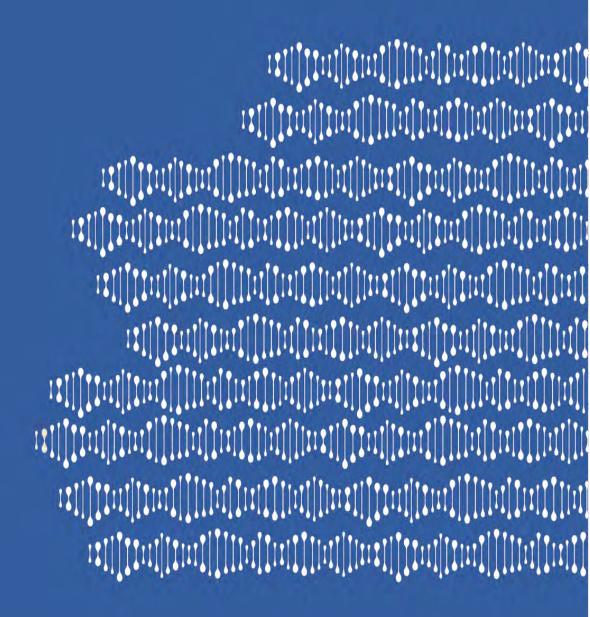
# Oversight Committee Meeting

August 16, 2017





# Summary Overview of the August 16, 2017, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the August 16, 2017, Oversight Committee meeting.

# **CEO Report**

Wayne Roberts will present the CEO's report and address issues including available grant funds, consideration of a new CPRIT initiative, funding scenarios through 2023, 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 Early Translational Research Awards, Individual Investigator Research Awards, Core Facility Research Awards, High-Impact/High-Risk Research Awards, Recruitment of First-Time, Tenure-Track Faculty Members, and Recruitment of Established Investigators totaling \$79,481,933. The recommendations include 11 awards that were previously deferred by the PIC. Note - one applicant withdrew a recruitment application after the PIC meeting.

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 Prevention and Communications Officer Report and Grant Award Recommendations**

Dr. Becky Garcia will update the Oversight Committee on the on the agency's communications activities and present the PIC's eight award recommendations. The recommended awards include Colorectal Cancer Prevention Coalition; Competitive Continuation/Expansion-Evidence-Based Prevention Services; Evidence-Based Prevention Services; and Tobacco Control and Lung Cancer Screening totaling \$14,019,137. The recommendations include one award that the PIC previously deferred.

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.

# 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 award recommendation for Texas Company Product Development Research Awards. Also included is a letter from the Chief Executive Officer requesting authority to advance funds if the Oversight Committee approves the award.

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.

# **Program Priorities**

The program officers will present a status update on the alignment of CPRIT awards with program priorities for FY 2015 – FY 2017.

# **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.

#### **FY 2018 Honoraria Policy**

Mr. Roberts will present the FY 2018 honoraria policy for peer reviewers. There are no changes from the FY 2017 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, Amy Mitchell, and Will Montgomery. The Oversight Committee approved substantially similar waivers for these five individuals for FY 2017.

# Resolution Transferring Management Authority to the Texas Treasury Safekeeping Trust Company

Effective September 1, 2017, recent changes to CPRIT's statute authorize CPRIT to transfer asset management to the Texas Treasury Safekeeping Trust Company. CPRIT staff recommends four equity assets for transfer to the Trust Company on or after September 1, 2017. The resolution approves transfer of the four assets and delegates authority to CPRIT's CEO to take all actions necessary to complete the transfer of the four assets.

#### **Internal Auditor Report**

Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and present two internal audit reports concerning pre-award grant management and purchasing and P-cards, as well as follow-up procedures conducting on four previous audits. Weaver and Tidwell will also present the FY2017 annual internal audit report. 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 an amendment to Chapter 703 that the Oversight Committee provisionally approved at the May meeting. If approved, the amendment 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 Oversight Committee Bylaws**

The Board Governance Subcommittee has completed its annual assessment of internal policies and recommends that the Oversight Committee bylaws be amended to include guidance related to training required for new Oversight Committee members. The proposed changes specify what training must be completed by a new Oversight Committee member as well as deadlines for training. The proposed change permits a new Oversight Committee member to attend meetings before all training is completed; however, he or she would not be allowed to vote on award recommendations or contract recommendations until specific training is completed.

# Mirna Shareholder Vote

Ms. Doyle will present the recommendation that the Oversight Committee delegate authority to CPRIT's CEO to vote CPRIT's shares in Mirna regarding the company's proposed merger.

# Chief Operating Officer Report, Contract Approvals, and FY 2018 Bond Issuance Resolution

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.

#### **Subcommittee Business**

The nominations subcommittee has recommended new subcommittee assignments for fiscal year 2018-2019 based on the preferences expressed by members. The Oversight Committee must vote to approve the changes to subcommittee membership.

#### **Election of Board Officers**

The Nominations subcommittee recommends the following officers for FY 2018 – FY 2019: Will Montgomery, Presiding Officer (Chair), Dee Margo, Assistant Presiding Officer (Vice Chair), and Amy Mitchell, Secretary. The Chair of the Nominations Subcommittee worked with the outgoing Oversight Committee Chair to develop the slate of officers.



# Oversight Committee Meeting Agenda

Texas Higher Education Coordinating Board 1200 E. Anderson Lane, Austin, TX 78752 Board Room 1.170

> August 16, 2017 10:00 a.m.

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

1.	Call to Order	
2.	Roll Call/Excused Absences	
3.	Adoption of Minutes from the May 17, 2017, meeting	TAB 1
4.	Public Comment	
5.	Grantee Presentations	TAB 2
6.	Chief Executive Officer Report	TAB 3
	• Funding scenarios through 2023	
7.	Chief Compliance Officer Report	TAB 4
8.	Chief Scientific Officer Report	TAB 5
	Grant Award Recommendations	
	<ul> <li>Proposed Request for Applications FY 2018 Process and Timeline</li> </ul>	
9.	Chief Prevention and Communications Officer Report	TAB 6
	Grant Award Recommendations	
	<ul> <li>Proposed Request for Applications FY 2018 Process and Timeline</li> </ul>	
10.	Chief Product Development Officer Report	<b>TAB 7</b>
	Grant Award Recommendations	
11.	Program Priorities	TAB 8
	• FY 2015 – FY 2017 Program Priorities Impact	
	FY 2018 Program Priorities Process	
12.	Scientific Research and Prevention Program Committee Appointments	TAB 9
13.	FY 2018 Honoraria Policy	<b>TAB 10</b>
14.	Health & Safety Code Section 102.1062 Waivers	<b>TAB</b> 11
15.	Resolution Transferring Management Authority to the Texas Treasury Safekeeping	<b>TAB 12</b>
	Trust Company	
16.	Internal Auditor Report	TAB 13
	<ul> <li>Internal Audit Report Over Pre-Award Grant Management</li> </ul>	
	<ul> <li>Internal Audit Report Over Purchasing and P-Cards</li> </ul>	
	• Internal Audit Follow-Up Procedures Over Prior Year Information Security Findings	
	<ul> <li>Internal Audit Follow-Up Procedures Over Prior Year Revenue Findings</li> </ul>	

• Internal Audit Follow-Up Procedures Over Prior Year Cash Management Findings • Internal Audit Follow-Up Procedures Over Prior Year Commodity and Service **Contract Findings** • Fiscal Year 2017 Annual Internal Audit Report 17. Amendments to 25 T.A.C. Chapter 703 **TAB 14** • Final Order Approving Amendment to Chapter 703 • Proposed Amendments to Chapter 703 and Authorization to Publish in Texas Register 18. Amendments to the Oversight Committee Bylaws **TAB 15** Mirna Shareholder Vote **TAB 16** • Delegation of Authority to the Chief Executive Officer **TAB 17** 20. Chief Operating Officer Report 21. Contract Approvals **TAB 18** • The Perryman Group • Weaver and Tidwell • Hahn Public Communications 22. Subcommittee Business **TAB 19** Approval of Subcommittee Assignments 23. **Election of Board Officers TAB 20** Compliance Investigation Pursuant to Health & Safety Code § 102.2631 24. 25. Consultation with General Counsel 26. Future Meeting Dates and Agenda Items **TAB 21** 27. Adjourn



# **Oversight Committee Meeting** May 17, 2017

#### 1. Call to Order

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

#### 2. Roll Call/Excused Absences

Committee Members Present:

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

# 3. Adoption of Minutes from the February 15, 2017, and April 17, 2017, meetings

Ms. Mitchell noted that the minutes of the Oversight Committee meeting of February 15, 2017, incorrectly stated that Dr. Cynthia Mulrow attended the meeting.

# **MOTION:**

On a motion made by Mr. Holmes and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meeting of February 15, 2017 as corrected, and the meeting of April 17, 2017, as presented.

#### 4. Public Comment

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

#### 5. Grantee Presentations

Dr. James Willson, Chief Scientific Officer, introduced Dr. Dean Edwards, Professor of Molecular and Cell Biology at Baylor College of Medicine. Dr. Edwards studies the role of hormonal control in the development and progression of breast cancer and it is this research that led him to a CPRIT Individual Investigator Award. He is also a Principal Investigator of a CPRIT Core Facility award, presenting today on "The Impact of CPRIT Core Facility Support Awards."

Dr. Edwards presented his CPRIT-funded project, the core facility award at Baylor College of Medicine. He concluded that the core facility has transformed the way they do research in genomics, proteomics, and metabolomics.

Dr. Edwards was asked whether the facility has made provisions for maintaining the laboratory when CPRIT funding is no longer available. Dr. Edwards responded that with the infrastructure in place, more grant money from other sources will become available to maintain the laboratory. Also, the users will be asked to share a larger percentage of funding from their grants.

When asked if there have been any new licensing or spinouts from the first five years of the core facility's operations, Dr. Edwards responded that the time required to achieve licensing or spinouts will be well past the second five years of their CPRIT grant, due to the nature of the research and length of time for clinical studies. He stated that some of the users have filed invention disclosures, but he does not have data on their status.

Michael Lang, Chief Product Development Officer, introduced Dr. Harpreet Singh, cofounder of Immatics Biotechnologies, GmbH, the parent company of Immatics US, Inc. He is currently Chief Executive Officer of Immatics US.

Dr. Singh reported on the work of his company, which is dedicated to cancer immunotherapy. He concluded by saying that Immatics US is committed to building a sustainable company in Texas. They have moved into a 15,000 square foot laboratory and office facility in Houston, and have hired 41 people and expect to reach 50 employees by the end of 2018. Chief Scientific Officer, Steffen Walter, and Dr. Singh both have moved from Germany to Houston with their families.

In response to a question about why Immatics US chose to operate in Texas as opposed to some of the other renowned centers of cancer research around the United States and the world. Dr. Singh responded that it was clear that the United States is leading the world in cell therapy research and MD Anderson Cancer Center is one of several well-known institutions that have experience in the science of cell therapy and additionally has an excellent infrastructure, allowing access to cancer patients in the biggest medical center of the world. Secondly, the CPRIT mechanism was clearly an important reason, being a catalyst to raise more money for Immatics and to show investors that there is local commitment. Thirdly, the "can do" attitude of Texas is very appealing to Dr. Singh.

Presiding Officer Geren thanked Dr. Edwards and Dr. Singh on behalf of the Oversight Committee for their presentations.

# 6. Agenda Item 6: Chief Executive Officer Report

Presiding Officer Geren recognized Mr. Wayne Roberts, Chief Executive Officer, to give his report.

Mr. Roberts stated that all legislative bills pertaining to CPRIT are still under consideration with support for the agency in both chambers. He expressed optimism that desired legislation would pass in the approximately two weeks before the close of the session.

Mr. Roberts reported that depending on legislative action, CPRIT's sunset date of either 2021 or 2023 is going to leave between \$807 and \$842 million for research grant awards, with additional funds for prevention grant awards. It is not yet known if CPRIT's sunset date will be extended, but either date will have an impact on the funding CPRIT has available for grant making and on how much can be awarded in each of its remaining years. Mr. Roberts referred to the spreadsheet included in the Oversight Committee meeting materials. He stated the assumptions used for calculations are identified on the spreadsheets. Several other assumptions will be explored in the weeks ahead. Using the projections in the spreadsheet, CPRIT staff is developing a proposal for allocating funds for Oversight Committee consideration at the August 2017 meeting. He noted that these projections could affect future program priorities adopted by the Oversight Committee. Staff believes that the funding and program priorities discussions are linked and should be combined for adoption by the Oversight Committee at its November 15, 2017, public meeting. This schedule allows time for staff to analyze the Legislature's sunset decision and for the Oversight Committee to review and modify a staff proposal through the fall priorities setting process.

Mr. Roberts affirmed that CPRIT has sufficient monies to fund the Scientific Review Council and Program Integration Committee recommendations being presented for approval today.

Mr. Roberts noted that the November 2017 meeting is scheduled Wednesday, November 15, the week before Thanksgiving. CPRIT's biennial conference is scheduled for Monday, November 13 and Tuesday, November 14. Staff will be requesting that the Oversight Committee consider moving the Oversight Committee meeting to another date as the meeting will have a large number of award recommendations presented in addition to the program priorities setting process, requiring extensive staff preparation. Moving the meeting date allows staff to give appropriate attention to both the meeting preparation and the conference preparation. An alternate date will be determined and presented to the Oversight Committee for it consideration and approval at the August 2017 meeting.

## 7. Agenda Item 10: Chief Product Development Officer Report

Mr. Michael Lang, Chief Product Development Officer, reported that the Request for Applications (RFAs) schedule has been set up such that CPRIT can accommodate the variability in the number of awards issued to maintain budgetary control. In general, Product Development issues two RFAs a year, resulting in awards being presented for Oversight Committee consideration every other meeting. This meeting is one at which no awards are being presented.

The FY 2017 Cycle 2 received 20 applications. Six of those applications were selected to present at Peer Review Panel meetings held April 25-26, where two firms were selected to progress to due diligence. Applications recommended by the Product Development Review

Council and the Program Integration Committee will be presented to the Oversight Committee in August for approval.

The FY 2018 Cycle 1 RFA is being edited for the planned June 29 opening of the CARS system to accept applications.

Mr. Lang reported that the Product Development Advisory Committee (PDAC) convened on March 30 to discuss how best to utilize remaining CPRIT funding and drafting the PDAC's annual report.

# 8. Agenda Item 11: Product Development Advisory Committee Annual Report

Mr. Lang introduced Dr. Jonathan MacQuitty, PDAC Chair, to present the advisory committee's annual report. He added that Dr. MacQuitty had come from California to present the committee report and Dr. MacQuitty and all the members of the PDAC provide a valuable service to CPRIT without compensation. Dr. MacQuitty is a venture partner in Lightspeed Venture Partners, a life science venture capital firm. He is also founder and Chief Executive Officer of 47 Inc., which is one of their investment companies in immuno-oncology areal, similar technologies to Immatics US technologies. He has been in the venture capital life sciences for 35 years.

Dr. MacQuitty presented the PDAC's annual report, which is included in the Oversight Committee meeting materials.

Dr. MacQuitty was asked what Texas needs to become a center of life science, including academic and commercial experience. He said that the over the last 20 years, the amount of seed funding has decreased. Funding has become more and more difficult for early stage clinical trials. The ability of CPRIT to take what looks like a \$25-30 million dollar insurmountable hurdle and put up \$15-20 million, reducing the funding gap, is critical. He believes that the reason venture capitalists are shunning life science investments is because they simply do not have enough capital for investing in a high dollar, high risk area. Dr. MacQuitty believes the mission of CPRIT allows it to take on the risk that others do not want to take on to help the development of potentially life-saving treatments. Essentially, it is a public policy issue.

Dr. MacQuitty was asked to speak about lessons learned from the California Institute for Regenerative Medicine (CIRM), which was funded in a similar manner to the way CPRIT was funded by the State of Texas. Dr. MacQuitty explained that CIRM focuses on stem cells in general and, consequently, because stems cells are involved in many cancers, much of their funding goes into cancer related activities. Part of the challenge for any funding agency like CIRM is the large amount of interesting and important academic projects that can be funded. At some point a report will have to be made to the legislature and to the voters who voted for it. Legislators and voters' enthusiasm for academic research may be tempered compared to their interest in prospective therapies being available in the near term. The feeling is that money spent on academic research and facilities could have been better spent elsewhere, such as on clinical trials to develop cures.

