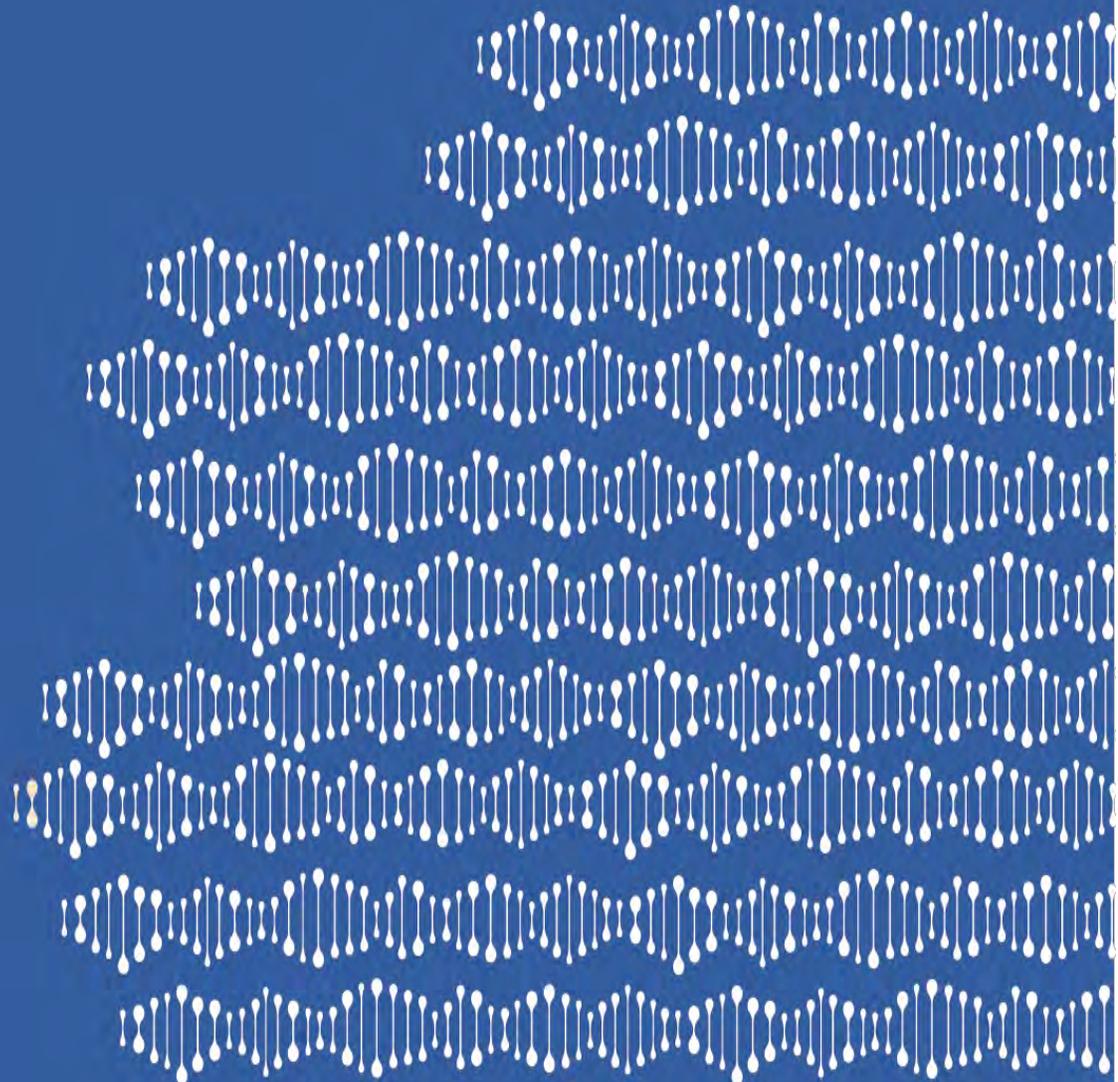




CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

# Oversight Committee Meeting

August 24, 2018







## **Summary Overview of the August 24, 2018, Oversight Committee Meeting**

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the August 24, 2018, Oversight Committee meeting.

### **CEO Report**

Wayne Roberts will present the CEO's report and address issues including a personnel update, grant funds available for FY 2018, the American Cancer Society Cancer Action Network events throughout the state, FY 2020 program priorities, a report on the 2020 CPRIT Innovations Conference, and other topics.

### **Chief Compliance Officer Report**

Vince Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews and site visits, annual compliance attestation, single audit tracking, and training.

### **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 (PIC) 51 award recommendations for Multi-Investigator Research Awards, Core Facility Support Awards, High-Impact/High-Risk Research Awards, Recruitment of First-Time, Tenure-Track Faculty Members, Recruitment of Rising Stars, and Recruitment of Established Investigators totaling \$112,156,309.

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

### **Chief Product Development Officer Report and Grant Award Recommendation**

Mr. Mike Lang will provide an update on the Product Development Program. He will also present the PIC's three award recommendations for Texas Company Product Development Research Awards totaling \$50,587,540. Also included is a letter from the Chief Executive Officer requesting authority to advance grant funds to the companies if the Oversight Committee approves the award recommendations and the companies execute the grant contract.

*CPRIT will not publicly disclose information related to the Product Development Research grant applications recommended for funding 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 update the Oversight Committee on the on the agency's prevention and communications activities and present the PIC's 10 award recommendations. The recommended

awards include Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations; Evidence-Based Cancer Prevention Services; and Tobacco Control and Lung Cancer Screening totaling \$14,322,379. Dr. Garcia will also present the Prevention Program's plan for FY 2019 Requests for Applications and proposed timeline.

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

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

The Chief Executive Officer has provisionally appointed four 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 appointments are final. Biographical sketches for the appointees are included for the Oversight Committee's consideration.

### **Appointments – Appointments to the Advisory Committee on Clinical Trials**

The Chief Executive Officer will present two appointments to the newly-created Advisory Committee on Clinical Trials.

### **FY 2019 Honoraria Policy**

Mr. Roberts will present the FY 2019 honoraria policy for peer reviewers. There are no changes from the FY 2018 honoraria policy, which the Oversight Committee approved last year.

### **Health & Safety Code § 102.1062 Waivers**

Mr. Roberts will present the five conflict of interest waivers pursuant to Texas Health and Safety Code 102.1062. The FY 2018 waivers are for Dr. Becky Garcia, Don Brandy, Dr. John Hellerstedt, Will Montgomery, and the Review Council Members. The Oversight Committee approved similar waivers for these five for FY 2018.

### **Internal Auditor Report**

Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and present an internal audit report concerning communications, as well as follow-up procedures conducting on three previous audits. Weaver and Tidwell will also present the FY2018 annual internal audit report and the FY 2019 audit plan. The internal auditor will present one of the follow-up procedures reports on Information Security in closed session due to the sensitive information regarding CPRIT's information technology.

### **Amendments to 25 TAC Chapter 703**

Ms. Eckel will present the final order approving amendments to Chapters 701 and 703, which the Oversight Committee provisionally approved at the May meeting. If approved, the amendments will become effective in September.

Ms. Eckel will also 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. Legal staff will bring back these rule changes to the Oversight Committee for final approval in November after the public has commented on the proposed rule changes.

**Amendments to CPRIT's Bylaws and Code of Conduct**

Ms. Doyle will present a proposed change to CPRIT's Bylaws and Code of Conduct. The proposed change is necessary to make the Code of Conduct consistent with CPRIT's statute.

**Chief Operating Officer Report and Contract Approvals**

Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the third quarter of FY 2017. She will also present recommendations for contract approvals for the following services: an economic assessment of the cost of cancer in Texas, internal audit, and strategic communications.





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CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

## Oversight Committee Meeting Agenda

Texas State Capitol Extension  
1100 Congress Avenue, Austin, Texas 78701  
Room E1.012

August 24, 2018  
10:00 a.m.

The Oversight Committee may discuss or act on 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 16, 2018, meeting **TAB 1**
4. Public Comment
5. Grantee Presentations **TAB 2**
6. Chief Executive Officer Report **TAB 3**
7. Chief Compliance Officer Report **TAB 4**
8. Chief Scientific Officer Report **TAB 5**
  - Grant Award Recommendations
9. Chief Product Development Officer Report **TAB 6**
  - Grant Award Recommendations
10. Chief Prevention and Communications Officer Report **TAB 7**
  - Grant Award Recommendations
  - FY 2019 Requests for Applications and Timeline
11. Scientific Research and Prevention Program Committee Appointments **TAB 8**
12. Advisory Committee on Clinical Trials Appointments **TAB 9**
13. FY 2019 Honoraria Policy **TAB 10**
14. Health & Safety Code Section 102.1062 Waivers **TAB 11**
15. Internal Auditor Report **TAB 12**
  - Internal Audit Report over Communication
  - Internal Audit Follow-Up Procedures Report over Procurement and P-Cards
  - Internal Audit Follow-Up Procedures Report over Pre-Award Grant Management
  - Internal Audit Follow-Up Procedures Report over Information Security
  - Fiscal Year 2019 Audit Plan
  - Fiscal Year 2018 Annual Internal Audit Report
16. Amendments to 25 T.A.C. Chapter 703 **TAB 13**
  - Final Order Approving Amendments to Chapters 701 and 703
  - Proposed Amendments to Chapter 703 and Authorization to Publish in *Texas Register*
17. Amendments to the Oversight Committee Bylaws and Code of Conduct **TAB 14**
18. Chief Operating Officer Report **TAB 15**

19. Contract Approvals **TAB 16**
  - Strategic Communications
  - Economic Assessment of the Cost of Cancer in Texas (renewal)
  - Internal Audit (renewal)
20. Subcommittee Business
  - Board Governance Subcommittee Chair
21. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
22. Consultation with General Counsel
23. Future Meeting Dates and Agenda Items **TAB 17**
  - November 28, 2018 Meeting and Fiscal Year 2019 Meeting Dates
24. Adjourn



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CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

**Oversight Committee Meeting  
May 16, 2018**

NOTE: Unless the information is confidential, the reports and presentations referenced in the minutes are available at [http://www.cprit.state.tx.us/cprit-media/oc\\_packet\\_05-16-2018.pdf](http://www.cprit.state.tx.us/cprit-media/oc_packet_05-16-2018.pdf). Information regarding the recommended awards is available at [http://www.cprit.state.tx.us/cprit-media/proposed\\_grant\\_awards\\_book\\_05162018.pdf](http://www.cprit.state.tx.us/cprit-media/proposed_grant_awards_book_05162018.pdf).

**Call to Order – Agenda Item 1**

A quorum being present, Presiding Officer Will Montgomery called the Oversight Committee to order at 10:01 a.m.

**Roll Call/Excused Absences – Agenda Item 2**

Committee Members Present

Angelos Angelou  
Bill Rice, M.D.  
Donald (Dee) Margo  
Will Montgomery  
Mahendra Patel, M.D.  
Craig Rosenfeld, M.D.

**Adoption of Minutes from the February 21, 2018 Meeting – Agenda Item 3 – Tab 1**

**MOTION:**

On a motion by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meeting of February 21, 2018, as presented.

**Public Comment – Agenda Item 4**

There were no requests to provide public comment.

**Honorary Resolution - Amy Mitchell – Agenda Item 5 – Tab 2**

Presiding Officer Montgomery presented an honorary resolution for the Oversight Committee's approval. The resolution recognized former Oversight Committee member Ms. Amy Mitchell for her years of service as an Oversight Committee member, including serving as secretary for the board.

**MOTION:**

On a motion made by Mr. Margo and seconded by Mr. Rice, the Oversight Committee unanimously voted to approve and sign the resolution for Ms. Mitchell.

Presiding Officer Montgomery recognized CPRIT Chief Executive Officer Wayne Roberts for a presentation to Ms. Mitchell on behalf of the CPRIT staff.

**Grantee Presentation – Agenda Item 6 – Tab 3**

CPRIT Chief Scientific Officer Dr. James Willson introduced Dr. James Brugarolas, Professor of Internal Medicine at The University of Texas Southwestern Medical Center (UTSW) and Director of the Harold Simmons Comprehensive Cancer Center Kidney Cancer Program.

Dr. Brugarolas reported on UTSW’s work, supported by CPRIT, to build one of the largest kidney cancer programs in the nation. His presentation included a high-level overview of the Kidney Cancer Specialized Program of Research Excellence (SPORE).

In response to an Oversight Committee member’s question on how others can export the success of the program’s survival rate - survival rates for stage 4 kidney cancer patients at UTSW are more than double the national benchmark - to clinics and communities, Dr. Brugarolas explained that his group shares their multi-disciplinary tumor board model and provides opportunities for clinicians across the state and country to present difficult cases to the group.

**Internal Auditor Report – Agenda Item 16 – Tab 13**

Presiding Officer Montgomery recognized CPRIT Internal Auditor Ms. Alyssa Martin, Weaver and Tidwell, LLP, to present a status update on the FY 2018 internal audit plan, the recent internal audit reports, and the reports on follow-up procedures. Ms. Martin directed members to the audit materials in the meeting packet at pages 13-1 – 13-4 and provided her report.

In response to an Oversight Committee member’s question, Ms. Martin explained that the Health Insurance Portability and Accountability Act of 1996 does not apply to any CPRIT grant information or processes.

There were no further questions for Ms. Martin.

**Advisory Committee on Product Development – Agenda Item 14 – Tab 11**

Presiding Officer Montgomery recognized Mr. Roberts to introduce Mr. Andrew Strong. Mr. Strong is a partner in the Houston and Austin offices of Pillsbury Winthrop. He works with several CPRIT product development applicants and grantees. Prior to joining Pillsbury, Mr. Strong was the founding president and CEO of Kalon Biotherapeutics, a 2012 CPRIT product development grantee. Fujifilm Diosynth Biotechnologies acquired Kalon in late 2014.

Mr. Strong presented the annual report on behalf of the Product Development Advisory Committee (PDAC). The PDAC report and PowerPoint presentation are included in the meeting packet at pages 11-1 – 11-20.

Following Mr. Strong's presentation, an Oversight Committee member inquired about whether there is any interaction between product development applicants and the review committee during the due diligence phase of the grant application review process. Mr. Strong replied that there is little interaction, if any, at this stage. CPRIT General Counsel Kristen Doyle commented that if CPRIT were to make changes in this area, the agency would need to develop and implement a new process. Another Oversight Committee member remarked that if CPRIT were to put such a process in place, all applicants would need equal access to the review committee in the due diligence phase to ensure a level playing field.

An Oversight Committee member asked Mr. Strong about whether it is better to provide larger amounts of funding to more-developed projects or smaller amounts of funding to earlier stage projects. Mr. Strong replied that the amount of funding depends on the development stage of the project. He explained that the biggest costs for these companies are clinical trials and manufacturing, so larger awards are more important to applicants that are seeking funding for Phase 1 and 2 clinical trials. Mr. Strong reported that companies are also excited about the new Seed Award program. The Seed Award will help fund early preclinical studies to help the companies get to the point where their project is more attractive to external investors.

An Oversight Committee member asked whether companies are more likely to attract investment at the later stages of development. Mr. Strong replied that typically big pharma is not interested until companies complete their Phase 2 clinical efficacy studies.

An Oversight Committee member asked whether smaller funding amounts (such as the amount offered through the Seed Award program) would help companies obtain experienced leadership. Mr. Strong replied that he does not believe that early stage companies will attract a CEO to relocate from Boston, for example, with a \$3M grant. Small funding awards, Mr. Strong explained, would go mostly towards further developing the technology, not attracting experienced management teams. Mr. Strong elaborated that the Seed Award could be useful when institutions such as MD Anderson or Baylor College of Medicine have a molecule that they want to put into a company. An accelerator could run that company, for example.

### **Advisory Committee on Childhood Cancer (ACCC) - Annual Report – Agenda Item 13 – Tab 10**

Dr. Willson introduced Dr. Susan Blaney, Chair of the Advisory Committee on Childhood Cancer (ACCC). Dr. Blaney is Professor of Pediatrics at Baylor College of Medicine and serves as Executive Vice Chair of the Department of Pediatrics and as Deputy Director Center and Hematology Center, Texas Children's Hospital. Dr. Willson noted that Dr. Blaney has provided outstanding guidance and support to CPRIT through her membership and leadership of the ACCC.

Dr. Blaney presented the ACCC 2017 annual report and recommendations to the Oversight Committee (pages 10-1 – 10-42 in the meeting packet) and provided an overview of the ACCC's mission.

Following her presentation, an Oversight Committee member asked about the impact of CPRIT Childhood Cancer Awards to date. Dr. Blaney responded that impact has been significant. She noted that the success rate of applications devoted to childhood and adolescent cancers has increased from 4% in 2014 to 24% in 2017. Dr. Blaney explained that the impact of the awards

funded by CPRIT is tremendous since the life-years for survivors of childhood cancer exceeds that of their adult counterparts significantly. She suggested CPRIT may measure evidence of success by publications and new grant dollars from the NIH and other peer reviewed sources.

#### **Chief Executive Officer Report – Agenda Item 7 – Tab 4**

Presiding Officer Montgomery recognized Mr. Roberts for the CEO report.

Mr. Roberts reported that if the Oversight Committee approves all recommendations presented at the meeting, there will be \$170 million in available grant funds for the rest of the year.

After providing a personnel update, Mr. Roberts gave an overview of two recent CPRIT outreach events. On May 1, 2018, Mr. Montgomery delivered the lunch keynote at the Texas Healthcare & Bioscience Institute Annual Summit. The Houston City Council held its National Cancer Research Month Proclamation event held May 15, which was well attended by CPRIT staff and Houston area grantees. Mr. Roberts thanked staff members Chris Cutrone and Spencer Miller-Payne for working with the Houston City Council for this occasion.

Mr. Roberts reported that he and CPRIT's Chief Product Development Officer Michael Lang will attend the BIO conference in a few weeks in Boston and will have meetings with interested companies at the conference.

There were no questions for Mr. Roberts.

#### **Chief Compliance Officer Report – Agenda Item 8 – Tab 5**

Mr. Vince Burgess, Chief Compliance Officer, presented his compliance program update (in the meeting packet beginning at page 5-1) on the status of required grantee reports, second-level reviews of financial status report, single audit tracking, desk reviews, onsite visits, annual compliance attestations, and trainings.

Mr. Burgess directed Oversight Committee members to the chart on page 5-5 in the meeting packet. He noted that the dotted line indicated a 5% non-compliance threshold for the approximately 570 reports submitted every month. Overall, delinquent reporting for FY18 has been under 5% threshold, except for January. Mr. Burgess reminded Oversight Committee members that at the February 2018 meeting he discussed recent changes to CPRIT's grants management system that led to the increase in the number of delinquent reports.

Mr. Burgess also informed the Oversight Committee members CPRIT is instituting a change so that the Single Audit Determination (SAD) form will be submitted for each institution via email annually. The SAD form is used to certify whether a grantee has expended \$750,000 or more in state awards. Previously the grantee submitted the form through the grants management system for each active grant separately; this was an administrative burden for grantees. This new process will allow CPRIT to collect information at the grant level.

Mr. Burgess noted that CPRIT staff conducted a grantee training webinar on March 7, 2018, with 190 grantee staff in attendance. Also, CPRIT compliance staff was invited to make a training

presentation at the National Council of University Research Administrators Region V conference on May 8 in San Marcos.

There were no questions for Mr. Burgess.

### **Compliance Investigation Pursuant to Health & Safety Code 102.2631 – Agenda Item 24 Consultation with General Counsel – Agenda Item 25**

At 11:50 a.m. Presiding Officer Montgomery called the Oversight Committee into closed session to discuss agenda items 24 and 25 pursuant to the Texas Open Meeting Act § 551.074, and Texas Health & Safety Code § 102.2631 to discuss an ongoing compliance investigation and to receive advice from counsel. Mr. Montgomery asked Ms. Doyle, Mr. Roberts, Mr. Burgess, and Dr. Willson to join the Oversight Committee in the closed Session.

Mr. Montgomery reconvened the open meeting at 12:47 p.m. The Oversight Committee did take any action.

### **Future Meeting Dates and Agenda Items – Agenda Item 26**

Presiding Officer Montgomery reminded members that the Oversight Committee will hold its next regular meeting on August 15, 2018.

He also noted that the regularly scheduled November meeting date will conflict with the Thanksgiving holiday. He advised members that the Oversight Committee will meet either November 28 or 29 instead. Mr. Roberts will coordinate with individual members regarding their schedules and update the Oversight Committee with the final date.

### **Chief Scientific Officer Report – Agenda Item 9 – Tab 6**

#### Academic Research Award Recommendations

Presiding Officer Montgomery recognized Dr. Willson to present the academic research award slates recommended by the CPRIT Scientific Review Council (SRC) and the Program Integration Committee (PIC). Dr. Willson presented the eight recruitment grant awards recommended by the SRC and the PIC totaling \$29,986,494. He provided a summary of each of the four Established Investigator candidates and four First-Time Tenure Track Faculty candidates.

#### Compliance Certification (Academic Research and Prevention Awards)

Mr. Burgess presented his certification of the review process for the proposed grant awards recommended to the Oversight Committee (included in the proposed grant awards packet at pages 47 - 51). He reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the seven academic research award mechanisms and four prevention award mechanisms.

## Conflict of Interest Notification

Presiding Officer Montgomery noted that Mr. Angelou reported a conflict of interest with grant application RR180034 submitted by The University of Texas at Austin.

Presiding Officer Montgomery suggested that, unless a member objected, the Oversight Committee consider all the academic research award recommendations together in one vote except for the proposed award to The University of Texas at Austin, which the committee would vote on separately. No member objected.

Rank	App ID	Candidate	Mechanism	Organization	Budget	Overall Score
1	RR180025	Sheetz, Michael	REI	The University of Texas Medical Branch at Galveston	\$6,000,000	1.0
2	RR180029	Sung, Patrick	REI	The University of Texas Health Science Center at San Antonio	\$6,000,000	1.0
3	RR180035	Shen, John	RFTFM	The University of Texas M. D. Anderson Cancer Center	\$2,000,000	1.3
4	RR180046	Chung, Stephen	RFTFM	The University of Texas Southwestern Medical Center	\$2,000,000	1.6
5	RR180040	Xiao, Xinshu	REI	Baylor College of Medicine	\$4,000,000	1.8
6	RR180044	Yi, Qing	REI	The Methodist Hospital Research Institute	\$5,986,494	2.2
7	RR180034	Powers, John	RFTFM	The University of Texas at Austin	\$2,000,000	2.2
8	RR180041	Musah, Samira	RFTFM	Rice University	\$2,000,000	2.3

RRS: Recruitment of Established Investigators

RFTFM: Recruitment of First-Time Tenure Track Faculty Members

In response to an Oversight Committee member's question about scoring applications, Dr. Willson noted that the SRC considers the qualification of the candidate, the institutional commitment, and the prospects that the recruitment will lead to a significant impact on cancer.

### **MOTION:**

On a motion made by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the PIC's recommendations for The University of Texas at Austin grant application RR180034.

Presiding Officer Montgomery noted for the record that Mr. Angelou did not vote on these recommendations.

### **MOTION:**

On a motion made by Mr. Margo and seconded by Mr. Rice, the Oversight Committee unanimously voted to approve the PIC's recommendations for the remaining seven Recruitment Awards.

**MOTION:**

On a motion made by Mr. Margo and seconded by Dr. Rice, 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.

Academic Research Program Report

Dr. Willson presented his report (pages 6-1 to 6-7 in the meeting packet).

Proposed Plan for RFAs for FY 2019 Cycle 2

Dr. Willson noted the Academic Research Program is proposing an additional RFA for FY 2019 Cycle 2 as discussed at Oversight Committee’s February meeting. He provided a high-level overview of the proposed RFA, “Collaborative Action Program to Reduce Liver Cancer Mortality in Texas.” Dr. Willson noted that CPRIT convened a group of thought leaders in liver cancer early in May whom collectively provided input and guidance that CPRIT will reflect in the RFA.

An Oversight Committee member asked if the funding for the project (\$18M) was sufficient. Dr. Willson responded that the funding alone was not enough to fully address the epidemic of hepatocellular cancer in Texas, but he noted that the funding will support important dissemination and implementation research and will be a strong catalyst to generate additional funds from the federal government and charitable foundations to continue the promising research projects.

In response to a question regarding the operational aspects of the proposed Center for Collaborative Action, Dr. Willson stated the Center’s purpose is not as a coordination center, but as a hub for promoting collaborations across the research projects, dissemination of findings, and outreach to promote uptake of screening guidelines by physicians and community practice health systems.

**MOTION:**

On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the Academic Research Program’s plan for proposed RFAs for the second cycle of FY 2019.

Delegation of Contract authority for RP150058

Mr. Roberts and Dr. Willson presented a request for a delegation of authority to replace the primary investigator and approved continued disbursement of funds for grant RR150058.

**MOTION:**

On a motion made by Mr. Angelou and seconded by Mr. Margo, the Oversight Committee unanimously voted to delegating authority to CPRIT’s CEO to approve replacing the primary investigator on grant RR150058 and to contribute distributing grant funds according to a plan and budget approved by Mr. Roberts.

## Chief Prevention and Communications Officer Report – Agenda Item 10 – Tab 7

### Communications Report

Dr. Garcia reported on Communications activities (pages 7-4 – 7-38 in the meeting packet). She shared a slide and videos highlighting three notable pieces of coverage.

- Governor Abbott tweeted about a Dallas Morning News article announcing CPRIT’s new Company Seed Grant Award.
- In a video clip, Governor Abbott thanked THBI for their work and in it recognized CPRIT’s work.
- A press conference held in April at Texas Tech El Paso to announce the Recruitment of CPRIT Scholar Dr. Gadad resulted in 11 different news items on television and in print.

In other activities, Chris Cutrone, Spencer Miller-Payne, and Wayne Roberts attended the City of Houston Proclamation event recognizing National Cancer Research month on May 15, 2018. Mr. Cutrone worked with the City of Houston and CPRIT grantee institutions to plan and coordinate the event.

There were no questions for Dr. Garcia.

### Prevention Award Recommendations

Presiding Officer Montgomery recognized Dr. Garcia to present the Prevention Review Council (PRC) and PIC’s recommendations for prevention awards and to provide the prevention program update. She reported that the PRC and PIC recommended one “Dissemination of CPRIT Funded Cancer Control Interventions” project for \$300,000. Dr. Garcia reported that the recommended application addresses one or more of the Prevention Program priorities.

### Prevention Grant Award Recommendations – Dissemination Cycle 18.3

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP180110	DI	Training CHWs to disseminate culturally competent, family health history-based cancer prevention and navigation services among Chinese Americans	Chen, Lei-Shih	Texas A&M University	2.0	1	\$300,000

DI: Dissemination of CPRIT-Funded Cancer Control Interventions

An Oversight Committee member questioned which ten Texas counties had the highest Chinese American population. CPRIT Senior Director for Prevention Programs Ramona Magid provided the information to the member immediately after the meeting. The ten counties are Harris, Fort Bend, Collin, Dallas, Travis, Tarrant, Bexar, Denton, Williamson, and Brazos counties.

### Compliance Certification

Presiding Officer Montgomery noted that Mr. Burgess previously certified compliance of the prevention awards process.

### Conflict of Interest Notification

Presiding Officer Montgomery noted that no Oversight Committee member reported a conflict of interest with the applications under consideration.

#### **MOTION:**

On a motion made by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the PIC's recommendations for one Dissemination of CPRIT-Funded Cancer Control Intervention award.

#### **MOTION:**

On a motion made by Dr. Rice and seconded by Dr. Patel, 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 contract on behalf of CPRIT.

### **Chief Product Development Officer Report – Agenda Item 11 – Tab 8**

Mr. Roberts presented the Product Development program update on behalf of Mr. Lang, whom was unable to attend the Oversight Committee meeting.

There were no questions for Mr. Roberts.

### **Scientific Research and Prevention Program Committee Appointments – Agenda Item 12 – Tab 9**

Presiding Officer Montgomery recognized Mr. Roberts to present one appointee to CPRIT's Scientific Research and Prevention Program Committee. Mr. Roberts recommends the appointment to the peer review committees for Oversight Committee approval. He noted that CPRIT provided the biographical information for the appointee in the meeting packet (pages 9-1 - 9-10) and that the Nominations Subcommittee discussed the appointment at their May 11, 2018, subcommittee meeting and recommends approval.

There were no questions for Mr. Roberts.

#### **MOTION:**

On a motion by Dr. Rosenfeld and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the Scientific Research and Prevention Program Committee appointment.

### **Advisory Committee on Clinical Trials – Agenda Item 15 – Tab 12**

Mr. Roberts and Dr. Willson presented the Advisory Committee on Clinical Trials Charter.

**MOTION:**

On a motion made by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the creation and charter of the Clinical Trials Advisory Committee.

Mr. Roberts and Dr. Willson presented the inaugural members of the Advisory Committee on Clinical Trials for the Oversight Committee's consideration.

**MOTION:**

On a motion made by Dr. Patel and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the proposed members of the Clinical Trials Advisory Committee.

**Oversight Committee Secretary Position – Agenda Item 17**

Presiding Officer Montgomery informed that Oversight Committee members that with the resignation of Ms. Amy Mitchell the position of Secretary was now vacant. He requested that Dr. Patel fill this position until the next election of Oversight Committee officers in 2019. Dr. Patel accepted.

**MOTION:**

On a motion by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee unanimously voted to appoint Dr. Patel as Secretary of the Oversight Committee.

**Health & Safety Code Section 102.1062 Waiver – Agenda Item 18 – Tab 14**

Mr. Roberts presented a conflict of interest waiver related to review council members pursuant to Texas Health & Safety Code Section 102.1062. The waiver request is included in the meeting packet at Tab 14.

In response to a question from the Oversight Committee, Ms. Doyle clarified that even with the waiver in place, the review council member cannot discuss or advocate for the individual application with which he or she has the conflict. However, approving the waiver will allow the review council member to take part in a discussion and vote involving all grants considered by the panel, even if the application that gives rise to the conflict is part of the larger group of awards. She explained that usually this will occur when the panel is discussing the panel's overall award recommendations.

**MOTION:**

On a motion made by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the proposed Health & Safety Code Section 102.1062 waiver.

**Amendments to 25 T.A.C. Chapters 701 - 703 – Agenda Item 19 – Tab 15**

Presiding Officer Montgomery recognized CPRIT Staff Attorney Ms. Cameron Eckel to present the rule changes for Oversight Committee Action. Ms. Eckel referred members to the final rule changes and proposed amendments in the meeting packet at pages 15-1 – 15-30. She reported that

the Board Governance subcommittee recommended final approval for amendments to Texas Administrative Code Chapter 701 and 703, originally considered by the Oversight Committee at the February 2018 meeting. In addition, Ms. Eckel reported that the Board Governance subcommittee recommended that the Oversight Committee approve publication in the *Texas Register* of three proposed rule changes to Texas Administrative Code Chapters 701 and 703.

**MOTION:**

On a motion by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the final orders adopting rules changes to the Texas Administrative Code Chapters 701 and 703 and to approve the publication of the proposed changes to the Texas Administrative Code Chapters 701 and 703 in the *Texas Register*.

**Fiscal Year 2019 Bond Issuance Resolution – Agenda Item 20 – Tab 16**

Presiding Officer Montgomery called upon Ms. Heidi McConnell, Chief Operating Officer, to present the staff recommendation and resolution in the meeting packet at pages 16-1 – 16-7. She reported that CPRIT is requesting the Texas Public Finance Authority to issue debt on behalf of CPRIT in FY 2019. The \$300 million in bond proceeds is appropriated to CPRIT for its operations and prevention and research grant awards.

**MOTION:**

On a motion by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the bond issuance resolution requesting that the Texas Public Finance Authority issue debt on behalf of CPRIT in FY 2019.

**Chief Operating Officer Report – Agenda Item 21 – Tab 17**

Presiding Officer Montgomery asked Ms. McConnell to present the Chief Operating Officer's report. Ms. McConnell reported on the operating budget, performance measures, debt issuance history for the second quarter of Fiscal Year 2018, State Agency Strategic Planning for the 2018 – 2019 biennium, and CPRIT's Legislative Appropriations Request (LAR) for the 2020 – 2021 budget, noting that the information is in the meeting packet at pages 17-1 – 17-14.

Ms. McConnell noted that the LAR is due before the next regular meeting Oversight Committee scheduled for August. She requested that the Oversight Committee provide preliminary approval now and designate the Audit Subcommittee to review the final draft prior to submission to confirm that the items presented are consistent with LAR request items as listed in the meeting packet at pages 17-13 – 17-14 the Oversight Committee.

In response to a question from the Oversight Committee, Ms. McConnell explained that after the Oversight Committee approves the 2020-21 LAR, it is submitted to Legislature and Governor for consideration during the next legislative session that begins January 2019.

**MOTION:**

On a motion by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the draft Legislative Appropriations Request, subject to final review by the Audit subcommittee.

**Contract Approvals – Agenda Item 22 – Tab 18**

Ms. McConnell presented five contracts that staff recommends CPRIT award. Three memos explaining the contract needs are in the meeting packet at pages 18-1 – 18-6. She noted for the record that no Oversight Committee members and CPRIT staff reported financial conflicts with any of the firms that CPRIT intends to enter into a contract. The contracts recommended for award include:

- Due Diligence Support Services Contract with ICON Clinical Research for \$212,200
- Grant Management Support Services Contract Renewal with CSRA for \$8,400,443
- Outside Counsel Contracts for legal services to prepare intellectual property due diligence reviews as well as revenue sharing agreements:
  - Vinson & Elkins, LLP for \$125,000
  - Baker Botts, LLP for \$125,000
  - Yudell Isidore, LLP for \$125,000

**MOTION:**

On a motion by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve contracts with ICON, CSRA, Baker Botts, Vinson & Elkins, and Yudell Isidore.

**Subcommittee Business – Agenda Item 23**

There was no discussion or action on this standing agenda item.

**Adjourn – Agenda Item 27**

**MOTION:**

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

Meeting adjourned at 1:59 p.m.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date



**Barbara J Turner MD, MSED, MA, MACP** is a practicing general internist and health services researcher focusing improving quality and outcomes of primary care for vulnerable populations. She is a Professor of Medicine at UT Health San Antonio and the Founding and Former Director of the Center for Research to Advance Community Health (ReACH). She received her medical training at the University of Pennsylvania, followed by research fellowships at St. Thomas Hospital in London and the Robert Wood Johnson Clinical Scholars Program at the University of Pennsylvania. She started her career at Jefferson Medical College then moved to Penn where she was the director of a HRSA-funded T32 training program for primary care physician-scientists. She also was Chair of HRSA’s Advisory Committee on Training in Primary Care Medicine and Dentistry. Starting in 2001, she was an Associate Editor of the *Annals of Internal Medicine* and, in 2009, became the full-time Executive Deputy Editor. Dr. Turner has over 180 peer-reviewed publications and editorials on: quality of ambulatory care; cardiovascular and cancer preventive care; HIV care; chronic pain/opioid use; substance abuse; primary care practice redesign; and patient adherence to care. Her research has focused on studying models of care for complex chronic diseases in low-income populations. Since 2013 she has led studies to implement universal screening for hepatitis C virus in baby boomers (born 1945 –1965). This research has advanced our knowledge of the infrastructure necessary to successfully conduct screening and ensure that patients receive adequate support to access highly effective anti-HCV medication. For this work, she has received the U.S. Department of Health and Human Services (HHS) Viral Hepatitis Testing Recognition Award. She currently leads two federally funded and two CPRIT state funded projects to implement baby boomer screening in primary care practices across Texas.





CANCER PREVENTION & RESEARCH  
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**MEMORANDUM**

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**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER  
**SUBJECT:** AGENDA ITEM 6: CHIEF EXECUTIVE OFFICER REPORT  
**DATE:** AUGUST 8, 2018

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As of this writing the Chief Executive Officer's Report for the August 24, 2018, Oversight Committee meeting will consist of the following items:

- Personnel update
- FY 2018 Grant Award Funds Available (attached)
- Report on the American Cancer Society Cancer Action Network Events
  - Austin-August 21
  - Fort Worth-August 23
  - San Antonio-August 29
  - Houston-October 25
- FY 2020 Program Priorities Process (for November meeting)
- Report on the October/November 2020 *Innovations VI* Conference (memo attached)

Other topics may be added as warranted.

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

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CPRIT has awarded **1,255** grants totaling **\$1.982 billion**

- 199 prevention awards totaling \$208.8 million
- 1,056 academic research and product development research awards totaling \$1.774 billion

Of the \$1.774 billion in academic research and product development research awards,

- 28.8% of the funding (\$510.0 million) supports clinical research projects
- 26.0% of the funding (\$461.4 million) supports translational research projects
- 27.1% of funding (\$480.1 million) supports recruitment awards
- 14.7% of the funding (\$262.2 million) supports discovery stage research projects
- 3.4% of funding (\$59.9 million) supports training programs.

CPRIT has 10 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Product Development Research
- 4 Prevention





CANCER PREVENTION & RESEARCH  
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**MEMORANDUM**

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**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER  
**SUBJECT:** 2020 CPRIT CONFERENCE  
**DATE:** AUGUST 8, 2018

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**Summary:**

Since 2015, CPRIT has convened a conference in November of odd-numbered years. Rather than holding the next conference in 2019, the next CPRIT conference will be held in the last quarter of 2020 (likely November 2020). Making this change aligns the conference with the legislative cycle, increases the opportunity for more venue choices, and allows CPRIT staff to repurpose the existing 2012 conference registration system for use in future conferences by making it fully compliant with current agency security standards.

**Background:**

CPRIT's conferences are designed to highlight the accomplishments of CPRIT grantees to the Legislature, general public and state media and to provide educational and networking opportunities for grantees. CPRIT has held five conferences in the fall of 2010, 2011, 2012, 2015 and 2017. Each conference has attracted between 750 and 850 people. Most attendees have been CPRIT grantees, with about two-thirds being researchers and one-third being public health professionals. CPRIT encourages grantees to attend, allowing them to use grant funds to register up to two people involved in a funded project. All conferences have been well received.

Registration fees will offset a portion of the conference cost; CPRIT must fund remaining costs through our operational budget, which is already constrained for fiscal years 2019 and 2020. The largest expense has been for food and beverage, followed by the conference registration and abstract system, meeting planning services and meeting décor. Food and beverage is a variable cost based on number of attendees, which CPRIT must cover through registration revenue. CPRIT will develop a budget after the venue contract is signed.

**Discussion:**

The last two conferences have been off cycle with legislative sessions, thereby minimizing their value to the legislative community and foregoing opportunities to highlight CPRIT grantees' considerable progress. In identifying dates for the next conference, we prioritized realigning it with the 2021 legislative session.

Another major consideration for realigning the conference with the legislative session is the additional time it provides to get an adequate number of venue proposals. Potential conference hotel venues have shown little interest in responding to our RFP for the last several conferences, thereby seriously limiting CPRIT's choices. The RFP for the 2017 conference was posted 16 months before the preferred date but resulted in only two proposals for CPRIT to consider. With the two-year lead time afforded by holding the conference in 2020, hotels are more likely to have dates and space available, which should result in more responses to the RFP and increase the pool of potential venues.

The additional time gained by holding a conference in 2020 instead of 2019 also allows CPRIT IT to repurpose the conference registration system originally created for the 2012 conference and set up hosting on CPRIT's existing cloud platform, lowering the cost of the system for CPRIT and ensuring the system's compliance with the agency's currently defined security standards. CPRIT estimates the cost of outsourcing a registration and abstract system for a 2019 conference to be \$200,000 or more. The main drivers of the cost of an outsourced registration and abstract system are the security requirements for a SOC2 report of the system, quarterly penetration and vulnerability testing by a qualified third-party service provider, integration with *Texas.gov*'s credit card payment processing platform, and the truncated timeline to get the system operational by the end of January 2019 which would require substantial amounts of vendor time over major U.S. holidays such as Christmas and New Year's. January 2019 is necessary to allow enough time for abstract submissions for the conference. This cost of this expedited timeline is not part of CPRIT's FY 2019 operating budget, which means that CPRIT will need to request approval from the LBB to move money from the research grant award budget line item to the agency grant award operations line item in FY 2019.

It is worth noting that none of the prior RFP respondents for the registration and abstract system, including the selected vendor in 2017, were able to meet the SOC2 and third-party testing requirements. If CPRIT holds the conference in 2019, it is likely that CPRIT will need to provide the vendor with an exception to the agency's current IT security requirements to accommodate the truncated development time (60 days). This increases the potential risks of either operational or security platform failure.

A high-level timeline for conference program planning follows.

#### **Program Planning Timeline:**

- Contracting with a meeting planner: we have the option to renew the previous contract. If we choose not to renew the contract, we need 6-8 weeks to secure a new planner. (RFP should be posted for 4 weeks, 2-4 weeks to evaluate, interview, sign contract).
- Developing and releasing an RFP for hotel venues in Austin, the Metroplex, Houston and San Antonio: 3 months (30-day RFP review by Comptroller's Office before publication, post for 30 days, and 30 days for proposal review to complete hotel selection). Having a contract in place with a meeting planner is preferred so they can assist in RFP development.

- Procuring hotel contract: Oversight Committee must approve contracts over \$100,000, approval at November 2018 meeting
- Developing registration and abstract system: 6-8 months development and testing time using a combination of in-house and contracted software developers. Development includes configuration of CPRIT's cloud platform using the existing 2012 conference registration system source code with the addition of an abstract acceptable module, integration with the *Texas.gov* credit card payment processing platform, user acceptance testing of the payment system in conjunction with the Comptroller's Office, and verification that the completed system is compliant with Payment Card Industry (PCI) standards.
- Planning program content can begin at any time and speaker invitations can begin after a conference date is determined.



**FY 2018 GRANT AWARD FUNDS AVAILABLE**

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	\$ 28,022,956	\$ 255,239,310		\$ 16,737,734	\$ 300,000,000
Appropriations Transfer to DSHS		\$ (2,969,554)		\$ 2,969,554	
Adjusted Appropriations	\$ 28,022,956	\$ 252,269,756		\$ 19,707,288	\$ 300,000,000
<b>Total Available for All Grants</b>			<b>\$ 280,292,712</b>		
<b>1% of Total Available Grant Funding</b>			<b>\$ 2,802,927</b>		
<b>Adjusted Grant Award Funding</b>	<b>28,022,956</b>	<b>\$ 249,466,829</b>			<b>\$ 277,489,785</b>

	Prevention Grants	Academic Research Grants	PD Research Grants	
<b>Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)</b>	<b>\$ 28,022,956</b>	<b>\$ 189,202,317</b>	<b>\$ 63,067,439</b>	<b>\$ 280,292,712</b>
<b>Total Available for Grant Awards Incorporating 1% Grant Funding Buffer</b>	<b>\$ 28,022,956</b>	<b>\$ 187,100,122</b>	<b>\$ 62,366,707</b>	<b>\$ 277,489,785</b>

**Announced Grant Awards**

11/29/17 Prevention Dissemination Award	\$ 294,804		\$ -	
11/29/17 AR Recruitment Awards (3)		\$ 10,000,000		
11/29/17 AR Core Facility Supplement (RP170691)		\$ 943,570	\$ -	
2/21/18 Prevention Dissemination Award	\$ 299,571			
2/21/18 Prevention Awards	\$ 12,806,002			
2/21/18 AR Recruitment Awards (5)		\$ 14,000,000		
2/21/18 Individual Investigator Research Awards		\$ 46,195,197		
5/16/18 Prevention Dissemination Award	\$ 300,000	\$ -		
5/16/18 AR Recruitment Awards	\$ -	\$ 29,986,494		
<b>Announced Grant Award Subtotal</b>	<b>\$ 13,700,377</b>	<b>\$ 101,125,261</b>	<b>\$ -</b>	<b>\$ 114,825,638</b>
<b>Grant Award Adjustments</b>				
Declined Recruit Award (MDACC-Skok) 11/2017 Slate	\$ -	\$ (6,000,000)	\$ -	\$ (6,000,000)
Declined Recruit Award (MDACC-Bose) 2/2018 Slate		\$ (2,000,000)		\$ (2,000,000)
Reduction to RP180457 for Grant Overlap		\$ (290,946)		\$ (290,946)
Declined Recruit Award (Rice-Musah) 5/2018 Slate		\$ (2,000,000)		\$ (2,000,000)
Declined Recruit Award (BCM-Xiao) 5/2018 Slate		\$ (4,000,000)		\$ (4,000,000)
Reduction to RP180553 for Grant Overlap		\$ (391,692)		\$ (391,692)
<b>Revised Grant Award Subtotal</b>	<b>\$ 13,700,377</b>	<b>\$ 86,442,623</b>	<b>\$ -</b>	<b>\$ 100,143,000</b>
<b>Available Funds as of July 23, 2018</b>	<b>\$ 14,322,579</b>	<b>\$ 100,657,499</b>	<b>\$ 62,366,707</b>	<b>\$ 177,346,785</b>

**Pending Grants-PIC Recommendations**

Prevention Awards	\$ 14,322,379	\$ -		
AR Recruitment Awards		\$ 32,000,000		
HIHR Awards		\$ 4,998,787		
Core Facility Support Awards		\$ 45,215,573		
MIR Awards		\$ 29,941,949		
PDR Awards			\$ 50,587,540	
<b>Pending Award Subtotal</b>	<b>\$ 14,322,379</b>	<b>\$ 112,156,309</b>	<b>\$ 50,587,540</b>	<b>\$ 177,066,228</b>
<b>Rebudget of Remaining PDR Target Funds to ACR</b>		<b>\$ 11,779,167</b>	<b>\$ (11,779,167)</b>	
<b>Revised Available Grant Funds</b>	<b>\$ 14,322,579</b>	<b>\$ 112,436,666</b>	<b>\$ 50,587,540</b>	
<b>Total Potential Grant Funding Committed</b>	<b>\$ 28,022,756</b>	<b>\$ 198,598,932</b>	<b>\$ 50,587,540</b>	<b>\$ 277,209,228</b>
<b>Potential Available Funds as of August 25, 2018</b>	<b>\$ 200</b>	<b>\$ 280,357</b>	<b>\$ -</b>	<b>\$ 280,557</b>
<b>1% Grant Funding Buffer</b>	<b>\$ -</b>	<b>\$ 2,102,195</b>	<b>\$ 700,732</b>	<b>\$ 2,802,927</b>
<b>Total Remaining Funds</b>	<b>\$ 200</b>	<b>\$ 2,382,552</b>	<b>\$ 700,732</b>	<b>\$ 3,083,484</b>

**Operating Budget Detail**

Indirect Administration		\$ 3,030,652
Grant Review & Award Operations		\$ 13,707,082
Subtotal, CPRIT Operating Costs		\$ 16,737,734
Cancer Registry Operating Cost Transfer		\$ 2,969,554
Total, Operating Costs		\$ 19,707,288



**CPRIT MANAGEMENT DASHBOARD  
FISCAL YEAR 2018**

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
<b>ACCOUNTABILITY</b>														
Announced Grant Awards	0		4			57			9				70	
New Grant Contracts Signed	9	19	7	11	6	44	2	35	12	4	5		154	
New Grant Contracts In Negotiation			12			24			8				44	
Grant Reimbursements Processed (#)	191	172	138	120	126	216	174	163	193	208	138		1,839	
Grant Reimbursements Processed (\$)	\$ 14,402,580	\$ 24,849,514	\$ 12,652,218	\$ 16,464,363	\$ 12,888,800	\$ 15,287,606	\$ 30,698,463	\$ 20,199,295	\$ 13,292,876	\$ 19,226,586	\$ 22,476,261		\$ 202,438,562	
Revenue Sharing Payments Received	\$ 1,500	\$ 35,140	\$ 7,557	\$ -	\$ 21,969	\$ -	\$ 6,298	\$ 18,165	\$ -	\$ 64,631	\$ -		\$ 155,260	\$ 3,389,476
Total Value of Grants Contracted (\$)	\$ 11,469,175	\$ 30,088,458	\$ 9,750,000	\$ 16,294,571	\$ 10,138,500	\$ 23,821,567	\$ 6,200,000	\$ 37,619,680	\$ 20,798,445	\$ 4,600,994	\$ 7,794,086		\$ 178,575,476	
Grants Awarded (#)/ Applications Rec'd (#)	13%	13%	13%	13%	12%	13%	13%	13%	13%	12%	12%			
Debt Issued (\$)/Funding Awarded (\$)	73%	73%	72%	72%	72%	70%	75%	75%	75%	75%	78%			
Grantee Compliance Trainings/Monitoring Visits	0	1	0	0	1	1	4	6	5	10	9		37	
Awards with Delinquent Reimbursement Submission (FSR)			1			1			0					
Awards with Delinquent Matching Funds Verification			8			19			0					
Awards with Delinquent Progress Report Submission			7			3			1					
IA Agency Operational Recommendations Implemented	0	0	0	0	0	3	0	0	11	0	7		21	
IA Agency Operational Recommendations In Progress	24	24	24	24	24	21	21	21	10	10	3			
Open RFAs	6	7	7	12	12	9	4	4	9	16	10			
Prevention Applications Received	38	4	0	1	0	31	1	0	0	1	0		76	792
Product Development Applications Received	0	0	0	0	0	20	0	0	0	0	0		20	422
Academic Research Applications Received	2	2	5	1	208	8	9	12	6	406	3		662	6,675
Help Desk Calls/Emails	161	192	121	132	285	243	189	125	230	147	212		2,037	
<b>MISSION</b>														
<b>ACADEMIC RESEARCH PROGRAM</b>														
Number of Research Grants Announced (Annual)	0		3			49			8				60	
Recruited Scientists Announced														205
Recruited Scientists Accepted														158
Recruited Scientists Contracted														153
Published Articles on CPRIT-Funded Projects (#)														
Jobs Created & Maintained (#)														
Trainees in CPRIT-Funded Training Programs (#)														
Clinical Trials (#)														71
Number of Patents Resulting from Research														

**CPRIT MANAGEMENT DASHBOARD  
FISCAL YEAR 2018**

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Patent Applications														
Number of Investigational New Drugs														
<b>PRODUCT DEVELOPMENT RESEARCH PROGRAM</b>														
Number of Product Development Grant Announced (Annual)			0			0			0				0	
Life Science Companies Recruited (in TX)														9
Published Articles on CPRIT-Funded Projects														
Number of Jobs Created & Maintained														515
Clinical Trials (#)														15
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
<b>PREVENTION PROGRAM</b>														
Number of Prevention Grants Announced (Annual)			1			8			1				10	
People Served by CPRIT-Funded Prevention and Control Activities			282,167			218,357			239,125				739,649	
People Served through CPRIT-Funded Education and Training			201,481			111,558			142,772				455,811	
People Served through CPRIT-Funded Clinical Services			80,686			106,799			96,353				283,838	
<b>TRANSPARENCY</b>														
Total Website Hits (Sessions)	5,959	5,881	5,928	5,613	7,209	6,655	5,736	5,671	8,299	5,705	5,020		67,676	
Total Unique Visitors to Website (Users)	4,359	4,234	4,305	4,417	4,773	4,657	4,281	4,114	5,771	4,218	3,722		48,851	



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

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**MEMORANDUM**

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**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER  
**SUBJECT:** CPRIT MAY AND JUNE ACTIVITIES UPDATE  
**DATE:** JUNE 29, 2018

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Topics in this memo cover the period May 2018 through the end of June and include recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, upcoming American Cancer Society Cancer Action Network events highlighting CPRIT's prevention activities, and updates from Compliance, Programs, Legal and Regulatory, and Operations.

