programs, we would not have been able to reach so many people, save lives through early detection and raise the quality of life for cancer survivors.

The number of cancer survivors nationwide has topped 15 million and continues to rise.

Thanks to Texas voters who funded CPRIT, our state is leading the way in the fight against cancer.

Already, 110 top cancer researchers and their labs have moved to Texas.

As we take time to celebrate our nation's independence, we also celebrate the vision we share with all Texans — one that is independent of cancer.

Dr. Keith E. Argenbright is director of the Moncrief Cancer Institute and a professor at UT Southwestern Medical Center.

Return to agenda

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT:	PRODUCT DEVELOPMENT UPDATE
DATE:	AUGUST 17, 2016

Summary and Recommendation

This memo summarizes Product Development activities since the last Oversight Committee meeting in May. Subjects include:

- Status of applications under review
- Update on development of the Product Development Research program priorities
- Discussion on targeted requests for applications (RFAs) and repeat applicant policy
- Update on strategy to accelerate university spinouts
- Update on asset management

Product Development Application Review Process Updates

Product Development Review Cycle 16.2

RFAs for Texas Company and Company Relocation were released in December. Thirty-two applications were submitted, making this among our largest submission pools. The screening teleconference was held April 7 & 8. Thirteen of the 32 companies were selected to be invited to present at the Peer Review meeting on May 10-12. Seven of these were selected for diligence. Diligence is underway for planned PDRC review in October. Award recommendations from this cycle are expected to be presented for Oversight Committee consideration at the November meeting.

Product Development Review Cycle 17.1

The Cycle 17.1 RFAs opened on June 30 and will close on August 11. The applications will begin peer review in September; recommended applications are expected to be presented at the February 2017 Oversight Committee meeting. SRA reports that the number of applications started to date is running slightly ahead of previous cycles.

Product Development Research Program Priorities

CPRIT's Product Development program operates under the following principles:

1. Support commercial development of novel products to address unmet cancer diagnosis and treatment needs;
2. Stimulate the Texas life sciences ecosystem by funding areas that lack private investment;
3. Invest in projects based on sound scientific research with strong management and sound business plans that may attract follow-on private investment.

These principles guide investment decisions and all investments must comport with them. CPRIT receives ten-fold more applications than it has resources to fund. Hence we undertake a comprehensive assessment process to select the most attractive programs for funding. Funding selection is based on the following criteria:

1. Funding novel projects that offer therapeutic or diagnostic benefits not currently available; i.e., disruptive technologies;
2. Funding projects addressing large or challenging unmet medical needs;
3. Investing in early-stage projects, when private capital is least available;
4. Stimulating commercialization of technologies developed at Texas institutions;
5. Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to seed clusters of life science expertise at various Texas locations;
6. Providing appropriate return on Texas taxpayer investment.

We have 28 active companies in our portfolio with the following attributes:

Sector	Devices and Diagnostics	Therapeutics (Drugs)
Active investments	10 companies or 36%	18 companies or 64%
Total Invested	$42MM or 14%	$264 MM or 86%
Average Investment	$4.2 MM	$14 MM

Since inception, 80% of research awards have been made to academic institutions and 20% to companies. In FY 2017, CPRIT targets $63.5 MM or 25% of total research award to companies.

FY 2016 and FY 2017 Honoraria

CPRIT's peer reviewers are paid pursuant to CPRIT's honoraria policy. A change was made to the FY 2016 Honoraria Policy in July to address honoraria paid to Product Development peer review panel members that conducted first-time reviews of the business plans submitted by Early Translational Research Award (ETRA) grantees. CPRIT requires ETRA grantees to develop and submit business plans after the first year of their project is complete. We recruited four Product Development peer review panel members with business expertise to individually review the 19 business plans and provide specific feedback to the individual ETRA grantees.

The Honoraria Policy is updated annually. Consideration of the FY 2017 Honoraria Policy is an agenda item for the August Oversight Committee meeting. Honoraria for Product Development reviewers in FY 2017 will remain at the same as FY 2016.

Targeted Request for Applications - Diagnostics

Diagnostic technologies can be highly cost effective. They are less expensive to develop and deploy and can provide significant system cost savings. Cancer is often easier to cure when detected early. However early stage cancer are notoriously difficult to detect and diagnose. Improved diagnostic technologies afford preventive or earlier therapeutic intervention. These are often less expensive and more effective than later stage therapies.

Given the benefits of diagnostics, and our relatively small share of diagnostics investment, we would like to enhance the number of diagnostic applicants. A targeted RFA, focusing on diagnostics, is under consideration. When combined with outreach to diagnostic firms and revenue sharing terms tailored to the diagnostic industry, we believe a targeted RFA will increase the number of diagnostic applications.

We are reactivating CPRIT's Product Development Advisory Committee and plan to solicit their input on a targeted RFA for diagnostic applications.

Repeat Awardees

As more CPRIT grantees complete their initial awards, there will be increased opportunities to make repeat awards to the same companies. CPRIT has limited resources (budgeted $63.5MM for FY 2017 Product Development awards) and receives numerous product development applications (approximately 70 in FY 2016). CPRIT only funds a small fraction of applicants.

As discussed in the May Oversight Committee meeting, we modified the most recent RFA to accommodate these circumstances by precluding repeat awards. Awarding our limited funds to new companies grows the Texas bioscience industry and increases the number of novel technologies under development. We can modify this RFA provision in the future if the venture funding environment changes and subject to counsel from the Product Development Advisory Committee and Product Development Subcommittee discussion.

University Spinouts

I have had initial discussions with several Texas academic institutions to evaluate interest in collaborating to increase academic commercialization. To date I have met with MD Anderson, UT Southwestern, Baylor College of Medicine and Dell Medical School at UT Austin.

These institutions have well-developed commercialization initiatives within their technology transfer offices which:

- Prioritize research assets with greatest commercial potential;
- Conduct follow-on translation research and development to further develop and de-risk these assets; and
- Seek to license assets to industry for later-stage development and commercialization.

These institutions seek to expand their programs with additional staff and development funding. All expressed interest in collaborating more extensively with CPRIT.

A new funding mechanism could provide ongoing support to accelerate commercialization of CPRIT and NCI funded research. Key attributes required for a successful program include:

- Institutions need both commercialization staff and development funding;
- Establish a methodology to select which assets are developed or allow institution to select;
- Structure the funding program to accommodate project attrition and changing project needs;
- Funding program structured to accommodate differences between institutions.

Such a program would provide resources to Texas research institutions not specifically tied to a single investigator. This could bridge the gap between our Academic Research and Product Development Research Programs. We plan to solicit the input of CPRIT's Product Development Advisory Committee and the University Advisory Committee on how best to structure this potential new award mechanism. Given that the funds for these new awards would need to come

from CPRIT's research programs, the programs would need time to accommodate integration into the funding portfolio.

Asset Management

CPRIT investments have generated asset holding with potentially significant monetary value. Most CPRIT investments have royalty-based return. In addition, we hold equity in three firms.

We have reviewed all grants to assess if royalties due to CPRIT are in fact being paid. Five awardees are revenue stage firms--four companies are in compliance with their royalty obligations and one royalty obligation assessment is underway. All other CPRIT awardees are pre-revenue and do not have a current royalty obligation.

A monitoring process will be required to insure compliance now that some CPRIT awardees are progressing towards revenue generation. CPRIT investments have been primarily in cancer therapeutics. These projects are characterized by long development cycles, high attrition rates and large returns for the few successes. CPRIT will need an on-going monitoring system that addresses these issues. This will need to be structured to account for the unique circumstances of drug development companies. In addition, CPRIT currently holds equity in three companies: two privately held and one publicly traded. The number of equity positions held by CPRIT may rise as our product development portfolio grows and an increasing number of CPRIT-funded companies engage in follow-on financings, acquisitions or other transactions.

Currently, CPRIT does not have the resources or personnel internally to implement a long-term monitoring system or actively manage equity assets. The Texas Treasury Safekeeping Trust Company (part of the Comptroller's Office) provides these services for other assets owned by the state. We are exploring the option of having the Safekeeping Trust Company monitor and manage assets generated by CPRIT's revenue sharing terms. If the Safekeeping Trust Company is not able to assist CPRIT, we will need to contract with a third party for these services.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Recommendations for Scientific Research Peer Review Panels

- Steve Altschuler, Ph.D.
- Paul A. Bunn, M.D.
- Arion Chatziioannou, Ph.D.
- Michael A. Hollingsworth, Ph.D.
- David A. Mankoff, M.D., Ph.D.
- Alexander Meissner, Ph.D.
- Carolyn D. Runowicz, M.D.
- Kristin R. Swanson, Ph.D.
- Cameron Turtle, M.D., Ph.D.
- Eliezer M. Van Allen, M.D.
- Henry VanBrocklin, Ph.D.
- Lani Wu, Ph.D.

Recommendation for Prevention Peer Review Panels

- Bob Riter

Recommendations for Product Development Peer Review Panels

- C. Glenn Begley, Ph.D.
- Renzo Canetta, M.D.
- Terence Porter, Ph.D.
- Sandra Silberman, M.D., Ph.D.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

The CV's for the SRPP recommendations can be viewed separately on our website, click on link below:
http://www.cprit.state.tx.us/images/uploads/oc_packet_peer_reviewer_recommendations_08172016.pdf

Return to agenda

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: FY 2017 HONORARIA POLICY
DATE: AUGUST 10, 2016

Summary and Recommendation:

The 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 approved the FY 2016 honoraria policy at the August 2015 meeting. The FY2017 honoraria policy has been revised to reflect the additional time spent by Prevention and Academic Research panel members related to peer review activities. I recommend approval of the FY 2016 honoraria policy.

Discussion:

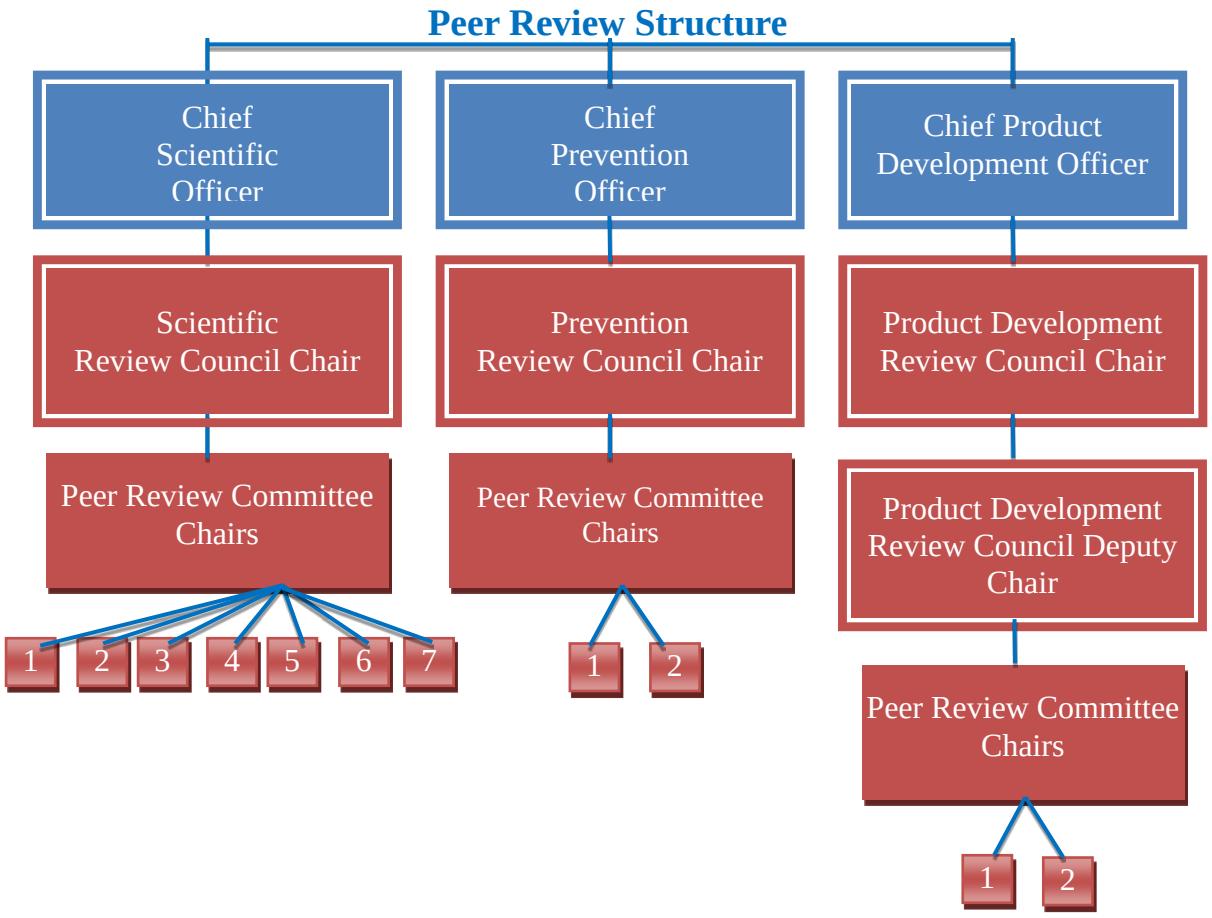
CPRIT's Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research (including product development) in Texas. State 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.

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.

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 FY 2017 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 2017 honorarium amount paid for each role. In the event that honoraria rates are not standard across the prevention, academic research, and product development programs, the policy justifies the reasons for paying different amounts. The policy fully implements the statutory mandate and audit recommendations.

CPRIT PEER REVIEW FY 2017 HONORARIA POLICY[1]

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 academic 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 190 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

[1] Adopted pursuant to TEX. HEALTH & SAFETY CODE Section 102.151(e).
[2] The National Academies of Sciences recommends a tiered approach to peer review.

the peer review committees are used to develop the list of grant applications recommended for CPRIT grant awards.[3]

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 from 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 individuals 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.

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[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.
[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 confirmation 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 confirmations and approves payment of quarterly honoraria 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 confirmations 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.

CPRIT's third party grant administrator pays peer reviewers 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, Review Council chairs, and Committee chairs travel to attend peer review meetings. CPRIT relies upon standard travel documentation for travel reimbursements.

In the event a Review Council chair, Committee chair, or peer reviewer is not able to complete a full review cycle due to unforeseen circumstances, the CPRIT Program Officer may approve, in his or her discretion, a partial payment of the honorarium. The Program Officer should explain in writing the basis for approving a change to the reviewer's honorarium; CPRIT will retain such explanation as part of the grant review records. Nothing herein prevents the Program Officer from approving full payment even if the reviewer is unable to participate in every aspect of the review cycle so long as the reason is well justified.

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, Scientific, 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 FY 2017. 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 – 2016 review cycle information and the projected workload for FY 2017.

NOTE: In addition to the regular Council Chair duties in FY 2017, CPRIT anticipates that the Product Development Review Council Chair will perform services totaling approximately 60 additional hours. 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. In FY 2016, CPRIT created the Product Development Review Council Deputy Chair position. This position is substantially equivalent to the Council Chair position except that the Deputy Chair will not prepare slate recommendation for the Chief Executive Officer, review draft RFAs, propose new RFAs, or analyze data for the Product Development program. CPRIT will continue to use a Deputy Chair position for FY 2017.

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.

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 Review 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 review 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 and Product Development Review Committee chairs are expected to commit approximately 200 hours to CPRIT-related activities in FY 2017, 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 – 2016 review cycle information and the projected workload for FY 2017.

[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.

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 limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is considerably greater than the $28,000 - $46,000 honoraria paid to CPRIT Review Committee Chairs.

Review Committee Members

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. Academic 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 2009–2016 review cycle information and the projected workload for FY 2017.

In addition to peer review activities, some Product Development Research peer review committee members may conduct post-award review of business plans submitted by Early Translational Research Award (ETRA) grantees. Activities associated with the post award review of business plans include: preparing written critiques of the business plans, participating in follow-up telephonic conferences with individual grantees to discuss the review, and providing a written summary of the conference calls with the ETRA grantees. The information in Table 4 reflects the activities, hours, and units used to project the ETRA business plan reviewer workload. The ETRA business plan reviewers submit the critiques and the conference call summary to CPRIT to document the work completed. Reviewers are not required to travel for the business plan reviews.

Hourly Rate Proxy: Honorarium is paid for the service of Academic 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 Academic Research and Prevention peer reviewers equates to a rate of $50/hour. Honoraria paid to Product Development peer reviewers is $65/hour. These

[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.

reviewers must have both academic research 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 (See Table 5 for an explanation of the correlation between units and hours.)

Table 1 - Review Council Chair Activities, Hours, Units						
Academic Research Review		**Prevention Review**		**Product Development Review**		
Units	Activity	Units	Activity	Units Chair	Units Deputy	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	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	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	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	0	Review draft RFAs, propose new ones, etc.
5	Communicate with Committee Chairs prior to peer review & programmatic mtg	1	Communicate with Committee Chairs prior to peer review & programmatic mtg	6	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	4	Prepare for Programmatic meetings; review materials
2	Lead programmatic review	6	Lead programmatic review	5	5	Lead programmatic review
4	Prepare slate recommendations for ED	1	Prepare slate recommendations for ED	4	0	Prepare slate recommendations for ED
20	Review recruitment applications, become familiar with applications to be discussed	15	Review abstracts, attend portions of panel meetings, back up for panel Chair	12	12	Review abstracts, attend portions of panel meetings, back up for panel Chair
5	Lead quarterly discussion on recruitment awards	4	Collaborate on articles for publication	4	0	Analyze data for Product Development program
4	Analyze data for Research program	4	Analyze population and other data for Prevention program	12.5	12.5	Review annual and final progress reports, including milestone achievement reports, advise on activities of funded product development grants
		3	Prepare and participate in quarterly Review Council teleconference			
57		4	Review Annual and Final progress reports	62.5	48.5	
$ 1,200	Unit cost	53			$1,200	Unit cost
$ 250	Hourly rate	$1,200	Unit cost		$250	Hourly rate
$68,400	Annual honoraria	$250	Hourly rate		**$75,000**	Annual honoraria Chair
					$58,200	Annual honoraria Deputy Chair
		$64,000	Annual honoraria			

Table 2. Committee Chair Activities

Table 2 - Committee Chair Activities, Hours, Units					
Academic Research Review		**Prevention Review**		**Product Development Review**	
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)
12	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.
			Prepare and participate in quarterly Review Council teleconferences		
20	Review recruitment applications	3			
3	Participate in quarterly review of recruitment applications				
52		32		45	
$875	Unit cost	$875	Unit cost	$875	Unit cost
$200	Hourly	$200	Hourly	$200	Hourly
$45,500	**$46K** Annual honoraria	$28,000	**$28 K** Annual honoraria	$39,375	**$40K** Annual honoraria

See Table 5 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 Review:~30 reviewers		**Prevention Review:~ 33 reviewers**		**Academic Research Review: ~ 140 reviewers**	
Units	**Activity**	**Units**	**Activity**	**Units**	**Activity**
1	Declaration of expertise and conflicts	1	Declaration of expertise and conflicts	1	Declaration of expertise and conflicts
7	Preparation of full critiques	7	Preparation of full critiques	9	Preparation of critiques*
2	Screening teleconference	3	Travel to/from meetings	3	Travel to/from on-site meeting
3	Travel to/from on-site meeting	4	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 $4,000 in person per cycle		$250 Unit cost $50 avg. hourly rate $4,250 per cycle

* This may be less for reviewers that participate only in the preliminary application review. The grant mechanism specifies when a preliminary reviews are used.
** Post-meeting discussion activities may include: finalizing funding recommendations, finalizing critiques, clarifying recommendations related to funding or goals/objective changes, de-briefing about the review cycle, and/or other activities specified by the CPRIT Program Officer.

NOTE: As reflected in the table, key activities are assigned a unit cost. (See Table 5 for an explanation of the correlation between units and hours.) 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. In the event a Review Council chair, Committee chair, or peer reviewer is not able to complete a full review cycle due to unforeseen circumstances, the CPRIT Program Officer may approve, in his or her discretion, a partial payment of the honorarium.

Table 4. Post-Award Activities for Product Development Review Panel Members

Product Development ETRA Business Plan Review	
Units*	**Activity**
2.5	Review of assigned business plans submitted by ETRA grantees; drafting written critiques
2.5	Preparation for and telephone conferences with ETRA grantees to provide feedback on business plans
1	Drafting written summary of conferences with ETRA grantees
	$325 Unit cost $65 avg. hourly rate $2,000 per cycle*

*Units and per cycle honorarium are based on conducting four business plan reviews per cycle. The honorarium paid to an individual reviewer may be more or less depending upon whether the reviewer evaluated more or less than four business plan reviews in the cycle.

Table 5. 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		$64,000 - $75,000 annually	$28,000 - $46,000 annually	$4,000 - $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 & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER—DONALD BRANDY
DATE:	AUGUST 11, 2016

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2017 for Mr. Donald Brandy, CPRIT's Purchaser and HUB Coordinator, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The Oversight Committee approved the same waiver for Mr. Brandy in FY 2015 and FY 2016.

Mr. Brandy is not involved in the grant application or reporting process in his official capacity as purchaser of goods and services for the agency. However, the waiver ensures transparency regarding Mr. Brandy's relationship with some universities that receive CPRIT grants. Furthermore, CPRIT's Code of Conduct makes it clear that the agency's conflict of interest provisions apply to any expenditure of CPRIT funds. Although it is unlikely that CPRIT will procure goods and services from a university receiving grant funds from CPRIT, having the conflict of interest waiver in place ensures that Mr. Brandy can perform his duties. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for a conflict of interest to unduly influencing agency purchases.

Background

Mr. Brandy serves as the agency purchaser, responsible for planning, organizing, coordinating, and preparing bid specifications and procurement documents to acquire goods and services from vendors and outside contractors used by the agency. The agency purchaser role requires little, if any, involvement with CPRIT's grant award process because CPRIT's grant award contracts are not considered vendor or outside service contracts.

At the time that he was hired, Mr. Brandy requested approval to continue his outside employment as a referee for tennis tournaments held in and around Austin. In addition to refereeing for adult and junior-level tournaments, he serves occasionally as a referee for NCAA tennis matches held at area universities, including The University of Texas at Austin. Mr. Brandy is paid for his services as an independent contractor by the university athletic department when he referees collegiate matches.

CPRIT employees may engage in outside employment so long as the employment does not detract from the employee's ability to reasonably fulfill his or her responsibilities to CPRIT. Employees must receive written approval from the CEO to engage in outside employment and I am required to notify the Audit Subcommittee regarding any approvals and to annually report all approved outside employment. I notified the Audit Subcommittee regarding my approval for Mr. Brandy's outside employment and it was discussed at the December18, 2014, subcommittee meeting.

Exceptional Circumstances Requiring Mr. Brandy's Participation

In order to approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process or other expenditure of CPRIT funds.[1]

This conflict of interest waiver is different than other waivers I have requested in that it is not seeking a waiver for actions related to CPRIT's grant review or grant monitoring process. As CPRIT's purchaser, I do not anticipate that Mr. Brandy will play any role in the review process for grant applications or grant reports. The purchaser deals only with agency procurement matters and has no influence over the grant award processes of the agency. To the extent that his outside employment necessitates involvement with university personnel, it is with collegiate athletic department staff that have no interaction with researchers working on or applying for grants. Nevertheless, if Mr. Brandy must be part of the review process or grant monitoring activities, he will comply with CPRIT's conflict of interest notification and recusal requirements.

However, during the course of his official duties there may be circumstances requiring Mr. Brandy to procure goods or services on CPRIT's behalf from a university that has also employed him as a tennis referee. This is unlikely to occur; to date, CPRIT has only one services contract with an academic institution, Texas Tech University. However, as CPRIT's lead contact for agency purchases, Mr. Brandy should be allowed to perform his official duties to the fullest extent possible. Any involvement with university athletic department personnel resulting from his outside employment is unlikely to be the same individuals at the university responsible for contracting with CPRIT.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Health & Safety Code Section 102.106(c)(3), I recommend that Mr. Brandy be permitted to perform all duties assigned as purchaser, subject to the limitations stated below:

[1] CPRIT's Code of Conduct Section III.B(2) states that, "The conflict of interest statutory and administrative rule provisions **apply to any decision to commit CPRIT funds**, whether or not the commitment is part of the grant award process or to a Grant Applicant." (emphasis added)

1. Provide the Chief Operating Officer a list of universities that have used his services as referee during the past twelve months;
2. Notify the Chief Operating Officer prior to taking any action on a contract or other procurement document that would result in payment of CPRIT funds to a university on the list referenced above; and
3. The Chief Operating Officer, in conjunction with the CEO, Chief Compliance Officer and General Counsel, can review the circumstances and determine whether Mr. Brandy should be recused from involvement in the procurement.

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or review this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval of any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request. To the extent that Mr. Brandy has a conflict of interest not address in this waiver, then Mr. Brandy will follow the required notification and recusal process.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER – DR. BECKY GARCIA
DATE:	AUGUST 11, 2016

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2017 for Program Integration Committee ("PIC") member Dr. Becky Garcia, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Dr. Garcia was appointed to the advisory committee serving the Texas Health Improvement Network ("THIN") in 2016. THIN is a statutorily-created program that is administratively attached to The University of Texas System. The waiver is necessary for Dr. Garcia to participate in CPRIT's review process as a PIC member. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria. The waiver is the same as the waiver approved by the Oversight Committee for FY 2016.

Background

In 2015, the Legislature created the THIN with the purpose to "address urgent health care challenges and improve the health care system in this state and the nation and to develop, based on population health research, health care initiatives, policies, and best practices." Texas Health and Safety Code § 118.051(a). By statute, THIN is administratively attached to the University of Texas System, which coordinates the program and provides administrative support. Texas Health and Safety Code § 118.054. Dr. Garcia, CPRIT Chief Prevention Officer, was appointed to serve on the advisory council that advises THIN on health care needs of Texas.