Dr. MacQuitty suggested that as a measure of CPRIT success, CPRIT should use the metric "the number of patients in CPRIT funded clinical studies." No one can guarantee the success of clinical studies; it is certain that without clinical studies there can be no success.

Presiding Officer Geren thanked Dr. MacQuitty for his presentation and his service today.

# 9. Agenda Item 7: Chief Compliance Officer Report

Mr. Vince Burgess, Chief Compliance Officer, presented his report on grant compliance activities. Some of the other compliance activities are grantee monitoring, desk reviews and onsite reviews, audit tracking and attestation tracking, and training and support. He pointed to the chart provided in the Oversight Committee meeting materials titled Grant Recipient Report Monitoring 4-16 thru 4-17, Delinquent/Missing Reports. The chart shows a 13-month span of reporting where the non-compliance falls consistently below the 5 percent threshold. The 13-month average is at 1.5 percent. Staff meets weekly to review delinquent reporting, and works with grantees to resolve any issues regarding required reporting. Staff has also conducted 157 desk reviews this fiscal year and 13 on-site reviews. Another 10 onsite reviews and 20-30 desk reviews are scheduled though the end of August.

Mr. Burgess reported that CPRIT staff conducted grantee training on March 9, with approximately 150 grantee representatives in attendance. The webinar covered required reporting, administrative rule changes, grant closeouts, and an overview of the compliance program. Staff conducted a training for a new product development grantee on May 3, which included a hands-on navigation of the grants management system. Staff also conducted a second training on May 3, for three new Authorized Signing Officials (ASOs). CPRIT has scheduled another grantee training for June 7.

There were no questions for Mr. Burgess.

# 10. Agenda Item 8: Chief Scientific Officer Report and Grant Award Recommendations

Dr. James Willson, Chief Scientific Officer, presented the recommendations of the Scientific Review Council and the Program Integration Committee.

#### **Academic Research Grant Award Recommendations**

Dr. Willson ten awards in three slates corresponding to grant mechanisms and totaling \$25,104,127 for Oversight Committee approval. The applications proposed to the Program Integration Committee for funding address the following Academic Research Program Priorities: Recruitment of outstanding cancer researchers to Texas, Childhood Cancers, Cancers of Importance in Texas and Computational Biology.

#### **Academic Research Grant Award Recommendations**

App ID	Candidate	Mech.	Organization	Budget		
RR170023	Mack,	RFTFM	Baylor College of Medicine	\$2,000,000		
	Stephen					
RR170039	Yun, Jihye	RFTFM	Baylor College of Medicine	\$2,000,000		
RR170030	Hilton,	RFTFM	Rice University	\$2,000,000		
	Isaac					
RR170040	Jasper,	RRS	Baylor College of Medicine	\$4,000,000		
	Heinrich					
RR170033	Skau,	RFTFM	The University of Texas	\$2,000,000		
	Colleen		Southwestern Medical Center			
RR170037	Lu, Chao	RFTFM	The University of Texas	\$2,000,000		
			Southwestern Medical Center			
RR170026	Fregly,	REI	Rice University	\$5,104,127		
	Benjamin					
RR170024	Velez,	RFTFM	Baylor College of Medicine	\$2,000,000		
	Valentina					
RR170036	Hodges,	RFTFM	Baylor College of Medicine	\$2,000,000		
	Courtney					
RR170020	Gadad,	RFTFM	Texas Tech University Health	\$2,000,000		
	Shrikanth		Science Center at El Paso			

REI: Recruitment of Established Investigators

RRS: Recruitment of Rising Stars

RFTFM: Recruitment of First-Time Tenure Track Faculty Members

# **Compliance Certification**

Mr. Vince Burgess, Chief Compliance Officer, reported reviewing the compliance pedigrees for the grant applications submitted to CPRIT for the following mechanisms:

- Recruitment of Established Investigators
- Recruitment of Rising Stars
- Recruitment of First-Time, Tenure-Track Faculty Members

Mr. Burgess stated that he had conferred with staff at CPRIT and SRA, International (SRA), CPRIT's contracted third-party grants administrator, regarding academic research awards and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings.

Mr. Burgess reported that he was satisfied that the application review process that resulted in the above mechanisms recommended by the Program Integration Committee (PIC) followed applicable laws and agency administrative rules. He certified the academic research award recommendations for the Oversight Committee's consideration.

# Conflict of Interest Notification

Presiding Officer Geren noted for the record that no Oversight Committee member had reported a conflict of interest with any recruitment award being presented.

#### **MOTION:**

On a motion made by Mr. Holmes and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations for recruitment awards.

#### **MOTION:**

On a motion made by Mr. Holmes and seconded by Ms. Mitchell, 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.

# 11. Agenda Item 9: Chief Prevention and Communications Officer Report

# **Prevention Program Update**

Dr. Rebecca Garcia, Chief Prevention and Communications Officer, presented her report on Prevention program activities. She stated that the Prevention program presented recommendations two times a year and no recommendations were being presented today.

Dr. Garcia reported that the peer review panels would be meeting on May 31-June 2 in Dallas to consider 37 applications submitted for the second cycle of FY 2017. These applications request about \$52 million in total. CPRIT has about \$14 million available for Preventions grants for the rest of FY 2017. The Program Integration Committee and the Oversight Committee will consider grant recommendations in August.

Dr. Garcia noted that CPRIT will release the following RFAs in June and will be for the first award cycle of FY 2018:

- Evidence-Based Cancer Prevention Services
- Dissemination of CPRIT-Funded Cancer Control Interventions
- Cancer Prevention Promotion and Navigation to Clinical Services
- Tobacco Control and Lung Cancer Screening

Dr. Garcia reported that discussion with the Prevention Subcommittee has begun about strategies on how CPRIT might provide better coverage in rural areas. Currently grantees are covering all but two counties in the state; however, there are some gaps in the types of available services.

Mr. Margo, Chair of the Prevention Subcommittee, noted that the subcommittee had discussed needs and outcomes, and the fact that sometimes the need was there but grant application expertise was not. The subcommittee discussed ways to address the issue of

entities in rural areas with capacity to provide services but without the expertise to complete a successful application and/or complete the required grant reporting.

# **Communications Program Update**

Dr. Garcia directed the Oversight Committee members to the Communications update memo in the Oversight Committee meeting materials.

Staff has developed a media strategy to get coverage of CPRIT grantees in local markets during cancer awareness months. Dr. Garcia showed a media clip as an example of how that strategy is working.

Communications staff has also increased its production of videos, some revolving around cancer awareness months, and others with grantee interviews that can be used on social media and CPRIT's website

Of interest, May is Cancer Research Month and the Communications Specialist has been working with the City of Houston to get a proclamation by the city. The goal is to have May proclaimed as National Cancer Research Month at a Houston City Council meeting and have CPRIT grantees present. Staff is still working on the scheduling details.

There were no questions for Dr. Garcia.

# 12. Agenda Item 12: Scientific Research and Prevention Program Committee Appointments

Mr. Roberts presented the list of appointees to CPRIT review panels for Oversight Committee approval. He stated the Nominations Subcommittee discussed the appointments and recommended approval.

#### **MOTION:**

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

# 13. Agenda Item 13: Product Development Advisory Committee (PDAC) Appointments and Charter

Mr. Roberts presented the listing of appointees to PDAC for Oversight Committee approval. He reports that the Nominations Subcommittee discussed the appointments and recommends approval.

Mr. Roberts emphasized that these appointees have served on the PDAC previously and have provided valuable service to CPRIT. Mr. Roberts anticipates this advisory committee will be consulted more frequently going forward.

#### **MOTION:**

On a motion made by Mr. Margo and seconded by Mr. Holmes, the Oversight Committee unanimously voted to approve the nominations to the PDAC.

#### **MOTION:**

On a motion made by Mr. Margo and seconded by Mr. Holmes, the Oversight Committee unanimously voted to approve the PDAC charter.

# 14. Agenda Item 14: Internal Auditor Report

Presiding Officer Geren recognized Dan Graves from Weaver and Tidwell, LLP, to present the Internal Auditor Report.

Mr. Graves reported that the training program audit covered training of the Oversight Committee members, CPRIT staff and grant recipients. The audit resulted in the highest rating of strong.

The internal agency compliance audit addressed compliance with administrative rules, state requirements, ethics, and CPRIT policy for all of the participants' involved in the grants process. The audit resulted in the highest rating of strong.

Mr. Graves reported that Weaver has completed field work for the pre-award grant management audit. Field work for the procurement and P-Cards audit is in progress.

Mr. Graves noted that the overall findings matrix and audit progress from 2015 to date is in the Oversight Committee meeting materials.

Presiding Officer Geren noted that the Audit Subcommittee met on May 8, 2017, to review the reports and recommended approval.

There were no questions for Mr. Graves.

#### **MOTION:**

On a motion made by Mr. Holmes and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Internal Audit Reports over Internal Agency Compliance and Training Program.

# 15. Agenda Item 16: Amendments to 25 T.A.C. Chapters 701 and 703

Ms. Cameron Eckel, Staff Attorney, presented the following rules changes, which the Board Governance Subcommittee discussed and recommends approval:

• Final Order Approving Amendments to Chapters 701 and 703

Ms. Eckel noted that CPRIT legal staff presented these amendments initially at the February 2017 Oversight Committee. The Oversight Committee approved publication in the *Texas Register*; the proposed amendments were published in the March 30 edition and were available on CPRIT's website. CPRIT received one comment related to the definition of relative in Chapter 701. Ms. Eckel explained that the purpose of the amendment was to clean up the definition and have it mirror the requirements found in the Government Code, Chapter 573. The requestor wanted in-laws included within the definition of relative—father-in-law, mother-in-law, son -and daughter-in-law, brother- and sister-in-law, as well as cousins, nieces and nephews, and aunts and uncles. Staff based CPRIT's definition on the second degree of consanguinity and affinity consistent with Chapter 573, which does not include uncles and aunts, nieces and nephews and cousins. CPRIT has declined to make the requested change to include uncles, aunts, nephews, nieces, and cousins.

If approved today, CPRIT will file the final orders with the Secretary of State and they will become effective 20 days after filing.

• Proposed Amendments to Chapter 703 and Authorization to Publish in *Texas Register* 

Ms. Eckel explained that the proposed rule change allows grant awards with a contract effective date in the last quarter of a state fiscal year to have an initial financial reporting period beginning September 1st of the following state fiscal year. Awards approved by the Oversight Committee in the last quarter of a fiscal year must have a contract effective date of August 31st. This causes CPRIT's Grant Management System (CGMS) to create a partial quarter or "fifth quarter" for those grant awards that remains in CGMS for the life of the grant. Ms. Eckel noted that the "fifth quarter" issue often causes confusion and reporting difficulties for grantees. The proposed rule amendment addresses this issue by eliminating the partial quarter and allowing grantees to report expenses for the partial quarter on the Financial Status Report period beginning September 1st.

Ms. Eckel explained that once the Oversight Committee approves the proposed amendment, CPRIT will publish it in the *Texas Register*. The publication date begins the 30-day period soliciting public comment. CPRIT staff 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 change in August.

There were no questions for Ms. Eckel.

#### **MOTION:**

On a motion made by Mr. Holmes and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the final orders adopting rule changes to the Texas Administrative Code Chapters 701 and 703.

#### **MOTION:**

On a motion made by Mr. Montgomery and seconded by Mr. Holmes, the Oversight Committee unanimously voted to approve the proposed change to Texas Administrative Code Chapter 703 for publication in the *Texas Register*.

# 16. Agenda Item 16: Chief Operating Officer Report

Ms. Heidi McConnell, Chief Operating Officer, reported on the following items.

# • FY 2017, Quarter 2 Operating Budget

During this quarter, the agency received about \$21,000 in revenue sharing payments, bringing the total payments received through February 2017 to about \$37,000. The overall total collected is still about \$3.1 million since the inception of the agency.

# • <u>Debt Issuance History</u>

CPRIT has issued \$222.9 million in debt this year, a combination of commercial paper and long-term financing that the Texas Public Finance Authority issued on CPRIT's behalf in February. To date, CPRIT has issued almost \$1.3 billion in debt since CPRIT's inception.

There were no questions for Ms. McConnell.

# 17. Agenda Item 17: Contract Approvals

Ms. McConnell presented staff's recommendation that the Oversight Committee approve the following contracts for FY 2018:

- Contract renewal with ICON Clinical Research for \$206,000 to provide due diligence services.
- Contract renewal with SRA International, Inc., a CSRA Company, for \$8,995,852 to provide grant management support services;
- Contract renewal with CohnReznick for \$163,220 to provide compliance monitoring services;
- Contract extension with Vinson & Elkins, LLP for \$125,000 to provide outside counsel services;
- Contract extension with Baker Botts, LLP for \$125,000 to provide outside counsel services; and
- Contract with Yudell Isidore, PLLC for \$125,000 to provide outside counsel services.

Ms. McConnell explained that the contract amounts are not-to-exceed amounts; payment is based on the delivery of actual services from the vendor, either time and materials or a unit cost.

Ms. McConnell reported that the renewals with CSRA, Vinson & Elkins, and Baker Botts will require approval from the Legislative Budget Board before CPRIT finalizes the contracts. In addition, the Office of the Attorney General must approve all outside counsel agreements and contract extensions prior to contract execution.

There were no questions for Ms. McConnell.

#### **MOTION:**

On a motion made by Mr. Margo and seconded by Mr. Holmes, the Oversight Committee unanimously voted to approve contracts for the following services: ICON (due diligence); CSRA (grant management support); CohnReznick (compliance monitoring); and Vinson & Elkins, Yudell Isidore and Baker Botts (outside legal counsel).

# 18. Agenda Item 18: FY 2018 Bond Issuance Resolution

Ms. McConnell presented the FY 2018 Bond Issuance Resolution for an aggregate amount of \$300 million for Oversight Committee approval.

There were no questions for Ms. McConnell.

#### **MOTION:**

On a motion made by Mr. Margo and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the FY 2018 bond issuance resolution.

# 19. Agenda Item 19: Election of Board Officer Process

Presiding Officer Geren explained that the Oversight Committee bylaws call for the election of a Chairperson and Vice Chairperson at the last regular meeting of each odd-numbered fiscal year. This means that new officers will be elected at the Oversight Committee meeting in August. He reminded the members that officers are elected by a simple majority vote.

During the last elections, the Oversight Committee tasked the Nominations Subcommittee to facilitate the elections process. The Nomination Subcommittee will accept nominations and recommend candidates for Oversight Committee consideration.

- 20. Agenda Item 20: Subcommittee Business
- 21. Agenda Item 21: Compliance Investigation Pursuant to Health & Safety Code § 102.2631
- 22. Agenda Item 22: Consultation with General Counsel

Presiding Officer Geren reported that the Oversight Committee would not take up items 20, 21, and 22.

### 23. Agenda Item 23: Future Meeting Dates and Agenda Items

Presiding Officer Geren announced the next regular Oversight Committee meeting is scheduled for August 16, 2017, at 10:00 a.m.

#### 24. Agenda Item: Adjourn

There being no further business, the Oversight Committee unanimously approved a moti adjourn made by Presiding Officer Geren and seconded Dr. Rice.  Meeting adjourned at 12:50 p.m.											
Meeting adjourned at 12:50 p.m.											
Signature	Date										

**MOTION:** 

# Peter Houghton, Ph.D.



PROFESSOR, MOLECULAR MEDICINE UT HEALTH SCIENCE CENTER SAN ANTONIO

DIRECTOR, GREEHEY CHILDREN'S CANCER RESEARCH INSTITUTE

PROFESSOR, MOLECULAR MEDICINE

GREEHEY DISTINGUISHED CHAIR FOR THE CHILDREN'S CANCER RESEARCH INSTITUTE

#### **EDUCATION**

Ph.D., Biochemistry/Pharmacology, University of London, 1976

RESEARCH

Dr. Peter Houghton is the Director of the Greehey Children's Cancer Research Institute (GCCRI), and holder of the Greehey Distinguished Chair for the Children's Cancer Research Institute.

His studies are aimed at understanding mechanisms of cancer initiation in children and using this information to develop more effective and less toxic treatments that will increase the cure rate and improve quality of life for cancer survivors. He has been consistently funded through NIH for over 30 years, has directed NIH program grants for over 25 years, and served as chair for both the Experimental Therapeutics and Drug Discovery Molecular Pharmacology NIH Study Sections. He has served on several committees within the Children's Oncology Group, and was elected Fellow of the American Association for the Advancement of Science in 2011.