**Recent Milestones in the Fight Against Cancer**

CPRIT Grantees in the News

- CPRIT grantee Dr. Ralph DeBerardinis, Professor of Pediatrics at The University of Texas Southwestern Medical Center (UTSW), has been selected as a Howard Hughes Medical Institute (HHMI) Investigator. His selection makes him one of a select group of 19 distinguished biomedical scientists named HHMI Investigators this year; UTSW now has 15 HHMI investigators. HHMI is a philanthropic organization advancing basic biomedical research and science education for the benefit of humanity. Each of the new investigators receives \$8 million over a seven-year term, which is renewable pending a scientific review.

Dr. DeBerardinis' research on cancer metabolism opens new avenues for the study of potential therapeutics as well as new imaging techniques for cancer. He received one of the first CPRIT grants in 2010 and subsequently holds three additional CPRIT awards. As Dr. DeBerardinis writes, "Funding from CPRIT has been a major factor in my development as an independent scientist. I was fortunate to receive one of the very first CPRIT grants as an Assistant Professor. Progress on that award led to additional CPRIT research awards and I have been able to leverage CPRIT funding into several new grants including NCI and the HHMI award."

- The esteemed scientific journal *Nature* has ranked UTSW the top health care institution for its output of published research for the third year in a row. The rankings are based on the number of publications appearing in 82 leading journals in the past year. UTSW has led the list specific to health care institutions since *Nature* began its rankings in 2016. UTSW ranks 15<sup>th</sup> for output in the life sciences among all (world-wide) academic institutions. Joining UTSW in the top ten, *Nature* ranked The University of Texas MD Anderson Cancer Center seventh in the list specific to health care institutions.

- An [op-ed piece](#) in the *Bryan/College Station Eagle* published May 4 highlights the work of Texas A&M University's multiple CPRIT-funded cancer screening projects led by Drs. David McClellan and Jane Bolin.
- A *Baylor College of Medicine News* [story](#) about HPV-related cancers on June 7 features two of CPRIT's Prevention program multi-award recipients at Baylor College of Medicine, Dr. Matthew Anderson and Dr. Maria Jibaja-Weiss.

### Notable CPRIT Supported Research and Prevention Accomplishments

- UTSW researchers published blueprints of the brain nicotinic acetylcholine receptors in the journal *Nature* (*Nature* 557:261-265, 2018). A structural understanding of the nicotinic receptor, found in neurons, could lead to new ways to treat nicotine addiction from smoking and vaping. Researchers obtained the high-resolution structures necessary to reveal the protein's structure using the CPRIT supported cryo-electron microscopy (cryo-EM) facility, where samples are rapidly frozen to prevent the formation of damaging ice crystals and then viewed at minus 321 degrees Fahrenheit (cryogenic temperatures). The facility is one of the world's top facilities for cryo-EM structural biology, a technology revolutionizing life science research that was the subject of a 2017 Nobel prize.
- CPRIT grantee Dr. Beth Levine, Professor of Internal Medicine at UTSW, reports in the journal *Nature* (*Nature* 10.1038, 2018) that mice with persistently increased levels of autophagy - the process a cell uses to dispose of unwanted or toxic substances that can harm cellular health - live longer and are healthier. Dr. Levine and her colleagues discovered beclin 1, which is a key gene in the biological process of autophagy. The group's research has since shown that autophagy is important in many aspects of human health, such as preventing neurodegenerative diseases, combating cancer, and fighting infection.
- Clinical investigators from MD Anderson report in the journal *Nature Medicine* (*Nat Med.* 24:638-646, 2018) on early clinical trial results in a previously untreatable form of lung cancer. Preclinical research, funded in part by CPRIT, provided the scientific underpinning for current clinical trials testing the drug poziotinib. Scientists are testing the drug against non-small-cell lung cancer that has a specific alteration, called an exon 20 insertion, in either the epidermal growth factor receptor (EGFR) or the human epidermal growth factor receptor. Early clinical trial results that show 7 of 11 patients with EGFR exon 20 mutations have tumor shrinkage after poziotinib treatment.
- CPRIT grantee James Amatruda, M.D., Ph.D., Associate Professor Pediatrics, UTSW, reports in the journal *eLife* on the development of a zebrafish model for rhabdomyosarcoma, a childhood cancer of skeletal muscle. Knowing that a genetic error resulting in an abnormal gene called PAX3-FOXO1 causes rhabdomyosarcomas, Dr. Amatruda inserted the human gene PAX3-FOXO1 into the zebrafish DNA. He found that rhabdomyosarcomas like the human disease formed in zebrafish. Dr. Amatruda discovered that the PAX3-FOXO1 gene causes the cancers by turning on another gene, HES3, leading to overproduction of the

skeletal muscle precursor cells. The zebrafish model of rhabdomyosarcoma is important because it has identified a new target for drug discovery that could slow the tumor's growth without exposing the patient's normal tissue to side effects from chemotherapy and radiation.

- Aravive Biologics, Inc. announced that the company completed the single ascending dose portion of their ongoing Phase 1 study (32 subjects). The study objective is to evaluate safety, pharmacokinetics, and pharmacodynamics for their lead candidate, AVB-S6-500, as well as to demonstrate proof-of-mechanism in decreasing free circulating GAS6 in serum. GAS6 is an important tumor-signaling agent in multiple cancers. Aravive is developing novel therapies to inhibit GAS6 proliferation in tumor cells. This study successfully demonstrated clinical proof-of-mechanism for AVB-S6-500 in neutralizing GAS6. Aravive expects to complete the repeat-dose portion of the study during and will present full results of the trial at a major medical meeting later in 2018.

In addition, the company announced an agreement to merge with Versartis, Inc. The boards of both companies have approved this all-stock transaction. The merger provides additional financial and leadership personnel to support Aravive Biologics as it moves forward into clinical trials. The company will remain headquartered in Houston. After the merger, Aravive will trade on the Nasdaq exchange. Aravive received a \$20 million Product Development Award from CPRIT in November 2015.

- OncoNano Medicine, Inc. announces the closing of an \$11.7 million Series A financing. Salem Partners arranged the transaction and participated as a principal investor. The company will use the funding to support the continued clinical development of a new class of pH-activated compounds. The company's first program is ONM-100, an injectable imaging agent that targets the acidic pH within tumors to accurately distinguish cancer cells from healthy tissue during surgery. ONM-100 aims to eliminate the guesswork often associated with the removal of tumors by providing surgeons with an easier and more effective method to assess lymph nodes and tumor margins in real time during surgery. OncoNano received a \$6 million Product Development Award from CPRIT in August 2014.
- DNATRIX reports that preliminary findings demonstrate the company's oncolytic virus DNX-2401 can be injected safely in pediatric patients during a biopsy procedure with minimal side effects. Evidence for clinical activity has been observed. DNATRIX is conducting a Phase 1 clinical trial of DNX-2401 in pediatric patients with newly diagnosed diffuse intrinsic pontine gliomas (DIPG). DIPG is a rare, aggressive, infiltrative tumor of the brainstem with the worst prognosis of any pediatric cancer. No effective treatments are available and novel treatment approaches are needed.
- A cost benefit analysis of the young adult smoking cessation program headed by Dr. Amelie Ramirez of The University of Texas Health Science Center at San Antonio reports 800 life years and 1,056 quality-adjusted life years gained due to not smoking. In addition, the analysis projects the cost savings to individuals of not smoking to be \$65 million over their lifetime and \$9.5 million in health care cost savings.

- Sustainability and systems change are important components of CPRIT Prevention awards. Both the John Peter Smith and Parkland safety-net health systems committed internal funding to continue a now-closed CPRIT-funded tumor screening program to identify genetic mutations. This screening program originated at UTSW by Dr. Keith Argenbright.

## Personnel

CPRIT has 35 authorized full-time equivalent (FTE) positions, 34 of which CPRIT has filled.

- Melanie Cleveland has permanently replaced the temporary contract worker as Executive Assistant.
- We are in the process of filling the vacant Grant Compliance Specialist position.

## CPRIT Outreach

- On May 1 Presiding Officer Will Montgomery gave a keynote address at the Texas Healthcare and Bioscience Institute (THBI) annual meeting concerning CPRIT's momentum and keeping the state's competitive edge in cancer research and prevention. THBI is the state's largest trade association for the life sciences industry. Chief Product Development Officer Michael Lang, Deputy Executive Director Kristen Doyle, Program Manager for Product Development Rosemary French, and I attended the conference.
- The Houston City Council adopted a proclamation on May 15 decreeing May 2018 as National Cancer Research Month in Houston. The University of Texas MD Anderson Cancer Center, Baylor College of Medicine's Dan L. Duncan Comprehensive Cancer Center, University of Houston, The University of Texas Health Science Center at Houston, Houston Methodist Research Institute, Rice University, and The University of Texas Medical Branch at Galveston were all recognized for their advances in cancer research through CPRIT support. Institutional representatives made comments and praised CPRIT's contributions to enhancing the state's national standing in cancer research. I also made brief comments acknowledging the institutions' work in fulfilling CPRIT's mission. Chris Cutrone, Senior Communications Specialist, and Spencer Miller-Payne, Information Specialist, also attended. Mr. Cutrone and Mr. Miller-Payne distributed information about the event via social media.
- On May 30 I attended a luncheon celebration of Senator Kirk Watson's contributions to the founding of the Dell Medical School hosted by the Livestrong Cancer Institute. Speakers emphasized the progress made in cancer research. Several CPRIT scholars and researchers with CPRIT grants attended the event.
- Ms. French attended Baylor College of Medicine's THINC@BCM Symposium 2018: "Therapeutics of Gene Regulation" on May 31 – June 1. The Therapeutic Innovation Center's (THINC) goal is to further the understanding of diseases of RNA and chromatin biology.

- Mr. Lang and I attended the annual international Biotechnology Innovation Organization (BIO) conference in Boston June 4 - 7. BIO represents 1,100 biotech companies, academic institutions, state biotech centers, and related organizations across the United States and more than 30 other nations. More than 18,000 people attended the conference. We shared space in the Texas booth sponsored by the Texas Healthcare and Bioscience Institute, the Governor's Office of Economic Development and Tourism, and the Texas Economic Development Corporation. I gave invited presentations about CPRIT at two different events for BIO attendees interested in Texas opportunities. Mr. Lang and I also conducted numerous one-on-one meetings with biotech company representatives throughout the three days. CPRIT will participate in the 2019 BIO conference in Philadelphia June 3 - 6, 2019. Communications staff provided updates about CPRIT's activities at BIO via social media.
- Mr. Lang and Ms. French met with several prospective Houston-area Seed Award applicants on June 11 at JLABS' Houston office. Part of Johnson & Johnson Innovations, the JLABS Houston site is the largest JLABS footprint in the country with over 34,000 square feet of common, wet lab, and office space.
- Chief Prevention Officer Dr. Becky Garcia and Senior Manager for Prevention Programs Ramona Magid attended the American Cancer Society's (ACS) launch of their National HPV campaign, "Mission: HPV Cancer Free" June 12. CPRIT supported ACS's effort by distributing information on the ACS campaign through CPRIT's social media. CPRIT also re-released a video with Dr. Garcia on the importance of vaccinations for children and cervical cancer screening for women.
- Mr. Lang and Ms. French attended the BioAustin Spring 2018 BioBash networking event on June 12.
- Mr. Lang attended the Santé Ventures annual meeting and networking event in Austin on June 15. Santé Ventures is a venture capital group based in Austin that invests in life sciences companies.
- I met with staff of Representative Zerwas on June 20 to discuss agency operations and plans for the 86<sup>th</sup> Texas Legislature that convenes in January 2019.
- On June 20 Mr. Lang and Ms. French presented information on the Seed Award at the Dell Medical School in Austin and held one-on-one meetings with potential applicants.
- On June 26 I met with staff of Senator Nelson to discuss agency operations and plans for the 86<sup>th</sup> Texas Legislature.
- I met with Representative Michael Schofield on June 27 to discuss agency operations and plans for the 86<sup>th</sup> Texas Legislature.
- On June 28 Chris Cutrone, Senior Communications Specialist and I met with staff of Senator Schwertner to discuss agency operations and plans for the 86<sup>th</sup> Texas Legislature.

## **Upcoming American Cancer Society Cancer Action Network Events Featuring CPRIT**

The American Cancer Society's Cancer Action Network (ASC CAN) will hold three events in August highlighting CPRIT activities. This is the third year that ASC CAN has featured CPRIT in its annual policy forum series, which are well attended by legislators and the advocate community around Texas. This year ACS CAN will feature CPRIT's prevention program and early detection work. Dr. Garcia will speak at each of the events, as will area legislators, program directors for CPRIT-funded prevention projects, and Texans that have benefitted from the prevention services. ACS CAN invites Oversight Committee members to attend any or all of presentations listed below:

- **Austin** at the Texas Medical Association - August 21, 2018, 7:30 a.m. – 9:00 a.m.
- **Fort Worth** at the Moncrief Cancer Institute - August 24, 2018, 8:00 a.m. – 9:30 a.m.
- **San Antonio** - either August 29 or 30, 2018, 7:30 a.m. – 9:00 a.m. (waiting for confirmation on the venue site and date)

In addition to these policy forums, ACS CAN is planning an event in College Station in September or October with a mix of legislators and CPRIT beneficiaries including research, product development, and prevention grantees. ACS CAN will also host the "ACS CAN Texas Research Breakfast" in late October in Houston. NBC correspondent Janet Shamlian will emcee the event and Texas A&M Chancellor John Sharp will be the guest of honor for his role in establishing CPRIT. We will keep you updated on all these events.

## **Compliance Program Update**

### Submission Status of Required Grant Recipient Reports

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

As of June 18, 2018, four entities have not filed four required reports by the due date; two missing reports (50%) were for Product Development Research grants and two (50%) were for Academic Research grants. CPRIT's grant accountants and grant compliance specialists continue to review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

### Financial Status Report Reviews

CPRIT's Grant Compliance Specialists performed 190 second-level reviews of grantee Financial Status Reports (FSRs) for the month of May. CPRIT completed 592 reviews for the quarter ending in May 31. Sixteen FSRs (8%) 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.

### 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 \$750,000 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 entity must submit the independent audit report listing the findings to CPRIT within 30 days of the grantee's receipt, but no later than 9 months after the grantee's fiscal year.

Grant Compliance Specialists are working with one grantee to remediate audit findings. CPRIT allows grantees 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there are no grantees with delinquent audits. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

CPRIT recently revised the Annual Single Audit Determination (SAD) form process. Grantees will now complete one form for their institution annually and submit the completed form to CPRIT via email. Prior to this change, the grantee completed a SAD form for each active grant held by the grantee and submitted each through CPRIT's grants management system. The due date for all future SAD forms will be 60 days after the organization's fiscal year end date. As of May 31, 2018, 47 grantees have submitted their updated SAD forms to CPRIT. Agency staff will follow up with the remaining three grantees that have not submitted their SAD form.

### Desk Reviews

Grant Compliance Specialists performed 15 desk-based financial monitoring/reviews in May to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Grant Compliance Specialists are working with one grantee to remediate desk review findings.

### On-Site Reviews

Grant Compliance Specialists performed five on-site reviews in May. On-site reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance.

### Annual Compliance Attestation (Self-Certification)

CPRIT requires grantees to submit an annual self-certification by December 31<sup>st</sup> demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, the grant contract, and Uniform Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Grant Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. All grantees have submitted their 2018 Attestation form to CPRIT. Compliance staff are working with one grantee who required corrective action related to their attestation.

## Training and Support

CPRIT staff conducted a Grantee training webinar on June 6, 2018. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the second training offered this year in support of the 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. More than 100 grantee staff attended the webinar, with 44 Grantees fulfilling their annual training requirements. CPRIT will schedule a third Grantee training for October.

CPRIT has scheduled two new ASO trainings: one with UT San Antonio and the second with Baylor University. New ASO training covers grant reporting requirements, administrative rule changes, grant closeout, an overview of the compliance program including fraud, waste, and abuse reporting, and a hands-on navigation of CPRIT's grants management system. CPRIT requires new ASOs to complete compliance training within 60 days of the change

## **Academic Research Program Update**

### FY 2018 Cycle 2 (18.2) RFAs Update

Applicants submitted 200+ proposals for FY 2018 Cycle 2 (18.2) grant awards. CPRIT conducted peer review May 18 – 25 in Grapevine. Dr. Willson will present the Scientific Review Committee's recommendations to the Program Integration Committee (PIC) and Oversight Committee in August.

Table 1: FY2018.2 Application Submissions by Mechanism

Mechanism	Number Received	Total Funds Requested
Core Facility Support Awards	27	\$134,701,329
High Impact/High Risk Awards	153	\$30,331,245
Multi-Investigator Research Awards	23	\$135,215,282
<b>TOTAL</b>	<b>203</b>	<b>\$300,247,856</b>

### FY 2019 Cycle 1 (19.1) RFAs Update

Academic research institutions submitted more than 400 proposals for the FY 2019 Cycle 1 (19.1) awards. CPRIT will convene the peer reviewers in Dallas October 18 - October 25. Dr. Willson will present recommendations to the PIC and Oversight Committee in February 2019.

Table 2: FY 2019.1 Application Submissions by Mechanism

Mechanism	Number Received	Total Funds Requested
Individual Investigator Research Award (IIRA)	268	\$233,976,917
IIRA for Cancer in Children and Adolescents	37	\$44,382,130
IIRA for Clinical Translation	33	\$52,321,758
IIRA for Computational Biology	27	\$20,580,933
IIRA for Prevention and Early Detection	36	\$34,294,805
<b>Total</b>	<b>401</b>	<b>\$385,556,543</b>

### Recruitment Summary Data

CPRIT received 17 recruitment applications during recruitment cycles 18.10 and 18.11. Dr. Willson will present the recommendations to the PIC and Oversight Committee in August.

Table 3: Summary of Recruitment Application Submissions for Cycles 18.10 and 18.11

Mechanism	Number Received
Recruitment Established Investigators	3
Recruitment Rising Stars	3
Recruitment of First-Time Tenure Track Faculty Members	11
<b>TOTAL</b>	<b>17</b>

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

#### Product Development Research FY 2018 Cycle 2

CPRIT opened the Product Development Award FY 2018 Cycle 2 to receive applications from December 22, 2017, through February 7, 2018. Twenty companies submitted applications for peer review. CPRIT's peer reviewers met March 26 and 27 and invited 10 companies to present at the in-person peer review panel meeting held April 23 - 26, 2018. Following the presentations in April, the peer review panel meeting selected six applicants to proceed to due diligence. Technical, commercial, and intellectual property due diligence is underway for these six firms by our diligence service providers. The Product Development Review Council (PDRC) will meet in July to evaluate the due diligence information and make recommendations for grant awards. Mr. Lang will present the PDRC recommendations to the PIC and Oversight Committee in August.

## Product Development Research Applications FY 2019 Cycle 1

The Oversight Committee approved the schedule and RFA topics for the Product Development FY 2019 Award Cycle 1 at the February 21 meeting. CPRIT released three RFAs (Texas Company Product Development Award, Company Relocation Product Development Award, the new Seed Award for Product Development Research) on May 17. CPRIT will accept applications June 28 through August 8, 2018. Mr. Lang will present applications recommended for grant awards to the PIC and the Oversight Committee in February 2019 for approval.

The new Seed Award, together with the modified Early Translation Research Award (ETRA), bridge research funding opportunities between current academic and product development programs. An extensive outreach campaign is underway to build awareness of both the ETRA and Seed programs with potential applicants. Mr. Lang and Ms. French are engaging with regional and statewide trade associations, public policy groups, biotech incubators, investment groups, and academic tech transfer offices to raise awareness of these funding opportunities among potential applicants.

### **Prevention Program Update**

#### FY 2018 Cycle 2 (18.2) Prevention Applications

CPRIT released three RFAs in November 2017 for the second review cycle of FY 2018. Peer review panels met May 22 - 25 to evaluate the 31 FY18.2 prevention applications requesting \$51,031,896 (see table below). The Prevention Review Council (PRC) will meet July 6 to make award recommendations to the PIC. Dr. Garcia will present the PIC recommendations to the Oversight Committee in August.

Table 4: Summary of FY 18.2 Prevention Application Submissions

<b>Mechanism</b>	<b>Number Received</b>	<b>Total Requested</b>
Evidence-based Cancer Prevention Services	13	\$17,537,453
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	9	\$21,645,686
Tobacco Control and Lung Cancer Screening	9	\$11,848,757
<b>TOTAL</b>	<b>31</b>	<b>\$51,031,896</b>

CPRIT received one application this quarter for the Dissemination of CPRIT-Funded Cancer Control Interventions mechanism. The PRC will review the application on July 20 and forward their recommendation to the PIC. Dr. Garcia will present the PIC recommendation to the Oversight Committee in August.

## FY 2019 Cycle 1 Prevention RFAs

CPRIT released four FY 2019 Cycle 1 RFAs on May 10 that the Oversight Committee previously approved. Applications are due on September 5. CPRIT has scheduled peer review for December 10-13, 2018. Dr. Garcia will present the PIC recommendations to the Oversight Committee in February 2019.

## Other activities

Prevention program staff continue to work with Dr. Jennifer Knight on drafting the *2018 Texas Cancer Plan*. A workgroup from the Cancer Alliance of Texas recently provided feedback and the final draft is being prepared.

## **Communications Update**

### Cancer Awareness Months

- Communications staff are in the planning stages for Childhood Cancer month in September, Breast Cancer Awareness month in October, and Lung Cancer Awareness month in November.

### Social Media Metrics

Facebook (last 28 days):

- Reach: 1,787
- Engagement: 564
- Most popular post: “On May 15, 2018, cancer researchers and representatives from MD Anderson Cancer Center, Baylor College of Medicine, UTHealth and University of Houston joined Sylvester Turner, Mayor of Houston and Mayor Pro Tem Ellen Cohen as the Houston City Council recognized National Cancer Research Month and the contributions Houston institutions at the Texas Medical Center make in the field of cancer research with the support of CPRIT. #NCRM18 #ResearchSavesLives”

Twitter (May):

- 15,900 impressions
- Top tweet: “Thank you @SylvesterTurner and @EllenCohen1 for recognizing #NCRM18 and the contributions @MDAndersonNews, @bcmhouston, @UTHealth, @UHouston and other Houston institutions make in the field of cancer research. #ResearchSavesLives”

## **Legal and Regulatory**

On June 22 the Governor’s Office instructed all state agencies to send to them for their review any proposed rule prior to publication in the *Texas Register*. The review requires certain information and seven specific analyses. The instructions do not say whether their “approval” is necessary prior publication. This could mean that once we send the required analyses to them we can immediately proceed with *Texas Register* publication.

Staff is reviewing the impact of these instructions, but I expect them to add workload and possible delays in rules modification necessary to address grantee issues arising from our existing specific statutory requirements concerning program and agency operations.

Some clarification is needed from the Governor's Office. However, CPRIT will comply with the instructions once clarified.

### **Operations, Audit and Finance Update**

CPRIT's *Agency Strategic Plan for 2019-2023* was submitted to the Governor's Office, Lieutenant Governor's Office, Speaker's Office, Legislative Budget Board, State Auditor's Office, and Sunset Commission on June 7 (due date was June 8).

On June 22, the Governor's Office and Legislative Budget Board released instructions for the 2020-21 Legislative Appropriations Request (LAR). The format of and information required in the LAR remains relatively unchanged from two years ago although there is an additional schedule required of all state agencies about savings realized in the 2018-19 biennium from reducing printing for general office administration and publications.

The Weaver audit team completed the Follow-up Procedures Over the Purchasing and P-Card Audit Report and the Communications Audit Report. They also completed field work on the follow-up items for the Information Security Audit, which is the last audit for FY 2018.

### **Upcoming Subcommittee Meetings**

There is a special Audit Subcommittee scheduled for July 26 at 11:00 a.m.

Listed below are the regularly scheduled subcommittees in advance of the August 15, 2018, Oversight Committee meeting.

Board Governance	August 2 at 10:00 a.m.
Audit	August 6 at 10:00 a.m.
Prevention	August 7 at 10:00 a.m.
Academic Research	August 8 at 10:00 a.m.
Product Development	August 9 at 10:00 a.m.
Nominations	August 10 at 10:30 a.m.

CPRIT will send an agenda, call-in information, and supporting material to the subcommittees one week prior to the meeting date.

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CPRIT has awarded **1,255** grants totaling **\$1.982 billion**

- 199 prevention awards totaling \$208.8 million
- 1,056 academic research and product development research awards totaling \$1.774 billion

Of the \$1.774 billion in academic research and product development research awards,

- 28.8% of the funding (\$510.0 million) supports clinical research projects
- 26.0% of the funding (\$461.4 million) supports translational research projects
- 27.1% of funding (\$480.1 million) supports recruitment awards
- 14.7% of the funding (\$262.2 million) supports discovery stage research projects
- 3.4% of funding (\$59.9 million) supports training programs.

CPRIT has 10 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Product Development Research
- 4 Prevention



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

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**MEMORANDUM**

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**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER  
**SUBJECT:** CPRIT ACTIVITIES UPDATE JULY 2018  
**DATE:** JULY 30, 2018

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Topics in this memo cover the month of July 2018 and include preparation for the August 15, 2018, Oversight Committee meeting, recent milestones in our fight against cancer, CPRIT outreach efforts, upcoming American Cancer Society Cancer Action Network events highlighting CPRIT's prevention activities, the 2018 Texas Cancer Plan, Texas Public Finance Authority and Bond Review Board meetings to approve CPRIT bonds, a staffing summary, and updates from Compliance, Programs, and Operations.

**Upcoming Oversight Committee Meeting**

The Oversight Committee will meet August 15, 2018, at 10:00 a.m. in Room E1.012 of the Texas Capitol Extension. CPRIT will post the final agenda for the Oversight Committee meeting by August 7; a tentative agenda is attached. We have six members of the Oversight Committee and do not expect new appointments before the August meeting. A quorum of five members is necessary to conduct official business. **Please notify me as soon as possible if you are unable to attend the August meeting or have travel arrangements that will cause you to arrive late or leave the meeting early.**

You will receive an email from CPRIT by August 3 with a link and password to access the Program Integration Committee's award 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. We expect that the Oversight Committee will consider more than 40 award recommendations at the August meeting; please allow some time to complete the individual conflict of interest checks and review the supporting material.

Oversight Committee members will receive an electronic copy of the agenda packet by August 8. Hard copies of the agenda packet will be available at the meeting.

## Recent Milestones in the Fight Against Cancer

### CPRIT Grantees in the News

- The Board of Trustees of Baylor College of Medicine (BCOM) has named CPRIT grantee Dr. Bert O'Malley, longtime chair of the BCOM Department of Molecular and Cellular Biology, as chancellor of the College, effective July 1. Considered the “founding father” of the field of molecular endocrinology, O'Malley is a member of the National Academy of Sciences and the National Academy of Medicine. He won the National Medal of Science in 2007, accepting it in a ceremony at the White House in 2008. He has received more than 65 honors and science prizes in his career.
- Immatics Biotechnologies announced a research collaboration and license agreement with Genmab A/S (Nasdaq Copenhagen: GEN) to develop next-generation, T-cell engaging bispecific immunotherapies targeting multiple cancer indications. Immatics is a clinical-stage biopharmaceutical company active in the discovery and development of T-cell redirecting (TCR) immunotherapies for the treatment of cancer. The company is developing two platform technologies – Adoptive Cell Therapies and Bispecific TCR molecules. These products target tumors that have been identified and validated by Immatics' proprietary XPRESIDENT® technology. Immatics licensed their core technology from MD Anderson Cancer Center.

As part of the collaboration, Immatics and Genmab will conduct joint research, funded by Genmab, to combine Immatics' XPRESIDENT® and Bispecific TCR technology platforms with Genmab's proprietary antibody technologies to develop multiple bio specific immunotherapies in oncology. The companies will exclusively discover and develop immunotherapies directed against three proprietary targets. Under the terms of the agreement, Immatics will receive an upfront fee of \$54 million plus development, regulatory and commercial milestone payments for each product, and royalty payments once commercialized. Genmab has the option to exclusively license up to two additional targets. Immatics received a \$19.7 million CPRIT Product Development Research award in February 2015.

- Medicenna Therapeutics announced that the U.S. Patent and Trademark Officer issued a Notice of Allowance related to the company's MDNA57 program. The Patent Office sends the Notice of Allowance after the patent examiner decides to issue the requested patent. MDNA57 targets the IL-4 receptor, which is frequently expressed by more than 20 types of cancers and associated with poor survival outcomes in various cancers including bladder, mesothelioma, and pancreatic cancer. MDNA57 is the next generation version of Medicenna's lead clinical candidate MDNA55, which is currently in Phase 2 clinical trials for recurrent glioblastoma (rGBM). CPRIT funds development of MDNA55. The company has studied MDNA55 in three clinical trials involving 72 patients with rGBM, a uniformly fatal form of brain cancer. The company reports that it has shown compelling indications of superior efficacy to the current standard of care.

- The Centers for Disease Control and Prevention's (CDC) Office on Smoking and Health selected the University of Houston's tobacco cessation project led by Dr. Lorraine Reitzel for inclusion in an article, "Tobacco Cessation Interventions and Smoke-Free Policies in Mental Health and Substance Abuse Treatment Facilities — United States, 2016," appearing in the CDC's *Morbidity and Mortality Weekly Report* (May 11, 2018 / 67(18); 519–523.) Dr. Reitzel's prevention project was also selected as an example of a successful tobacco cessation project and is highlighted on the CDC [website](#).

#### Notable CPRIT Supported Research and Prevention Accomplishments

- An early translation research project led by Dr. John Hancock at The University of Texas Health Science Center at Houston identified a promising lead compound that selectively stopped the growth of KRAS-transformed pancreatic, colon, and endometrial cancer cells. This CPRIT funded research, reported online in the *Journal of Biological Chemistry*, is notable because past efforts to target the RAS protein, which is responsible for a substantial portion of common cancer, has eluded scientists.
- CPRIT grantee Dr. James Chen, Howard Hughes Medical Institute Investigator and Professor of Molecular Biology at The University of Texas Southwestern Medical Center has continued to make important advances in his seminal research on how the body's innate immune system is activated. The journal *Science* reported Dr. Chen's latest finding, which was supported in part by a CPRIT Individual Investigator Research Award. It is important because the innate immune system guards the body against threats it first encounters and a detailed understanding of the pathway promises to enable the design of new immunotherapy drugs for cancer and other diseases.
- Rosa Uribe, Ph.D., who Rice University recruited in 2017 with a CPRIT Scholar award, created a zebrafish that produces fluorescent tags in migratory embryonic neural crest cells (nerve precursor cells). The journal *Genesis* reports that Dr. Uribe uses the zebrafish model to search for the origins of neuroblastoma, the third-most common pediatric cancer in the United States. She observed "Our work on neuroblastoma could only happen with the support of CPRIT."
- DNATRIX announced updated clinical study results. Initial clinical studies indicate that clinicians can safely administer the company's lead compound, DNX-2401, to the pons in the brainstem of pediatric patients with minimal side effects. The company reported: "We have treated six pediatric [diffuse intrinsic pontine glioma (DIPG)] patients with DNX-2401 and observed no grade 3 or 4 adverse events, indicating that this a safe therapy for pediatric patients with brain tumors. Based on these results, we intend to test DNX-2401 in a range of brain tumors that affect children. DNX-2401 can be delivered safely via cannula directly into the pontine glioma, which circumvents the challenge of drugs failing to reach the target. Early results are encouraging."

The company also reports results from new preclinical studies demonstrating the synergistic antitumor activity of DNX-2401 and radiation in animal models of high grade glioma and

DIPG. DIPG, also known as diffuse midline glioma, is a rare and aggressive infiltrative tumor of the brainstem with the worst prognosis of any pediatric cancer. No effective treatments are available, and clinicians need novel treatment approaches. Prior research of DNX-2401, in adult DIPG patients with recurrent glioblastoma, demonstrated prolonged survival while maintaining a favorable safety profile. DNATRIX received a \$10.8 million CPRIT Product Development Research award in February 2014.

- MHP Salud and Nuestra Clinica del Valle reached over 7,000 colonia residents from Cameron county in the Rio Grande Valley with education on breast, cervical and colorectal cancer. The program screened 2,292 for breast, 1,170 for cervical and 1,191 for colorectal cancers. The screenings detected 39 breast cancers, 6 cervical cancers and 12 colorectal cancers. Without this program and CPRIT funding, these colonia residents would not have been screened or had their cancers detected. The Medicaid Breast and Cervical Cancer Program, Hidalgo County Indigent Program and the Doctors Hospital at Renaissance provided medical care and treatment at low to no cost for those receiving cancer diagnoses.

### **CPRIT Outreach**

- On July 9 Chief Scientific Officer Dr. Jim Willson, Deputy Executive Officer and General Counsel Kristen Doyle and I met with Larry Schlesinger, M.D., the new Chief Executive Officer of the Texas Biomedical Research Institute about CPRIT funding opportunities and his plans to expand his institute's current research of infectious diseases into cancer.
- Dr. Willson was a featured speaker at the July 12 HealthTech Austin Personalized Medicine Conference where he participated in the *Cancer and Personalized Medicine: Redefining Prevention and Treatment* panel.
- I met with Representative Donna Howard on July 17 to provide an update on CPRIT activities and plans for the 86<sup>th</sup> Texas Legislature that convenes in January 2019.
- On July 26 Product Development Program Manager Rosemary French was part of a panel discussion about the Texas Startup Ecosystem. The event was held at The University of Texas at Austin's IC2 Institute. Ms. French addressed a delegation of entrepreneurs from India, explaining how state-led entities like CPRIT contribute to the creation of a startup network. Oversight Committee Angelos Angelou hosted the event.

### **Upcoming American Cancer Society Cancer Action Network Events Featuring CPRIT**

The American Cancer Society's Cancer Action Network (ASC CAN) will hold three events in August highlighting CPRIT activities. This is the third year that ASC CAN has featured CPRIT in its annual policy forum series, which are well attended by legislators and the advocate community around Texas. This year ACS CAN will feature CPRIT's prevention program and early detection work. Dr. Garcia will speak at each of the events, as will area legislators, program directors for CPRIT-funded prevention projects, and Texans that have benefitted from the prevention services.

ACS CAN invites Oversight Committee members to attend any or all of presentations listed below:

- **Austin** at the Texas Medical Association - August 21, 2018, 7:30 a.m. – 9:00 a.m.
- **Fort Worth** at the Moncrief Cancer Institute - August 24, 2018, 8:00 a.m. – 9:30 a.m.
- **San Antonio** at the Baptist School for Health Professionals - August 29, 2018, 7:30 a.m. – 9:00 a.m.

In addition to these policy forums, ACS CAN may hold an event in College Station in October with a mix of legislators and CPRIT beneficiaries including research, product development, and prevention grantees. ACS CAN will also host the “ACS CAN Texas Research Breakfast” on October 25 in Houston. NBC correspondent Janet Shamlian will emcee the event and Texas A&M Chancellor John Sharp will be the guest of honor for his role in establishing CPRIT. We will keep you updated on all these events.

### **Texas Cancer Plan to Be Released in August**

CPRIT’s statute directs CPRIT to develop and implement the Texas Cancer Plan. CPRIT contracted with Dr. Jennifer Knight, Assistant Professor at the University of Kentucky College of Public Health and a Co-Investigator for the Kentucky Cancer Consortium, for assistance drafting the 2018 Texas Cancer Plan. The CPRIT Prevention Program staff would like to thank the Texas Department of State Health Services for providing data, the Cancer Alliance of Texas for their continued assistance in drafting this revision, The University of Texas MD Anderson Cancer Center for sharing their population health strategic plan, and the others who provided feedback. CPRIT will release the 2018 Texas Cancer Plan in August.

### **FY 2019 Request for Financing Approved by the Bond Review Board**

On July 19, 2018, Heidi McConnell and I attended the Texas Public Finance Authority (TPFA) and Bond Review Board (BRB) meetings, which were held on the same day. The TPFA board unanimously approved the CPRIT’s FY 2019 request for financing of \$300 million in General Obligation Commercial Paper Notes while the Bond Review Board approved the same request for financing by a vote of 2-1 with the Comptroller’s designee dissenting.

### **Personnel**

CPRIT has 35 authorized full-time equivalent (FTE) positions, of which 34 are filled. We are in the process of filling the vacant Grant Compliance Specialist position.

### **Compliance Program Update**

#### Submission Status of Required Grant Recipient Reports

CPRIT’s grant management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT’s compliance staff to follow up with grantees. CPRIT typically has 570+ grants that are either active or wrapping up grant activities and receives an average of 570 grantee reports each month.

As of July 24, 2018, three entities have not filed 30 required reports by the due date; 29 (97%) delinquent reports were for Academic Research grants and one (3%) was for a Product Development Research grant. CPRIT's grant accountants and grant compliance specialists continue to review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

### FSR Reviews

CPRIT's Compliance Specialists performed 95 second-level reviews of grantee Financial Status Reports (FSRs) for the month of July. CPRIT has completed 298 reviews for the current quarter ending August 31. Three FSRs (3%) 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.

### Single Audit Tracking

As part of ongoing monitoring efforts, compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend \$750,000 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 grantee must submit the independent audit report with any audit findings to CPRIT within 30 days of receipt, but no later than 9 months after the end of the grantee's fiscal year.

Compliance Specialists are working with one grantee to remediate audit findings. CPRIT gives grantees 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there are no grantees with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

CPRIT recently revised the Annual Single Audit Determination (SAD) form process. Grantees will now complete one form for their institution annually and submit the completed form to CPRIT via email. Prior to this change, the grantee completed a SAD form for each active grant held by the grantee and submitted each through CPRIT's grants management system. The due date for all future SAD forms will be 60 days after the organization's fiscal year end date. As of July 31, 2018, 47 grantees have submitted their updated SAD forms to CPRIT. Agency staff will follow up with the remaining three grantees that have not submitted their SAD form.

### Desk Reviews

Compliance Specialists performed 20 desk-based financial monitoring/reviews in July to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with one grantee to remediate desk review findings.

## On-Site Reviews

Compliance Specialists performed eight on-site reviews in July. On-site reviews examine the grantee’s financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance.

## Annual Compliance Attestation (Self-Certification)

CPRIT requires grantees to submit an annual self-certification by December 31, demonstrating compliance with statutory and administrative grant requirements, CPRIT’s policies and procedures, the grant contract, and Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. All grantees have submitted their 2018 Attestation form to CPRIT. Compliance staff are working with one grantee who required corrective action.

## Training and Support

CPRIT conducted two Authorized Signing Official (ASO) trainings on June 11 and June 20 with Baylor University and The University of Texas at San Antonio. The training covered grant reporting requirements, administrative rule changes, grant closeout, an overview of the compliance program, and fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, new ASOs must complete a compliance training within 60 days of the change.

CPRIT has scheduled a compliance training for July 27, 2018, at of The University of Texas Southwestern Medical Center (UTSW) as part of their Research Administration Demonstration Training Series. UTSW designed this training for grantee staff working on CPRIT grants to provide targeted technical assistance related to the financial reporting and compliance processes.

## **Academic Research Program Update**

### FY 2018 Cycle 2 (18.2) RFAs Update

Applicants submitted 200+ proposals for FY 2018 Cycle 2 (18.2) grant awards. CPRIT conducted peer review May 18 – 25 in Grapevine. Dr. Willson will present the Scientific Review Committee’s recommendations to the Program Integration Committee (PIC) and Oversight Committee in August.

Table 1: FY 2018.2 (18.2) Application Submission by Mechanism

<b>Mechanism</b>	<b>Received</b>	<b>Funds Requested</b>	<b>Recommended by SRC</b>
Core Facility Support Awards	27	\$134,701,329	10
High Impact/High Risk Awards	153	\$30,331,245	25
Multi-Investigator Research Awards	23	\$135,215,282	5
<b>TOTAL</b>	<b>203</b>	<b>\$300,247,856</b>	<b>40</b>

FY 2019 Cycle 1 (19.1) RFAs Update

Academic research institutions submitted more than 400 proposals for the FY 2019 Cycle 1 (19.1) awards. CPRIT will convene the peer reviewers in Dallas October 18 - October 25. Dr. Willson will present recommendations to the PIC and Oversight Committee in February 2019.

Table 2: FY 2019.1 (19.1) Application Submission by Mechanism

Mechanism	Received	Funds Requested
Individual Investigator Research Award (IIRA)	268	\$233,976,917
IIRA for Cancer in Children and Adolescents	37	\$44,382,130
IIRA for Clinical Translation	33	\$52,321,758
IIRA for Computational Biology	27	\$20,580,933
IIRA for Prevention and Early Detection	36	\$34,294,805
<b>Total</b>	<b>401</b>	<b>\$385,556,543</b>

Recruitment Summary Data

CPRIT received 22 recruitment applications during recruitment cycles 18.10, 18.11 and 18.12. Dr. Willson will present the Scientific Review Council’s 11 recommendations to the PIC and Oversight Committee in August.

Table 3: FY 2018.1 Recruitment RFA data by Mechanism for Cycles 18.10, 18.11 and 18.12

Mechanism	Received	Funds Requested	Recommended by SRC
Recruitment Established Investigators	5	\$30,000,000	2
Recruitment Rising Stars	3	\$12,000,000	1
Recruitment of First-Time Tenure Track Faculty Members	13	\$26,000,000	8
<b>TOTAL</b>	<b>22</b>	<b>\$68,000,000</b>	<b>11</b>

FY 2019 Cycle 2 Academic Research RFAs

The FY 2019 RFA release schedule, which the Oversight Committee approved in February 2018, follows:

- *Recruitment of Established Investigators (FY19)*  
 Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.  
 Award: Up to \$6 million over a period of five years.