Texas Health & Safety Code § 102.106(c)(1) holds that a professional conflict of interest exists if a PIC member is a member of any committee affiliated with an entity receiving or applying to receive money from CPRIT during the same grant cycle. The University of Texas System is composed of several institutions, many of which are current CPRIT grantees, including, but not limited to, UT Southwestern Medical Center, M.D. Anderson Cancer Center, and UT Health Science Center at San Antonio. Since Dr. Garcia serves on a committee administered by a university system that includes CPRIT grantees, a professional conflict of interest arises.

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

Exceptional Circumstances Requiring Dr. Garcia's Participation

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

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Section 102.106(c)(1), I recommend that Dr. Garcia be permitted to continue to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. If THIN submits an application for a CPRIT grant award, Dr. Garcia must recuse herself from any discussion, review and vote related to the application.
2. If a principal investigator applying for CPRIT funds has also received funds from THIN for the same project, Dr. Garcia must recuse herself from any discussion, review and vote related to the application.

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

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request. To the extent that Dr. Garcia has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(1), then Dr. Garcia will follow the required notification and recusal process.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	**OVERSIGHT COMMITTEE CHAIR DR. WILLIAM RICE**
FROM:	**WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER**
SUBJECT:	**SECTION 102.1062 WAIVER – DR. JOHN HELLERSTEDT**
DATE:	**AUGUST 11, 2016**

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2017 for Program Integration Committee (PIC) member DSHS Commissioner Dr. John Hellerstedt, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Commissioner Hellerstedt to participate in CPRIT's review process as a PIC member. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria. The waiver is the same as approved by the Oversight Committee for FY 2016.

Background

Dr. Hellerstedt was appointed Commissioner of the Department of State Health Services (DSHS) on January 1, 2016. The DSHS Commissioner is a statutorily designated member of the PIC. As a PIC member, Commissioner Hellerstedt is called upon to exercise discretion related to whether applications proposed for grant awards by the peer review committees should be recommended to the Oversight Committee for final approval.

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

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

Exceptional Circumstances Requiring Commissioner Hellerstedt's Participation

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

Proposed Waiver and Limitations

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

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

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

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request. To the extent that Commissioner Hellerstedt has a conflict of interest with an application that

is not the conflict identified in Section 102.106(c)(3), then Commissioner Hellerstedt will follow the required notification and recusal process.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	**OVERSIGHT COMMITTEE MEMBERS**
FROM:	**WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER**
SUBJECT:	**SECTION 102.1062 WAIVER – AMY MITCHELL**
DATE:	**AUGUST 11, 2016**

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2017 for Ms. Amy Mitchell, CPRIT Oversight Committee member, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Ms. Mitchell to fully participate in the grant award approval process. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

Background

Ms. Mitchell is Senior Counsel at Norton Rose Fulbright, an international law firm with 3800 attorneys. Her practice focuses on matters related to improved and unimproved real property including sales and acquisitions, leases, ground leases, subleases, real estate financing, real estate development, environmental issues affecting real property, construction matters for owners, general contractors and subcontractors, and the formation of entities to acquire, develop, finance and operate real property. Ms. Mitchell does not personally represent CPRIT grant recipients; however, some lawyers employed by Norton Rose Fulbright provide legal services to the following grant applicants and grant recipients:

- University Health System
- University of Texas at Austin, Arlington, Brownsville, Dallas, and El Paso
- University of Texas-Pan American
- University of Texas of the Permian Basin
- University of Texas Medical Branch at Galveston
- University of Texas Health Science Center at San Antonio
- University of Texas M.D. Anderson Cancer Center
- University of Texas Southwestern Medical Center
- University of Texas Health Science Center at Houston, and Tyler
- Angelo State University
- University of Houston

- University Houston-Clear Lake, Downtown, and Victoria,
- Baylor University
- Baylor College of Medicine
- Baylor Research Institute
- Methodist Hospital Research Institute
- Rice University
- Texas Tech University
- Texas Tech University Health Science Center
- Texas A&M University
- Prairie View A&M University
- Texas A&M University Commerce, Kingsville, Corpus Christi, Texarkana, Central Texas, and San Antonio
- Tarleton State University
- West Texas A&M University
- Texas A&M International University
- Texas A&M University Health Science Center
- Texas A&M University System
- Texas A&M Health Science Center
- Texas A&M Engineering Experiment Station
- Texas A&M Agrilife Extension Services
- Texas A&M Agrilife Research

Health & Safety Code Section 102.106(c)(4) mandates that a professional conflict of interest exists if an Oversight Committee member represents an entity applying to receive or receiving CPRIT funds. Similarly, Texas Administrative Code Section 702.11(d) finds that there is a professional conflict of interest if an Oversight Committee member "represents in business or law an entity receiving or applying to receive money from the Institute…"

The entities listed above were clients of the law firm prior to Ms. Mitchell's appointment to the Oversight Committee. Although Ms. Mitchell does not perform legal work for these entities or supervise anyone who does so, she has previously recused herself from participating in the grant award process related to these entities out of an abundance of caution. She does not have an economic interest in the revenues associated with these entities paid to Norton Rose Fulbright, aside from her position as Senior Counsel at the firm.

It is reasonable to expect that the same conflict will affect Ms. Mitchell's participation in more than one grant review cycle in this fiscal year as well. CPRIT's administrative rule Section 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Ms. Mitchell's Participation

In order to approve a waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. There are compelling reasons warranting Ms. Mitchell's participation in the review process when she would otherwise be excluded because of the conflict. One of the principal duties for an Oversight Committee member is to approve grant award recommendations submitted by the Program Integration Committee. The statute requires a two-thirds vote of the Oversight Committee to approve a grant award. The vast majority of CPRIT's grant applicants and grant recipients are academic institutions, including many of the entities listed above. Excluding Ms. Mitchell from participation in the decision-making process related to grant awards reduces the number of Oversight Committee members that are able to perform the critical task of reviewing information about potential grantees and the review process associated with the grant recommendations.

The proposed limitations and CPRIT's existing process and procedures will substantially mitigate any potential for bias.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Health & Safety Code Section 102.106(c)(4), I recommend that Ms. Mitchell be permitted to participate in the review process for applications submitted by the following entities, subject to the limitations stated below:

- University Health System
- University of Texas at Austin, Arlington, Brownsville, Dallas, and El Paso
- University of Texas-Pan American
- University of Texas of the Permian Basin
- University of Texas Medical Branch at Galveston
- University of Texas Health Science Center at San Antonio
- University of Texas M.D. Anderson Cancer Center
- University of Texas Southwestern Medical Center
- University of Texas Health Science Center at Houston, and Tyler
- Angelo State University
- University of Houston
- University Houston-Clear Lake, Downtown, and Victoria,
- Baylor University
- Baylor College of Medicine
- Baylor Research Institute
- Methodist Hospital Research Institute
- Rice University
- Texas Tech University

- Texas Tech University Health Science Center
- Texas A&M University
- Prairie View A&M University
- Texas A&M University Commerce, Kingsville, Corpus Christi, Texarkana, Central Texas, and San Antonio
- Tarleton State University
- West Texas A&M University
- Texas A&M International University
- Texas A&M University Health Science Center
- Texas A&M University System
- Texas A&M Health Science Center
- Texas A&M Engineering Experiment Station
- Texas A&M Agrilife Extension Services
- Texas A&M Agrilife Research

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request, Health & Safety Code Section 102.106(c)(4). To the extent that Ms. Mitchell has a conflict of interest with an application submitted by an entity listed herein that is not the conflict identified in Section 102.106(c)(4), then Ms. Mitchell will follow the required notification and recusal process.
- The waiver is limited to the entities specified in the request and based upon the circumstances stated herein. If circumstances change such that Ms. Mitchell is required to personally represent one of the entities listed herein or to supervise the work of someone representing the entity, she will notify the Chief Executive Officer and the presiding officer of the Oversight Committee.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	**OVERSIGHT COMMITTEE CHAIR DR. WILLIAM RICE**
FROM:	**WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER**
SUBJECT:	**SECTION 102.1062 WAIVER – WILL MONTGOMERY**
DATE:	**AUGUST 11, 2016**

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2017 for Mr. Will Montgomery, CPRIT Oversight Committee member, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Mr. Montgomery's waiver is the same as the one approved by the Oversight Committee for FY 2016. The waiver is necessary for Mr. Montgomery to fully participate in the grant award approval process. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

Background

Mr. Montgomery is a partner at Jackson Walker L.L.P., a long-time, Texas-based law firm that employs more than 350 attorneys. Mr. Montgomery's legal practice focuses on disputes related to the financial services industry, including regulatory investigations, enforcement proceedings, and internal investigations relating to securities, options, derivatives, commodities and futures. Mr. Montgomery does not personally represent CPRIT grant recipients; however, some lawyers employed by Jackson Walker provide legal services to the following grant applicants and grant recipients:

- Rice University
- Texas A & M University System
- Texas A & M System Technology Commercialization
- Texas A & M Institute for Biosciences & Technology
- Methodist Hospital System (Houston)
- UT Southwestern
- UT School of Public Health
- UT Medical Branch, Galveston
- Children's Medical Center Research Institute
- UT San Antonio
- UT Austin

- UT Health Science Center at Houston
- Texas Association of Nurse Anesthetists
- University General Health system
- MHMR Tarrant County
- Texas Tech University
- UNT Health Science Center
- Baylor University

Health & Safety Code Section 102.106(c)(4) mandates that a professional conflict of interest exists if an Oversight Committee member represents an entity applying to receive or receiving CPRIT funds. Similarly, Texas Administrative Code Section 702.11(d) finds that there is a professional conflict of interest if an Oversight Committee member "represents in business or law an entity receiving or applying to receive money from the Institute…"

The entities listed above were clients of the law firm prior to Mr. Montgomery's appointment to the Oversight Committee. Although Mr. Montgomery does not perform legal work for these entities or supervise anyone who does so, he has previously recused himself from participating in the grant award process related to these entities out of an abundance of caution. He does not have an economic interest in the revenues associated with these entities paid to Jackson Walker, aside from his position as a partner of the firm. However, Mr. Montgomery's percentage of ownership interest in the law firm is not impacted whether or not these entities are clients of the firm.

It is reasonable to expect that the same conflict will affect Mr. Montgomery's participation in more than one grant review cycle in the 2017 fiscal year as well. CPRIT's administrative rule Section 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Mr. Montgomery's Participation

In order to approve a waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. There are compelling reasons warranting Mr. Montgomery's participation in the review process when he would otherwise be excluded because of the conflict. One of the principal duties for an Oversight Committee member is to approve grant award recommendations submitted by the Program Integration Committee. The statute requires a two-thirds vote of the Oversight Committee to approve a grant award. The vast majority of CPRIT's grant applicants and grant recipients are academic institutions, including many of the entities listed above. Excluding Mr. Montgomery from participation in the decision-making process related to grant awards reduces the number of Oversight Committee members that are able to perform the critical task of reviewing information about potential grantees and the review process associated with the grant recommendations.

The proposed limitations and CPRIT's existing process and procedures will substantially mitigate any potential for bias.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Health & Safety Code Section 102.106(c)(4), I recommend that Mr. Montgomery be permitted to participate in the review process for applications submitted by the following entities, subject to the limitations stated below:

- Rice University
- Texas A & M University System
- Texas A & M System Technology Commercialization
- Texas A & M Institute for Biosciences & Technology
- Methodist Hospital System (Houston)
- UT Southwestern
- UT School of Public Health
- UT Medical Branch, Galveston
- Children's Medical Center Research Institute
- UT San Antonio
- UT Austin
- UT Health Science Center at Houston
- Texas Association of Nurse Anesthetists
- University General Health system
- MHMR Tarrant County
- Texas Tech University
- UNT Health Science Center
- Baylor University

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request, Health & Safety Code Section 102.106(c)(4). To the extent that Mr. Montgomery has a conflict of interest with an application submitted by an entity listed herein that is not the conflict identified in Section 102.106(c)(4), then Mr. Montgomery will follow the required notification and recusal process.
- The waiver is limited to the entities specified in the request and based upon the circumstances stated herein. If circumstances change such that Mr. Montgomery is

required to personally represent one of the entities listed herein or to supervise the work of someone representing the entity, he will notify the Chief Executive Officer and the presiding officer of the Oversight Committee.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	**OVERSIGHT COMMITTEE MEMBERS**
FROM:	**KRISTEN PAULING DOYLE, GENERAL COUNSEL** **CAMERON L. ECKEL, STAFF ATTORNEY**
SUBJECT:	**SUMMARY OF PROPOSED RULE CHANGES TO BE PROPOSED AUGUST 2016**
DATE:	**AUGUST 10, 2016**

Summary

CPRIT staff recommends that the Oversight Committee approve the publication of proposed changes to CPRIT's administrative rules in the *Texas Register*. The proposed changes, including any revisions suggested during the public comment period, will be brought to the Oversight Committee in November for final approval.

Discussion

State law requires an agency to set policy using a rulemaking process, which includes an opportunity for public comment on proposed rules and rule changes before the agency formally adopts the policy. The Oversight Committee establishes policies guiding CPRIT's grant review, grant contracting, and grant monitoring processes through CPRIT's administrative rules.

CPRIT staff conducted an extensive review of existing procedures related to grant applications and grant awards earlier this year. Fifty-three different rule changes affecting 27 administrative rules resulted from this review. The attached chart provides a summary of each of the proposed changes. Most of the changes are non-substantive or clarifying revisions meant to align the agency's administrative rules with current practices. These changes do not impose new burdens on grantees or grant applications and, for the most part, are codifying practices and processes that CPRIT already uses and are familiar to the grantee. There are seven new rules or rule sections that are substantive changes. These rules are shaded in yellow on the attached chart and will be discussed at the Oversight Committee meeting.

With one exception, the Board Governance subcommittee reviewed the proposed amendments and recommends that the Oversight Committee approve publication. The exception is a proposed amendment to § 703.13, related to agreed upon audit procedures, that was drafted after the Board Governance subcommittee met on August 3. The change is based on guidance from CPRIT's internal auditor and will provide additional clarity for grantees that must submit an annual audit to CPRIT.

Next Steps

Once approved by the Oversight Committee, the proposed rule changes will be published in the *Texas Register* and be available through CPRIT's website. The public may provide input via written comments for at least 30 days from the time that the changes are available in the *Texas Register*. Any comments on the proposed rules will be summarized and provided to the Oversight Committee for consideration before the rules are formally adopted at the November meeting.

Proposed Administrative Rule Changes – Chapters 701, 702 and 703	
Chapter 701	
§ 701.3 Definitions	§ 701.3 Clarifies that grantee institutions may designate an alternate Authorized Signing Official (ASO) in the grant management system; the change updates the definition to recognize alternate ASOs. Proposed change conforms the administrative rule to existing practice.
§ 701.7 Compliance Program	§ 701.7(c)(2)(C) Clarifies the frequency of the Chief Compliance Officer's reporting obligation. The statute requires that the Chief Compliance Officer report on the grantees' compliance with CPRIT's administrative rules and contractual requirements at least annually. In practice, the Chief Compliance Officer makes this report at the quarterly Oversight Committee meetings. Proposed change conforms the administrative rule to existing practice.
§ 701.9 Report and Compliance of Compliance Violations	§ 701.9(a) Adds "fraud, waste, and abuse" to the list of suspected compliance violation investigations the Chief Compliance Officer oversees. Proposed change conforms the administrative rule and description of Chief Compliance Officer's duties to existing practice.
	§ 701.9(b) Adds allegations of "fraud, waste, and abuse" to the types of confidential reports that may made CPRIT's Ethics Hotline. Proposed change conforms the administrative rule to existing practice.
§ 701.19 - Advance Payment of Grant Funds **New Title: Texas Location for Grant Awards**	§ 701.19 Deletes text. Text is moved to new rule § 703.23(a) "Disbursement of Grant Award Funds" NEW RULE - Substantive Adds new text related to Texas location requirements for grantees.
§ 701.27 Publicly Available Institute Reports and Records	§ 701.27(15) Recognizes exceptions to the gift reporting requirements already adopted in § 702.7(f).

Chapter 702	
§ 702.7 Acceptance of Gifts and Donations by the Institute	§ 702.7(c)(3)(4) Removes references to "Executive Committee" and makes conforming changes (e.g. replacing vote by Executive Committee to a majority vote by the Oversight Committee.) Clarifies that the CEO will create a report for potential gifts valued in excess of $1 million.
	§ 702.7(f)(3) Clarifies that the conference fees referred to in this paragraph are for a conference hosted by CPRIT.
§ 702.9 Code of Conduct	§ 702.9(c)(16) Changes the individual designated to receive reports of gifts from Chief Executive Officer to Chief Compliance Officer. Proposed change conforms the administrative rule to existing practice and CPRIT's Code of Conduct.
§ 702.13 Disclosure of Conflicts of Interest and Recusal from Review	§ 702.13(a)(1) The statute requires Oversight Committee members and PIC members provide "written notice" of a conflict of interest to the CEO. The change clarifies that the member's designation of a conflict of interest via the grant review portal constitutes the required notice. Proposed change conforms the administrative rule to existing practice.
	§ 702.13(b)(1) The statute requires peer review committee members to provide "written notice" of a conflict of interest to the CEO. Like the proposed change to § 703.13(a)(1), this change clarifies that the member's designation of a conflict of interest via the grant review portal constitutes the required notice. Proposed change conforms the administrative rule to existing practice.
§ 702.19 Restriction on Communication Regarding Pending Grant Awards	§ 702.19(e) Clarifies that notice to the Oversight Committee is made at the time the communication restriction waiver is granted by the CEO and that the waiver is publicly available via the CEO affidavit. Proposed change conforms the administrative rule to existing practice.

Chapter 703	
§ 703.3 **Grant Applications**	§ 703.3(b)(3) Adds new subsection indicating that CPRIT may cap the number of applications submitted by an entity responding to a particular request for applications. Institutional limits, if any, on the number of applications that an entity may submit are included in the request for applications. CPRIT uses institutional limits when a large number of submissions are expected in response to a request for applications. Proposed change conforms the administrative rule to existing practice.
	§ 703.3(e) Deletes text requiring applicants to provide information regarding product development prospects. As currently written, this appears to be a global requirement applicable to all grant mechanisms. In practice, the request for applications will specifically request information about product development prospects if it is necessary for the review process. Adds new text clarifying that CPRIT may limit the number of times an applicant may resubmit an application not recommended in a previous grant review cycle. Proposed new text conforms the administrative rule to existing practice.
	§ 703.3(g)(1) – (3) New text clarifies process for extending the deadline for application submission, including specifying the individual responsible for approving the extension request. Proposed change conforms the administrative rule to existing practice.
	§ 703.3(i)(A) Replaces deleted text with new text clarifying the requirement to provide a capitalization table is limited to Product Development grant applicants.
	§ 703.3(j) Proposed change conforms the administrative rule to the grant contract, which requires the grantee to certify that the entity, employees, and collaborators/contractors working on the project are not debarred, suspended, ineligible, or otherwise excluded from another federal or state grant award.
	§ 703.3(k)(3) Adds new subsection authorizing CPRIT to withdraw a Product Development grant application from consideration if the applicant does not submit the application fee within seven business days following the application deadline. Proposed change conforms the administrative rule to existing practice.

§ 703.5 Scientific Research and Prevention Programs Committees	§ 703.5(a) Adds text to include post-award review of grantee progress reports to the list of the peer review activities peer review committee members may perform. Proposed change conforms the administrative rule to existing practice.
§ 703.6 Grants Review Process	§ 703.6(d)(3) Adds a new subsection requiring that the PIC/Oversight Committee take final action on the Review Council's recommendations in the same fiscal year that Review Council submits its formal recommendations to the PIC and the Oversight Committee. Proposed change conforms the administrative rule to existing practice and is consistent with the statute.
	§ 703.6(f) Adds text regarding Oversight Committee members' attendance at peer review meetings. Proposed change conforms the administrative rule to existing practice.
	§ 703.6(i) Adds text requiring CPRIT employees and Oversight Committee members attending peer review meetings to complete the post-review compliance statement. This new requirement documents compliance with the conflict of interest rules.
§ 703.7 Program Integration Committee Funding Recommendations	§ 703.7(d)(8) Adds new subsection to specify that a list of deferred applications should be provided to the Oversight Committee at the time the PIC submits its award recommendations. Proposed change conforms the administrative rule to existing practice.
§ 703.8 Oversight Committee Consideration of Program Integration Funding Recommendations	§ 703.8(1)(B) Adds text clarifying that the Chief Compliance Officer documents any variances in a grant application, as well as the grant review process. Proposed change conforms the administrative rule to existing practice.
	§ 703.8(2) Replaces the CEO's proposed "corrective actions" with "good cause" when considering variances affecting award recommendations. This language clarifies that variances may occur in the application; it does not change how variances are documented or what action the Oversight Committee may be take. Proposed change conforms the administrative rule to existing practice.
	§ 703.8(3) Adds subsection clarifying that the Oversight Committee may take up and vote on more than one application. The Oversight Committee typically votes on awards as a slate rather than individual recommendations. Proposed change conforms the administrative rule to existing practice.
	§ 703.8(4)

	Replaces "failure to follow" with "not approving."
§ 703.10 Awarding Grants by Contract	§ 703.10(23) Adds new subsection indicating that the grantee is legally responsible for the integrity of the fiscal and programmatic management of the organization. Proposed change conforms the administrative rule to grant contract terms regarding grantee responsibility.
	§ 703.10(24) Adds new subsection indicating that the grantee is legally responsible for the actions of its employees and research collaborators, including third parties, involved in the project. Proposed change conforms the administrative rule to grant contract terms regarding grantee responsibility.
§ 703.11 Requirement to Demonstrate Available Funds for Cancer Research Grants	§ 703.11(e) Replaces "yearly" with defined term "project year."
	§ 703.11(h) Replaces "period" with defined term "project year."
§ 703.12 Limitation on Use of Grant Funds	§ 703.12(b) Deletes text related to unallowable expenses. Text is moved to new rule § 703.26 "Allowable Expenses."
§ 703.13 Audits and Investigations	§ 703.13(b) Adds text related to the single audit determination form that grantees must submit, including raising the minimum amount necessary to trigger the audit requirement.
	§ 703.13(e) New subsection (e) clarifies acceptable standards for agreed upon procedures audits.
§ 703.14 Termination, Extension, Close-Out of Grants and De-Obligation of Unused Grant Funds	§ 703.14(c)(1) Deletes "only" and adds text indicating CPRIT's decision is final. Proposed deletion will reduce confusion among grantees; the additional text conforms the administrative rule to existing practice.
	§ 703.14(c)(2) Adds text clarifying the process a grantee must follow to request a no cost extension outside of the rule's timeframe. Proposed change conforms the administrative rule to existing practice.
	§ 703.14(c)(3) Adds text clarifying process for requesting and approving no cost extensions. Proposed change conforms the administrative rule to existing practice.
	§ 703.14(d) Adds text clarifying due date of final financial status report (FSR); similar non-substantive change made to (d)(1). Proposed change makes the due date of the final FSR consistent with the due date

	of other FSRs. There is some confusion under the current rule about due date of the final FSR when the contract ends in the middle of a fiscal quarter. Additional text clarifies that the final Progress Report and other required reports, which are collectively referred to as "close out documents" may have a different due date (90 days from the termination date of the grant contract) than the FSR due date.
	§ 703.14(e) Adds text clarifying that the agency may make allowable costs adjustments up to 90 days after the final FSR is approved. Proposed change clarifies the period when CPRIT may make costs adjustments to a grant after the termination date.
	§ 703.14(h) – NEW SECTION Adds new subsection authorizing CPRIT to de-obligate grant award funds not expended at the termination of the grant contract. The proposed change is necessary so that CPRIT may make available grant funds to other projects or statutory purposes when grant funds are unused at the time the grant terminates.
§ 703.15 **Multiyear Grant Projects** **New Title:** **Fiscal Policies Applicable to Grant Awards**	§ 703.15 Deletes text related to multiyear projects. Deleted text is incorporated in § 703.8(3)(A) and new rules §§ 703.24 and 703.25. NEW RULE – Fiscal Policies Applicable to Grant Awards Adds new text related to required fiscal policies. The proposed changes codify agency practice.
§ 703.16 **Intellectual Property Agreement**	§ 703.16(c) Deletes text that is not applicable to all grants.
	§ 703.16(d)(6) Deletes subsection that is not applicable to all grants.
§ 703.17 **Revenue Sharing Standards**	§ 703.17(e) Adds new subsection about revenue sharing. The proposed rule change is consistent with the agency's standard revenue sharing standards.
§ 703.21 **Monitoring Grant Award Performance**	§ 703.21(a) Replaces "Chief Executive Officer" with "Chief Compliance Officer." The proposed change is consistent with agency practice.
	§ 703.21(b)(1) Deletes text regarding FSR due dates; text is moved to new rule § 703.24.
	§ 703.21(b)(2)

	Deletes text regarding FSR due dates, waiver of reimbursement for failing to timely submit FSRs, and appeal of waiver. Deleted text is moved to new rule § 703.24. Adds new text regarding monitoring timely submission of reports and withholding reimbursement until delinquent reports are submitted and approved. The proposed change is consistent with agency practice.
	§ 703.21(b)(3)(E) Removes clause indicating that a grant manager performs the evaluation; CPRIT relies upon peer reviewers or contractors with subject matter expertise to perform the evaluation. The proposed change is consistent with agency practice.
New Rule § 703.23 Disbursement of Grant Award Funds	New § 703.23 Clarifies CPRIT's policies regarding disbursing grant funds by reimbursement or advancement. The new rule incorporates text from § 701.19.
New Rule § 703.24 Financial Status Reports	New § 703.24 Addresses requirements for quarterly and final financial status reports. The new rule incorporates text originally from § 703.21(b)(1) and(2)
New Rule § 703.25 Grant Award Budget	New § 703.25 Codifies existing practice specified in the grant contract regarding approved budgets, including budget transfer requests.
New Rule § 703.26 Allowable Costs	New § 703.26 Codifies existing practice specified in the grant contract regarding allowable costs. Incorporates deleted text from 703.12 regarding unallowable costs.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	PRODUCT DEVELOPMENT SUBCOMMITTEE MEMBERS
FROM:	MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER KRISTEN PAULING DOYLE, GENERAL COUNSEL
SUBJECT:	TEXAS-BASED LOCATION POLICY
DATE:	AUGUST 3, 2016

Summary and Recommendation

CPRIT staff recommends adopting criteria for a company to be considered a "Texas-based entity" eligible for product development awards. CPRIT's statute does not speak directly to residency or location requirements for CPRIT grants. The proposed criteria fulfill the statutory intent to promote a substantial increase in cancer research and the creation of high-quality new jobs in the state. Adopting a Texas location policy is recommended because it provides companies some flexibility to manage business operations and make economically rational decisions when spending grant funds, while ensuring that CPRIT is acting consistent with statutory intent. Once adopted, the criteria will be incorporated in the grant contract and will be monitored for compliance throughout the life of the grant.