His current projects include:

- 1. Signaling pathways in childhood sarcoma
- 2. The Pediatric Preclinical Consortium (PPTC)
- 3. Low-Grade Glioma Brain tumors

#### **Selected Publications:**

Singh M, Leasure JM, Chronowski C, Geier B, Bondra K, Duan W, Hensley LA, Villalona-Calero M, Li N, Vergis AM, Kurmasheva RT, Shen C, Woods G, Sebastian N, Fabian D, Kaplon R, Hammond S, Palanichamy K, Chakravarti A, Houghton PJ. FANCD2 is a potential therapeutic target and biomarker in alveolar rhabdomyosarcoma harboring the PAX3-FOXO1 fusion gene. doi: 10.1158/1078-0432.CCR-13-0556. Epub 2014 Apr 30.PMID: 24787670

Cam M, Bid HK, Xiao L, Zambetti GP, Houghton PJ, Cam H. J. p53/TAp63 and AKT regulate mammalian target of rapamycin complex 1 (mTORC1) signaling through two independent parallel pathways in the presence of DNA damage. Biol Chem. 2014 Feb 14;289(7):4083-94. doi: 10.1074/jbc.M113.530303. Epub 2013 Dec 23.PMID: 24366874

Bid HK, Roberts RD, Cam M, Audino A, Kurmasheva RT, Lin J, **Houghton PJ,** Cam H. **ΔNp63 promotes pediatric neuroblastoma and osteosarcoma by regulating tumor angiogenesis.** Cancer Res. 2014 Jan 1;74(1):320-9. doi: 10.1158/0008-5472.CAN-13-0894. Epub 2013 Oct 23.PMID: 24154873

Balkhi MY, Iwenofu OH, Bakkar N, Ladner KJ, Chandler DS, Houghton PJ, London CA, Kraybill W, Perrotti D, Croce CM, Keller C, Guttridge DC. miR-29 acts as a decoy in sarcomas to protect the tumor suppressor A20 mRNA from degradation by HuR.Sci Signal. 2013 Jul 30;6(286):ra63. doi: 10.1126/scisignal.2004177. Erratum in: Sci Signal. 2013 Sep 10;6(292):er6. Balkhi, Mumtaz Y [corrected to Balkhi, M Y]. PMID: 23901138

Shen C, Houghton PJ. The mTOR pathway negatively controls ATM by up-regulating miRNAs. Proc Natl Acad Sci U S A. 2013 Jul 16;110(29):11869-74. doi: 10.1073/pnas.1220898110. Epub 2013 Jul 1.PMID: 23818585

# Fahar Merchant, PhD, Chairman, President and CEO



Dr. Merchant is a 25-year biotech veteran, a serial entrepreneur and co-founder of Medicenna. Previously he was President and CEO of Protox Therapeutics (TSX.V and TSX; now Sophiris Bio, Nasdaq) where he established a late clinical stage urology company. At Protox he raised more than \$70M through multiple PIPEs, including a \$35M investment by Warburg Pincus. In 1992, he co-founded IntelliGene Expressions, Inc., a biologics manufacturing company, and built it to one of the fastest growing companies in Canada. In 2000, by strategic in-licensing, he co-founded Avicenna Medica, Inc., a clinical stage oncology company that was sold a year later to KS Biomedix (LSE) for \$90M. Fahar was Chief Techology Officer and Director of

KS Biomedix until its acquisition by Xenova (Nasdaq and LSE; now Celtic Pharma). Fahar has closed several transactions valued at more than \$300M. He has a PhD in Biochemical Engineering from Western University.



#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER

**SUBJECT:** AGENDA ITEM 6, CHIEF EXECUTIVE OFFICER REPORT

**DATE:** AUGUST 7, 2017

As of this writing the Chief Executive Officer Report for the August 16, 2017, Oversight Committee (OC) meeting will consist of the following items:

- Personnel update
- FY 2017 Grant Award Funds Available
- New initiative scoping
- CPRIT Funding Scenarios Through FY 2023 (with Heidi McConnell, Chief Operating Officer)

Other topics may be added as warranted

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

\*\*\*\*

# CPRIT has awarded 1,132 grants totaling \$1.791 billion

- 181 prevention awards totaling \$181.1 million
- 951 academic research and product development research awards totaling \$1.610 billion

Of the \$1.610 billion in academic research and product development awards,

- 29.6% of the funding (\$476.7 million) supports clinical research projects
- 26.3% of the funding (\$423.6 million) supports translational research projects
- 25.6% of funding (\$412.1 million) supports recruitment awards
- 14.8% of the funding (\$237.4 million) supports discovery stage research projects
- 3.7% of funding (\$59.9 million) supports training programs.

# CPRIT has 8 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Prevention
- 2 Product Development

#### FY 2017 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	F	Prevention	Academic / Produc Resea			-	Prevention Percentage Based on Available Award Appropriations		(	Operating Budget	A	Total ppropriations
Available Appropriated Funds	\$	28,319,312	\$	254,879,810					\$	16,800,878	\$	300,000,000
Unexpended Bond Proceeds Carry Forward Unexpended Balance Carry Forward			\$	-							\$	-
Approved Adjustment to Operating Costs			\$ \$	-					\$	_		
Appropriations Transfer to DSHS			\$	(2,969,554)					\$	2,969,554		
Adjusted Appropriations	\$	28,319,312	_	251,910,256					\$	19,770,432	\$	300,000,00
Total Available for All Grants							\$ 280,2	29,568				
Calculated 10% for Prevention Grants of Total Availab	le G	rant Funding					\$ 28,0	22,957				
Adjustment for 10% Prevention Grants Limit Adjustment to Address Avg Prevention Historical		(296,355)	\$	296,355								
Limit		(1,851,835)		1,851,835						10 770 422	^	300 000 00
Revised Adjusted Appropriations		26,171,122 Prevention	\$	254,058,446 Academic		PD Research			\$	19,770,432	>	300,000,000
		Grants	R	esearch Grants		Grants						
Total Available for Grant Awards (Total GO Bond												
Proceeds Less Operating Budget)	\$	26,171,122	\$	190,543,834	\$	63,514,612					\$	280,229,56
Announced Grant Awards												
9/14/16 AR Core Facilities Awards			\$	16,062,539								
9/14/16 AR Recruitment Awards			\$	34,000,000								
11/16/16 PDR Awards-2 companies					\$	32,146,716						
11/16/16 AR Awards-Translational Research			\$	3,974,486								
11/16/16 AR Awards-IIRA			\$	17,892,210								
11/16/16 AR Awards-Childhood/Adolescent Cancers			\$	8,035,738								
11/16/16 AR Awards-Computational Biology			\$	2,634,668								
11/16/16 AR Awards-Prevention and Early Detection			\$ \$	5,819,500								
11/16/16 AR Awards-Research Training 11/16/16 AR Recruitment Awards			\$	14,866,638 8,000,000								
2/15/17 AR Recruitment Awards			\$	22,000,000								
2/15/17 Increase to AR Award RP170259			\$	576,748								
2/15/17 Prevention Awards	\$	12,024,696										
5/17/17 Recruitment Awards			\$	25,104,127								
Announced Grant Award Subtotal	\$	12,024,696	\$	158,966,654	\$	32,146,716	\$	-			\$	203,138,066
Grant Award Adjustments												
Declined Recruit Award (MDACC-Ye) 9/2016 Slate			\$	(2,000,000)							\$	(2,000,00
Declined IIRA (BCM-Scott) 11/2016 Slate			\$	(875,757)							\$	(875,75
Declined Recruit Award (MDACC-Clarke) 9/2016 Slate			\$	(6,000,000)							\$	(6,000,00
Declined Recruit Award (MDA-Evan) 2/2017 Slate			\$	(6,000,000)							\$	(6,000,00
Declined IIRA (MDACC-J. Chen) 11/2016 Slate Reduction to IIRA (UTHSCSA-Aguiar) 11/2016 Slate			\$ \$	(900,000) (267,840)							\$	(900,00 (267,84
Declined Recruit Award (MDACC-Pelicci) 2/2017 Slate			\$	(6,000,000)							\$	(6,000,00
Declined Recruit Award (BCM-Jasper) 5/2017 Slate			\$	(4,000,000)							\$	(4,000,00
Declined Recruit Award (UTSW-Lu) 5/2017 Slate			\$	(2,000,000)							\$	(2,000,00
Revised Grant Award Subtotal	\$	12,024,696	\$	130,923,057	\$	32,146,716					\$	175,094,469
Available Funds June 27, 2017	\$	14,146,426	\$	59,620,777	\$	31,367,896					\$	105,135,099
Pending Grants-PIC Recommendations												
Product Development Research Awards			\$	-	\$	8,998,067						
Recruitment Awards (15)			\$	38,000,000								
08/08/17 Declined Recruit Award (UTSW-Obeng)			\$	(2,000,000)								
Early Translational Research Awards			\$	2,744,006								
Individual Investigator Research Awards			\$	6,436,283								
High Impact/High Risk Research Awards Core Facility Support Awards			\$ \$	3,799,366 30,502,278								
Prevention Awards	Ś	14,019,137	ڔ	30,302,210								
Pending Award Subtotal	-	14,019,137	\$	79,481,933	\$	8,998,067					\$	102,499,13
<b>Total Potential Grant Funding Committed</b>	\$	26,043,833	\$	210,404,990	\$	41,144,783					\$	277,593,60
Rebudget of remaining PDR funds to ACR			\$	22,369,829	\$	(22,369,829)						
Potential Available Funds as of August 1, 2017	\$	127,289	\$	2,508,673	\$	-					\$	2,635,96
Operating Budget Detail												
Indirect Administration									\$	3,030,652		
Indirect Administration Grant Review & Award Operations									\$	13,770,226		
Indirect Administration												



#### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER

**SUBJECT:** NEW INITIATIVE SCOPING

**DATE:** AUGUST 7, 2017

A working group consisting of CPRIT staff, Mr. Geren and Dr. Rice is evaluating the possibility of a new funding mechanism possibly emanating from the Academic Research Program. This could be a new Request for Applications (RFA) that identifies a specific problem or issue in cancer research, treatment or prevention to be addressed through an interinstitutional and interdisciplinary collaboration. The issue or problem may be Texas-centric. Collaborators could include private sector health care providers, nongovernmental organizations, and third-party payers.

This initiative is largely stimulated by a presentation made by Ms. Susan Dawson at the February 15, 2016, Oversight Committee meeting. Ms. Dawson is an engineer with technology and educational entrepreneurial experience and has chaired the Greater Austin Chamber of Commerce. Her February presentation piqued the interest of Mr. Geren and Dr. Rice who have continued a dialogue, primarily with Kristen Doyle, Deputy Executive Officer, and me concerning some type of new initiative along the lines proposed by Ms. Dawson.

In the ensuing weeks Ms. Dawson has met individually with Dr. Willson, Chief Scientific Officer, Ms. Doyle, and me to expand on her ideas.

If such an initiative appears viable, it could be a new grant making approach to complement CPRIT's existing portfolio of RFA mechanisms. It could represent a new policy direction with fiscal implications. As such, I requested that Mr. Geren and Dr. Rice participate in the development of this initiative to ensure OC awareness of and input to this effort.

The first meeting occurred August 1 with subsequent meetings planned after the August 16 Oversight Committee meeting.

Updates on this activity will be provided as warranted.



#### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS

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

HEIDI MCCONNELL, CHIEF OPERATING OFFICER

**SUBJECT:** CPRIT FUNDING SCENARIOS THROUGH FY 2023

**DATE:** AUGUST 7, 2017

#### **Summary**

Three funding scenarios are presented to illustrate projected annual budgets and to stimulate discussion of how CPRIT can best use its remaining funds now that our sunset date has been extended from FY 2021 to FY 2023. No action is required.

#### **Discussion**

At the May 17, 2017, two agency annual funding projections were discussed: 1) assuming CPRIT's sunset date occurred at the end of FY 2021, and 2) assuming that CPRIT's sunset date would be extended to the end of FY 2023.

At the time CPRIT's sunset extension request had not been approved by the Legislature and signed into law by the Governor. With the certainty of CPRIT's new sunset date, staff has refined the FY 2023 annual projections. As you can see in the attachments, appropriations from our bond authority tail off in fiscal years 2020 and 2021. Unexpended balances and deobligation of awarded but unused funds can be used at any point in the remaining five years of grant making authority to allow grant awards in an amount not to exceed \$300 million per year (statutory cap: V.T.C.A., Health & Safety Code §102.253) plus operational expenses and transfers to the Department of State Health Services for the Texas Cancer Registry (about \$20 million per year).

The reduction in funds available for grants in out years necessitates discussion about how best to make use of those funds. Although the unexpended and deobligated balances could be used beginning as soon as FY 2018, my suggestion is to continue operating at the current \$300 million per year level (about \$280 million per year for awards) and hold the balances for a "gentle downward slope" towards FY 2023. There are operational advantages to this that will be discussed at the Oversight Committee meeting. However, the OC may choose a different tact within statutory and constitutional constraints.

To illustrate the situation, staff provides three scenarios for consideration. The primary rationale behind the three scenarios is continuing grant making through FY 2022, the last year the agency

can award grants, with the least costly operating costs to support the grant making process. The rationale for each will be explained in more detail at the meeting on August 16.

- 1. Fund Only Academic Research Recruitment Awards in FY 2022
- 2. Fund Only Academic Research Recruitment and Product Development Awards in FY 2022
- 3. Fund Academic Research Recruitment, Prevention Dissemination and Product Development Awards in FY 2022

Again, these are not the only scenarios one could devise but are presented to stimulate discussion. No action is necessary on August 16.