- *Recruitment of Rising Stars (FY19)*  
 Recruits outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.  
 Award: Up to \$4 million over a period of five years.
- *Recruitment of First-Time Tenure Track Faculty Members (FY19)*  
 Supports promising emerging investigators, pursuing their first faculty appointment in Texas, who can make outstanding contributions to the field of cancer research.  
 Award: Up to \$2 million over a period of five years.
- *Core Facilities Support Awards (CFSA) (RFA R-19.2 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.
- *High Impact/High Risk Research Awards (HIHR) (RFA R-19.2 HIHR)*  
 Provides short-term funding to explore the feasibility of high-risk projects that, if successful, could contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.  
 Award: Up to \$200,000 (total costs); Maximum duration: 2 years.
- *Early Translational Research Awards (ETRA) (RFA-R-19.2 ETRA)*  
 Supports projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario and preclinical toxicology and formulation to de-risk the development of lead compounds or devices. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. CPRIT requires presentation of a time line with stage gates for development. A public or private company is not eligible.  
 Award: \$1 to 2 million in total costs over a period of 1-2 years.
- *Collaborative Action Program to reduce liver cancer mortality in Texas: Collaborative Action Center Award (RFA-R-19.2 CAP: CAC)*  
 Supports a single Collaborative Action Center (Center) to: (1) promote interactions and collaborations across the CAP Research Awards funded under the companion RFA, R-19.2 CAP:RA; (2) provide opportunities for academic content experts, health care providers and community stakeholders to exchange ideas and to explore new opportunities to impact the rise of hepatocellular cancer (HCC) in Texas, and (3) educate health care providers and the public on best practices to alter the trajectory of HCC in Texas.  
 Award: CPRIT plans to make one award to a single applicant in response to this RFA. Up to \$3 million in total costs over a period of 5 years.

- *Collaborative Action Program to reduce liver cancer mortality in Texas: Investigator Initiated Research Awards (RFA-R-19.2 CAP: RA)*  
Supports investigator-initiated research projects designed to understand the reasons for the increased incidence of hepatocellular cancer (HCC) in Texas, to identify risk factors for cirrhosis and HCC, to identify biomarkers for HCC early detection, and to develop and implement prevention and early detection strategies.  
Award: CPRIT plans to make multiple awards in response to this RFA. Up to \$500,000 in total costs per year for 5 years.

## **Product Development Research Program Update**

### Product Development Research FY 2018 Cycle 2

Applicants submitted 20 proposals by the February 7, 2018, deadline for consideration in the second cycle of FY 2018 Product Development Awards. After an initial review in March, CPRIT's peer reviewers invited 10 companies to present their proposed projects at the peer review panel meetings held April 23 – 26, 2018. Following the presentations, six applicants moved forward to technical, commercial, and intellectual property due diligence review. The Product Development Review Council (PDRC) evaluated the diligence reports and met on July 16 to make award recommendations. Of the six applications, the PDRC recommends three proposals for award consideration by the PIC and the Oversight Committee in August and requested additional information from two more applicants before making a final decision. The PDRC decided not to recommend the sixth application for Oversight Committee consideration. The PDRC expects to make a final decision on the two pending applications in FY 2019.

### Product Development Research Applications FY 2019 Cycle 1

The Oversight Committee approved the schedule and RFA topics for the Product Development FY 2019 Award Cycle 1 at the February 21 meeting. CPRIT released three RFAs, described below, in mid-May and will accept applications through August 8, 2018. In person peer review is scheduled for October 23-26. After due diligence reviews, Mr. Lang will present the PDRC's recommendations to the PIC and the Oversight Committee in February 2019 for approval.

The three open RFAs are:

- Texas Company Product Development Awards supporting Texas-based companies;
- Company Relocation Product Development Awards supporting companies relocating to Texas; and
- The new Seed Awards for Product Development Research supporting new company formation.

## Prevention Program Update

### FY 2018 Cycle 2 (18.2) Prevention Applications

CPRIT released three RFAs in November 2017 for the second review cycle of FY 2018. Peer review panels met May 22 - 25 to evaluate the 31 FY 18.2 prevention applications requesting \$51,031,896 (see table below). The Prevention Review Council (PRC) met July 6 and is recommending 10 awards totaling \$14,322,379 to the PIC. Dr. Garcia will present the PIC recommendations to the Oversight Committee in August.

Mechanism	Number Received	Total \$ Requested
Evidence-based Cancer Prevention Services	13	\$17,537,453
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	9	\$21,645,686
Tobacco Control and Lung Cancer Screening	9	\$11,848,757
TOTAL	31	\$51,031,896

CPRIT received one application this quarter for the Dissemination of CPRIT-Funded Cancer Control Interventions mechanism. The PRC reviewed the application on July 20, 2018 but did not recommend the project for funding.

### FY 2019 Cycle 1 Prevention RFAs

CPRIT released the four approved FY 2019 Cycle 1 RFAs May 10, 2018. Applications are due on September 5 and peer review takes place December 10-13, 2018. Dr. Garcia will present the PRC's recommendations to the PIC and the Oversight Committee in February 2019.

## Communications Update

### Special Events

- Communications is assisting BioHouston and Texas Healthcare and Bioscience Institute (THBI) with planning a luncheon event at the Life Science Plaza in Houston, tentatively scheduled for October 31, 2018. The purpose of the event is for CEOs from CPRIT-supported product development companies to meet with area legislators and staff. The tentative itinerary includes a tour of the Immatix facility followed by a panel discussion with key CPRIT stakeholders. The event will be part of a series of events around the state called "Life Sciences Week" that THBI is organizing.
- Communications is planning a public announcement that would highlight the burden of liver cancer in Texas. The public announcement will coincide with the release of CPRIT's Liver Cancer Collaborative Action Program (CAP) RFAs and be done in conjunction with the American Cancer Society's Cancer Action Network policy forum on August 29 hosted by the Baptist School for Health Professionals in San Antonio.

## Other activities

- Communication staff are finalizing a redesign of the Achievements Report for FY19. The report will be published after the August Oversight Committee Meeting.
- Initial planning for a 2020 CPRIT Innovations Conference has begun. Venue, IT, and timing issues were discussed at the July 26 Audit Subcommittee meeting. CPRIT will provide more information at the Oversight Committee meeting in August.

## Social Media Metrics

### **Facebook (last 28 days):**

- Reach: 814
- Engagement: 92
- Most popular post: The Texas State Agency Business Administrators' Association (TSABAA) has named CPRIT CEO Wayne Roberts its Administrator of the Year for "outstanding leadership" and for "distinguishing himself as an example for all administrators in the public sector." For more, read our [press release](#).

### **Twitter:**

- 5,500 impressions
- Top tweet: TSABAA has named CPRIT CEO Wayne Roberts its Administrator of the Year for "outstanding leadership" and for "distinguishing himself as an example for all administrators in the public sector."

## **Operations, Audit, and Finance Update**

Since the Governor's Office and Legislative Budget Board released instructions for the 2020-21 Legislative Appropriations Request (LAR) on June 22, CPRIT finance staff has worked to complete the components of the LAR. At the special Audit Subcommittee meeting on July 26 the subcommittee determined that the draft LAR is consistent with the items approved for inclusion by the Oversight Committee at its May 16 meeting. The LAR is due on August 3, 2018.

The Weaver audit team completed the Follow-up Procedures Over the Information Security Audit Report, which is the last audit for FY 2018. On July 30, the Weaver audit team, CPRIT staff, and Presiding Officer Will Montgomery met to review and update the annual risk assessment risk ratings associated with CPRIT's significant operational activities. The ratings from this review, together with the audits conducted over the past few years, shape the next three-year internal audit plan (2019-2021) that the Oversight Committee will consider at the August meeting.

## Upcoming Subcommittee Meetings

Listed below are the regularly scheduled subcommittees in advance of the August 15, 2018, Oversight Committee meeting.

Special Issues	August 27 at 9:00 a.m.
Board Governance	August 2 at 10:00 a.m.
Audit	August 6 at 10:00 a.m.
Prevention	August 7 at 10:00 a.m.
Academic Research	August 8 at 10:00 a.m.
Product Development	August 9 at 10:00 a.m.
Nominations	August 10 at 10:30 a.m.

CPRIT will send an agenda, call-in information, and supporting material to the subcommittees one week prior to the meeting date.

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CPRIT has awarded **1,255** grants totaling **\$1.982 billion**

- 199 prevention awards totaling \$208.8 million
- 1,056 academic research and product development research awards totaling \$1.774 billion

Of the \$1.774 billion in academic research and product development research awards,

- 28.8% of the funding (\$510.0 million) supports clinical research projects
- 26.0% of the funding (\$461.4 million) supports translational research projects
- 27.1% of funding (\$480.1 million) supports recruitment awards
- 14.7% of the funding (\$262.2 million) supports discovery stage research projects
- 3.4% of funding (\$59.9 million) supports training programs.

CPRIT has 10 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Product Development Research
- 4 Prevention



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

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**MEMORANDUM**

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**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** VINCE BURGESS, CHIEF COMPLIANCE OFFICER  
**SUBJECT:** COMPLIANCE PROGRAM UPDATE  
**DATE:** AUGUST 6, 2018

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The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities and assuring the Oversight Committee that controls are in place to prevent, detect and mitigate compliance risk. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules and agency policies. In addition, the Compliance Officer is responsible for monitoring the timely submission status of required grant recipient reports and notifying 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

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

As of July 30, 2018, three entities have not filed 23 required reports by the due date; 22 (96%) delinquent reports were for Academic Research grants and one (4%) was for a Product Development Research grant. CPRIT's grant accountants and grant compliance specialists continue to review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

FSR Reviews

CPRIT's Compliance Specialists performed 145 second-level reviews of grantee Financial Status Reports (FSRs) for the month of July. A total of 322 reviews were completed for the current

fiscal quarter ending in August. Three FSRs (2%) required resubmission this month 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.

### Single Audit Tracking

As part of ongoing monitoring efforts, compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend \$750,000 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 9 months after the grantee's fiscal year.

Compliance Specialists are working with one grantee to remediate audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there are no grantees with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

CPRIT recently revised the Annual Single Audit Determination (SAD) form process. Grantees will now complete one form for their institution annually and submit the completed form to CPRIT via email. Prior to this change, the grantee completed a SAD form for each active grant held by the grantee and submitted each through CPRIT's grants management system. The due date for all future SAD forms will be 60 days after the organization's fiscal year end date. As of July 31, 2018, 47 grantees have submitted their updated SAD forms to CPRIT. Agency staff will follow up with the remaining three grantees that have not submitted their SAD form.

### Desk Reviews

Compliance Specialists performed 31 desk-based financial monitoring/reviews in July to verify that grantees expend funds in compliance with specific grant requirements and guidelines. A total of 64 desk reviews have been performed for the current fiscal quarter. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with six grantees to remediate desk review findings.

## On-Site Reviews

Compliance Specialists performed eight on-site reviews in July. A total of 16 on-site reviews have been performed for the current fiscal quarter. On-site reviews typically examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance Specialists are working with four grantees to remediate onsite review findings.

## Annual Compliance Attestation (Self-Certification)

CPRIT requires grantees to submit an annual self-certification by December 31 of each year, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, the grant contract, and Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. All grantees have submitted their 2018 Attestation form to CPRIT. Compliance staff are working with one grantee who required corrective action related to their attestation.

## Training and Support

Two Authorized Signing Official (ASO) trainings were conducted on June 11 and June 20 with Baylor University and UT San Antonio. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, new ASOs are required to complete a compliance training within 60 days of the change.

CPRIT staff conducted a grantee training on July 27, 2018, at of the University of Texas Southwestern Medical Center as part of their Research Administration Demonstration Training Series. This training was designed for grantee staff working on CPRIT grants and provided targeted technical assistance related to financial status reporting and compliance processes. Approximately 50 grantee staff attended the interactive training which included an extended time of Q&A with CPRIT's compliance, financial, and legal staff.

## FY19 Grantee Risk Assessment and Monitoring Plan

CPRIT's Compliance Program has completed the FY19 Grantee Risk Assessment process. Risk Assessments are performed on a quarterly and annual basis. The Risk Assessment Model considers several factors in determining grantee risk including:

- Financial exposure,
- Entity maturity, and
- Prior experience administering grants.

Annual Risk Assessments assign a priority ranking (1, 2, or 3) to grant recipients, which is used to determine monitoring and training needs for the coming fiscal year. Based on the results of the Risk Assessment, grantees will receive a desk review or an onsite monitoring review completed by CPRIT staff. Compliance monitoring reviews are designed to evaluate a grantee's compliance with grant requirements included in the Texas Administrative Code, Texas Health and Safety Code, CPRIT Policies and Procedures, Uniform Grant Management Standards, and terms of the grant contract.



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

**MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** JAMES WILLSON, MD., CHIEF SCIENTIFIC OFFICER  
**SUBJECT:** ACADEMIC RESEARCH PROGRAM UPDATE  
**DATE:** AUGUST 15, 2018

FY 2018 Cycle 2 (18.2) RFAs Update

Table 1 displays an overview of FY 2018 Cycle 2 (18.2) data by submission rates, funding requests, reviews, and status of the Program Integration Committee recommendations and Oversight Committee approvals. Peer review was conducted May 18<sup>th</sup> through 25<sup>th</sup> in Grapevine, Texas and Dr. Willson will present the Program Integration Committee recommendation to the Oversight Committee August 24, 2018.

**Table 1: FY 2018.2 (18.2) RFA Data by Mechanism**

Mechanism	Number Received	Funds Requested	Number Recommended by SRC	Number Recommended by PIC	Number Approved by Oversight Committee	Funds Approved by Oversight Committee
Core Facility Support Awards	27	\$134,701,329	10	10	TBD	TBD
High Impact/High Risk Awards	153	\$30,331,245	25	25	TBD	TBD
Multi-Investigator Research Awards	23	\$135,215,282	5	5	TBD	TBD
<b>TOTAL</b>	<b>203</b>	<b>\$300,247,856</b>	<b>40</b>	<b>40</b>		

FY 2019 Cycle 1 (19.1) RFAs Update

Table 2 displays an overview of FY 2019 Cycle 1 (19.1) data by mechanism. Peer review for the 19.1 cycle is scheduled October 18, 2018 through October 25, 2018 in Dallas, Texas. Dr. Willson will present the Scientific Review Committee’s award recommendations to the Program Integration Committee and the Oversight Committee in February 2019.

**Table 2: FY 2019.1 (19.1) RFA Data by Mechanism**

Mechanism	Number Received	Funds Requested	Number Recommended by SRC	Number Recommended by PIC	Number Approved by Oversight Committee	Funds Approved by Oversight Committee
Individual Investigator Research Award (IIRA)	268	\$233,976,917	TBD	TBD	TBD	TBD
IIRA for Cancer in Children and Adolescents	37	\$44,382,130	TBD	TBD	TBD	TBD
IIRA for Clinical Translation	33	\$52,321,758	TBD	TBD	TBD	TBD
IIRA for Computational Biology	27	\$20,580,933	TBD	TBD	TBD	TBD
IIRA for Prevention and Early Detection	36	\$34,294,805	TBD	TBD	TBD	TBD
<b>Total</b>	<b>401</b>	<b>\$385,556,543</b>				

Recruitment Summary Data

Table 3 displays an overview of FY 2018. recruitment data for the final quarter (Cycles 18.10,18.11 and 18.12). Dr. Willson will present the Program Integration Committee recommendations to the Oversight Committee August 24, 2018.

**Table 3: FY 2018.1 Recruitment RFA data by Mechanism for Cycles 18.10, 18.11 and 18.12**

Mechanism	Number Received	Funds Requested	Number Recommended by SRC	Number Recommended by PIC	Number Approved by Oversight Committee	Funds Approved by Oversight Committee
Recruitment Established Investigators	5	\$30,000,000	2	2	TBD	TBD
Recruitment Rising Stars	3	\$12,000,000	1	1	TBD	TBD
Recruitment of First-Time Tenure Track Faculty Members	13	\$26,000,000	8	8	TBD	TBD
<b>TOTAL</b>	<b>22</b>	<b>\$68,000,000</b>	<b>11</b>	<b>11</b>		

**FY 2019 Cycle 2 Academic Research RFAs (Approved)**

The FY 2019 RFA release schedule was approved by the Oversight Committee on February 21, 2018 as follows:

- **Recruitment of Established Investigators (FY19)**  
 Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.  
 Award: Up to \$6 million over a period of five years.
- **Recruitment of Rising Stars (FY19)**  
 Recruits outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.  
 Award: Up to \$4 million over a period of five years.
- **Recruitment of First-Time Tenure Track Faculty Members (FY19)**  
 Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research.  
 Award: Up to \$2 million over a period of five years.
- **Core Facilities Support Awards (CFSA) (RFA R-19.2 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 \$3M (total costs) for the first 2 years and up to \$1M (total costs) for each subsequent year; Maximum duration: 5 years.
- **High Impact/High Risk Research Awards (HIHR) (RFA R-19.2 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.
- **Early Translational Research Awards (ETRA) (RFA-R-19.2 ETRA)**  
 Supports projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario and preclinical toxicology and formulation to de-risk the development of lead compounds or devices. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. Presentation of a time line with stage gates for development is required. A public or private company is not eligible.  
 Award: up to \$ 2 million in total costs over a period of 1-2 years.
- **Collaborative Action Program to reduce liver cancer mortality in Texas: Collaborative Action Center Award (RFA-R-19.2 CAP: CAC)**  
 Supports a Collaborative Action Center whose function will be to: (1) promote interactions and collaborations across the CAP Research Awards funded under the companion RFA, R-19.2 CAP:RA; (2) provide opportunities for academic content experts, health care providers and community stakeholders to exchange ideas and to explore new opportunities to impact

the rise of hepatocellular cancer (HCC) in Texas and (3) educate health care providers and the public on best practices to alter the trajectory of HCC in Texas.

Award: CPRIT plans to make one award. Up to \$3,000,000 in total costs over a period of 5 years.

- **Collaborative Action Program to reduce liver cancer mortality in Texas: Investigator Initiated Research Awards (RFA-R-19.2 CAP: RA)**

Supports investigator-initiated research projects designed to understand the reasons for the increased incidence of HCC in Texas, to identify risk factors for cirrhosis and HCC, to identify biomarkers for HCC early detection, and to develop and implement prevention and early detection strategies.

Award: CPRIT plans to make multiple awards in response to this RFA. Up to \$500,000 each in total costs per year for 5 years.



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CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

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**MEMORANDUM**

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**TO:** CPRIT OVERSIGHT COMMITTEE  
**FROM:** MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER  
**SUBJECT:** CPRIT PRODUCT DEVELOPMENT UPDATE  
**DATE:** AUGUST 9, 2018

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**Product Development Research Award Update**

Product Development Research FY 2018 Cycle 2

Twenty applications were submitted Product Development Award FY 2018 Cycle 2 and accepted for peer review. CPRIT's Peer Reviewers invited 10 companies to present at the Peer Review Panel meeting where 6 applicants were selected to proceed to due diligence.

The product development review committee completed their review of the diligence reports and made the following recommendations;

- Three applications are recommended for Oversight Committee approval, one with contingencies. These will be presented to the Oversight Committee at the August meeting. Total requested budget for these three applications is \$50,587,540.
- The PDRC requested additional information on two applications to complete their review. They will finish the review once the requested information is provided.
- One application was not recommended for Oversight Committee approval.

Product Development Research Applications FY 2019 Cycle 1

Product Development Award FY 2019 Cycle 1 was approved by the Oversight Committee in the February 21 meeting. The schedule has been finalized and RFAs have been posted in CARS. CARS was open to receive application June 28 to August 8, 2018. Peer review is scheduled for October 23-26. Selected applicants will be presented to the OC in February 2019 for approval. Three RFAs are posted:

- Texas company RFA supporting TX based companies (TXCO)
- Relocation company RFA supporting companies relocating to TX (RELCO)
- New Seed Award RFA supporting new company formation (SEED)

As of August 9, 2018, the count of application submissions is 27 SEED, 9 RELCO, and 5 TXCO. We are waiting on responses regarding extension requests due to technical difficulties, etc., which may result in a slight increase in number of submissions for this round. This is the first application round in which CPRIT has opened the SEED RFA.





CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

**MEMORANDUM**

**TO:** CPRIT OVERSIGHT COMMITTEE MEMBERS  
**FROM:** REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER  
**SUBJECT:** PREVENTION PROGRAM REPORT  
**DATE:** AUGUST 6, 2018

FY 2018 Cycle 2 (18.2) Prevention Applications

CPRIT released three RFAs in November 2017 for the second review cycle of FY 2018. Peer review panels met May 22 - 25 to evaluate the 31 FY18.2 prevention applications requesting \$51,031,896 (see table below). The Prevention Review Council (PRC) met July 6 and is recommending 10 awards totaling \$14,322,379 to the Program Integration Committee (PIC). Dr. Garcia will present the PIC recommendations to the Oversight Committee at the August meeting.

Mechanism	Number Received	Total \$ Requested
Evidence-based Cancer Prevention Services	13	\$17,537,453
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	9	\$21,645,686
Tobacco Control and Lung Cancer Screening	9	\$11,848,757
<b>TOTAL</b>	<b>31</b>	<b>\$51,031,896</b>

CPRIT received one application this quarter for the Dissemination of CPRIT-Funded Cancer Control Interventions mechanism. The PRC reviewed the application on July 20, 2018 but did not recommend the project for funding.

FY 2019 Cycle 1 Prevention RFAs

The 4 approved FY 2019 Cycle 1 RFAs were released May 10, 2018. Applications are due on September 5 and peer review is scheduled for December 10-13, 2018. Dr. Garcia will present the PIC recommendations to the Oversight Committee in February 2019.

FY 2019 Cycle 2 Prevention RFAs and schedule

The proposed schedule and RFAs to be released for FY 2019 Cycle 2 will be considered at the August 15, 2018 Oversight Committee meeting.

Timeline - Cycles 19.1 – 19.2

	19.1 In progress	19.2 For approval
Submission	Sept. 5, 2018	Feb. 29, 2019
Peer Review	Dec. 10-13, 2018	May 2019
PRC	Jan. 2019	July 2019
PIC	Feb. 12, 2019	Aug. 6, 2019
OC	Feb. 20, 2019	Aug. 21, 2019

Proposed RFAs

- **Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations**  
Up to \$2 million in direct costs for up to 36 months
- **Evidence-Based Cancer Prevention Services**  
Up to \$1 million in direct costs for up to 36 months
- **Tobacco Control and Lung Cancer Screening**  
Up to \$1 million in direct costs for up to 36 months
- **Dissemination of CPRIT-Funded Cancer Control Interventions**  
Up to \$300,000 in direct costs for up to 24 months

Other activities

Prevention program staff continue to work with Dr. Jennifer Knight on drafting the 2018 Texas Cancer Plan. The Plan is scheduled to be released in August.



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** REBECCA GARCIA, PH.D. CHIEF PREVENTION AND  
COMMUNICATIONS OFFICER  
**SUBJECT:** COMMUNICATIONS UPDATE  
**DATE:** AUGUST 24, 2018

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The following is an overview of the agency's communication activities for August 2018.

### **Earned Media**

**Coverage:** Below is an quarterly summary of media coverage featuring or mentioning CPRIT.

- 50 articles featured CPRIT
- 21 mentions in news articles

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

- May 17, 2018, *Xconomy, OncoNano, Maker of Tumor Imaging Technology, Raises \$11.7 Million*
- May 17, 2018, *San Antonio Business Journal, UT Health SA gets Millions from State to Bring Talent back Home*
- May 30, 2018, *Xconomy, Eying Clinical Trials, Shattuck Labs Adds \$46M for Immunotherapy R&D*
- June 4, 2018, *Exome, aravive Seeks NASDAQ Perch Via Reverse Merger with Biotech Versartis*
- June 10, 2018, *TMC News, Fluorescent Fish Genes Light Path to Neuroblastoma*
- June 30, 2018, *Austin Monitor, Dell Medical Investment Begins to Pay Dividends*
- July 13, 2018, *Quorum Report, People on the Move*

### **Special Events**

- Communications is assisting BioHouston and Texas Healthcare and Bioscience Institute (THBI) with planning a luncheon event at the Life Science Plaza in Houston, tentatively scheduled for October 31, 2018. The purpose of the event is for CEOs from CPRITsupported product development companies to meet with area legislators and staff. The tentative itinerary includes a tour of the Immatics facility followed by a panel discussion with key CPRIT stakeholders. The event will be part of a series of events around the state called "Life Sciences Week" that THBI is organizing.

- Communications is planning a public announcement that would highlight the burden of liver cancer in Texas. The public announcement will coincide with the release of CPRIT's Liver Cancer Collaborative Action Program (CAP) RFAs and be done in conjunction with the American Cancer Society's Cancer Action Network policy forum on August 29 hosted by the Baptist School for Health Professionals in San Antonio.

### **Cancer Awareness Months**

- Communications staff are in the planning stages for Childhood Cancer Awareness month in September, Breast Cancer Awareness and Liver Cancer Awareness month in October and Lung Cancer Awareness month in November.

### **Other activities**

- A redesign of the Achievements Report for FY19 is being finalized and will be published after the August Oversight Committee Meeting.
- Initial planning for a 2020 CPRIT Innovations Conference has begun. Venue, IT, and timing issues were discussed at the July 26 Audit Subcommittee meeting. CPRIT will provide more information at the Oversight Committee meeting in August.
- The communications team continues to design and develop content for CPRIT's soon-to-be-launched digital newsroom; a multi-channel platform for posting, curating and distributing CPRIT and related content.

### **Social Media Metrics**

#### **Facebook (last 28 days):**

- Reach: 814
- Engagement: 92
- Most popular post: The Texas State Agency Business Administrators' Association (TSABAA) has named CPRIT CEO Wayne Roberts its Administrator of the Year for "outstanding leadership" and for "distinguishing himself as an example for all administrators in the public sector." For more, read our press release: <https://cprit.us/2meEo4E>

#### **Twitter:**

- 5,500 impressions
- Top tweet: TSABAA has named CPRIT CEO Wayne Roberts its Administrator of the Year for "outstanding leadership" and for "distinguishing himself as an example for all administrators in the public sector." <https://cprit.us/2meEo4E>

- Tweet Highlight: @SarahforHD134 - What an honor to meet the man whose research made the chemo that saved my life. Thank you, Dr. Nicolaou! Let's all be grateful for @CPRITTexas <http://news.rice.edu/2018/08/01/state-rep-davis-tours-k-c-nicolaou-research-accelerator/>

(Tweet link: <https://twitter.com/SarahforHD134/status/1024756848266825728>)



## OncoNano, Maker of Tumor Imaging Technology, Raises \$11.7 Million



**Angela Shah**  
May 17th, 2018

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[@xconomy](#)

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**Xconomy Texas** — *Dallas*—OncoNano Medicine, which is developing an imaging agent to help surgeons better remove tumors, has raised \$11.7 million in Series A funding.

OncoNano’s lead product, ONM-100, is an injectable imaging agent that targets the acidic pH within tumors to better distinguish cancer cells from healthy ones during surgery.

OncoNano said the new funding was arranged by Salem Partners, which also participated as a principal investor. The round included institutional and individual investors that the company did not name. The new investment follows a \$6 million grant the company received from the Cancer Prevention and Research Institute of Texas (CPRIT).

Ravi Srinivasan, OncoNano’s co-founder and CEO, says the new funds will be used to pay for an ongoing Phase 1-2 clinical trial of ONM-100 in about 30 patients, which is scheduled to end in November.

“This is a proven, robust biomarker that is well-known,” he says. “Unlike proteins, which are overexpressed in tumors but vary by patient to patient or tumor to tumor, or by stage of disease, pH is a very simple but broadly applicable biomarker.”

OncoNano says imaging eliminates the guesswork often associated with the removal of tumors by providing surgeons real-time information during surgery.

The Texas company isn’t the only one seeking to innovate in this arena. Blaze Bioscience in Seattle is developing “tumor paint” to help surgeons differentiate healthy tissue from tumors that should be removed. Last October, the Seattle-based company raised a \$16.1 million Series B-1 round of funding from existing investors, bringing its total to \$33 million, according to a story written at the time by David Holley, Xconomy’s national correspondent.

The company's lead product candidate, BLZ-100, is made up of a genetically engineered peptide that Blaze says binds to and enters numerous tumor types. The peptide, which is chemically linked to a fluorescent beacon, is injected into tumor tissue in a surgical site. Delineating exactly where the tumor is helps surgeons avoid leaving behind bits of the tumor, which could cause relapse.

OncoNano is a spinout company from the University of Texas Southwestern Medical Center in Dallas, with technology invented by Jinming Gao, a professor of pharmacology and otolaryngology, and Baran D. Sumer, an associate professor of otolaryngology. The company, which is based in the Fort Worth suburb of Southlake, was founded in 2014.

In addition to the new funding, OncoNano announced half a dozen new board members, including Al Guillem, chairman of the Board and former president of ZS Pharma, a biotech firm that was founded in neighboring Coppell, TX. In late 2015, British drugmaker **AstraZeneca announced it was buying ZS Pharma** in a \$2.7 billion deal. The Texas company had moved to California following its \$107 million IPO in 2014.

Srinivasan says he is not setting the goal for a similar outcome for OncoNano yet. "Our goal would be to stay independent and grow," he says.

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July 13, 2018 10:58 AM

## People on the Move

**A power player brings a Washington firm to Austin, senior staffers moving on to new ventures, promotions earn congratulations, and some award winners to brag about**

I take a couple days off and you folks make all kinds of news. Wasn't this supposed to be the dog days of summer?

First, a personal milestone to share: The 100<sup>th</sup> episode of the *Texas Take Podcast* that I co-host with **Mike Ward** at the *Houston Chronicle* and **Ryan Poppe** of *Texas Public Radio* is [now available here](#) along with the previous 99 episodes. How is it possible we've already done 100 of these? It's all thanks to those of you who listen each week and to our *Quorum Report* advertisers including the *Texas Association of Counties* and the *Texas Association of Realtors*. It is humbling that anybody cares what I have to say about any of this in print or in audio form. If you have yet to check out the show, subscribe on *iTunes* [or listen here](#). Thanks so much.

Enough about me. People on the Move is about you.

As always, if you have career news to share, send a note to [ksbraddock@gmail.com](mailto:ksbraddock@gmail.com) and put "POTM" or "People on the Move" in the subject line. Here's Texas' weekly roundup of *People on the Move*:

**Kaleb McLaurin** is taking over as Executive Director of Government and Public Affairs for the *Texas and Southwestern Cattle Raisers Association* (TSCRA) on Sept. 1. He will oversee TSCRA's federal and state legislative, regulatory, and political efforts. He's worked in the TSCRA Austin office for four years and replaces **Jason Skaggs**, who will become Executive Vice President/CEO of TSCRA.

**Ben Stratmann** announced he's leaving Sen. **Brian Birdwell's** office. "As I've had the chance to share with a few of you, July 31st will be my last day," he said in an email to colleagues. "While I'm extremely excited about what's next, I would be lying if I told you I won't sincerely miss being 'inside the building.'"

"The *Texas Capitol* is simply an awesome place to work. If there's anything I've found myself emphasizing to newer/younger folks working here, it's a reminder to never take it for granted," Stratmann said. Wise words.

Stay tuned for what's next for Ben.

**Ryan Skrobarczyk** is leaving Rep. **Kyle Kacal's** office after serving there for more than 5 years. We hear he'll now be the Director of Legislative and Regulatory Affairs at the *Texas Nursery and Landscape Association*. Ryan will also handle all PAC duties. Prior to working for Representative Kacal, Ryan interned for the late Sen. **Chris Harris** during the 82nd Session.

After leaving Gov. **Greg Abbott's** office, **Jerry Strickland** will join a firm called *BGR Group* as Vice President. He started this week. "In this role, Jerry will open and lead a new Texas office for BGR Group in Austin. Jerry will strengthen the firm's advocacy on behalf of clients before the Texas Congressional delegation as well as state agencies," the company said.

"I have been privileged to have Jerry Strickland as a trusted advisor for nearly 15 years in the Attorney General's office and as Governor. Jerry's policy, communications, and advocacy skills on behalf of state agencies before the entire Texas Congressional delegation, White House and federal agencies have served our state well," Gov. Abbott said. "I am truly grateful for Jerry's commitment to Texas. He has built strong relationships in Austin and Washington, D.C. Jerry's tenacity makes him a strong asset to have to have on your side."

**Stephen L. Tatum, Jr.**, most recently a Deputy Commissioner of the *Texas Commission on Environmental Quality*, has joined *Cantey Hanger LLP* as a Partner. He'll advise clients on things like the environment, energy, and eminent domain as well as government and regulatory matters. Tatum was the lead author of *The Deepwater Horizon Oil Spill: A Review of the Historic Civil and Criminal Liabilities From America's Worst Environmental Catastrophe*. He joins his father at the firm.

AG **Ken Paxton** named former *Supreme Court* Clerk **Zina Bash** as Senior Counsel on the AG's Executive Leadership Team.

**Rudy Sandoval**, who's been at the *Texas Workforce Commission* in the Governmental Relations Office as a Governmental Relations Liaison since 2003 is now the Director, Government & Community Relations at *Central Texas College* in Killeen. "Glad to have served the Texas Workforce Commission and looking forward to a successful tenure with Central Texas College," he said.

Earlier in the week, we told you that Workforce Commission Chairman **Andres Alcantar** is leaving the agency as well to become Chief Operating Officer and Executive Vice President of *Texas Association of Business*.

TAB's CEO **Jeff Moseley** said, "No one has fought harder to bring jobs and paychecks to Texas than Andres!"

"I have great respect for TAB, and their mission aligns perfectly with my experience," said Alcantar.

**Chris Furlow** takes over as the new President and CEO at the *Texas Bankers Association*. He was a senior member of the founding staff at the *U.S. Department of Homeland Security*.

After a national search, *The Greater Brownsville Incentives Corporation* welcomes **Mario Lozoya** as its new Executive Director. Most recently he served as director of government relations and external affairs in the corporate communications office of *Toyota Motor Manufacturing Texas Inc.*, where he led Toyota's workforce development efforts, establishing and nurturing local supply chains, and enhancing the economic transformation of south San Antonio.

The *Texas Access to Justice Foundation* announced the creation of the **Randy Chapman** Fellowship program for legal aid lawyers. This follows Chapman's retirement as the executive director of *Texas Legal Services Center*.

"Chapman has a deep commitment and passion for the cause of justice and is uniquely known for his creative approaches to legal aid challenges," said **Richard Tate**, chairman of the board. "This fellowship will encourage new ideas and creative approaches to the delivery of legal services as a lasting reminder of Randy's work for those in need of legal help."

At a ceremony in San Antonio, the *Texas State Agency Business Administrators' Association* named **Wayne Roberts**, Chief Executive Officer of the *Cancer Prevention & Research Institute of Texas*, as its Administrator of the Year.

"Wayne Roberts exemplifies the qualities we look for in state administrators – integrity, sound leadership and proven expertise in public policy," said **Rebecca Trevino**, TSABAA President and Chief Financial Officer of the *Texas Water Development Board*.

And the winners of the *2018 Texas Gavel Awards* from the *State Bar of Texas* include a *Quorum Report* alum: Reporter **Eleanor Dearman** is now at the *Corpus Christi Caller Times* where she and her colleague **Krista M. Torralva** used public records requests and interviews to reveal that a sitting judge, accused in a road rage incident of pointing a gun at a vehicle's occupants, had been involved in other, earlier road rage cases.

All the [winners are here](#). Congrats.

By Scott Braddock

*IID 28137*

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## UT Health SA gets millions from state to bring talent back home

By W. Scott Bailey

San Antonio Business Journal

UT Health San Antonio has been awarded \$6 million in grant funding from the Cancer Prevention and Research Institute of Texas, which enabled the local institution to recruit a leading researcher and professor.

UT Health San Antonio is using the money — which was among \$30 million across nine new grants awarded by CPRIT — to recruit Dr. Patrick Sung, professor of biophysics, biochemistry, therapeutic radiology and epidemiology at Yale University. He will occupy the Robert A. Welch Distinguished Chair in Chemistry at UT Health San Antonio and be appointed professor in the Department of Biochemistry & Structural Biology.

Sung will also be associate dean for research in the Joe R. and Teresa Lozano Long School of Medicine and lead a new research program in genetic integrity at UT Health San Antonio's Mays Cancer Center.

Dr. Robert Hromas, dean of the Long School of Medicine and vice president for medical affairs at UT Health San Antonio, said the CPRIT money was critical in the Alamo City's ability to get someone of Sung's stature.

"We would not have recruited him without those funds," Hromas told me.

Sung, a native of Hong Kong, is no stranger to Texas — or to San Antonio. His initial faculty appointment was at the University of Texas Medical Branch at Galveston.

In 1997, Sung moved to UT Health San Antonio as assistant professor and was promoted to professor and the Zachry Distinguished Professor of Molecular Medicine. From 2001 to 2003, he was co-director of a National Cancer Institute-funded training program in DNA repair at the university.

Sung left UT Health San Antonio in 2003 for Yale. One of the factors that attracted him back to the Alamo City is the opportunity to help expand UT Health San Antonio's capabilities for taking bench research and translating it into human application. Sung plans to bring with him a lab team of more than a dozen people who will begin work at UT Health San Antonio in early 2019.

Dr. Ruben Mesa, director of the Mays Cancer Center, said Sung's recruitment represents a strong commitment by that institution and UT Health San Antonio to "bring the most cutting-edge research and cancer care to San Antonio."



## Eying Clinical Trials, Shattuck Labs Adds \$46M for Immunotherapy R&D



**David Holley**  
May 30th, 2018

@xconholley

@xconomy

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**Xconomy Texas** — Austin — *[Updated 5/30/18, 11:08 a.m. See below.]* Shattuck Labs, a biotech that licensed technology from cancer drug developer Heat Biologics, added a cash windfall right before the holiday weekend—a \$46.6 million equity round of financing, according to a May 25 securities **filing**.

Austin-based Shattuck has an experimental immunotherapy in preclinical development that it believes can fulfill two lofty goals that are currently among the hottest areas of oncology. Its so-called “fusion proteins” aim to combine two approaches to cancer treatment in a single therapy. Its drug would work as a checkpoint inhibitor, blocking molecules that put a brake on the immune system. The drug would also stimulate certain receptors (the tumor necrosis factor **superfamily** of proteins) on T cells, the immune system’s cancer-killing cells.

The company hasn’t yet revealed many more details about how it will do so. The company has said, however, that besides cancer, its technology has potential applications in inflammatory disease. *[Wording changed in first paragraph to remove the description of Shattuck as a spinout. The company believes the word might imply it was previously a subsidiary or a unit within Heat, which could create confusion. Shattuck licensed technology and rented lab space from Heat.]*

Shattuck calls its program the Agonist Redirected Checkpoint **platform**, and it licensed the initial provisional patent applications and “know-how” in June 2016 related to fusion proteins to treat cancer and other diseases from **Durham, NC-based Heat** (NASDAQ: **HTBX**), another immunotherapy drug developer, according to a securities **filing**. Shattuck rented lab space from Heat through early January 2017, and now has R&D facilities in Research Triangle Park, NC, in addition to its Austin headquarters. *[Additional words added, paraphrased from Heat Biologics securities filing.]*

Last August, Shattuck **announced** it signed a deal to collaborate with Takeda Pharmaceutical and its cancer **subsidiary, Millennium Pharmaceuticals**. Takeda is providing funding for preclinical and clinical development of two pre-clinical and four discovery-stage drug candidates, and in exchange gained the option to license up to four of the molecules, according to a news release. Other terms weren't disclosed.

Josiah Hornblower, Shattuck's chairman and CEO, said the company has been quiet by design. Shattuck is considering whether to provide further comment. Notably, Hornblower is the former CEO of another Texas biotech company: Pelican Therapeutics, another immunology drug developer founded by Heat in 2009.

Pelican spun out as a separate company in 2011 because Heat didn't have the funding to develop Pelican's two drug candidates, **Heat founder** and CEO Jeffrey Wolf told Xconomy last year. Heat decided to re-acquire Pelican in March of 2017. Rahul Jasuja, a former board member, took over as CEO of Pelican in **April**, and a month later, **Pelican** received a \$15.2 million grant from the Cancer Prevention and Research Institute of Texas (known as CPRIT in the state) to perform preclinical work on its monoclonal antibody and its protein that aim to stimulate or proliferate the response of T cells.

**Pelican moved its headquarters from Austin to San Antonio** last September in part because of a \$200,000 grant from the city's government. The City of San Antonio has offered similar grants to other companies, including another immunotherapy business, **Houston-based Kiromic, most recently**.

Hornblower is known for more than his work in biotech. He was in “Born Rich,” a 2003 documentary by Johnson & Johnson (NYSE: **JNJ**) heir Jamie Johnson about descendants of the country’s wealthiest individuals. Besides Hornblower—a descendant of Whitneys and Vanderbilts, **according** to Town & Country magazine—the film also interviewed Ivanka Trump, Georgina Bloomberg, and numerous other heirs to fortunes.

Shattuck last raised a \$7 million debt round of **financing** in March 2017. Hornblower **told** the Austin Business Journal in April of that year that \$5 million came from an international pharmaceutical company, declining to name specific investors. Shattuck announced the deal with Takeda four months later. Shattuck’s website currently states that it expects to start clinical trials by early 2019. If the company plans to develop therapies that are not covered by its Takeda collaboration—the phrasing of a news release indicates the Takeda deal may only cover oncology, not necessarily inflammation—the latest equity investment provides the company the cash to do so.

**Immunotherapy** is a highly competitive field. Checkpoint inhibitors from Merck (NYSE: **MRK**), Bristol-Myers Squibb (NYSE: **BMS**), Roche/Genentech and others have won approvals in cancers of the skin, lung, kidney, and more, but they don’t work for all patients, leading pharmaceutical companies to look for drug combinations that could broaden their use and help the non-responders respond, as Xconomy’s Frank Vinluan wrote **earlier this month**. Eli Lilly (NYSE: **LLY**) plans to add engineered cytokines—substances secreted by immune cells during an immune response—to the mix of combination therapies through a deal announced earlier this month to acquire Redwood City, CA-based Armo BioSciences (NASDAQ: **ARMO**) for **\$1.6 billion**.

Shattuck says on its website that its technology could “build directly on the clinical success” of immunotherapies now marketed by Merck, Bristol-Myers Squibb (NYSE: **BMS**), and Roche. The Texas company adds that its technology could apply to multiple tumor types and it expects to start clinical testing early next year.

<https://www.xconomy.com/texas/2018/05/30/eying-clinical-trials-shattuck-labs-adds-46m-for-immunotherapy-rd/>

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## Aravive Seeks NASDAQ Perch Via Reverse Merger With Biotech Versartis



**Angela Shah**  
June 4th, 2018

@angelashah

@xconomy

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**Xconomy Texas** — Houston biotech Aravive Biologics is going public **through a reverse merger with Versartis**, a Menlo Park, CA-based company whose lead drug failed a clinical trial last year.

Under the deal, Versartis and Aravive shareholders will each own about 50 percent of the combined company, according to a press release. Aravive will get Versartis's (NASDAQ: **VSAR**) NASDAQ listing. Jay Shepard, Versartis' president and CEO, lead the combined company, which will be based in Houston. The transaction is expected to close during the second half of the year, pending approval by shareholders of each company.

IPOs are the typical path for companies seeking to go public, and the **window has been wide open for biotechs** over the past several years. But reverse mergers are an option as well, offering an alternative, faster way to Wall Street while avoiding the extra scrutiny from investors and regulators that comes with registering securities. (The downside to reverse mergers, **as Xconomy explained here**, is overcoming the perception of "backing onto Wall Street.")

Aravive is the latest biotech to go the reverse merger route. **Others to utilize the strategy** over the past few years include include San Diego companies Arcturus and Organovo, Houston biotech Oncolix, Austin-based Savara, Lexington, MA-based Pulmatrix, and Enumeral Biomedical, of Cambridge and New York.

Aravive is developing an experimental cancer drug, AVB-S6-500, currently in Phase 1 testing. The drug blocks what's known as the GAS6-AXL signaling axis, which is implicated in tumor growth. Aravive aims to combine the drug with others to boost their effectiveness. The company, for example, plans to test AVB-S6-500 alongside standard of care therapies in ovarian cancers in the ongoing Phase 1 trial later this year, the press release stated.

Aravive will go public through the shell of Versartis, whose experimental drug for pediatric growth hormone deficiency (pGHD) failed a phase 3 trial in September. Shares of the company **plummeted more than 80 percent** on the news, eviscerating most of its value. Versartis went public in 2014 in an \$126 million IPO, pricing shares at \$21 apiece (they now trade at just \$1.50).

Aravive was founded in 2016, has raised about \$11.4 million in venture capital, and has received a \$20 million grant from the Cancer Prevention and Research Institute of Texas (CPRIT.) The company will announce a new ticker symbol at a later date.

## Fluorescent fish genes light path to neuroblastoma

Neurodevelopmental biologist [Rosa Uribe](#), a CPRIT Scholar who was recruited to Rice University in 2017 with a grant from the [Cancer Prevention and Research Institute of Texas](#), has a new tool in the search for the origins of neuroblastoma, the third-most common pediatric cancer in the United States.

A new type of zebrafish that produces fluorescent tags in migratory embryonic nerve precursor cells could help a Rice University neurobiologist and cancer researcher find the origins of the third-most common pediatric cancer in the U.S.

Uribe created the transgenic fish with colleagues at the University of Illinois at Chicago and California Institute of Technology and co-authored a [new paper](#) about them this month in the journal *Genesis*.

“You can see they’ve already started to migrate that way, and a lot of them are transitioning,” Uribe said in her office as she traced the movements of green neural crest cells in a time-lapse movie playing on her computer. In humans, neural crest cells are the point of origin for [neuroblastoma](#), a common pediatric cancer, and Uribe’s hoping the new fish can provide clues the disease.

“You can see that a lot of them are transitioning,” she said of the cells on her screen. “Some of them are dividing there, there, there. And then they turn off the green, which means they’re done dividing.”

Why the cells stop dividing is one of the key questions she hopes to answer. [SOX10](#) is one of more than 20 varieties of [SOX](#) proteins, and all of them regulate rapid cell division in fast-growing embryos. The same SOX proteins are also often found activated in cancer cells. Finding the “off” switch for SOX10 in neural crest cells could potentially lead to treatments for cancers where SOX proteins play a role, she said.

Uribe earned her bachelor's degree in cell and molecular biology from San Francisco State University and her doctorate from the University of Texas at Austin. She joined Rice following a postdoctoral fellowship at Caltech, where she first began to study the [enteric nervous system](#) — another area of focus for her lab — which forms from neural crest cells.

“Neural crest cells are stem cells that form from the earliest portion of our central nervous system, the neural tube,” said Uribe, assistant professor of biosciences. “They express SOX10 in addition to a bunch of other really important genes.”

To view neural crest cells during embryonic development, Uribe's team keeps a stock of breeder fish in a state-of-the-art fish room with hundreds of tanks. Embryos — for the new reporter line and more than a dozen others — are removed from the tanks by hand each day and brought to the laboratory for observation.

Zebrafish are used for the studies for several reasons. First, SOX and many other genes in the fish are virtually identical to genes that serve the same basic roles in humans. Second, biologists have amassed a huge body of knowledge about zebrafish, which have been studied as a model organism for decades. Finally, zebrafish breed and develop quickly — a new batch of embryos can be studied each day in Uribe's lab — and the fish are transparent, which means researchers can watch what's happening inside them while they are alive.