Discussion

CPRIT's purpose is to enhance and accelerate the potential for innovative breakthroughs in cancer prevention, detection, and treatments. Public and private entities are crucial to this initiative. Gaps exist in the market's ability to translate research insights and product visions into FDA-approved and commercially available products. These gaps may delay or deny cancer patient access to important scientific advances. CPRIT invests in research projects conducted by companies to bridge those gaps and expedite the progression of new cancer drugs, diagnostics, and therapies from the laboratory into clinical practice.

Since its inception, CPRIT has invested grant funds in Texas-based entities for projects taking place in Texas. Although CPRIT's statute does not speak directly to residency or location requirements for CPRIT grants, one of the statutory purposes for CPRIT is to enhance research capabilities at public and private entities "that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state." Tex. Health & Safety Code §102.002(2). Investing CPRIT grant funds in Texas with Texas-based entities contributes to the growth of the state's emerging life sciences industry, which catalyzes economic development and creates high-quality new jobs in Texas.

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Defining a "Texas-based entity" poses potential challenges in the technology-driven marketplace. Traditional metrics such as the physical location of company headquarters, personnel, and major activities do not easily translate to biotech start-ups. It may be a better option for a start-up company to conserve cash on hand by relying on a virtual workplace rather than spend limited capital on bricks and mortar. Technology, rented lab space, and virtual research hubs all make this option possible and potentially preferable when a new company forms.

Similarly, long-established concepts regarding personnel do not necessarily apply to an early-stage biotechnology company. It may be feasible, and sometimes desirable, for company personnel to be located in multiple locations. For example, companies developing a cancer drug typically rely upon clinical trial sites at multiple academic medical centers across the country (or countries) in order to access patient populations and enroll an adequate number of trial participants. Company personnel supervising the clinical trials may be located at clinical trial sites and away from company headquarters for extended periods. Even the conventional concept of "personnel" is evolving. Team members may be employees, short-term and long-term service providers, and consultants. The makeup of the company's extended team may change several times as the company grows and moves into new stages of product development.

Texas-Based Location Criteria

Developing novel cancer therapeutics or diagnostic products is a complex endeavor requiring specialized skills and resources. These are not always available in one location or even in one state. CPRIT staff proposes adopting a policy that clearly states location criteria sufficient for consideration as a "Texas-based entity," while permitting companies some flexibility to manage business operations. CPRIT wants grantees to make economically rational and scientifically justified decisions when spending grant funds. At the same time, it is critical to ensure that CPRIT is acting consistent with statutory intent. The proposed criteria fulfill both objectives.

1. The U.S. headquarters is physically located in Texas;
2. The Chief Executive Officer resides in Texas;
3. A majority of the company's personnel, including at least two other C-level employees (or equivalent) reside in Texas;
4. Manufacturing activities take place in Texas;

   Rationale for consideration as location criteria: Manufacturing is a key activity in the development phase of a new company. Drug manufacturing is highly specialized and is often subcontracted. A strong biotechnology manufacturing industry in Texas is a crucial infrastructure component to grow the state's life sciences economy. Grantees using Texas-based manufacturers are supporting the development of industry-specific skill sets, attracting or expanding private sector entities in the state, and creating high-quality new jobs (§§ 102.002(2), 102.251(a)(2)(C)(x)). This will have a demonstrable economic development benefit to Texas (§102.251(a)(2)(C)(viii).

5. At least 90% of Grant Award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.

   Rationale for consideration as location criteria: CPRIT's statute directs grantees to use good faith efforts to purchase more than 50 percent of goods and services from Texas suppliers (§102.258). This criterion exceeds the statutory directive and ensures that grant funds are spent in Texas and paid to Texans, maximizing the economic impact of CPRIT investment to Texas.

6. At least one clinical trial site in Texas.

   Rationale for consideration as location criteria: A clinical trial site in Texas insures that innovative treatments are available to Texans as soon as possible, fulfilling CPRIT's statutory purpose to expedite innovation in medical breakthroughs (§102.002(1)) and supports medical research facilities in Texas carrying out clinical trials (§102.051(2)).

7. Collaboration with a medical research organization in Texas, including a public or private institution of higher education.

   Rationale for consideration as location criteria: Collaboration with Texas research institutions grows the state's research infrastructure and optimizes the opportunities for Texas research institutions to commercialize their research. It fulfills statutory mandates to expand research capabilities of Texas institutions of higher education (§102.002(2)), and encourages collaborations between private and non-profit entities (§102.251(a)(2)(C)(vii)).

Implementation

The first three location criteria listed above align with the traditional metrics for consideration as a "Texas-based entity." If the company meets all three criteria, then the company will fulfill CPRIT's location requirement. However, if the company is not able to meet one or more of the first three criteria, then the company must demonstrate that it fulfills at least four of the seven criteria or propose a different metric for the Oversight Committee's approval.

The grant applicant will complete a form indicating the location criteria it will meet if it receives a CPRIT award. Once approved by the Oversight Committee, the company's selected location criteria will be incorporated in the grant contract. The company will certify that it will fulfill the criteria within the first year of receiving award funds, unless the company and CPRIT agree to a different timeframe for compliance. (For example, a clinical trial site may not be established until the second year of the funded project.) The company will attest to maintaining the location criteria when it submits its annual progress report. CPRIT's compliance team will monitor compliance with the location criteria as part of the on-site or desk review process.

Failure to maintain compliance with the location criteria results in consequences ranging from suspension of grant funding, early contract termination, and repayment of grant funds.

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 §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, including designated alternates, 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, Texas 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 §102.203(c), Texas Health and Safety Code.

(40) Numerical Ranking Score--the score given to a Grant Application by the Review Council that is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also signifies the Review Council's view related to how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

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

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

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

(44) Patient Advocate--a trained individual who meets the qualifications set by the Institute and is appointed to a Scientific Research and Prevention Programs Committee to specifically represent the interests of cancer patients as part of the Peer Review of Grant Applications assigned to the individual's committee.

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

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

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

(48) Primary Reviewer--a Scientific Research and Prevention Programs Committee member responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the general impression of the Grant Application's merit.

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

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

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

(52) Program Income--income from fees for services performed, from the use or rental of real or personal property acquired with Grant Award funds, and from the sale of commodities 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 §§573.021 - 573.025, Texas 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.

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~~ presented at each quarterly 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.

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, including fraud, waste, and abuse.

(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, including allegations of fraud, waste, and abuse. 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, Texas 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, Texas Government Code, to discuss an on-going compliance investigation into issues related to fraud, waste or abuse of state resources.

RULE § 701.19 ~~Advance Payment of Grant Award Funds~~ Texas Location for Grant Awards

~~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.~~

(a) Except as addressed by the Request for Applications or this rule, only Texas-based entities are eligible to receive Grant Awards.

(b) Grant Applicants responding to a Request for Applications may be located outside the state of Texas when the Grant application is submitted and reviewed. However, the Institute requires the Grant Applicant to demonstrate that it will relocate to Texas as a condition of the Grant Award.

(c) A Grant Applicant for a Product Development Grant Award may demonstrate compliance with subsection (b) by fulfilling a majority of the following requirements:

(1) The U.S. headquarters is physically located in Texas;

(2) The Chief Executive Officer resides in Texas;

(3) A majority of the company's personnel, including at least two other C-level employees (or equivalent) reside in Texas;

(4) Manufacturing activities take place in Texas;

(5) At least 90% of Grant Award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors;

(6) At least one clinical trial site in Texas; and

(7) Collaboration with a medical research organization in Texas, including a public or private institution of higher education.

(d) The location criteria to be fulfilled by the Grant Recipient are reflected in the Grant Contract.

(e) Unless otherwise specified by the Grant Contract, the Grant Recipient must fulfill the requirements within one year of receiving the disbursement of Grant Award funds.

(f) The Grant Recipient will report on the location criteria at least annually.

(g) The Institute will monitor compliance with this policy. Failure to meet and maintain the Texas location requirements may result in suspension of the Grant Award, termination of the Grant Contract, repayment of Grant Award funds; or other appropriate action as determined by the Chief Executive Officer and reported to the Oversight Committee.

(h) Nothing herein prohibits the Grant Recipient from proposing and the Institute from approving one or more alternative or additional location requirements. The Chief Executive Officer shall notify the Oversight Committee of the alternative criteria at an open meeting. The proposed alternative location requirement is approved unless a simple majority of the Oversight Committee votes to reject the Chief Executive Officer's recommendation.

RULE § 701.27 Publicly Available Institute Reports and Records

To promote transparency in its activities, the Institute maintains the information described in this section 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 in this paragraph 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) Except as excluded by 702.7(f) of this Title, ~~I~~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) days 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 §659.026, Texas Government Code

RULE § 702.7 Acceptance of Gifts and Donations by the Institute

(a) As authorized by Texas Health and Safety Code §102.054, the Institute may solicit and accept gifts from any source to support the operations of the Institute and to further its purposes; except that the Institute may not supplement the salary of any Institute Employee with a gift or grant received by the Institute.

(b) An Oversight Committee Member or an Institute Employee shall not authorize a donor to use the property of the Institute unless the property is used in accordance with a contract between the Institute and the donor, the contract is found by the Institute to serve a public purpose, the contract contains provisions to ensure the public purpose continues, and the Institute is reasonably compensated for the use of the property.

(c) Procedure for acceptance of gifts.

(1) Gifts to the Institute may be designated for one of the following categories:

(A) Unrestricted General Support;

(B) Restricted Programmatic Support;

(C) Endowed and Restricted Funds; or

(D) Other (includes gifts of real or personal property).

(2) Gifts of ten thousand dollars ($10,000) or less may be accepted on behalf of the Institute by the Chief Executive Officer.

(3) The ~~Executive Committee of the~~ Oversight Committee by a majority vote 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)~~, gifts of real property regardless of value, and all other gifts not herein described 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) For gifts ~~Acceptance of gifts~~ made to the Institute of cash, stock, bonds, or personal property with a value in excess of one million dollars, gifts of real property regardless of value, and all other gifts not herein described ~~shall be approved by a majority vote of the Oversight Committee. To assist in its decision~~, a report shall be created by the Chief Executive Officer for the Oversight Committee that includes the following information:

(A) Name and biographical data regarding the individual or organization making the gift;

(B) A description of the gift;

(C) A list of conditions or requirements to be imposed on the Institute as a result of accepting the gift;

(D) If one of the conditions is naming, then include a description of the object to be named and whether there is a time limit on continuing the name;

(E) If the gift is real property, an evaluation of the gift by the General Land Office;

(F) If the gift is stock or other investments, a description of how they will be sold and the expected net proceeds; and

(G) A description of how the gift will be used.

(5) All funds received from donations to the Institute will be deposited to the state treasury and used for the purpose specified by the donor or for general Institute programs when no purpose is specified.

(d) The Institute encourages the offer of gifts of additional revenue and real and personal property through naming.

(1) Naming can be given to both real objects and inanimate objects, such as Grant Awards.

(2) The Oversight Committee will consider a request for naming in connection with a gift of real or personal property of substantial value to the Institute and its programs. In determining whether a gift has substantial value, the Oversight Committee will evaluate the following factors:

(A) The size of the real or personal property in relation to other fund sources--including bonds--available at the same time and consideration of whether the donation will make a material contribution to the Institute's goals and programs that otherwise would not be made;

(B) Availability of the real or personal property; and

(C) The degree of flexibility and discretion the Institute will have in the use of the real or personal property.

(3) The Oversight Committee must approve the recommendation to name an object or program by a majority vote of its members.

(e) The Oversight Committee may refuse a gift to the Institute for any reason, including:

(1) The gift requires an initial and/or on-going expenditure that will likely equal or exceed the value of the gift.

(2) The gift is from an institution, entity, or organization, or a director, officer, or an executive of an institution, entity or organization that has applied for funding from the Institute, or currently receives funding from the Institute, or the gift is from a Senior Member or Key Personnel of the research or prevention program team listed on a Grant Application or Grant Award.

(3) The Institute may return a gift made by an institution, entity, organization, or individual that was otherwise eligible to make the donation at the time that the gift was accepted by the Institute in the event that the donor subsequently submits a Grant Application for funding from the Institute within the fiscal year of the donation.

(4) For purposes of this section, the limitation on gifts does not apply to a donation made as the result of the final bequeathal.

(f) The Institute shall report information pertaining to gifts, grants, or other consideration provided to the Institute, an Institute Employee, or a member of an Institute committee, subject to the requirements in this subsection.

(1) The information shall be posted on the Institute's Internet website.

(2) The information to be posted shall include the donor's name, the date of the donor's donation, and the amount of the donor's donation.

(3) The reporting requirement applies to all gifts, grants, or other consideration provided to the Institute except that individual conference registration fees for a conference hosted by the Institute and paid to the Institute ~~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) A gift or other benefit conferred on account of kinship or a personal, professional, or business relationship independent of the official status of the recipient so long as:

(i) The personal friend or a Relative of the personal friend is not an employee of an entity receiving or applying to receive money from the Institute; and

(ii) The individual subject to this provision has no reason to believe that the item or consideration is being offered through an intermediary in an attempt to evade reporting requirements.

(C) Items with a value of less than $50, excluding cash or a negotiable instrument described by §3.104, Business and Commerce Code.

(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 with a value of less than $50, excluding cash or a negotiable instrument as described by §3.104, Business and Commerce Code.

(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) A gift or other benefit conferred on account of kinship or personal, professional, or business relationship independent of the official status of the recipient so long as:

(i) The personal friend or a Relative of the personal friend is not an employee of an entity receiving or applying to receive money from the Institute; and

(ii) The individual subject to this provision has no reason to believe that the item or consideration is being offered through an intermediary in an attempt to evade reporting requirements.

(B) If the individual participates in the Grant Review Process, then the individual must report gifts, grants, or other consideration given to the Advisory Committee member by a Grant Applicant or Grant Recipient during the period that the Advisory Committee member participates in the Grant Review Process except that the following items are not considered gifts, grants or consideration subject to the reporting requirement:

(i) Books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of the Advisory Committee member and that are accepted by the individual for use in performing the individual's job duties.

(ii) Items with a value of less than $50, excluding cash or a negotiable instrument as described by §3.104, Business and Commerce Code.

(C) For purposes of this subsection, participation in the Grant Review Process by an Advisory Committee member does not include submitting a Grant Application or receiving a Grant Award.

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

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

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

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

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

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

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

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

(5) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not intentionally or knowingly solicit, accept, or agree to accept any benefit for exercising his or her official powers or performing the member or employee's official duties in favor of another.

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

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

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

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

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

(11) A member of the Oversight Committee, Institute Employee, Program Integration Committee Member, or the spouse of an individual governed by this provision shall not serve on the Grant Recipient's board of directors or similar committee that exercises governing powers over the Grant Recipient. This prohibition also applies to serving on the board of directors or similar committee of a non-profit foundation established to benefit the Grant Recipient.

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

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

(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 Compliance ~~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 paragraph 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 paragraph 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 paragraph, "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 paragraph, "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 §572.021 shall be simultaneously filed with the Institute

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

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

(1) Provide written notice of the Conflict of Interest to the Chief Executive Officer and the presiding officer of the Oversight Committee (or the next ranking member of the Oversight Committee if the presiding officer has the Conflict of Interest). For purposes of this requirement, an Oversight Committee member or Program Integration Committee member who designates the Conflict of Interest on the secure website provided to review the recommended Grant Awards is deemed to have provided written notice;

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

(3) Recuse himself or herself from participation in the review, discussion, deliberation and vote on the entity or Grant Application, including access to information regarding the matter to be decided, unless a waiver has been granted pursuant to §702.15 of this chapter (relating to Investigation of Unreported Conflicts of Interest Affecting the Grant Review Process).

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

(1) Provide written notice of the Conflict of Interest to the Chief Executive Officer. For purposes of this requirement, a Scientific Research and Prevention Program Committee Member who designates the Conflict of Interest on the secure website provided to review the Grant Applications is deemed to have provided written notice; and

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

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

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

(2) The individual subject to this provision is actively seeking employment with a Grant Applicant. For the purposes of this paragraph, "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 Employee or independent contractor involved in the Grant Review Process has a Conflict of Interest as described in this chapter with respect to a Grant Application that comes before the individual for review or other action, the Institute Employee or independent contractor shall:

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

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

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

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

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

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

(f) Individuals subject to this chapter are encouraged to self-report. Any individual who self-reports a potential Conflict of Interest or any impropriety or self-dealing, and who fully complies with any recommendations of the General Counsel and recusal from any discussion, voting, deliberation or access to information regarding the matter, shall be considered by the Institute to be in compliance with this chapter. The individual is still subject to the operation of other laws, rules, requirements or prohibitions. Substantial compliance with the procedures provided herein constitutes compliance.

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

RULE § 702.19 Restriction on Communication Regarding Pending Grant Application

(a) Communication regarding the substance of a pending Grant Application between the Grant Applicant and an Oversight Committee Member, a Program Integration Committee Member, or a Scientific Research and Prevention Programs Committee Member is prohibited.

(b) The prohibition on communication begins on the first day that Grant Applications for the Grant Mechanism are accepted by the Institute and extends until the Grant Applicant receives notice regarding a final decision on the Grant Application.

(1) The prohibition on communication does not apply to the time period when pre-applications or letters of interest are accepted.

(2) In special circumstances, an Oversight Committee Member or a Program Integration Committee Member may respond to a question or request for more information from a Grant Applicant so long as the response is made available to all Grant Applicants.

(c) Intentional, serious, or frequent violations of this rule may result in the disqualification of the Grant Applicant from further consideration for a Grant Award.

(d) This rule is not intended to prohibit open dialogue between the public and the Chief Executive Officer, a Program Integration Committee Member or a member of the Oversight Committee regarding the general status or nature of pending Grant Applications.

(e) The Chief Executive Officer may grant a waiver from the general prohibition on communication upon finding that the waiver is in the interest of promoting the objectives of the Institute and is not intended to give one or more Grant Applicants an unfair advantage. The waiver shall be provided to the Oversight Committee in writing at the time it is granted and state the reasons for the granting the waiver. The waiver shall be ~~publicly available~~included as part of the public information supporting the Chief Executive Officer's affidavit(s) for Grant Award recommendations in the Grant Review Cycle(s) corresponding to the waiver.

(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 Chapter 703, §703.7 of this title (relating to Program Integration Committee Funding Recommendation). 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 § 703.3 Grant Applications

(a) The Institute shall accept Grant Applications for Cancer Research and Cancer Prevention programs to be funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute in response to standard format Requests for Applications issued by the Institute.

(b) Each Request for Applications shall be publicly available through the Institute's Internet website. The Institute reserves the right to modify the format and content requirements for the Requests for Applications from time to time. Notice of modifications will be announced and available through the Institute's Internet website. The Request for Applications shall:

(1) Include guidelines for the proposed projects and may be accompanied by instructions provided by the Institute.

(2) State the criteria to be used during the Grant Review Process to evaluate the merit of the Grant Application, including guidance regarding the range of possible scores.

(A) The specific criteria and scoring guidance shall be developed by the Chief Program Officer in consultation with the Review Council.

(B) When the Institute will use a preliminary evaluation process as described in §703.6 of this chapter (relating to Grants Review Process) for the Grant Applications submitted pursuant to a particular Grant Mechanism, the Request for Applications shall state the criteria and Grant Application components to be included in the preliminary evaluation.

(3) Specify limits, if any, on the number of Grant Applications that may be submitted by an entity for a particular Grant Mechanism to ensure timely and high-quality review when a large number of Grant Applications are anticipated.

(c) Requests for Applications for Cancer Research and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:

(1) Basic research;

(2) Translational research, including proof of concept, preclinical, and Product Development activities;

(3) Clinical research;

(4) Population based research;

(5) Training;

(6) Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;

(7) Infrastructure, including centers, core facilities, and shared instrumentation;

(8) Implementation of the Texas Cancer Plan; and

(9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.

(d) An otherwise qualified applicant is eligible solely for the Grant Mechanism specified by the Request for Applications under which the Grant Application was submitted.

(e) The Institute may limit the number of times a Grant Application not recommended for a Grant Award during a previous Grant Review Cycle may be resubmitted in a subsequent Grant Review Cycle. The Request for Applications will state the resubmission guidelines, including specific instructions for resubmissions. ~~The request for Grant Applications for Cancer Research projects shall seek information from Grant Applicants regarding whether the proposed project has Product Development prospects, including, but not limited to, anticipated regulatory filings, commercial abstracts or business plans.~~

(f) Failure to comply with the material and substantive requirements set forth in the Request for Applications may serve as grounds for disqualification from further consideration of the Grant Application by the Institute. A Grant Application determined by the Institute to be incomplete or otherwise noncompliant with the terms or instructions set forth by the Request for Applications shall not be eligible for consideration of a Grant Award.

(g) Only those Grant Applications submitted via the designated electronic portal designated by the Institute by the deadline, if any, stated in the Request for Applications shall be eligible for consideration of a Grant Award.

(1) Nothing herein shall prohibit the Institute from extending the submission deadline for one or more Grant Applications upon a showing of good cause, as determined by the Chief Program Officer.

(2) A request to extend the Grant Application submission deadline must be in writing and sent to the CPRIT Helpdesk via electronic mail, within 24 hours of the submission deadline.

(3) ~~(2)~~ The Institute shall document any deadline extension granted, including the good cause ~~reason~~ for extending the deadline and will cause the documentation to be maintained as part of the Grant Review Process records.

(h) The Grant Applicant shall certify that it has not made and will not make a donation to the Institute or any foundation created to benefit the Institute.

(1) Grant Applicants that make a donation to the Institute or any foundation created to benefit the Institute on or after June 14, 2013, are ineligible to be considered for a Grant Award.

(2) For purposes of the required certification, the Grant Applicant includes the following individuals or the spouse or dependent child(ren) of the following individuals:

(A) the Principal Investigator, Program Director, or Company Representative;

(B) a Senior Member or Key Personnel listed on the Grant Application;

(C) an officer or director of the Grant Applicant.

(3) Notwithstanding the foregoing, one or more donations exceeding $500 by an employee of a Grant Applicant not described by paragraph (2) of this subsection shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.

(4) The certification shall be made at the time the Grant Application is submitted.

(5) The Chief Compliance Officer shall compare the list of Grant Applicants to a current list of donors to the Institute and any foundation created to benefit the Institute.

(6) To the extent that the Chief Compliance Officer has reason to believe that a Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, the Chief Compliance Officer shall seek information from the Grant Applicant to resolve any issue. The Grant Application may continue in the Grant Review Process during the time the additional information is sought and under review by the Institute.

(7) If the Chief Compliance Officer determines that the Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, then the Institute shall take appropriate action. Appropriate action may entail:

(A) Withdrawal of the Grant Application from further consideration;

(B) Return of the donation, if the return of the donation is possible without impairing Institute operations.

(8) If the donation is returned to the Applicant, then the Grant Application is eligible to be considered for a Grant Award.

(i) Grant Applicants shall identify by name all sources of funding~~, including a capitalization table that reflects private investors, if any,~~ contributing to the project proposed for a Grant Award. A Grant Applicant for a Product Development Research Grant Award must provide a capitalization table ~~This information shall~~ that includes those individuals or entities that have an investment, stock or rights in the ~~project~~company. The Institute shall make the information provided by the Grant Applicant available to Scientific Research and Prevention Programs Committee members, Institute employees, independent contractors participating in the Grant Review Process, Program Integration Committee Members and Oversight Committee Members for purposes of identifying potential Conflicts of Interest prior to reviewing or taking action on the Grant Application. The information shall be maintained in the Institute's Grant Review Process records.

(j) A Grant Applicant shall indicate if the Grant Applicant is currently ineligible to receive Federal or State grant funds due to debarment or suspension 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.~~ personnel, including collarborators or contractors, who will be working on the Grant Award. A Grant Applicant is not eligible to receive a Grant Award if the Grant Applicant is debarred, suspended, ineligible or otherwise excluded from participation in a federal or state grant award.

(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.

(3) Unless a request to submit the fee after the deadline has been approved by the Institute, the Institute may administratively withdraw a Grant Application if the application review fee is not received by the Institute within seven business days of the Grant Application submission deadline.

(l) During the course of administrative review of the Grant Application, the Institute may contact the Grant Applicant to seek clarification on information provided in the Grant Application or to request additional information if such information clarifies the Grant Application. The Institute shall keep a record of requests made under this subsection for review by the Chief Compliance Officer.

RULE § 703.5 Scientific Research and Prevention Programs Committees

(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. Such Peer Review activities may include post award evaluation of Grant Progress Reports. The Chief Executive Officer, with approval by simple majority of the Oversight Committee, is responsible for appointing experts in the fields of Cancer Research, Prevention life science Product Development, and patient advocacy to serve as Scientific Research and Prevention Programs Committee members for terms designated by the Chief Executive Officer.