CPRIT FUNDING SCENARIOS THROUGH FY 2023

#### SCENARIO 1: FUND ONLY ACADEMIC RESEARCH RECRUITMENT AWARDS IN 2022

Ī			Appropriations																				
	Appropriation Year	Original Appropriations	Obligated Appropriations Authority	Issued Debt	Unobligated Appropriations Authority	Available Funds from Deobligated Grants (Remaining Balances from Closed Grants as of July 2017)	Reduction for ERS Transfers for DSHS Retired Employee Insurance Payments	Revised Available Funds from Deobligated Grants	Apply Previously Unobligated Appropriations Authority	Apply Funds from Grant Deobligations	Revised Appropriations	Appropriations for Agency Operations and Transfer to DSHS	Appropriations Available for Grant Awards (Post Transfers to Operations)	Prevention Grants Announced/ Projected	Percent PREV Awards of Available Award Funding	Academic Research Grants Awarded/ Projected	Percent AR Awards of Available Award Funding	Development	Percent PDR Awards of Available Award Funding	Total Grant Awards Awarded/ Projected	Total Research Award Funding Only	Percent AR Awards of Available Research Awards	PDR Awards of
	2010	\$ 225,000,000	,,			\$ 37,004,515	\$ (10,779)	\$ 36,993,736	\$ -					\$ 21,700,848	10.0%	\$ 165,064,450	76.4%	\$ 29,367,880	13.6%	\$ 216,133,178	\$ 194,432,330	84.9%	15.1%
ļ	2011	\$ 225,000,000	, , , , , , , , , , , , , , , , , , , ,			\$ 4,606,702	\$ (11,953)		·					\$ 21,699,312	10.2%	\$ 183,271,663	86.0%	\$ 5,680,310			\$ 188,951,973		
ļ	2012	\$ 300,000,000	\$ 287,928,167	\$ 277,905,393		\$ 10,711,004	\$ (103,591)	, .,,	•					\$ 28,932,838	10.3%	\$ 179,570,602	63.8%	\$ 60,844,537			\$ 240,415,139		
Moratorium	2013	\$ 300,000,000	\$ 122,244,623	\$ 107,499,420		\$ 1,606,595	\$ (91,534)						\$ 280,409,352		4.8%	\$ 91,917,150		\$ -	0.0%	\$ 105,493,808			0.0%
ł	2014	\$ 300,000,000	\$ 276,327,248			\$ 1,465,134	\$ (134,151)	\$ 1,330,983					\$ 279,507,332		10.1%	\$ 132,614,775	47.4%	\$ 94,873,114	33.9% 20.4%		\$ 227,487,889	58.3%	41.7%
H	2015 2016	\$ 300,000,000 \$ 300,000,000	\$ 292,332,529 \$ 298,792,850				\$ (129,694) \$ (133,767)	\$ (129,694) \$ (133,767)	•				\$ 279,308,900 \$ 279,658,846		10.0% 9.6%	\$ 184,874,401 \$ 197,599,561	66.2%	\$ 57,042,276 \$ 53,913,939	20.4%		\$ 241,916,677 \$ 251,513,500		
In progress	2017	\$ 300,000,000	\$ 290,792,030	\$ 28,292,974		¢ -	\$ (133,767)	\$ (133,767)	•				,,.	\$ 26,043,833	9.3%	\$ 212,911,661	76.0%	\$ 41.144.783	14.7%		\$ 254,056,444		
Appropriated	2017	\$ 300,000,000		20,272,774		\$ -	\$ (133,767)	\$ (133,767)	•					\$ 28,022,956	10.0%	\$ 176.453.843		\$ 75.623.075			\$ 252,076,918		
Appropriated	2019	\$ 300,000,000				\$ -	\$ (133,767)	\$ (133,767)	•					\$ 28,022,956	10.0%	\$ 176,453,843	63.0%	\$ 75,623,075			\$ 252,076,918		
Original Last Award Year	2020	\$ 137,000,000				\$ -	\$ (133,767)	\$ (133,767)		\$ -	\$ 192,000,000	\$ 20,000,000	\$ 172,000,000		10.0%	\$ 108,360,000		\$ 46,440,000			\$ 154,800,000		
Original Sunset	2021	\$ 13,000,000				\$ -	\$ (133,767)	\$ (133,767)	· · · · · ·		\$ 156,949,628	\$ 20,000,000	\$ 136,949,628		10.0%	\$ 86,278,266	63.0%	\$ 36,976,400			\$ 123,254,665	70.0%	
Revised Last Award Year	2022*	\$ -				\$ -	\$ (133,767)	\$ (133,767)	\$ 13,000,000	\$ 53,842,111	\$ 66,842,111	\$ 13,000,000	\$ 53,842,111	\$ -	0.0%	\$ 53,842,111	100.0%	\$ -	0.0%	\$ 53,842,111	\$ 53,842,111	100.0%	0.0%
Revised Sunset	2023**	\$ -				\$ -	\$ (133,767)	\$ (133,767)	\$ 13,000,000	\$ -	\$ 13,000,000	\$ 13,000,000		\$ -		\$ -		\$ -		\$ -	\$ -		
İ		\$ 3,000,000,000		\$ 1,293,800,000	\$ 224,949,628	\$ 55,393,949	\$ (1,551,838)	\$ 53,842,111	\$ 224,949,628	\$ 53,842,111	\$ 428,791,739			\$ 282,069,898		\$ 1,949,212,326		\$ 577,529,389		\$ 2,808,811,612	\$ 2,526,741,714		

<sup>\*</sup>Assumptions: 1) No peer review panels meetings; 2) SRC only meets by phone to review recruitment applications during first 6 months of year then disband to reduce honorariam costs further; 3) Honoraria only paid to PRC thair and PDRC at reduced amounts for progress report review; 4) Don't know administrative costs for Texas Safekeeping Trust grant award management and research grant revenue sharing monitoring.

\*\* Assumptions: Operating funds for necessary post-award grant management, compliance monitoring program, and other required agency functions.

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CPRIT FUNDING SCENARIOS THROUGH FY 2023

#### SCENARIO 2: FUND ACADEMIC RESEARCH RECRUITMENT AND PRODUCT DEVELOPMENT AWARDS IN 2022

- [							Appropri	ations								Gr	ant Funding						
	Appropriation Year	Original Appropriations	Obligated Appropriations Authority	Issued Debt	Unobligated Appropriations Authority	Available Funds from Deobligated Grants (Remaining Balances from Closed Grants as of July 2017)	Reduction for ERS Transfers for DSHS Retired Employee Insurance Payments	Revised Available Funds from Deobligated Grants	Apply Previously Unobligated Appropriations Authority	Apply Funds from Grant Deobligations	Revised Appropriations	Appropriations for Agency Operations and Transfer to DSHS	Appropriations Available for Grant Awards (Post Transfers to Operations)	Prevention Grants Announced/ Projected	Percent PREV Awards of Available Award Funding		Percent AR Awards of Available Award Funding	Product Development Research Grants Awarded/ Projected	Percent PDR Awards of Available Award Funding	Total Grant Awards Awarded/ Projected	Total Research Award Funding Only	Awards of	PDR Awards o
	2010	\$ 225,000,000	\$ 225,000,000	\$ 225,000,000	\$ -	\$ 37,004,515	\$ (10,779)	\$ 36,993,736	\$ -				\$ 216,163,477	\$ 21,700,848	10.0%	\$ 165,064,450	76.4%	\$ 29,367,880	13.6%	\$ 216,133,178	\$ 194,432,330	84.9%	15.1%
	2011	\$ 225,000,000	\$ 222,424,955	\$ 207,458,391	\$ 2,575,045	\$ 4,606,702	\$ (11,953)	\$ 4,594,749	\$ -				\$ 213,226,330	\$ 21,699,312	10.2%	\$ 183,271,663	86.0%	\$ 5,680,310	2.7%	\$ 210,651,285	\$ 188,951,973	97.0%	3.0%
	2012	\$ 300,000,000	\$ 287,928,167	\$ 277,905,393	\$ 12,071,833	\$ 10,711,004	\$ (103,591)	\$ 10,607,413	\$ -				\$ 281,408,334	\$ 28,932,838	10.3%	\$ 179,570,602	63.8%	\$ 60,844,537	21.6%	\$ 269,347,977	\$ 240,415,139	74.7%	25.3%
ratorium	2013	\$ 300,000,000	\$ 122,244,623	\$ 107,499,420	\$ 177,755,377	\$ 1,606,595	\$ (91,534)	\$ 1,515,061	\$ -				\$ 280,409,352	\$ 13,576,658	4.8%	\$ 91,917,150	32.8%	\$ -	0.0%	\$ 105,493,808	\$ 91,917,150	100.0%	0.0%
	2014	\$ 300,000,000	\$ 276,327,248	\$ 217,410,055	\$ 23,672,752	\$ 1,465,134	\$ (134,151)	\$ 1,330,983	\$ -				\$ 279,507,332	\$ 28,346,692	10.1%	\$ 132,614,775	47.4%	\$ 94,873,114	33.9%	\$ 255,834,581	\$ 227,487,889	58.3%	41.7%
	2015	\$ 300,000,000	\$ 292,332,529	\$ 138,323,708	\$ 7,667,471	\$ -	\$ (129,694)	\$ (129,694)	\$ -				\$ 279,308,900	\$ 27,890,646	10.0%	\$ 184,874,401	66.2%	\$ 57,042,276	20.4%	\$ 269,807,323	\$ 241,916,677	76.4%	23.6%
	2016	\$ 300,000,000	\$ 298,792,850	\$ 91,910,059	\$ 1,207,150	\$ -	\$ (133,767)	\$ (133,767)	\$ -				\$ 279,658,846	\$ 26,938,196	9.6%	\$ 197,599,561	70.7%	\$ 53,913,939	19.3%	\$ 278,451,696	\$ 251,513,500	78.6%	21.4%
rogress	2017	\$ 300,000,000		\$ 28,292,974		\$ -	\$ (133,767)	\$ (133,767)	\$ -				\$ 280,229,568	\$ 26,043,833	9.3%	\$ 212,911,661	76.0%	\$ 41,144,783	14.7%	\$ 280,100,277	\$ 254,056,444	83.8%	16.2%
propriated	2018	\$ 300,000,000				\$ -	\$ (133,767)	\$ (133,767)	\$ -	·			\$ 280,099,874	\$ 28,022,956	10.0%	\$ 176,453,843	63.0%	\$ 75,623,075	27.0%	\$ 280,099,874	\$ 252,076,918	70.0%	30.0%
ropriated	2019	\$ 300,000,000				\$ -	\$ (133,767)	\$ (133,767)	\$ -	·			\$ 280,099,874	\$ 28,022,956	10.0%	\$ 176,453,843	63.0%	\$ 75,623,075	27.0%	\$ 280,099,874	\$ 252,076,918	70.0%	30.0%
nal Last Award Year	2020	\$ 137,000,000				\$ -	\$ (133,767)	\$ (133,767)	\$ 55,000,000	\$ -	\$ 192,000,000	\$ 20,000,000	\$ 172,000,000	\$ 17,200,000	10.0%	\$ 108,360,000	63.0%	\$ 46,440,000	27.0%	\$ 172,000,000	\$ 154,800,000	70.0%	30.0%
nal Sunset	2021	\$ 13,000,000				\$ -	\$ (133,767)	\$ (133,767)	\$ 142,949,628	\$ -	\$ 155,949,628	\$ 20,000,000	\$ 135,949,628	\$ 13,594,963	10.0%	\$ 85,648,266	63.0%	\$ 36,706,400	27.0%	\$ 135,949,628	\$ 122,354,665	70.0%	30.0%
ed Last Award Year	2022*	\$ -				\$ -	\$ (133,767)	\$ (133,767)	\$ 14,000,000	\$ 53,842,111	\$ 67,842,111	\$ 14,000,000	\$ 53,842,111	\$ -	0.0%	\$ 37,689,478	70.0%	\$ 16,152,633	30.0%	\$ 53,842,111	\$ 53,842,111	70.0%	30.0%
ed Sunset	2023**	\$ -				\$ -	\$ (133,767)	\$ (133,767)	\$ 13,000,000	\$ -	\$ 13,000,000	\$ 13,000,000	\$ -	\$ -		\$ -		\$ -		\$ -	\$ -		
Ī		\$ 3,000,000,000		\$ 1,293,800,000	\$ 224,949,628	\$ 55,393,949	\$ (1,551,838)	\$ 53,842,111	\$ 224,949,628	\$ 53,842,111	\$ 428,791,739			\$ 281,969,898		\$ 1,932,429,692		\$ 593,412,022		\$ 2,807,811,612	\$ 2,525,841,714		

<sup>\*</sup> Assumptions: 1) SRC only meets by phone to review recruitment applications during first 6 months of year then disband as in first scenario; 2) PDRC and one product development review product development applications during first 6 months of year along with legal and business management due diligence contracts in place; 3) Honoraria only paid to PRC chair and PDRC at reduced amounts for progress report review after first 6 months of year; 4) Don't know administrative costs for Texas Safekeeping Trust grant award management and research grant revenue sharing monitoring.

2

<sup>\*\*</sup> Assumptions: Operating funds for necessary post-award grant management, compliance monitoring program, and other required agency functions.

CPRIT FUNDING SCENARIOS THROUGH FY 2023

#### SCENARIO 3: FUND ACADEMIC RESEARCH RECRUITMENT, PREVENTION DISSEMINATION, AND PRODUCT DEVELOPMENT AWARDS IN 2022

SCENARIO S. FUND F			Appropriations Grant Funding																				
	Appropriation Year	Original Appropriations	Obligated Appropriations Authority	Issued Debt	Unobligated Appropriations Authority	Available Funds from Deobligated Grants (Remaining Balances from Closed Grants as of July 2017)	Reduction for	Revised Available Funds from Deobligated Grants	Apply Previously Unobligated Appropriations Authority	Apply Funds from Grant Deobligations	Revised Appropriations	Appropriations for Agency Operations and Transfer to DSHS	Appropriations Available for Grant Awards (Post Transfers to Operations)	Prevention Grants Announced/ Projected	Percent PREV Awards of Available Award Funding	Academic	Percent AR	Product Development	Percent PDR Awards of Available Award Funding	Total Grant Awards Awarded/ Projected	Total Research Award Funding Only	Awards of Available Research	PDR Awards of
	2010	\$ 225,000,000	\$ 225,000,000	\$ 225,000,000	\$ -	\$ 37,004,515	\$ (10,779)	\$ 36,993,736	\$ -				\$ 216,163,477	\$ 21,700,848	10.0%	\$ 165,064,450	76.4%	\$ 29,367,880	13.6%	\$ 216,133,178	\$ 194,432,330	84.9%	15.1%
	2011	\$ 225,000,000	\$ 222,424,955	\$ 207,458,391	\$ 2,575,045	\$ 4,606,702	\$ (11,953)	\$ 4,594,749	\$ -				\$ 213,226,330	\$ 21,699,312	10.2%	\$ 183,271,663	86.0%	\$ 5,680,310	2.7%	\$ 210,651,285	\$ 188,951,973		
	2012	\$ 300,000,000	\$ 287,928,167	\$ 277,905,393	\$ 12,071,833	\$ 10,711,004	\$ (103,591)	\$ 10,607,413	\$ -				\$ 281,408,334	\$ 28,932,838	10.3%	\$ 179,570,602	63.8%	\$ 60,844,537	21.6%	\$ 269,347,977	\$ 240,415,139	74.7%	25.3%
Moratorium	2013	\$ 300,000,000	\$ 122,244,623	\$ 107,499,420	\$ 177,755,377	\$ 1,606,595	\$ (91,534)	\$ 1,515,061	\$ -				\$ 280,409,352	\$ 13,576,658	4.8%	\$ 91,917,150	32.8%	\$ -	0.0%	\$ 105,493,808	\$ 91,917,150		
	2014	\$ 300,000,000	\$ 276,327,248			\$ 1,465,134	\$ (134,151)	\$ 1,330,983	\$ -				\$ 279,507,332	\$ 28,346,692	10.1%	\$ 132,614,775	47.4%	\$ 94,873,114	33.9%	\$ 255,834,581	\$ 227,487,889		41.7%
	2015	\$ 300,000,000	\$ 292,332,529	\$ 138,323,708	\$ 7,667,471	\$ -	\$ (129,694)	\$ (129,694)	\$ -				\$ 279,308,900	\$ 27,890,646	10.0%	\$ 184,874,401	66.2%	\$ 57,042,276	20.4%	\$ 269,807,323	\$ 241,916,677	76.4%	23.6%
	2016	\$ 300,000,000	\$ 298,792,850	\$ 91,910,059	\$ 1,207,150	\$ -	\$ (133,767)	\$ (133,767)	\$ -				\$ 279,658,846	\$ 26,938,196	9.6%	\$ 197,599,561	70.7%	\$ 53,913,939	19.3%	\$ 278,451,696	\$ 251,513,500	78.6%	21.4%
In progress	2017	\$ 300,000,000		\$ 28,292,974		\$ -	\$ (133,767)	\$ (133,767)	\$ -				\$ 280,229,568	\$ 26,043,833	9.3%	\$ 212,911,661	76.0%	\$ 41,144,783	14.7%	\$ 280,100,277	\$ 254,056,444	83.8%	16.2%
Appropriated	2018	\$ 300,000,000				\$ -	\$ (133,767)	\$ (133,767)	\$ -				\$ 280,099,874	\$ 28,022,956	10.0%	\$ 176,453,843	63.0%	\$ 75,623,075	27.0%	\$ 280,099,874	\$ 252,076,918	70.0%	30.0%
Appropriated	2019	\$ 300,000,000				\$ -	\$ (133,767)	, . ,						\$ 28,022,956		\$ 176,453,843		,,	27.0%		\$ 252,076,918		30.0%
Original Last Award Year	2020	\$ 137,000,000				\$ -	\$ (133,767)	, . ,	\$ 55,000,000	\$ -	\$ 192,000,000	\$ 20,000,000	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	\$ 17,200,000		\$ 108,360,000		\$ 46,440,000	27.0%		\$ 154,800,000		30.0%
Original Sunset	2021	\$ 13,000,000				\$ -	\$ (133,767)	, . ,	\$ 142,799,628	\$ -	\$ 155,799,628			\$ 13,579,963				\$ 36,665,900			\$ 122,219,665		30.0%
Revised Last Award Year	2022*	\$ -				\$ -	\$ (133,767)	, . ,	7					\$ 5,384,211	10.0%	\$ 33,920,530	63.0%	\$ 14,537,370	27.0%	\$ 53,842,111	\$ 48,457,900	70.0%	30.0%
Revised Sunset	2023**	\$ -				\$ -	\$ (133,767)	\$ (133,767)		-	\$ 13,000,000	\$ 13,000,000	\$ -	\$ -		\$ -		\$ -		\$ -	\$ -		
		\$ 3,000,000,000	\$ 1,725,050,372	\$ 1,293,800,000	\$ 224,949,628	\$ 55,393,949	\$ (1,551,838)	\$ 53,842,111	\$ 224,949,628	\$ 53,842,111	\$ 428,791,739			\$ 287,339,109		\$ 1,928,566,245		\$ 591,756,259		\$ 2,807,661,612	\$ 2,520,322,503		

<sup>\*</sup> Assumptions: 1) SRC only meets by phone to review recruitment applications during first six months of year then disband as in first scenario; 2) PRC only meets by phone to review product development applications during first half of year along with legal and business management due diligence contracts in place; 3) PRC only meets by phone to review prevention dissemination applications during the first 6 months of year then disband, 4) Honoraria only paid to PRC chair and PDRC at reduced amounts for progress report review after first 6 months of year, 5) Don't know administrative costs for Texas Safekeeping Trust grant award management and research grant revenue sharing monitoring. 6) Last year to make \$2.9 million transfer to DSHS for

<sup>\*\*</sup> Assumptions: Operating funds for necessary post-award grant management, compliance monitoring program, and other required agency functions.