Using a variety of methods and microscopes, Uribe and her students immobilize live embryos and take photographs to trace their development over a period of hours. For example, the neural crest cells, which first appear in zebrafish embryos about 12 hours after fertilization, were tracked and observed for up to four hours.

“Neural crest cells also do something else that's relevant to cancer,” Uribe said. “They undergo something called the epithelial-to-mesenchymal transition, or [EMT](#), shortly after they form, and this is what allows them to break away and migrate to the various places in the embryo.”

EMT is important for embryonic development because it allows cells to revert backward along their developmental path and become more stem-like. This malleability allows embryonic cells to form new tissues, but researchers have found many metastatic cancers that use the [same genetic circuitry](#).

Metastasis, or the spread of cancer to other parts of the body, causes more than 90 percent of cancer deaths. EMT is the switch [employed by many cancer cells](#) to break away and become metastatic.

Having the ability to observe neural crest cells from the moment they form until they finish migrating is one key to understanding them. Uribe's team will use the new cell line for this, in addition to others that have different colored tags for different reporter genes. They'll also mix and match genes in new strains of zebrafish to test what happens when cells make either too much of a specific protein or too little. Uribe's lab will use a variety of techniques for this, including CRISPR-Cas9.

Microscopes capable of gathering time-lapse images of the variously colored glowing cells are also critical, and Uribe's lab has seven of them. These include a state-of-the-art robotic instrument with tiny hoses and pumps that can draw a single embryo from a numbered test chamber up through a hose, transport it to the microscope focal plane, bring it into focus, rotate it for photos from any angle and then return it and repeat the process for up to 95 more embryos.

"For the migration time-lapse images there is software that's capable of following individual cells for hours," Uribe said. "We can get angles and trajectories, maps of routes taken by one cell or groups of cells, and we can get quantitative data, like velocities and proliferation rates."

Uribe said CPRIT funding was critical for the purchase of lab equipment that she'll be using to trace the origins of neuroblastoma in neural crest cells.

"Our work on neuroblastoma could only happen with the support of CPRIT," she said.



## **Dell Medical investment begins to pay dividends**

Dell Medical, the University of Texas' new medical school, wants Travis County residents to know it is spending their tax dollars wisely – and equitably.

In 2012, voters approved \$54 million of new property taxes to build Dell Med in conjunction with \$85 million of matching local and federal funds. Construction of the school's facilities on Red River is still ongoing, but that has not stopped it from teaching students or providing health care to the Austin area. Dell Med welcomed its first class in the summer of 2016, and the school has already begun opening clinics and seeing patients.

On Tuesday, Dr. Maninder "Mini" Kahlon and Dr. Michael Pignone made a presentation to the Travis County Commissioners Court detailing some of Dell Med's first health care efforts.

"When we think about our impact in our community, the first way we create impact is through clinics and operations," Kahlon said. She said Dell Med opened its first clinic in mid-October, and through April, the school has seen 2,700 patients, a "large majority" of which were on public health care programs such as Medicare, Medicaid and Central Health's Medical Access Program.

"This shows you immediately that we're beginning to see folks. And most of these areas are sub-specialty areas that didn't have this kind of care focus before – these are new areas for our community," Kahlon said.

Kahlon said Dell Med is also partnering with local health care providers, such as Seton Medical and the People's Community Clinic, contributing its expertise, teaching focus and financial resources. For example, Amy Young of Dell Med's Department of Women's Health worked with local hospitals to examine the use of opioids and cut back their usage where it wasn't necessary. They were able to reduce opioid usage by 40 percent.

"We've also been talking to the community ... and we have come to understand a few priorities from the community that won't surprise you," Kahlon said. In order, they were mental and behavioral health, youth and workforce development, and the mandate to keep Dell Med a "responsible organization for the community."

And being a responsible medical school means providing equitable health care, which is illustrated by Dr. Pignone's work treating colorectal cancer in Travis County.

“Compared to national norms, those cancers are diagnosed at a little bit later stage here than we would like to have them be,” Pignone said. “Part of that reason is because of our high rate of uninsuredness and the number of people who do not have easy access to cancer screening.” Pignone said Travis County’s screening rate for colorectal cancer is 25 percent, while the national average for adults between 50 and 75 years old is about 63 percent.

Pignone wants to close that gap within three years. So, Dell Med worked with the Cancer Prevention Institute of Texas to obtain a \$2.3 million federal grant to introduce a new low-cost screening option – the fecal immunochemical test (FIT), which allows patients to sample their stools at home and mail them in instead of taking time off to get tested at a clinic.

All of this fits in with Dell Med’s mission to train future physicians. “We’re also including our residents and medical students in the projects that they have ... that build their education, help them understand the community’s issues,” Pignone said. “And most importantly, improve the health of our residents.”

The commissioners seemed impressed by Dell Med’s work.

“The area that I represent is often impacted in a disparate way, so I’m certainly interested in being helpful wherever I can. ... I want to be involved in trying to help build the resources that are necessary to address issues,” said Commissioner Jeff Travillion.

“From 2016, about 1,400 Medical Access Program patients, which were the very low-income folks, were on a waiting list of up to a year to see a specialist, and you’ve eliminated the waiting list in roughly seven months. That’s fabulous. In the past we were hearing from people who were on those waiting lists who were in agony and were having to wait what seemed like an eternity to be seen,” Commissioner Brigid Shea said.

“I really appreciate your work with us in the jail, on women’s health, and on many other (areas),” County Judge Sarah Eckhardt said. “It’s very, very helpful to us, and I hope it’s helpful to you all in designing that care delivery system that really has the least among us in mind – those that are most in need of these resources.”

“We want to design the programs for those that have the least access to appropriate health care. Once we’ve done that, then it’s easier to open it up to people that have more resources,” Kahlon said. “Going the other way is dangerous. Because if you design the program for people that have a lot of resources, then try to make it work for those that don’t, that doesn’t work as well.”

Pignone said Dell Med's clinic, UT Health Austin, will begin providing primary care around mid-August.

"If you have friends or family that don't have doctors or are looking for doctors, we're happy to take new patients," he said.

*Correction: The photo accompanying an earlier version of this article was of Seton's hospital. Photo of Dell Medical School courtesy of Dell Medical School.*

*The Austin Monitor's work is made possible by donations from the community. Though our reporting covers donors from time to time, we are careful to keep business and editorial efforts separate while maintaining transparency. A complete list of donors is available [here](#), and our code of ethics is explained [here](#).*

<https://www.austinmonitor.com/stories/2018/07/dell-medical-investment-begins-to-pay-dividends/>





CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

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**MEMORANDUM**

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**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** CAMERON ECKEL, STAFF ATTORNEY  
**SUBJECT:** APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND  
PREVENTION PROGRAMS COMMITTEE  
**DATE:** AUGUST 10, 2018

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**Summary and Recommendation**

The Chief Executive Officer has appointed four experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires the appointments be approved by the Oversight Committee. The Nominations Subcommittee discussed the appointments at its meeting on August 10, 2018, and recommends that the Oversight Committee vote to approve the appointments.

**Discussion**

Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research, including product development research. Peer reviewers perform an important role for the state; all CPRIT grant awards must first be recommended by a Scientific Research and Prevention Programs committee. Individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members must be exceptionally qualified, highly respected, well-established members of the cancer research, product development research, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Nominations Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The Nominations Subcommittee considered the pending peer reviewer appointments and recommends Oversight Committee approval.



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CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

Recommendations for Academic Research Peer Review Panels

- David Feldser, Ph.D
- Thomas Kodadek, Ph.D.
- Sandra Ryeom, Ph.D.
- James Taylor, Ph.D.

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Feldser, David M.

eRA COMMONS USER NAME: dfeldser

POSITION TITLE: Assistant Professor

**EDUCATION/TRAINING**

INSTITUTION AND LOCATION	DEGREE/ POSITION	COMPLETION DATE	FIELD OF STUDY
Juniata College, Huntingdon, PA	BS	05/1998	Biochemistry and Molecular Biology
Johns Hopkins School of Medicine, Baltimore, MD	PHD	12/2006	Human Genetics
Massachusetts Institute of Technology, Cambridge, MA	Postdoctoral Fellow	12/2012	Cancer Biology

**A. Personal Statement**

I founded my laboratory with the explicit goal of identifying the molecular underpinnings of prominent cell state changes that occur during the evolution of deadly forms of lung cancer. Changes in cell state are driven by the stochastic acquisition of genetic and epigenetic alterations that ultimately provide a selective advantage to individual cells within expanding tumors. Understanding the molecular details for how cancer changes its physiological states over time could identify key opportunities to limit the evolution toward, or reverse evolution from, aggressive forms of cancer. To understand this process, my laboratory employs genetically-engineered murine cancer models that recapitulate the genetics, histological progression, treatment response, metastatic capability, and gene expression patterns of prevalent human lung cancer types. In these models, tumors are initiated within the appropriate tissue microenvironment and evolve toward malignant and metastatic states. To elucidate causal relationships between genetic and epigenetic alterations associated with cancer development, our laboratory has developed powerful germline embedded gene switches, as well as virally transduced somatic cell engineering technologies. We leverage our innovative genetic tools to create cancer cell intrinsic alterations to oncogenic signaling, tumor suppressive, and epigenome maintenance pathways that are linked to human cancer. Within these genetically defined *in vivo* systems, we have molecularly defined signaling pathways that influence the cancer cell of origin, drivers of malignant progression, cellular lineage fidelity, and metastatic competency. Because the foundation of our approach is an autochthonous cancer model, the relevant physiological context wherein these cancers form allows us to additionally examine interactions within the tumor microenvironment and the impact of experimental pharmacological interventions. Thus, the scope of our research spans basic fundamental discovery science to translational research approaches that each aim to change the future of cancer therapy.

The bulk of the past research in my laboratory has focused on determining the canonical roles of oncogenes and tumor suppressors such as KRAS and p53 in oncogenic signaling and tumor progression or maintenance. However, our laboratory has recently identified two distinct pathways that control the epigenome to constrain lung cancer progression and metastasis. First, we identified that the major role for the RB tumor suppressor is to constrain epigenetic cell states and that RB loss facilitates lineage infidelity and metastatic ability. Second, we identified SETD2, a histone methyltransferase, as a potent tumor suppressor in lung adenocarcinoma in a systematic *in vivo* screen in the mouse. These discoveries have been pivotal for our laboratory and expanded our research efforts toward elucidating the epigenetic mechanisms deregulated by tumor suppressor gene loss in cancer. Deregulation of the epigenome as an important driver of malignancy and as a treatment vulnerability is becoming increasingly more appreciated, yet our understanding of the resultant cell state changes and the relevant molecular underpinnings is only just beginning to come into focus. Therefore, our current and future research projects address multiple major unmet challenges in cancer.

## **B. Positions and Employment**

1998 - 2000	Research Technician, Johns Hopkins School of Medicine, Gregg Semenza's Laboratory, Baltimore, MD
2000 - 2006	Graduate Student, Johns Hopkins School of Medicine, Carol Greider's Laboratory, Baltimore, MD
2007 - 2012	Postdoctoral Fellow, Massachusetts Institute of Technology, Tyler Jacks' Laboratory, Cambridge, MA
2013 - Present	Assistant Professor, Department of Cancer Biology, University of Pennsylvania, Philadelphia, PA

## **Other Experience and Professional Memberships**

2006 -Present	Member, American Association of Cancer Research
2011	Participant, Mouse Models of Human Cancer Consortium
2013-Present	Member, Penn Cell and Molecular Biology Graduate Program
2013-Present	Member, Penn Immunology Graduate Group
2013-Present	Assistant Investigator, Abramson Family Cancer Research Institute
2015	Reviewer, NCI Small Grants Program for Cancer Research
2017	Reviewer, Cancer Research UK
2018-Present	Member, Penn Epigenetics Institute
2018-Present	Member, Penn Center for Pulmonary Biology

## **Honors**

2005	Fellowship, Department of Molecular Biology and Genetics Training Grant
2006	Scholar in Training Award, American Association of Cancer Research
2007	New England Area Postdoctoral Fellow, American Cancer Society
2007	Postdoctoral Fellowship Award Recipient, Life Sciences Research Foundation
2007	Postdoctoral Fellowship, Anna Fuller Fund
2008-2010	Postdoctoral Fellowship Award, Leukemia and Lymphoma Society
2011	Outstanding Mentor, Undergraduate Research Symposium at MIT
2011	Pathway to Independence Award (K99), NIH/NCI
2013	McCabe Award, University of Pennsylvania
2016	Richard A. "Buz" Cooper Scholar Award, Abramson Cancer Center
2017	Discovery Award, Abramson Family Cancer Research Institute
2017	Alan Steinberg Scholar Award, Department of Cancer Biology

## **C. Contributions to Science**

1. **Mechanisms of tumor progression:** Our work has defined multiple cellular state changes that drive the step-wise evolution of cancer. We have identified that the Raf/Mek/Erk (MAPK) pathway downstream of oncogenic KRAS is thresholded at two key steps during lung adenocarcinoma progression: 1) at the moment of tumor initiation which is related to the cell type of origin, and 2) during the transition to

malignancy that is governed by the p53 tumor suppressor. We have further established that p53 acts to suppress malignant lung adenocarcinomas, by responding to amplified MAPK signaling and leading to apoptotic and immune-mediated destruction of lung adenocarcinomas. We are actively deconstructing this process of p53-mediated tumor cell destruction, and exploring novel therapeutic strategies to sensitize lung adenocarcinomas to p53-reactivating therapies.

We have expanded our research to identify mechanisms of action for the RB tumor suppressor in lung adenocarcinoma, whose role is surprisingly poorly understood. We showed that *Rb* inactivation enables cancer cells to bypass two distinct barriers during tumor progression: 1) RB loss abrogates the requirement for MAPK signal amplification during malignant progression that we defined previously. 2) RB loss deregulates expression of cell state-determining factors to facilitate lineage infidelity, accelerate the acquisition of metastatic competency, and enhance metastatic proclivity. Using our innovative genetic system described below, we found that reactivation of RB expression reprograms advanced tumors toward a less aggressive, non-metastatic state. Nevertheless, RB reactivation is unable to halt cell proliferation and primary tumor growth due to adaptive rewiring of MAPK pathway signaling which supports a cyclin dependent kinase 2 (CDK2)-dependent suppression of RB. Importantly, this observation has highlighted a synergistic interaction for the combined loss of CDK2 and inhibition of CDK4/6 in mouse and human lung adenocarcinomas.

- a. Yates, T.J., Kim-Kisilek, C., Wang, W.Z., Gudiel, A.A., Cicchini, M., Buza, E., Stokes, K.L., Walter, D.M., **Feldser, D.M.** Stage-specific roles of Rb constrain tumour progression, lineage fidelity, and metastasis. [Manuscript in revision at Nature].
- b. Cicchini M, Buza E.L., Sagal K.M., Gudiel A.A., Durham A.C., and **Feldser DM**. Context dependent effects of amplified MAPK signaling during lung adenocarcinoma initiation and progression. 2017 Cell Reports. 2017 Feb 21;18(8):1958-1969. PMID: 28228261 ; PubMed Central PMCID:PMC5405440
- c. **Feldser DM**, Kostova KK, Winslow MM, Taylor SE, Cashman C, Whittaker CA, Sanchez-Rivera FJ, Resnick R, Bronson R, Hemann MT, Jacks T. Stage-specific sensitivity to p53 restoration during lung cancer progression. Nature. 2010 Nov 25;468(7323):572-5. PubMed PMID: 21107428; PubMed Central PMCID: PMC3003305.

2. **Advances in cancer modeling in the mouse:** My laboratory has made several major technological advancements to facilitate interrogation of gene function within *in vivo* mouse model systems. We have developed gene trap elements that can be regulated by the action of site-specific recombinases to simultaneously inactivate gene function and report endogenous gene expression. Currently two systems are available: 1) CK alleles faithfully report endogenous gene expression by maintaining expression of the endogenous mRNA thereby accounting for proper post-transcriptional processing while reporting gene expression. 2) XTR alleles allow the sequential inactivation of endogenous gene loci through the action of Cre recombinase, and also allow the accurate restoration of gene function via controlled induction of the Flp recombinase.

Additionally, we have developed a lentiviral vector system to enable CRISPR/Cas-mediated gene disruption in the context of Cre-inducible mouse model systems. We systematically screened genes that are mutated in human lung adenocarcinoma but lack functional validation of their causal relationship with the disease. We identified SETD2, a histone methyltransferase frequently mutated in multiple human tumor types, as a *bona fide* tumor suppressor in oncogenic KRAS-driven lung adenocarcinoma. Unknown however, is the manner in which epigenetic remodeling caused by SETD2 loss effectuates cancer progression. Identifying these mechanisms in our genetically lung adenocarcinoma model is a major ongoing research program in my laboratory that will have important implications for the plethora of tumor types that also frequently harbor SETD2 mutation. Our CRISPR/Cas lentiviral vectors that made this discovery possible are freely available and have been distributed to more than a hundred different laboratories around the world thus far.

- a. Acosta J, Wang W, and **Feldser DM** (2018). Off and Back-On Again: A Tumor Suppressor's Tale. Oncogene. 2018 Mar 15. doi: 10.1038/s41388-018-0186-3. [Epub ahead of print] Review. PMID: 29540833
- b. Walter DM, Venancio OS, Buza EL, Tobias JW, Deshpande C, Gudiel AA, Kim-Kisilek C, Cicchini M, Yates TJ, and **Feldser DM**. Systematic *in vivo* inactivation of chromatin regulating enzymes identifies Setd2 as a potent tumor suppressor in lung adenocarcinoma. Cancer Res. 2017 Apr 1;77(7):1719-1729. doi: 10.1158/0008-5472.CAN-16-2159. Epub 2017 Feb 15. PMID: 28202515; PubMed Central PMCID: PMC5380596

- c. Robles-Oteiza C, Taylor S, Yates T, Cicchini M, Lauderback B, Cashman CR, Burds AA, Winslow MM, Jacks T, **Feldser DM**. Recombinase-based conditional and reversible gene regulation via XTR alleles. *Nat Commun*. 2015 Nov 5;6:8783. PubMed PMID: 26537451; PubMed Central PMCID: PMC4635517
  - d. Chiou SH, Kim-Kiselak C, Risca VI, Heimann MK, Chuang CH, Burds AA, Greenleaf WJ, Jacks TE, **Feldser DM**, Winslow MM. A conditional system to specifically link disruption of protein-coding function with reporter expression in mice. *Cell Rep*. 2014 Jun 26;7(6):2078-86. PubMed PMID: 24931605; PubMed Central PMCID: PMC4113058.
3. **Telomere dysfunction in cancer:** I established a working framework for how short dysfunctional telomeres might impinge on cancer development and then used a mouse model of Burkitt's lymphoma to assess the impact that short telomeres would have on the development of that B cell malignancy. We found that short telomeres would strongly induce the p53 pathway and potentially select for resultant tumors that harbored mutations in the p53 gene. What was noteworthy about our findings was for the first time, we were able to demonstrate that short telomeres could limit tumor formation by inducing a p53-dependent senescence response within the mouse. At the time, senescence was just emerging as a bona fide tumor suppressor mechanism and despite the fact that short telomeres were discovered as the original inducer of senescence in cultured cells, no one had yet observed this phenomenon in an *in vivo* cancer system.
- a. **Feldser DM**, Greider CW. Short telomeres limit tumor progression *in vivo* by inducing senescence. *Cancer Cell*. 2007 May;11(5):461-9. PubMed PMID: 17433785; PubMed Central PMCID: PMC1945093.
  - b. **Feldser D**, Strong MA, Greider CW. Ataxia telangiectasia mutated (Atm) is not required for telomerase-mediated elongation of short telomeres. *Proc Natl Acad Sci U S A*. 2006 Feb 14;103(7):2249-51. PubMed PMID: 16467146; PubMed Central PMCID: PMC1413760.
  - c. **Feldser DM**, Hackett JA, Greider CW. Telomere dysfunction and the initiation of genome instability. *Nat Rev Cancer*. 2003 Aug;3(8):623-7. PubMed PMID: 12894250.

Complete List of Published Work in My Bibliography:  
<http://1.usa.gov/2115Mkr>

## D. Additional Information: Research Support

### Ongoing Research Support

R01 CA193602	Feldser, David (PI)	07/01/15-06/30/20
p53-Mediated Tumor Immune Surveillance		
Role: PI		

LCD-400095, American Lung Association	Feldser, David (PI)	07/01/16-06/30/18
Restoration of the Rb Pathway by Cdk2 inhibition in lung adenocarcinoma		
Role: PI		

### Pending Research Support

R01CA222503 (7th percentile)	Feldser, David (PI)	07/01/18-06/30/23
Deconstructing the multi-faceted roles of Rb in tumor progression		
Role: PI		

### Completed Research Support

R21 CA205340	Feldser, David (PI)	04/01/16-03/31/18
Identifying Mechanisms of p53 and Rb Tumor Suppression In Small Cell Lung Cancer		
Role: PI		

American Cancer Society: Abramson Cancer Center Award		
Breakthrough Bike Challenge	Feldser, David (PI)	02/01/16-01/31/17
Modeling the therapeutic effects of p53 and Rb pathway restoration in prostate cancer		
Role: PI		



**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Thomas Kodadek

eRA COMMONS USER NAME (credential, e.g., agency login): tkodadek

POSITION TITLE: Professor

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Miami (Coral Gables, FL)	B.S.	1977-1981	Chemistry
Stanford University (Stanford, CA)	Ph.D.	1981-1985	Organic Chemistry
University of California, San Francisco	Post-Doc	1987-1987	Biochemistry

**A. Personal Statement**

I am qualified to lead this project. My laboratory has broad expertise in many areas of chemistry and biology and significant experience in proteasome biochemistry. On the chemical side, I have pioneered the synthesis and screening of large libraries of non-peptidic oligomers as a rich source of high affinity and selectivity protein ligands, including recently published work using DNA-encoded libraries. We have discovered the only Rpn13 inhibitor. On the biological side, we have made several discoveries regarding the role of the proteasome in transcription.

1. Mendes, K., Malone, M.L., Ndungu, J.M., Saponitsky-Kroyter, I., Cavett, V., McEnaney, P.J., MacConnell, A.B., Doran, T.M., Ronacher, K., Stanley, K., Utset, O., Walzl, G., Paegel, B.M. and Kodadek, T. (2017) "High-throughput identification of DNA-encoded IgG ligands that distinguish active and latent Mycobacterium Tuberculosis infections" **ACS Chem. Biol.** 12, 234-243. PMC5250564.
2. Trader, D.J., Simanski, S. and Kodadek, T. (2015) "A reversible and highly selective inhibitor of the Ubiquitin receptor Rpn13 is toxic to multiple myeloma cells" **J. Amer. Chem. Soc.** 137, 6312-6319. DOI: 10.1021/jacs.5b02069. PMC4455945.
3. Nalley, K., Johnston, S.A. and Kodadek, T. (2006) "Proteolytic turnover of Gal4 is not required for function in vivo" **Nature** 442, 1054-1057.
4. Archer, C.T., Burdine, L., Liu, B., Ferdous, A., Johnston, S.A. and Kodadek, T. (2008) Physical and functional interaction of mono-ubiquitylated transactivators with the proteasome" **J. Biol. Chem.** 283, 21789-21798.

**B. Positions & Honors:** Professor of Chemistry, Scripps Florida (2009-Present). Professor of Internal Medicine and Molecular Biology (1998-2009) UT-Southwestern Medical Center. Professor of Chemistry and Biochemistry, University of Texas at Austin (1987-1997).

**Awards:** National Merit Scholar, Presidential Scholar, Jane Coffin Childs Postdoctoral Fellow (1985-1987). American Cancer Society Junior Faculty Research Award (1989-1991). Fellow of the AAAS (elected 1999). NIH Director's Pioneer Award (2006-2011). Amer. Chem. Soc. Cope Scholar Award (2016). National Academy of Inventors (elected 2016),

## **Professional Activities and Services**

Founding Chair of the Editorial Board of *Molecular Biosystems* (Royal Society of Chemistry)(2004-2009). Associate Editor of *Chemistry & Biology* (1999-2003). Co-Editor of January 2000 & Feb. 2005 issues of *Curr. Opin. Chem. Biol.* Member, NIH BNP Study Section (2000-2004) and Chair (2002-2004). Vice Chair (2002) and Chair (2004) of the Gordon Conference on the Chemistry and Biology of Peptides.

## **C. Contribution to Science**

**1. The Protein Machine” for Homologous Recombination.** Early work in my laboratory focused on unraveling the biochemistry of homologous genetic recombination. At the time (late 1980s) virtually all of the attention of recombination biochemists was focused on the *E. coli* RecA protein and the prevailing idea is that this single protein drove virtually all aspects of exchange of DNA strands in recombination. However, the genetics of recombination in prokaryotic organisms suggested a far more complex machinery and earlier studies in DNA replication had made clear that this process was driven by very large, dynamic, multi-protein complexes. My work in the phage T4 model system systemically assigned biochemical functions to most of the proteins implicated genetically as having a role in recombination. For example, we discovered the function of the UvsY accessory protein, which aids the UvsX protein (the T4 analogue of RecA) in assembling onto single-stranded DNA coated with gp32 (the T4 single-stranded DNA binding protein) and then stabilizes the nucleoprotein filaments, which are the key intermediates in strand exchange. We also showed that two different DNA helicases play critical roles in regulating the size and stability of recombination intermediates. In summary our work illuminated the structure and function of the “protein machine” for genetic recombination for the first time. Subsequent work by other laboratories in mammalian systems has shown that these cells have analogues of the T4 proteins whose function we worked out and that the same mechanisms discovered by us are employed by higher eukaryotes.

- A. Kodadek, T.; Gan, D. C. and Stemke-Hale, K. (1989) “The phage T4 uvsY recombination protein stabilizes presynaptic filaments” **J. Biol. Chem.** 264, 16451-16457.
- B. Kodadek, T. (1990) “The role of the bacteriophage gene 32 protein in homologous pairing” **J. Biol. Chem.** 265, 20966-20969.
- C. Houston, P. and Kodadek, T. (1994) “Spectrophotometric assay for enzyme-mediated unwinding of double-stranded DNA” **Proc. Natl. Acad. Sci. USA** 91, 5471-5474.
- D. Salinas, F. and Kodadek, T. (1995) “Phage T4 homologous strand exchange: A DNA helicase, not the strand transferase, drives polar branch migration” **Cell** 82, 111-119.

**2. Multiple Roles of the Proteasome In Eukaryotic Transcription.** The other major area of biology that attracted my attention in the early and middle part of my career was eukaryotic transcription. Much of this work was done in collaboration with Prof. Stephen Johnston, whose expertise in molecular genetics mixed well with my skills in chemistry and biochemistry. Several important contributions came from this work. First, using the yeast Gal4 transactivator as a model system, we discovered new mechanisms that allow the transactivator to associate with a promoter and thus drive transcription to a high level. These included the demonstration that transactivators rely on contacts with the general transcription machinery to remain stably bound to the promoter and that transactivators can bind cooperatively to chromatin without physically contacting one other through nucleosome positioning effects. In another phase of this work, we made the important discovery that a sub-unit of the proteasome, specifically the ring of six protein-unwinding ATPases, plays a non-proteolytic role in the transcription of many genes. Its primary role is to stimulate transcriptional elongation but it also regulates the establishment of an activated transcription complex at the promoter. This work opened up a whole new sub-field of transcription enzymology.

- A. Vashee, S. and Kodadek, T. (1995) “The activation domain of GAL4 protein mediates cooperative promoter binding with general transcription factors in vivo” **Proc. Natl. Acad. Sci. USA** 92, 10683-10687.
- B. Vashee, S., Melcher, K., Ding, W., Johnston, S.A. and Kodadek, T. (1998) “Two novel mechanisms for cooperative binding of transcription factors to promoters in vivo” **Curr. Biol.** 8, 452-458.
- C. Ferdous, A., Gonzalez, F., Sun, L., Kodadek, T. and Johnston, S.A. (2001) “The 19S regulatory particle of the proteasome is required for efficient transcription elongation by RNA polymerase II” **Mol. Cell** 7, 981-991.

D. Gonzalez, F., Delahoude, A., Kodadek, T. and Johnston, S.A. (2002) "A sub-complex of the 19S proteasome regulatory complex is recruited to an activated promoter" **Science**, 296, 548-550.

3. **Chemical Tools for the Study of Protein Complexes.** As indicated in the two synopses discussed above, I have long been fascinated by the workings of multi-protein complexes, sometimes called "protein machines". Given my training in chemistry, I have a longstanding interest in developing new chemical tools with which to study these complexes, including their structure, dynamics and mechanism of action. For example, we developed new protein-protein and protein-small molecule cross-linking reagents that are far faster and more efficient than traditional reagents. For example, we developed hyper-fast and efficient photo-triggered cross-linking reaction using water-soluble Ru(II) complexes. When illuminated for less than one second with visible light in the presence of a single electron acceptor, a Ru(III) complex is formed that oxidizes tyrosine or tryptophan residues efficiently, resulting in the production of protein radicals, which rapidly undergo cross-linking to nearby residues. Because of the short half-life of the radical, if the oxidized protein is not closely associated with a partner, no cross-links are formed, in stark contrast to traditional cross-linking reagents, which exhibit a high level of "false positive" cross-linking. Another useful oxidative chemistry we developed was the periodate-mediated oxidation of small molecules, peptide, or proteins tagged with a 1,2-dihydroxybenzene (catechol) unit such as DOPA. This results in the formation of an electrophilic ortho-quinone that cross-links rapidly and efficiently to nearby nucleophilic residues. Again, the reactive intermediate has a short half-life in biological buffers so if the tagged molecule is not bound to a partner no cross-linking is observed. We and others have used these reactions extensively. For example, the Ru-mediated cross-linking reaction is now the method of choice to examine interactions between amyloid proteins. We have employed the DOPA chemistry to work out how transcription factor mono-ubiquitylation enhances the ability of the protein to engage DNA. An interesting outgrowth of the Ru chemistry has been the development of photo-triggered antagonists that inactivate their protein target via a photo-triggered burst of locally delivered singlet oxygen.

A. Fancy, D.A., Kodadek, T. (1999) "Chemistry for the analysis of protein-protein interactions: Rapid and efficient cross-linking triggered by long wavelength light" **Proc. Natl. Acad. Sci. USA** 96, 6020-6024.

B. Fancy, D.A., Denison, C., Kim, K., Xie, Y., Holdeman, T., Amini, F. and Kodadek, T. (2000) "Scope, limitations and mechanistic aspects of the photo-induced cross-linking of proteins by water-soluble metal complexes" **Chem. & Biol.** 7, 697-708.

C. Liu, B., Burdine, L. and Kodadek, T. (2006) "Chemistry of periodate-mediated cross-linking of 3,4-dihydroxyphenylalanine (DOPA)-containing molecules to proteins" **J. Amer. Chem. Soc.** 128, 15228-15235.

D. Liu, B., Archer, C.T., Burdine, L., Gillette, T.G. and Kodadek, T. (2007) "Label transfer chemistry for the characterization of protein-protein interactions" **J. Amer. Chem. Soc.** 129, 12348-12349.

4. **Rapid Discovery Of Protein Ligands With High Affinity And Selectivity: Application to Medical Diagnostics and Drug Development.** Much of my effort over the last 12 years has been focused on developing the next generation of screening technology for the discovery of bioactive compounds. Briefly, we have elaborated and optimized the split and pool solid-phase synthesis of one bead one compound libraries such that it is now a powerful and reliable method for the discovery of high affinity and selectivity protein ligands. A particularly important advance has been the development of new chemistry with which conformationally constrained oligomers can be made in vast numbers using these technique, which had previously been largely restricted to "floppy" molecules like peptide and peptoids. As expected, libraries of this type have yielded vastly superior protein ligands relative to similar peptide and peptoid libraries. Efforts are underway to apply this technology to the discovery of useful probe molecules and drug leads. We have applied this technology in a particularly innovative way (recognized by an NIH Director's Pioneer Award) to discover diagnostically useful antibody biomarkers of disease. This is done by carrying out differential screens with case and control serum samples and identifying compounds that bind far more antibodies from the case samples than the controls. While a number of technical difficulties had to be surmounted, this protocol is now working well and is yielding diagnostically valuable antibody-binding reagents. A extension of this technology is that the synthetic "antigen surrogates" can be used to affinity purify the antibodies to which they

bind. These, in turn, can be used to “fish out” the native antigens recognized by the disease-linked antibodies. We have recently used this approach to identify novel autoantigens for Type 1 diabetes.

- A. Udugamasooriya, D.G., Dineen, S.P., Brekken, R.A. and Kodadek, T. (2008) “A peptoid “antibody surrogate” that antagonizes VEGF Receptor 2 activity” **J. Amer. Chem. Soc.** 130, 5744-52.
- B. Lim, H.-Y., Archer, C.T. and Kodadek, T. (2007) “Identification of a peptoid inhibitor of the proteasome 19S regulatory particle” **J. Amer. Chem. Soc.** 129, 7750-7751.
- C. Aquino, C., Sarkar, M., Chalmers, M.J., Mendes, K., Kodadek, T. and Micalizio, G. (2011) “ A Biomimetic polyketide-inspired approach to small molecule ligand discovery” **Nature Chemistry** 4, 99-104. PMC3266625
- D. Doran, T.M., Morimoto, J., Simanski S., Koesema E, Clark L.F., Pels, K., Stoops S.L., Pugliese A., Skyler J. and Kodadek, T. (2016) “Discovery of phosphorylated peripherin as a major humoral autoantigen in type 1 diabetes mellitus using ‘epitope surrogate’ technology” **Cell Chem. Biol.** 23, 618-628.

Complete List of Published Work in My Bibliography:

<http://www.ncbi.nlm.nih.gov/sites/myncbi/thomas.kodadek.1/bibliography/46530392/public/?sort=date&direction=ascending>

**D. Research Support.**

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Ryeom, Sandra

eRA COMMONS USER NAME (credential, e.g., agency login): sryeom

POSITION TITLE: Associate Professor with Tenure,  
Co-leader of Tumor Biology Program, Abramson Cancer Center

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Wellesley College, Wellesley, MA	B.A.	1985-1989	Physics
Weill Cornell Graduate School of Medical Sciences, New York, NY	Ph.D.	1991-1996	Cell Biology & Genetics
Harvard Medical School, Boston MA	Post-doctoral fellowship	1997-2005	Cell Biology

**A. Personal Statement**

I am currently an Associate Professor in the Department of Cancer Biology and an Associate Member in the Abramson Family Cancer Research Institute. My work is focused on understanding the mechanisms that regulate the tumor microenvironment in both primary tumors and early metastatic lesions, during development and in different organ environments and as a critical cellular population in stem cell niches. We are interested in many different tumor types including lung, breast, gastric, pancreatic, sarcoma and glioblastoma and how organ specific tumor microenvironments are differentially regulated. My lab also investigates regulation of endogenous angiogenesis inhibitors and links to classic tumor suppressive pathways as well as cross talk between endothelial cells and stromal cells during pathologic conditions as well as during development. We have a large effort directed towards isolating, characterizing and understanding regulation of primary endothelial cells in different organ environments and their role in tumor progression and generating pre-metastatic sites in normal organs as well as bone marrow-derived endothelial progenitors and their role in normal developmental processes, in promoting tumor growth and in other pathologic conditions including benign disease. Another area of interest is focused on understanding the role of the ser/thr phosphatase calcineurin and its downstream signaling pathway in the tumor microenvironment both in endothelial cells, fibroblasts and other stromal cells such as megakaryocytes and platelets. I have extensive experience in investigating mechanisms that regulate physiologic and pathologic angiogenesis, endothelial cell activation and the tumor vasculature using mouse models, biochemical and molecular biological approaches. I also have significant expertise in generating genetically engineered mouse models of cancer with targeted transgenic, tissue specific, inducible, conditional and reversible approaches.

**B. Positions and Honors****Positions**

1989-1991 Research Assistant, Division of Infectious Diseases, Beth Israel Hospital, Boston, MA  
1991-1996 Graduate Student, Dept. of Cell Biology and Genetics, Cornell University, NYC, NY  
1997-2005 Postdoctoral Fellow: Dept. of Cell Biology Harvard Medical School, Boston, MA  
2006-2009 Research Associate, Vascular Biology Program, Children's Hospital  
Instructor/Assistant Professor, Harvard Medical School, Boston, MA

- 2009-2016 Assistant Professor, Dept. of Cancer Biology, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA; Assistant Member, Abramson Family Cancer Research Institute, Philadelphia PA
- 2016-present Associate Professor with Tenure, Dept. of Cancer Biology, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA; Associate Member, Abramson Family Cancer Research Institute, Philadelphia PA
- 2016-present Co-leader, Tumor Biology Program, Abramson Cancer Center, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA.
- 2018-present Chair, Cancer Biology Graduate Program, Abramson Cancer Center, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA.

### Honors

- 1989 Senior Physics Thesis Research Honors, Wellesley College, Wellesley, MA.
- 1994 Award of Excellence, Vincent Du Vigneaud Symposium, Cornell University, New York, NY.
- 1994 Trainee Investigator Award, American Federation of Clinical Research, Baltimore, MD.
- 2004 Recipient of speaker award, FASEB "Protein Phosphatase" Conference Snowmass, CO.
- 2016 Selected as Penn Fellow, University of Pennsylvania, Philadelphia PA.

### C. Contribution to Science

1. **Calcineurin regulation.** During my post-doc, I identified a family of endogenous regulators of the calcium activated ser/thr phosphatase, calcineurin, the target of the immunosuppressive drugs cyclosporin A and FK506. This was one of the first studies to demonstrate a new level of calcium independent regulation of calcineurin in lymphocytes and demonstrated that calcineurin can downregulate its own activity through classical feedback inhibition through transcriptional upregulation of the calcipressin, CSP1 (now renamed as DSCR1).
  - a. **Ryeom S**, Greenwald RJ, Sharpe AH, McKeon F. (2003) The threshold pattern of calcineurin-dependent gene expression is altered by loss of the endogenous inhibitor calcipressin. *Nature Immunol.* 4:874-81.
2. **Calcineurin signaling, Down syndrome, tumor angiogenesis and tumor growth.** My lab demonstrated the bi-phasic effects of endothelial cell activation during tumor angiogenesis and subsequent tumor growth. For many years, the assumption in the field of tumor angiogenesis was that the extent of endothelial activation correlated with the degree of tumor angiogenesis. We showed that both low and high levels endothelial activation inhibited tumor angiogenesis and tumor growth through different mechanisms. Further, my work has also demonstrated that the endogenous calcineurin inhibitor, CSP1, re-named the Down syndrome candidate region-1 (*DSCR*) gene, plays an important role in regulating tumor angiogenesis by inhibiting calcineurin-NFAT signaling. We showed the physiological relevance and importance of calcineurin signaling in tumor angiogenesis illustrated by the protection against solid tumors observed in Down syndrome (DS) individuals. Our work shows that significantly decreased tumor growth in DS is due in part to attenuation of calcineurin signaling in endothelial cells by the increased expression of chromosome 21-encoded inhibitors of this pathway including *Dscr1* suggesting that these two genes may be targetable therapeutic options for cancer prevention.
  - a. **Ryeom S\***. et al. (2008). Targeted deletion of the calcineurin inhibitor DSCR1 suppresses tumor growth. *Cancer Cell* 13:420-31. \*corresponding author
  - b. Baek KH, Zaslavsky A, Lynch RC, Britt C, Okada Y, Siarey RJ, Lensch MW, Park, IH, Yoon SS, Minami T, Reeves R, Korenberg JR, Folkman J, Daley GQ, Aird WC, Galdzicki Z, **Ryeom S**. Down's syndrome suppression of tumour growth and the role of the calcineurin inhibitor DSCR1. (2009). *Nature* 459:1126-30. PMID: PMC2724004
3. **Calcineurin signaling, tumorigenesis and the pre-metastatic niche.** We have also shown that calcineurin signaling in the vascular endothelium plays an important role in metastatic progression in the lung. Our studies showed that the calcineurin-NFAT pathway is activated in lung endothelium, contributing to a pre-metastatic niche for tumor cells that preferentially metastasize to the lung. Recent studies have also

identified thrombospondin-1 (TSP1) as a direct target of calcineurin-NFAT signaling and activation of this pathway via shear stress is critical for tumor vessel remodeling. We have also shown that calcineurin signaling in megakaryocytes contributes to acute megakaryoblastic leukemia as evidenced by the increased incidence of this subtype of myeloid leukemia in children with Down syndrome who demonstrate attenuation of calcineurin signaling.

- a. Minami T, Jiang S, Schadler K, Suehiro J, Osawa T, Oike Y, Miura M, Naito M, Kodama T, **Ryeom S.** (2013). The Calcineurin-NFAT-Angiopoietin 2 signaling axis in lung endothelium is critical for the establishment of lung metastases. *Cell Reports* 4:709-723. PMID: PMC3763962
  - b. Zaslavsky A, Chou ST, Schadler K, Lieberman A, Pimkin M, Kim YJ, Baek KH, Aird WC, Weiss MJ, **Ryeom S.** (2013). The calcineurin-NFAT pathway negatively regulates megakaryopoiesis. *Blood* 121:3205-3215. PMID: PMC3630833
  - c. Schadler KL, Thomas NJ, Galie PA, Bhang DH, Roby KC, Addai P, Till JE, Sturgeon K, Zaslavsky A, Chen CS, **Ryeom S** (2016). Tumor vessel normalization after aerobic exercise enhance chemotherapeutic efficacy. *Oncotarget* 7(40):65429-65440. PMID: PMC5323166
4. **Novel functions for Thrombospondin-1.** Our work has shown that one of the most potent angiogenesis inhibitors, thrombospondin-1 (TSP-1) may be a potential biomarker for tumor growth and regression by its level of expression in platelets and that TSP-1 also plays a role in lung cancer cells and T cells. Our work on TSP-1 in lung cancer cells is the first to demonstrate a previously unknown cancer cell autonomous function for TSP-1 to sustain oncogenic Ras-induced senescence in the lung. Further work on the role of TSP-1 in lymphocytes demonstrates that T cells can produce TSP-1 to block tumor angiogenesis and that production of lymphocyte-derived TSP-1 can be manipulated via T cell activation. Collectively work from my lab on TSP-1 illustrates context specific functions for angiogenic proteins and identifies novel roles for TSP-1 in lung cancer.
- a. Zaslavsky A, Baek KH, Lynch RC, Short S, Grillo J, Folkman J, Italiano JE, **Ryeom S.** (2010). Platelet-derived thrombospondin-1 (TSP-1) is a critical negative regulator and potential biomarker of angiogenesis. *Blood* 115:4605-13. PMID: PMC2881490
  - b. Baek KH, Bhang DH, Zaslavsky A, Wang LC, Vachani A, Kim CF, Albelda SM, Evan GI, **Ryeom S.** (2013). Thrombospondin-1 mediates oncogenic Ras-induced senescence in pre-malignant lung tumors. *J. Clin. Invest.* 123:4375-4389. PMID: PMC3784530
  - c. Schadler KL, Crosby EJ, Zhou AY, Bhang DH, Braunstein L, Baek KH, Crawford D, Crawford A, Angelosanto J, Wherry EJ, **Ryeom S.** (2014). Immunosurveillance by antiangiogenesis: tumor growth arrest by T cell-derived thrombospondin-1. *Cancer Res.* 74(8):2171-81. PMID: PMC4061618
5. **Cyclosporin A and tumor growth.** We have identified calcineurin-independent effects of the immunosuppressive drug cyclosporin A in promoting tumor growth. Long-term treatment of organ transplant recipients with cyclosporin A leads to an increased incidence of cancer. However, the mechanism of tumor promotion by cyclosporin A is not understood. Our work demonstrates that cyclosporin A promotes tumor growth by increasing tumor angiogenesis via upregulation of reactive oxygen species. This work implicates that co-treatment of patients on long-term cyclosporin A therapy with anti-oxidants may suppress the increased incidence of cancer in this population.
- a. Zhou AY, **Ryeom S.** (2014). Cyclosporin A promotes tumor angiogenesis in a calcineurin-independent manner by increasing mitochondrial reactive oxygen species. *Mol Cancer Res.* 12(11):1663-76. PMID: PMC4233164

**URL for a full list of my published work:**

<https://www.ncbi.nlm.nih.gov/myncbi/browse/collection/41163786/?sort=date&direction=descending>

**D. Additional Information: Research Support and/or Scholastic Performance**

**Ongoing Research Support**

R01 CA118374-06  
NIH/NCI

Ryeom (PI)

04/01/15-03/31/20

**“Calcineurin-NFAT regulates endothelial activation in pre-metastatic sites”**

The major goals of this project are: 1) To determine whether *Dscr1* mediates cancer protection in genetically engineered mouse models of *Dscr1* over-expression and Down syndrome; 2) To examine the role of thrombospondin-1 as a recently identified target of VEGF-calcineurin-NFAT signaling in endothelial cells, in modulating tumor angiogenesis; 3) To determine the differential mechanisms by which DSCR1 and cyclosporin A block calcineurin activity.

Role: PI

No Grant #

Ryeom (PI)

4/01/17-03/30/18

Breast Cancer Research Foundation

**“The Role of Endothelial Cells in the Tumor Microenvironment”**

This grant is investigating the role of endothelial cells in tumor angiogenesis and in crosstalk with stromal cells in both primary tumors and early metastatic sites.

No Grant #

Ryeom (PI)

12/1/16-11/30/18

TedDriven Foundation

**“Tumor Angiogenesis”**

This grant investigates cellular and molecular mechanisms of tumor angiogenesis.

Role:PI

**Completed Research Support**

2R01 CA094214-10

Costas Koumenis (PI)

08/01/12-07/30/17

NIH/NCI

**“Role of eIF2a phosphorylation and ER stress in hypoxia tolerance and tumor growth”**

R01 to examine how the integrated stress response transducers PERK and GCN2, which are activated under conditions of tumor microenvironmental stress, activate pathways that lead to increased cell survival and angiogenesis and contribute to metastasis.

Role: Co-Investigator

P30-DK050306

Anil Rustgi (PI)

7/1/16-6/30/17

NIDDK Center Grant

**“E-cadherin is the gatekeeper to primary gastric tumorigenesis”**

Pilot grant to characterize a newly generated mouse model of gastric cancer with oncogenic Kras expression, E-cadherin and p53 loss driven by Cre expression in gastric parietal cells via Atp4B-driven Cre.

Role: Pilot grant recipient

N/A

Ryeom (PI)

05/01/13-12/31/16

Pennsylvania Department of Health (CURE Fund)

**“VEGF Receptor Inhibition in Lung and Liver Metastases”**

Commonwealth of PA funds to investigate how differential expression of VEGF receptor 1 and VEGF receptor 2 on lung versus liver endothelial cells effect VEGF receptor inhibition in the progression of lung and liver metastases.