(b) The Chief Executive Officer may provisionally appoint an individual as a Scientific Research and Prevention Programs Committee Member until such time that the individual can be considered for approval by the Oversight Committee. The provisional appointee may participate in the Peer Review Process prior to a vote of the Oversight Committee on the appointment so long as the appointment is considered at the next regular Oversight Committee meeting.

(c) A Scientific Research and Prevention Programs Committee Member is responsible for conducting Peer Review of the Grant Applications assigned to the individual member's Peer Review Panel.

(d) A Scientific Research and Prevention Programs Committee Member may receive an honorarium in accordance with the policy described in Chapter 701, §701.15 of this title (relating to the Scientific Research and Prevention Programs Committee Honoraria Policy).

(e) A member of a Scientific Research and Prevention Programs Committee is prohibited from attempting to use the committee member's official position to influence a decision to approve or award a grant or contract to the committee member's employer.

(f) A member of a Scientific Research and Prevention Programs Committee must comply with the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Texas 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:

(1) Represent an organization or other community of people;

(2) Demonstrate prior community involvement or other work on behalf of cancer patients;

(3) Possess good communication and writing skills, including the ability to analyze information and make judgments with consideration of patient impact;

(4) Express interest in and fundamental knowledge of the medical research process, including basic and translational scientific research and prevention concepts;

(5) Reside outside of the state of Texas;

(6) Have science-based training. This training requirement shall be considered fulfilled if the Patient Advocate has:

(A) attended a science-based training program from the American Association for Cancer Research Survivor-Scientist Program, American Society of Clinical Oncology Research Review Sessions for Patient Advocates, Research Advocacy Network Advocate Institute or National Breast Cancer Coalition Project LEAD no more than three years prior to appointment to the Institute's Scientific Research and Prevention Programs Committee; or

(B) participated in at least one full cycle of grant review conducted by the Institute, National Institutes of Health, Department of Defense Congressionally Directed Medical Research Programs, Federal Drug Administration or Patient-Centered Outcomes Research Institute no more than three years prior to appointment to the Institute's Scientific Research and Prevention Programs Committee.

(m) An individual interested in a Patient Advocate appointment shall submit an application, in a format specified by the Institute that includes at least the following information:

(1) Dates of service on a peer review panel within the past three years, or dates of attendance at advocate training programs within the past three years as documentation of the fulfillment of the science-based training program requirement;

(2) Current resume or curriculum vitae;

(3) A letter of recommendation from a community-based organization and a personal statement on advocacy and education if the applicant has attended a training program but not yet served on a peer review panel

RULE § 703.6 Grant Review Process

(a) For all Grant Applications that are not administratively withdrawn by the Institute for noncompliance or otherwise withdrawn by the Grant Applicant, the Institute shall use a two-stage Peer Review process.

(1) The Peer Review process, as described herein, is used to identify and recommend meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control projects for Grant Award consideration by the Program Integration Committee and the Oversight Committee.

(2) Peer Review will be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Texas Health and Safety Code.

(b) The two stages of the Peer Review Process used by the Institute are:

(1) Evaluation of Grant Applications by Peer Review Panels; and

(2) Prioritization of Grant Applications by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council, as may be appropriate for the Grant Program.

(c) Except as described in subsection (e) of this section, the Peer Review Panel evaluation process encompasses the following actions, which will be consistently applied:

(1) The Institute distributes all Grant Applications submitted for a particular Grant Mechanism to one or more Peer Review Panels.

(2) The Peer Review Panel chairperson assigns each Grant Application to no less than two panel members that serve as the Primary Reviewers for the Grant Application. Assignments are made based upon the expertise and background of the Primary Reviewer in relation to the Grant Application.

(3) The Primary Reviewer is responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the Primary Reviewer's general impression of the Grant Application's merit. The Primary Reviewers' individual Overall Evaluation Scores are averaged together to produce a single initial Overall Evaluation Score for the Grant Application.

(4) The Peer Review Panel meets to discuss the Grant Applications assigned to the Peer Review Panel. If there is insufficient time to discuss all Grant Applications, the Peer Review Panel chairperson determines the Grant Applications to be discussed by the panel. The chairperson's decision is based largely on the Grant Application's initial Overall Evaluation Score; however a Peer Review Panel member may request that a Grant Application be discussed by the Peer Review Panel.

(A) If a Grant Application is not discussed by the Peer Review Panel, then the initial Overall Evaluation Score serves as the final Overall Evaluation Score for the Grant Application. The Grant Application is not considered further during the Grant Review Cycle.

(B) If a Grant Application is discussed by the Peer Review Panel, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The

submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(i) The panel chairperson participates in the discussion but does not score Grant Applications.

(ii) A Primary Reviewer has the option to revise his or her score for the Grant Application after panel discussion or to keep the same score submitted during the initial review.

(C) If the Peer Review Panel recommends changes to the Grant Award funds amount requested by the Grant Applicant or to the goals and objectives or timeline for the proposed project, then the recommended changes and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(5) At the conclusion of the Peer Review Panel evaluation, the Peer Review Panel chairperson submits to the appropriate Review Council a list of Grant Applications discussed by the panel ranked in order by the final Overall Evaluation Score. Any changes to the Grant Award funding amount or to the project goals and objectives or timeline recommended by the Peer Review Panel shall be provided to the Review Council at that time.

(d) The Review Council's prioritization process for Grant Award recommendations encompasses the following actions, which will be consistently applied:

(1) The Review Council prioritizes the Grant Application recommendations across all the Peer Review Panels by assigning a Numerical Ranking Score to each Grant Application that was discussed by a Peer Review Panel. The Numerical Ranking Score is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

(2) The Review Council's recommendations are submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. The recommendations, listed in order by Numerical Ranking Score shall include:

(A) An explanation describing how the Grant Application meets the Review Council's standards for Grant Award funding;

(B) The final Overall Evaluation Score assigned to the Grant Application by the Peer Review Panel, including an explanation for ranking one or more Grant Applications ahead of another Grant Application with a more favorable final Overall Evaluation Score; and

(C) The specified amount of the Grant Award funding for each Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline.

(3) A Grant Award recommendation is not final until the Review Council formally submits the recommendation to the presiding officers of the Program Integration Committee and the Oversight Committee. The Program Integration Committee, and, if appropriate, the Oversight Committee must make a final decision on the Grant Award recommendation in the same state fiscal year that the Review Council submits its final recommendation.

(e) Circumstances relevant to a particular Grant Mechanism or to a Grant Review Cycle may justify changes to the dual-stage Peer Review process described in subsections (c) and (d) of this section. Peer Review process changes the Institute may implement are described in this subsection. The list is not intended to be exhaustive. Any material changes to the Peer Review process, including those listed in this subsection, shall be described in the Request for Applications or communicated to all Grant Applicants.

(1) The Institute may use a preliminary evaluation process if the volume of Grant Applications submitted pursuant to a specific Request for Applications is such that timely review may be impeded. The preliminary evaluation will be conducted after Grant Applications are assigned to Peer Review Panels but prior to the initial review described in subsection (c) of this section. The preliminary evaluation encompasses the following actions:

(A) The criteria and the specific Grant Application components used for the preliminary evaluation shall be stated in the Request for Applications;

(B) No less than two Peer Review Panel members are assigned to conduct the preliminary evaluation for a Grant Application and provide a preliminary score that conveys the general impression of the Grant Application's merit pursuant to the specified criteria; and

(C) The Peer Review Panel chairperson is responsible for determining the Grant Applications that move forward to initial review as described in subsection (c) of this section. The decision will be based upon preliminary evaluation scores. A Grant Application that does not move forward to initial review will not be considered further and the average of the preliminary evaluation scores received becomes the final Overall Evaluation Score for the Grant Application.

(2) The Institute shall assign all Grant Applications submitted for recruitment of researchers and clinicians to the Scientific Review Council.

(A) The Scientific Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the proposed recruitment.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one recruitment Grant Application is reviewed by the Scientific Review Council during the Grant Review Cycle, then the Scientific Review Council shall assign a Numerical Ranking Score to each Grant Application to convey its prioritization ranking.

(D) If the Scientific Review Council recommends a change to the Grant Award funds requested by the Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Scientific Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(3) The Institute may assign continuation Grant Applications to the appropriate Review Council.

(A) The Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the progress and continued funding.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one continuation Grant Application is reviewed by the Review Council during the Grant Review Cycle, then the Review Council shall assign a Numerical Ranking Score to each continuation Grant Application to convey its prioritization ranking.

(D) If the Review Council recommends a change to the Grant Award funds or to the scope of work or timeline requested by the continuation Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(4) The Institute's Peer Review process described in subsections (c) and (d) of this section may include the following additional process steps for Product Development of Cancer Research Grant Applications:

(A) A Grant Applicant may be invited to deliver an in-person presentation to the Peer Review Panel. The Product Development Review Council chairperson is responsible for deciding which Grant Applicants will make in-person presentations. The decision is based upon the initial Overall Evaluation Scores of the primary reviewers following a discussion with Peer Review Panel members, as well as explicit criteria published in the Request for Applications.

(i) Peer Review Panel members may submit questions to be addressed by the Grant Applicant at the in-person presentation.

(ii) A Grant Application that is not presented in-person will not be considered further. The average of the primary reviewers' initial Overall Evaluation Scores will be the final Overall Evaluation Score for the Grant Application.

(iii) Following the in-person presentation, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(B) A Grant Application may undergo business operations and management due diligence review and an intellectual property review conducted by third parties. The Peer Review Panel decides which Grant Applications will undergo business operations and management due diligence and intellectual property review. The decision is based upon the Grant Application's final Overall Evaluation Score, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for

Applications. A Grant Application that is not recommended for due diligence and intellectual property review will not be considered further.

(C) After receipt of the business operations and management due diligence and intellectual property reviews for a Grant Application, the Product Development Review Council and the Primary Reviewers meet to determine whether to recommend the Grant Application for a Grant Award based upon the information set forth in the due diligence and intellectual property reviews. The Product Development Review Council may recommend changes to the Grant Award budget and goals and objectives or timeline

D) The Product Development Review Council assigns a Numerical Ranking Score to each Grant Application recommended for a Grant Award.

(f) Institute Employees and Oversight Committee members may attend Peer Review Panel and Review Council meetings. If an Institute Employee or an Oversight Committee member attends a Peer Review Panel meeting or a Review Council meeting, the ~~Institute Employee's~~ attendance shall be recorded and the Institute Employee or Oversight Committee member shall certify in writing ~~that the Institute Employee complied~~ compliance with the Institute's Conflict of Interest rules. The Institute Employee's and Oversight Committee member's attendance at the Peer Review Panel meeting or Review Council meeting is subject to the following restrictions:

(1) Unless waived pursuant to the process described in Chapter 702, §702.17 of this title (relating to Exceptional Circumstances Requiring Participation), ~~the~~ Institute Employees andOversight Committee members shall not be present for any discussion, vote, or other action taken related to a Grant Applicant if the Institute Employee or Oversight Committee member has a Conflict of Interest with that Grant Applicant; and

(2) The Institute Employee or Oversight Committee member shall not participate in a discussion of the merits, vote, or other action taken related to a Grant Application, except to answer technical or administrative questions unrelated to the merits of the Grant Application and to provide input on the Institute's Grant Review Process.

(g) The Institute's Chief Compliance Officer shall observe meetings of the Peer Review Panel and Review Council where Grant Applications are discussed.

(1) The Chief Compliance Officer shall 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 Chief Compliance Officer shall report to the Oversight Committee prior to a vote on the award recommendations specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(3) Nothing herein shall prevent the Institute from contracting with an independent third party to serve as a neutral observer of meetings of the Peer Review Panel and/or the Review Council where Grant

Applications are discussed and to assume the reporting responsibilities of the Chief Compliance Officer described in this subsection. In the event that the independent third party observes the meeting of the Peer Review Panel and/or the Review Council, then the independent third party reviewer shall issue a report to the Chief Compliance Officer specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(h) Excepting a finding of an undisclosed Conflict of Interest as set forth in §703.9 of this chapter (relating to Limitation on Review of Grant Process), the Review Council's decision to not include a Grant Application on the prioritized list of Grant Applications submitted to the Program Integration Committee and the Oversight Committee is final. A Grant Application not included on the prioritized list created by the Review Council shall not be considered further during the Grant Review Cycle.

(i) At the time that the Peer Review Panel or the Review Council concludes its tasks for the Grant Review Cycle, each member shall certify in writing that the member complied with the Institute's Conflict of Interest rules. An Institute Employee or an Oversight Committee member attending one or more Peer Review Panel meetings during the Grant Review Cycle shall certify compliance with the Institute's Conflict of Interest rules.

(j) The Institute shall retain a review record for a Grant Application submitted to the Institute, even if the Grant Application did not receive a Grant Award. Such records will be retained by the Institute's electronic Grant Management System. The records retained by the Institute must include the following information:

(1) The final Overall Evaluation Score and Numerical Ranking Score, if applicable, assigned to the Grant Application;

(2) The specified amount of the Grant Award funding for the Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline;

(3) The Scientific Research and Prevention Programs Committee that reviewed the Grant Application;

(4) Conflicts of Interest, if any, with the Grant Application identified by a member of the Scientific Research and Prevention Programs Committee, the Review Council, the Program Integration Committee, or the Oversight Committee; and

(5) Documentation of steps taken to recuse any member or members from the Grant Review Process because of disclosed Conflicts of Interest.

(k) For purposes of this rule, a Peer Review Panel chairperson or a Review Council chairperson that is unable to carry out his or her assigned duties due to a Conflict of Interest with regard to one or more Grant Applications or for any other reason may designate a co-chairperson from among the appointed Scientific Research and Prevention Programs committee members to fulfill the chairperson role. Such designation shall be recorded in writing and include the specific time and extent of the designation

RULE § 703.7 Program Integration Committee Funding Recommendation

(a) The Institute uses a Program Review process undertaken by the Institute's Program Integration Committee to identify and recommend for funding a final list of meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control Program projects that are in the best overall interest of the State.

(b) Program Review shall be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Texas 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, including a list of Grant Applications, if any, that have been deferred until a future meeting of the Program Integration 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 paragraph (2) of this subsection;

(4) Explain in writing the reasons for not recommending a Grant Application that was recommended for a Grant Award by the Review Council or for deferring a Grant Application recommendation until a future meeting date;

(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; and ~~.~~

(8) Provide a list of deferred Grant Applications, if any.

(e) In the event that the Program Integration Committee's vote on the final list of Grant Award recommendations or deferrals 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 or deferrals. The explanation may include the Program Integration Committee Member or Members' recommended prioritized list of Grant Award recommendations or deferrals.

(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;

(2) A finding of an undisclosed Conflict of Interest as set forth in §703.9 of this chapter (relating to Limitation on Review of Grant Process); or

(3) A decision by the Program Integration Committee to defer a decision to include a Grant Application on the prioritized list of Grant Applications submitted to the Oversight Committee until a future meeting of the Program Integration Committee, subject to subsection (k).

(g) The Chief Compliance Officer shall attend and observe Program Integration Committee meetings to document compliance with Chapter 102, Texas 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.

(k) The Program Integration Committee's decision to defer the final Grant Award recommendation for a Grant Application is only effective for the state fiscal year in which the Program Integration Committee's deferral decision is made.

(1) A Grant Application that is deferred by the Program Integration Committee and is pending a final Grant Award recommendation at the end of the state fiscal year shall be considered not recommended for a Grant Award without further action from the Program Integration Committee.

(2) A Grant Application that is deferred and pending a final Grant Award recommendation at the end of the state fiscal year may be resubmitted by the Grant Applicant in a subsequent review cycle. Such resubmission will not count against the resubmission limit, if any, stated in the Request for Applications

RULE § 703.8 Oversight Committee Consideration of the Program Integration Committee's Funding Recommendation

The Oversight Committee must vote to approve each Grant Award recommendation submitted by the Program Integration Committee.

(1) Prior to the Oversight Committee's consideration and approval of the Program Integration Committee's Grant Award recommendations, the Chief Compliance Officer must review the process documentation for each Grant Application recommended for a Grant Award by the Program Integration Committee and report the findings to the Chief Executive Officer and to the Oversight Committee. The Chief Compliance Officer's report shall:

(A) Publicly certify that the Grant Review Process complied with the Institute's administrative rules and procedures, including those procedures stated in the Request for Applications.

(B) Indicate variances, if any, ~~in~~from the Institute's administrative rules and procedures with a Grant Application or the Grant Review Process.

(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) The Chief Executive Officer may recommend good cause for considering ~~corrective actions to address~~ variances, if any, identified by the Chief Compliance Officer. The Oversight Committee shall consider and may approve the recommendation, which may include ~~proposed~~ corrective actions at that time that the Grant Award recommendations are approved by a vote of a simple majority of Oversight Committee members present and voting.

(3) Two-thirds of the Oversight Committee Members present and voting must approve each Grant Award recommendation. The Oversight Committee may take up more than one Grant Award recommendation at a time unless an Oversight Committee member requests taking up a recommendation individually. 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.

(4) 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 not approving ~~the failure to follow~~ the Grant Award recommendation.

(5) The Oversight Committee may not award more than $300 million in Grant Awards in a fiscal year.

(6) No Oversight Committee action is necessary related to the Program Integration Committee's decision made pursuant to §703.7 to defer a final Grant Award recommendation for one or more Grant Applications.

(7) Nothing herein prevents the Oversight Committee from voting to defer a final decision on a Grant Award recommendation made by the Program Integration Committee until a future meeting date pursuant to the following process:

(A) The motion to defer a final decision on a Grant Award recommendation must be made by an Oversight Committee member that is not recused from taking action on the Grant Application;

(B) The motion must be approved by two-thirds of the Oversight Committee Members present and voting;

(C) The reason for deferring a final decision on one or more Grant Award recommendations must be recorded in the minutes of the Oversight Committee meeting;

(D) Applications that have been deferred shall be considered by the Program Integration Committee at a future meeting date pursuant to §703.7;

(E) The decision to defer the final Grant Award recommendation is only effective for the state fiscal year in which the deferral decision is made;

(F) A Grant Application that is deferred and pending a final Grant Award recommendation at the end of the state fiscal year shall be considered not recommended for a Grant Award without further action from the Program Integration Committee or the Oversight Committee; and

(G) A Grant Application that is deferred and pending a final Grant Award recommendation at the end of the state fiscal year may be resubmitted by the Grant Applicant in a subsequent review cycle. Such resubmission will not count against the resubmission limit, if any, stated in the Request for Applications.

RULE § 703.10 Awarding Grants by Contract

a) The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds and enter into a written contract with the Grant Recipient.

(b) The Oversight Committee may delegate Grant Contract negotiation duties to the Chief Executive Officer and the General Counsel for the Institute. The Chief Executive Officer may enter into a written contract with the Grant Recipient on behalf of the Oversight Committee.

(c) The Grant Contract shall include the following provisions:

(1) If any portion of the Grant Contract has been approved by the Oversight Committee to be used to build a capital improvement, the Grant Contract shall specify that:

(A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale;

(2) Terms relating to Intellectual Property Rights and the sharing with the Institute of revenues generated by the sale, license, or other conveyance of such Project Results consistent with the standards established by this chapter;

(3) Terms relating to publication of materials created with Grant Award funds or related to the Cancer Research or Cancer Prevention project that is the subject of the Grant Award, including an acknowledgement of Institute funding and copyright ownership, if applicable;

(4) Repayment terms, including interest rates, to be enforced if the Grant Recipient has not used Grant Award funds for the purposes for which the Grant Award was intended;

(5) A statement that the Institute does not assume responsibility for the conduct of the Cancer Research or Cancer Prevention project, and that the conduct of the project and activities of all investigators are under the scope and direction of the Grant Recipient;

(6) A statement that the Cancer Research or Cancer Prevention project is conducted with full consideration for the ethical and medical implications of the project and that the project will comply with all federal and state laws regarding the conduct of the Cancer Research or Prevention project;

(7) Terms related to the Standards established by the Oversight Committee in Chapter 701 of this title (relating to Policies and Procedures) to ensure that Grant Recipients, to the extent reasonably possible, demonstrate good faith effort to purchase goods and services for the Grant Award project from suppliers in this state and from historically underutilized businesses as defined by Chapter 2161, Texas Government Code, and any other state law;

(8) An agreement by the Grant Recipient to submit to regular inspection reviews of the Grant Award project by Institute staff during normal business hours and upon reasonable notice to ensure compliance with the terms of the Grant Contract and continued merit of the project;

(9) An agreement by the Grant Recipient to submit Grant Progress Reports to the Institute on a schedule specified by the Grant Contract that include information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Institute funding;

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

(11) An agreement that the Grant Recipient will abide by the Uniform Grant Management Standards (UGMS) adopted by the Governor's Office, if applicable unless one or more standards conflicts with a provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules. Such interpretation of the Institute rules and UGMS shall be made by the Institute;

(12) An agreement that the Grant Recipient is under a continuing obligation to notify the Institute of any adverse conditions that materially impact milestones and objectives included in the Grant Contract;

(13) An agreement that the design, conduct, and reporting of the Cancer Research or Prevention project will not be biased by conflicting financial interest of the Grant Recipient or any individuals associated with the Grant Award. This duty is fulfilled by certifying that an appropriate written, enforced Conflict of Interest policy governs the Grant Recipient.

(14) An agreement regarding the amount, schedule, and requirements for payment of Grant Award funds, if such advance payments are approved by the Oversight Committee in accordance with this chapter. Notwithstanding the foregoing, the Institute may require that up to ten percent of the final tranche of funds approved for the Grant Award must be expended on a reimbursement basis. Such reimbursement payment shall not be made until close out documents described in this section and required by the Grant Contract have been submitted and approved by the Institute;

(15) An agreement to provide quarterly Financial Status Reports and supporting documentation for expenses submitted for reimbursement or, if appropriate, to demonstrate how advanced funds were expended;

(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 (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants);

(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.

(23) An agreement that the Grant Recipient is legally responsible for the integrity of the fiscal and programmatic management of the organization.

(24) An agreement that the Grant Recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The Grant Recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the Institute if the infraction is related to a Grant Award.

(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

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

(a) Prior to the disbursement of Grant Award funds, the Grant Recipient of a Cancer Research Grant Award shall demonstrate that the Grant Recipient has an amount of Encumbered Funds equal to one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award. The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract. A Grant Recipient of a multiyear Grant Award may certify Matching Funds on a year-by-year basis for the amount of Award Funds to be distributed for the Project Year based upon the Approved Budget. A Grant Recipient receiving multiple Grant Awards may provide certification at the institutional level.

(b) For purposes of the certification required by subsection (a) of this section, a Grant Recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the five percent (5%) Indirect Cost limit imposed by §102.203(c), Texas Health and Safety Code, subject to the following requirements:

(1) The Grant Recipient shall file certification with the Institute documenting the federal indirect cost rate authorized for research grants awarded to the Grant Recipient;

(2) To the extent that the Grant Recipient's Matching Funds credit does not equal or exceed one-half of the Grant Award funds to be distributed for the Project Year, then the Grant Recipient's Matching Funds certification shall demonstrate that a combination of the dollar amount equivalent credit and the funds to be dedicated to the Grant Award project as described in subsection (c) of this section is available and sufficient to meet or exceed the Matching Fund requirement;

(3) Calculation of the portion of federal indirect cost rate credit associated with subcontracted work performed for the Grant Recipient shall be in accordance with the Grant Recipient's established internal policy; and

(4) If the Grant Recipient's federal indirect cost rate changes less than six months following the anniversary of the Effective Date of the Grant Contract, then the Grant Recipient may use the new federal indirect cost rate for the purpose of calculating the Grant Recipient's Matching Funds credit for the entirety of the Project Year.

(c) For purposes of the certification required by subsection (a) of this section, Encumbered Funds must be spent directly on the Grant Project or spent on closely related work that supports, extends, or facilitates the Grant Project and may include:

(1) Federal funds, including, but not limited to, American Recovery and Reinvestment Act of 2009 funds, and the fair market value of drug development support provided to the recipient by the National Cancer Institute or other similar programs;

(2) State of Texas funds;

(3) funds of other states;

(4) Non-governmental funds, including private funds, foundation grants, gifts and donations;

(5) Unrecovered Indirect Costs not to exceed ten percent (10%) of the Grant Award amount, subject to the following conditions:

(A) These costs are not otherwise charged against the Grant Award as the five percent (5%) indirect funds amount allowed under §703.12(c) of this chapter (relating to Limitation on Use of Funds);

(B) The Grant Recipient must have a documented federal indirect cost rate or an indirect cost rate certified by an independent accounting firm; and

(C) The Grant Recipient is not a public or private institution of higher education as defined by §61.003 of the Texas Education Code.

(6) Funds contributed by a subcontractor or subawardee and spent on the Grant Project, so long as the subcontractor's or subawardee's portion of otherwise allowable Matching Funds for a Project Year may not exceed the percentage of the total Grant Funds paid to the subcontractor or subawardee for the same Project Year.

(d) For purposes of the certification required by subsection (a) of this section, the following items do not qualify as Encumbered Funds:

(1) In-kind costs;

(2) Volunteer services furnished to the Grant Recipient;

(3) Noncash contributions;

(4) Income earned by the Grant Recipient that is not available at the time of Grant Award;

(5) Pre-existing real estate of the Grant Recipient including building, facilities and land;

(6) Deferred giving such as a charitable remainder annuity trust, a charitable remainder unitrust, or a pooled income fund; or

(7) Other items as may be determined by the Oversight Committee.

(e) To the extent that a Grant Recipient of a multiyear Grant Award elects to certify Matching Funds on a ~~yearly~~ Project Year basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year ~~shall~~ may serve as grounds for suspending reimbursement or advancement of Grant Funds for project costs or terminating the Grant Contract.