#### CPRIT MANAGEMENT DASHBOARD FISCAL YEAR 2017

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG		CUMULATIVE
ACCOUNTABILITY													(ANNUAL)	(TO DATE)
Announced Grant Awards	42		40			14			10				84	
	12		48						10					
New Grant Contracts Signed	9	15	6	4	21	11	10	20	5	3	1		105	
New Grant Contracts In Negotiation			41			15			13				69	
Grant Reimbursements Processed (#)	147	182	186	289	216	217	237	181	100	268	164		2,187	
<b>Grant Reimbursements Processed (\$)</b>	\$ 16,840,484	\$ 13,844,271	\$ 15,610,663	\$ 25,547,229	\$ 24,395,194	\$ 35,405,089	\$ 22,446,293	\$ 17,441,664	\$ 10,746,189	\$ 23,995,193	\$ 16,305,485		\$ 222,577,754	
Revenue Sharing Payments Received	\$ 4,000	\$ -	\$ 11,862	\$ -	\$ -	\$ 21,339	\$ -	\$ 5,728	\$ 12,889	\$ 18,126	\$ -		\$ 73,945	\$ 3,209,148
Total Value of Grants Contracted (\$)	\$ 30,061,230	\$ 29,635,362	\$18,107,181	\$ 2,866,290	\$ 35,989,029	\$ 19,487,212	\$ 21,237,864	\$ 47,311,317	\$ 7,564,206	\$ 9,494,530	\$ 2,000,000		\$ 223,754,221	
Grants Awarded (#)/ Applications Rec'd (#)	12%	12%	13%	13%	13%	13%	13%	13%	13%	12%	12%			
Debt Issued (\$)/Funding Awarded (\$)	64%	67%	64%	64%	67%	73%	73%	73%	72%	72%	72%			
Grantee Compliance Trainings/Monitoring Visits	0	4	3	0	0	4	4	5	3	2	7		32	
Awards with Delinquent Reimbursement Submission (FSR)			1			0			11					63
Awards with Delinquent Matching Funds Verification			0			0			0					22
Awards with Delinquent Progress Report Submission			2			0			7					31
IA Agency Operational Recommendations Implemented	0	0	0	0	0	0	0	0	0	8	8			
IA Agency Operational Recommendations In Progress	8	8	8	8	8	8	8	8	8	0	0			
Open RFAs	11	3	5	10	10	10	13	8	8	13	8			
Prevention Applications Received	36	0	0	0	0	0	40	0	0	0	0		76	716
Product Development Applications Received	19	0	0	0	0	20	0	0	0	0	0		39	383
Research Applications Received	2	2	3	3	169	7	12	12	0	532	0		742	6,010
Help Desk Calls/Emails	230	247	167	110	254	254	163	195	331	214	269		2,434	
MISSION														
ACADEMIC RESEARCH														
PROGRAM Number of Descends Create Awarded														
Number of Research Grants Awarded (Annual)			46			6			10				62	
Recruited Scientists Announced														173
Recruited Scientists Accepted														135
Recruited Scientists Contracted														124
Published Articles on CPRIT-Funded														
Projects (#)														
Jobs Created & Maintained (#)														
Trainees in CPRIT-Funded Training Programs (#)														
Open Clinical Trials (#)														33
Number of Patents Resulting from Research														
Number of Patent Applications														

#### CPRIT MANAGEMENT DASHBOARD FISCAL YEAR 2017

	SEPT	ОСТ	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Investigational New Drugs														
DD ODLIGT DEVEL ODMENT														
PRODUCT DEVELOPMENT RESEARCH PROGRAM														
Number of Product Development Grant			2			0			0				2	
Awarded (Annual)			2			U			0				2	
Life Science Companies Recruited (in TX)														9
Published Articles on CPRIT-Funded														
Projects														
Number of Jobs Created & Maintained														
Open Clinical Trials (#)														7
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)			0			9			0				9	
People Served by CPRIT-Funded Prevention and Control Activities			181,686			211,700			217,524				610,910	
People Served through CPRIT-Funded Education and Training			89,885			107,761			95,298				292,944	
People Served through CPRIT-Funded Clinical Services			91,801			103,939			122,226				317,966	
TRANSPARENCY														
Total Website Hits (Sessions)	5,975	5,618	7,019	5,137	8,089	7,798	6,805	5,577	7,072	6,612	5,202		70,904	
Total Unique Visitors to Website (Users)	4,485	4,009	4,768	3,608	5,563	5,673	4,978	3,848	4,692	4,653	3,883		50,160	



#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

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

**SUBJECT:** CPRIT ACTIVITIES UPDATE – JUNE 2017

**DATE:** JUNE 30, 2017

Topics in this memo include recent milestones in our fight against cancer, a legislative wrap-up, a staffing summary, CPRIT outreach efforts, and updates from Compliance, Programs, and Operations.

# **Recent Milestones in the Fight Against Cancer**

#### CPRIT Grantees & Advisors in the News

- Peter Jones, Ph.D., D.Sc., CPRIT Scientific Review Council member and Chief Scientific
  Officer of the Van Andel Research Institute, received the National Cancer Institute's
  Outstanding Investigator Award. Dr. Jones is one of 25 recipients of the Outstanding
  Investigator Award. The National Cancer Institute created the award to provide extended
  funding stability and encourage investigators to embark on projects of unusual potential in
  cancer research. The National Academy of Sciences elected Dr. Jones as a member last year.
- The New York Academy of Sciences named UT Southwestern biochemist and CPRIT grantee, Dr. Benjamin Tu, a finalist for the 2017 Blavatnik National Awards for Young Scientists. The awards celebrate the excellence of outstanding early-career scientists and engineers from institutions across the United States. Dr. Tu is one of 10 finalists in the Life Sciences category selected from over 300 nominations. Dr. Tu recently published a study in *Molecular Cell* that determined that cellular modifications in histones a class of proteins that package DNA serve an unexpected metabolic function with implications in a variety of diseases, including cancer.
- Dr. Adrian Gee, Ph.D., Professor, Pediatrics, Baylor College of Medicine, and Principal Investigator of the CPRIT-supported Texas Assistance for Cancer Cell Therapy core resource was cited in a recent editorial appearing in *Science*, "For experimental cancer therapy, a struggle to ensure supply keeps up with demand." The editorial described the challenges in providing patients access to chimeric antigen receptor T- cell therapy (CAR-T). CAR-T cells are a transformative cancer therapy based on modified immune cells designed to seek out and destroy cancer. The approach for blood cancers in particular has been remarkable, saving patients who had exhausted all other treatment options. CAR-T cell therapy requires access to a specialized cell therapy facility to remove a patient's immune cells, genetically modify them to fight their particular cancer, and then transfuse them back. The lack of facilities to

prepare the cells hampers access to CAR-T cell therapy. In the *Science* editorial, Dr. Gee pointed out that investments in a facility at Baylor to manufacture CAR-T cells have supported innovative clinical trials in Texas providing patients access to CAR-T cells.

# Notable CPRIT Supported Research and Prevention Accomplishments

- CPRIT grantee, Padmanee Sharma, M.D., Ph.D., of MD Anderson Cancer Center, reported in *The Lancet Oncology* on the results of a clinical trial of the PD-I inhibitor, nivolumab, that led to durable responses in patients with metastatic bladder cancer who had previously failed standard chemotherapy. Nivolumab produced responses in one-fifth of patients treated, and the tumors that expressed the PD-L1 biomarker were the most likely to respond. The clinical trial supported the recent "Accelerated Approval" by the U.S. Food and Drug Administration of nivolumab in previously treated advanced bladder cancers.
- A clinical trial led by CPRIT grantee Robert Timmerman, M.D., at UT Southwestern successfully decreased early-stage breast cancer treatments from nearly two months to just days. The trial, reported in the *International Journal of Radiation Oncology, Biology and Physics*, found that stereotactic partial breast radiation was as safe as traditional radiation but decreased treatment time from six weeks to just days. Stereotactic radiation therapy delivers precisely targeted radiation in fewer high-dose treatments than traditional therapy, which decreases treatment time, preserves healthy tissue, and improves cosmetic results.
- Genetic manipulation of exosomes, virus-sized particles released by all cells, offers a new therapeutic approach to treating pancreatic cancer, according to a CPRIT funded study at The University of Texas MD Anderson Cancer Center. Findings published in *Nature* demonstrate that exosomes may serve as vehicles for gene therapy against pancreatic cancers. The treatment, utilizing a targeting method called "RNA interference" (RNAi) delivered via the exosomes, zeroes in on pancreas cancer cells and turns off the targeted gene responsible for the cancer. This important study demonstrates that exosomes have the potential to overcome a major limitation of gene therapy by efficiently homing in on a cancer to deliver a gene-targeted therapy.
- Scientists at The University of Texas at Dallas have found that some types of cancers have more of a "sweet tooth" than other cancers. Cancer cells are known to be heavily dependent on sugar as a fuel for growth. A CPRIT funded project reported in *Nature Communications*, found that one specific cancer type squamous cell carcinoma is remarkably more dependent on sugar compared to other cancers. This increased dependence was explained by the presence of higher levels of glut1, the protein responsible for transporting sugar into cells. When the scientists treated mice with the squamous cell carcinoma with a drug that blocks glut1's action, the tumors stopped growing. This research suggests the role that altered sugar uptake has in the development of some cancers and that sugar consumption is not only a problem that can lead to complications like diabetes, but may also affect some cancers that are highly dependent on sugar. The UT Dallas group plans to examine the effect of a sugar-restricted diet on the progression of cancer in an animal model.

- The University of Texas Health Science Center at Tyler's colorectal coalition CPRIT grant, "Improving Access to Colorectal Cancer Screening in East Texas" was recognized as a "remarkable project" at the America Essential Hospitals Conference in Chicago (VITAL2017) on June 22. Carlton Allen, Program Manager, presented at the conference on June 21-23.
- Aravive Biologics (formerly Ruga Corporation) announced the hiring of a new CEO, Dr. Stephen Eck, to lead the company's drug candidate into clinical trials. Dr. Eck is a hematologist with extensive expertise and experience in the drug development industry. Aravive is developing unique cancer therapies targeting advanced or metastatic disease. The company has generated strong preclinical data in acute myeloid leukemia and certain advanced solid tumors, including ovarian, pancreatic, and breast cancers. Aravive's success attracting an industry veteran in drug development to lead the company is an encouraging sign for the Aravive's potential. Aravive received a Product Development Research grant in November 2015.
- DNAtrix Therapeutics announced results from preclinical and clinical studies of their oncolytic poxvirus therapy at conferences this spring.

DNAtrix presented favorable safety and efficacy data for its lead adenovirus-based product for the treatment of glioblastoma at the 2017 Annual Meeting of the American Society of Clinical Oncology in Chicago. Frederick F. Lang, MD, FACS, FAANS, Director of Clinical Research in the Department of Neurosurgery at The University of Texas MD Anderson Cancer Center, presented the clinical results. The study showed that the therapy provided clinical benefit and extended survival for patients with recurrent glioblastoma.

Dr. Grant McFadden presented the results of a preclinical study at the 2017 Annual Meeting of the American Society of Gene & Cell Therapy in Washington D.C. The study shows that treating stem cells with the myxoma virus prior to transplantation efficiently eliminates residual chemotherapy-resistant myeloma cells that remain in the transplant recipient. Eliminating these resistant cells should improve the success rate of this therapy. The myxoma virus has the ability to selectively kill cancer cells without infecting or interfering with normal cells. It can use T-cells and other white blood cells as virus "carriers" that can target and destroy tumors. DNAtrix received a Product Development Research grant in February 2014.

 Medicenna Therapeutics Corp. announced that the company has entered into a multi-year sponsored research agreement with MD Anderson Cancer Center to develop next-generation fully human IL4-Empowered Cytokines for the treatment of non-central nervous system cancers. The company raised \$14 million through a series of private placement financings to provide working capital for their lead drug development and the new IL-4 cytokines program.

# Legislative Wrap-Up

The regular session of the 85<sup>th</sup> Texas Legislature ended May 29. Appendix 1 to this memo summarizes the outcome of CPRIT's various legislative requests. We received full funding, exemption of our interest and sinking fund from funds consolidation, authority to hire three additional compliance personnel, an extension from August 31, 2021 to August 31, 2023, for our sunset date, and authority to transfer royalty and equity portfolio management to the Texas Treasury Safekeeping Trust Company. In addition, we were able to secure several operational efficiency and transparency improvements.

The one high priority item for CPRIT not approved by the Legislature was an end the annual transfer of \$2,969,554 to the Department of State Health Services to fund the Texas Cancer Registry. Given the tight fiscal constraints faced by the Legislature for the 2018-19 biennium, we knew getting this request was unlikely.

This was a difficult budget session for most state agencies and institutions of higher education. In light of the state's fiscal situation and the Legislature's struggle to get many significant statutory changes enacted -- as evidenced by the Governor's call for a special session beginning July 18 with 20 items eligible for consideration -- CPRIT's success is satisfying. It does not appear that the Governor's agenda for the special session will affect CPRIT. We will monitor the special session in the event this changes.

Many legislators participated in making this a successful session but a few deserve special recognition. Senators Jane Nelson and Kirk Watson and Representatives Sarah Davis and John Zerwas did the heavy lifting by championing this historical effort to prevent and cure cancer. The support CPRIT received from the advocacy community and Texas' institutions of higher education not only made championing CPRIT easier for our legislative friends, it also serves as a constant reminder of the hopes Texans have placed on CPRIT to accomplish our mission.

## Personnel

As of June 30, 2017, CPRIT has filled all 32 of its authorized full-time equivalent (FTE) positions.

Governor Abbott imposed a hiring freeze at all state agencies and institutions of higher education on January 31 to last through August 31, 2017. CPRIT was screening and interviewing candidates to fill the two open Grant Accountant positions and one open Grant Specialist position when the Governor announced the freeze. Due to the importance of this compliance activity, we have contracted for two temporary accountants and one temporary grant specialist to fill the three open positions.

Cathy Allen, Program Manager for Product Development will retire August 31. CPRIT has posted her position, as well as the open accountant positions in anticipation of making offers to successful candidates for September 1, 2017, start dates.

#### **CPRIT Outreach**

- Michael Lang was a panel speaker at the "Developing Diagnostics: Navigating the Path from Concept to Commercialization" workshop hosted by The University of Texas at Austin Dell Medical Center on May 4.
- Mr. Lang and Dr. Jim Willson attended the American Society of Clinical Oncologists (ASCO) Annual Meeting June 2- 6 in Chicago, Illinois. The Annual Meeting brings together more than 30,000 oncology professionals from around the world to discuss state-of-the-art treatment modalities, new therapies, and on-going controversies in the field.
- On June 8, Dr. Becky Garcia presented the keynote address at the Texas Conference on Health Disparities hosted by the University of North Texas Health Science Center in Fort Worth. The title of this year's conference was "Evidence Based Approaches to Reducing Cancer Health Disparities."
- Mr. Lang attended the BIO International Convention in San Diego, California June 18 21. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the U.S. and more than 30 nations. Mr. Lang was part of the Texas delegation, led by Texas Secretary of State Rolando Pablos and included representatives from the Texas Economic Development Corporation, the Office of Governor Greg Abbott, the Texas Healthcare and Bioscience Institute, and economic development organizations from across the State of Texas. The Texas delegation promoted Texas' advantages for businesses in the biotechnology and biomedical industries. Secretary Pablos and the delegation met with industry leaders from Australia, Belgium, France, Italy, Japan, Korea, and Spain, among other nations, to discuss the strengths of conducting cutting-edge medical and medical technology research in Texas.
- Mr. Lang and I will visit with staff of the National Cancer Institute in Rockville, Maryland on July 18. The meeting is to discuss best practices and collaboration opportunities, primarily between NCI's Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs and CPRIT's Product Development Research program. The SBIR/STTR programs are federally funded programs supporting domestic small businesses engaging in research and development with the potential for commercialization and public benefit.