Role: PI

N/A

Ryeom (PI)

06/01/13-12/31/16

Pennsylvania Department of Health (CURE Fund)

**“Calcineurin-NFAT signaling in megakaryocytic leukemia of Down syndrome**

Commonwealth of PA funds investigate the role of the calcineurin pathway in promoting megakaryopoiesis and to determine how a chromosome 21 encoded inhibitor of this pathway may underlie the increased incidence in acute megakaryocytic leukemia in the Down syndrome population/

Role: PI

U54 CA155850

Kathryn Schmitz (PI)

06/24/11-05/31/16

NIH/NCI

**“Penn TREC Survivor Center”**

U54 program project to establish a sustainable transdisciplinary research program extending from “bench to trench”. Project 1 will explore whether exercise and/or weight loss will alter breast cancer recurrence in mice and explore effects on biomarkers of potential mechanistic pathways.

Role: Co-Investigator (Project 1)

No Grant #  
(NCE)

Jill Ginsburg - CHOP (PI)

07/01/14-06/30/16

St. Baldrick’s Foundation

**“Testicular Tissue Cryopreservation Consortium”**

St. Baldrick’s Foundation Funds to investigate the role of testicular endothelial cells (TECs) in supporting the maintenance and self-renewal of spermatogonial stem cells (SSCs) to culture SSCs long-term providing a possible fertility preservation option for prepubertal boys newly diagnosed with cancer.

Role: Co-PI

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## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

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NAME: Taylor, James Peter

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eRA COMMONS USER NAME (credential, e.g., agency login): jpt4.nyu

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POSITION TITLE: Ralph S. O'Connor Associate Professor of Biology, Associate Professor of Computer Science

---

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Vermont, Burlington VT	B.S.	12/2000	Computer Science
Penn State University, University Park PA	PhD	05/2006	Computer Science

### A. Personal Statement

I have extensive experience in the analysis and management of high throughput genomic data. As one of the lead PIs on the Galaxy project, I have spent years working on approaches to managing large-scale sequence datasets, making the analysis of these datasets tractable, and ensuring that computational analysis can be transparently and reproducibly communicated within research groups and to the public. I have a background in software engineering and have successfully managed the engineering efforts of the Galaxy team, including integrating ongoing contributions from the community while still maintaining a reliable high-quality software framework for nearly 10 years. In addition to participating in several genome analysis and annotation projects, I have been and am involved in several large-scale functional genomic efforts. I was a participant in several core analysis groups of the ENCODE pilot project, and was particularly involved in the integrated analysis of datasets related to transcriptional regulation. In all of these projects, I have experience in applying statistical and machine learning methods to predict functional regions with high confidence and to identify predictive relationships between features. Additionally, I have substantial experience in the analysis of 3-D chromatin organization data generated from 3C, 5C, Hi-C and related assays.

### B. Positions and Honors

#### Positions and Employment

1999-2001	Senior Software Engineer, The NYBOR Corporation, Williston VT
2001-2003	Senior Software Engineer, 4Lane Digital, Burlington VT
2003-2006	Research Assistant, Penn State University, University Park PA
2006-2008	Visiting Member / Courant Instructor, New York University, New York NY
2008-2013	Associate Professor, Emory University, Atlanta GA
2014-	Associate Professor, Johns Hopkins University, Baltimore MD

## C. Contribution to Science

**Software to enable data-intensive biomedical research:** High-throughput data production techniques, including DNA sequencing, have transformed modern biology into a data intensive science. However, lack of informatics resources and expertise prevent many researchers from making effective use of these techniques. In 2005 we created Galaxy (<http://galaxyproject.org>), a software framework for making complex analysis tools accessible for researchers without informatics expertise. Galaxy makes analysis easier to perform, while at the same time providing automatic provenance, thus greatly increasing transparency and reproducibility of the resulting analyses. We have extended Galaxy with support for cloud computing, interactive visualization and visual analytics, and sharing of tools and workflows while retaining precise reproducibility. Galaxy is open-source software and has become one of the mostly widely used tools in genomic research.

1. Goecks J, The Galaxy Team, Nekrutenko A, **Taylor J**. “A comprehensive approach for supporting accessible, reproducible, and transparent computational research in the life sciences”. *Genome Biology* 2010 Sep; 11:R86. PMID: PMC2945788
2. Afgan E, Baker D, Coraor N, Goto H, Paul IM, Makova KD, Nekrutenko A, **Taylor J**. “Harnessing cloud-computing with Galaxy Cloud”. *Nature Biotechnology* 2011 Nov; 29:972–974. PMID: PMC3868438.
3. Goecks J, Coraor N, The Galaxy Team, Nekrutenko A\*, and **Taylor J\***. “NGS analyses by visualization with Trackster”. *Nature Biotechnology* 2012 Nov; 30:1036–1039. PMID: PMC3889118.
4. Goecks J, Eberhard C, Too T, The Galaxy Team, Nekrutenko A, **Taylor J**. “Web-based Visual Analysis for High-throughput Genomics”. *BMC Genomics*. 2013 June; 14(1):397. PMID: PMC3691752

**High-resolution analysis of 3D chromatin organization:** Chromatin is organized in complex multi-scale architectures in the nucleus, allowing distant regions of the genome to be folded and looped into spatial proximity. In recent years, sequencing based proximity assays have established many features of chromosome organization at the megabase-scale and above. Finer-scale organizational features have proven more difficult to elucidate. Genomic elements that regulate gene expression – *cis*-regulatory modules or CRMs – can interact with genes that are millions of bases away, even in the presence of intervening genes. It is difficult to predict what target genes a given element interacts with, nor are the mechanisms that bring these regions into close proximity in the nucleus understood. We have developed new probabilistic modeling approaches to estimate and correct for several systematic biases affecting 5C and hi-C data, to assess the significance of individual interactions, and to produce high-resolution, normalized interaction maps. We have applied this approach in mouse to produce kilobase-resolution architecture maps across seven genomic loci in embryonic stem cells and neural progenitor cells. We found marked changes in chromatin structure at important developmental loci, and showed that chromatin are demarcated by different DNA binding proteins, and implicate the proteins CTCF, Mediator, and cohesin in different scales of organization as well as constitutive vs cell-type specific structure. We also demonstrated a role for Mediator/cohesin interactions in bridging proximal enhancers with promoters.

1. Phillips-Cremins JE, Sauria MEG, Sanyal A, Gerasimova TI, Lajoie BR, Bell JK, Ong C, Hookway TA, Guo C, Sun Y, Bland MJ, Wagstaff W, Dalton S, McDevitt TC, Sen R, Dekker J\*, **Taylor J\***, Corces VG\*. “Architectural Protein Subclasses Shape 3D Organization of Genomes during Lineage Commitment”. *Cell* 2013 June; 153(6):1281-95 PMID: PMC3712340.
2. Pope BD, Ryba T, Dileep V, Yue F, Wu W, Denas O, Vera DL, Wang Y, ... “Topologically associating domains are stable units of replication-timing regulation” *Nature* 2014 Nov; 515 (7527), 402-405. PMID: PMC4251741
3. Gehring ME, Phillips-Cremins JE, Corces VG, **Taylor J**. “HiFive: a tool suite for easy and efficient HiC and 5C data analysis.” *Genome Biology* 2015 Oct; 16:237

**Identification of functional elements in mammalian genomes:** Regulation of gene expression is fundamental to animal development and cellular differentiation. In vertebrates, regulation involves (at least) coordinated action of elements that enhance or silence expression, or insulate elements from interacting with genes. Evolution of these *cis*-regulatory modules (CRMs) appears to contribute substantially more to phenotypic diversity than evolution of genes themselves. However comprehensively identifying these elements has presented a significant challenge. In early work we developed machine-learning approaches which used patterns learned from genome sequence alignments to predict CRM locations genome wide. The resulting predictions have been validated in transfection assays at an impressive rate. Later, new techniques for directly

assaying transcription factor binding and other epigenomic features have become available (e.g. ChIP-seq). As participants in several projects to identify functional elements genome wide (e.g. ENCODE and Mouse ENCODE) we have continued to develop data integration methods to predict the location of these elements and to relate epigenomic signals to gene expression.

1. **Taylor J**, Tyekucheva S, King DC, Hardison RC, Miller W, and Chiaromonte F. “ESPERR: Learning strong and weak signals in genomic sequence alignments to identify functional elements”. *Genome Research* 2006 Dec; 16(12):1596-604. PMID: PMC1665643
2. The ENCODE Project Consortium. “Identification and analysis of functional elements in 1% of the human genome by the ENCODE pilot project”. *Nature* 2007 Jun; 14;447(7146):799-816. PMID: PMC2212820
3. King DC\*, **Taylor J\***, Zhang Y, Cheng Y, Lawson HA, Martin J, ENCODE groups for Transcriptional Regulation and Multispecies Alignment, Chiaromonte F, Miller W, Hardison RC. “Finding cis-regulatory elements using comparative genomics: some lessons from ENCODE data”. *Genome Research* 2007 Jun; 17(6):775-86. PMID: PMC1891337
4. Yue F, Cheng Y, Breschi A, Vierstra J, Wu W, Ryba T, Sandstrom R, Ma Z, ... “A comparative encyclopedia of DNA elements in the mouse genome” *Nature* 2014 Nov; 515 (7527), 355-364. PMID: PMC4266106

**Comparative Genomics and Genome Evolution:** The extent to which CRMs are under evolutionary constraint remains controversial, and tissue specific cross species comparisons show surprisingly little overlap in transcription factor occupancy. The Mouse ENCODE project (in which we participated) has annotated a large number of transcription factors and histone modifications, as well as DNaseI hypersensitivity, in mouse cell lines and primary tissues. Several of these cell lines are derived from analogous cell types as assayed extensively by the human ENCODE project, providing a unique opportunity to investigate conservation of protein occupancy. We developed new methods for orthology mapping particularly suited to these sorts of annotations. We then established that though binding may not be conserved when comparing analogous cell types, those regions are more likely than chance to be bound in some other cell type, suggesting an interplay of turnover and element reuse in mammalian evolution, and providing a strong case for exaptation in regulatory elements. We are also broadly interested in genome evolution and the generation and transmission of mutations. In early work we developed methods for analyzing male-mutation bias, establishing the magnitude of this bias since the human-chimpanzee divergence at different classes of sites in the genome.

1. Denas O, Sandstrom R, Cheng Y, Beal K, Herrero J, Hardison RC, **Taylor J**. “Genome-wide comparative analysis reveals human-mouse regulatory landscape and evolution”. *BMC Genomics* 2015 Feb; 16(1):87. PMID: PMC4333152
2. **Taylor J**, Tyekucheva S, Zody M, Chiaromonte F, Makova KD. “Strong and Weak Male Mutation Bias at Different Sites in the Primate Genomes: Insights from the Human-Chimpanzee Comparison”. *Molecular Biology and Evolution* 2006 Mar; 23(3):565-573.
3. Goto H, Dickins B, Afgan E, Paul I, **Taylor J\***, Makova K\*, and Nekrutenko A\*. “Dynamics of mitochondrial heteroplasmy in three families: A fully reproducible re-sequencing study”. *Genome Biology*. 2011 Jun; 12:R59. PMID: PMC3218847

**List of published works in NCBI MyBibliography:**

<http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/40279876/?sort=date&direction=ascending>

## D. Research Support

### Ongoing research support

NSF ACI-1445604 (Stewart PI) 12/1/2014 – 11/31/2018  
*High Performance Computing System Acquisition: Jetstream - a self-provisioned, scalable science and engineering cloud environment*  
Acquire and deploy Jetstream, a new cloud computing resource for supporting data intensive science.  
Role: Co-PI

NIH U01CA184826 (Berman PI) 5/13/2014 – 4/30/2017  
*Software Tools For Regulatory Analysis of Large Cancer Methylome Datasets*  
Build tools and workflows for the analysis of cancer Methylomes integrated in Galaxy.  
Role: Co-PI

NIH 2U41HG006620 (Taylor PD) 1/01/2016 – 12/31/2020  
*Democratization of data analysis in life sciences through Galaxy*  
Build and maintain the Galaxy software framework, and related components including the Galaxy Tool Shed.  
Role: PD/PI

### Completed research support

NSF IIS-1247813 (Morgan PI) 8/01/2013 – 7/31/2015  
*Scalable Statistical Computing for Emerging Omics Data Streams*  
More tightly integrate the Galaxy web framework with the Bioconductor tool suite and provide a scalable cloud-based deployment of the combined solution.  
Role: Co-PI

NIH R01HG004909 (Nekruntenko PI) 1/1/2009-12/31/2013  
*An efficient lightweight environment for biomedical computation*  
Development of workflow and library functionality within the Galaxy framework  
Role: Co-PI

NIH R01DK065806 (Hardison PD) 2/1/2009-3/31/2014  
*Global Predictions and Tests of Erythroid Regulation*  
Identify important cis elements responsible for erythroid gene expression and study their features through functional testing.  
Role: Co-PI

assaying transcription factor binding and other epigenomic features have become available (e.g. ChIP-seq). As participants in several projects to identify functional elements genome wide (e.g. ENCODE and Mouse ENCODE) we have continued to develop data integration methods to predict the location of these elements and to relate epigenomic signals to gene expression.

1. **Taylor J**, Tyekucheva S, King DC, Hardison RC, Miller W, and Chiaromonte F. “ESPERR: Learning strong and weak signals in genomic sequence alignments to identify functional elements”. *Genome Research* 2006 Dec; 16(12):1596-604. PMID: PMC1665643
2. The ENCODE Project Consortium. “Identification and analysis of functional elements in 1% of the human genome by the ENCODE pilot project”. *Nature* 2007 Jun; 14;447(7146):799-816. PMID: PMC2212820
3. King DC\*, **Taylor J\***, Zhang Y, Cheng Y, Lawson HA, Martin J, ENCODE groups for Transcriptional Regulation and Multispecies Alignment, Chiaromonte F, Miller W, Hardison RC. “Finding cis-regulatory elements using comparative genomics: some lessons from ENCODE data”. *Genome Research* 2007 Jun; 17(6):775-86. PMID: PMC1891337
4. Yue F, Cheng Y, Breschi A, Vierstra J, Wu W, Ryba T, Sandstrom R, Ma Z, ... “A comparative encyclopedia of DNA elements in the mouse genome” *Nature* 2014 Nov; 515 (7527), 355-364. PMID: PMC4266106

**Comparative Genomics and Genome Evolution:** The extent to which CRMs are under evolutionary constraint remains controversial, and tissue specific cross species comparisons show surprisingly little overlap in transcription factor occupancy. The Mouse ENCODE project (in which we participated) has annotated a large number of transcription factors and histone modifications, as well as DNaseI hypersensitivity, in mouse cell lines and primary tissues. Several of these cell lines are derived from analogous cell types as assayed extensively by the human ENCODE project, providing a unique opportunity to investigate conservation of protein occupancy. We developed new methods for orthology mapping particularly suited to these sorts of annotations. We then established that though binding may not be conserved when comparing analogous cell types, those regions are more likely than chance to be bound in some other cell type, suggesting an interplay of turnover and element reuse in mammalian evolution, and providing a strong case for exaptation in regulatory elements. We are also broadly interested in genome evolution and the generation and transmission of mutations. In early work we developed methods for analyzing male-mutation bias, establishing the magnitude of this bias since the human-chimpanzee divergence at different classes of sites in the genome.

1. Denas O, Sandstrom R, Cheng Y, Beal K, Herrero J, Hardison RC, **Taylor J**. “Genome-wide comparative analysis reveals human-mouse regulatory landscape and evolution”. *BMC Genomics* 2015 Feb; 16(1):87. PMID: PMC4333152
2. **Taylor J**, Tyekucheva S, Zody M, Chiaromonte F, Makova KD. “Strong and Weak Male Mutation Bias at Different Sites in the Primate Genomes: Insights from the Human-Chimpanzee Comparison”. *Molecular Biology and Evolution* 2006 Mar; 23(3):565-573.
3. Goto H, Dickins B, Afgan E, Paul I, **Taylor J\***, Makova K\*, and Nekrutenko A\*. “Dynamics of mitochondrial heteroplasmy in three families: A fully reproducible re-sequencing study”. *Genome Biology*. 2011 Jun; 12:R59. PMID: PMC3218847

**List of published works in NCBI MyBibliography:**

<http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/40279876/?sort=date&direction=ascending>

## D. Research Support

### Ongoing research support

NSF ACI-1445604 (Stewart PI) 12/1/2014 – 11/31/2018  
*High Performance Computing System Acquisition: Jetstream - a self-provisioned, scalable science and engineering cloud environment*  
Acquire and deploy Jetstream, a new cloud computing resource for supporting data intensive science.  
Role: Co-PI

NIH U01CA184826 (Berman PI) 5/13/2014 – 4/30/2017  
*Software Tools For Regulatory Analysis of Large Cancer Methylome Datasets*  
Build tools and workflows for the analysis of cancer Methylomes integrated in Galaxy.  
Role: Co-PI

NIH 2U41HG006620 (Taylor PD) 1/01/2016 – 12/31/2020  
*Democratization of data analysis in life sciences through Galaxy*  
Build and maintain the Galaxy software framework, and related components including the Galaxy Tool Shed.  
Role: PD/PI

### Completed research support

NSF IIS-1247813 (Morgan PI) 8/01/2013 – 7/31/2015  
*Scalable Statistical Computing for Emerging Omics Data Streams*  
More tightly integrate the Galaxy web framework with the Bioconductor tool suite and provide a scalable cloud-based deployment of the combined solution.  
Role: Co-PI

NIH R01HG004909 (Nekruntenko PI) 1/1/2009-12/31/2013  
*An efficient lightweight environment for biomedical computation*  
Development of workflow and library functionality within the Galaxy framework  
Role: Co-PI

NIH R01DK065806 (Hardison PD) 2/1/2009-3/31/2014  
*Global Predictions and Tests of Erythroid Regulation*  
Identify important cis elements responsible for erythroid gene expression and study their features through functional testing.  
Role: Co-PI



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CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

Recommendations for Clinical Trials Advisory Committee

- Stephen Eck, M.D., Ph.D.
- Ray Tabibiazar , M.D.



## **Stephen Eck, M.D. Ph.D.**

Chief Medical Officer, Immatics US, Inc.

As Chief Medical Officer of Immatics US Inc. Stephen Eck leads the clinical development of Immatics Adoptive Cell Therapy programs in Houston.

Stephen Eck joined Immatics US in April 2018 from Astellas. Stephen Eck previously served as VP Oncology Medical Sciences at Astellas Pharma Global Development managing a portfolio of assets which included enzalutamide (Xtandi), erlotinib (Tarceva) and gilteritinib.

Stephen Eck is a Hematologist and Oncologist with more than 25 years of experience in academic and industrial biomedical research. He began his professional career at Monsanto in cancer target discovery and later joined the University of Pennsylvania, where he was the Anne B. Young Assistant Professor of Cancer Research and the Director of the Cancer Gene Therapy Program. He subsequently held leadership roles in drug development at Pfizer, as VP Translational Medicine and Molecular Profiling, and at Lilly, as VP Translational Medicine, Pharmacology and Pharmacogenomics, prior to joining Astellas.

Stephen Eck has authored numerous publications in basic and clinical research and public policy. He is a fellow of the American Association for the Advancement of Science and Chairman of the Personalized Medicine Coalition (Washington DC). He serves on the Board of Directors of Luminex Corporation (Austin, TX), on the Board of Directors of the Central Pennsylvania Clinic (Belleville, PA), and the External Advisory Committee of the University of Pennsylvania Orphan Diseases Program (Philadelphia). He is a Trustee of the Keck Graduate Institute (Claremont, CA).

Stephen Eck received an BA (chemistry) from Kalamazoo College, an MS and a PhD (chemistry) from Harvard University and an MD from the University of Mississippi with Residency (Internal Medicine) and Fellowship (Hematology & Oncology) training at the University of Michigan.

**Stephen L. Eck, MD, Ph.D.**  
**Houston, TX**  
(revised June 1, 2018)

## **Research and Development Pipeline**

Broad discovery and development experience including academia, small biotechnology companies and large multinational pharmaceutical companies with greater than 20 years of drug discovery and development experience including target discovery through phase 4 life cycle management. Key responsibilities have included:

- Basic research in angiogenesis target and drug discovery at Monsanto using phenotypic screening.
- Selection of molecular targets for drug discovery. Served on the Lilly's Discovery Executive Team (reporting to William Chin, MD) which had responsibility for recommending new targets for initiation of New Chemical Entity (NCE) lead identification. Included target indications in diabetes, inflammation, neuroscience, pain, oncology and metabolic disease.
- Managed the progression of Lilly's early pipeline in all therapeutic areas from candidate selection through phase 3 commitments. Increased Lilly's NCE's in phase 1 from ~10 NCE's/yr. to 15-17/yr. (5 consecutive years) by reducing cycle times in late discovery and selective in licensing.
- Optimized resource utilization and productivity at reduced cost by strategic out sourcing of routine phase 1 work (to Covance), decreasing overhead (closed one in-house phase 1 unit) and expanding specialty phase 1 capabilities to meet new strategic objectives (revamped Lilly's Singapore Phase 1 unit to produce a low cost, high efficiency resource).
- Restructured Lilly's Clinical Pharmacology operations through use of strategic partners, on site extemporaneous preparations, and biomarker intensive phase 1a/b studies.
- Restructured Pharmacogenomics Strategy at Pfizer and at Lilly to focus on enhancing the commercial value of mid to late stage assets.
- Managed the development of companion diagnostic strategies at Pfizer and at Lilly including direct responsibility for the Diagnostic & Experimental Medicine Group and the Laboratory for Experimental Medicine at Lilly. Major accomplishments include identification of unique patient subsets responsive to proprietary assets. Oversaw development of pharmacogenic analysis of clopidogrel and prasugrel data (Lilly). Filed sNDA for erlotinib (Tarceva) with a companion diagnostic (in collaboration with Roche Molecular Systems) in late 2012. Developed companion diagnostic strategies at Astellas for several mid to late stage programs (gilteritinib, enzalutamide, ASP8273)
- Managed late stage pipeline assets at several companies with significant activities including: representing Takeda at FDA Advisory Committee for pioglitazone (Actos); leading Pfizer's tremelimumab phase 3 development program; as Head of Clinical Neurosciences at Pfizer (Ann Arbor) assembled and managed the asenipine (Saphris) clinical development team, managed the pregabalin (Lyrica) clinical development team during the successful filing and approval; served on Lilly's Product Development Committee responsible for all phase 3 & 4 development; managed Astellas's late stage Oncology portfolio including erlotinib (Tarceva); NCE filing of enzalutamide (Xtandi) and tivozanib, all with NDA and or MAA filings in 2012-2015; developed Astellas's Oncology development strategy for Xtandi filing in China.
- Managed design, conduct and sNDA filing of TERRAIN study (enzalutamide vs. bicalutamide) for Astellas, as well as several post approval commitment studies for enzalutamide.

- While at Astellas, managed the design and implementation of gilteritinib studies including phase 1 study and 4 phase 3 studies (on going) for various AML indications.
- Managed the design and implementation of A8272 studies including phase 1 study and phase 3 studies (on going) for NSCLC indications for Astellas.
- Extensive due diligence experience for potential and realized asset acquisitions

### **Managerial Experience with Accountabilities for Discovery and Development**

- Set strategic direction for product development for assets in all phase of discovery and product development, including setting priorities for resource utilization. Founded StemGuard, a neuroscience discovery company, and served as CEO of Aravive Biologics, a clinical stage oncology company (subsequently merged with Versartis), designing the overall business strategy.
- Managed and conducted Board of Director meetings in both private companies (Aravive Biologics) and not for profit organizations (Personalized Medicine Coalition, and Central Pennsylvania Clinic), as well as serving on the board of a publicly traded company (Luminex), to assure strategic alignment, efficient execution of plans, appropriate use of resources and compliance with local, state and federal laws.
- Built and fostered a business environment, based on respect for individuals and their unique talents, that empowers professional teams that are engaged, productive and enjoy a common sense of purpose.
- Direct line management responsibilities (Pfizer, Lilly, Astellas, Aravive, Immatics) for groups ranging from 12 to 250+. Specific positions included Head of Clinical Oncology (Pfizer, Ann Arbor), Head of Clinical Neurosciences (Pfizer, Ann Arbor, MI), Molecular Profiling and Translational Medicine (Pfizer, New London, CT), Translational Medicine and Pharmacogenomics (Lilly, Indianapolis, IN), and Oncology Medical Sciences (Astellas, Northbrook, IL) and President and CEO of Aravive Biologics.
- Provided direct and indirect leadership through corporate governance committees, including protocol review committees and development review committees (Pfizer, Astellas), Lead & Candidate Development Committee (Lilly), Product Development Committee (Lilly), Portfolio Management Committee (Lilly), and Oncology Star Leadership Team (Astellas), as well as one on one management of staff at all levels.
- Expanded the Quantitative Pharmacology program and co-developed the Biostatistics Center of Excellence and the Tailored Therapeutics (Personalized Medicine) Center of Excellence at Eli Lilly & Company. As a Trustee of the Keck Graduate Institute, helped design and launch a new College of Pharmacy offering the Pharm degree, and a new degreed program in Genetic Counseling.
- Strategic partner management as part of drug development programs including prasugrel (Effient) with Daiichi Sankyo; served on corporate Joint Steering Committees with Medivation (enzalutimide, Xtandi), Ambit Biosciences (quizartinib), AVEO (tivozanib), Roche/Genentech (erlotinib, Tarceva) and MD Anderson Cancer Center (novel biologic for AML). At Aravive manage key strategic partnerships with WuXi (contract manufacturing) as well as other service providers for preclinical and clinical work.
- Active involvement in due diligence in a variety of strategic partnership evaluations (Lilly, Pfizer, Astellas, Aravive, Immatics). At Lilly this including review of all phase 1- 4 in licensing opportunities with specific attention to pharmacology, biomarkers (including companion diagnostics), proposed development strategies and a variety of inflammation and

oncology agents (Pfizer, Astellas). At Aravive, sought out and reviewed strategic partner opportunities for Aravive's assets as well as asset for potential acquisition.

- Regular presentations to top leadership and Board (Lilly, Pfizer, Astellas, Aravive) including Subcommittees of Board of Directors (Pfizer, Lilly) and Executive Committee (Astellas).

### **Major Strategies and Change Programs**

- Restructured service laboratory functions at Pfizer into a global line function (pharmacogenomics, proteomics, metabonomics, imaging, diagnostics and other clinical technologies).
- Built Lilly's Pharmacogenomics program and focused it on Lilly's Personalized Medicine ("Tailored Therapeutics") strategy, including specific required activities for all development teams.
- Restructured and re-aligned Clinical and Diagnostic Service group at Lilly to more fully integrate into Clinical Operations.
- Outsourced key service functions at Lilly to provide more efficient use of capital and more flexibility in year-to-year resource allocation (includes outsourcing of key aspects of phase 1 studies, pharmacogenomics, biopharmacology studies and biomarker and diagnostics development).
- Reorganized and consolidated redundant/overlapping functions to contain costs and streamline function (e.g., mass spectrometry services and diagnostic development at Lilly; omics technologies at Pfizer).
- Built and managed a streamlined, cost effective, Oncology Development organization at Astellas

### **Interactions with Regulatory Authorities**

- Extensive interactions with the United States, Canadian, Chinese and European Health Authorities at all stages of drug development. Notably over 60 INDs for NCE's many with pre-IND meetings, as well as EOP2 meetings, SPA negotiation, and pre-NDA/sNDA meetings.
- Served on advisory panels to the FDA to provide input on new regulations.
- VSGD (VSXD) submissions to FDA as well as meeting with the EMEA on regulatory issues related to genetic research.

### **External Engagement & Influencing**

- Developed and/or managed key external engagements with not for profit and governmental agencies including the NIH and Institute of Medicine (developed Genetic Association Information Network while at Pfizer, served on Executive Committee of Biomarker Consortium, and Institute of Medicine Roundtable on Pharmacogenomics).
- Currently Chairman, Board of Directors of Personalized Medicine Coalition (Washington D.C.), and President's Pharmacy Advisory Board of the Keck Graduate School (Claremont, CA).
- Member of the Board of Trustees of the Keck Graduate Institute (Claremont, CA)
- Chair of Steering Committee, "Chicago Paradigm: Thriving in a World of Change" sponsored by the Chicago Life Sciences Consortium, Chicago, IL (2014)

- Program Committee Harvard Business/Medical School Conference on Personalized Medicine, Boston, MA. (2010-2018).
- Chairman and prior Vice-Chairman of the Board of Directors of the Personal Medicine Coalition, Washington, DC (2013-2018)
- Member, Board of Directors, Central Pennsylvania Clinic (Belleville, PA) focusing on rare disease and undeserved rural populations (2015-2018).
- External Advisor to Structured BioEquity (Cambridge, MA) and StemGuard (Menlo Park, CA) and Zinfandel Pharmaceuticals
- Organizing Committee, CNS Anticancer Drug Discovery and Development Conference 2014, Miami Beach, Florida.
- External Advisory Board Member, University of Pennsylvania Orphan Disease Center, Philadelphia, PA (2016-2018).
- Board of Directors, Nomination and Governance subcommittee and Science & Development subcommittee, and Compensation subcommittee, Luminex Corporation, Austin, TX (2016-2018)
- Presentations at a variety of professional scientific and pharmaceutical business meetings and conferences.
- Extensive public speaking experience to governmental and business leaders including presentation to US House and Senate elected officials and their staff, National Press Club public announcements and meetings with foreign diplomats.

## **Leadership Style & Climate**

Strong focus on capturing and focusing true innovation to achieve for long-term success. Utilization of a variety of strategies that are both sensitive to unique corporate environments (culture) while focusing on key financial accountabilities (productivity and profitability). Establishing a clear line of sight from novel idea to commercial potential while taking appropriate risks managed through clearly defined stopping (or accelerating) guidance. At Lilly and Astellas and Aravive this included providing greater understanding of drug development obstacles and opportunities to the Discovery leaders and Board. Developing a clear understanding of what the marketplace values to enable success at the Discovery and Development phases. Promote operational decisions being managed at the lowest level that can achieve maximum speed and flexibility in decision-making while ensuring accountability based on open communication and transparency. Establishing clear goals, with links to rewards, to foster and maintain accountability. Provide mentoring and career development to achieve diverse employee talent development and retention. Promote an inclusive management style that allows all talented people and groups to make their best contribution by expressing their creativity, and the desire to positively transform society. Promote essential principles that govern employee conduct including absolute integrity at all times, respect for individuals, recognition of the unique contribution each person can make, and always striving for excellence.

## **Education and Academic Career**

1971-1975	B.A.	Kalamazoo College (Chemistry)
1975-1977	M.S.	Harvard University (Chemistry)
1977-1981	Ph.D.	Harvard University (Chemistry)
1983-1987	M.D.	University of Mississippi School of Medicine

## **Employment History**

1981-1982	Senior Scientist, Monsanto Company, St. Louis, MO.
1981-1982	Instructor, St. Louis Community College
1982-1987	Res. Associate, Dept. of Biochemistry, Univ. Miss. School of Medicine, Jackson, MS.
1987-1988	Intern in Medicine, University of Michigan Hospitals, Ann Arbor, MI
1988-1989	Residency in Medicine, University of Michigan Hospitals, Ann Arbor, MI
1989-1992	Hematology/Oncology Fellow, Univ. of Michigan Hospitals, Ann Arbor, MI
1992-1993	Lecturer in Internal Medicine, Hematology/Oncology, University of Michigan.
1993-2002	Ann B. Young Assistant Professor of Cancer Research, Hem/Oncology, University of Pennsylvania (an Endowed Chair).
2002	Senior Associate, Director, Clinical Development, Oncology, Pfizer Inc., Ann Arbor, MI
2003	Senior Director, Oncology Therapeutic Area Leader, Oncology, Pfizer Inc., Ann Arbor, MI
2003 -2004	Exec. Director, Clinical Site Head, Oncology & Neurosciences, Pfizer Inc., Ann Arbor, MI
2004-2005	Executive Director, Full Development Team Leader, CTLA4, Pfizer, Inc, New London CT
2005-2007	Vice President, Molecular Medicine, Pfizer, Inc, Ann Arbor, MI
2007	Vice President, Translational & Molecular Medicine Pfizer, Inc, New London CT
2007-2011	Vice President, Translational Medicine & Pharmacogenomics, Eli Lilly, Indianapolis, IN
2011-2017	Vice President, Global Head of Oncology Medical Sciences, Astellas Pharma Global Development, Northbrook, IL
2017-2018	President and Chief Executive Officer, Aravive Biologics, Houston, TX

**Military Service:** None

### **Hospital, Administrative Academic and Business Appointments**

1992 Admissions Committee, University of Michigan School of Medicine.  
1992-1993 Home Infusion Service, Experimental Therapeutics Grant Review Committee. University of Michigan School of Medicine  
1994-2002 Director of Cancer Gene Therapy Program, Institute for Human Gene Therapy, University of Pennsylvania.  
1993-1998 Co-Director, Gene Therapy Program, the University of Pennsylvania Cancer Center  
1999-2002 Director, Gene Therapy Program, The University of Pennsylvania Cancer Center  
1999-2007 Cancer Gene Therapy Committee, ASGT; Chairman 2002-2003  
2005-present Scientific Advisory Council, Alliance for Cancer Gene Therapy, Stamford, CT  
2007-2012 Scientific Advisory Board, Fairbanks Institute, Indianapolis, IN  
2010-present Board of Directors, Personalized Medicine Coalition, Washington, DC  
2013-2016 Vice Chairman, Personalized Medicine Coalition, Washington, DC  
2016-present Chairman, Personalized Medicine Coalition, Washington, DC  
2015-present Trustee, Keck Graduate Institute, Claremont, CA  
2013-present Advisory Board, Keck Graduate Institute School of Pharmacy, Claremont, CA  
2015-present Board of Directors, Central Pennsylvania Clinic, Belleville, PA  
2015-present External Advisory Board, University of Pennsylvania Orphan Disease Program  
2016-present Board of Directors, Luminex Corporation, Austin, TX

### **Specialty Certification**

1990 Board Certified, American Board of Internal Medicine  
1996 Board Certified, Hematology  
1994 Board Eligible, Medical Oncology

### **Awards, Honors and Membership in Honorary Societies**

1972-1975 Heyl Fellowship in Science, Kalamazoo College  
1975 Honors Thesis, Kalamazoo College  
1992-1995 Merck-American Fed. Clinical Research, M.D. /Ph.D. Postdoctoral Fellowship  
1994-2002 Anne B. Young Assistant Professor for Cancer Research,  
1995-1996 Measly Fellowship Award  
2010 Fellow, American Association for the Advancement of Science (Pharmacology)

### **National Scientific Committees**

ECOG, Gene Therapy Committee, member	1996-2002
NIH, NCI PO1 Review, Boston, MA	6/25-27/95
US Army Breast Can. Res. Program, Ad hoc reviewer	11/13-15/95
Breast Cancer Research Program, University of CA	1996-1998
NCI RFA Review Committee, Ad hoc reviewer	6/11-13/96
NIH, Neurosciences 3 Study Section, Ad hoc reviewer	6/26-28/96
NIH, NCI PO1 Review, New York,	7/7-9/96
NIH, NCI, Medicine Branch, Ad hoc reviewer, Wash. D.C.	9/10-12/96

NIMH PO1 Review, Washington, DC. Ad hoc reviewer,	12/96
NIH, NCI Ad hoc Reviewer	6/30/97
State of Massachusetts Breast Cancer Program	1997, 1998, 2000
North American Brain Tumor Consortium (NABTC) and New Approaches to Brain Tumor Therapy (NABTT) consortium multigroup glioma gene therapy clinical trial. Data and Safety Monitoring Committee, Chairman	1998-2000
External Reviewer NCI PO1, Massachusetts General Hospital	5/1998
NIH, NCI PO1 Review, Los Angeles,	7/27-29/1998
State of Massachusetts Breast Cancer Program	10/24-25/1998
NCI, Subcommittee D “Clinical Research Studies”	11/30-12/1/1998
US Army Ovarian Cancer Study Section	1/20/99-1/22/1999
NCI, Subcommittee D “Clinical Research Studies”	4/14-5/99
NCI, RAID Review	3/31/99-4/1/1999
NIH, Career Development Award Review	6/21-22/1999
NCI, Ovarian Cancer Spore Grants Review	6/27-29/1999
NIH, NCI PO1 Review, Durham, NC	1/7/00-1/8/2000
National Gene Vector Laboratories (NIH), Scientific Review Board	2000-2002
NIH, NCI, Special Emphasis Study Section in Clinical Oncology	4/00 –3/2001
NIH, NCI, Clinical Oncology Study Section	2001
NCI, RAID Review	10/1/00
External Reviewer NCI PO1, Mt. Sinai Medical Center, NY	2/2003
External Reviewer, NIH, NINDS, Duke Medical Center, Durham, NC	3/2003
External Reviewer NCI, PO1’s, SPOREs & Training Awards	2004
ACGT Grant reviews,	2003-2015

### **Editorial Positions**

Scientific Advisor, Education Committee, Pennsylvania Biotechnology Assoc., State College, PA 1995  
 Cancer Gene Therapy, Editorial Board, Simon & Schuster Publisher 1996-2007  
 Gene Therapy, Editorial Board, Stockton Press. 1999-2006  
 Current Gene Therapy, Editorial Board 2000-2004  
 The Journal of Rare Disorders, Editorial Board, 2013- 2015  
 Journal of Cancer Biology & Research, Editorial Board, 2013-2014  
 Ad hoc reviewer for:  
 Human Gene Therapy, Journal of Immunology, Gene Therapy, Cancer Research, Journal of Virology, JAMA, Nature Medicine, Annals of Neurology, Proc. Nat’l Acad. Sciences, DNA and Cell Biology.

### **Academic Committees at the University of Pennsylvania and Affiliated Hospitals (1993-2002)**

Clinical Trials Scientific Review and Monitoring Committee, Cancer Center 1996-1999  
 University of Penn. General Clinical Research Center Internal Review Committee 1996-97  
 Faculty Grievance Commission 1997-2002  
 Molecular Life Sciences Advisory Committee 1998-2002  
 Vagelos Scholars Advisory Committee 1998-2002  
 Short Term Experience in Research Advisory Committee 1999-2002  
 Office of Human Research Faculty Advisory Committee, School of Medicine 2001-2002

Combined Degree, Cell and Molecular Biology Recruitment Committee 2000-2002  
Faculty Advisory Committee for the Office of Human Research 2000-2002

### **Major Teaching and Clinical Responsibilities at the University of Pennsylvania**

- 1993-1999 Attending Physician, Oncology & Hematology Services, Hospitals of the University of Pennsylvania.
- 1994-1999 Attending Physician, Oncology & Hematology Services, Philadelphia Veterans Administration Hospital.
- 1996, 1998-9 Human Biology (Biology 6)
- 1996 Critical Care Nurse Practitioner Course, "Hematology in the Critical Care Setting"
- 1995-1999 Selected Topics in Chemistry (Chemistry 700)
- 1996-2000 The Molecular Basis of Gene Therapy, (CAMB 610)
- 2000-2001 Medicine 101C, Differential Diagnosis
- 1997-1999 Introduction to Gene Therapy (CAMB 610, Fall)
- 1999, 2000 Advanced Seminar in Cancer Gene Therapy (CAMB 633, Spring 1999)  
Course Director
- 1997 Wistar Cancer Biology Graduate Student Seminar
- 1997-8, 2000 Cancer Biology and Genetics Course (CAMB 512, Pathology, Fall)
- 1998-2000 Topics in Cancer Pharmacology (PHARM 640 Fall 1998, 1999, 2000)
- 1999, 2000 Cancer Pharmacology (PHARM 560)
- 2000 Ethics of Human Subjects Research, Medical School Curriculum 2000
- 2000-2002 Introduction to Anatomy and Physiology (BSTA 510), A course for Biostatistics Graduate students
- 2001 Frontiers of Pharmacology (FR508) 4th year medical student elective course
- 2001 Radiobiology (2001) A course for Radiation Oncology Fellows
- 2001 "Standard Operating Procedures for Good Clinical Practice" A course for faculty engaged in FDA regulated research
- 2001 MD-PHD Clinical Connections Program Evaluation Preceptor

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Research Publications, peer reviewed

Wender, P.A. and Eck, S.L.: Organobiscuprates. A Single-Step Spiroannulation Method. *Tetrahedron Letters*, 18: (14) 1245-1248, 1977.

Wender, P.A., and Eck, S.L.: The Olefin Metathesis/Transannular Ene Sequence: A Method for the Stereo-controlled Synthesis of Trans-Decalin Derivatives. *Total Synthesis of Warburganal*. *Tetrahedron Letters*, 23 :(18) 1871-1874, 1982.

Wilson, V. E., Eck, S.L., and Bates, E.R.: Diagnosis and Management of Acute Myocardial Infarction Complicating Systemic Lupus Erythematosus. *Chest*, 101:420-424, 1991.

Eck, S.L., Morse J.M., Janssen, D.A., Emerson, S.G., and Markovitz, D.M.: Angioedema Presenting as Gastrointestinal Symptoms. *Am. J. Gastro.*, 88:436-439, 1993.

Eck, S.L., Perkins, N.D., Carr, D.P., and Nabel, G.J.: The Inhibition of Phorbol Ester Induced Cellular Adhesion by Competitive Binding of NF- $\kappa$ B In Vivo. *Mole. Cell. Biol.*, 13: 6530-6536, 1993.

- Smythe, W.R., Kaiser, L.R., Hwuang, H.C., Amin, K.M., Pilewski, J.M., Eck, S.L., Wilson, J.M., and Albelda, S.M.: Successful Adenovirus-Mediated Gene Transfer in an In Vivo Model of Human Malignant Mesothelioma. *Ann Thoracic Surg.* 57:1395-401, 1994.
- Smythe, W.R., Hwuang, H.C., Amin, K.M., Eck, S.L., Davidson, B.L., Wilson, J.M., Kaiser, L.R., and Albelda, S.M.: Use of Recombinant Adenovirus to Transfer the HSV-Thymidine Kinase Gene to Thoracic Neoplasms: An Effective In Vitro Drug Sensitization System. *Cancer Res.*, 1994, 54:2055-2059.
- Smythe, W.R., Hwuang, H.C., Amin, K.M., Eck, S.L., Davidson, B.L., Wilson, J.M., Kaiser, L.R., and Albelda, S.M.: Treatment of Experimental Human Mesothelioma Using Adenovirus Transfer of the Herpes Simplex-Thymidine Kinase Gene. *Annals of Surgery.* 1995, 222(1):78-86.
- Coughlin, C., Wysocka, M., Kurzawa, H., Lee, W., Trinchieri, G., Eck, S.L.: B7-1 and IL-12 Synergistically Induce Anti-Tumor Immunity. *Cancer Research* 55:4980-87, (1995).
- Eck, S.L., Alavi, J.B., Alavi, A., Davis, A. Hackney, D.B., Judy, K.D., Mollman, J., Phillips, P. C., Wheeldon, E.B. and Wilson, J.M., Treatment of Advanced CNS Malignancy with the Recombinant Adenovirus H5.010RSVTK: A Phase I Trial, *Human Gene Therapy* 1996)7: 1469-1486.
- Smith, J.G., Raper, S.E., Wheeldon, E.B., Hackney, D., Judy, K., Wilson, J.M., and Eck, S.L. Intracranial administration of adenovirus expressing HSVTK in combination with ganciclovir produces a dose dependent, self-limiting inflammatory response. *Human Gene Therapy.* 1997, 8(8):943-954.
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### **Books**

Eck, S.L., editor Hematology/Oncology Clinics of North America: Gene Therapy, 1998, W.B. Saunders, Philadelphia.

Eck, S. L. “Cancer Care and Sequencing: A Futurist’s View”, in The Economics of Genomic Medicine Workshop, Institute of Medicine, Washington, DC. July 2013

### **Recent Presentations**

“The Impact of Genome Sequencing on Health”, Harvard Medical School/Harvard Business School Personalized Medicine Conference, Boston, MA Nov.28, 2012

“Incentivizing Personalized Medicine Diagnostic Development”, panel discussant at BIO & PMC sponsored conference “Evidence, Coverage, and Incentives”. Washington DC, April 17, 2013.

“Business Plan Competition”, Keck Graduate Institute, Claremont, CA, May 1, 2013

“How Will Genetics Revolutionize Medical Care?”, Northwestern Medical School. Chicago. IL, May 6, 2013.

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JW Park, XS Zhang, J Yang, SL Eck. “A single arm sequential monitoring design for claiming positive or negative safety signals in patients from multiple baseline risk groups” The 2013 Joint Statistical Meetings, Montréal, August 3 - 8, 2013.

“Can the Industry Capitalize on the Potential of Personalized Medicine”, Financial Times Pharmaceutical & Biotechnology Conference, London, UK December 3, 2013.

“Personalized Medicine: A brief Introduction”, Columbia University, New York, March 25, 2014.

“Oncology R&D Collaboration Networks and Beyond,” Oracle Industry Connect Conference, Boston, March 26 2014.

“Addressing Value and Cost of Cancer Care”, Turning the Tide Against Cancer Conference,

Washington DC, October 9, 2014.

“Developing Drugs for Patients: The complexity of bringing innovative medicines to market”  
Stanford Oncology and Hematology Annual Research Retreat, Asilomar, CA, November 6, 2014

“Information Technology & Big Data”, 10<sup>th</sup> Annual Personalized Medicine Conference,  
Harvard University, Boston, MA, November 13, 2014.

“The Principles & Practice of Pharmaceutical Research”, University of Illinois - Chicago, Department of  
Pharmacology, Chicago, IL November 9, 2015.

“Emerging Trends in Academic & Industry Collaborations”, 10<sup>th</sup> Annual Business of Biotech Conference,  
Moffitt Cancer Center, Tampa, FL, February 2016.

“Bring Personalized Medicines from the Lab to the Patient”, American Medical Assn Annual Meeting  
Chicago, IL, June 2016.

“Pioneering Precision: Charting a Course for Cutting-Edge Innovations”, 12th Annual Personalized  
Medicine Conference, Harvard Medical School, November 2016

## **Patents**

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immune responses. PCT Int. Appl. WO2002088304A2 Published on November 07, 2002.

## **Ray Tabibiazar, MD**

Executive Chairman, Aravive

Dr. Tabibiazar brings nearly 15 years of leadership experience in the healthcare industry, including key executive positions within the biopharmaceutical industry, as well as diagnostics, and venture capital. In addition to his role at Aravive, he is also the Managing Director of 526 Ventures, a life sciences strategic consulting company working with both public and private biopharmaceutical firms. Prior to joining Aravive, Dr. Tabibiazar was a Venture Partner at Bay City Capital LLC, a large venture capital firm in the Bay Area with more than \$1.3 billion under management. Prior to that, Dr. Tabibiazar served as the Chief Scientific Officer of Aviiir, a molecular diagnostic company, as well as Vice President of Translational Research of VIA Pharmaceuticals, a cardiometabolic therapeutic company. Before moving to industry, Dr. Tabibiazar was a practicing cardiologist and an adjunct clinical instructor in medicine at Stanford University. Dr. Tabibiazar received his medical degree from Harvard Medical School and trained as an internist and cardiologist at Stanford University, while also receiving finance education at Stanford Business School. Dr. Tabibiazar received board certifications in Internal Medicine, Cardiovascular Medicine, Nuclear Medicine, and Cardiovascular Imaging. He has won numerous honors and research awards and has authored several peer reviewed papers and inventor on more than 20 patents.