(f) In no event shall Grant Award funds for a Project Year be advanced or reimbursed, as may be appropriate for the Grant Award and specified in the Grant Contract, until the certification required by subsection (a) of this section is filed and approved by the Institute.

(g) No later than 30 days following the due date of the FSR reflecting expenses incurred during the last quarter of the Grant Recipient's Project Year, 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 Project Year~~period~~, the Institute shall:

(1) Carry forward and add to the Matching Fund requirement for the next Project Year the dollar amount equal to the deficiency between the actual amount of Grant Award funds distributed and the actual Matching Funds expended, so long as the deficiency is equal to or less than twenty percent (20%) of the total Matching Funds required for the same period and the Grant Recipient has not previously had a Matching Funds deficiency for the project;

(2) Suspend distributing Grant Award funds for the project to the Grant Recipient if the deficiency between the actual amount of Grant Funds distributed and the Matching Funds expended is greater than twenty percent (20%) but less than fifty percent (50%) of the total Matching Funds required for the period.

(A) The Grant Recipient will have no less than eight months from the anniversary of the Grant Contract's effective date to demonstrate that it has expended Encumbered Funds sufficient to fulfill the Matching Funds deficiency for the project.

(B) If the Grant Recipient fails to fulfill the Matching Funds deficiency within the specified period, then the Grant Contract shall be considered in default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract;

(3) Declare the Grant Contract in default if the deficiency between the actual amount of Grant Award funds distributed and the Matching Funds expended is greater than fifty percent (50%) of the total Matching Funds required for the period. The Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract; or

(4) Take appropriate action, including withholding reimbursement, requiring repayment of the deficiency, or terminating the Grant Contract if a deficiency exists between the actual amount of Grant Award funds distributed and the Matching Funds expended and it is the last year of the Grant Contract;

(i) Nothing herein shall preclude the Institute from taking action other than described in subsection (h) of this section based upon the specific reasons for the deficiency. To the extent that other action not described herein is taken by the Institute, such action shall be documented in writing and included in Grant Contract records. The options described in subsection (h)(1) and (2) of this section may be used by the Grant Recipient only one time for the particular project. A second deficiency of any amount shall be considered an event of default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract.

(j) The Grant Recipient shall maintain adequate documentation supporting the source and use of the Matching Funds reported in the certification required by subsection (a) of this section. The Institute shall conduct an annual review of the documentation supporting the source and use of Matching Funds reported in the required certification for a risk-identified sample of Grant Recipients. Based upon the results of the sample, the Institute may elect to expand the review of supporting documentation to other Grant Recipients. Nothing herein restricts the authority of the Institute to review supporting documentation for one or more Grant Recipients or to conduct a review of Matching Funds documentation more frequently

RULE § 703.12 Limitation on Use of Funds

(a) A Grant Recipient may use Grant Award funds only for Cancer Research and Cancer Prevention projects consistent with the purpose of the Act, and in accordance with the Grant Contract. Grant Award funds may not be used for purposes other than those purposes for which the grant was awarded. The Institute may require a Grant Recipient to repay Grant Award funds if the Grant Recipient fails to expend the Grant Award funds in accordance with the terms and conditions of the Grant Contract and the provisions of this chapter.

(b) ~~Grant Award funds must be used for Authorized Expenses.~~

~~(1) Expenses that are not authorized and shall not be paid from Grant Award funds, include, but are not limited to:~~

~~(A) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.~~

~~(B) Contributions to a contingency reserve or any similar provision for unforeseen events.~~

~~(C) Contributions and donations made to any individual or organization.~~

~~(D) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.~~

~~(E) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.~~

~~(F) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.~~

~~(G) An honorary gift or a gratuitous payment.~~

~~(H) Interest and other financial costs related to borrowing and the cost of financing.~~

~~(I) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.~~

~~(J) Liability insurance coverage.~~

~~(K) Benefit replacement pay or legislatively mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.~~

~~(L) Professional association fees or dues for the Grant Recipient or an individual.~~

~~(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.~~

~~(O) Fees for visa services.~~

~~(2) Additional guidance regarding Authorized Expenses for a specific program may be provided by the terms of the Grant Contract and by the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from UGMS on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.~~

~~(3) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Authorized Expense.~~

~~(c)~~ A Grant Recipient of Grant Award funds for a Cancer Research or Cancer Prevention project may not spend more than five percent (5%) of the Grant Award funds for Indirect Costs.

~~(d)~~(c) The Institute may not award more than five percent (5%) of the total Grant Award funds for each fiscal year to be used for facility purchase, construction, remodel, or renovation purposes during any year. Any Grant Award funds that are to be expended by a Grant Recipient for facility purchase, construction, remodel, or renovations are subject to the following conditions:

(1) The use of Grant Award funds must be specifically approved by the Chief Executive Officer with notification to the Oversight Committee;

(2) Grant Award funds spent on facility purchase, construction, remodel, or renovation projects must benefit Cancer Prevention and Research;

(3) If Grant Award funds are used to build a capital improvement, then the state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award funds used to pay for the capital improvement. If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award funds used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale.

~~(e)~~(d) The Institute may not award more than ten percent (10%) of the money awarded from the Cancer Prevention and Research Fund or from the proceeds of bonds issued on behalf of the Institute to be used for Cancer Prevention and Control programs during any year. Grant Awards for Cancer Prevention research projects shall not be counted toward the Grant Award amount limit for Cancer Prevention and Control Programs. For purposes of this subsection, the Institute is presumed to award the full amount of funds available. At the first regular Oversight Committee meeting of the fiscal year, the Chief Executive Officer shall report that full amount of Grant Award funds available to be awarded for the fiscal year subject to periodic updates announced at regular meetings of the Oversight Committee.

RULE § 703.13 Audits and Investigations

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the end of the Grant Recipient's fiscal year during which the Grant Contract was terminated.

(b) Notwithstanding the foregoing, ~~a~~ the Grant Recipient ~~expending~~shall submit a single audit determination form within 60 days of the anniversary date of the Grant Contract effective date. The Grant Recipient shall report whether the Grant Recipient has expended ~~$500,000~~ $750,000 or more in state awards during ~~its~~ the Grant Recipient's fiscal year. If the Grant Recipient has expended $750,000 or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e).

~~(1) A single audit is required if funds from more than one state program are spent by a Grant Recipient that does not meet the definition of an institution of higher education in Texas Education Code, §61.003.~~

(2) The audited time period is the Grant Recipient's fiscal year.

(3) The audit must be submitted to the Institute within 30 days of receipt by the Grant Recipient but no later than 270 days following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than the 270th day following the close of the Grant Recipient's fiscal year.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

(e) For purposes of this rule, an agreed upon procedures engagement is one in which an independent certified public accountant is hired by the Grant Recipient to issue a report of findings based on specific procedures to be performed on a subject matter.

(1) The option to perform an agreed upon procedures engagement is intended for a non-profit or for-profit Grant Recipient that is not subject to Generally Accepted Government Audit Standards (also known as the Yellow Book) published by the U.S. Government Accountability Office.

(2) The agreed upon procedures engagement will be conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants.

(3) The certified public accountant is to perform procedures prescribed by the Institute and to report his or her findings attesting to whether the Grant Recipient records is in agreement with stated criteria.

(4) The agreed upon procedures apply to all current year expenditures for Grant Awards received by the Grant Recipient. Nothing herein prohibits the use of a statistical sample consistent with the American Institute of Certified Public Accountants' guidance regarding government auditing standards and Circular A-133 audits.

(5) At a minimum, the agreed upon procedures report should address:

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

(E) Grant Award expenditures (payroll and non-payroll related transactions);

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

(6) The certified public accountant should consider the specific Grant Mechanism and update or modify the procedures accordingly to meet the requirements of each Grant Award and the Grant Contract reviewed.

RULE § 703.14 Termination, Ext~~ensi~~on, and Close Out of Grant Contracts, and De-Obligation of Grant Award Funds

(a) The termination date of a Grant Contract shall be the date stated in the Grant Contract, except:

(1) The Chief Executive Officer may elect to terminate the Grant Contract earlier because the Grant Recipient has failed to fulfill contractual obligations, including timely submission of required reports or certifications;

(2) The Institute terminates the Grant Contract because funds allocated to the Grant Award are reduced, depleted, or unavailable during the award period, and the Institute is unable to obtain additional funds for such purposes; or

(3) The Institute and the Grant Recipient mutually agree to terminate the Grant Contract earlier.

(b) If the Institute elects to terminate the Grant Contract pursuant to subsection (a)(1) or (2) of this section, then the Chief Executive Officer shall notify the Grant Recipient in writing of the intent to terminate funding at least 30 days before the intended termination date. The notice shall state the reasons for termination, and the procedure and time period for seeking reconsideration of the decision to terminate. Nothing herein restricts the Institute's ability to terminate the Grant Contract immediately or to seek additional remedies if justified by the circumstances of the event leading to early termination.

(c) The Institute may approve the Grant Recipient's written request to extend the termination date of the Grant Contract to permit the Grant Recipient additional time to complete the work of the project.

(1) A no cost extension may be granted ~~only~~ if the Grant Recipient is in good fiscal and programmatic standing. The Institute's decision to approve or deny a no cost extension request is final.

(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.

(A) If a Grant Recipient ~~does not~~ fails to request a no cost extension within the required timeframe, the Grant Recipient may petition the Chief Executive Officer in writing to consider the no cost extension. The Grant Recipient's petition must show good cause for failing submit the request within the timeframe specified in the above subsection.

(B) Upon a finding of good cause, the Chief Executive Officer may ~~approve~~ consider the request~~for good cause~~. If a no cost extension request is approved under this subsection, the Chief Executive Officer must notify the Oversight Committee in writing and provide justification for the approval.

(3) The Institute may approve one or more no cost extensions.~~,~~ ~~t~~The duration of ~~which~~ each no cost extension 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.

(A) The Grant Recipient's first no cost extension that is less than or equal to six months will be approved so long as the Grant Recipient is in good fiscal and programmatic standing

(B) If a grant recipient requests a second no cost extension or requests a no cost extension greater than six months, the grantee must provide good cause for approving the request.

(4) If the Institute approves the request to extend the termination date of the Grant Contract, then the termination date shall be amended to reflect the change.

(5) Nothing herein prohibits the Institute and the Grant Recipient from taking action more than 180 days prior to the termination date of the Grant contract to extend the termination date of the Grant Contract. Approval of an extension must be supported by a finding of good cause and the Grant Contract shall be amended to reflect the change.

(d) ~~Within ninety (90) days, t~~The Grant Recipient must submit a final Financial Status Report and final Grant Progress Report as well as any other required reports as specified in the Grant Contract. For purposes of this rule, ~~these~~ the final Grant Progress Report and other required reports shall be collectively referred to as "close out documents."

(1) The final Financial Status Report shall be submitted to the Institute within ninety (90) days of the end of the state fiscal quarter that includes the termination date of the Grant Contract. ~~If the Grant Recipient has submitted the final Financial Status Report on or before the 30th day following the due date specified in §703.21(b), but has not submitted other close out documents, then the final reimbursement payment shall not be made until such other close out documents have been submitted and approved by the Institute.~~ The Grant Recipient's failure to submit the Financial Status report within 30 days following the due date specified in ~~§703.21(b)~~this subsection will waive reimbursement of project costs incurred during the reporting period. The Institute may approve additional time to submit the final Financial Status Report if the Grant Recipient can show good cause for failing to timely submit the final Financial Status Report.

(2) Close out documents must be submitted with ninety (90) days of the termination date of the Grant Contract. The final reimbursement payment shall not be made until all close out documents have been submitted and approved by the Institute. Failure to submit ~~all other~~ one or more close out documents within 180 days of the Grant Contract termination date shall result in the Grant Recipient being ineligible to receive new Grant Awards or continuation Grant Awards until such time that the close out documents are submitted unless the Institute waives the final submission of close out documents by the Grant Recipient.

(A) Approval of the Grant Recipient's request to waive the submission of close out documents is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(B) The Oversight Committee shall be notified in writing of the Grant Recipient's waiver request and the Chief Executive Officer's decision to approve or reject the waiver request.

(C) Unless the Oversight Committee votes by a simple majority of members present and able to vote to overturn the Chief Executive Officer's decision regarding the waiver, the Chief Executive Officer's decision shall be considered final.

(e) The Institute may make upward or downward adjustments to the Allowable Costs requested by the Grant Recipient within ninety (90) days following the ~~receipt~~ approval of the close out reports or the final Financial Status Report, whichever is later.

(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.

(h) Grant Award funds approved by the Oversight Committee and specified in the Grant Contract but not spent by the Grant Recipient at the time that the Grant Contract is terminated are considered de-obligated for the purposes of calculating the maximum amount of annual Grant Awards and the total amount authorized by Section 67, Article III, Texas Constitution. Such de-obligated funds are available for all purposes authorized by the statute.

RULE § 703.15 ~~Multiyear Projects~~ Financial Policies Applicable to Grant Awards

~~(a) The Oversight Committee may approve Grant Award funds for a multiyear project. The total amount of Grant Award funds for the project shall be specified at the time that the Grant Award recommendation is approved by the Oversight Committee.~~

~~(b) The Grant Contract shall include an Approved Budget that reflects the amount of the Grant Award funds to be spent for each Project Year.~~

~~(c) The Institute shall distribute Grant Award funds to reimburse Allowable costs as reflected in the Approved Budget and pursuant to the Grant Recipient's submission of the quarterly Financial Status Report or the request to advance Grant Award funds. Remaining Grant Award funds shall be distributed as needed in each subsequent Project Year of the Grant Contract.~~

~~(d) A Grant Recipient awarded a Grant Award for a multiyear project that fails to expend the total Project Year budget may carry forward the unexpended budget balance to the next Project Year. If the amount of the unexpended budget balance to carry forward exceeds ten percent (10%) of the total Grant Award amount, the Grant Recipient must provide specific justification for why the total Grant Award amount should not be reduced by the unexpended balance.~~

(a) The Grant Recipient is responsible for managing the day-to-day operations of the activities supported by the Grant Award and is accountable to Institute for the performance of the Grant Award, including the appropriate expenditure of Grant Award funds by all parties and all other obligations of the Grant Recipient.

(b) The Grant Recipient must maintain a sound financial management system that provides appropriate fiscal controls and accounting procedures to ensure accurate preparation of reports by the Grant Contract and adequate identification of the source and application of Grant Award funds.

(1) The Grant Recipient may use its established controls and policies, as long as the controls and policies are consistent with requirements described in the Institute's administrative rules, the Grant Contract, and other applicable standards.

(2) The Grant Recipient's system of internal controls should encompass segregation of functions, proper authorization of transactions, proper recording of transactions, limited access to assets, and monitoring of internal controls. The extent to which internal controls are established is dependent upon the nature and size of the organization involved.

(3) The Grant Recipient's accounting system must conform to Generally Accepted Accounting Principles applicable to state and federal grant funds and conform to the standards for financial management set forth in the Uniform Grant Management Standards.

(4) The Institute may review the adequacy of the financial management system of any Grant Recipient to ensure that the system is appropriate to fulfill the Institute's administrative rules, the Grant Contract, and other applicable standards.

(c) The Grant Recipient shall use cash basis accounting when reporting expenses to be reimbursed with Grant Award funds.

(1) A Grant Recipient utilizing an accrual basis of accounting in its normal operations must present expenses on a cash basis and reflect actual costs incurred during the payment period.

(2) A subcontractor is not required to record the adjustment in the general ledger; the adjustment should be documented by memo entries along with a reconciliation of the expense reported to the Institute and the expense recorded to the general ledger.

RULE § 703.16 Intellectual Property Agreement

(a) To the extent that there is a conflict between this chapter and the Grant Contract between the Institute and the Grant Recipient, the Grant Contract terms will control.

(b) The Grant Recipient may retain, assign or transfer all or a portion of any of the Intellectual Property Rights relating to the project results. Any such assignment or transfer to a third party is subject to the following requirements:

(1) The Grant Recipient shall notify the Institute of the proposed transfer or assignment;

(2) The Grant Recipient shall ensure that the assignment or transfer is subject to the licenses, interests and other rights provided to the Institute pursuant to the Grant Contract and any applicable law or regulation; and

(3) Unless the transfer is taking place pursuant to an exercise of the United States government's rights under 35 U.S.C. §203, the Institute may provide comments to the Grant Recipient related to the proposed transfer or assignment of rights, which the Grant Recipient shall consider in good faith and use reasonable efforts to account for and incorporate such comments into the actual transfer or assignment of such rights.

(c) Unless specifically authorized by the Institute, Grant Award proceeds shall not be used to pay the costs or expenses associated with the efforts to protect the Intellectual Property Rights ~~or to pay the costs or expenses associated with commercialization activities~~.

(d) As a condition of accepting Grant Award funding from the Institute, the Grant Recipient agrees to the following required commitments as defined in the Grant Contract with regard to any project results:

(1) To use commercially reasonable efforts to protect, develop, commercialize, or otherwise bring Project Results to practical application to the fullest extent feasible as determined by the Grant Recipient. The Grant Recipient is relieved of its obligations pursuant to this section so long as the Grant Recipient complies with paragraph (3) of this subsection and §703.19 of this chapter (relating to Opt-Out and Default).

(2) To share with the Institute a portion of the benefit derived from the commercial development of the Project Results, as set forth in the Grant Contract.

(3) To notify the Institute in writing prior to declining to pursue, abandoning, waiving or disclaiming some or all Intellectual Property Rights related to the Project Results. Such notification shall be made with sufficient time to provide the Institute an opportunity to license or pursue the appropriate applications and other protections for such Intellectual Property Rights to the fullest extent permitted by law.

(4) To keep the Institute promptly and reasonably informed regarding the activities undertaken by the Grant Recipient to protect and/or commercialize the Project Results and to consider in good faith Institute input, if any, regarding same. Such activities may include, but are not limited to, the following:

(A) Filing of an invention disclosure forms (including updates and revisions);

(B) Creation of commercial development plans;

(C) Application, issuance, prosecution and maintenance of patents; and

(D) Negotiation of final term sheets and License Agreements.

(5) To allow access to the books and records of the Grant Recipient for the purpose of conducting an audit during normal business hours with reasonable notice to verify amounts paid to the Institute pursuant to this chapter. Notwithstanding the time limitation provided in §703.13 of this chapter (relating to Audits and Investigations), the right to audit the books and records of the Grant Recipient to verify amounts required to be paid to the Institute shall continue for so long as the payments shall be made.

~~(6) To report to the Institute at least annually describing commercialization activities for the Project Results in a manner and form to be prescribed by the Institute.~~

RULE § 703.17 Revenue Sharing Standards

(a) The Institute shall share in the financial benefit received by the Grant Recipient resulting from the patents, royalties, assignments, sales, conveyances, licenses and/or other benefits associated with the Project Results, including interest or proceeds resulting from securities and equity ownership. Such payment may include royalties, income, milestone payments, or other financial interest in an existing company or other entity.

(b) The Institute's election as to form of payment and the calculation of such payment shall be specified in the Grant Contract.

(c) Unless otherwise provided by the Grant Contract between the Institute and the Grant Recipient, payments to the Institute required by this section shall be made no less than annually pursuant to a schedule set forth in the Grant Contract and shall be accompanied by an appropriate financial statement supporting the calculation of the payment.

(d) Nothing herein shall affect or otherwise impair the application of federal laws for projects receiving some portion of funding from the U.S. Government.

(e) Unless the Grant Contract specifically states otherwise, the obligation to share revenues with the Institute is continuous so long as the product resulting from the Institute supported project enjoys government exclusivity.

RULE § 703.21 Monitoring Grant Award Performance and Expenditures

(a) The Institute, under the direction of the Chief Compliance ~~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 – The Institute shall 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~~ Grant Award expenditures reported by Grant Recipients on the quarterly Financial Status Reports 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~~ Grant Award Reports – The Institute shall monitor the submission of all required reports and implement a process to ensure that Grant Award funds are not disbursed to a Grant Recipient with one or more delinquent reports. ~~Except as provided herein, the Grant Recipient waives the right to reimbursement of project costs incurred during the reporting period if the financial status report (FSR) for that quarter is not submitted to the Institute within 30 days of the FSR due date. Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.~~

~~(A) For purposes of this rule, the "FSR due date" is 90 days following the end of the state fiscal quarter.~~

~~(B) The Chief Executive Officer may approve a Grant Recipient's request to defer submission of the reimbursement request for the current fiscal quarter until the next fiscal quarter if, on or before the original FSR due date, the Grant Recipient submits a written explanation for the Grant Recipient's inability to complete a timely submission of the FSR.~~

~~(C) A Grant Recipient may appeal the waiver of its right to reimbursement of project costs.~~

~~(i) The appeal shall be in writing, provide good cause for failing to submit the FSR within 30 days of the FSR due date, and be submitted through CPRIT's Grant Management System.~~

~~(ii) The Chief Executive Officer may approve the appeal for good cause. The decision by the Chief Executive Officer to approve or deny the grant recipient's appeal shall be in writing and provided through CPRIT's Grant Management System.~~

~~(iii) The Chief Executive Officer's decision to approve or deny the Grant Recipient's appeal is final, unless the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision by the Oversight Committee.~~

~~(iv) The Grant Recipient may request that the Oversight Committee reconsider the Chief Executive Officer's decision regarding the Grant Recipient's appeal. The request for reconsideration shall be in writing and submitted to the Chief Executive Officer within 10 days of the date that the Chief Executive Officer notifies the Grant Recipient of the decision regarding the appeal as noted in clause (iii) of this subparagraph.~~

~~(v) The Chief Executive Officer shall notify the Oversight Committee in writing of the decision to approve or deny the Grant Recipient's appeal. The notice should provide justification for the Chief Executive Officer's decision. In the event that the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision, the Chief Executive Officer shall provide the Grant Recipient's written request to the Oversight Committee at the same time.~~

~~(vi) The Grant Recipient's request for reconsideration is deemed denied unless three or more Oversight Committee members request that the Chief Executive Officer add the Grant Recipient's request for reconsideration to the agenda for action at the next regular Oversight Committee meeting. The decision made by the Oversight Committee is final.~~

~~(vii) If the Grant Recipient's appeal is approved by the Chief Executive Officer or the Oversight Committee, the Grant Recipient shall report the project costs and provide supporting documentation for the costs incurred during the reporting period covered by the appeal on the next available financial status report to be filed by the Grant Recipient.~~

~~(viii) Approval of the waiver appeal does not connote approval of the expenditures; the expenditures and supporting documentation shall be reviewed according to paragraph (1) of this subsection.~~

~~(ix) This subsection applies to any waivers of its reimbursement decided by the Institute on or after September 1, 2015.~~

~~(D) Notwithstanding paragraph (2) of this subsection, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding FSR(s). The approval shall be in writing and maintained in the Institute's electronic Grants Management System. The Chief Program Officer's approval may cover more than one FSR and more than one fiscal quarter.~~

~~(E) In order to receive disbursement of grant funds, the most recently due FSR must be approved by CPRIT.~~

(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, which shall be submitted pursuant to the timeline in §703.11. In order to receive disbursement of grant funds, the most recently due verification of the amount of Matching Funds must be approved by CPRIT;

(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) Notwithstanding subparagraph (B) of this paragraph, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding reports. The approval shall be in writing and maintained in the Institute's electronic Grants Management System. The Chief Program Officer's approval may cover more than one report and more than one fiscal quarter.

(D) 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.

(E) 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. In order to receive disbursement of grant funds, the final progress report must be approved by CPRIT.

(F) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts).

(G) 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.

(H) In order to receive disbursement of grant funds, the most recently due progress report must be approved by CPRIT.

(I) If a Grant Recipient fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Award funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is approved.

(J) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific tranches of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a tranche of funding shall be known as "Tranche Grant Progress Report."

(i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.

(ii) Grant Funds for the next tranche of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.

(4) Desk Reviews - The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

(5) Site Visits and Inspection Reviews - The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.

(6) Audit Reports - The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).

(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) of this section 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 §703.4 of this chapter (relating to Grants Management System).

(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 § 703.23 Disbursement of Grant Award Funds

(a) The Institute disburses Grant Award funds by reimbursing the Grant Recipient for allowable costs already expended; 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 authorization from the Oversight Committee to disburse Grant Award funds by advance payment.

(A) A simple majority of Oversight Committee Members present and voting must approve the Chief Executive Officer's advance payment recommendation for the Grant Award.

(B) Unless specifically stated at the time of the Oversight Committee's vote, the Oversight Committee's approval to disburse Grant Award funds by advance payment is effective for the term of the Grant Award.

(2) Unless otherwise specified in the Grant Contract, the amount of Grant Award funds advanced in any particular tranche may not exceed the budget amount for the corresponding Project Year.

(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) The Grant Recipient must comply with all financial reporting requirements regarding use of Grant Award funds, including timely submission of quarterly Financial Status Reports.

(5) The Grant Recipient must expend at least 90% of the Grant Award funds in a tranche before Institute will advance additional grant funds or reimburse additional costs. To the extent possible, the Institute will work with the Grant Recipient to coordinate the advancement of Grant Award fund tranches in such a way as to avoid affecting work in progress or project planning.

(6) 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 for the advance payment of Grant Award funds, or may revert to payment on a reimbursement-basis. Unless specifically stated in the Grant Contract, the Institute will disburse the last ten percent (10%) of the total Grant Award funds using the reimbursement method of funding.

(b) The Institute will disburse Grant Award funds for actual cash expenditures reported on the Grant Recipient's quarterly Financial Status Report.

(1) Only expenses that are allowable and supported by adequate documentation are eligible to be paid with Grant Award funds.

(2) A Grant Recipient must pay their vendors and subcontractors prior to requesting reimbursement from CPRIT.