# **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 26, 2017, seven required reports from five entities have not been filed by the set due date; four are Academic Research grants, one is a Product Development Research grant, and two are Prevention grants. In most cases, CPRIT does not disburse grant funds until the grantee files the required report(s). In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to resolve filing issues.

Also, during May and June two Financial Status Reports (FSRs) were submitted late and reimbursement was subsequently waived. CPRIT's administrative rules state that a grantee waives the right to reimbursement of project costs incurred during the reporting period if the FSR for that quarter is not submitted to CPRIT within 30 days of the FSR due date.

## **FSR Reviews**

CPRIT's Grant Compliance Specialists performed 154 second-level reviews of grantee Financial Status Reports (FSRs) during the month of June. Thirteen 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.

#### Desk Reviews

CPRIT staff performed eight desk reviews in June. So far this fiscal year, Compliance staff has completed 165 desk reviews. Grant Compliance Specialists perform desk-based financial monitoring/reviews during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, subcontractor monitoring, and timeliness of required grantee report submission. Grant Compliance Specialists are working with six grantees to remediate desk review findings.

#### **On-Site Reviews**

Grant Compliance staff performed one on-site review during June. On-site reviews typically include an examination of the grantee's financial and administrative operations, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Grant Compliance Specialists are working with five grantees to remediate on-site review findings.

## Annual Compliance Attestation (Self-Certification)

Grantees must submit an annual self-certification demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, the grant contract, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Grant Compliance Specialists to work proactively with grantees towards full compliance prior to a desk review or on-site

review. Compliance staff is working with nine grantees to remediate deficiencies identified in their attestations.

# 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 findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year.

Grant Compliance Specialists are working with 10 grantees to remediate audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. There is currently one grantee with a delinquent Corrective Action Plan. 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.

## **Training & Support**

CPRIT staff conducted a grantee training webinar on June 7, 2017 with approximately 160 grantee staff in attendance. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process. This webinar met the annual compliance training requirement that the Authorized Signing Official and at least one other employee from each grantee organization must attend an annual compliance training by November 1 of each year. The Compliance team has scheduled a third grantee training webinar for October 11, 2017.

# **Academic Research Program Update**

#### FY 2018 Cycle 1 (18.1) Academic Research Review Cycle

The deadline for submitting an application for the 18.1 Academic Research Program cycle was June 8, 2017. CPRIT received 532 applications. Peer review panels will evaluate these applications in October. The Scientific Review Council (SRC) will present the applications recommended for funding to the Program Integration Committee and Oversight Committee in February 2018.

CPRIT introduced a new RFA in the 18.1 cycle: *The Individual Investigator Research Award for Clinical Translation*. This mechanism will support the conduct of early phase clinical trials of novel cancer therapies or devices. Such clinical trials offer important opportunities to incorporate biomarkers, pharmacokinetic and pharmacodynamic monitoring, and/or imaging studies to provide more precise knowledge about what works, in whom, and in which types of cancer and to guide subsequent clinical development of a novel cancer therapy.

It is worth noting that the number of applications submitted for the 18.1 cycle increased by 28% compared to the first cycle of FY 2017 (17.1). The table below displays a comparison of the 17.1 and 18.1 Individual Investigator Research Award application submissions by grant type.

Table 1: Comparison of FY17.1 and FY18.1 IIRA Application Submissions by Mechanism

Fiscal Year RFA Cycles	IIRA Submitted	IIRACCA Submitted	*IIRACT Submitted	IIRACB Submitted	IIRAP Submitted	Total Submissions
18.1	356	39	54	43	40	532
17.1	292	45	n/a	44	35	416

IIRA: Individual Investigator Research Awards

IIRACCA: Individual Investigator Research Awards for Cancer in Children and Adolescents

IIRACB: Individual Investigator Research Awards for Computational Biology IIRACT: Individual Investigator Research Awards for Clinical Translation

IIRAP: Individual Investigator Research Awards for Prevention and Early Detection

#### Recruitment Cycles 17.10 – 17.12

Table 2 displays the number of applications submitted for Cycles 17.10 through 17.12, which the SRC will review in July 2017. Note that because the recruitment RFAs are continuously open and the SRC meets monthly, there are 12 review cycles. The SRC will present its recommended grant applications to the Program Integration Committee and Oversight Committee in August 2017.

Table 2: Summary of Recruitment Application Submissions Cycles 17.10 – 17.12

Cycles 17.10-17.12	# Applications Submitted
Recruitment Established Investigators	4
Recruitment Rising Stars	2
Recruitment of First-Time Tenure Track Faculty Members	19
Total	25

Table 3 displays FY 2015, FY 2016 and FY 2017 comparative recruitment data by grant type. Note that FY 17 data represents information collected for cycles 17.1 through 17.9.

Table 3: FY 2015, FY 2016 and FY 2017\* Comparative Data

		I ubic c	• = = = • = • ;	1 2010 unu 1 1 2017 Comparative Duta							
	Recruitr	nent Establ	ished	Recruitm	ent Rising	Stars	Recruitment of First-Time				
	In	Investigators					Tenure Track Faculty Members				
Fiscal	Submitted	Approved	Approval	Submitted	Approved	Approval	Submitted	Approved	Approval		
Year			Rate			Rate			Rate		
2015	10	6	60%	12	7	58%	37	22	59%		
2016	17	9	53%	10	4	40%	45	23	51%		
2017*	9	5	56%	7	2	29%	24	11	46%		
Total	37	20		27	13		106	56			
Average			54%			42%			52%		

<sup>\*</sup>FY17 data reflects 9 months 17.1-17.9

# **Product Development Research Program Update**

# FY 2017 Cycle 2 Product Development Research Applications

Twenty companies applied for Product Development Research awards in the second cycle of FY 2017. After peer review of the applications and in-person presentations, two applicants have moved forward to due diligence review. The Product Development Review Council (PDRC) will meet mid-July to consider the due diligence reports and make recommendations for grant funding. Mr. Lang will present the PDRC's recommendations for approval to the Program Integration Committee and the Oversight Committee in August.

# FY 2018 Cycle 1 Product Development Research Applications

CPRIT will post the RFAs for the first Product Development Research review cycle of FY 2018 (18.1) next week. CPRIT will accept applications starting June 29.

## Catalyzing Commercialization of Texas-Based University Research

The Product Development Advisory Council (PDAC) recommended CPRIT should seek to stimulate more university research spinouts by collaborating with academic institutions in Texas to increase company formation and commercialization activities. PDAC Chair Dr. Jonathan MacQuitty spoke about this at the May OC meeting. CPRIT is following up on this recommendation by planning two new or modified grant programs that bridge the current academic and product development programs. Dr. Willson and Mr. Lang are evaluating restarting the CPRIT ETRA program and modifying the program to focus more on clinical and commercial objectives. Mr. Lang is planning a new Seed Award program to provide startup funding to new company spinouts from Texas research institutions.

# **Prevention Program Update**

## FY 2017 Cycle 2 Prevention Applications

CPRIT released five RFAs for the second review cycle of FY 2017 (17.2) in November 2016. Peer review panels met May 31 – June 2 in Dallas to evaluate the 37 17.2 prevention applications requesting \$52,906,830. The Prevention Review Council (PRC) is meeting July 6. Dr. Garcia will present the PRC's recommendations to the Program Integration Committee and the Oversight Committee in August.

Mechanism	Number Received	Total \$ Requested
Evidence-based Cancer Prevention Services	17	\$22,511,797
Colorectal Cancer Coalition	4	\$14,619,126
Cancer Prevention Promotion and Navigation to Clinical Services	6	\$ 2,396,537
Tobacco Control and Lung Cancer Screening	10	\$13,379,370
TOTAL	37	\$52,906,830

## FY 2018 Cycle 1 Prevention RFAs

CPRIT released three RFAs for the first cycle of FY 2018 on June 8. Applications are due September 14 with peer review panels meeting December 11-14. The Oversight Committee will consider the recommendations at the February 2018 meeting. RFAs released June 8 include:

## • Evidence-Based Cancer Prevention Services

This award mechanism seeks to fund projects that will deliver evidence-based cancer prevention and control clinical services. Priority will be given to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects. Award: Maximum of \$1.5M; Maximum duration of 36 months.

## • Tobacco Control and Lung Cancer Screening

This award mechanism seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth. Award: Maximum of \$1.5M; Maximum duration of 36 months

#### • Dissemination of CPRIT-Funded Cancer Control Interventions

This award mechanism seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be in a position to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding. Award: Maximum of \$300,000; Maximum duration of 24 months.

#### FY 2018 Cycle 2 Prevention RFAs

Dr. Garcia drafted a background paper outlining new rural prevention services ideas for RFAs for the second cycle of FY 2018 (18.2). Conference calls with Prevention subcommittee members to discuss the ideas occurred June 28 and 29. We hope to release the 18.2 RFAs this fall with applications due in March, peer review in May/June, and consideration by Oversight Committee in August 2018.

#### Other activities

Prevention program staff are developing plans for updating the 2012 Texas Cancer Plan. The DSHS' Texas Comprehensive Cancer Control program, Texas Cancer Registry and Office of Surveillance, Epidemiology and Research are updating the statistics and providing input.

#### **Communications**

Dr. Garcia, Spencer Miller-Payne, and Chris Cutrone met with CPRIT institutional partners in Houston June 26-28. Meetings include discussion of communications strategies for the next 18 months, how CPRIT can assist and bring value to the institutions' initiatives and events and how to best promote the work of CPRIT grantees. Meetings occurred with government relations and communications staff of MD Anderson Cancer Center, Baylor College of Medicine, UT Health Science Center at Houston, University of Houston System, Rice University, Texas Children's Hospital, and the City of Houston.

Communications is working with Texas Tech Health Sciences Center at El Paso on a press conference to announce their first CPRIT Scholars Recruitment grant. The grant is for a First-Time, Tenure-Track Faculty member.

#### Social Media

- The Communications team continues to be active on social media focusing on cancer-related awareness such as National Cancer Survivor's Day, National Men's Health Week, National Women's Health Week, as well as promoting the work of CPRIT grantees.
- CPRIT shared a post-session update from me on Senate Bill 81 over social media and some of CPRIT's institutional partners.

#### **Innovations Conference, November 13-14**

CPRIT released a call for abstracts on June 1. Registration opens by June 30. A preliminary schedule is posted and the majority of speakers are confirmed. Calls with invited speakers to discuss logistics are being scheduled.

## **Operations and Finance Update**

- Heidi McConnell represented CPRIT at the Texas Public Finance Authority (TPFA) Board meeting on June 23. Ms. McConnell presented an update of CPRIT's activities to the TPFA before it approved CPRIT's FY 2018 request for financing for \$300 million of general obligation debt. TPFA will present its recommendation to the Bond Review Board on July 11 and 20.
- The Weaver audit team completed reports over pre-award grant management and information security. The audit team also completed fieldwork for the internal audit over procurement and P-card and follow-up procedure audits over commodity and service contracts, revenue, and cash management. Weaver is finalizing the reports for these audits.
- CPRIT issued a competitive solicitation for continuity of operations planning services on June 20 and proposals are due by July 21. The selected vendor will assist CPRIT with updating its existing business continuity plan to comply with the Federal Emergency Management Agency (FEMA) proscribed continuity of operations plan format adopted by

the state and testing the plan according to FEMA and Department of Homeland Security standards.

# **Upcoming Subcommittee Meetings**

Listed below are upcoming August Oversight Committee subcommittee meetings.

Subcommittee	Date & Time
Board Governance	August 3 at 10:00 a.m.
Audit	August 7 at 10:00 a.m.
Prevention	August 8 at 10:00 a.m.
Scientific Research	August 9 at 10:00 a.m.
Product Development	August 10 at 10:00 a.m.
Nominations*	July 28 at 10:30 a.m.

<sup>\*</sup> Note the changed time and date for the Nominations subcommittee meeting.

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

\*\*\*\*

# CPRIT has awarded 1,132 grants totaling \$1.791 billion

- 181 prevention awards totaling \$181.1 million
- 951 academic research and product development research awards totaling \$1.610 billion

Of the \$1.610 billion in academic research and product development awards,

- 29.6% of the funding (\$476.7 million) supports clinical research projects
- 26.3% of the funding (\$423.6 million) supports translational research projects
- 25.6% of funding (\$412.1 million) supports recruitment awards
- 14.8% of the funding (\$237.4 million) supports discovery stage research projects
- 3.7% of funding (\$59.9 million) supports training programs.

## CPRIT has 8 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Prevention
- 2 Product Development



#### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS

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

**SUBJECT:** CPRIT ACTIVITIES UPDATE – JULY 2017

**DATE:** JULY 31, 2017

Topics in this memo include the upcoming Oversight Committee meeting, recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, CPRIT's 2017 biennial conference preparations, and updates from Compliance, Programs, and Operations.

# **Preparation for the August 16 Oversight Committee Meeting**

The Oversight Committee will meet August 16 at 10:00 a.m. in Board Room 1.170 of the <u>Texas Higher Education Coordinating Board</u>, 1200 E. Anderson Lane, Austin, <u>Texas 78752</u>. We used this same meeting room for the most recent Oversight Committee meeting. CPRIT will post the final agenda for the Oversight Committee meeting by August 8, 2017; a tentative agenda is attached.

We have an ambitious agenda, with grant award recommendations from all three programs as well as board officer elections, end of the fiscal year updates, several audit reports, and a discussion of program priorities. Please notify me if you are not able to attend the August meeting or have travel arrangements that will cause you to leave the meeting early.

You will receive an email from CPRIT by August 4 with a link and password to access the Program Integration Committee's recommendations via the grant award portal. The portal has supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, and grant pedigree. A summary of the award slate will also be available through the portal. There will be more than 50 recommended awards; please allow time to complete the individual conflict of interest checks and review the supporting material.

Oversight Committee members should receive an electronic copy of the agenda packet by August 9. Hard copies of the agenda packet will be available at the meeting.

#### **Recent Milestones in the Fight Against Cancer**

#### Notable CPRIT Supported Research and Prevention Accomplishments

• Salarius Pharmaceuticals received FDA Orphan drug designation and FDA Pediatric Priority Review Voucher designation. Receiving an Orphan Drug designation is important because it

qualifies the company for various development incentives. To encouragement development of pediatric drugs, FDA issues a limited number of Pediatric Priority Review Vouchers. The voucher entitles the holder to accelerated FDA review (6 months vs. 10 or more months for a standard review). The company may use the voucher for one of its products or sell the voucher to another company, usually a large pharmaceutical company. These vouchers are valuable.

The Pediatric Preclinical Testing Consortium (PPTC) Steering Committee also selected Salarius for prioritized therapeutic development in childhood cancers. The PPTC seeks to accelerate the development of more effective treatments for children with cancer through funding provided by the National Cancer Institute (NCI). The Oversight Committee approved Salarius for a Product Development Research grant in May 2016.

- CPRIT Scholar Ilya Finkelstein, PhD, an assistant professor in the Department of Molecular Biosciences at UT Austin, has developed a technique that can spot editing mistakes a popular gene-editing tool known as CRISPR makes to an individual's genome. Scientists are developing CRISPR-based gene editing to correct disease causing genes and promises to have an enormous impact on human health. CRISPR gene-editing works much like fixing a recurring typo in a document with an auto-correct feature, but CRISPR sometimes targets the wrong genes, acting more like an auto-correct feature that turns correctly spelled words into typos. Editing the wrong gene could create new problems, such as causing healthy cells to become cancerous. The research reported in the journal *Cell* is an important step toward developing safer CRISPR gene-editing strategies for life-threatening disorders.
- Based on preclinical research supported in part by CPRIT, MD Anderson investigators have launched a first-in-human clinical trial of cord-blood-derived, chimeric antigen receptorequipped natural killer cells for patients with relapsed acute lymphocytic leukemia or non-Hodgkin lymphoma. The research reported in the journal *Leukemia* demonstrated that scientists can modify natural killer cells derived from donated umbilical cords to seek and destroy some types of leukemia and lymphoma.
- Baylor College of Medicine investigators reported in the *Proceedings of the National Academy of Sciences* on CPRIT supported research that identified a new target for the treatment of glioblastoma multiforme, the deadliest type of brain cancer. They discovered that CD44, a cell-surface protein, gives glioblastoma multiforme a survival advantage. In the lab, scientists can eliminate this advantage by reducing the amount of CD44 suggesting that targeting CD44s could potentially impair the growth of glioblastomas.
- During the course of Dr. Abbey Berenson's *Prenatal Education and Postpartum Administration of HPV Vaccine* project at The University of Texas Medical Branch at Galveston, many low-income women who were previously unable to obtain the HPV vaccination initiated, continued, or completed the vaccine series while in the postpartum ward. The effectiveness of the one-on-one counseling was apparent by the large number of women (3,531 doses) receiving the vaccine. CPRIT funding supports hiring, training, and maintaining the staff dedicated to the project. Rather than adding to the workload of nurses and providers, the project added a layer of support for their work and for the patients.