## **RAY TABIBIAZAR, MD**

Home: 2700 Brazos #4508  
Houston, TX 77006  
Cell: (650) 906-9468  
Personal Email: tabibiazar@gmail.com

Dr. Tabibiazar brings nearly 15 years of leadership experience in healthcare and biopharma industry that included venture capital, pharmaceutical, diagnostics, and life sciences. As a scientist-entrepreneur his efforts have focused on creating new ventures in form of new companies or spinouts to translate innovative science into commercially viable products. Through his venture capital and finance experience at a large VC firm, he has also been involved in evaluation and management of few of the firm's investments. Prior to moving to the industry, Dr. Tabibiazar was a practicing cardiologist and an adjunct faculty at Stanford University having trained as a physician scientist at Harvard Medical School and a cardiologist at Stanford Medical Center.

Ray is the managing director of 526 Ventures LLC, a life science strategic consulting company working with both public and private biopharmaceutical firms. Through 526 ventures, he advises partner companies on corporate strategy and business development activities as well as new product and growth opportunities in underserved areas of focus and has been involved in more than 30 deals. Ray is also the Chairman of the Board at Aravive Biologics, a clinical stage cancer company which he has helped create with lead scientists from Stanford University and MD Anderson Cancer Center in Texas. He has secured financing for the company through multiple sources including traditional institutional investors, partnerships and various government grants. With the help of world class scientists and management team, Ray has also lead the research and development of 3 innovative cancer drugs culminating in multi-million dollar partnerships for 2 of the programs and advancement of the third program to clinical trials.

Previously, Ray has worked as a Venture Partner at Bay City Capital, a large life science Venture Capital firm with more than \$1.3B under their management. During his stint at the firm, Ray was involved in evaluation and management of few of the firm's investments. Prior to his venture capital stint, Ray had served as the VP of Research and Development and Chief Science Officer of Aviir, Inc. where he lead the discovery and early development of the company's diagnostics products which is now being marketed by GD Biosciences. He was also involved in the formation of the company and the two early rounds of its financing. Prior to Aviir, Ray has also served as the vice president of translational medicine for VIA pharmaceuticals (later became Madrigal NASDAQ: MDGL). VIAP was a drug development company focused on drugs that treat inflammation and cardiometabolic diseases where he also helped with formation of the company and successful early clinical development of then the lead program.

Dr. Tabibiazar received his Medical Degree from Harvard Medical School with Research Fellowship at Howard Hughes Medical Institute. He trained as an Internist and a Cardiologist at Stanford University with finance education at Stanford Business School. He has authored numerous peer review papers and is an inventor on more than 20 patents. Dr. Tabibiazar board certifications are in Internal Medicine, Cardiovascular Medicine, Nuclear Medicine, and Cardiovascular Computed Tomography.

**Professional Experience:**

***Industry Experience:***

526 Ventures LLC

Managing Director, 2011- *present*

*A boutique life science strategic consulting company working with small public and private biopharmaceutical companies, active engagements:*

- Twist Biosciences (Private): Corporate Strategy and Business Development
- Jazz Pharma (NYSE: JAZZ): consultant, new opportunity evaluation, Corporate Development
- Synthetic Biologics (NYSE: SYN): Head of Corporate & Business Development
- Quest Diagnostics (NYSE: DGX): Senior Advisor Neurology & CV commercial Franchises
- Distributed Bio (Private): advisor
- Rennexion (Private): Corporate Strategy & previous Board of Directors
- Emeryville Pharma (Private): previous Board of Directors
- Global Discovery Biosciences (Private): Senior Advisor to CEO & BOD
- Single Cell Technology (Private): Advisor to BOD
- Booz (now part of PWC): External Advisor
- Full list available upon request

Aravive Biologics,

Chairman (2017 to present)

President & Chief Executive Officer, and Director (2010-2017)

*A private pharmaceutical company developing genetically targeted oncology therapeutics*

- Co-founded the company
- Multiple round of financing
- Lead the research and development of a pipeline of cancer drugs toward IND
- In-licensing and acquisition of promising external development programs
- Partnership of 2 internal programs with multi-million dollar potential

Bay City Capital, LLC

Venture Partner (2007- 2010)

*A large life science venture capital firm with >\$1.3B committed capital*

- Evaluation and management of several of the firm's investments.
- Deal team in antibody investments
- Deal team in life sciences tool, diagnostics and clinical stage investments

Aviir, Inc.

Chief Scientific Officer, 2006-2007

Vice President of Research & Development (2006)

*Cardiovascular and Inflammation diagnostic company*

- Co-founded the company
- Secured Series A & Series B financing totaling near \$40M
- Lead discovery and successful early development of now marketed diagnostic test

VIA Pharmaceuticals Inc. (later became Madrigal NASDAQ: MDGL)

Vice President of Translational Research (2003-2006)

*A drug development company focused on compounds that target vascular, inflammation and cardiometabolic diseases*

- Part of the foundation team
- Contributed core science and platform for company formation
- Part of the team securing multiple rounds of financing totaling over \$100M
- Part of the in-licensing and drug evaluation team
- Lead the discovery and participated in successful early clinical development of the lead program

***Clinical Experience:***

2008- 2013     Attending Cardiologist, Preventive & Interventional Cardiovascular Medicine, San Jose  
2005- 2010     Adjunct Clinical Instructor in Cardiovascular Medicine, Stanford University  
2002- 2003     Faculty mentor, Stanford Biodesign fellowship  
1999- 2005     Attending Physician, Palo Alto Medical Foundation, Palo Alto, CA, Menlo Park Veterans  
Hospital, Menlo Park, CA, Mills Peninsula Hospital, Burlingame, CA, and Mariner Medical  
Clinic, Fremont, CA

**Credentials:**

2009-           Board Certified in Cardiovascular Computed Tomography  
2008-           Board Certified in Nuclear Cardiology, Certification Board of Nuclear Cardiology  
2007-2017     Vascular Ultrasound, Advanced Training  
2005-2015     Board Certified in Cardiovascular Medicine, American Board of Internal Medicine  
2001-2011     Board Certified in Internal Medicine, American Board of Internal Medicine  
1999-           Medical License, Medical Board of California

**Education:**

2006           Stanford University, Graduate School of Business, Executive Education  
2001-2005     Stanford University, Fellowship, Cardiovascular Medicine  
1999-2001     Stanford University, Residency, Internal Medicine  
1998-1999     Stanford University, Internship, Internal Medicine  
1993-1998     Harvard Medical School, MD (Honors, Cum Laude)  
1995-1996     Howard Hughes Medical Institute, Research Fellowship  
1991-1993     UCLA, Bachelor of Science, Biology (Summa Cum Laude)

**Peer-reviewed Scientific Publications and List of Patent filing,**

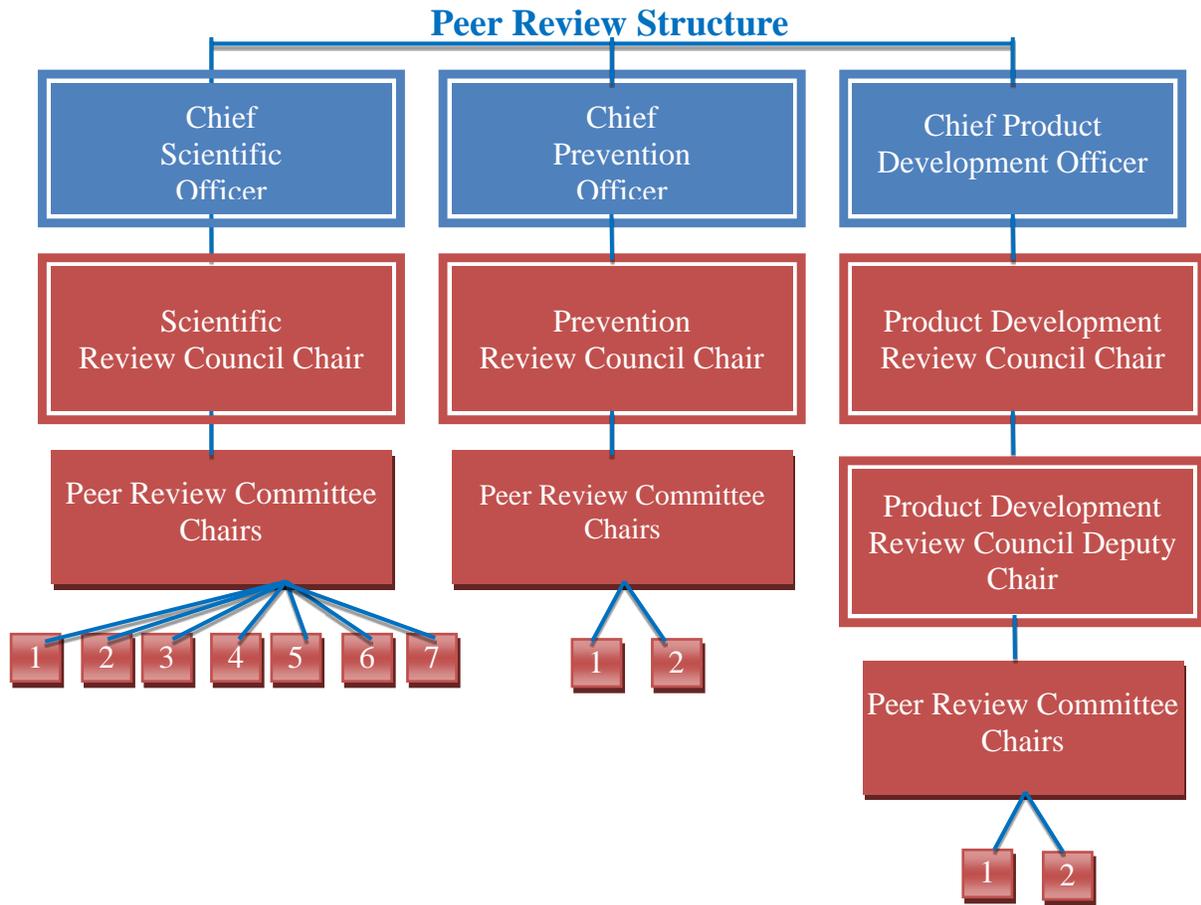
Upon Request

**Deal Sheet**

Upon Request

# CPRIT PEER REVIEW FY 2019 HONORARIA POLICY<sup>1</sup>

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.<sup>2</sup> 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

<sup>1</sup> Adopted pursuant to TEX. HEALTH & SAFETY CODE Section 102.151(e).  
<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup> 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 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 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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<sup>3</sup> 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.

<sup>4</sup> 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: CPRIT pays honorarium for the annual service of the Review Council chair or Committee chair. The payment does not use 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. CPRIT uses the hourly estimate 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: CPRIT expects Council Chairs to commit approximately 240 hours to CPRIT-related activities in FY 2019. 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 reflects 2009 – 2018 review cycle information and the projected workload for FY 2019.

NOTE: In addition to the regular Council Chair duties in FY 2019, 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 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 2019.

Hourly Rate Proxy: CPRIT pays honorarium 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.<sup>5</sup> 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 greater than the \$60,000 - \$75,000 honoraria paid to CPRIT Review Council Chairs.

## Review Committee Chairs

A Committee Chair leads each peer review committee. 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. CPRIT expects Scientific and Product Development Review Committee chairs to commit approximately 200 hours to CPRIT-related activities in FY 2019, 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 reflects 2009 – 2018 review cycle information and the projected workload for FY 2019.

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<sup>5</sup> 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: CPRIT pays honorarium 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.<sup>6</sup> 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 reviewer spends 6 – 8 hours for a full review of a single application, but the reviewer may require substantially more time for complex, highly technical applications. A typical CPRIT grant application averages about 40 pages in length with additional supporting documentation. Applications for multimillion-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 reflects 2009–2018 review cycle information and the projected workload for FY 2019.

Hourly Rate Proxy: CPRIT pays honorarium to Academic Research and Prevention peer reviewers for a given review cycle, which 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 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

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<sup>6</sup> 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.

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 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 paid different honoraria depending on the role of the reviewer. Chairs often received more than committee members did, and teleconference or online reviewers typically received less compensation than those members who participated in-person. The report did not compute an average based on the supplied data.<sup>7</sup>
- 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.

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<sup>7</sup> 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 4 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		Activity
				Chair	Deputy	
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			
		4	Review Annual and Final progress reports			
57		4		62.5	48.5	
\$ 1,200	Unit cost	53			\$1,200	Unit cost
\$ 250	Hourly rate	\$1,200	Unit cost		\$250	Hourly rate
<b>\$68,400</b>	Annual honoraria	\$250	Hourly rate	<b>\$75,000</b>		Annual honoraria Chair
		<b>\$64,000</b>	Annual honoraria	<b>\$58,200</b>		Annual honoraria Deputy Chair

**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.
20	Review recruitment applications	3	Prepare and participate in quarterly Review Council teleconferences		
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	<b>\$46K</b> Annual honoraria	\$28,000	<b>\$28 K</b> Annual honoraria	\$39,375	<b>\$40K</b> Annual honoraria

See Table 4 for an explanation of the correlation between units and hours.

**Table 3. Peer Reviewer Activities per Cycle**

Table 3 - Peer Reviewers Activity by Program					
Product Development 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 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 4 for an explanation of the correlation between units and hours.) CPRIT pays peer reviewers 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 CPRIT subtracts \$750 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. 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				





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**MEMORANDUM**

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**To:                   OVERSIGHT COMMITTEE CHAIR WILL MONTGOMERY**  
**From:               WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER**  
**Subject:           SECTION 102.1062 WAIVER—DONALD BRANDY**  
**Date:               AUGUST 8, 2018**

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**Waiver Request and Recommendation**

I request that the Oversight Committee approve a conflict of interest waiver for FY 2019 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 since FY 2015.

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 influence 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 vendor or outside service contracts.

At the time CPRIT hired Mr. Brandy, he 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. The university athletic department pays Mr. Brandy for his services as an independent contractor 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 fulfill his or her responsibilities to CPRIT. Employees must receive written approval from the CEO to engage in outside employment and I notify the Audit Subcommittee regarding any approvals. I also annually report to the Oversight Committee all approved outside employment. I notified the Audit Subcommittee regarding my approval for Mr. Brandy's outside employment and the subcommittee first discussed it at the December 18, 2014, subcommittee meeting.

### **Exceptional Circumstances Requiring Mr. Brandy's Participation**

To approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process or other expenditure of CPRIT funds.<sup>1</sup>

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

However, as part 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 had only one services contract (now closed) with an academic institution, Texas Tech University. However, as CPRIT's lead contact for agency purchases, Mr. Brandy should be able to perform his official duties as fully as 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 the Oversight Committee permit Mr. Brandy to perform all duties assigned as purchaser, subject to the limitations stated below:

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

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.
- CPRIT limits this waiver 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.



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**MEMORANDUM**

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**TO:** OVERSIGHT COMMITTEE CHAIR WILL MONTGOMERY  
**FROM:** WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER  
**SUBJECT:** SECTION 102.1062 WAIVER – DR. BECKY GARCIA  
**DATE:** AUGUST 8, 2018

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**Waiver Request and Recommendation**

I request that the Oversight Committee approve a conflict of interest waiver for FY 2019 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 2018.

**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, serves by appointment 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.

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**

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. The proposed waiver should be granted so that CPRIT may fulfill legislative intent that the Chief Prevention Officer serve as a PIC member. The proposed limitations will mitigate substantially 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 the Oversight Committee permit Dr. Garcia to continue to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. If THIN applies 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 statute requires the Chief Compliance Officer 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.
- CPRIT limits this waiver 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.



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**MEMORANDUM**

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**To:                   OVERSIGHT COMMITTEE CHAIR WILL MONTGOMERY**  
**From:               WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER**  
**Subject:           SECTION 102.1062 WAIVER – DR. JOHN HELLERSTEDT**  
**Date:               AUGUST 8, 2018**

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**Waiver Request and Recommendation**

I request that the Oversight Committee approve a conflict of interest waiver for FY 2019 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 factors other than merit and the established grant criteria affecting the award of grant funds. The waiver is the same as approved by the Oversight Committee for FY 2018.

**Background**

Governor Abbott appointed Dr. Hellerstedt as 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 must exercise discretion related to whether to recommend applications proposed for grant awards 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**

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 Commissioner Hellerstedt's participation in the review process. The Oversight Committee should grant the proposed waiver so that CPRIT may fulfill legislative intent that the DSHS Commissioner serve as a PIC member. 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 the Oversight Committee permit Commissioner Hellerstedt 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 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 Commissioner Hellerstedt provides information 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 statute requires the Chief Compliance Officer to attend PIC meetings to document compliance with CPRIT's rules and processes, including adherence to this limitation. The Chief 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.

- CPRIT limits this waiver 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.



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**MEMORANDUM**

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**To: OVERSIGHT COMMITTEE MEMBERS**  
**From: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER**  
**Subject: SECTION 102.1062 WAIVER – WILL MONTGOMERY**  
**Date: AUGUST 8, 2018**

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**Waiver Request and Recommendation**

I request that the Oversight Committee approve a conflict of interest waiver for FY 2019 for Mr. Will Montgomery, presiding officer of the CPRIT Oversight Committee, 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 2018. 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 factors other than merit and established criteria to affect the award of grant funds.

**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)
- The University of Texas Southwestern Medical Center
- The University of Texas School of Public Health
- The University of Texas Medical Branch, Galveston
- Children's Medical Center Research Institute
- The University of Texas San Antonio

- The University of Texas at Austin
- The University of Texas Health Science Center at Houston
- The University of Texas M.D. Anderson Cancer Center
- Texas Association of Nurse Anesthetists
- University General Health system
- MHMR Tarrant County
- Texas Tech University
- Texas Tech University Health Science Center
- UNT Health Science Center
- Baylor University
- Baylor College of Medicine

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 paid to Jackson Walker by these entities, 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 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 2019 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**

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 recuse himself 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 significant 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 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 mitigate substantially 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 the Oversight Committee permit Mr. Montgomery 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
- UT M.D. Anderson Cancer Center
- Texas Association of Nurse Anesthetists
- University General Health system
- MHMR Tarrant County
- Texas Tech University
- Texas Tech University Health Science Center
- UNT Health Science Center
- Baylor University
- Baylor College of Medicine

### **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.

- CPRIT limits this waiver 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.
- CPRIT limits the waiver to the entities specified in the request and based upon the circumstances stated herein. If circumstances change such that Mr. Montgomery personally represents one of the entities listed herein or supervises 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

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**MEMORANDUM**

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**TO:** OVERSIGHT COMMITTEE MEMBERS  
**FROM:** WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER  
**SUBJECT:** SECTION 102.1062 WAIVER – REVIEW COUNCIL MEMBERS  
**DATE:** AUGUST 8, 2018

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**Waiver Request and Recommendation**

I request that the Oversight Committee approve a fiscal year 2019 conflict of interest waiver for review council members pursuant to Health & Safety Code § 102.1062 “Exceptional Circumstances Requiring Participation.” Unlike other conflict of interest waivers that the Oversight Committee has approved previously, this waiver is not granted for a specific conflict of interest or person. Instead, CPRIT intends to invoke this waiver as necessary to address the unusual scenario when a review council member has a conflict with a grant application that is part of the larger group of proposals that the review panel or review council must act upon (usually to recommend for awards). The waiver is necessary for a review council member to participate in the overall discussion and vote on the slate of award recommendations. This waiver is the same waiver the Oversight Committee approved for FY 2018.

Although it would be ideal to consider each instance individually before granting the conflict of interest waiver, a prospective waiver is necessary in this scenario given the timing of the review process and scheduled Oversight Committee meetings. It is unlikely that review panel schedules will align with Oversight Committee meeting dates such that CPRIT will be able to secure a conflict of interest waiver in time for the review council member to participate in the review process. However, adequate protections are in place that, together with the waiver’s proposed limitations, mitigate the opportunity for factors other than merit and established criteria to influence review council members’ decisions regarding the award of grant funds.

**Background**

Health & Safety Code § 102.1062 directs the Oversight Committee to adopt administrative rules governing the waiver of the conflict of interest requirements of the statute in exceptional circumstances. 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. The rules require that a majority of the Oversight Committee members must vote to approve the waiver. CPRIT must report any approved waiver to the lieutenant governor, speaker of the

house of representatives, the governor, and the standing committees of each house of the legislature with primary jurisdiction over CPRIT matters.

The issue addressed by this waiver results from of the role review council members play in the review process. At the review panel level, the review council member chairs the review panel meeting. Occasionally, a review council member will identify a conflict of interest with an application assigned to the member's panel. If CPRIT is unable to reassign the application to a different panel, then the review council member follows the process set forth in CPRIT's conflict of interest rules and recuses himself or herself from any discussion, scoring, deliberation, or vote on the application. The proposed waiver will not change the review council member's responsibility to disclose the conflict or to recuse from the review of the application.

The difficulty arises when the review council member must lead the discussion, in his or her role as chair of the review panel, about the group of applications the panel recommends moving forward to the review council. If the application with which the review council member is in conflict advances as part of the group that scored well enough to move forward, the review council member's participation in the discussion on the group as a whole violates the member's agreement to not participate in "any discussion" of the conflicted application.

A similar challenge arises at the review council level. If the application with which the member is in conflict is part of the group considered by the review council, the conflict of interest rules prohibit the member from participating in the review council's discussion or vote on the group of awards. The review council member is unable to address questions about other applications heard by his or her panel due to his or her recusal from the process, potentially disadvantaging the other applications.

### **Exceptional Circumstances Requiring the Review Council Member'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. In this case, exceptional circumstances exist due to the necessity of the review council member's participation in the process to develop the overall award recommendation slates and the Oversight Committee should grant the proposed waiver. The limitations mitigate the potential for bias.

CPRIT's administrative rules require the Chief Compliance Officer to attend or designate an independent third party to attend peer review meetings and review council meetings when the panel discusses grant applications. The third-party observer must document that the reviewers follow CPRIT's grant review process consistently, including observing CPRIT's conflict of interest rules. The third-party observer will document any violation of this waiver in his or her written report, which CPRIT provides to the Oversight Committee prior to the vote on the award recommendations.

## **Proposed Waiver and Limitations**

In granting the conflict of interest waiver, I recommend that CPRIT permit the review council member to continue to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. The review council member must disclose any conflict in writing pursuant to the electronic grant management process CPRIT has in place.
2. The review council member must recuse himself or herself from participation in the review, discussion, scoring, deliberation, and vote on the specific grant(s) identified as the conflict.
3. When the review panel or review council takes up the grant applications as a group, the review council member may participate in the discussion and vote on the proposed awards, so long as the review council member does not advocate for or against the application that the member has identified as a conflict.
4. Whenever CPRIT invokes this waiver, the Chief Compliance Officer will provide information about the use of the waiver, including the name of the review council member and the identified conflict, in the Chief Compliance Officer's Certification report. I will also include this information in the CEO affidavit I submit for the grant award mechanism.

Due to the nature of the conflict or the type of review process, this conflict of interest waiver will not apply to following:

- When the review council member's conflict of interest is a conflict described by T.A.C. § 702.13(c); or
- When the review council is acting as the only review panel in the review process (e.g. CPRIT recruitment awards and prevention dissemination awards.)

## **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.
- CPRIT limits this waiver to review council members operating under the circumstances specified in this request.



**August 2018 Oversight Committee  
Internal Audit Status Report  
As of August 1, 2018**

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 and Daniel Graves, Partner.

**2018 Internal Audit Plan and Schedule**

Weaver has completed fieldwork and issued reports for all of the active projects on the 2018 Internal Audit Plan.

NEW INTERNAL AUDITS		
Internal Audit	Description	Timing
Post Award Grant Contracting and Monitoring	<p>Fieldwork for the Post Award Grant Contracting and Monitoring audit was completed on December 20, 2017. We issued the report on February 1, 2018. The audit resulted in an overall assessment of "Strong" with one finding.</p> <p>Moderate Risk Findings:</p> <ol style="list-style-type: none"> <li>1. Separated Employee User Access in the outsourced partner's grant monitoring portal</li> </ol> <p>Follow-up procedures on the remediation of the findings will be included in the proposed audit plan for fiscal year 2019.</p>	Complete
Communications	<p>Fieldwork for the Communications audit was completed on April 30, 2018. We issued the report on May 25, 2018. The audit resulted in an overall assessment of "Satisfactory" with five findings.</p> <p>High Risk Findings:</p> <ol style="list-style-type: none"> <li>1. Non-compliance with state website requirements</li> </ol> <p>Moderate Risk Findings:</p> <ol style="list-style-type: none"> <li>2. Formal process for review and approval for Website Content</li> <li>3. Formal process for review and approval for Social Media Posting</li> <li>4. Access to MailChimp should be restricted to appropriate personnel</li> </ol> <p>Low Risk Findings:</p> <ol style="list-style-type: none"> <li>5. Timely and accurate issuance of Achievement Reports</li> </ol> <p>Follow-up procedures on the remediation of the findings will be included in the proposed audit plan for fiscal year 2019.</p>	Complete

State Reporting	The Internal Audit was postponed to FY 2019.	Deferred
Information Technology General Computer Controls	The Internal Audit was postponed to allow Internal Audit to perform additional follow-up procedures over open Information Security findings.	Deferred

FOLLOW-UP PROCEDURES		
Follow-Up	Description	Timing
Training Follow-Up <ul style="list-style-type: none"> <li>• 2 Moderate Findings</li> </ul>	Fieldwork for these follow-up procedures was completed on January 19, 2018. The report was issued February 2, 2018. Both findings from the prior year's audit were remediated.	Complete
Internal Agency Compliance Follow-Up <ul style="list-style-type: none"> <li>• 1 Low Finding</li> </ul>	Fieldwork for these follow-up procedures was completed on January 19, 2018. The report was issued February 2, 2018. The one finding from the prior year's audit was remediated.	Complete
IT Security Follow-Up <ul style="list-style-type: none"> <li>• 7 Findings</li> </ul>	Fieldwork for initial follow-up procedures was completed on July 13, 2018. The report was issued on July 30, 2018. Five of the seven open findings were remediated. The remaining two findings were partially remediated.  Additional follow-up procedures are scheduled to be performed in FY 2019.	Complete
Pre-Award Grant Management Follow-up <ul style="list-style-type: none"> <li>• 1 High Finding</li> <li>• 2 Moderate Findings</li> </ul>	Fieldwork for these follow-up procedures was completed on April 24, 2018. The report was issued May 10, 2018. The three findings from the prior year's audit were remediated.	Complete
Procurement and P-Cards Follow-up <ul style="list-style-type: none"> <li>• 7 Moderate Findings</li> <li>• 2 Low Findings</li> </ul>	Fieldwork for these follow-up procedures was completed on April 30, 2018. The report was issued May 25, 2018. Seven of the nine findings from the prior year's audit were remediated, one finding was closed by management, and one finding was partially remediated. Partially remediated finding is indicated by a P.  Open Moderate Risk Findings <ul style="list-style-type: none"> <li>• Timeliness of P-Card and Travel Card Reconciliations<sup>P</sup></li> </ul>	Complete

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.

The annual update of the Internal Audit Risk Assessment was performed on July 30, 2018. The results of the risk assessment update are presented in the attached Risk Rated Significant Activity Summary. The risk assessment update resulted in recommended changes to the Fiscal Year 2019 Internal Audit Plan. Those changes are incorporated into the proposed FY 2019 Internal Audit Plan presented today. Based on internal audit activity approved, this information will be included in the required Annual Internal Audit Report, due November 1, 2018.

In addition, we have prepared a draft of the Annual Internal Audit Report, as required by the Texas Internal Auditing Act. The report has been prepared in accordance with the most recent prescribed format of the State Auditor's Office, published for fiscal year ending August 31, 2018. The 2018 fiscal year's guidance was published on August 1, 2018 and includes a new requirement for providing a brief description of the risk assessment including consideration of risks associated with information technology and benefits proportionality. In addition, there is a new reporting requirement whereby if the approved and reported 2019 Internal Audit Plan is changed during the year, we must submit the revised Internal Audit Plan to the oversight bodies.



Alyssa G. Martin, CPA, MBA, Internal Auditor  
Executive Partner  
Weaver and Tidwell L.L.P

**Cancer Prevention and Research Institute of Texas  
Risk Rated Significant Activity Summary  
July 2018**

2018 Risk Assessment Update

Risk Factor				Composite Risk Rating		
Ranking	SIGNIFICANT ACTIVITIES	Last Year Audited	Prior Ranking	P	I	Total
1	Pre-Award Grant Management	2018	1	5.00	5.00	5.00
2	Post-Award Grant Monitoring	2018	2	4.70	5.00	4.85
3	Information Security	2018	3	4.55	4.55	4.55
4	Commodity and Service Contracts	2017	4	3.93	4.15	4.04
5	Procurement and P-Cards	2018	5	3.60	4.42	4.01
6	Disaster Recovery and Business Continuity Planning		6	3.56	4.33	3.95
7	Internal Agency Compliance	2018	8	3.76	3.91	3.84
8	Information Technology General Computer Controls	2015	9	3.50	3.90	3.70
9	Governance	2015	7	3.41	3.84	3.63
10	Records Management		N/A	3.01	4.06	3.54
11	Application Development and Management		13	3.48	3.48	3.48
12	Grant Contracting	2018	10	3.30	3.65	3.48
13	Budget and Planning	*2019	11	3.42	3.44	3.43
14	Communications	2018	16	3.28	3.56	3.42
15	State Reporting Requirements	*2019	14	3.11	3.55	3.33
16	Revenue	2017	15	2.80	3.71	3.26
17	Cash Management	2017	17	2.97	3.42	3.20
18	Oversight Committee Reporting		18	2.41	3.91	3.16
19	Training	2018	12	2.78	3.36	3.07
20	Financial Close and Reporting		20	2.75	3.33	3.04
21	Employee Management		19	2.63	3.40	3.02
22	Non-Grant Expenditures	2017	21	2.55	3.40	2.98
23	Data/Information Reporting		N/A	2.78	2.93	2.86
24	Payroll (DHHS Inter-Agency Contract)		22	2.58	2.95	2.77
25	Travel (In and Out of State)		24	2.07	1.82	1.95
26	Benefits Administration		25	1.81	1.81	1.81
27	Capital Assets	2014	26	1.80	1.57	1.69

\* Proposed on the fiscal year 2019 Internal Audit Plan

**Cancer Research and Prevention Institute of Texas  
Proposed - 2019 Internal Audit Plan  
For the Year Ending August 31, 2019**

Audit Area	Risk Rating	Summary Procedures	Audit Focus
<b>2019 Planned New Internal Audits</b>			
State Reporting	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's State Reporting practices. Activities to be considered in the evaluation will include Annual Reports, Research/Analytical Supporting, Texas Cancer Plan, Public Information Act Requests, and Ad Hoc Reporting.	Internal Audit
Budget and Planning	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Budgeting and Planning practices. Activities to be considered in the evaluation will include Strategic Plan, Budgeting and Planning Process, Legislative Appropriations Request, Review and Amendment, Capital Expenditures Budget, and Budget Monitoring.	Internal Audit
<b>2019 Planned Internal Audit Follow-up</b>			
Communications	Moderate	Internal Audit will perform follow-up procedures on the 5 open findings from the 2018 Internal Audit to ensure corrective action has been taken.	Follow-up
Post-Award Grant Monitoring	High	Internal Audit will perform follow-up procedures on the 1 open findings from the 2018 Internal Audit to ensure corrective action has been taken.	Follow-up
Procurement and P-Cards	High	Internal Audit will perform follow-up procedures on the 1 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up
Information Security	High	Internal Audit will perform follow-up procedures on the 2 open findings from the 2016 Internal Audit to ensure corrective action has been taken.	Follow-up
SAO Report on Performance Measures		Internal Audit will perform follow-up procedures on the 3 open findings from the 2017 Audit to ensure corrective action has been taken.	Follow-up
<b>2019 Planned Annual Requirements</b>			
Project Management	NA	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management
Update Risk Assessment	NA	Perform required annual update of risk assessment	Policy Compliance
Annual and Quarterly Board Reports	NA	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Committee of internal audit activities.	Policy Compliance

**Cancer Prevention and Research Institute of Texas  
Schedule of Audits, Status, and Findings Summary  
As of July 31, 2018**

Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	Open Findings			Closed Findings			Total Findings				
					High	Mod	Low	High	Mod	Low	High	Mod	Low	Total	
<b>Fiscal Year 2015</b>															
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
2014 Governance and IT Follow-Up	2015	Complete	August 14, 2015	Satisfactory	-	-	-	9	-	-	-	-	-	1	2
2014 Grantee Monitoring Follow-Up	2015	Complete	July 31, 2015	Satisfactory	-	-	-	14	-	-	-	-	-	2	3
<b>Fiscal Year 2015 Subtotal</b>					-	8	3	34	-	-	-	-	18	1	16
<b>Fiscal Year 2016</b>															
Commodity and Service Contracts Internal Audit	2016	Complete	May 13, 2016	Satisfactory	-	3	2	5	-	-	-	-	3	2	5
Revenue Internal Audit	2016	Complete	July 8, 2016	Strong	-	-	2	2	-	-	-	-	-	2	2
Information Security Internal Audit	2016	Complete	August 3, 2016		-	-	-	-	-	-	-	-	-	-	-
Cash Management Internal Audit	2016	Complete	August 12, 2016	Strong	-	1	-	1	-	-	-	-	-	1	1
2015 Grant Management Follow-Up	2016	Complete	June 9, 2016	Strong	-	8	1	9	-	-	-	-	-	8	1
2015 Information Technology Follow-Up	2016	Complete	N/A	N/A	-	1	1	2	-	-	-	-	-	1	2
<b>Fiscal Year 2016 Subtotal</b>					-	13	6	19	-	9	2	11	-	4	8
<b>Fiscal Year 2017</b>															
Training Program Internal Audit	2017	Complete	March 10, 2017	Strong	-	2	-	2	-	-	-	-	-	2	2
Internal Agency Compliance	2017	Complete	April 17, 2017	Strong	-	1	-	1	-	-	-	-	-	1	1
Pre-Award Grant Management	2017	Complete	May 30, 2017	Satisfactory	1	2	-	3	-	-	-	-	1	2	3
Procurement and P-Card Internal Audit	2017	Complete	August 4, 2017	Satisfactory	-	7	2	9	-	-	-	-	-	7	2
2016 Information Security Follow-Up	2017	Complete	May 30, 2017		-	-	-	-	-	-	-	-	-	-	-
2016 Commodity and Service Contracts Follow-Up	2017	Complete	July 13, 2017	Strong	-	3	2	5	-	-	-	-	-	3	2
2016 Revenue Follow-Up	2017	Complete	July 8, 2017	Strong	-	-	2	2	-	-	-	-	-	2	2
2016 Cash Management Follow-Up	2017	Complete	July 13, 2017	Strong	-	1	-	1	-	-	-	-	-	1	1
<b>Fiscal Year 2017 Subtotal</b>					1	16	6	23	-	4	4	8	1	12	15
<b>Fiscal Year 2018</b>															
Post Award Grant Monitoring Internal Audit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	-	1	1
Grant Contracting Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	4	5
Communication Internal Audit	2018	FY 2019	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-
State Reporting Internal Audit	2018	FY 2019	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-
Information Technology Services Internal Audit	2018	Complete	July 17, 2018		-	-	-	-	-	-	-	-	-	-	-
2016 Information Security Follow-Up	2018	Complete	January 19, 2018	Strong	-	2	-	2	-	-	-	-	-	2	2
2017 Training Program Follow-Up	2018	Complete	January 19, 2018	Strong	-	1	-	1	-	-	-	-	-	1	1
2017 Internal Agency Compliance Follow-Up	2018	Complete	April 24, 2018	Strong	1	2	-	3	1	2	-	-	-	3	3
2017 Pre-Award Grant Management Follow-Up	2018	Complete	April 30, 2018	Strong	-	7	2	9	-	-	-	-	-	6	2
2017 Procurement and P-Card Follow-Up	2018	Complete	April 30, 2018	Strong	2	17	2	21	1	11	2	14	1	6	7
<b>Fiscal Year 2018 Subtotal</b>					4	37	17	54	2	14	11	25	2	12	17
<b>FISCAL YEAR 2018 SUMMARY</b>															
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			
Post Award Grant Monitoring Internal Audit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	1	FY 2019	
Grant Contracting Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	4	FY 2019	
Communication Internal Audit	2018	FY 2019	TBD	TBD	-	-	-	-	-	-	-	-	-		
State Reporting Internal Audit	2018	FY 2019	TBD	TBD	-	-	-	-	-	-	-	-	-		
Information Technology Services Internal Audit	2018	Complete	July 17, 2018		-	-	-	-	-	-	-	-	-		
2016 Information Security Follow-Up	2018	Complete	January 19, 2018	Strong	-	2	-	2	-	-	-	-	-		
2017 Training Program Follow-Up	2018	Complete	January 19, 2018	Strong	-	1	-	1	-	-	-	-	-		
2017 Internal Agency Compliance Follow-Up	2018	Complete	April 24, 2018	Strong	1	2	-	3	1	2	-	-	-		
2017 Pre-Award Grant Management Follow-Up	2018	Complete	April 30, 2018	Strong	-	7	2	9	-	-	-	-	-		
2017 Procurement and P-Card Follow-Up	2018	Complete	April 30, 2018	Strong	2	17	2	21	1	11	2	14	1		
<b>Total Findings For Internal Audit Follow-Up</b>					4	37	17	54	2	14	11	25	2		

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

IA # 04-18 Internal Audit Report over Communication

Report Date: April 30, 2018

Issued: May 25, 2018

# CONTENTS

	Page
Internal Audit Report Transmittal Letter To The Oversight Committee.....	1
Background.....	2
Audit Objective and Scope.....	3
Executive Summary.....	6
Conclusion.....	7
Detailed Procedures Performed, Findings, Recommendations and Management Response.....	8
Objective A: Design of Internal Controls.....	9
Objective B: Effectiveness of Internal Controls.....	12
Objective C: System Access.....	15
Appendix.....	16



The Oversight Committee  
Cancer Prevention & Research Institute of Texas  
1701 North Congress Avenue, Suite 6-127  
Austin, Texas 78701

This report presents the results of the internal audit procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period March 20, 2018, through April 30, 2018 relating to the communication process.

The objectives of the internal audit were to evaluate the design and effectiveness of CPRIT's communication process. The objectives were organized as follows:

- A. Determine whether internal controls over communication processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.
- B. Ensure that controls over critical communication processes are operating effectively and according to authoritative guidance.
- C. Ensure that access controls to CPRIT's website and applications used in communication processes are appropriately restricted.

To accomplish these objectives, we conducted interviews with CPRIT personnel responsible for the communication process. We also reviewed documentation and performed specific testing procedures to assess controls. Procedures were performed at CPRIT's office and completed on April 30, 2018.

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  
April 30, 2018

# Cancer Prevention & Research Institute of Texas

## IA #04-18 Internal Audit Report over Communication

April 30, 2018

Issued May 25, 2018

### Background

As a state agency responsible for awarding \$3 billion in grants, CPRIT relies on an effective communications process to provide transparency of its activities and educate its audiences including cancer advocates, universities, state legislators and the general public about grant opportunities and the agency's impact on cancer research and prevention. CPRIT utilizes various communications tools to provide their message to others, including:

- CPRIT's website
- Social media (Facebook and Twitter)
- Achievement Reports
- Listserv communications (mass e-mail)
- Traditional media

CPRIT's executive team, communications and information technology staff are responsible for managing the communications process for the agency. The communications team is led by the Chief Prevention and Communications Officer and includes a Senior Communications Specialist and an Information Specialist. CPRIT's communication strategy is developed with the assistance of a third-party strategic communications services firm.

At the beginning of each fiscal year, the strategic communications services firm, in conjunction with CPRIT's communications staff, outlines an annual communication strategy and presents it to CPRIT's executive team for consideration. The strategy is reviewed by CPRIT's communication and management team composed of the Chief Executive Officer, General Counsel, Chief Program Officers for each of CPRIT's programs (prevention, academic research and product development research), and communications staff. Changes to the strategy resulting from CPRIT's review are incorporated in the annual strategic materials presented by the communications services firm. Biweekly, the same team of CPRIT's executive leadership and communications staff meets with representatives from the communications firm to discuss implementation of the strategy and update the communications strategy, as needed.

CPRIT's website serves as one of the primary communication tools for the agency. All updates to the website are completed by the Information Technology Manager upon review and approval by program management. Requests for website updates are submitted to an IT ticketing system to ensure timely completion and adequate documentation. In addition to processing content updates, the Information Specialist monitors website traffic using the Google Analytics monitoring tool. Website statistics are presented to the Oversight Committee during their quarterly meetings.

Annually, a team composed of the data workgroup chair, Staff Attorney, and Information Specialist conduct a website content compliance review to ensure the agency's compliance with all applicable state requirements for website content. The review checklist is updated annually as new regulations pertaining to state agency websites are introduced.

Quarterly, CPRIT personnel prepare an Achievement Report which is posted on the website after each Oversight Committee Meeting. The Achievement Report provides important grant statistics and highlights the agency's impact. Data included in the report is compiled primarily from internal sources by the data workgroup chair and reviewed for accuracy and completeness by program management. Once the data is compiled and report drafted, the Senior Communications Specialist reviews and approves the report for accuracy, completeness and appropriateness. Prior to the Oversight Committee Meeting, the CEO performs a final review and approval of the report.

# Cancer Prevention & Research Institute of Texas

## IA #04-18 Internal Audit Report over Communication

April 30, 2018

Issued May 25, 2018

In addition to the website, CPRIT utilizes listservs, or mass email communications, to communicate with its stakeholders, including grantees. Listserv communications include information such as grant opportunities, CPRIT conference reminders, changes to agency rules, and training webinars. Listserv content is drafted by the Information Specialist upon request by program management. As with website updates, CPRIT utilizes the IT ticketing system to document requests for creating listserv notices as well as review and approval of the content. After each listserv notice is processed, the Information Technology Manager reviews delivery rates to ensure successful delivery of the communication. We identified a total of 74 listserv communications during the 18-month period of September 1, 2016, through February 28, 2018.

Further, all communications with traditional media (television and newsprint) are referred to the Senior Communications Specialist. CPRIT receives approximately 10 media inquiries annually. We identified a total of 18 inquiries during the 18-month period of September 1, 2016, through February 28, 2018. The Senior Communications Specialist responds immediately to minor inquiries for information that is already publicly available. All official responses must be approved by the CEO and Chief Prevention and Communications Officer. Responses that may have legal consequences are approved by the General Counsel. CPRIT utilizes the Meltwater software to continuously monitor media coverage of CPRIT. The Senior Communications Specialist contacts media when instances of coverage are identified that require clarification or correction of information to ensure that CPRIT's information is clear and necessary corrections are made.

### Audit Objective and Scope

The audit focused on the CPRIT communication processes in place within the communications team. We reviewed the procedures in place for appropriate risk and regulatory coverage and compliance to ensure efficient and effective processes. Key functions and sub-processes within the communication process reviewed include:

- External Communication Strategy
- Grantee Communications
- Listserv
- Website Content Compliance
- Achievement Report
- Media Relations
- Publicly Available Information

The scope of the audit did not include communications related specifically to compliance with the Texas Public Information Act, training, internal agency compliance, website maintenance, pre-award grant management, post-award grant monitoring, or event management. In addition, the scope did not include an evaluation of content of communications, the administration of the CPRIT website, or the communications related to planning and financial reports.

# Cancer Prevention & Research Institute of Texas

## IA #04-18 Internal Audit Report over Communication

April 30, 2018

Issued May 25, 2018

Our procedures were designed to ensure relevant risks are covered and verify the following:

### External Communication Strategy

- External communications are aligned with CPRIT's mission and goals
- Communication strategy determined by CPRIT management to be relevant and timely is reviewed and approved
- Communication strategy is updated on a periodic and as needed basis
- Communication strategy for each target audience is identified
- External communication effectiveness is tracked and monitored

### Grantee Communications

- Grantee communication is conducted by appropriate CPRIT staff
- Grantee contact information is accurate, timely, and up-to-date
- Grantee communications are adequately approved and documented
- Grantee communication is consistent with CPRIT's goals and mission
- Grantee communication is conducted via appropriate communication methods

### Listserv

- Listserv content is determined to be relevant and aligned with CPRIT's goals and mission
- Listserv content is reviewed and approved prior to release
- Listserv e-mail list is accurate and complete
- Listserv emails are analyzed for SPAM content prior to release

### Website Content Compliance

- Website content is reviewed and approved prior to posting
- Updates to website content are made in a timely manner
- Website content is in compliance with applicable state regulations
- Social media posts are reviewed and approved
- Information posted on social media is consistent with CPRIT's goals and mission

### Achievement Report

- Reports are reviewed and approved prior to release
- Report data sources are approved and validated
- Report content is determined by CPRIT to be relevant, accurate and complete
- Reports are prepared and released in a timely manner

### Media Relations

- Media inquiries are referred to appropriate CPRIT personnel
- All media communications initiated by CPRIT staff are adequately reviewed and approved prior to release
- Information provided via media outlets is accurate, complete, and timely
- Appropriate individuals are notified prior to CPRIT staff communicating with media
- News releases and supporting documentation are adequately maintained

### Publicly Available Information

- Information required to be publicly available is complete and accurate
- CPRIT is in compliance with state requirements for publicly available information
- Publicly available information is provided timely
- Publicly available information is reviewed and approved prior to release

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

## **IA #04-18 Internal Audit Report over Communication**

April 30, 2018

Issued May 25, 2018

The objectives of this internal audit were as follows:

- A. Determine whether internal controls over communication processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.
- B. Ensure that controls over critical communication processes are operating effectively and according to authoritative guidance.
- C. Ensure that access controls to CPRIT's website and applications used in communication processes are appropriately restricted.

Our procedures included interviewing key personnel who perform communications and information technology work to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the processes. We evaluated the existing policies, procedures, and processes in their current state. Our coverage period was from September 1, 2016, through February 28, 2018.