(c) The Institute may withhold disbursing Grant Award funds if the Grant Recipient has not submitted required reports, including quarterly Financial Status Reports, Grant Progress Reports, Matching Fund

Reports, audits and other financial reports. Unless otherwise specified for the particular Grant Award, Institute approval of the required report(s) is necessary for disbursement of Grant Award funds.

(d) All Grant Award funds are disbursed pursuant to a fully executed Grant Contract. Grant Award funds shall not be disbursed prior to the effective date of the Grant Contract.

RULE § 703.24 Financial Status Reports

(a) Grant Recipients shall report expenditures to be reimbursed with Grant Award funds on the quarterly Financial Status Report form.

(1) Expenditures shall be reported by budget category consistent with the Grant Recipient's Approved Budget.

(2) All expenditures must be supported with appropriate documentation showing that the costs were incurred and paid. A Grant Recipient that is a public or private institution of higher education as defined by §61.003, Texas Education Code is not required to submit supporting documentation for an individual expense totaling less than $750 in the "supplies" or "other" budget categories.

(3) The Financial Status Report and supporting documentation must be submitted via the Grant Management System, unless the Grant Recipient is specifically directed in writing by the Institute to submit or provide it in another manner.

(4) The requirement to report and timely submit quarterly Financial Status Reports applies to all Grant Recipients, regardless of whether Grant Award funds are disbursed by reimbursement or in advance of incurring costs.

(b) 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:

(1) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(2) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(c) Except as provided herein, 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 Financial Status Report due date. Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.

(1) For purposes of this rule, the "Financial Status Report due date" is 90 days following the end of the state fiscal quarter.

(2) The Chief Executive Officer may approve a Grant Recipient's request to defer submission of the reimbursement request for the current fiscal quarter until the next fiscal quarter if, on or before the original Financial Status Report due date, the Grant Recipient submits a written explanation for the Grant Recipient's inability to complete a timely submission of the Financial Status Report.

(3) A Grant Recipient may appeal the waiver of its right to reimbursement of project costs.

(A) The appeal shall be in writing, provide good cause for failing to submit the Financial Status Report within 30 days of the Financial Status Report due date, and be submitted via the Grant Management System.

(B) The Chief Executive Officer may approve the appeal for good cause. The decision by the Chief Executive Officer to approve or deny the grant recipient's appeal shall be in writing and available to the Grant Recipeint via the Grant Management System.

(C) The Chief Executive Officer's decision to approve or deny the Grant Recipient's appeal is final, unless the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision by the Oversight Committee.

(D) The Grant Recipient may request that the Oversight Committee reconsider the Chief Executive Officer's decision regarding the Grant Recipient's appeal. The request for reconsideration shall be in writing and submitted to the Chief Executive Officer within 10 days of the date that the Chief Executive Officer notifies the Grant Recipient of the decision regarding the appeal as noted in clause (C) of this subsection.

(E) The Chief Executive Officer shall notify the Oversight Committee in writing of the decision to approve or deny the Grant Recipient's appeal. The notice should provide justification for the Chief Executive Officer's decision. In the event that the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision, the Chief Executive Officer shall provide the Grant Recipient's written request to the Oversight Committee at the same time.

(F) The Grant Recipient's request for reconsideration is deemed denied unless three or more Oversight Committee members request that the Chief Executive Officer add the Grant Recipient's request for reconsideration to the agenda for action at the next regular Oversight Committee meeting. The decision made by the Oversight Committee is final.

(G) If the Grant Recipient's appeal is approved by the Chief Executive Officer or the Oversight Committee, the Grant Recipient shall report the project costs and provide supporting documentation for the costs incurred during the reporting period covered by the appeal on the next available financial status report to be filed by the Grant Recipient.

(H) Approval of the waiver appeal does not connote approval of the expenditures; the expenditures and supporting documentation shall be reviewed according to paragraph (b) of this subsection.

(I) This subsection applies to any waivers of the Grant Recipient’s reimbursement decided by the Institute on or after September 1, 2015.

(4) Notwithstanding paragraph (c) of this section, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding Financial Status Report(s). The approval shall be in writing and maintained in the Grants Management System. The Chief Program Officer's approval may cover more than one Financial Status Report and more than one fiscal quarter.

(5) In order to receive disbursement of grant funds, the most recently due Financial Status Report must be approved by the Institute.

RULE § 703.25 Grant Award Budget

(a) The Grant Contract shall include an Approved Budget that reflects the amount of the Grant Award funds to be spent for each Project Year.

(b) All expenses charged to a Grant Award must be budgeted and reported in the appropriate budget category.

(c) Actual expenditures under each category should not exceed budgeted amounts authorized by the Grant Contract as reflected on the Approved Budget for each Grant Award.

(d) Recipients may make transfers between or among lines within budget categories listed on the Approved Budget so long as the transfer fits within the scope of the Grant Contract and the total Approved Budget; is beneficial to the achievement of project objectives; and is an efficient, effective use of Grant Award funds.

(e) All budget changes or transfers require Institute approval, except that the Grant Recipient may make budget changes or transfers without prior approval from the Institute for expenses not specified in the equipment category if:

(1) The total dollar amount of all changes of any single line item (individually and in the aggregate) within budget categories other than equipment is not more than 10% of the amount in that line item;

(2) The transfer will not increase or decrease the total grant budget; and

(3) The transfer will not materially change the nature, performance level, or scope of the project.

(f) A Grant Recipient awarded a Grant Award for a multiyear project that fails to expend the total Project Year budget may carry forward the unexpended budget balance to the next Project Year.

(1) If the amount of the unexpended budget balance in a Project Year exceeds ten percent (10%) of the total Grant Award amount, the Institute must approve the carry forward.

(2) For a budget carry forward requiring Institute approval, the Grant Recipient must provide justification for why the total Grant Award amount should not be reduced by the unexpended balance.

RULE § 703.26 Allowable Costs

(a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.

(1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.

(2) A cost is allocable if the cost:

(A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;

(B) Is assigned the Grant Award in accordance with the relative benefit received;

(C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;

(D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and

(E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.

(3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with § 703.24.

(b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, *Texas Health and Safety Code*, the Institute's administrative rules, and the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from the Uniform Grant Management Standards on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, *Texas Health and Safety Code* or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.

(d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.

(e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:

(1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(2) Contributions to a contingency reserve or any similar provision for unforeseen events.

(3) Contributions and donations made to any individual or organization.

(4) 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.

(5) 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.

(6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(7) An honorary gift or a gratuitous payment.

(8) Interest and other financial costs related to borrowing and the cost of financing.

(9) 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.

(10) Liability insurance coverage.

(11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(12) Professional association fees or dues for the Grant Recipient or an individual.

(13) 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.

(14) Fees for visa services.

(f) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.

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Fourth Quarter 2016 Oversight Committee
Internal Audit Status Report
As of July 29, 2016

Weaver and Tidwell, LLP (Weaver) is the outsourced internal auditor of the Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Alyssa Martin, Partner; Daniel Graves, Sr. Manager; and Adam Wright, Manager.

Weaver has completed or started fieldwork for all projects on the 2016 Internal Audit Plan.

2016 Internal Audit Plan

Internal Audit	Description
Commodity and Service Contracts	Fieldwork for the Commodity and Service Contracts audit was completed on May 18, 2016. We issued the report on June 10, 2016. The audit resulted in an overall assessment of "Satisfactory" with five total findings. Moderate Risk Findings • Maintenance of an accurate contract listing • Consistent budget certification for purchase orders • Compliance with vendor performance tracking and reporting Low Risk Findings • Vendor on-boarding • Segregated approval of commodity invoices Follow-up procedures on the remediation of the findings will be included in the proposed audit plan for fiscal year 2017.
Revenue	An exit conference for the Revenue audit was held on July 8, 2016. We identified two low risk findings. Weaver issued a formal findings and observations document for Management's response on July 15 and anticipates issuing a draft report by August 5, 2016.
Information Security	Fieldwork for this audit began on July 11, 2016, and an exit conference is scheduled to be held with CPRIT Management on August 3 to discuss the preliminary results.

Cash Management	Fieldwork for this audit began on July 25, 2016, and is ongoing. An exit conference is scheduled to be held with CPRIT Management on August 12, 2016, to discuss the preliminary results. The audit will include an evaluation of risks and internal controls in place related to CPRIT's Cash Management practices. Activities included in the evaluation include Cash Forecasting, Electronic Funds Transfer Processing, Cancellation of Warrant Review and Approvals, and Uniform Statewide Accounting System (USAS) Privileges. Attached is the scope and risk coverage document.
Information Technology Services Follow-Up • 1 Moderate Finding • 1 Low Finding	Fieldwork for this audit was scheduled to begin on May 31, 2016. Procedures were delayed to allow CPRIT time to prepare for the IT Security internal audit.

Information Technology Services Prior Findings Status		
Risk Rating	**Finding**	**Status**
Moderate	Formal IT Risk Assessment Not Performed	Open
Low	Security Access Review for CGMS	Open

Internal Audit	Description
Pre-Award Grant Management Post-Award Grant Management Grant Contracting Follow-Up • 8 Moderate Findings • 1 Low Finding	Fieldwork for these follow-up procedures was completed on June 9, 2016. The report was issued July 15, 2016. All nine findings from the prior year audit were remediated.
Project Management	Ongoing coordination internal audit activities with Management, tracking status of audit plan and reporting to Management.
Risk Assessment Update	Annual update of the internal audit risk assessment will be performed August 19, 2016.

Annual and Quarterly Oversight Committee Reports	Preparation and submission of the required Annual Internal Audit Report, due November 1, 2016, and quarterly reports to the Audit Subcommittee and Oversight Committee of internal audit activities.

We have prepared a summary schedule of audits, their status and a summary of the findings by risk rating. The schedule maps out the internal audit and follow-up procedures performed, by year, the report date, report rating, and the findings by risk rating. The summary schedule is attached.

Alyssa G. Martin, CPA, MBA, Internal Auditor
Executive Partner
Weaver and Tidwell L.L.P

Cancer Prevention and Research Institute of Texas
Internal Audit of Cash Management
Internal Audit Risk Coverage
July 2016

The audit will focus on the Cash Management processes in place at the Cancer Prevention Research Institute of Texas (CPRIT). We will review the procedures for relevant risk and regulatory coverage and compliance with CPRIT and State requirements. We will evaluate the design and effectiveness of the process to ensure that payments are only approved, initiated, processed and disbursed for valid expenditures and vendors. Key functions and sub-processes within the Cash Management process to be reviewed will include:

- Cash Forecasting
- Electronic Funds Transfer (EFT) Processing
- Cancellation of Warrant Review and Approvals
- Uniform Statewide Accounting System (USAS) Privileges

Monitored Risks

Cash Management		
Process Area	**Risks Monitored**	
Cash Forecasting	1	All appropriate and key factors are not considered when cash forecasting
	2	Cash forecasting is not performed on an appropriate frequency and does not cover an appropriate time period
	3	Anticipated cash shortfalls are not addressed appropriately and timely
Electronic Funds Transfer (EFT) Processing	4	EFT disbursement requests are not reviewed for accuracy and appropriateness
Cancellation of Warrant Review and Approvals	5	Cancelled warrants are not approved and accurately recorded
Uniform Statewide Accounting System (USAS) Privileges	6	Access to the USAS system is not appropriate

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
July 2016

					Open Findings				Closed Findings				Total Findings				
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	
Fiscal Year 2015																	
Grant Management	2015	Complete	July 27, 2015	Satisfactory	-	8	1	9					-	8	1	9	
Expenditures Internal Audit	2015	Complete	August 24, 2015	Strong	-	-	2	2					-	-	2	2	Note A
2014 Governance and IT Follow-Up	2015	Complete	August 14, 2015	Satisfactory				9				7	-	1	1	2	Note B
2014 Grantee Monitoring Follow-Up	2015	Complete	July 31, 2015	Satisfactory				14				11	1	-	2	3	Notes B, C
Fiscal Year 2015 Subtotal					-	8	3	34	-	-	-	18	1	9	6	16	
Fiscal Year 2016																	
Commodity and Service Contracts Internal Audit	2016	Complete	May 13, 2016	Satisfactory	-	3	2	5	-	-	-	-	-	3	2	5	
Revenue Internal Audit	2016	Fieldwork Complete	TBD	TBD	-	-	2	2	-	-	-	-	-	-	2	2	
Information Security Internal Audit	2016	In Progress															
Cash Management Internal Audit	2016	In Progress															
2015 Grant Management Follow-Up	2016	Complete	June 9, 2016	Strong	-	8	1	9	-	8	1	9	-	-	-	-	
2015 Information Technology Follow-Up	2016	Delayed			-	1	1	2	-	-	-	-	-	1	1	2	Note D
Fiscal Year 2016 Subtotal					-	12	6	18	-	8	1	9	-	4	5	9	
Fiscal Year 2017																	
External Affairs Internal Audit	2017	September 2016															
Non-Grant Expenditures Internal Audit	2017	November 2016															
Training Internal Audit	2017	January 2017															
Procurement Internal Audit	2017	July 2017															
2016 Information Security Follow-Up	2017	June 2017															
2016 Commodity and Service Contracts Follow-Up	2017	March 2017															
2016 Revenue Follow-Up	2017	May 2017															
2016 Cash Management Follow-Up	2017	August 2017															
Fiscal Year 2017 Subtotal																	
Fiscal Year 2018																	
Pre Award Grant Management Internal Audit																	
Post Award Grant Monitoring Internal Audit	2018																
Grant Contracting Internal Audit																	
Information Technology Services Internal Audit	2018																
Budget and Planning Internal Audit	2018																
2017 Procurement Follow-Up	2018																
2017 Non-Grant Expenditures Follow-Up	2018																
2017 Training Follow-Up	2018																
2017 External Affairs Follow-Up	2018																
Fiscal Year 2018 Subtotal																	

SUMMARY

Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**Findings**				**Closed Findings**				**Total Open Findings**				**Timing of Follow-Up Procedures by IA**
					High	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	
Grant Management	2015	Complete	July 27, 2015	Satisfactory	-	8	1	9	-	8	1	9	-	-	-	-	Follow-Up Completed June 2016
Expenditures Internal Audit	2015	Complete	August 24, 2015	Strong	-	-	2	2	-	-	-	-	-	-	2	2	Note A
2014 Governance and IT Follow-Up	2015	Complete	August 14, 2015	Satisfactory	-			9	-	-	-	7	-	1	1	2	Notes B, D
2014 Grantee Monitoring Follow-Up	2015	Complete	July 31, 2015	Satisfactory		-		14	-	-	-	11	1	-	2	3	Notes B, C
Commodity and Service Contracts Internal Audit	2016	Complete	May 13, 2016	Satisfactory	-	3	2	5	-	-	-	-	-	3	2	5	March 2017
Revenue Internal Audit	2016	Fieldwork Complete	TBD	TBD	-	-	2	2	-	-	-	-	-	-	2	2	May 2017
Sub-Total of Findings					-	11	7	41	-	8	1	27	1	4	9	14	
Less: Findings For Management or Compliance Follow-Up					-	-	2	16	-	-	-	11	1	-	4	5	Notes A + C
Total Findings For Internal Audit Follow-Up					-	11	5	25	-	8	1	16	-	4	5	9	

NOTES

A	At the conclusion of the audit, no follow-up procedures were recommended to be performed by Internal Audit based on the nature and risk rating of the findings in the report. Internal Audit has recommended that Management perform their own follow-up procedures to validate remediation has occurred.
B	The prior internal auditor did not provide risk ratings for the individual findings in the final report. Therefore the number of findings and the findings remediated are shown in total.
C	At the conclusion of the audit, follow-up procedures were recommended to be performed by CPRIT's Compliance group, which is occurring. Internal Audit does not plan to perform follow-up procedures on these open findings.
D	Follow-up procedures were delayed to allow Management to prepare for the IT Security internal audit.

weaver

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

IA # 05-16 – INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR GRANT MANAGEMENT FINDINGS

REPORT DATE: JUNE 9, 2016

ISSUED: JULY 15, 2016

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weaver
Assurance · Tax · Advisory

The Oversight Committee
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (the Institute) during the period June 5, 2016 through June 9, 2016 relating to the findings from the 2015 Internal Audit Report over CPRIT Grant Management, dated July 27, 2015.

The objective of these follow-up procedures was to validate that adequate corrective action has been taken in order to remediate the issues identified in the prior year Internal Audit Report over Grant Management.

To accomplish this objective, we conducted interviews with key personnel responsible for grant management. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the Cancer Prevention and Research Institute of Texas office and were completed on June 9, 2016.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.
Austin, Texas
July 15, 2016

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS
IA# 05-16 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR GRANT MANAGEMENT FINDINGS
JUNE 9, 2016
ISSUED: JULY 15, 2016

BACKGROUND

In 2015, internal audit procedures over the Institute's grants management process were completed and reported to the Oversight Committee. The internal audit report over the CPRIT's grant management structure and activities identified nine areas for improvement related to financial reporting, grantee training, and monitoring.

The 2016 Internal Audit Plan included performing procedures to validate that CPRIT management has taken steps to address the internal audit findings.

FOLLOW-UP PROCEDURES OBJECTIVE AND SCOPE

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the findings included in the 2015 CPRIT Grant Management Internal Audit Report, and to validate that appropriate corrective action had been taken. The 2015 report identified the following findings:

1. CPRIT Grant Accountants used inconsistent standards to determine the adequacy of the supporting documentation provided by the grantee for Financial Status Report (FSR) expenditures.
2. CPRIT did not provide any onboarding training to grantees. Compliance training was provided on a periodic basis, but it was not mandatory for all grantees to attend.
3. CPRIT had no processes in place to verify that contractual requirements and administrative regulations were followed by a grantee's subcontractor.
4. CPRIT did not have a formalized process to ensure that all required reports were submitted prior to processing final grant expenditure reimbursements.
5. One grantee did not provide sufficient support for its Financial Status Report reimbursement request or provide adequate detail on salary expenses within the Personnel Level of Effort report.
6. CPRIT did not perform follow-up procedures on prior grantee monitoring findings to ensure the grantee had taken appropriate corrective action.
7. Funds were distributed to grantees with outstanding reports due to CPRIT.
8. CPRIT approved a no cost extension that was not made between 30 and 180 days prior to the contract expiration date, as required.
9. CPRIT processed final payment of the Financial Status Report while at least one required report was outstanding.

Our follow-up procedures included the following:

- Interviewing key grant management personnel to identify corrective actions taken to address prior findings
- Reviewing policies, procedures, and any other documentation
- Performing test procedures to ensure that policies and procedures are appropriately implemented to address prior findings

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS
IA# 05-16 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR GRANT MANAGEMENT FINDINGS
JUNE 9, 2016
ISSUED: JULY 15, 2016

EXECUTIVE SUMMARY

The findings from the 2015 Grant Management Internal Audit included non-compliance issues with CPRIT policies and procedures or rules and regulations required by law. The audit also identified an overall lack of internal controls in place to cover financial and operational risks to the agency.

Through our interviews, review of documentation, observations, and testing, we determined that all nine of the 2015 Grant Management findings were remediated.

A summary of our results, by audit objective, is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings.*

OVERALL ASSESSMENT	STRONG

SCOPE AREA	RESULT	RATING
Objective A: Validate that management has addressed and implemented procedures to remediate prior grant monitoring findings from the 2015 CPRIT grant management audit.	We identified that nine out of nine findings identified in the 2015 CPRIT Grant Management Internal Audit Report have been remediated by CPRIT management.	**STRONG**

CONCLUSION

Based on our evaluation, CPRIT management has remediated all nine of the findings from the 2015 CPRIT Grant Management Internal Audit Report.

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

Our procedures included interviewing key personnel, examining existing documentation or communication, and performing test procedures to validate corrective actions taken. In addition, we evaluated the existing policies, procedures and processes.

FY 15 Finding 1 – MODERATE – Review of Financial Status Reports (FSR): CPRIT Grant Accountants have inconsistent standards by which FSRs are reviewed. The inconsistencies relate to determining the sufficiency of the supporting documentation provided by the grantee. For example, some Grant Accountants require third-party supporting documentation such as an invoice to be provided for expenses above $1,000 while others have a more stringent threshold for the same requirement. In addition, CPRIT does not have a formal timeframe for completion of the FSR review. Grant Accountants are instructed to complete the review as soon as possible. A formal deadline by which Grant Accountants must complete the review has not been established.

Procedures Performed: We reviewed the FSR Required Supporting Documentation guidelines and verified that it was updated to provide detailed explanations on documentation requirements for CPRIT. We verified that the Grant Report Verification Procedures for Grant Payment Release were updated to state that the objective is to complete FSR reviews within 30 days of receipt. We verified that the CPRIT Grant Policy and Procedures Guide was updated to specify that CPRIT requires supporting documentation for all costs reported on an FSR.

We selected a sample of 30 FSRs and verified that the FSRs were reviewed within 30 days.

Results: Finding remediated.

Finding 2 – MODERATE – Grantee Onboarding and Training: CPRIT does not provide any onboarding training to grantees. CPRIT's General Counsel, Chief Compliance Officer and Grant Specialist Manager provide compliance training to grantees on a periodic basis (several times per year). This training is not mandatory for all grantees to attend.

Procedures Performed: We reviewed the Required Training for Grant Recipients found in Texas Administrative Code 25.11.703.22 and verified that grantees are required to complete the initial compliance training prior to receiving disbursement of Grant Awards Funds. Additionally, all Grant Recipients are required to complete an annual compliance training program.

We determined that the onboarding training contained appropriate information and that training was attended by appropriate grantee personnel. We verified the one new grantee during the period of January 1 through April 30, 2016 attended onboarding training. We also verified that the Compliance group is monitoring the completion of periodic compliance training for all grantees. The monitoring includes ensuring that training was attended by appropriate grantee personnel, including the Authorized Signing Official and at least one other individual employed by the grantee. The compliance training materials contained all recommended and required components, including Administrative Rule Requirements, Reporting Requirements, CGMS Overview, Compliance Program Review, and Change Requests and Grant Closeouts.

Results: Finding remediated.

Finding 3 – MODERATE– Subcontractor Monitoring: Grantees are responsible for ensuring that CPRIT's contractual requirements and administrative regulations are followed by their subcontractor. Grantees accept this responsibility by executing the grant contract. However, CPRIT has no process in place to verify that contractual requirements and administrative regulations are followed by a grantee's subcontractor. Indirect costs and invoices from subcontractor are reviewed by Grant Accountants as part of the Financial Statement Report review, but they are not treated differently than other vendor invoices.

Procedures Performed: We verified that the CPRIT Onsite Review Checklist was updated to include requiring that grantees verify subcontracting agreements include all clauses required by CPRIT and that the grantee has appropriate policies and procedures in place to monitor subcontractor performance. The Grantee Annual Compliance Attestation was updated to include a section on subcontractor monitoring. Grantees complete the attestation annually and confirm that they have procedures in place to ensure that subcontractor agreements contain all requirements, subcontractors are monitored, and that payments are made in accordance with Texas Governmental Code, Chapter 2251.

Results: Finding remediated.

Finding 4 - MODERATE - Grant Close-Out: During the audit period, CPRIT considered a grant to be closed and eligible for final payment when a grantee submits their final Financial Status Report (FSR) and Progress Report. However, a grantee may still have been delinquent in submitting other required reports, such as an Inventory Report or Historically Underutilized Business Report. Consequently, CPRIT did not have a mechanism to enforce the submission of all required reports until it began holding final payments until all reports were submitted. CPRIT is in the process of modifying the business rules in the CPRIT Grants Management System (CGMS) to increase the period of time before the system automatically closes a grant, preventing the submission of other required reports.

Procedures Performed: We reviewed the Grant Applications and Funding Awards policies and procedures and verified that Closeout Reviews are conducted upon grant termination. The review consists of verifying that all final reports were submitted, validating the accuracy of final expenditures, and verifying that all grant post-close out requirements are met. CPRIT implemented the Grant Award Pedigree form which is used to monitor grantee reporting submissions and verify that all required reports are submitted prior to releasing payment.

We selected a sample of 10 closed contracts and verified that the Grant Award Pedigree was completed and all required reports were submitted prior to processing the final payment.

Results: Finding remediated.

Finding 5 - MODERATE – Salary Supporting Documentation: For one of 70 grant disbursements reviewed, we determined that the grantee did not provide sufficient support for its Financial Status Report reimbursement request. No employees were listed on the grantee's Personnel Level of Effort submitted with the report, but the grantee claimed reimbursement of salary expenses. The payment was made in June 2014 and CPRIT subsequently began requiring additional supporting documentation for salary and benefit expenses in July 2014.

Procedures Performed: We reviewed the FSR required supporting documentation and verified that it was updated to state that grantees must submit a personnel cost report for salary reimbursements and the names and titles must match the Personnel Level of Effort form in the CGMS system. Grantees must provide copies of payroll ledger information with supporting documentation, such as timesheets and payroll statements.

We selected a sample of 30 FSRs and verified that all salary reimbursements contained appropriate supporting documentation.

Results: Finding remediated.

Finding 6 - MODERATE - No Follow-up of Prior Grantee Monitoring Findings: Twelve of the prior 13 corrective actions recommended as a result of prior internal audit monitoring of grantees did not have evidence of follow-up by CPRIT to validate corrective action had been implemented by grantees.

Procedures Performed: We reviewed the Desk and Onsite Review workbook provided by the third party grant monitoring vendor and verified that grantees were monitored for compliance, training, and corrective action for prior audit findings with desk or onsite reviews. The workbook contains adequate supporting detail and documentation, including descriptions of findings or concerns, follow-up procedures performed, and commentary for closed findings. Grantees are given notice of corrective action required and correspondence is recorded in the Findings and Concerns log.

Results: Finding remediated.

Finding 7 - MODERATE - Incomplete Grantee Reporting: Of the 70 grants tested, funds were distributed to 23 grantees who had reports outstanding and due to CPRIT.