Practitioners now offer follow-up doses to mothers at the well-baby or 6-week postpartum visit as accepted standard of care because of the great success of this project. The Oversight Committee originally approved a Prevention grant award for Dr. Berenson's project in 2012 and awarded a competitive continuation grant in August 2016.

• Dr. Keith Argenbright's (The University of Texas Southwestern Medical Center) *Evidence-based Colorectal Cancer Screening for the Uninsured* CPRIT funded project enabled the provision of colorectal cancer screening (FIT testing) and patient navigation to low-income, uninsured patients not currently being reached. This project demonstrates the success of organized outreach as an effective model for population-based screening. Offering a less invasive and more convenient option for colorectal screening, the FIT test, expands the John Peter Smith (JPS) health system's capacity while engaging patients who would otherwise opt out of a colonoscopy. As a result of the program's success, JPS is adopting FIT testing system-wide. JPS has added additional providers and made facility scheduling changes to accommodate the increased need for follow-up colonoscopies because of the much larger volume of FIT tests. Work from this program has laid the foundation for the coalition project currently underway in a 21 county region. The Oversight Committee awarded Dr. Argenbright a Prevention Program grant for this multi-year project in May 2015.

#### Personnel

As of July 31, 2017, CPRIT has filled all 32 of its authorized full-time equivalent (FTE) positions.

Governor Abbott imposed a hiring freeze at all state agencies and institutions of higher education on January 31 to last through August 31, 2017. CPRIT was screening and interviewing candidates to fill the two open Grant Accountant positions and one open Grant Specialist position when the Governor announced the freeze. Due to the importance of this compliance activity, we have contracted for two temporary accountants and one temporary grant specialist to fill the three open positions.

CPRIT has interviewed candidates for the open grant accountant positions and have prepared offers to three individuals who start work September 1, 2017. The full time positions for the additional compliance program positions approved by the Texas Legislature are posted.

CPRIT's Program Manager for Product Development will retire August 31. We have posted the position with expectations of receiving successful candidates available for a September 1<sup>st</sup> start date.

#### **CPRIT Outreach**

• As a member of the advisory board, Dr. Garcia participated in the July 17 Texas Health Improvement Network Advisory Meeting in Austin. The Legislature established the network to address the urgent health care challenges and improve the health care system in Texas.

• Mike Lang, Chief Product Development Officer, and I met with the National Cancer Institute's Small Business Innovation Research (SBIR) and Small Business Technology Transfer Reauthorization (STTR) program staff in Rockville, Maryland, on July 18, 2017, to discuss opportunities for collaboration and to share information. The NCI's SBIR program is similar to CPRIT's Product Development Research program; both programs support product development projects at early stage companies. NCI noted that many SBIR awardees later become CPRIT applicants.

## **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 23, 2017, 19 required reports from four entities have not been filed by the set due date; 17 are Academic Research grants, one is a Product Development Research grant, and one is a Prevention grant. In most cases, CPRIT does not disburse grant funds until the grantee files the required report(s). In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to resolve filing issues.

## **FSR Reviews**

CPRIT's Grant Compliance Specialists performed 103 second-level reviews of grantee Financial Status Reports (FSRs) during July. Eight 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.

#### Desk Reviews

CPRIT staff performed 11 desk reviews in July. So far this fiscal year, Compliance staff has completed 178 desk reviews. Grant Compliance Specialists perform desk-based financial monitoring/reviews during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, subcontractor monitoring, and timeliness of required grantee report submission. Grant Compliance Specialists are working with eight grantees to remediate desk review findings.

#### On-Site Reviews

Grant Compliance staff performed seven on-site reviews during July. On-site reviews typically include an examination of the grantee's financial and administrative operations, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Grant Compliance Specialists are working with eight grantees to remediate on-site review findings.

## Annual Compliance Attestation (Self-Certification)

Grantees must submit an annual self-certification demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, the grant contract, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Grant Compliance Specialists to work proactively with grantees towards full compliance prior to a desk review or on-site review. Compliance staff is working with four grantees to remediate deficiencies identified in their attestations.

#### 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 findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year.

Grant Compliance Specialists are working with 10 grantees to remediate audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. There are currently no grantees with a delinquent Corrective Action Plan. 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.

#### Training & Support

CPRIT staff conducted a training on July 25, 2017, for the new Authorized Signing Official (ASO) for NanoTx, a Product Development Research grantee. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. CPRIT's administrative rules state that a new ASO shall complete the annual compliance training program within 60 days of change. Failure to do so may result in withholding grant award funds until training is completed.

## **Academic Research Program Update**

## FY 2017 Cycle 2 (17.2) Academic Research Review Cycle

CPRIT received 143 applications for High Impact/High Risk awards and 24 applications for Core Facility Support awards in cycle 17.2. Peer Review panels met in Dallas in April to evaluate the High Impact/High Risk and Core Facility applications. The Scientific Review Council (SRC) recommended that the Oversight Committee award grants for 26 High Impact/High Risk and Core Facility grants, totaling approximately \$34.3 million. Dr. Willson will present the grant applications recommended by the SRC to the Program Integration Committee and Oversight Committee in August.

# FY 2018 Cycle 1 (18.1) Academic Research Review Cycle

The deadline for submitting an application for the 18.1 Academic Research Program cycle was June 8, 2017. CPRIT received 532 applications, a 28% increase in applications compared to review cycle 17.1. Peer review panels will evaluate these applications in October. The Scientific Review Council (SRC) will present the applications recommended for funding to the Program Integration Committee and Oversight Committee in February 2018. The 18.1 review cycle includes a first-time grant opportunity: *The Individual Investigator Research Award for Clinical Translation*. This mechanism will support the conduct of early phase clinical trials of novel cancer therapies or devices.

#### Recruitment Cycles 17.10 – 17.12

The SRC met in July to review recruitment applications submitted for Cycles 17.10 through 17.12. (Because the recruitment RFAs are continuously open and the SRC meets monthly, there are 12 review cycles per year.) The SRC recommends that the Oversight Committee approve recruitment grants for 15 applications totaling \$38 million. Dr. Willson will present the SRC's recommendations to the Program Integration Committee and Oversight Committee in August.

# **Product Development Research Program Update**

## FY 2017 Cycle 2 (17.2) Product Development Research Applications

Twenty companies applied for Product Development Research awards in the second cycle of FY 2017. After peer review of the applications and in-person presentations in late April, two applicants moved forward to due diligence review. The Product Development Review Council (PDRC) considered the due diligence reports and made recommendations for grant funding. Mr. Lang will present one PDRC recommendation to the Program Integration Committee and the Oversight Committee in August.

## FY 2018 Cycle 1 (18.1) Product Development Research Applications

CPRIT released the RFAs for the first review cycle of FY 2018 on June 22, 2017, and started accepting applications on June 29. As of July 28, 11 applications have been started. The deadline for applications is August 10. CPRIT expects to start the review of the applications in October, with any award recommendations presented to the PIC and the Oversight Committee in February 2018.

#### Catalyzing Commercialization

The Product Development Advisory Council recommended CPRIT seek to stimulate more university research spinouts by collaborating with academic institutions to increase company formation and commercialization. The PDAC Chairman, Dr. Jonathan MacQuitty spoke about this at the May OC meeting.

CPRIT plans two new or modified grant programs that would bridge between current academic and product development programs. We are evaluating restarting the CPRIT ETRA program. Mr. Lang and Dr. Willson are working together on modifications to the program to include more focus on clinical and commercial objectives and ensure support is available for this work at academic institutions. Mr. Lang is also developing a new Seed Award program to provide

startup funding to new company spinouts from Texas research institutions. RFAs for both award mechanisms are under development.

# **Prevention Program Update**

# FY 2017 Cycle 2 (17.2) Prevention Applications

CPRIT released five RFAs for the second review cycle of FY 2017 in November 2016. Peer review panels met May 31 – June 2 to evaluate the 37 17.2 prevention applications requesting \$52,906,830. The Prevention Review Council (PRC) met July 6 to make award recommendations to the PIC and the Oversight Committee. Dr. Garcia will present the PIC's recommendations to the Oversight Committee in August.

Mechanism	Number Received	Total \$ Requested
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CPRIT released three RFAs for the first cycle of FY 2018 on June 8. Applications are due September 14 with peer review panels meeting December 11-14. The Oversight Committee will consider the recommendations at the February 2018 meeting. RFAs released June 8 include:

#### • Evidence-Based Cancer Prevention Services

This award mechanism seeks projects to deliver evidence-based cancer prevention and control clinical services. Priority will be given to projects that address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects. Award: Maximum of \$1.5M; Maximum duration of 36 months.

# • Tobacco Control and Lung Cancer Screening

This award mechanism seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobaccorelated cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth. Award: Maximum of \$1.5M; Maximum duration of 36 months.

# • Dissemination of CPRIT-Funded Cancer Control Interventions (DI)

This award mechanism seeks projects to facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be in a position to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding. Award: Maximum of \$300,000; Maximum duration of 24 months.

## Reposting of Dissemination (DI) RFA

To speed up the review and approval of applications to the Dissemination RFA, we are revising the submission and review process for this mechanism. The DI RFA will now be open continuously and reviewed only by the Prevention Review Council quarterly. Recommendations of meritorious applications, if any, will be forwarded to the Oversight Committee for consideration at the quarterly meetings. CPRIT reposted the DI RFA with submissions due October 3.

## FY 2018 Cycle 2 (18.2) Prevention RFAs

Dr. Garcia drafted a background paper outlining ideas for RFAs for the second cycle of FY 2018. Conference calls with Prevention subcommittee members to discuss the ideas occurred June 28 and 29. Ideas being explored include an RFA to expand services to rural and medically underserved areas of the state. The plan is to release the 18.2 RFAs this fall with applications due in March, peer review in May/June, and consideration by Oversight Committee in August 2018.

#### Texas Cancer Plan

Prevention program staff are planning to update the 2012 Texas Cancer Plan. The DSHS' Texas Comprehensive Cancer Control program, Texas Cancer Registry and Office of Surveillance, Epidemiology and Research are updating the statistics and providing input. CPRIT has contracted with Dr. Jennifer Redmond Knight, Assistant Professor, University of Kentucky College of Public Health and Co-Principle Investigator, Kentucky Cancer Consortium, to help with the revision.

#### **Advisory Committees**

Rice University hosted a special meeting of the University Advisory Committee (UAC) on July 25 at its Bioscience Research Collaborative to address opportunities to increase the commercialization of discoveries made at Texas research institutions. The UAC invited representatives from technology transfer offices (TTO) throughout Texas to attend; more than 40 attended in person with others joining by phone. Dr. Willson, Mr. Lang, Dr. Garcia, Kristen Doyle and I represented CPRIT. Dr. Willson opened the substantive part of the meeting and Mr. Lang presented a proposal to use the re-introduced Early Translational Research Award (ETRA) and proposed Seed Award grant programs to bridge the gap between laboratory discoveries and new company formation to develop promising outcomes. The TTO representatives provided valuable input on critical needs at the universities. CPRIT will build on the discussions to continue developing this project.

#### **Communications**

- Chris Cutrone met in Houston with Houston Methodist Hospital. Plans are being made to
  hold similar meetings with the Texas Medical Center, Texas Children's Hospital, UT
  Southwestern, the Moncrief Institute, UNT Health Science Center, and UTHealth San
  Antonio. Meetings include discussion of communications strategies for the next 18 months,
  how CPRIT can assist and bring value to the institutions' initiatives and events, and how to
  best promote the work of CPRIT grantees.
- Communications continues to be active on social media and earned-media planning with our partners on cancer-related awareness events such as World Lung Cancer Day, Childhood Cancer Awareness Month, Gynecologic Cancer Awareness Month, and National Breast Cancer Awareness Month.
- Work has begun on a video featuring the Texas Hepatocellular Carcinoma Consortium, a liver cancer research project involving four institutions Baylor College of Medicine, MD Anderson, UT Southwestern and UTHealth San Antonio. The plan is to finish production in time for National Liver Cancer Awareness Month in October.
- Communications has started CPRIT Enews, an internal email newsletter, sent to all staff and Oversight Committee members containing a daily roundup of CPRIT grantee and general cancer-related news coverage. This replaces the morning clipping service provided by Hahn Public Communications
- Work on CPRIT's 2017 Annual Report will begin in mid-August.

## CPRIT's 2017 Innovations in Cancer Prevention and Research Conference

The CPRIT's biennial conference will occur November 13 – 14, 2017, at the Renaissance Arboretum Hotel in Austin. Preliminary schedule and other details can be found at <a href="http://cprit2017.org/">http://cprit2017.org/</a>. CPRIT opened conference registration July 28. CPRIT sent a second call for abstracts earlier this month.

## **Operations and Finance Update**

- Heidi McConnell and I attended the Bond Review Board planning meeting on July 11 as well as their formal meeting on July 20 where the board approved CPRIT's FY 2018 request for financing for \$300 million of general obligation debt.
- The Weaver audit team completed reports over procurement and P-card and follow-up procedure audits over commodity and service contracts, revenue, and cash management. These complete all of the FY 2017 audits. The audit team is preparing to review the agency's risk assessment with CPRIT staff on August 7. The audit team will use this review to make any necessary updates to the FY 2018 audit plan.

- In July the CPRIT operations staff completed user acceptance testing of the financials component of the state's Centralized Accounting and Payroll/Personnel System (CAPPS) after working with the Comptroller's CAPPS project team since September 2016 to match CPRIT's business processes with the financial business processes included in CAPPS. The CAPPS financials component integrates accounts payable, general ledger/commitment control, purchasing, and asset management and automates transactions among those modules. CPRIT's CAPPS financials component will be deployed on September 1 along with those of another 19 small state agencies included in this deployment cohort. The state started deploying CAPPS in 2011.
- CPRIT issued a competitive solicitation for continuity of operations planning services on June 20 but received no vendor responses by the July 21 due date. The vendor is expected to assist CPRIT with updating its existing business continuity plan to comply with the Federal Emergency Management Agency (FEMA) proscribed continuity of operations plan format adopted by the state and testing the plan according to FEMA and Department of Homeland Security standards. Don Brandy, CPRIT's purchaser, is contacting potential vendors on state contracting lists to find out why no bids were received. After evaluating these responses, staff will determine how to proceed with another solicitation.

# **Upcoming Subcommittee Meetings**

Listed below are upcoming August Oversight Committee subcommittee meetings.

Subcommittee	Date & Time
Board Governance	August 3 at 10:00 a.m.
Audit	August 7 at 10:00 a.m.
Prevention	August 8 at 10:00 a.m.
Scientific Research	August 9 at 10:00 a.m.
Product Development*	August 8 at 2:30 p.m.
Nominations*	July 28 at 10:00 a.m.

<sup>\*</sup> Note the changed time and date for the Product Development and Nominations subcommittee meetings.

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

\*\*\*\*

# CPRIT has awarded 1,132 grants totaling \$1.791 billion

- 181 prevention awards totaling \$181.1 million
- 951 academic research and product development research awards totaling \$1.610 billion

Of the \$1.610 billion in academic research and product development awards,

- 29.6% of the funding (\$476.7 million) supports clinical research projects
- 26.3% of the funding (\$423.6 million) supports translational research projects
- 25.6% of funding (\$412.1 million) supports recruitment awards
- 14.8% of the funding (\$237.4 million) supports discovery stage research projects
- 3.7% of funding (\$59.9 million) supports training programs.