# Cancer Prevention & Research Institute of Texas

## IA #04-18 Internal Audit Report over Communication

April 30, 2018

Issued May 25, 2018

### 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 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.

<b>OVERALL ASSESSMENT</b>		<b>SATISFACTORY</b>
<b>SCOPE AREA</b>	<b>RESULT</b>	<b>RATING</b>
<p><b>Objective A:</b> Determine whether internal controls over communication processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.</p>	<p>We identified 24 controls to be in place in the processes. However, there are opportunities to strengthen the processes and control environment including:</p> <ul style="list-style-type: none"> <li>• Define approval requirements for website changes and document approvals</li> <li>• Develop procedures for review and approval of social media posts</li> <li>• Ensure that Achievement Reports are accurate and approved timely</li> </ul>	<b>SATISFACTORY</b>
<p><b>Objective B:</b> Ensure that controls over critical communication processes are operating effectively and according to authoritative guidance.</p>	<p>Controls appear to be in place; however, all are not consistently executed. We identified the following opportunities for improvement:</p> <ul style="list-style-type: none"> <li>• Document the review and approval of website content updates</li> <li>• Ensure compliance with state communications requirements, throughout the implementation of the CPRIT's new website</li> </ul>	<b>SATISFACTORY</b>
<p><b>Objective C:</b> Ensure that access controls to CPRIT's website and applications used in communication processes are appropriately restricted.</p>	<p>Access to CPRIT's website is appropriately restricted. However, CPRIT should remove inappropriate employee access to the MailChimp software.</p>	<b>SATISFACTORY</b>

# Cancer Prevention & Research Institute of Texas

IA #04-18 Internal Audit Report over Communication

April 30, 2018

Issued May 25, 2018

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 CPRIT policies and procedures. These are considered process improvement observations and the intent of the recommendations are to strengthen current CPRIT processes and controls. These observations were provided to management separately.

## Conclusion

Based on our evaluation, the communication function has procedures and controls in place to conduct effective management of the significant processes within CPRIT. However, we identified five opportunities to improve the effectiveness of the controls within the communication process. Specifically, CPRIT should ensure compliance with all state website requirements as the new agency website is implemented. In addition, CPRIT should define and document procedures for the review and approval of website content updates.

CPRIT should implement procedures for the review and approval of social media posts prior to their posting by someone other than the preparer. The procedures should define which types of posts require approval and who the appropriate approver is for the category of the post. In addition, CPRIT should ensure that user access to the MailChimp software is appropriate by editing or removing the Purchaser's access.

Further, CPRIT should continue to utilize the process implemented in February 2018 to ensure that Achievement Reports are accurate and approved timely.

Follow-up procedures will be performed in Fiscal Year 2019 to evaluate the effectiveness of remediation efforts taken to address the findings identified.

**Detailed Procedures Performed, Findings,  
Recommendations and Management  
Response**

# Cancer Prevention & Research Institute of Texas

IA #04-18 Internal Audit Report over Communications

April 30, 2018

Issued May 25, 2018

## Detailed Procedures Performed, Findings, Recommendations and Management Response

Our procedures included interviewing key personnel who perform communications and information technology work to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the processes. We evaluated the existing policies, procedures, and processes in their current state.

### Objective A: Design of Internal Controls

Determine whether internal controls over communication processes are in place to ensure that consistent processes are implemented and designed effectively to address the risks within the associated sub-processes and to ensure effective operations.

**Procedures Performed:** We conducted interviews of key personnel who perform communications and information technology work and examined existing documentation to gain an understanding of the current communication processes. We documented understanding of the processes and identified internal controls over the following sub processes:

- External Communication Strategy
- Grantee Communications
- Listserv
- Website Content Compliance
- Achievement Report
- Media Relations
- Publicly Available Information

We evaluated the controls identified against expected controls to determine whether the identified reoccurring communication procedures and internal controls are sufficiently designed to mitigate the critical risks associated with the communication 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 24 controls in place over the significant activities within the communication and function. We identified three findings where improvements in the process can be made.

# Cancer Prevention & Research Institute of Texas

IA #04-18 Internal Audit Report over Communications

April 30, 2018

Issued May 25, 2018

Process Area	Control Coverage	Findings / Observations
<b>Communications Processes</b>		
External Communication Strategy	6	
Grantee Communications	2	
Listserv	5	
Website Content Compliance	3	<b>Finding 1 Finding 2</b>
Achievement Report	4	<b>Finding 3</b>
Media Relations	4	
Publicly Available Information	4	
<b>Total</b>	<b>28*</b>	

\*Duplicate Control: The total number of identified controls is 24. However, based on their design, controls address risks in multiple processes. We have mapped the 24 unique controls to the processes in which they mitigate the risks within the processes

**Finding 1 – MODERATE – Website Content Updates:** While CPRIT utilizes a ticketing system to track and monitor updates to website content, the protocols and workflow lack definition to include the required review of postings and the timing of the completion of the updates.

The existing workflow does not have criteria identified to define which updates to website content require a review by communications prior to posting or procedures to document the review and approval of website content updates. Currently, website content updates are requested by CPRIT personnel via the IT ticketing system. All website updates are completed by the Information Technology Manager and the completion is documented within the ticketing system. Although the Information Specialist is notified of all tickets requesting website updates, the updates are not consistently reviewed and approved by communications prior to posting.

Additionally, the requirements to post updates in a specific timeframe are inconsistently defined. Only when individuals include a posting deadline in the update request ticket are posting deadlines established.

We reviewed 50 out of 351 website updates that were completed during the period of September 1, 2016, through February 28, 2018 and identified the following:

- 5 out of 50 sample items tested, documentation to demonstrate the website content updates were completed timely could not be provided. Timing of completion dates recorded in the ticketing system range from 78 to 418 days after requests were submitted. Additionally, 1 of the 5 changes was not completed accurately
- 2 out of 50 samples that were posted 1 and 6 days after the deadline indicated in the ticket.

# Cancer Prevention & Research Institute of Texas

IA #04-18 Internal Audit Report over Communications

April 30, 2018

Issued May 25, 2018

**Recommendation:** CPRIT should define and document the requirements of the changes to the website that require approval from communications personnel. The definition could include different classifications of the website updates based on the content type and identify the approval requirements for each category. Certain content updates, such as those not related to CPRIT's messaging, may not require approval by communications personnel.

The review process should include a method to document the personnel who performed the review. The requirements should also include a definition of the timely completion of changes requested.

**Management Response:** CPRIT management agrees with the condition as stated. Both the Information Specialist and Information Technology Manager make updates to CPRIT's public websites. CPRIT currently utilizes the IT ticketing system to provide and track ticket verification. Staff who submit a ticket receive automated updates when ticket activities occur, including when work is performed, and must review and accept the content change to ensure it is done correctly. The communications team is copied on a ticket when a content update impacts agency messaging.

CPRIT management agrees that the content approval process being used needs to be formally documented including base service levels for content updates and content type classifications requiring approval by communications personnel. Communications and IT staff will develop a content classification system and procedures for required management approvals and draft an approval document. CPRIT also notes that communications and IT staff are actively working to close the gap in tracking tickets between the timeframe when work is performed and when tickets are updated.

**Responsible Party:** Senior Communications Specialist, Information Specialist, Information Technology Manager

**Implementation Date:** August 31, 2018

**Finding 2 – MODERATE – Social Media Posting:** CPRIT does not have procedures in place for someone other than the preparer to review and approval of social media content before posting. Currently, CPRIT maintains three social media accounts, Facebook, Twitter and YouTube. All social media posts are prepared and posted by the Information Specialist without review and approval by supervisory communications staff.

**Recommendation:** CPRIT should implement procedures for the review and approval of social media posts by someone other than the preparer prior to posting. The procedures should define which types of posts require approval and who the appropriate approver is for the category of the post. Social media posts could be prepared by the Information Specialist and reviewed and approved by the Senior Communications Specialist or another approver, depending on the type of post, prior to publishing the post.

**Management Response:** CPRIT management agrees with the condition as stated. The agency has begun drafting a written social media posting process that describes which types of postings require approval and by whom.

**Responsible Party:** Information Specialist

**Implementation Date:** August 31, 2018

# Cancer Prevention & Research Institute of Texas

## IA #04-18 Internal Audit Report over Communications

April 30, 2018

Issued May 25, 2018

**Finding 3 – MODERATE – Accuracy and Timeliness of Achievement Reports:** Through the preparation of the Achievement Report, CPRIT has identified that the agency inconsistently meets their internally established deadlines and requirements to draft, review, approve, and publish the report. Therefore, new procedures were implemented in February 2018 to address the preparation of the report. Through the dynamic process to draft, review and edit the report, the final review and approval of Achievement Reports is not consistently documented as part of the established workflow. Additionally, information included in Achievement Reports is not consistently accurate.

According to CPRIT's recently implemented internal timeline, Achievement Reports should be completed and approved before an Oversight Committee meeting. Prior to February 2018, the internal timeline for completion and approval of Achievement Reports was one week after the Oversight Committee meeting. We selected a sample of 3 out of 6 Achievement Reports that were posted during the period of September 1, 2016, through February 28, 2018 and identified the following exceptions:

- All 3 reports were not approved prior to CPRIT's internal deadline
- 2 reports contained inaccurate information, totaling 5 errors in the reports

**Recommendation:** CPRIT should continue to utilize the process implemented in February 2018 to ensure that Achievement Reports are accurate and approved timely. Through the review process emphasis should be placed on the review of the accuracy of data included in the report by data owners. A routing sheet of approvals could be created to document the review and approval of individuals throughout the preparation of the report. Alternatively, signoff on the physical copy of the reviewed report or emails of the approval could be maintained. If approvals of the reports are verbal, communications staff could document the date that approval was provided.

**Management Response:** CPRIT management agrees with the condition as stated. The new data verification process established for the February 2018 report will continue to be implemented. In addition, procedures to document review and approval throughout that process will be developed.

**Responsible Party:** Senior Communications Specialist

**Implementation Date:** August 30, 2018

### Objective B: Effectiveness of Internal Controls

Ensure that controls over critical communication processes are operating effectively and according to authoritative guidance.

1. **Procedures Performed:** We selected a sample of 25 out of 74 listserv communications that occurred during the period of September 1, 2016, through February 28, 2018. For each selected item, we verified the following:
  - Communication was conducted by appropriate CPRIT staff
  - Communication was adequately reviewed and approved
  - Communication was consistent with CPRIT's communications strategy
  - Communication was analyzed for SPAM content prior to release

**Results:** No findings identified.

# Cancer Prevention & Research Institute of Texas

## IA #04-18 Internal Audit Report over Communications

April 30, 2018

Issued May 25, 2018

**2. Procedures Performed:** We selected a sample of 50 out of 351 website content updates that occurred during the scope period of September 1, 2016 through February 28, 2018. For each selected item, we verified the following:

- Added/updated content was complete and accurate
- Content was in compliance with applicable state regulations
- Content update was made in a timely manner
- Content was reviewed and approved prior to release

**Results:** Of the 50 website updates tested, we identified:

- 5 updates where documentation to demonstrate the website content updates were completed timely could not be provided. Timing of completion dates were recorded in the ticketing system range from 78 to 418 days after requests were submitted. Additionally, 1 of the 5 changes was not completed accurately
- 2 updates were posted 1 and 6 days after the deadline indicated in the ticket

### **Finding 1 – MODERATE – Website Content Updates**

**3. Procedures Performed:** We reviewed the most recent website compliance review performed by CPRIT personnel in February 2018, and verified the following:

- Applicable state regulations were identified
- CPRIT is in compliance with all applicable State requirements including the requirements for publicly available information

**Results:** We determined that CPRIT is not in compliance with two state communications requirements, 1 TAC 206 and 13 TAC 3.

**Finding 4 – HIGH – CPRIT Website Compliance:** In February 2018 CPRIT's Senior Program Manager for Prevention, Staff Attorney and Information Specialist conducted an annual website review to assess compliance with applicable state requirements and identified that CPRIT is not in compliance with the following requirements:

- 1 TAC 206.54(a) & 13 TAC 3.4(3) - Requirement to include meta data tags on all publications
- 1 TAC 206.54(b) - Requirement to include TRAIL meta data on the homepage
- 13 TAC 3.4(2)(a) - Requirement for accessibility of publications
- 13 TAC 3.2(b) - Requirement for posting the date that each publication is produced or distributed
- 1 TAC 206.51 - Requirement for translation of the website
- 1 TAC 206.50(c) - Requirement for maintaining an alternative version page with equivalent information or functionality
- 1 TAC 206.50(d) - Requirement for accessibility testing
- 1 TAC 206.55(d) - Requirement for address of the web page with high-value data set.

CPRIT personnel identified the non-compliance prior to this audit and are actively working on addressing these issues with the ongoing implementation of the new agency website.

# Cancer Prevention & Research Institute of Texas

## IA #04-18 Internal Audit Report over Communications

April 30, 2018

Issued May 25, 2018

**Recommendation:** CPRIT should continue to implement the new website. As part of the implementation, CPRIT should ensure that the website is in compliance with all communications requirements.

**Management Response:** CPRIT management agrees with the condition as stated. The implementation of the new website is critical and will ensure that an annual website content compliance review is performed. The agency is currently working to procure a cloud-based service, Siteimprove, to automate accessibility testing, issue reporting and tracking on the agency's public websites. As part of the new agency website implementation, Google's Cloud Translation Application Programming Interface (API) will be integrated to provide automated translation of the agency's website text content. The implementation of CPRIT's new primary website will occur in three phases. First, the completion of the migration to the content management platform (phase 1), then the implementation of a newly designed website look and feel (phase 2), and finally, a focused effort on implementing site wide translation and accessibility testing (phase 3).

**Responsible Party:** Staff Attorney, Information Technology Manager

**Implementation Date:** October 31, 2018

**4. Procedures Performed:** We selected a sample of 50 out of 454 social media posts that were posted during the scope period of September 1, 2016, through February 28, 2018. For each selected item, we verified the following:

- Social media post was aligned with CPRIT's communication strategy
- Social media post was posted timely

**Results:** No findings identified.

**5. Procedures Performed:** We selected a sample of 3 out of 6 Achievement Reports that were issued during the scope period of September 1, 2016, through February 28, 2018. For each selected item, we verified the following:

- Report was reviewed and approved prior to release
- Report sources were approved and reliable
- Report was prepared and released in a timely manner
- Report content was determined by CPRIT to be relevant, accurate and complete

**Results:** Based on the results of our testing, we have identified the following as exceptions:

- All 3 reports were not approved prior to CPRIT's internal deadline
- 2 reports contained inaccurate information, totaling 5 errors in the reports

**Finding 3 – MODERATE – Accuracy and Timeliness of Achievement Reports**

# Cancer Prevention & Research Institute of Texas

IA #04-18 Internal Audit Report over Communications

April 30, 2018

Issued May 25, 2018

**6. Procedures Performed:** We selected a sample of 9 out of 18 media inquiries that occurred during the scope period of September 1, 2016, through February 28, 2018. For each selected item, we verified the following:

- Media inquiry was referred to the Senior Communications Specialist
- CPRIT's response was reviewed and approved prior to release
- Information provided to media was accurate, complete and timely
- Appropriate individuals were notified of the inquiry
- CPRIT's response, related news releases and supporting documentation were adequately maintained

**Results:** No findings identified.

## Objective C: System Access

Ensure that access controls to CPRIT's website and applications used in communication processes are appropriately restricted.

**Procedures Performed:** We evaluated CPRIT employee user access to the website administration and the MailChimp application used for processing listserv communications. As part of the evaluation, we verified the following:

- User access is appropriate for the employee's position and job responsibilities
- User access is formally reviewed and approved for appropriateness on a periodic basis

**Results:** We identified one instance of inappropriate access to MailChimp. CPRIT's Purchaser has the ability to edit the contact list maintained in MailChimp, as well as to create and send Listserv communications to subscribers, legislators, and grantees whose email contact information is maintained in MailChimp contact lists.

**Finding 5 – MODERATE – Inappropriate User Access:** In order to obtain MailChimp billing information for the monthly P-Card reconciliation, the Purchaser has "modify" access to this application used for processing listserv communications. As a result, the Purchaser has the ability to edit the contact list maintained in MailChimp as well as create and send listserv communications to subscribers, legislators, grantees whose email contact information is maintained in MailChimp contact lists.

**Recommendation:** CPRIT should remove the Purchaser's access to the MailChimp software. Invoice information should be provided to the Purchaser by another CPRIT employee such as the Information Specialist or Information Technology Manager.

**Management Response:** CPRIT management agrees with the condition as stated. The Purchaser's access to the MailChip application has been removed with the Chief Operating Officer's authorization. Notification of the rights change was provided to CPRIT's Information Technology Governance Committee.

**Responsible Party:** Information Technology Manager, Chief Operating Officer

**Implementation Date:** May 18, 2018

# Appendix

# Cancer Prevention & Research Institute of Texas

## IA #04-18 Internal Audit Report over Communications

April 30, 2018

Issued May 25, 2018

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.

# Cancer Prevention & Research Institute of Texas

IA #04-18 Internal Audit Report over Communications

April 30, 2018

Issued May 25, 2018

## 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 agency
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

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

IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards

Report Date: April 30, 2018

Issued: May 25, 2018

# CONTENTS

	Page
Internal Audit Report Transmittal Letter To The Oversight Committee .....	1
Background.....	2
Follow-Up Objective and Scope.....	2
Executive Summary .....	3
Conclusion.....	3
Detailed Follow-Up Results, Recommendations and Management Response .....	4
Appendix .....	11



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 (CPRIT) during the period April 9, 2018, through April 13, 2018, related to the findings from the Internal Audit Report over Procurement and P-Cards dated June 21, 2017.

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 2017 Internal Audit Report over Procurement and P-Cards.

To accomplish this objective, we conducted interviews with key CPRIT personnel responsible for procurement and P-Cards. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the CPRIT's office and an exit meeting was conducted on April 30, 2018.

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  
April 30, 2018

**Cancer Prevention and Research Institute of Texas**  
IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards  
April 30, 2018  
Issued: May 25, 2018

## **Background**

In 2017, internal audit procedures over CPRIT's Procurement and P-Card processes were completed and reported to the Oversight Committee. The internal audit report over CPRIT's procurement and P-Card procedures and activities identified nine areas for improvement related to the consistent execution of procedures, completion of process documentation, monitoring purchases as well as the use and reconciliation of Travel Cards and P-Cards.

The 2018 Internal Audit Plan included performing procedures to validate that CPRIT management has taken steps to address internal audit findings.

## **Follow-Up Procedures Objective and Scope**

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address findings included in the 2017 Internal Audit Report over Procurement and P-Cards, and to validate that appropriate corrective action had been taken. The 2017 report identified the following findings:

- Purchasing procedures are not consistently enforced to require requisitions for all purchases
- Procedures to determine, document, and utilize the most appropriate purchase method are not followed
- RFP approvals by the Chief Operating Officer are not consistently documented and retained
- Financial Interest Disclosures are not completed by all CPRIT personnel participating in the evaluation of vendor proposals
- There are no procedures in place to consistently ensure that all disclosures, certifications and reviews are completed prior to entering into a contract with a vendor
- Documented processes are not in place to monitor serial, sequential or split purchases
- Travel Card use is shared by multiple agency employees while responsibility for the travel card is assigned to the Accountant
- Travel requisitions are not consistently approved
- P-Card and Travel Card reconciliations are not performed timely

Our follow-up procedures included verification of the following:

- Purchase requisitions are consistently created and approved
- Appropriate purchasing method is utilized and adequately documented
- RFPs are reviewed and approved by the Chief Operating Officer
- Financial Interest Disclosure forms are completed by all CPRIT personnel participating in the evaluation of vendor proposals as part of the formal solicitation process
- Disclosures, certifications, and reviews are completed for each contract
- Purchases are monitored to identify potential split purchases and to consolidate purchases
- The Procurement Plan and Contract Management Handbook has been updated to reflect existing Travel Card procedures and that Travel Card activity is reviewed by the Accountant
- Travel requisitions were consistently approved
- P-Card and Travel Card reconciliations are performed timely

**Cancer Prevention and Research Institute of Texas**  
 IA # 05-18 Internal Audit Follow-Up Procedures Report  
 over Procurement and P-Cards  
 April 30, 2018  
 Issued: May 25, 2018

**Executive Summary**

The findings from the 2017 Internal Audit Report over Procurement and P-Cards include those items that were identified and are considered to be non-compliance issues with CPRIT's policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have significant financial or operational implications.

Through our interviews, review of documentation, observations and testing we determined that of the nine findings where corrective action was evaluated, seven were fully remediated while one was partially remediated, and one was closed by management.

Risk Rating	Total Findings	Remediated	Closed by Management	Partially Remediated	Open
High	-	-	-	-	-
Moderate	7	5	1	1	-
Low	2	2	-	-	-
<b>Total</b>	<b>9</b>	<b>7</b>	<b>1</b>	<b>1</b>	<b>-</b>

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.

FOLLOW-UP ASSESSMENT		STRONG
SCOPE AREA	RESULT	RATING
<b>Objective:</b> Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2017 Internal Audit Report over Procurement and P-Cards.	We identified that procedures implemented by management addressed and remediated prior open findings. However, management should continue their efforts to remediate the remaining open finding: <ul style="list-style-type: none"> <li>Ensure that Travel Card reconciliations are performed timely</li> </ul>	<b>STRONG</b>

**Conclusion**

Based on our evaluation, key personnel in procurement and finance made efforts to remediate the findings from the 2017 Internal Audit Report. However, additional efforts should be made to remediate the one finding that was partially remediated.

We recommend CPRIT continue to remediate the remaining procurement and P-Card finding and strengthen existing processes. CPRIT should ensure that all Travel Card reconciliations and payments of the card are completed in a timely manner.

Follow-up procedures should be conducted in Fiscal Year 2019 to validate the effectiveness of the remediation efforts taken to address the remaining open finding.

**Detailed Follow-Up Results, Findings,  
Recommendations and Management  
Response**

**Cancer Prevention and Research Institute of Texas**  
IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards  
April 30, 2018  
Issued: May 25, 2018

**Detailed Follow-Up Results, Recommendations and Management Response**

Our procedures included interviewing key personnel in Procurement and Finance to gain an understanding of the corrective actions taken in order to address the findings identified in the 2017 Internal Audit Report over Procurement and P-Cards, as well as examining existing documentation and communications and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

**Objective: Validate Remediation**

Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2017 Internal Audit Report over Procurement and P-Cards.

**Finding 1 – MODERATE – Purchase Requisition Creation and Approval:** CPRIT does not consistently enforce procedures to submit and approve a purchase requisition for all purchases in accordance with the agency's Procurement Plan and Contract Management Handbook.

Of the 30 purchases tested, 18 exceptions were identified:

- 17 purchases did not have a purchase requisition created; 14 of the 17 were for purchases off of cooperative contracts for contract labor
- 1 purchase had a purchase requisition that was not reviewed and approved by the COO

Of the 30 P-Card purchases tested, 15 did not have a purchase requisition created. These were monthly and annual charges for recurring services provided to CPRIT's IT Department.

**Results: Finding remediated**

We reviewed the FY 2018 CPRIT Procurement Plan and Contract Management Handbook and verified that purchasing procedures were updated to include a requirement for the Purchaser to create a purchase requisition in CAPPs. In addition, we met with the Purchaser and the Operations Specialist and observed that requisitions must be approved prior to creating a purchase order in CAPPs.

We selected samples of 25 out of 82 purchase orders and 25 out of 107 P-card transactions that occurred during the period of September 1, 2017, through March 31, 2018, and verified that corresponding requisitions were created and approved in CAPPs.

**Finding 2 – MODERATE – Purchase Method:** CPRIT does not consistently follow the procedures to determine, document, and utilize the most appropriate purchase method as required by the State of Texas Procurement Manual and CPRIT's purchasing requirements.

**Cancer Prevention and Research Institute of Texas**  
IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards  
April 30, 2018  
Issued: May 25, 2018

Of the 30 purchases tested, 2 exceptions were identified:

- 1 purchase did not have the required documentation of the determination of best value for the purchase method utilized. The UT Document Solutions purchase did not have the required documentation to support the purchase method. The print shop job request was appropriately submitted through the state portal. However, Step 3 of the State of Texas procedure for procuring print related services requires the Purchaser to document the performance of the analysis determining best value for the purchase. No support for the analysis was provided.
- 1 purchase did not have the required support and evaluation for an Open Market Informal Solicitation. The purchase from PDME was within the procurement threshold of \$5,000 and \$25,000, which required a solicitation of goods from at least 3 CMBL vendors, including 2 HUB vendors. However, the purchase was made without the 3 required solicitations.

**Results: Finding remediated**

We selected a sample of 25 out of 82 purchase orders that occurred during the period of September 1, 2017, through March 31, 2018, and verified that purchasing guidelines were followed and appropriate purchasing method was used based on the purchase amount. In addition, we verified that all supporting documentation was adequately maintained.

**Finding 3 – MODERATE – Missing RFP Approval:** CPRIT does not consistently document and retain the approval of RFPs. Current RFP approval methods include verbal, email, or signature approvals from the Chief Operating Officer. However, documentation of the approval is not consistently maintained within the procurement file.

Of the 5 contracts requiring formal bids that were tested, CPRIT was unable to provide evidence of the approval for 3 of the RFPs. These 3 were likely verbal approvals.

**Results: Finding remediated**

We interviewed the Chief Operating Officer and the Purchaser and determined that the formal review and approval of the solicitation document was implemented. In addition, we reviewed the FY 2018 Procurement Plan and Contract Management Handbook and verified that procedures for final approval of the solicitation document by the Chief Operating Officer was included.

We reviewed two solicitations that were posted during the scope period of September 1, 2017 through March 31, 2018 and verified that both solicitations were approved by the Chief Operating Officer, as evidenced by the dated signoff.

**Finding 4 – LOW – Financial Interest Disclosure:** All CPRIT personnel participating in the evaluation of vendor proposals as a part of the formal solicitation process are not required to sign a Financial Interest Disclosure for that solicitation. The Financial Interest Disclosure is only signed by Oversight Committee members and certain CPRIT staff such as the Purchaser, COO, General Counsel and CEO. CPRIT awards contracts to top-rated vendors based on the evaluation, which includes input from subject-matter experts.

**Results: Finding remediated**

**Cancer Prevention and Research Institute of Texas**  
IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards  
April 30, 2018  
Issued: May 25, 2018

We reviewed the updated CPRIT Procurement Plan and Contract Management Handbook and determined that all CPRIT staff involved in the procurement process, including evaluators of proposals, are required to sign the Financial Disclosure of Interest.

We determined that there was only one evaluation of RFP proposals during the scope period of October 31, 2017, through March 31, 2018, RFP 542-18-002. We verified that Financial Interest Disclosure forms were signed by all CPRIT staff who participated in the evaluation of proposals.

**Finding 5 – MODERATE – Required Disclosures, Certifications, and Reviews:** CPRIT does not have procedures in place to consistently ensure that all disclosures, certifications and reviews are completed prior to entering into a contract with a vendor.

Senate Bill 20, 84R requires Oversight Committee members to disclose that they do not have any financial interest prior to entering into a contract for the purchase of goods and services. Additionally, the Purchaser must obtain the Certificate of Interested Parties (Form 1295) from each vendor on contracts requiring governing board approval or are \$1 million or more prior to signing a contract with the vendor. Form 1295 is a form filed with the Texas Ethics Commission to certify there are no controlling or intermediary interested parties to the contract associated with the vendor. Further, contracts for commodities that exceed \$25,000 and services estimated to exceed \$100,000, require review by the Comptroller's State Procurement Division (SPD).

Of the 5 contracts requiring formal bids tested, we identified 4 exceptions:

- 1 contract did not have the required No Financial Interest Disclosure of an Oversight Committee member
- 2 contracts did not have a signed and notarized copy of the Form 1295 available in the contract file
- 1 contract did not complete the SPD Contract Advisory Team Review

**Results: Finding remediated**

We reviewed the Contract Award Checklist which is utilized by the Purchaser to ensure that all required disclosures, certifications, and reviews have been completed prior to executing contracts. We verified that the checklist includes the following items:

- The vendor has not been debarred from the General Services Administration's System for Award Management or the State Purchasing Division's Debarred Vendor List
- COO must obtain written certifications of no financial interest with a selected vendor from the Oversight Committee members, the Chief Executive Officer, the General Counsel, and Chief Operating Officer, the Purchaser and all other staff who participated in the procurement process
- Vendor must file Form 1295, Certificate of Interested Parties with the Texas Ethics Commission

Based on the listing of executed contracts and interview with the Purchaser, only one contract was executed during the period of September 1, 2017, through March 31, 2018. We verified that the Contract Award Checklist was completed for this contract.

**Cancer Prevention and Research Institute of Texas**  
IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards  
April 30, 2018  
Issued: May 25, 2018

**Finding 6 – MODERATE – Monitoring Split Purchases and Consolidation of Purchases:** CPRIT's Purchaser does not have a documented process in place to monitor serial, sequential or split purchases to ensure that purchases are not "split" for the purpose of avoiding formal procurement requirements, or to identify opportunities to consolidate purchases to leverage purchasing power. CPRIT's Procurement Plan and Contract Management Handbook requires purchases of commodities and services that exceed \$25,000 to follow a formal bidding process and purchases between \$5,000 and \$25,000 require an informal bidding process. The Purchaser maintains a purchase order log; however, the Purchaser does not utilize the log to perform monitor and identify potential split purchases.

**Results: Finding closed.** Management has determined to accept the risk associated with this finding.

**Finding 7 – LOW – Travel Card Usage Authorization:** CPRIT Executive Assistants utilize CPRIT's central billed Travel Card, which is assigned to the Accountant, to book travel arrangements, as CPRIT's internal procedures require the Executive Assistants to book travel. Currently, there are three employees with access to the agency's travel card information, including two Executive Assistants and the Special Assistant to the Chief Executive Officer.

**Results: Finding remediated**

We reviewed the updated version of the CPRIT Procurement Plan and Contract Management Handbook and verified that policies within the Travel Card section conform to the current practices performed by the agency. The Handbook identifies the Accountant as the agency's Travel Coordinator responsible for ensuring that all transactions charged to the Travel Card are for appropriate and approved travel on a travel requisition form signed by the COO or CEO. In addition, the Travel Coordinator supervises the use of travel charge card by the administrative staff when they book airfare and lodging for CPRIT staff. The Travel Coordinator is responsible for reconciling the receipts and folios to the monthly travel charge card statement.

Based on our interview with the Accountant and review of Travel Card reconciliation documentation, a reconciliation is performed monthly prior to issuing a voucher for payment of the travel charge card. The Accountant agrees the receipts and other supporting documentation to each line item on the Citibank Statement and highlights the amounts to evidence the review.

**Finding 8 – MODERATE – Travel Requisition Approval:** CPRIT does not have procedures in place to consistently document the enforcement of requirements to obtain appropriate authorization and budget verification on travel requisitions prior to using the Travel Card for travel expenditures.

Of the 30 Travel Card transactions tested, we identified 9 exceptions:

- 3 transactions did not have the appropriate approval by the COO or CEO
- 4 transactions did not have the appropriate budget certification
- 2 transactions did not have the appropriate approval by the COO or CEO, or the budget certification.

**Results: Finding remediated**

**Cancer Prevention and Research Institute of Texas**  
IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards  
April 30, 2018  
Issued: May 25, 2018

We reviewed the updated version of the CPRIT Procurement Plan and Contract Management Handbook and verified that the Travel Coordinator is responsible for ensuring that all airline, hotel, and other travel payments for employees charged to the travel charge card are approved on a travel requisition form by the Chief Operating Officer or the Chief Executive Officer.

We selected a sample of 25 out of 37 travel card transactions for the period of September 1, 2017, through March 31, 2018 and verified that corresponding requisitions were adequately reviewed and approved in CAPPs.

**Finding 9 – MODERATE – Timeliness of P-Card and Travel Card Reconciliations:** CPRIT does not have procedures in place to ensure that P-Card and Travel Card reconciliations are performed timely. P-Card and Travel Card reconciliations are performed prior to submitting the transactions for payment. The monthly statements must be reconciled and submitted within 30 days to meet the payment requirement of the Texas Prompt Payment Act.

Of the 6 monthly P-Card reconciliations tested, 1 was not completed and reviewed in a timely manner. The reconciliation was completed and reviewed 45 days after receipt of the statement resulting in a delayed payment of the P-Card.

Of the 6 monthly Travel Card reconciliations tested, 4 were not completed and reviewed in a timely manner. Reconciliations were completed between 34 and 70 days after receipt of the statement resulting in a delayed payment of the Travel Card.

**Results: Finding partially remediated**

We reviewed the updated version of the CPRIT Procurement Plan and Contract Handbook and determined that the Purchaser must reconcile the procurement card transactions on every payment card statement against the approved Purchase Requisitions and initiate an internal Purchase Order in CAPPs to pay the previously approved purchases on each monthly payment card statement. The Accountant is responsible for reconciling Travel Card Statements.

We reviewed the March P-Card statement reconciliation and related supporting documentation and verified that P-Card statement was reconciled timely with adequate supporting documentation.

We reviewed the 4 Travel Card statement reconciliations for the period of December 2017 through March 2018 and determined that 3 of the 4 reconciliations were not completed timely, within 30 days from the receipt of the statement. Reconciliations were completed 48, 59, and 66 days after receipt of the statement.

**Cancer Prevention and Research Institute of Texas**  
IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards  
April 30, 2018  
Issued: May 25, 2018

**Updated Management Response:** CPRIT management agrees that the reconciliation of the P-Card and Travel Card should occur within the 30-day prompt payment period. While the CAPPs system has automated the payment process of purchases and travel expenses, it has not improved the efficiency of reconciling travel receipts against the Travel Card statements because this must still be done manually with documents collected from travelers, hotels, or other systems since the transaction is not recorded in CAPPs. Furthermore, since CPRIT's CAPPs financials access started on September 1, 2017, both the Accountant and Purchaser have sought assistance from the CAPPs support team to complete transactions because there is no user guide for CAPPs. The Accountant is revising procedures to ensure that Travel Card statements are reconciled within the 30-day timeframe.

**Responsible Party:** Chief Operating Officer, Accountant  
**Date:** August 31, 2018

# Appendix

**Cancer Prevention and Research Institute of Texas**  
IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards  
April 30, 2018  
Issued: May 25, 2018

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.

**Cancer Prevention and Research Institute of Texas**  
IA # 05-18 Internal Audit Follow-Up Procedures Report  
over Procurement and P-Cards  
April 30, 2018  
Issued: May 25, 2018

## 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 # 06 -18 Internal Audit Follow-Up Procedures

Report over Pre-Award Grant Management

Report Date: April 24, 2018

Issued: May 10, 2018

# CONTENTS

	Page
Internal Audit Report Transmittal Letter to the Oversight Committee.....	1
Background .....	2
Follow-Up Procedures Objective and Scope .....	2
Executive Summary .....	2
Conclusion .....	3
Detailed Procedures Performed, Findings, Recommendations and Management Response .....	4
Appendix .....	7



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 (CPRIT) during the period April 10, 2018, through April 24, 2018 relating to the findings from the 2017 Internal Audit Report over Pre-Award Grant Management, dated April 19, 2017.

The objective of these follow-up procedures was to validate that adequate corrective action has been taken in order to remediate the issue identified in the 2017 Internal Audit Report over Pre-Award Grant Management.

To accomplish this objective, we conducted interviews with key personnel responsible for Pre-Award 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 April 24, 2018.

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  
April 24, 2018

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

IA # 06 -18 Internal Audit Follow-Up Procedures Report over

Pre-Award Grant Management

Report Date: April 24, 2018

Issued: May 10, 2018

## **Background**

In 2017, internal audit procedures over CPRIT's Pre-Award Grant Management process were completed and reported to the Oversight Committee. The internal audit report over CPRIT's Pre-Award Grant Management procedures and activities identified three areas for improvement related to reviewing availability of grant funds for accuracy, ensuring Post Review Statements are completed by Scientific Research and Prevention Programs Committee (SRPPC) panel chairs to disclose conflicts of interest, and reviewing user access for the CSRA SharePoint site.

The 2018 Internal Audit Plan included performing procedures to validate that CPRIT management has taken steps to address the internal audit finding.

## **Follow-Up Procedures Objective and Scope**

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the finding included in the 2017 Internal Audit Report over Pre-Award Grant Management, and to validate that appropriate corrective action had been taken. The 2017 report identified the following findings:

- The responsibility to review the updated Available Grant Funds Monitoring spreadsheet is not assigned to a specific individual within CPRIT.
- For two out of 40 applications tested, we were unable to verify that the panel chair completed the Post-Review Statement at the completion of the SRPPC panel meeting.
- Two CPRIT employees and one CSRA employee had active user IDs in the CSRA SharePoint portal after they separated employment from their respective organization.

Our follow-up procedures included the following:

- Verification that the available grant fund spreadsheets are reviewed for completeness and accuracy.
- Verification that each SRPPC panel chair discloses conflicts of interest by completing a Post Review Statement after meeting with their panel.
- Verification that the user access permissions to the CSRA SharePoint are appropriately restricted based on job titles and responsibilities.

## **Executive Summary**

The findings from the 2017 Internal Audit Report over Pre-Award Grant Management include non-compliance issues with 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 risks to CPRIT. These issues could have financial or operational implications.

We evaluated the corrective action of all three internal audit findings identified in the 2017 Internal Audit Report over Pre-Award Grant Management.

# Cancer Prevention and Research Institute of Texas

## IA # 06 -18 Internal Audit Follow-Up Procedures Report over Pre-Award Grant Management

Report Date: April 24, 2018

Issued: May 10, 2018

Procedures included interviews, reviews of documentation, observations and testing to determine if remediation efforts were completed. We determined that all three findings were fully remediated.

Risk Rating	Finding	Remediated	Open
High	1	1	-
Moderate	2	2	-
Low	-	-	-
Total	<b>3</b>	<b>3</b>	-

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.

<b>FOLLOW-UP ASSESSMENT</b>	<b>STRONG</b>
-----------------------------	---------------

SCOPE AREA	RESULT	RATING
<b>Objective:</b> Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2017 Internal Audit Report over Pre-Award Grant Management.	We identified that procedures implemented by management adequately addressed and remediated the prior open finding.	<b>STRONG</b>

### Conclusion

Based on our evaluation, CPRIT management has made satisfactory effort to remediate the finding from the 2017 internal audit report. We recommend continued diligence in maintaining internal controls over internal agency compliance processes.

**Detailed Procedures Performed, Findings,  
Recommendations and Management  
Response**

# Cancer Prevention and Research Institute of Texas

IA # 06 -18 Internal Audit Follow-Up Procedures Report over

Pre-Award Grant Management

Report Date: April 24, 2018

Issued: May 10, 2018

## 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.

### Objective: Validate Remediation

Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2017 Internal Audit Report over Pre-Award Grant Management.

#### Finding 1 – HIGH – Available Grant Funds Monitoring

The responsibility to review the updated Available Grant Funds Monitoring spreadsheet is not assigned to a specific individual within CPRIT. The spreadsheet is updated by the Chief Operating Officer prior to each Oversight Committee meeting and is emailed to the officers and managers of each program for review. However, there is not a specifically designated employee within the agency who has the responsibility to perform a detailed review of the grant awards against the award slates or a review of the award declines against supporting documentation for each update.

We identified that the FY 2016 Available Grant Funds Monitoring spreadsheet was incomplete due to the omission of \$13,050,420 in grant awards from the Announced Grant Awards in the spreadsheet and an omitted correction totaling \$19,427. The total error resulted in an understatement of grant awards of \$13,069,847.

**Procedures Performed:** We verified that available grants funds were monitored by management and were secondarily reviewed by the Operations Manager after each update. We selected a sample of four grant funding spreadsheets and determined that all were accurate and appropriately reviewed.

**Results:** Finding remediated.

#### Finding 2 – MODERATE – Missing Post-Review Statement

For two out of 40 applications tested, we were unable to verify that the panel chair completed the Post-Review Statement at the completion of the SRPPC panel meeting. Both of these applications were reviewed at the 16.2 Clinical & Translational Cancer Research and Translational Cancer Research SRPPC panel meeting on March 9, 2016, through March 10, 2016. The 40 applications tested were associated with 21 review panels composed of 340 SRPPC members. The Clinical & Translational Cancer Research and Translational Cancer Research Panel contained 32 SRPPC members, for whom 31 Post Review Statements were provided. However, CPRIT was unable to provide the Post-Review Statement for the panel chair.

# Cancer Prevention and Research Institute of Texas

IA # 06 -18 Internal Audit Follow-Up Procedures Report over

Pre-Award Grant Management

Report Date: April 24, 2018

Issued: May 10, 2018

**Procedures Performed:** We verified that each Panel Chair Member discloses conflicts of interest by signing a Post-Statement Conflict of Interest after each Panel meeting.

We selected a sample of eight out of 18 Panel meetings that were held during the period from September 1, 2017 to March 31, 2018. We verified that all Panel Chairs submitted a Post-Review Conflict of Interest after each Panel meeting.

**Results:** Finding remediated.

### **Finding 3 – MODERATE – Separated Employee User Access**

We identified that two CPRIT employees and one CSRA employee had active user IDs in the CSRA SharePoint portal after they separated employment from their respective organization. The CPRIT employees' user IDs were deactivated prior to April 2017. Their access was removed 909 days and 302 days after their separation date. However, the CSRA employee still has an active user ID on the SharePoint site. Passwords for the user accounts are automatically reset every six months due to a CSRA configuration for the SharePoint site. Further, in order for any CPRIT employee to access CPRIT data, the employee must have access to CPRIT email in order to reset the password.

**Procedures Performed:** We verified that the user access to the CSRA SharePoint is appropriately restricted based on job titles and responsibilities.

We reviewed all 48 active users and six terminated users and determined that the user IDs had appropriate access based on the employees' job title and responsibilities. In addition, we ensured that access for terminated employees was deactivated in a timely manner.

**Results:** Finding remediated.

# Appendix

# Cancer Prevention and Research Institute of Texas

IA # 06 -18 Internal Audit Follow-Up Procedures Report over

Pre-Award Grant Management

Report Date: April 24, 2018

Issued: May 10, 2018

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.

# Cancer Prevention and Research Institute of Texas

IA # 06 -18 Internal Audit Follow-Up Procedures Report over

Pre-Award Grant Management

Report Date: April 24, 2018

Issued: May 10, 2018

## 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 and Research Institute of Texas**

Fiscal Year 2018 Annual Internal Audit Report

August 31, 2018

# **C O N T E N T S**

	Page
I. COMPLIANCE WITH TEXAS GOVERNMENT CODE 2102.015.....	1
II. INTERNAL AUDIT PLAN FOR FISCAL YEAR 2018.....	1
III. CONSULTING SERVICES AND NONAUDIT SERVICES COMPLETED.....	2
IV. EXTERNAL QUALITY ASSURANCE REVIEW.....	5
V. INTERNAL AUDIT PLAN FOR FISCAL YEAR 2019.....	6
VI. EXTERNAL AUDIT SERVICES PROCURED IN FISCAL YEAR 2017.....	7
VII. REPORTING SUSPECTED FRAUD AND ABUSE.....	7

**Cancer Prevention and Research Institute of Texas**  
Fiscal Year 2018 Annual Internal Audit Report  
Issued: August 31, 2018

**I. Compliance with Texas Government Code, Section 2102.015: Posting the Internal Audit Plan, Internal Audit Annual Report, and Other Audit information on Internet Web site**

Texas Government Code, Section 2102.015 requires state agencies and higher education institutions, as defined in the statute, to post their Internal Audit Plan, Internal Audit Annual Report, and other audit information on the Internet.

The Cancer Prevention and Research Institute of Texas (CPRIT or the agency) will post this report and its Fiscal Year 2019 Internal Audit Plan on its website at [www.cprit.state.tx.us](http://www.cprit.state.tx.us) by August 31, 2018. CPRIT's Oversight Committee reviewed and approved the Annual Internal Audit Report as part of their regular meeting held on August 24, 2018.

CPRIT will update its posting with a detailed summary of the weaknesses, deficiencies, wrongdoings or other concerns raised by performance of the audit plan as they are identified or by November 1, 2018. CPRIT will also update the posting with the corrective action taken to address any issues identified.

**II. Internal Audit Plan for Fiscal Year 2018**

The internal audits planned and performed for fiscal year 2018 were selected to address the agency's highest risk areas, based on the risk assessment process conducted during the fall of 2013, which included input from CPRIT management. The audits conducted during fiscal year 2018 are listed below.

Internal Audit	Report #	Report Date	Current Status
Post Award Grant Contracting and Monitoring	IA #01-18	December 20, 2017	The report was issued February 1, 2018.  Follow-up procedures to verify that corrective action has been performed are included in the proposed 2019 Internal Audit Plan.
Communications	IA #04-18	April 30, 2018	The report was issued May 25, 2018.  Follow-up procedures to verify that corrective action has been performed are included in the proposed 2019 Internal Audit Plan.
State Reporting	N/A	N/A	The Internal Audit was postponed to FY 2019.
Information Technology General Computer Controls	N/A	N/A	The Internal Audit was postponed to FY 2019 to allow Internal Audit to perform additional follow-up procedures over open Information Security findings.

**Cancer Prevention and Research Institute of Texas**  
 Fiscal Year 2018 Annual Internal Audit Report  
 Issued: August 31, 2018

Internal Audit	Report #	Report Date	Current Status
Internal Audit Follow-Up over Internal Agency Compliance	IA #02-18	January 19, 2018	The report was issued February 2, 2018. All prior findings were remediated.
Internal Audit Follow-Up over Training	IA #03-18	January 19, 2018	The report was issued February 2, 2018. All prior findings were remediated.
Internal Audit Follow-Up over Pre-Award Grant Management	IA #06-18	April 24, 2018	The report was issued May 10, 2018. All prior findings were remediated or closed.
Internal Audit Follow-Up over Procurement and P-Cards	IA #05-18	April 30, 2018	The report was issued May 25, 2018. Follow-up procedures to verify that corrective action has been performed on the remaining open findings are included in the proposed 2019 Internal Audit Plan.
Internal Audit Follow-Up over IT Security	IA-07-18	July 17, 2018	The report was issued on July 30, 2018. Follow-up procedures to verify that corrective action has been performed on the remaining open findings are included in the proposed 2019 Internal Audit Plan.

**III. Consulting Services and Nonaudit Services Completed**

As defined in the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing and the Government Auditing Standards, 2011 Revision, Sections 3.33 – 3.58, CPRIT completed the following consulting and non-audit services for FY 2018:

Consulting and nonaudit services were provided by Business and Financial Management Solutions, LLC (BFMS). CPRIT engaged BFMS as the third party to observe each in-person and telephone conference Peer Review Panel meeting and ensure compliance with conflict of interest and staff participation requirements.