Procedures Performed: We verified that CPRIT created a Required Reports and Consequences Table, which lists the following: required reports, due dates, and consequences for late filing of reports. CPRIT implemented a Grant Award Pedigree to monitor grantee reporting submissions and verify that all required reports are submitted prior to releasing payment.

We selected a sample of 30 FSRs and verified that all required documentation was submitted prior to processing payment.

Results: Finding remediated.

Finding 8 - LOW – No Cost Extensions: We determined that one out of 72 contract extensions from the period was requested outside the allowed timeframe of 30-180 days from the contract's end date. This no cost extension was requested on June 27, 2014, just 3 days prior to contract expiration date of June 30, 2014. The request for extension received final approval on July 29, 2014. CPRIT adopted an administrative rule effective January 2014 outlining the submission timeline. However, CPRIT did not implement a business rule in CGMS to enforce the timeline until June 27, 2014.

Procedures Performed: We reviewed TAC 25.11.703.14 and verified that the code was updated to state that if a Grant Recipient requests a no cost extension outside of the required timeframe, the Chief Executive Officer may approve the no cost extension and must notify the Oversight Committee and provide justification for the approval.

We selected a sample of six No Cost Extensions and verified that they were submitted between 30-180 days prior to the contract end date and were appropriately reviewed and approved.

Results: Finding remediated.

Finding 9 - MODERATE – Grant Close-Out Payments: We determined that for five of 42 grants tested during the period with a termination date between June 1, 2014, and May, 31, 2015, CPRIT processed payment of the Final Financial Status Report while at least one required report from the grantee was outstanding. Four of the five grants were missing at least one required Financial Report, and one of the five did not have a Final Progress Report prior to final payment.

Procedures Performed: We reviewed the updated Grant Applications and Funding Awards policies and procedures and verified that closeout reviews are conducted upon grant termination. The review consists of verifying that final reports were submitted, validating final expenditures, and verifying that grant post-close out requirements are complete. CPRIT implemented a Grant Award Pedigree used to monitor grantee reporting submissions and to verify that all required reports are submitted prior to releasing payment.

We selected a sample of 10 closed contracts and verified that the Grant Award Pedigree was completed and all required reports were submitted prior to processing the final payment.

Results: Finding remediated.

APPENDIX

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

REPORT RATINGS

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

RISK RATINGS

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

IA # 01-16 – INTERNAL AUDIT REPORT OVER COMMODITY AND SERVICE CONTRACTS

REPORT DATE: MAY 13, 2016

ISSUED: JUNE 10, 2016

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The Oversight Committee
Cancer Prevention and Research Institute of Texas
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This report presents the results of the internal audit procedures performed for the Cancer Prevention and Research Institute of Texas (the Institute) during the period May 2, 2016 through May 13, 2016 relating to the Institute's commodity and service contracts processes.

The objectives of this internal audit were to evaluate the design and effectiveness of CPRIT's commodity and service contracts processes. The objectives were organized as follows:

A. Verify that internal controls over Commodity and Service Contracts are designed to ensure effective management of the process and address all key risks.
B. Ensure that the controls in place over high-risk processes are operating effectively.
C. Ensure expenditures comply with the contract terms and CPRIT's internal policies and procedures.

To accomplish these objectives, we conducted interviews with key personnel responsible for the commodity and service contracts process. We also reviewed documentation and performed specific test procedures to assess controls. Procedures were performed at the Cancer Prevention and Research Institute of Texas office and were completed on May 13, 2016.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.
Austin, Texas
June 10, 2016

AN INDEPENDENT MEMBER OF BAKER TILLY INTERNATIONAL

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CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS
IA# 01-16 INTERNAL AUDIT REPORT OVER COMMODITY AND SERVICE CONTRACTS
MAY 13, 2016
ISSUED: JUNE 10, 2016

BACKGROUND

The Cancer Prevention and Research Institute of Texas (CPRIT) was established with the goal to expedite innovation in cancer research and product development, and to enhance access to evidence-based prevention programs throughout the State of Texas. CPRIT enters into service and commodity contracts in order to conduct its operations and achieve these goals.

The Comptroller has delegated authority to CPRIT to make the following purchases:

- Purchases of commodities or services with an estimated purchase price not greater than $5,000
- Commodities with an estimated purchase price not greater than $25,000, except for commodities on the Texas Procurement and Support Services (TPASS) TxSmartBuy term or TPASS Managed contracts
- Services with an estimated purchase price not greater than $100,000
- Purchases of publications directly from the publisher

When possible, CPRIT makes commodity or service purchases through purchasing cooperatives such as the Department of Information Resources (DIR) contracts, TIBH Industries, Inc., Texas Correction Industries (TCI), TPASS Managed Contracts, TPASS TxSmartBuy Term Contracts, or TPASS Texas Multiple Award Schedule (TXMAS) contracts.

If a commodity or service is not available through a cooperative agreement, CPRIT proceeds with a competitive bidding process for commodities and services with a value above $5,000. CPRIT develops and issues a Request for Proposal (RFP), Invitation for Bid (IFB), Request for Offer (RFO), Request for Information (RFI), or Request for Qualifications (RFQ) to solicit offers from vendors for service and commodity contracts. CPRIT reviews all bids received, evaluates submissions, and awards commodity and service contracts. Throughout the application and contract award processes, applicants and the personnel responsible for evaluating applicants must disclose any conflicts of interest.

CPRIT's governing body, the Oversight Committee, reviews and approves contracts that exceed $100,000. In addition, the Legislative Budget Board reviews and approves all contracts that exceed $250,000 as required by the agency's appropriation rider. After the Oversight Committee approves contract recommendations, contracts are negotiated and executed with the approved vendor. Once contracts are executed, CPRIT oversees the performance of vendors through periodic meetings and continuous communication with the vendor.

As a State of Texas agency, CPRIT is required by the Texas Administrative Code to complete a vendor performance evaluation upon completion of services, for any contract and/or purchase greater than $25,000.

AUDIT OBJECTIVE AND SCOPE

The audit focused on the Commodity and Service Contracts processes in place at the Cancer Prevention Research Institute of Texas (CPRIT). We reviewed the procedures for appropriate risk and regulatory coverage and compliance. Key functions and sub-processes within the Commodity and Service Contracts process we reviewed included:

- Contract Initiation and Execution
- Contract Management
- Contract Close-out

The audit did not include an evaluation of the future state of procedures and controls. The focus of our evaluation was on reoccurring procedures that were in place throughout the coverage period and were anticipated to remain in place in the future. Further, the audit evaluated only non-grant contracts and did not evaluate the procurement process.

Our procedures were designed to ensure relevant risks were covered and verify the following:

Throughout the Process

- Policies and procedures are in place to ensure that inconsistencies or errors are identified in the authorization, processing, and monitoring of contracts
- Appropriate segregation of duties exists in the review, approval, execution, and monitoring of contracts

Contract Initiation and Execution

- Vendors whose goods or services require contracts are appropriately identified
- Standard contract terms and conditions are identified and documented
- Contract elements are in compliance with State requirements
- Contract modifications are properly reviewed and approved
- Contracts are properly authorized and executed by appropriate individuals
- Contracts exceeding oversight thresholds are appropriately approved
- Usage of cooperative contracts is appropriately reported
- Vendors are properly on-boarded

Contract Management

- Contract obligations are accurately computed
- Contract invoices are reviewed for compliance with contract terms
- Contract budgets are monitored
- Changes, modifications, and/or amendments to existing contracts are appropriately addressed by authorized individuals
- Contracts that are set to renew are renewed timely and appropriately
- Contract performance is monitored or managed to ensure timely delivery of services, compliance with contract terms, and performed as agreed
- Vendor performance evaluations are performed in accordance with State statutes
- Program Managers have adequate training to comply with vendor evaluation and reporting requirements

Contract Close-out

- Contracts that are expired or become obsolete are identified
- Contracts are adequately closed for subsequent monitoring and reporting

The objectives of this internal audit were as follows:

A. Verify that internal controls over Commodity and Service Contracts are designed to ensure effective management of the process and address all key risks.
B. Ensure that the controls in place over high-risk processes are operating effectively.
C. Ensure expenditures comply with the contract terms and CPRIT's internal policies and procedures.

Our procedures included interviewing key personnel within the Operations group to gain an understanding of the current processes in place, examining existing documentation, evaluating the internal controls over the process, and testing the effectiveness of the controls in place. We evaluated the existing policies, procedures and processes in their current state. Our coverage period was from September 1, 2014, through March 31, 2016.

EXECUTIVE SUMMARY

Through our interviews, evaluation of internal control design and testing of transactions we identified five findings. The listing of findings include those items that have been identified and are considered to be non-compliance issues with documented CPRIT policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover significant risks to CPRIT. These issues could have significant financial or operational implications.

A summary of our results, by audit objective, is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings.*

OVERALL ASSESSMENT	SATISFACTORY

SCOPE AREA	RESULT	RATING
Objective A: Verify that internal controls over Commodity and Service Contracts are designed to ensure effective management of the process.	We identified 26 controls to be in place in the process. There are opportunities to improve the process and control environment, including: • Document commodity contract determination • Maintain accurate contract listing • Perform vendor on-boarding • Certify budget availability • Track and report vendor performance	**SATISFACTORY**
Objective B: Ensure that the controls in place over high-risk processes are operating effectively.	Controls in place were generally operating as designed. We identified the following opportunities for improvement: • Track and report vendor performance	**STRONG**
Objective C: Ensure expenditures comply with the contract terms and CPRIT's internal policies and procedures.	Expenditures generally comply with contract terms and internal policies and procedures. There are opportunities to improve the process and control environment, including: • Approve invoices timely • Certify budget availability	**STRONG**

Other opportunities for improvement were identified through our interviews, evaluation of internal control design, and transactional testing. These observations include those items that are not considered to be non-compliance issues with documented agency policies and procedures. These are considered process improvement observations and the intent for the recommendations are to strengthen current agency processes and controls. These observations were provided to management separately.

CONCLUSION

Based on our evaluation, the Commodity and Service Contracts function has procedures and controls in place to conduct effective management of the significant processes within CPRIT. The controls and processes for the management of service contracts are strong.

However, we identified several opportunities to improve the processes and effectiveness of the controls over commodity contracts and purchases. CPRIT staff should maintain an updated listing of all contracts in place.

CPRIT should also implement processes to evaluate vendor performance at the end of a contract and report the performance to the Comptroller, as well as to validate budget availability for commodity and service purchases is fully competed and filed for record keeping purposes.

We recommend that CPRIT implement additional formalized procedures over Commodity and Service Contracts and strengthen the control weaknesses identified. Internal Audit will conduct follow-up procedures to validate remediation efforts in Fiscal Year 2017.

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

Our procedures included interviewing key personnel responsible for the commodity and service contracts process to gain an understanding of the current processes in place, examining existing documentation, evaluating the internal controls over the process, and testing the effectiveness of the controls in place. We evaluated the existing policies, procedures and processes in their current state.

Objective A: Design of Internal Controls

Verify that internal controls over Commodity and Service Contracts are designed to ensure effective management of the process and address all key risks.

Procedures Performed: We gained an understanding of the current commodity and service contracts processes by conducting interviews with key personnel; reviewing existing procedures, standardized forms and documents used by CPRIT's personnel; and assessing CPRIT's administrative rules to identify key controls. We examined the following sub-processes:

- **Contract Initiation and Execution**
  - Vendor selection/contract identification
  - Contract negotiations
  - Contract review and recommendation
  - Approval, award and execution
  - Vendor on-boarding
- **Contract Management**
  - Review and approval of invoices
  - Budget monitoring
  - Change order processing and approval
  - Contract amendment
  - Contract extension
  - Contract renewal
  - Contract compliance and term monitoring
  - Performance metrics identification
  - Vendor performance evaluation
  - Agreements with subcontractors
  - Cooperative reporting
- **Contract Close-out**
  - Validation of service performance/delivery of goods
  - Final payment release

We evaluated the controls identified against expected controls to determine whether the identified reoccurring contract monitoring procedures and internal controls are sufficiently designed to mitigate the critical risks associated with the Commodity and Service Contracts process. We identified any unacceptable risk exposures due to gaps in the existing control structure as well as opportunities to strengthen the effectiveness and efficiency of the existing procedures.

Results: We identified 26 controls in place over the significant activities within the Commodity and Service Contracts function. We identified five findings where improvements in the processes, polices, and procedures can be made.

Cancer Prevention and Research Institute of Texas Commodity and Service Contracts - Control Design Evaluation		
Sub-Process	**Identified Controls**	**Findings**
Contract Initiation and Execution		
Vendor Selection / Contract Identification	1	
Contract Negotiations	1	
Contract Review and Recommendation	3	
Approval, Award, and Execution	4	Finding 1
Vendor On-Boarding	1	Finding 2
Contract Management		
Review and Approval of Invoices	1	Finding 3
Budget Monitoring	1	Finding 1, Finding 4
Change Order Processing and Approval	1	
Contract Amendment	3	
Contract Extension	3	
Contract Renewal	1	
Contract Compliance and Term Monitoring	1	Finding 1
Performance Metrics Identification	1	
Vendor Performance Evaluation	-	Finding 5
Agreements with Subcontractors	1	
Cooperative Reporting	1	
Contract Close-Out		
Validation of Service Performance / Delivery of Goods	1	Finding 5
Final Payment Release	1	
Total	**26**	**5**

Finding 1 – MODERATE – Contract Listing: CPRIT's centralized listing of active contracts is not updated upon the execution of new contracts. Two contracts that were approved by the Oversight Committee in November of 2015 for Award Year 16 (AY16) were not added to the listing until May 2016. Further, the Health and Human Services Commission contract is not on the contract listing. The Purchaser uses the list to identify contracts that need to be removed or closed. This listing is also used to identify contracts that are nearing expiration and need to be closed out, contract renewals and extensions, add contract term to the list, start and end date.

The Accountant receives and logs all invoices for contracted services and keeps track of the service expenditures against all known contract amounts. We determined that the Accountant had not been notified of all existing contracts and consequently did not monitor the contract expenses against the contracted amount for the following contracts:

- Spencer Stuart - expenditures in AY15 and AY16
- The Perryman Group - expenditures in AY16
- Andrews Kurth - no expenditures at the time of procedures

Recommendation: CPRIT should implement a process to review the contract list to verify it is updated when new contracts are executed. The contract listing should be distributed each time it is updated to all individuals who are responsible for managing contracts and recording contract transactions. On a monthly basis, the Accountant should perform a secondary review to validate that the listing is accurate by comparing the list to the contracts on hand.

CPRIT Management Response: CPRIT agrees with this finding and will adjust its processes so that the Purchaser provides an updated contract list to the Chief Operating Officer when new contracts or contract renewals are executed during the fiscal year. The updated contract list will be provided to the Accountant in conjunction with a copy of the executed new contract or contract renewal to ensure that the expenses for each active contract are monitored appropriately.

Responsible Party: Chief Operating Officer, Purchaser
Implementation Date: September 1, 2016

Finding 2 – LOW – Vendor On-Boarding: Vendor and Contractor on-boarding is not formally documented. The vendors and contractors are contacted informally by the designated CPRIT Contract Administrator who discusses the contract, expected services, and any on-boarding needs directly with the vendor/contractor.

Recommendation: CPRIT should implement a vendor/contractor on-boarding checklist to ensure all considerations are addressed when on-boarding a new vendor/contractor. The on-boarding should include addressing expectations for timelines, billing and payment, expected deliverables, and any reporting requirements. The checklist should be completed by the Contract Administrator and kept with the contract file.

CPRIT Management Response: CPRIT agrees with the finding and will develop a vendor on-boarding checklist document that the Purchaser will complete with the assistance of the Contract Administrator to verify expected deliverables and any reporting requirements. The Purchaser will transmit the on-boarding document along with notification of the CPRIT Contract Administrator to a vendor following the vendor's acceptance of the notification of award for a new or renewed contract. The Contract Administrator will ensure that the vendor understands all of the items listed in the checklist document at their initial on-boarding meeting.

Responsible Party: Chief Operating Officer, Purchaser
Implementation Date: September 1, 2016

Finding 3 - LOW - Invoice Approval: Commodity invoices are not consistently reviewed and approved by appropriate personnel. This can create a segregation of duties issue in which a purchase is initiated, executed, and the invoice is approved by the same individual. For two out of 30 commodity expenditures tested, the Purchaser provided approval for the invoice and was also responsible for initiating the purchase. The COO approved the associated purchase order and payment.

For one out of 30 commodity expenditures tested, we were unable to verify that the invoice was reviewed and approved prior to the payment. We were able to verify that the purchase order and the payment were approved by the COO.

Recommendation: CPRIT should ensure all invoices are reviewed and approved by an individual with sufficient authority and knowledge of the purchase and delivery of goods or services. Payment should not be processed without a corresponding approved invoice.

Further, CPRIT should document and retain all purchase requests with the voucher packet to complete the purchase documentation and demonstrate appropriate segregation of duties.

CPRIT Management Response: CPRIT agrees with the finding. However, it will modify the implementation of the recommendation by having one of the three administrative assistant staff verify that general office supply commodities received match the goods invoiced and acknowledge that verification by signing the invoice to demonstrate the appropriate segregation of duties. Given the small number of employees in the agency, there is not always staff with sufficient authority and knowledge of each purchase of office supplies beyond the Chief Operating Officer and the Purchaser. To add additional purchasing authority in this respect would impact the efficiency of the agency operations. It is already standard practice for the receipt of information technology commodities to be matched with the invoice and acknowledged by the Information Technology Manager.

Responsible Party: Chief Operating Officer, Purchaser
Implementation Date: September 1, 2016

Finding 4 - MODERATE - Budget Certification: CPRIT does not consistently follow its procedures to ensure that the budget certification sign-off on the purchase order and/or purchase request is completed consistently. The Chief Operating Officer monitors the budget on an ongoing basis and is the final signatory authority on Purchase Orders. Purchases of goods and services are considered as part of the annual operating budget. However, CPRIT policy also requires sign-off on purchases to verify budget availability.

For two out of 23 commodity expenditures tested that had purchase orders, Accounting did not sign-off verifying the budget prior to the purchase.

For purchases made through a P-Card that were not monthly re-occurring fees, one out of 23 purchase requests did not have Accounting personnel sign-off on the form verifying the budget prior to the purchase.

Recommendation: CPRIT should ensure the budget certification is verified and signed-off on the purchase order or purchase request, prior to the procurement of the good or service. The Purchaser should not process purchase requests that do not have evidence of completed budget certification. In the event of an emergency purchase, the Purchase should retroactively document the budget certification to ensure the documentation is complete.

CPRIT Management Response: CPRIT agrees with the finding. The Purchaser will seek a sign-off on the budget certification retroactively when a purchase order or purchase request is processed in the absence of the staff responsible for the budget verification.

Responsible Party: Purchaser
Implementation Date: September 1, 2016

Finding 5 - MODERATE - Vendor Performance Tracking: Contract Administrators are not consistently aware of the Vendor Performance Tracking System reporting requirement of the Comptroller of Public Accounts. Contract Administrators do not submit Vendor Performance Forms for contracts that are greater than $25,000 as required by the Comptroller of Public Accounts. Currently, the Purchaser is responsible for completing the vendor performance reporting during the performance of the contract closeout procedures.

Vendor Performance Evaluations are inconsistently performed. We identified three contracts closed out during the period with expenditures exceeding $25,000. For the three identified contacts:

- One of the contracts, the closeout checklist was marked "N/A" for vendor performance evaluation completed.
- Two of the contracts, the closeout checklist did not have the step "vendor performance evaluation completed" on the form.
- For all three contracts, we searched the VPTS database and were unable to find any instances of a vendor performance evaluation completed by CPRIT.

Recommendation: CPRIT should reassign the vendor performance reporting function to the Contract Administrator level, since the Contract Administrators have the most experience working with the Contractors. The Purchaser should be responsible for tracking to ensure performance reporting is complete and timely. This would distribute the vendor performance reporting responsibility and help ensure that CPRIT meets the reporting requirements, and that the feedback is accurate and relevant for each contract.

CPRIT Management Response: CPRIT agrees that vendor performance should be reported. However, the recommendation will be modified in implementation by having the Purchaser complete the Vendor Performance Evaluations in the Vendor Performance Tracking System with the input necessary from the Contract Administrator. The system is not simple to use for those unfamiliar with the procurement performance reporting process and requires a password to access. The Purchaser will develop an evaluation document with the vendor performance information required by the system for the Contract Administrator to complete, and the Purchaser will use the completed evaluation document to enter information into the system.

Responsible Party: Chief Operating Officer, Purchaser
Implementation Date: September 1, 2016

Objective B: Effectiveness of Controls

Ensure that the controls in place over high-risk processes are operating effectively.

Procedures Performed: We obtained a listing of service contracts active during the scope period of September 1, 2014, through March 31, 2016, and selected a sample of 14 contracts. For each, we obtained evidence to verify the following:

- Contract was authorized by the Oversight Committee (if necessary)
- Contract was authorized by the Legislative Budget Board (if necessary)
- Contract was executed by an authorized individual
- Amendments were approved
- Renewals were approved
- Contract closing checklist was completed
- Contracts were not executed with vendors on the State's Debarred List
- Vendor performance evaluation was completed (if necessary)

Results: All 14 contracts and any associated amendments and extensions were appropriately authorized and executed. No contracts were made with debarred vendors. However, none of the three closed contracts in our sample with a value over $25,000 had evidence that vendor performance was evaluated.

Finding 5 - MODERATE - Vendor Performance Tracking

Objective C: Expenditures Testing

Ensure expenditures comply with the contract terms and CPRIT's internal policies and procedures.

1. **Procedures Performed:** We selected a sample of 30 service contract expenditures submitted during the scope period of September 1, 2014, through March 31, 2016, and verified the following:

   - Invoice charges were in line with the contracted terms, the work performed was within the scope of the contracted work, and the rates charged agreed to the contract
   - Invoices were reviewed and approved by the Contract Administrator
   - The Chief Operating Officer or the Chief Executive Officer reviewed and approved the payment
   - The contract budget was monitored to ensure the contract expenditures did not exceed the contracted amounts
   - The contract expenditures remained within the budgeted amounts

   Results: All expenditures were allowable, appropriately reviewed and approved, and remained within budgeted amounts. We identified four expenditures on contracts that were not included on the contract listing. The budgets were not tracked for these expenditures.

   Finding 1 – MODERATE – Contract Listing

2. Procedures Performed: We selected a sample of 30 commodity expenditures submitted during the scope period of September 1, 2014, through March 31, 2016, and verified the following:

- Invoice charges were in line with the contracted terms, the work performed was within the scope of the contracted work, and the rates charged agreed to the contract
- Invoices were reviewed and approved by the Contract Administrator
- The Chief Operating Officer or the Chief Executive Officer reviewed and approved the payment
- The contract budget was monitored to ensure the contract expenditures did not exceed the contracted amounts
- The contract expenditures remained within the budgeted amounts

Results: All expenditures were allowable and within budgeted amounts. We identified one purchase for which the invoice was not approved, and two invoices were not approved by an authorized individual. Additionally, the budget was not checked prior to payment for one expenditure and the purchase order was not retained for another.

Finding 3 - LOW - Invoice Approval

Finding 4 - MODERATE - Budget Certification

APPENDIX

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

REPORT RATINGS

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

RISK RATINGS

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	CHIEF OPERATING OFFICER REPORT
DATE:	AUGUST 9, 2016

CPRIT Financial Overview for FY 2016, Quarter 3

FY 2016, Quarter 3 Operating Budget

For the third quarter of FY 2016, CPRIT has expended or encumbered approximately $14.8 million, or 88%, of the agency's $16.7 million administrative budget between the Indirect Administration and Grant Review and Award Operations strategies. This administrative budget includes approximately $208,000 in expenses for the 2015 conference. Otherwise, the primary items of expenditure remain staff salaries and service contracts, particularly the contract with SRA International, Inc. (a CSRA company) for pre- and post-award grant management support services.

During this quarter, CPRIT received $15,102 in revenue sharing payments which were deposited into the General Revenue Fund (0001). Total revenue sharing payments received since CPRIT's inception through the end of May 2016 were approximately $2.3 million.

FY 2016, Quarter 3 Performance Measures

In June 2016, CPRIT reported third quarter performance to the LBB on the two output measures that have quarterly reporting requirements:

1) Number of People Served by Institute Funded Prevention and Control Activities and
2) Number of Entities Relocating to Texas for Cancer Research Related Projects.

The report reflects that the number of people served through the prevention program grants is well under the 800,000 target set by the 84th Legislature in state budget and that no companies funded through a product development research grant have relocated to the state through the first three quarters of the year.

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $92.1 million in commercial paper notes on CPRIT's behalf in May 2016 bringing the total commercial paper notes issued since the beginning of FY 2016 to $147.5 million. TPFA also issued $69.8 million in General Obligation Bonds when it fixed out $300 million in commercial paper notes into long-term debt through a refunding at the end of October 2015.

Legislative Appropriations Request for the 2018-19 Biennium

On July 12, 2016, the Audit Subcommittee reviewed the documents prepared by CPRIT staff to reflect the general budget assumptions that would be used to prepare the 2018-19 budget request

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to the Texas Legislature and Governor. The Audit Subcommittee confirmed that the Legislative Appropriations Request (LAR) was consistent with information provisionally approved by the Oversight Committee on May 18, 2016. The budget request for the 2018-19 biennium reflects a total budget of $296,955,752 in each year of the biennium which includes $16.8 million for agency administration, $28 million for cancer prevention grants, $252 million for cancer research grants, and the $2.9 million transfer to the Department of State Health Services for the Texas Cancer Registry operations based on current law. The request included an exceptional item for three (3) full-time equivalent positions for the compliance program.

CPRIT submitted the LAR on August 5, 2016. Oversight Committee members will be provided with a copy of the LAR for their use.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of May 31, 2016

Indirect Administration (B.1.1.)