## Cancer Prevention and Research Institute of Texas Fiscal Year 2018 Annual Internal Audit Report Issued: August 31, 2018

BFMS issued the following reports during fiscal year 2018:

### FY2018 Third Party Observer Reports

Review Panel	Report Date	Report Number	Status
<b>Academic Research</b>			
SRC recruitment meeting 18.1-.2	September 14, 2017	2017-09-14_REC_18.1-2	Complete
18.1 Cancer Biology Panel	October 16, 2017	2017-10-16_CB_18.1	Complete
18.1 Basic Cancer Research Panel 2	October 18, 2017	2017-10-18_BCR_18.1 Panel 2	Complete
18.1 Clinical/Translational Cancer Research Panel	October 19, 2017	2017-10-19_C/TCR_18.1	Complete
18.1 Basic Cancer Research Panel 1	October 20, 2017	2017-10-20_BCR_18.1 Panel 1	Complete
18.1 IT & Informatics	October 23, 2017	2017-10-23_ITI_18.1	Complete
18.1 Cancer Prevention Research	October 24, 2017	2017-10-24_CPR_18.1	Complete
SRC recruitment meeting 18.3-4	November 16, 2017	2017-11-16_REC_18.3.4	Complete
SRC 18.1	November 16, 2017	2017-11-16_SRC_18.1	Complete
SRC recruits 18.5	December 14, 2017	2017-12-14_REC_18.5	Complete
SRC 18.1	December 14, 2017	2017-12-14_SRC_18.1	Complete
SRC Recruits 18.6-.7	February 15, 2018	2018-02-15_REC_18.6-7	Complete
SRC Recruits 18.8	March 15, 2018	2018-03-15_REC_18.8	Complete
SRC recruits 18.9	April 24, 2018	2018-04-19_REC_18.9	Complete
SRC recruits 18.10	June 5, 2018	2018-05-17_ACR_REC_18.10	Complete
18.2 Cancer Prevention Research	June 5, 2018	2018-05-18_ACR_CPR_18.2	Complete
18.2 Basic Cancer Research-1	June 5, 2018	2018_05_21_ACR_BCR_18.2 Panel 1	Complete
18.2 Clinical/Translational Cancer Research Panel	June 5, 2018	2018-05-22_ACR_C/TCR_18.2	Complete
18.2 Basic Cancer Research -2	June 5, 2018	2018_05_21_ACR_BCR_18.2 Panel 2	Complete
18.2 IT & Informatics	June 5, 2018	2018-05-24_ACR_ITI_18.2	Complete
18.2 Cancer Biology	June 5, 2018	2018-05-25_ACR_CB_18.2	Complete
SRC recruits 18.11	June 21, 2018	2018-06-21_REC_18.11	Complete
18.2 SRC	July 17, 2018	2018-07-12_SRC_18.2	Complete
SRC Recruits 18.12	July 17, 2018	2018-07-12_REC_18.12	Complete
<b>Prevention</b>			
PRC 18.1 DI	October 24, 2017	2017-10-24_PREV_DI_18.1	Complete
18.1 Panel 1	December 12, 2017	2017-12-11- PREV	Complete
18.1 Panel 2	December 14, 2017	2017-12-13- PREV	Complete
PRC 18.1 (and DI 18.2)	January 18, 2018	2018-01-18_PRC_18.1	Complete
PRC DI 18.3	April 4, 2018	2018-04-03 Dissemination Interventions (18.3_PRV_DI)	Complete
18.2 Panel 1	June 5, 2018	2018-5-22 PRV_18.2_PP-1	Complete
18.2 Panel 2	June 5, 2018	2018-5-24 PRV_18.2_PP-2	Complete
18.2 PRC	July 9, 2018	2018-07-06_PRC_18.2	Complete

**Cancer Prevention and Research Institute of Texas**  
 Fiscal Year 2018 Annual Internal Audit Report  
 Issued: August 31, 2018

<b>Product Development</b>			
18.1 Panel 1 teleconference	September 25, 2017	2017-09-26_PDP_18.2	Complete
18.1 Panel 2 teleconference	September 26, 2017	2017-09-26_PDP_18.1-2	Complete
18.1 In person	October 25, 2017	2017-10-25_PDP_18.1-2	Complete
18.1 Due Diligence/PDRC	January 16, 2018	2018-01-16_PDR_18.1	Complete
18.2 Panel 1 Teleconference	March 27, 2018	2018-03-26_PDP_18.2 Panel 1	Complete
18.2 Panel 2 Teleconference	March 27, 2018	2018-03-26_PDP_18.2 Panel 2	Complete
18.2 Panel 1 Onsite	April 24, 2018	2018-04-23_PDP_18.2 Panel 1 Onsite	Complete
18.2 Panel 2 Onsite	April 27, 2018	2018-04-25_PDP_18.2 Panel 2 Onsite	Complete
18.2 Due Diligence/PDRC	July 17, 2018	2018-07-11-DD_PDR_18.2	Complete

**Cancer Prevention and Research Institute of Texas**  
Fiscal Year 2018 Annual Internal Audit Report  
Issued: August 31, 2018

**IV. External Quality Assurance Review**

In accordance with professional standards, and to meet the requirements of the Texas Internal Auditing Act, Internal Audit is required to undergo an external quality assurance review at least once every three years. Weaver's review was performed in October 2016.



**System Review Report**

To the Partners of Weaver and Tidwell, L.L.P.  
and the National Peer Review Committee

We have reviewed the system of quality control for the accounting and auditing practice of Weaver and Tidwell, L.L.P. (the "firm") applicable to engagements not subject to PCAOB permanent inspection in effect for the year ended May 31, 2016. Our peer review was conducted in accordance with the Standards for Performing and Reporting on Peer Reviews established by the Peer Review Board of the American Institute of Certified Public Accountants. As a part of our peer review, we considered reviews by regulatory entities, if applicable, in determining the nature and extent of our procedures. The firm is responsible for designing a system of quality control and complying with it to provide the firm with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Our responsibility is to express an opinion on the design of the system of quality control and the firm's compliance therewith based on our review. The nature, objectives, scope, limitations of, and the procedures performed in a System Review are described in the standards at [www.aicpa.org/prsummary](http://www.aicpa.org/prsummary).

As required by the standards, engagements selected for review included engagements performed under *Government Auditing Standards*, audits of employee benefit plans, audits performed under FDICIA, and examinations of service organizations [Service Organizations Control (SOC) 1 and 2 engagements].

In our opinion, the system of quality control for the accounting and auditing practice of Weaver and Tidwell, L.L.P. applicable to engagements not subject to PCAOB permanent inspection in effect for the year ended May 31, 2016, has been suitably designed and complied with to provide the firm with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Firms can receive a rating of *pass*, *pass with deficiency(ies)* or *fail*. Weaver and Tidwell, L.L.P. has received a peer review rating of *pass*.



Eide Bailly LLP  
October 7, 2016

[www.eidebailly.com](http://www.eidebailly.com)

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**Cancer Prevention and Research Institute of Texas**  
Fiscal Year 2018 Annual Internal Audit Report  
Issued: August 31, 2018

**V. Internal Audit Plan**

The Internal Audit Plan was submitted to the Audit Subcommittee of the CPRIT Oversight Committee. The Audit Subcommittee approved the plan on August 6, 2018, and the Oversight Committee subsequently approved the plan on August 24, 2018. Below is the Fiscal Year 2019 Internal Audit Plan submitted to the agency's Oversight Committee based on the results of the 2018 Internal Audit Risk Assessment Update. The approved internal audit plan was submitted to the State Auditor's Office prior to November 1, 2018.

<b>Fiscal Year 2019 Internal Audit Plan</b>		
<b>Audit Area</b>	<b>2018 Risk Rating</b>	<b>Estimated Hours</b>
State Reporting Requirements	<b>Moderate</b>	310 - 340
Budgeting and Planning	<b>Moderate</b>	270 - 300

Planned follow-up procedures for fiscal year 2018 to verify and communicate with Management the remediation efforts of prior Internal Audit Recommendations.

<b>Fiscal Year 2019 Follow-up Procedures</b>		
<b>Audit Area</b>	<b>2018 Risk Rating</b>	<b>Estimated Hours</b>
Communications	<b>Moderate</b>	90 - 115
Post-Award Grant Monitoring	<b>High</b>	50 - 65
Procurement and P-Cards	<b>High</b>	
Information Security	<b>High</b>	
SAO Report on Performance Measures	<b>N/A</b>	100 - 120

As part of the risk assessment, CPRIT assesses the probability and impact of the following risk categories across all significant activities of the agency, which include the significant information technology processes of information security, information technology general computer controls and application development and management:

- financial and fraud risk
- operations, complexity, and human capital risk
- information technology risk
- regulatory compliance and public policy risk, and
- reputational risk

Taking into consideration the input from the CPRIT management, all significant activities are assigned a risk score for probability and impact related to each risk category. The overall risk rating (High, Medium or Low) is assigned to each significant activity based on the activity's average risk score.

The internal audit plan is developed by considering risk ratings for each significant activity and prioritizing "High" risk activities. The risk assessment is updated on an annual basis.

**Cancer Prevention and Research Institute of Texas**  
Fiscal Year 2018 Annual Internal Audit Report  
Issued: August 31, 2018

The 2018 Internal Audit Risk Assessment Update resulted in 10 Significant Activities rated as "High" risk. Seven of the 10 Significant Activities are not included in the Fiscal Year 2019 Internal Audit Plan. Those risks are as follows:

1. **Pre-Award Grant Management** – Pre-Award Grant Management was not included in the 2019 Internal Audit Plan. Pre-Award Grants Management was included in the 2017 Internal Audit Plan, and was included in 2018 Follow-Up Procedures with all findings remediated.
2. **Commodity and Service Contracts** – Commodity and Service Contracts was not included in the 2019 Internal Audit Plan. Commodity and Service Contracts was included in the 2016 Internal Audit Plan, and was included in 2017 Follow-Up Procedures with all findings remediated.
3. **Disaster Recovery and Business Continuity Planning** – Disaster Recovery and Business Continuity Planning was not included in the 2019 Internal Audit Plan.
4. **Internal Agency Compliance** – Internal Agency Compliance was not included in the 2019 Internal Audit Plan. Internal Agency Compliance was included in the 2017 Internal Audit Plan and was included in the 2018 Follow-Up Procedures with all findings remediated.
5. **Information Technology General Computer Controls** – Information Technology General Computer Controls was not included in the 2019 Internal Audit Plan.
6. **Governance** – Governance was not included in the 2019 Internal Audit Plan. Governance was included in the 2014 Internal Audit Plan, and was included in the 2015 Follow-up Procedures with all findings remediated.
7. **Records Management** – Records Management was not included in the 2019 Internal Audit Plan.

#### VI. External Audit Services Procured in FY 2018

CPRIT engaged McConnell & Jones, LLP, a certified public accounting and consulting firm, as their external auditors for FY 2018. McConnell & Jones, LLP is registered with the Public Company Auditor Oversight Board (PCAOB).

#### VII. Reporting Suspected Fraud, Waste and Abuse

- CPRIT contracts with Red Flag Reporting to provide a confidential hotline for reporting fraud, waste and abuse. The agency has posted a link on its home page at [www.cprit.state.tx.us](http://www.cprit.state.tx.us) and also has a dedicated page to fraud prevention and reporting on its website at <http://www.cprit.state.tx.us/about-cprit/fraud-prevention/>.
- The CPRIT Chief Compliance Officer is the designated staff member within the agency to receive written or verbal allegations of suspected fraud, waste, and abuse. The Chief Compliance Officer has the authority to examine and investigate those allegations and turn over information of verified instances of fraud, waste, or abuse to the State Auditor's Office.





CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

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**MEMORANDUM**

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**To: OVERSIGHT COMMITTEE MEMBERS**  
**From: KRISTEN PAULING DOYLE, GENERAL COUNSEL**  
**CAMERON L. ECKEL, STAFF ATTORNEY**  
**Subject: CHAPTERS 701 AND 703 RULE CHANGES PROPOSED FOR FINAL ADOPTION**  
**Date: AUGUST 6, 2018**

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**Summary and Recommendation**

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule changes to Chapters 701 and 703 as originally considered at the May meeting. Once the Oversight Committee approves the final order adopting the rule changes, CPRIT will submit the amendments to the Secretary of State and the changes will be effective 20 days later.

**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 approved publication of proposed rule amendments at the May meeting. CPRIT published the proposed rules in the *Texas Register* and made the rules available on the agency's website. CPRIT received no comments regarding the proposed changes.

The Board Governance Subcommittee met on August 2nd to review the final order with CPRIT's General Counsel. The Subcommittee recommends the Oversight Committee approve the final order adopting the proposed rule changes.

**Next Steps**

After the Oversight Committee adopts the proposed rule changes, CPRIT will submit the final order to the Secretary of State. The rule changes become effective 20 days after the date CPRIT files the order with the Secretary of State.



TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 701. Policies and Procedures

The Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) adopts the amendments to §§ 701.3(58) and 701.27 without changes. The proposed amendments clarify the definition of “Request for Applications” and remove the requirement that CPRIT post the political contributions of Oversight Committee members on the Institute’s website. CPRIT published the proposed amendments in the June 1, 2018, issue of the *Texas Register* (43 TexReg 3573).

**Reasoned Justification**

The proposed amendment to § 701.3(58) clarifies that the defined term, “Request for Applications,” includes any associated instructions. The proposed amendment to § 701.27 makes the administrative rule consistent with a change to CPRIT’s statute made by the 2017 Texas Legislature regular session. The Legislature amended Texas Health & Safety Code Chapter 102 to remove the requirement that Oversight Committee members report political contributions over \$1,000 to CPRIT and that CPRIT posts the political contribution information on its website. Consistent with those changes, the amendment to § 701.27 deletes subsection (4), removing the report of Oversight Committee members’ political contributions from the list of items the Institute posts on its website.

**Summary of Public Comments and Staff Recommendation**

CPRIT received no public comments regarding the proposed amendments to §§ 701.3(58) and 701.27.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

**Certification**

The Institute hereby certifies that Kristen Pauling Doyle, Deputy Executive Officer and General Counsel, reviewed the adoption of the rules and found it to be a valid exercise of the agency’s legal authority.

To be filed with the Office of Secretary of State on August 17, 2018.

**§ 701.3**

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, biologics, 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;

(B) a husband and wife are related to each other in the first degree of affinity. For other relationship by affinity, the degree of relationship is the same as the degree of the underlying relationship by consanguinity;

(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. The Request for Applications

includes any associated written instructions provided by the Institute and available to all Grant Applicants.

(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.

### **§ 701.27**

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) The annual Grant Program priorities set by the Oversight Committee;
- (5) Oversight Committee Bylaws;
- (6) Code of Conduct and Ethics;
- (7) 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;
- (8) The Institute's honoraria policy for Scientific Research and Prevention Programs Committee Members;
- (9) 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;
- (10) 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;

(11) 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;

(12) 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;

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

(14) Except as excluded by 702.7(f) of this Title, 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;

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

(16) 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;

(17) 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;

(18) Information regarding staff compensation in compliance with §659.026, Texas Government Code.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) adopts the proposed amendment to § 703.11 without changes. The amendment changes the timeframe when a grant recipient may use a new federal indirect cost rate from “less than six months” to “six months or less.” CPRIT published the proposed amendment in the June 1, 2018, issue of the *Texas Register* (43 TexReg 3578).

**Reasoned Justification**

The proposed amendment to § 703.11(b)(4) revises the starting date when a grant recipient may use a new federal indirect cost rate (FICR) to calculate the matching funds requirement. A grant recipient that is a public or private institution, as defined by § 61.003, Texas Education Code, may use their FICR as a credit when calculating the grant recipient’s matching funds requirement. Currently, if the FICR changes less than six months following the anniversary date of the effective date of the grant contract, the grant recipient may use the new rate. The proposed amendment changes the time to “six months or less” for a grant recipient to use a new FICR. This change clarifies the timeframe calculation and gives grant recipients more time to use an updated FICR.

**Summary of Public Comments and Staff Recommendation**

CPRIT received no public comments regarding the proposed amendment to § 703.11.

The rule change is adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

**Certification**

The Institute hereby certifies that Kristen Pauling Doyle, General Counsel, reviewed the adoption of the rules and found it to be a valid exercise of the agency’s legal authority.

To be filed with the Office of Secretary of State on August 17, 2018.

**§ 703.11**

(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 at least 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.

(1) The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract.

(2) 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.

(3) A Grant Recipient receiving multiple Grant Awards may provide certification at the institutional level.

(4) Nothing herein restricts the Institute from requiring the Grant Recipient to demonstrate an amount of Encumbered Funds greater than 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. To the extent that a greater Matching Funds amount will be required, the Institute shall include the requirement in the Request for Applications and in the Grant Contract.

(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 six months or less 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 Project Year basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year 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 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 703.12. Limitation on Use of Funds.



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

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**MEMORANDUM**

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**To: OVERSIGHT COMMITTEE MEMBERS**  
**From: KRISTEN PAULING DOYLE, GENERAL COUNSEL**  
**CAMERON L. ECKEL, STAFF ATTORNEY**  
**Subject: CHAPTER 703 PROPOSED RULE CHANGES**  
**Date: AUGUST 6, 2018**

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**Summary and Recommendation**

The Board Governance Subcommittee recommends that the Oversight Committee approve the proposed administrative rule changes for publication in the *Texas Register* for public comment. The proposed changes affect Texas Administrative Code Chapter 703.

**Discussion**

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes as well as administering other requirements of Texas Health and Safety Code Chapter 102. State law requires agencies to use a rulemaking process, which includes an opportunity for the public to comment on proposed rules and rule changes before the agency adopts the final policy.

The Board Governance subcommittee met on August 2nd to discuss the proposed rule changes Chapter 703 with legal staff. The proposed amendments allow required grant filings to be submitted the next business day following a due date that falls on a weekend or federal holiday as designated by the U.S. Office of Personnel Management. The subcommittee voted to recommend approval and publication of the proposed rule changes to the Oversight Committee.

**Next Steps**

CPRIT will publish the proposed rule changes in the *Texas Register*. The publication date begins the 30-day period soliciting public comment. CPRIT will post the proposed rule on CPRIT's website and announce the opportunity for public comment via the CPRIT electronic list serve. CPRIT legal staff will summarize all public comments for the Oversight Committee's consideration when approving the final rule changes in November.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas (CPRIT or the Institute) proposes amendments to 25 Tex. Admin. Code §§ 703.11, 703.13, 703.14, 703.21, and 703.24. The proposed amendments allow a required filing to be submitted on the next business day if the due date falls on a Saturday, Sunday, or federal holiday.

**Background and Justification**

The proposed amendments to §§ 703.11, 703.13, 703.14, 703.21, and 703.24 allow required grant filings to be submitted the next business day following a due date that falls on a weekend or federal holiday as designated by the U.S. Office of Personnel Management. For example, if the due date of a Financial Status Report (FSR) falls on a Saturday, the grant recipient may submit the FSR on the first business day following the due date without the Institute considering the report delinquent. Moving the due date to a business day is consistent with the practice of most state and federal agencies. Implementing this change assists CPRIT’s grant recipients and may reduce the occurrence of delinquent reports.

**Fiscal Note**

Kristen Pauling Doyle, Deputy Executive Officer and General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule change is in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rules.

**Public Benefit and Costs**

Ms. Doyle has determined that for each year of the first five years the rule change is in effect the public benefit anticipated due to enforcing the rule will be clarifying that filings required by CPRIT’s administrative rules may be submitted on the next business day if the due date falls on a weekend or federal holiday.

**Small Business, Micro-Business, and Rural Communities Impact Analysis**

Ms. Doyle has determined that the rule change will not affect small businesses, micro businesses or rural communities.

**Government Growth Impact Statement**

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the section will be in effect:

- (1) the proposed rule changes will not create or eliminate a government program;
- (2) implementation of the proposed rule changes will not affect the number of employee positions;

- (3) implementation of the proposed rule changes will not require an increase or decrease in future legislative appropriations;
- (4) the proposed rule changes will not affect fees paid to the agency;
- (5) the proposed rule changes will not create new rules;
- (6) the proposed rule changes will not expand existing rules;
- (7) the proposed rule changes will not change the number of individuals subject to the rules; and
- (8) The rule changes are unlikely to have a significant impact on the state's economy. Although these changes are likely to have neutral impact on the state's economy, the Institute lacks sufficient data to predict the impact with certainty.

Submit written comments on the proposed rule changes to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than [CPRIT will insert appropriate date prior to submitting to *Texas Register*]. The Institute asks parties filing comments to indicate whether they support the rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to [kdoyle@cprit.texas.gov](mailto:kdoyle@cprit.texas.gov). Comments may be submitted by facsimile transmission to 512/475-2563.

### **Statutory Authority**

The Institute proposes the rule changes under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle has reviewed the proposed amendments and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article, or code affected by these rules.

703.11

(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 at least 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.

(1) The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract.

(2) 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.

(3) A Grant Recipient receiving multiple Grant Awards may provide certification at the institutional level.

(4) Nothing herein restricts the Institute from requiring the Grant Recipient to demonstrate an amount of Encumbered Funds greater than 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. To the extent that a greater Matching Funds amount will be required, the Institute shall include the requirement in the Request for Applications and in the Grant Contract.

(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 Project Year basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year 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 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 703.12. Limitation on Use of Funds

(k) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

703.13

(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 date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(1) A Grant Recipient shall maintain its records pertaining to the specific Grant Contract for a period of three years following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(2) The Grant Recipient may maintain its records in either electronic or paper format.

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. The Grant Recipient shall report whether the Grant Recipient has expended \$750,000 or more in state awards during 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) The audited time period is the Grant Recipient's fiscal year.

(2) 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 2 CFR Part 200, Subpart F, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

(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.

(f) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

703.14

(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 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 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 consider the request. 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. The duration of 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) 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, 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. The Grant Recipient's failure to submit the Financial Status report within 30 days following the due date specified in 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 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 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.

(i) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

703.21

(a) The Institute, under the direction of the Chief Compliance 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 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 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.

(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) Unless specifically stated otherwise herein, 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, which shall be submitted pursuant to the timeline in §703.13.

(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 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.

(h) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

703.24

(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 Institute may request in writing that a Grant Recipient provide more information or correct a deficiency in the supporting documentation for a Financial Status Report. If a Grant Recipient does not submit the requested information within 21 days after the request is submitted, the Financial Status Report will be disapproved by the Institute.

(A) Nothing herein restricts the Institute from disapproving the FSR without asking for additional information or prior to the submission of additional information.

(B) Nothing herein extends the FSR due date.

(5) 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) A Grant Award with a Grant Contract effective date within the last quarter of a state fiscal year (June 1-August 31) will have an initial financial reporting period beginning September 1 of the following state fiscal year.

(1) A Grant Recipient that incurs Authorized Expenses after the Grant Contract effective date but before the beginning of the next state fiscal year may request reimbursement for those Authorized Expenses.

(2) The Authorized Expenses described in paragraph (1) of this subsection must be reported in the Financial Status Report reflecting Authorized Expenses for the initial financial reporting period beginning September 1.

(d) 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 Recipient 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 subparagraph (C) of this paragraph.

(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 subsection (b) of this section.

(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 subsection (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.

(e) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.





## CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

### CODE OF CONDUCT and ETHICS

#### I. OVERVIEW

##### A. Authority

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

##### B. General Principles

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

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

##### C. Definitions

In this Code:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **D. Enforcement**

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

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

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

## **II. STANDARDS OF CONDUCT**

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

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

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

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

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

(4) practice responsible stewardship of CPRIT resources; and

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

### **B. Prohibited Conduct**

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

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

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

(11) submit a grant application to CPRIT;

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

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

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

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

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

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

### **C. Special Provisions**

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

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

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

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

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

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

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

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

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

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

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

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

(c) For purposes of this subsection, the term "particular matter" means a specific investigation, application, request for a ruling or determination, rulemaking proceeding, contract, claim, accusation, charge, arrest, or judicial or other proceeding, except that the prohibition of this subsection does not apply to a rulemaking proceeding that was conducted before the Oversight Committee Member's or Employee's service or employment ceased.

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

#### **D. Nepotism**

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

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

#### **E. Outside Employment or Business Activity**

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

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

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

(4) The CEO shall report to the Oversight Committee annually all approved outside employment or business activities of Employees. The report shall be submitted to the Oversight Committee no later than September 30.

### III. CONFLICTS OF INTEREST

#### A. Decision-Making Based on Merit.

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

#### B. Conflict of Interest Requirements.

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

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

### IV. GIFTS AND ENTERTAINMENT

#### A. Prohibition Against Acceptance of Gifts or Consideration

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

#### B. Exceptions

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

(1) an item with a value less than \$50, excluding cash or a negotiable instrument as described by 3.104, Business & Commerce Code or a gift or other benefit conferred on account of kinship;

(2) gifts or consideration of any value provided to the Oversight Committee Member, PIC Member, or Employee by a personal friend or colleague, so long as:

(a) The gift or consideration is given based solely on an existing personal, professional, or business relationship independent of the Oversight Committee Member's, PIC Member's, or Employee's official status;

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

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

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

(4) a political contribution as defined by Title 15, Election Code;

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

(6) food, lodging, transportation, or entertainment accepted as a guest with the donor present, and, if the donor is required by law to report those items, reported by the donor in accordance with that law;

(7) Lodging, transportation, and meals described by Chapter 36, Section 36.07(b) (Acceptance of Honorariums), Penal Code;

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

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

### **C. Gifts or Consideration from Lobbyists**

An Oversight Committee Member, PIC Member, or Employee shall immediately report to the Chief Compliance Officer any gift or consideration if the gift or consideration is provided by a

registered lobbyist.

#### **D. Return of Prohibited Gifts or Consideration**

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

#### **E. Reporting Requirements**

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

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

### **V. FINANCIAL DISCLOSURE AND COMPLIANCE STATEMENTS**

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

#### **A. Financial Disclosure Statements.**

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

(2) CPRIT must maintain a financial disclosure statement for at least five years after the date it is filed.

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

## **B. Ethics Compliance Statements.**

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

## **C. Conflict of Interest Compliance Statements.**

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

## **D. Non-Disclosure Agreements**

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

## **E. Certification of No Financial Interest.**

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

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

(a) ownership of stock or shares of the business entity; or

(b) ownership of any sum of the fair market value of the business entity; or

(c) receipt of any sum of the person's gross income for the preceding calendar year from the business entity; or

(d) any private investment in the business entity, such as debt obligation or equity interest that is not a publicly traded security.

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

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

#### **F. Statement of No Communication.**

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

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

#### **~~G. Disclosure of Political Contributions Pursuant to Health & Safety Code § 102.101(f)~~**

~~Each Oversight Committee member shall submit the information required by Health & Safety Code 102.101(f) to the Chief Compliance Officer no later than January 31 of each year. After the initial disclosure is made, each subsequent disclosure by the Oversight Committee member shall update the information for the previous calendar year.~~



CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

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**MEMORANDUM**

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**To: OVERSIGHT COMMITTEE MEMBERS**  
**From: HEIDI MCCONNELL, CHIEF OPERATING OFFICER**  
**Subject: CHIEF OPERATING OFFICER REPORT**  
**Date: AUGUST 6, 2018**

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**CPRIT Financial Overview for FY 2018, Quarter 3**

**FY 2018, Quarter 3 Operating Budget**

CPRIT expended or obligated approximately \$2.6 million in Indirect Administration during the year and approximately \$13.3 million in Grant Review and Award Operations, which is about 75% of the overall administrative budget for the fiscal year. The agency's biggest expenses remain staff salaries and contracted services.

During the third quarter, the agency received \$24,463 in revenue sharing payments deposited into the Cancer Prevention and Research Interest and Sinking Fund 5168. Total revenue sharing payments received through the first three-quarters of the year were \$90,628.

**FY 2018, Quarter 3 Performance Measure Report**

CPRIT reported on its two key quarterly performance measures to the Legislative Budget Board. CPRIT exceeded performance on the number of people served by Institute-funded prevention and contract activities. It did not meet performance on the product development research measure for company relocations to Texas because no company grant recipients relocated to Texas during the third quarter of the year.

**Debt Issuance History**

CPRIT requested an additional debt issuance of \$55 million in general obligation commercial paper notes in July 2018 from TPFAs. This was the last debt issuance for the year and brought the total amount issued in FY 2018 to \$222.2 million in general obligation commercial paper notes for operating expenses and grant award obligations.

**Legislative Appropriations Request (LAR) for the 2020-21 Biennium**

I presented a draft 2020-21 LAR to the Audit Subcommittee during a specially scheduled subcommittee meeting on July 26, 2018, and the subcommittee confirmed that the draft 2020-21 LAR was consistent with the items discussed at the May 16, 2018, Oversight Committee meeting. These included two exceptional items, one for \$164 million in General Revenue and the other for one additional full-time equivalent for an information technology staff position. They also included requests to revise CPRIT riders including eliminating the \$2.9 million transfer to the Department of State Health Services for the Texas Cancer Registry and allowing CPRIT to transfer funds between budget line items (strategies) under the same authority that other agencies

have. The 2020-21 LAR was submitted electronically on August 3, 2018, to the Legislative Budget Board and Governor's Office of Budget and Policy.

### **FY 2019 Operating Budget**

In FY 2019, CPRIT has an adjusted budget of \$3,265,161 for Indirect Administration and \$13,454,591 for Grant Review and Award Operations. The adjustment is due to the transfer of \$234,591 from the Grant Review and Award Operations budget line item to the Indirect Administration budget line item under the transfer authority provided to the agency by the 2018-19 General Appropriations Act, Art. IX, Sec. 14.01. The transfer is necessary to cover additional expenses for daily information technology operations including ongoing information security activities.

In addition, CPRIT plans to send a request to the Legislative Budget Board to transfer \$547,031 from the Award Cancer Research Grants budget line item to the Indirect Administration budget line item to cover additional information security activities and to bring CPRIT's business continuity and disaster recovery plan into alignment with the FEMA requirements and test the plan. If the LBB approves this transfer, the operating budget supporting all information technology items will equal \$1,527,710. This IT budget level will continue into the future and is projected to be more than \$1.8 million in FY 2020 and more than \$1.6 million in FY 2021, with the variability in costs attributed to the timing of software subscription renewals and hardware extended support renewals being due.

I anticipate that additional adjustments to the two operating budget line items will occur because we will have to carry forward some unexpended balances from at least two FY 2018 service contracts to FY 2019 to complete unfinished work under those contracts. However, I do not have exact amounts of the unexpended balances yet as the final expenses for FY 2018 are being tallied.

*The goal for IT operations is to automate as many processes as possible, build redundancy among the IT support personnel, and ensure documentation of the IT infrastructure and processes is up to date.*

**Cancer Prevention and Research Institute of Texas**  
**Quarterly Financial Report**  
As of May 31, 2018

**Indirect Administration (B.1.1.)**

	2018 Appropriated	2018 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001 Salaries and Wages	\$ 1,617,425	\$ 1,439,500		\$ 924,252	515,248	64%	\$ 924,252	\$ 515,248
1002 Other Personnel Costs	52,785	46,780		26,072	20,708	56%	26,072	20,708
2001 Professional Fees and Services	826,175	1,079,259		972,540	106,719	90%	972,540	106,719
2003 Consumable Supplies	27,584	27,584		16,257	11,327	59%	16,257	11,327
2004 Utilities	58,577	58,577		36,808	21,769	63%	36,808	21,769
2005 Travel	45,000	45,000		38,486	6,514	86%	38,486	6,514
2006 Rent-Building	-	33,076		32,542	534	0%	32,542	534
2007 Rent-Machine and Other	32,172	32,172		20,290	11,882	63%	20,290	11,882
2009 Other Operating Expenses	370,934	527,641		531,076	(3,435)	101%	531,076	(3,435)
<b>Subtotal - Indirect Administration (B.1.1.)</b>	<b>\$ 3,030,652</b>	<b>\$ 3,289,589</b>	<b>1.10%</b>	<b>\$ 2,598,323</b>	<b>\$ 691,266</b>	<b>79%</b>	<b>\$ 2,598,323</b>	<b>\$ 691,266</b>

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

	2018 Appropriated	2018 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001 Salaries and Wages	\$ 2,991,208	2,931,385		\$ 2,463,808	\$ 467,577	84%	\$ 2,463,808	\$ 467,577
1002 Other Personnel Costs	3,856	22,097		42,805	(20,708)	0%	42,805	(20,708)
2001 Professional Fees and Services	10,443,893	11,012,325		10,448,825	563,499	95%	10,448,825	563,499
2003 Consumable Supplies	-	-		-	-	0%	-	-
2004 Utilities	1,628	8,807		8,807	(0)	100%	8,807	(0)
2005 Travel	87,500	87,500		41,916	45,584	48%	41,916	45,584
2009 Other Operating Expenses	218,997	149,564		104,159	45,405	70%	104,159	45,405
Conference		277,230		234,922	42,308	85%	234,922	42,308
<b>Subtotal - Grant Operations (A.1.3.)</b>	<b>\$ 13,747,082</b>	<b>\$ 14,488,908</b>	<b>4.86%</b>	<b>\$ 13,345,242</b>	<b>\$ 1,143,666</b>	<b>92%</b>	<b>\$ 13,345,242</b>	<b>\$ 1,143,666</b>

**Grants**

	2018 Appropriated	2018 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000 Grants - Prevention (A.1.2)	\$ 28,037,956	\$ 28,037,956		\$ 13,400,377	\$ 14,637,579	48%	\$ 13,400,377	\$ 14,637,579
4000 Grants - Research (A.1.1.)	255,239,310	\$ 252,269,756		90,834,315	\$ 161,435,441	36%	90,834,315	161,435,441
<b>Subtotal - Grants</b>	<b>\$ 283,277,266</b>	<b>\$ 280,307,712</b>	<b>94.04%</b>	<b>\$ 104,234,692</b>	<b>\$ 176,073,020</b>	<b>37%</b>	<b>\$ 104,234,692</b>	<b>\$ 176,073,020</b>
<b>Grand Totals</b>	<b>\$ 300,055,000</b>	<b>\$ 298,086,209</b>	<b>100.00%</b>	<b>\$ 120,178,257</b>	<b>\$ 177,907,952</b>	<b>40%</b>	<b>\$ 120,178,257</b>	<b>\$ 177,907,952</b>

**Cancer Prevention and Research Institute of Texas  
Cancer Prevention and Research Institute Fund Account - 5136  
As of May 31, 2018**

	<b>05/01/2018- 05/31/2018</b>	<b>AY 18 Year to Date as of 05/31/2018</b>
<b>Beginning Balance : 09/01/2017</b>		<b>\$ 600,506</b>
<b>Increases:</b>		
(1)	\$ -	\$ -
(2)	-	
<b>Total Increases</b>	<b>\$ -</b>	<b>\$ 600,506.00</b>
<b>Reductions:</b>		
Expenditures - Appropriated	\$ -	\$ -
	\$ -	\$ -
	\$ -	\$ -
<b>Total Reductions</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Ending Balance, 05/31/2018</b>		<b>\$ 600,506.00</b>

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, 2018**

	<b>05/01/2018- 05/31/2018</b>	<b>AY 18 Year to Date as of 05/31/2018</b>
<b>Beginning Balance : 09/01/2017</b>		\$ -
<b>Increases:</b>		
(1) License Plate Revenue Received	\$ 1,013.80	\$ 8,104.95
<b>Total Increases</b>	<b>\$ 1,013.80</b>	<b>\$ 8,104.95</b>
<b>Reductions:</b>		
Expenditures - Appropriated	\$ -	\$ -
	-	-
<b>Total Reductions</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Ending Balance, 05/31/2018</b>		<b>\$ 8,104.95</b>

Note:

**Cancer Prevention and Research Institute of Texas**

**Appropriated Receipts - 666**

**As of May 31, 2018**

	<u>05/01/2018- 05/31/2018</u>	<u>AY 18 Year to Date as of 05/31/2018</u>
<b>Beginning Balance : 09/01/2017</b>		<b>\$ 126,079.19</b>
<b>Increases:</b>		
(1) Product Development Application Fees Received	\$ -	\$ 25,000.00
(2) Appropriated Receipts applied to payments	\$ -	\$ -
(3) Conference Registration Fees	\$ -	\$ 213,697.96
(4) Conference Registration Fees-Credit Card	\$ -	\$ 5,452.71
<b>Total Increases</b>	<b>\$ -</b>	<b>\$ 244,150.67</b>
<b>Reductions:</b>		
Conference Expenditures - Appropriated	\$ -	\$ -
Credit Card Fees Expended	\$ -	\$ (5,452.71)
Legal Services Expenses (Application Fees)	\$ -	\$ -
<b>Total Reductions</b>	<b>\$ -</b>	<b>\$ (5,452.71)</b>
<b>Ending Balance, 05/31/2018</b>		<b>\$ 364,777.15</b>

Note: Beginning balance is \$68,000.00 for application fees and \$58,079.19 for conference registration/credit card processing fees

**Cancer Prevention and Research Institute of Texas**  
**Interest & Sinking Fund Account - 5168**  
**As of May 31, 2018**

	<b>05/01/2018- 05/31/2018</b>	<b>AY 18 Year to Date as of 05/31/2018</b>
<b>Beginning Balance : 09/01/2017</b>		<b>\$ 38,695.04</b>
<b>Increases:</b>		
(1) Revenue Sharing / Royalties	\$ 185.73	\$ 91,552.60
<b>Total Increases</b>	<b>\$ 185.73</b>	<b>\$ 130,247.64</b>
<b>Reductions:</b>		
Expenditures - Appropriated	\$ -	\$ -
	\$ -	-
	\$ -	-
<b>Total Reductions</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Ending Balance, 05/31/2018</b>		<b>\$ 130,247.64</b>

Note: Beginning Balance \$38,695.04 Revenue Sharing/Royalties



**Cancer Prevention and Research Institute of Texas  
FY 2018, Quarter 3 Performance Measure Report**

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
<b>Number of People Served by Institute Funded Prevention and Control Activities</b>	500,000	282,167	218,357	239,125		739,649	147.93%
<b>Number of Entities Relocating to TX for Cancer Research Related Projects</b>	2	0	0	0		0	0.00%
<b>Annual Age-adjusted Cancer Mortality Rate</b>	156.8	N/A	N/A	N/A	N/A		0.00%
<b>Number of Published Articles on CPRIT-Funded Research Projects</b>	900	N/A	N/A	N/A	N/A		0.00%
<b>Number of New Jobs Created and Maintained</b>	1,325	N/A	N/A	N/A	N/A		0.00%

**Variance Explanations**

<b>Number of People Served by Institute Funded Prevention and Control Activities</b>
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 nor is it predictable.
<b>Number of Entities Relocating to TX for Cancer Research Related Projects</b>
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	\$ 51,000,000		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%
				\$ 62,800,000				
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				



**Cancer Prevention and Research Institute of Texas  
2019 Operating Budget**

	<b>Budget 2018</b>	<b>Budget 2019</b>	<b>2019 Budget Transfer</b>	<b>Request to Transfer from Strategy A.1.1. Research Awards</b>
<b><u>Institution Operations (Indirect)</u></b>				
Salaries and Wages	\$ 1,439,500	\$ 1,617,425		
Other Personnel Costs	38,785	38,785		
Professional Fees and Services:				
Temporary Staff Services (IT)	260,659	341,329		\$ 97,031
Temporary Staff Services (Other)				
Financial Services (McConnell & Jones)	40,000	40,000		
Internal Audit Services (Weaver)	243,750	171,000		
Payroll Services Contract (HHSC)	10,800	10,800		
Economic Services (Perryman Group)	150,000	150,000		
Strategic Communication (Hahn)	149,975	149,975		
IT Professional Services	41,341	98,560		
Website Design Services (TradeMark Media) 2017 Contract Ext	20,407	-		
IT Risk Assessment (Myer & Stauffer) 2017 Contract Ext	12,550	-		\$ 250,000
Other Professional Services	12,204	-		\$ 200,000
Consumable Supplies	27,584	24,000		
Utilities	58,577	58,600		
Travel	45,000	45,000		
Rent - Building	33,076	13,700		
Rent-Machine and Other	32,172	32,172		
Other Operating Expenses				
Cable services (Spectrum/Time Warner)	1,355	1,355		
DIR Telecommunications	18,000	14,500		
Computer Equipment	21,084	15,000		
Software Subscriptions	305,688	261,860		
Computer Hardware Warranty Services	10,678	11,600		
Printing Services	1,200	500		
Estimated Fringes Benefits (7040)	14,000	14,000		
Estimated Fringes Benefits (7042)	30,000	30,000		
Professional Development (7203) & (7243)	20,000	20,000		
Other (ie Mail/Delivery Services, Assessments)	129,626	105,000		
<b>Subtotal - Institution Operations</b>	<b>\$ 3,168,011</b>	<b>\$ 3,265,161</b>	<b>\$ 234,509</b>	<b>\$ 547,031</b>
<b><u>Grant Review and Award Operations</u></b>				
Salaries and Wages	\$ 2,908,022	\$ 3,078,084		
Benefits				
Other Personnel Costs	45,460	45,500		
Professional Fees and Services:				
Grant Management Support Services (SRA)	8,995,852	8,400,443		
Grant Management Support Services (SRA) 2017 Contract Ext	234,990	-		
Product Development Review Council Honoraria	263,200	263,200		
Prevention Review Council Honoraria	120,000	120,000		
Scientific Review Council Honoraria	390,000	390,000		
Payroll Services Contract (HHSC)	25,200	25,200		
Grant Compliance Monitoring (CohnReznick)	163,220	-		
Product Development Due Diligence Services (ICON)	206,000	212,200		
Outside Legal Services (Vinson & Elkins)	125,000	125,000		
Outside Legal Services (Yudell Isidore)	125,000	125,000		
Outside Legal Services (Baker Botts)	125,000	125,000		
Temporary Staff Services (IT)		237,120		
IT Professional Services - UB from 2017	210,000			
Professional Writing/Editing Services				
Scientific Editor (Steele) 2017 Extension	39,855	56,250		
Cancer Plan Editor (Knight) 2017 Extension	9,625	-		
Other Professional Services	49,833			
Utilities	9,935	12,000		
Travel	87,500	65,000		
Other Operating Expenses	50,125			
Fraud, Waste & Abuse Reporting (Red Flag Reporting)	3,500	2,750		
Peer Review Monitoring Services (BFMS)	54,235	71,864		
Other Items including Conference Preparation		99,980		
Conference Planning (Swift Solutions)	65,000	-		
Conference Registration & Abstract System (TMI)	36,679	-		
Other Conference Expenses	42,308	-		
Guest Speaker Fees and Travel	13,370	-		
Printing & Design	11,927	-		
Conference Site (Renaissance Hotel)	204,172	-		
Credit Card Processing Fees	5,453	-		
<b>Subtotal - Grant Operations</b>	<b>\$ 14,620,461</b>	<b>\$ 13,454,591</b>	<b>\$ (234,509)</b>	
<b><u>Grants</u></b>				
Grants - Prevention	\$ 28,037,956	\$ 28,037,956		
Grants - Research	252,269,756	252,327,738		\$ (547,031)
<b>Subtotal - Grants</b>	<b>\$ 280,307,712</b>	<b>\$ 280,365,694</b>		
<b>Grand Totals</b>	<b>\$ 298,096,184</b>	<b>\$ 297,085,446</b>		





CANCER PREVENTION & RESEARCH  
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**MEMORANDUM**

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**To: OVERSIGHT COMMITTEE MEMBERS**  
**From: REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS CONTRACT**  
**Subject: COMMUNICATIONS SERVICE CONTRACT**  
**Date: AUGUST 6, 2018**

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**Recommendation**

CPRIT staff recommends approval of a contract for strategic communication program services with Hahn Public Communications for \$149,975 effective for FY 2019.

**Background**

In May 2018, CPRIT released an RFP seeking proposals to establish a contract with an established, qualified and experienced public communications company to implement and coordinate a strategic communications program. Five proposals were received by the due date in June, evaluated and scored.

Hahn Public Communications was selected to provide strategic communication program services including communications strategy services, media relations support, digital media relations advisory services, and communication program evaluation and assessment.

Hahn Public Communications has worked effectively with CPRIT over the last 3 years. The proposed price of \$ 149,975 had not increased and it includes the services of their principal, Jeff Hahn.





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**MEMORANDUM**

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**To: OVERSIGHT COMMITTEE**  
**From: HEIDI MCCONNELL, CHIEF OPERATING OFFICER**  
**Subject: FY 2019 SERVICE CONTRACT APPROVALS**  
**Date: AUGUST 6, 2018**

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**Recommendation**

CPRIT staff recommends the Oversight Committee approve the following contracts for FY 2018:

- Contract renewal with The Perryman Group for \$150,000 to perform an economic assessment of the cost of cancer in Texas
- Contract renewal with Weaver and Tidwell for \$171,000 to provide internal audit services.

The contracts costs being considered are not-to-exceed amounts, and payment is based on the delivery of actual services from the vendor on either time and materials basis or a report.

The renewal with Weaver and Tidwell will require the State Auditor's Office to provide audit delegation authority to CPRIT prior to contract execution.

**Background**

Contract Renewal with The Perryman Group for an Economic Assessment of the Cost of Cancer in Texas

The report produced by the Perryman Group provides CPRIT with the:

- statutorily required cost of cancer in Texas measurement;
- measurement of key economic performance indicators based on CPRIT funding and program impact; and
- estimates of the economic impact to Texas if CPRIT were not to exist and no additional funding is provided beyond the \$3 billion in general obligation debt authorized by the Texas Constitution.

Contract Renewal with Weaver and Tidwell for Internal Audit Services

Weaver and Tidwell provides internal audit services to the agency based on an annual audit plan. The proposed FY 2019 audit plan includes audits over state reporting and budget and planning processes as well as follow-up on the communications, post-award grant monitoring, procurement and P-cards, and information security internal audits completed in FY 2018. Weaver and Tidwell would also perform a follow-up on the State Auditor's Office audit of CPRIT's performance measures that was also completed in FY 2018.

CPRIT awarded the initial contract to Weaver and Tidwell in FY 2016 and would exercise the third and final renewal option for services in FY 2019.





## Oversight Committee Meetings and Standing Subcommittees Meetings 2019

### November 2018

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
10/28	10/29	10/30 PIC Meeting CPRIT Staff Only	10/31 Portal Opens	1 Board Governance	2	3
4	5 Audit	6 Prevention	7 Academic Research	8 Product Development	9 Nominations	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	<b>28 Oversight Committee Meeting</b>	29	30	12/1

### February 2019

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
3	4	5 PIC Meeting CPRIT Staff Only	6 Portal Opens	7 Board Governance	8	9
10	11 Audit	12 Prevention	13 Academic Research	14 Product Development	15 Nominations	16
17	18	19	<b>20 Oversight Committee Meeting</b>	21	22	23

### May 2019

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
4/28	4/29	4/30 PIC Meeting CPRIT Staff Only	1 Portal Opens	2 Board Governance	3	4
5	6 Audit	7 Prevention	8 Academic Research	9 Product Development	10 Nominations	11
12	13	14	<b>15 Oversight Committee Meeting</b>	16	17	18

### August 2019

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
4	5	6 PIC Meeting CPRIT Staff Only	7 Portal Opens	8 Board Governance	9	10
11	12 Audit	13 Prevention	14 Academic Research	15 Product Development	16 Nominations	17
18	19	20	<b>21 Oversight Committee Meeting</b>	22	23	24

17-1

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.