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,413,921	$ 1,064,491		$ 953,771	110,720	90%	$ 953,771	$ 110,720
1002	Other Personnel Costs	51,000	51,000		13,423	37,577	26%	13,423	37,577
2001	Professional Fees and Services	1,015,500	947,015		979,630	(32,615)	103%	979,630	(32,615)
2003	Consumable Supplies	26,651	26,651		13,416	13,235	50%	13,416	13,235
2004	Utilities	64,921	64,921		23,008	41,913	35%	23,008	41,913
2005	Travel	36,095	36,095		38,452	(2,357)	107%	38,452	(2,357)
2006	Rent-Building	-	18,485		16,077	2,409	0%	16,077	2,409
2007	Rent-Machine and Other	24,995	24,995		18,686	6,309	75%	18,686	6,309
2009	Other Operating Expenses	349,402	819,480		174,951	644,529	21%	174,951	644,529
	Subtotal - Indirect Administration (B.1.1.)	**$ 2,982,485**	**$ 3,053,133**	**1.03%**	**$ 2,231,413**	**$ 821,720**	**73%**	**$ 2,231,413**	**$ 821,720**

Grant Review and Award Operations (A.1.3.)

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 2,679,624	2,686,966		$ 2,075,976	$ 610,990	77%	$ 2,075,976	$ 610,990
1002	Other Personnel Costs	3,726	3,726		56,630	(52,904)	0%	56,630	(52,904)
2001	Professional Fees and Services	11,040,000	11,646,352		10,120,507	1,525,845	87%	10,120,507	1,525,845
2003	Consumable Supplies	-	-		-	-	0%	-	-
2005	Travel	42,516	42,516		41,562	954	98%	41,562	954
2006	Rent - Building	33,534	33,534		24,673	8,861	74%	24,673	8,861
2007	Rent-Machine and Other	7,763	7,763		1,995	5,768	26%	1,995	5,768
2009	Other Operating Expenses	-	82,300		2,625	79,675	3%	2,625	79,675
	Conference		251,135		230,527	20,608	92%	230,527	20,608
	Subtotal - Grant Operations (A.1.3.)	**$ 13,807,163**	**$ 14,754,292**	**4.96%**	**$ 12,554,496**	**$ 2,199,796**	**85%**	**$ 12,554,496**	**$ 2,199,796**

Grants

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,340,035	$ 27,980,885		$ 13,247,742	$ 14,733,143	47%	$ 13,247,742	$ 14,733,143
4000	Grants - Research (A.1.1.)	251,955,763	$ 251,692,961		98,761,270	$ 152,931,691	39%	98,761,270	152,931,691
	Subtotal - Grants	**$ 280,295,798**	**$ 279,673,846**	**94.01%**	**$ 112,009,012**	**$ 167,664,834**	**40%**	**$ 112,009,012**	**$ 167,664,834**
	Grand Totals	**$ 297,085,446**	**$ 297,481,271**	**100.00%**	**$ 126,794,921**	**$ 170,686,350**	**43%**	**$ 126,794,921**	**$ 170,686,350**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of May 31, 2016

	05/01/2016 thru 05/31/2016	AY 16 Year to Date as of 05/31/2016
Beginning Balance : 05/01/2016		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 05/31/2016		**$ 600,506.00**

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds ($303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of May 31, 2016

	05/01/2016 thru 05/31/2016	AY 16 Year to Date as of 05/31/2016
Beginning Balance : 05/01/2016		**$ -**
Increases:		
(1) License Plate Revenue Received	$ 1,030.31	$ 10,048.59
Total Increases	**$ 1,030.31**	**$ 10,048.59**
Reductions:		
Expenditures - Appropriated	$ 0.00	$ 0.00
	-	-
	-	-
Total Reductions	**$ 0.00**	**$ 0.00**
Ending Balance, 05/31/2016		**$ 10,048.59**

Note:

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Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of May 31, 2016

		05/01/2016 thru 05/31/2016	AY 16 Year to Date as of 05/31/2016
Beginning Balance : 05/01/2016			**$ 62,102.00**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ 57,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ -	$ 184,880.00
(4)	Conference Registration Fees-Credit Card	$ -	$ 4,153.37
Total Increases		**$ -**	**$ 246,033.37**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ (226,373.35)
	Credit Card Fees Expended	$ -	$ (4,153.37)
		$ -	$ -
Total Reductions		**$ -**	**$ (230,526.72)**
Ending Balance, 05/31/2016			**$ 77,608.65**

Cancer Prevention and Research Institute of Texas

General Revenue Fund Account - 0001

As of May 31, 2016

		05/01/2016 thru 05/31/2016	AY 16 Year to Date as of 05/31/2016
Beginning Balance : 05/01/2016			**$ -**
Increases:			
(1)	Revenue Sharing / Royalties	$ 5,744.50	$ 51,300.36
Total Increases		**$ 5,744.50**	**$ 51,300.36**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
	Sweep Account	$ (5,744.50)	$ (51,300.36)
		$ -	$ -
Total Reductions		**$ (5,744.50)**	**$ (51,300.36)**
Ending Balance, 05/31/2016			**$ -**

Note:

Cancer Prevention and Research Institute of Texas
FY 2016, Quarter 3 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	800,000	114,072	125,498	150,596		390,166	48.77%
Number of Entities Relocating to TX for Cancer Research Related Projects	2.00	0.00	0.00	0.00		0.00	0.00%
Annual Age-adjusted Cancer Mortality Rate	155.3	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT-Funded Research Projects	450	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	315	N/A	N/A	N/A	N/A		0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT grantees deliver these education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter. CPRIT does not anticipate meeting the targeted number, which was doubled from the prior year, as the funded grant activities have not changed significantly from year to year.
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

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		
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable		
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable		
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
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		
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable		
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable		
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable		
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable		
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable		
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable		
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable		
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable		
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 244,600,000				

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
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable		
				$ 217,300,000				
TOTAL ISSUED TO DATE				**$ 1,010,675,000**				

Return to agenda

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	**OVERSIGHT COMMITTEE MEMBERS**
FROM:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER**
SUBJECT:	**APPROVAL OF FY 2017 SERVICE CONTRACTS**
DATE:	**AUGUST 9, 2016**

Recommendation
CPRIT staff recommends approval of the following four service contracts for FY 2017:

- Due Diligence Services with ICON Clinical Research for $309,000
- Economic Assessment of the Cost of Cancer in Texas with The Perryman Group for $150,000
- Outside Legal Services with Yudell Isidore for $200,000
- Strategic Communication Program Services with Hahn Public Communications for $149,975

CPRIT will be able to proceed with executing contracts for the majority of the services upon approval by the Oversight Committee. However, the contract that exceeds $250,000 also requires approval from the Legislative Budget Board before CPRIT will be able to execute it.

Due Diligence Services Contract
CPRIT staff would like to exercise the second renewal option with ICON Clinical Research for $309,000 to provide up to 12 business administration and regulatory due diligence reviews of company applicants in the Product Development Research Program. Business administration and regulatory due diligence review involves an in-depth evaluation of a company's management team, regulatory affairs, clinical trial design, manufacturability of the proposed product, market for the proposed product, marketing and so forth. These due diligence reports are not a re-review of the grant application but provide an independent analysis of the company applicant's potential to commercially develop the proposed, drug, device, diagnostic, technology, or service, which the Product Development Review Council uses to finalize their grant award recommendations.

Staff estimate that the Product Development Review Council will request due diligence on three to six company applicants per grant application cycle. Two application review cycles are planned in FY 2017. The cost of each report is a firm fixed price of $25,750, a three percent increase for inflation from the $25,000 per report price in FY 2016.

Economic Assessment of the Cost of Cancer in Texas Contract
CPRIT staff would like to exercise the first one-year renewal option on the contract with The Perryman Group for $150,000 to provide CPRIT with:

- The statutorily required cost of cancer in Texas measurement;

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- The measurement of key economic performance indicators related to CPRIT funding and program impact; and
- An estimate of the economic impact to Texas if CPRIT is not extended and no additional funding is provided beyond the issuance of $3 billion in general obligation debt authorized by the Texas Constitution.

Outside Legal Services Contracts
CPRIT relies on outside legal counsel with expertise in intellectual property to conduct a review of companies' intellectual property estate as part of the due diligence process. CPRIT staff would like authorization to exercise the agency's option to amend the contract for outside legal services with CPRIT's current provider, Yudell Isidore, by:

- increasing by $45,000 the contract limit previously authorized for FY 2016 (increasing the total value of the contract to $245,000); and
- extending the contract to cover outside legal services provided in FY 2017 and increasing the contract limit by $200,000 (increasing the total value of the contract to $445,000).

The unusually large number of product development applications recommended for due diligence review in FY 2016 Cycle 2 drives the FY 2016 amendment request. More companies applied to CPRIT in the FY 2016 Cycle 2 than had ever applied since the moratorium. CPRIT typically has two law firms under contract to perform due diligence work to balance workload and address conflicts of interest in the situation that one firm has a prior relationship with a company applicant. However, shortly after the Oversight Committee approved the two FY 2016 outside counsel contracts, the lead partner and many of the IP lawyers that performed CPRIT's work at the second law firm left the firm. As a result, CPRIT did not execute the contract with the second firm for FY 2016, relying solely upon Yudell Isidore for IP due diligence work. The amendment accounts for the increased workload and is necessary for Yudell Isidore to complete due diligence work in time for the recommendations to be considered at the November Oversight Committee meeting.

The FY 2017 amendment is consistent with CPRIT's practice to extend the outside counsel contract and provide continuity of service. CPRIT has started the process to retain at least one other law firm with this practice expertise in addition to Yudell Isidore to balance workload and expand expertise in FY 2017. New outside counsel contracts with a total value of $100,000 or more will be brought to the Oversight Committee for approval.

The Office of the Attorney General must approve outside counsel contracts and contract amendments.

Strategic Communications Program Services
CPRIT staff would like to exercise the second one-year renewal option on the contract with Hahn Public Communications for $149,975 to provide strategic communication program services including communications strategy services, media relations support, digital media relations advisory services, and communication program evaluation and assessment.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CYNTHIA MULROW, M.D., CHAIR, DIVERSITY SUBCOMMITTEE
SUBJECT:	DIVERSITY SUBCOMMITTEE REPORT
DATE:	AUGUST 5, 2016

Summary
The Oversight Committee's Subcommittee on Diversity (Subcommittee) met on August 5, 2016, and discussed grant recipient data collection related to diversity issues. The Subcommittee recommends that the value and necessity of collecting gender, ethnicity, racial and other population metrics be evaluated by the Academic Research, Product Development Research and Prevention OC Subcommittees for inclusion in an agency-wide diversity data collection policy developed by the staff based on subcommittee evaluations.

Additionally the Subcommittee discussed transferring the responsibilities of the Subcommittee to other OC subcommittees. The Subcommittee determined that diversity issues are an important aspect of CPRIT's mandate and are better addressed by integrating them into the three program and Audit subcommittees rather being handled by one separate Diversity Subcommittee. The Subcommittee formally recommends that its charges be transferred to the Academic Research, Product Development Research, Prevention and Audit Subcommittees at the OC's August 17, 2016, meeting.

Discussion

CPRIT Data Collection Related to Diversity Issues

The Subcommittee and staff continued its discussion from the May 6, 2016, Subcommittee meeting about diversity-related data collection difficulties. Dr. Willson restated his position that accurate data concerning research subjects, patients in clinical trials, and populations served are essential before reaching conclusions about diversity issues or establishing priorities or policies related to diversity in the three programs. In general, gender, ethnicity, race and other population metrics are collected by researchers as appropriate, both in research and in clinical trials. However, CPRIT does not collect these granular data points in the required grantee progress reports. Assuming that the transfer of the Diversity Subcommittee's charges occurs as is recommended, the Subcommittee recommends that the necessity—and feasibility—of collecting these data be evaluated by the Academic Research, Product Development Research and Prevention Subcommittees. Staff should then prepare a comprehensive data collection policy

that incorporates the conclusions of all three subcommittees for consideration by the full Oversight Committee at a future meeting. The Subcommittee concluded that although each program area's needs may differ, a comprehensive data collection policy incorporating these differences into a single coherent plan is desirable.

The Subcommittee also revisited the issue of gathering data concerning ethnic and racial characteristics of grantee principal investigators. Currently these metrics are not required but voluntarily provided. At the May Subcommittee meeting it was shown that 82.2 percent of principal investigators report these metrics voluntarily. A major issue discussed by the Subcommittee since its constitution in 2012 is how CPRIT can increase the number of its principal investigators from groups historically underrepresented in medicine and science. Although not absolutely necessary in developing incentives and/or training grants to increase participants from historically underrepresented groups, accurate demographic information concerning existing CPRIT awardees would be beneficial in establishing baseline metrics to determine the efficacy of developing any incentives or training grant Requests for Applications. While this is a critical issue, given the length of time it takes to encourage students to matriculate through the educational "pipeline" the metrics may have limited value if CPRIT is not continued beyond its current Sunset date of August 31, 2021. The Subcommittee, therefore, remains uncertain about requiring such reporting metrics of CPRIT's principal investigators.

Transferring the Responsibilities of the Diversity Subcommittee to Other Standing Subcommittees

Prior to the May Oversight Committee (OC) meeting staff requested that the Subcommittee consider recommending to the OC that its charges be transferred to the Academic Research, Product Development Research, Prevention and Audit Subcommittees. The rationale behind this request is that diversity issues are important and would be even better served by involving all OC members through their participation in one or more of the three main program and audit subcommittees. These issues include increasing participation by individuals from groups historically underrepresented in science and medicine, geographic and population services and dispersion of awards, agency employment practices and state mandated HUB vending requirements. Issues of increasing participation by individuals from groups historically underrepresented in science and medicine are perhaps best addressed through the three program subcommittees. HUB purchasing efforts and the diversity of agency personnel are perhaps best addressed with the agency operating budget and procurement issues already considered by the Audit Subcommittee.

In May the Subcommittee's request was considered by the OC with possible action anticipated at the August meeting. OC members were asked to provide comments to me or the staff concerning a transfer. As of August 5th two OC members have provided feedback, one via email and one via telephone. Both expressed agreement with the proposed transfer. After additional

discussion at the Subcommittee's meeting on August 5th, the Subcommittee recommends that the charges be transferred as described above. Staff will provide changes to the affected subcommittee charges to implement the recommendation.

The Subcommittee also recommends that the Oversight Committee emphasize its belief that the three program subcommittees are better positioned to strengthen and facilitate diversity policies than a single siloed subcommittee dedicated to such issues. Since each OC member is required to be a member of one of the three program subcommittees transferring these charges also broadens OC membership discussion of and participation in diversity issues.

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 November 22, 2013, and amended on August 17, 2016, 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,
- The balance between the Institute's investments in cancer prevention grants program and investment and activities directed toward cancer research and product development activities, and
- The implementation and 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.

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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. 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.

- **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. Report regarding the implementation and effectiveness of policies and procedures that may impact grant applicant diversity and outreach efforts in the Institute's cancer research and prevention funding opportunities.

- **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.

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 November 22, 2013, and amended August 17, 2016, 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;

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- 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; and

- The implementation and 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. 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. 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.

- **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. Report regarding the implementation and effectiveness of policies and procedures that may impact grant applicant diversity and outreach efforts in the Institute's cancer research and prevention funding opportunities.

- **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.

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 November 22, 2013, and amended August 17, 2016, 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;
- 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; and

- The implementation and 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. 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. 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.

- **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. Report regarding the implementation and effectiveness of policies and procedures that may impact grant applicant diversity and outreach efforts in the Institute's cancer research and prevention funding opportunities.

- **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

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 November 22, 2013, and amended August 17, 2016, 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 polices 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;

- Review the findings of any examinations by regulatory agencies, including the Texas State Auditor's Office;

- Review agency operational activities related to state diversity-related requirements, e.g. Historically Underutilized Business (HUB) requirements and personnel practices.

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 & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	AUGUST 5, 2016

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules, and agency policies (T.A.C. § 701.7). In addition, the compliance officer will 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.

Submission Status of Required Grant Recipient Reports

A delinquent report is produced by CPRIT's grant management system (CGMS) each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 550+ grants that are either active or wrapping up grant activities and receives approximately 570 grantee reports each month.

As of the most recent CGMS report (July 25, 2016), five required grantee reports from four entities have not been filed in the system by the set due date. Of the five delinquent reports, three (60%) are Prevention grants, one (20%) is an Academic Research grant, and one (20%) is a Product Development grant. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to promptly resolve filing issues.

FSR Reviews

CPRIT's Grant Compliance Specialists performed 402 second level reviews of grantee Financial Status Reports (FSRs) during this quarter. Fifteen FSRs required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting

staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Thirty-nine desk reviews were performed during this quarter, bringing the FY 2016 year-to-date total to 248 desk reviews performed. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission. Grant Compliance Specialists are working with two grantees to remediate desk review findings.

On-site Reviews

Grant compliance staff performed six on-site reviews so far this quarter covering Product Development Research and Prevention grants. On-site reviews typically include an examination of the grantee's financial and administrative operations, procurement and inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Grant Compliance Specialists are working with two grantees to remediate on-site review findings.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $500,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year.

There are currently 10 grantees with outstanding audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Grant compliance specialists are also working with two grantees regarding delinquent audit reports and one grantee regarding a delinquent Corrective Action Plan (CAP). Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless a request for additional time was submitted on or before the due date of the required audit and subsequently approved by CPRIT's CEO.

Training & Support

CPRIT staff conducted a grantee training webinar on June 15, 2016 with approximately 140 grantee staff in attendance. The webinar focused on administrative rules changes, grantee

reporting requirements, compliance program activities, and the grant closeout process. Grantees also had the opportunity to ask questions during the two-hour training webinar. This was the second webinar conducted for grantees this fiscal year in support of the new annual compliance training requirement which states that the Authorized Signing Official (ASO) and at least one other employee from each grantee organization must attend an annual compliance training by November 1 of each year. A third grantee training webinar is planned for October 12, 2016.

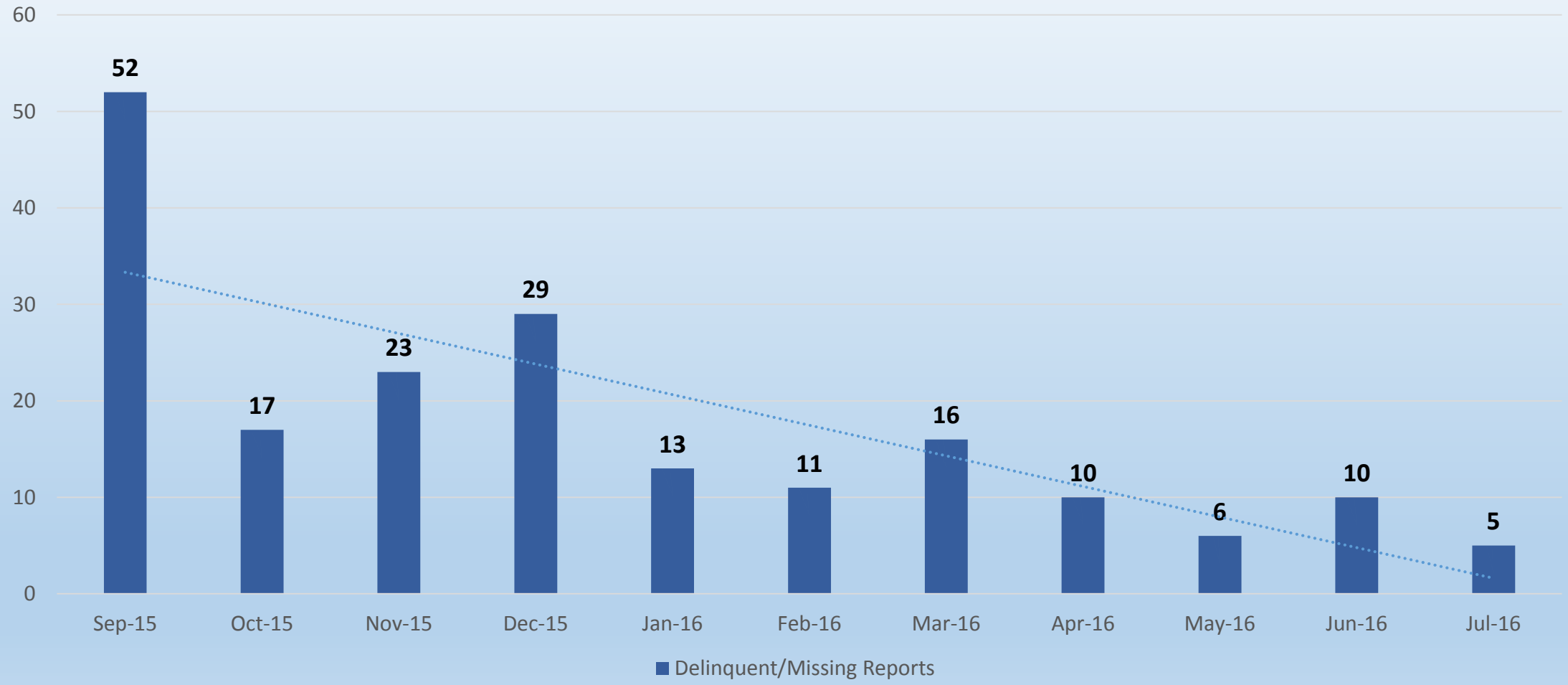
As a result of the grantee training webinars conducted in March and June, CPRIT staff drafted a Frequently Asked Questions (FAQ) document and posted on CPRIT's website as a resource for grantees. The FAQ document covers post-award topics such as required reporting timelines, financial status report supporting documentation, matching funds certification, travel expenses and documentation, and progress reports.

The Chief Compliance Officer and Staff Attorney conducted compliance and ethics training for all CPRIT employees during the month of June. The interactive training included an overview of CPRIT's Code of Conduct and Ethics, Conflict of Interest Policy, Non-Disclosure Agreement, and relevant sections from Health and Safety Code § 102 and Texas Administrative Code §§ 701-703.

Two new grantee trainings are scheduled for August 2016; both trainings are for Product Development grantees. CPRIT's administrative rules require that new grantees complete an initial compliance training program prior to the disbursement of grant award funds. The new grantee training covers a brief overview of CPRIT's history and mission, an overview of the compliance program, grantee reporting requirements, and a hands-on navigation of CPRIT's online grants management system.

CPRIT staff is scheduled to present at UT Southwestern Medical Center's Research Administration Demonstration Training Series on August 26. This interactive training will cover recent administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process and is open to all North Texas CPRIT grantees.

Grant Recipient Report Monitoring – FY 2016 To Date
Delinquent/Missing Reports



Reports Submitted: Approximately 6,800/Annually, Average 570/Monthly

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE

FROM: WAYNE R. ROBERTS, CEO, REBECCA GARCIA, CHIEF PREVENTION AND COMMUNICATIONS OFFICER

SUBJECT: 2017 PROGRAM PRIORITIES

DATE: AUGUST 8, 2016

Health and Safety Code: Chapter 102 requires CPRIT's Oversight Committee to establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio between and within its three programs as well as guide CPRIT staff and Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

The Oversight Committee reviewed the 2015 program priorities and determined that no changes to the priorities were needed for 2016 and approved them on November 19, 2015. The following tables outlines the steps and timeline for review and approval of the 2017 Program Priorities.

Date	Step
Week of Aug 8-12	**Aug. OC Program Subcommittee meetings**
	• Each OC program subcommittee to review and discuss current program priorities, also review across program priorities • Set date/time for additional meetings if needed
Sept 14	**Sept. OC meeting agenda**
	• OC Program Subcommittees report on their discussion and any ideas for new or revised priorities
	• OC review and discussion of across program priorities
Sept- Nov.	**Sept. to early Nov. OC Program Subcommittee work continues**
	• Each program works on any changes to priorities, convenes additional calls with OC program subcommittee if needed.
Week of Nov 7-11	**Nov. OC Program Subcommittee meetings**
	• Each OC Program Subcommittee to review and discuss changes, if any, to priorities that will go to OC for approval
Nov. 16	**Nov. 16 OC meeting agenda**
	• Approval of 2017 priorities

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Oversight Committee Meetings and Standing Subcommittee Meetings FY 2017

November 2016

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
10/30	10/31	1 PIC Meeting CPRIT Staff Only	2 Portal Opens	3 Board Governance	4 Diversity	5
6	7 Audit	8 Prevention	9 Sci Research	10 Prod Dev	11 Nominations	12
13	14	15	16 **Oversight Committee Meeting**	17	18	19

February 2017

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1/29	1/30	1/31 PIC Meeting CPRIT Staff Only	1 Portal Opens	2 Board Governance	3 Diversity	4
5	6 Audit	7 Prevention	8 Sci Research	9 Prod Dev	10 Nominations	11
12	13	14	15 **Oversight Committee Meeting**	16	17	18

May 2017

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
4/30	1	2 PIC Meeting CPRIT Staff Only	3 Portal Opens	4 Board Governance	5 Diversity	6
7	8 Audit	9 Prevention	10 Sci Research	11 Prod Dev	12 Nominations	13
14	15	16	17 **Oversight Committee Meeting**	18	19	20

August 2017

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
7/30	7/31	1 PIC Meeting CPRIT Staff Only	2 Portal Opens	3 Board Governance	4 Diversity	5
6	7 Audit	8 Prevention	9 Sci Research	10 Prod Dev	11 Nominations	12
13	14	15	16 **Oversight Committee Meeting**	17	18	19

Note: Unless the subcommittee members agree to a different time, all subcommittee meetings will begin at 10:00 a.m. with the exception of Diversity and Nominations that will begin at 10:30 a.m. Members of the Audit and Program subcommittees should allocate 1.5 hours for a meeting. All others subcommittee meetings require one hour.