# CPRIT has 8 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Prevention
- 2 Product Development



#### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS

FROM: VINCE BURGESS, CHIEF COMPLIANCE OFFICER

**SUBJECT:** COMPLIANCE PROGRAM UPDATE

**DATE:** AUGUST 7, 2017

# 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 August 1, 2017, 26 required reports from 10 entities have not been filed by the set due date; 25 are Academic Research grants and one is a Product Development Research grant. In most cases, CPRIT does not disburse grant funds until the grantee files the required report(s). In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to resolve filing issues.

#### FSR Reviews

CPRIT's Grant Compliance Specialists performed 355 second-level reviews of grantee Financial Status Reports (FSRs) so far this quarter. Thirty-two FSRs (9%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

## Desk Reviews

CPRIT staff performed 19 desk reviews this quarter. Grant Compliance Specialists perform desk-based financial monitoring/reviews during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may

target an organization's internal controls, current and past fiscal audits, subcontractor monitoring, and timeliness of required grantee report submission. Grant Compliance Specialists are working with eight grantees to remediate desk review findings.

## **On-Site Reviews**

Grant Compliance staff performed eight on-site reviews this quarter. On-site reviews typically include an examination of the grantee's financial and administrative operations, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Grant Compliance Specialists are working with eight grantees to remediate on-site review findings.

## Annual Compliance Attestation (Self-Certification)

Grantees must submit an annual self-certification demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, the grant contract, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Grant Compliance Specialists to work proactively with grantees towards full compliance prior to a desk review or on-site review. Compliance staff is working with two grantees to remediate deficiencies identified in their attestations.

# 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 findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year.

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

#### Grantee Risk Assessment

CPRIT's Compliance Program is finalizing the FY18 Grantee Risk Assessment and will begin implementation in September. Grantee Risk Assessments consider several factors in determining grantee risk including financial exposure, entity maturity, and prior experience administering grants. These risk assessments are conducted on a quarterly and annual basis. Quarterly assessments are performed for new grant recipients that receive funding during the year. Annual assessments provide for ongoing reviews of grant recipients with multi-year awards and those who receive grants over multiple years. Each Grantee Risk Assessment assigns a priority ranking to grant recipients, which assists in determining training and monitoring needs.

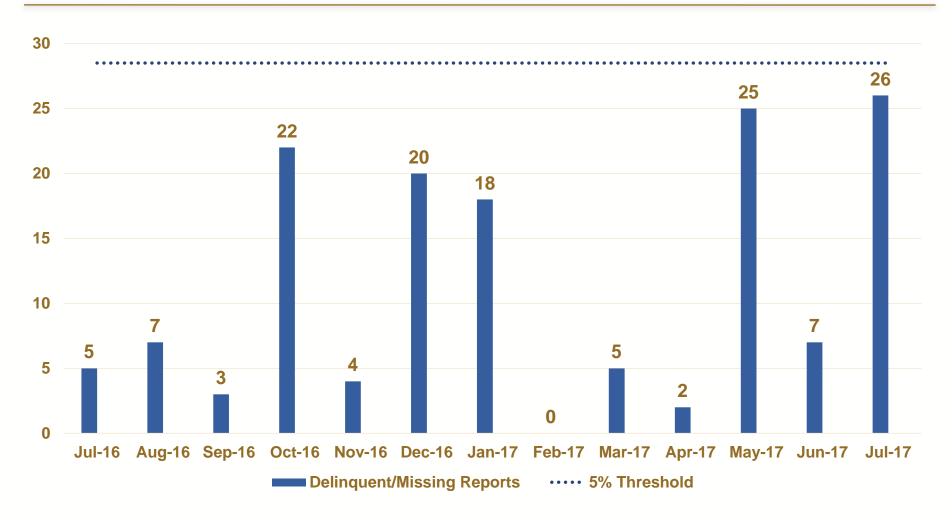
Based on the results of the FY18 Grantee Risk Assessment, grantees will receive a desk review or an on-site monitoring review conducted by compliance staff. Compliance monitoring reviews are designed to evaluate a grantee's compliance with grant requirements included in the Texas Administrative Code, Texas Health and Safety Code, CPRIT Policies and Procedures, Uniform Grant Management Standards, and terms of the grant contract.

# Training & Support

CPRIT staff conducted a grantee training webinar on June 7, 2017 with approximately 160 grantee staff in attendance. This was the second training webinar offered to grantees this year. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process. This webinar met the annual compliance training requirement 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. The Compliance team has scheduled a third grantee training webinar for October 11, 2017.

CPRIT staff conducted a training on July 25, 2017 for the new Authorized Signing Official (ASO) for NanoTx, a Product Development Research grantee. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. CPRIT's administrative rules state that a new ASO shall complete the annual compliance training program within 60 days of change. Failure to do so may result in withholding of Grant Award funds until the training is completed.

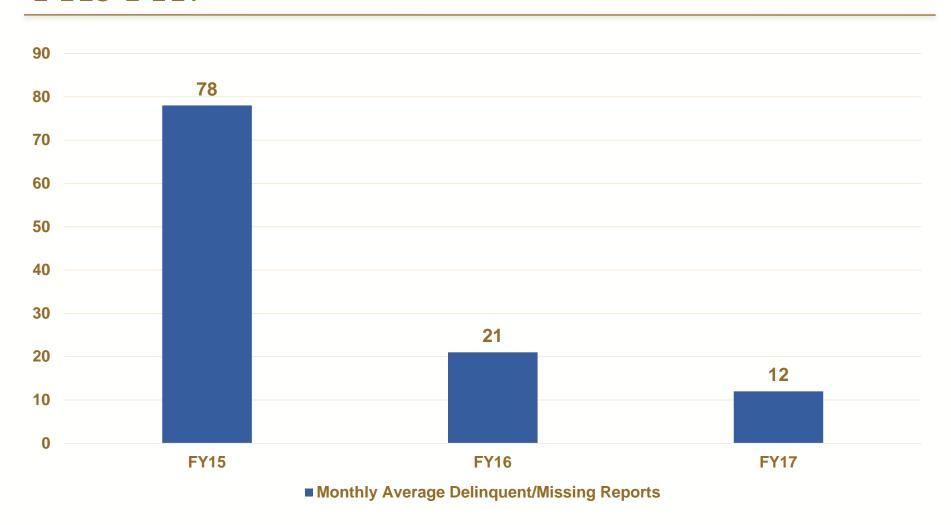
# **Grant Recipient Report Monitoring – 7-16 thru 7-17 Delinquent/Missing Reports**



Reports Submitted: Approximately 6,800/Annually, Average 570/Monthly



# Monthly Average Delinquent/Missing Reports FY15-FY17







# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: JAMES WILLSON, M.D., CHIEF SCIENTIFIC OFFICER

**SUBJECT:** ACADEMIC RESEARCH PROGRAM UPDATE

**DATE:** AUGUST 16, 2017

# **Recruitment Status Update**

As displayed in *table 1*, to date CPRIT has recruited 135 outstanding cancer researchers to Texas who collectively enhance Texas' cancer research capacity and life science infrastructure. The table also presents the acceptance rate of scholars.

Table 1

	# Scholars Approved by Oversight Committee	# Scholars Accepting Award	Acceptance Rate
First Time Tenure Track	111	89	80%
Rising Stars	23	13	57%
Established Investigators	43	30	70%
Missing Links	6	3	50%
Total	186	135	73%

# FY18 Academic Research Grant Applications Under Review

FY18 Academic Research Cycle 1 are currently under review. *Table 2* displays data by applications received for five Requests for Applications (RFAs) which closed for application receipt on June 8, 2017. Full scientific reviews will be conducted October 18-25 in Dallas. The Scientific Review Council and Program Integration Committee recommendations will be presented at the February 21, 2018 Oversight Committee meeting.

Table 2: 18.1 Academic Research RFA Submission Data

Funding Mechanism	Applications Submitted
Individual Investigator Research Awards	356
IIRA Childhood and Adolescent Cancers	39
IIRA Clinical Translational	54
IIRA Computational Biology	43
IIRA Prevention and Early Detection	40
Total	532

# FY 2018 Cycle 1: RFA Descriptions

### • Individual Investigator Research Awards (IIRA) (RFA R-18.1 IIRA)

Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.

Award: Up to \$300,000 per year.

Duration: Maximum 3 years.

# • IIRA Childhood and Adolescent Cancers (RFA R-18.1-IIRACCA)

Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.

Award: Up to \$300,000 per year. Applicants that plan on conducting a clinical trial as part of the project may request up to \$500,000 in total costs.

Duration: Maximum 4 years.

## • IIRA Computational Biology (RFA R-18.1-IIRACB)

Supports applications for innovative mathematical or computational research projects addressing questions that will advance our knowledge in any aspect of cancer. Areas of interest include data analysis of cellular pathways, microarrays, cellular imaging, cancer imaging or genomic, proteomic, and metabolomics databases; descriptive mathematical models of cancer, as well as mechanistic models of cellular processes and interactions and use of artificial intelligence approaches to build new tools for mining cancer research and treatment databases.

Award: Up to \$300,000 per year.

Duration: Maximum 3 years.

# • IIRA Prevention and Early Detection (RFA R-18.1-IIRAP)

Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. Research may be laboratory, clinical, or population-based, and may include behavioral/intervention, dissemination or health services/outcomes research to reduce cancer incidence or promote early detection. Competitive renewal applications accepted.

Award: Up to \$300,000 per year for laboratory and clinical research; Up to \$500,000 per year for population-based research.

Duration: Maximum 3 years.

# • IIRA Clinical Translation (RFA R-18.1 – IIRACT)

Supports applications for innovative clinical research that will lead to a better understanding of the clinical efficacy of a cancer therapy or diagnostic device. Applications submitted under this mechanism should propose innovative clinical studies that are hypothesis-driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known.

Award: Up to \$400,000 per year for a maximum of 3 years for laboratory and clinical research; Up to \$600,000 per year for up to 4 years if research includes the conduct of clinical trials.

Duration: Maximum 4 years.

# Impact of CPRIT Academic Research Program Priorities on Awards for FY 2015, 2016 and 2017

The 2017 program priorities for academic research adopted by the Oversight Committee include:

- ➤ Recruitment of outstanding cancer researchers to Texas
- > Investment in core facilities
- ➤ A broad range of innovative, investigator-initiated research projects
- > Prevention and early detection
- ➤ Computational biology and analytic methods
- Childhood cancers
- ➤ Population disparities and cancers of importance in Texas (lung, liver, cervix cancers)

As demonstrated in tables 1 and 2, a significant number of awards approved in FY15, FY16 and FY17 met one or more of the Oversight Committee's established CPRIT Academic Research Program Priorities.

Table 1: Cumulative Academic Research Funding and Awards for FY 2015, 2016 and 2017\*

Cycle	# Funded Awards	Funds Awarded
FY2015	112	\$188,180,000
FY2016	109	\$197,590,000
FY2017	122	\$212,911,662
Total	343	\$598,681,662

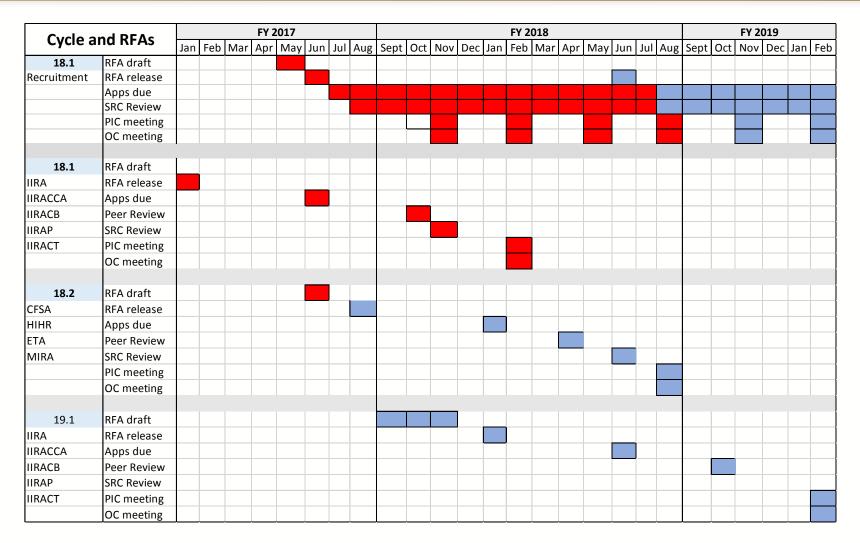
Table 2: Cumulative Priority Data by Priority for FY 2015, 2016 and 2017\*

Priority	# Funded	% of Total	Funds	% of Total
	Awards	Awards	Awarded	Funds
				Awarded
Recruitment of outstanding	76	22%	\$224,620,000	38%
cancer researchers to Texas				
Investment in core facilities	23	7%	\$107,852,278	18%
A broad range of innovative,	208	61%	\$198,276,326	33%
investigator-initiated research				
projects				
Prevention and Early Detection	44	13%	\$66,632,874	11%
Childhood Cancers	53	15%	\$89,310,927	16%
Population disparities and cancers	59	17%	\$73,878,951	12%
of importance in Texas				
Computational biology and	25	7%	\$71,033,744	12%
analytic methods				

Note: Projects may address more than one priority

<sup>\*</sup>Assumes adoption of August 1, 2017 PIC recommendations

# Academic Research Program RFA Schedule





# Description of Active and Proposed Academic Research RFA Mechanisms FY18 and 19.1

## • Recruitment of Established Investigators (FY18)

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 (FY18)

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 (FY18)

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-18.2 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-18.2 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 Translation Awards (ETA) (RFA-R-18.2 ETA)

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: \$1 to 2 million in total costs over a period of 1-2 years.

## • Multi-Investigator Research Awards (MIRA) (RFA-R-18.2 MIRA)

Supports integrated programs of collaborative and cross-disciplinary research among multiple investigators. Teams will focus on critical areas of cancer research. Laboratory research, translational studies, clinical, and population-based investigations may be supported.

Award: Up to \$6 M (total costs); Maximum duration: 4 years.

# -2- Description of Active and Proposed Academic Research RFA Mechanisms FY18 and 19.1

# • Individual Investigator Research Awards (18.1 and 19.1)

Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.

Award: Up to \$300,000 per year; maximum duration: 3 years.

# • IIRA Childhood and Adolescent Cancers (18.1 and 19.1)

Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.

Award: Up to \$300,000 per year; maximum duration: 4 years.

# • IIRA Computational Biology (18.1 and 19.1)

Supports applications for innovative mathematical or computational research projects addressing questions that will advance our knowledge in any aspect of cancer. Areas of interest include data analysis of cellular pathways, microarrays, cellular imaging, cancer imaging or genomic, proteomic, and metabolomics databases; descriptive mathematical models of cancer, as well as mechanistic models of cellular processes and interactions and use of artificial intelligence approaches to build new tools for mining cancer research and treatment databases.

Award: Up to \$300,000 per year; maximum duration: 3 years.

## • IIRA Clinical Translation (18.1 and 19.1)

Supports applications which propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.

Award: Up to \$400,000 per year. Maximum duration: 3 years. Applicants that plan on conducting a clinical trial as part of the project may request up to \$600,000 per year in total costs and a maximum duration of 4 years.

# • IIRA Prevention and Early Detection (18.1 and 19.1)

Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer and research. Research may be laboratory, clinical, or population-based, and may include behavioral/intervention, dissemination or health services/outcomes research and strategies for implementation research to reduce cancer incidence or promote early detection.

Award: Up to of \$300,000 per year for laboratory and clinical research; Up to \$500,000 per year for population-based research. Exceptions permitted if extremely well justified; maximum duration: 3 years.



### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA PHD, CHIEF PREVENTION AND

**COMMUNICATIONS OFFICER** 

**SUBJECT:** PREVENTION PROGRAM UPDATE

**DATE:** AUGUST 8, 2017

# FY 2017 Cycle 2 Prevention Applications

CPRIT released five RFAs for the second review cycle of FY 2017 (17.2) in November 2016. Peer review panels met May 31 – June 2 in Dallas to evaluate the 37 17.2 prevention applications requesting \$52,906,830. The Prevention Review Council (PRC) met July 6. The Oversight Committee will consider the Program Integration Committee's recommendations in August.

### FY 2018 Cycle 1 Prevention RFAs

CPRIT released three RFAs for the first cycle of FY 2018 on June 8. Applications are due September 14 with peer review panels meeting December 11-14. The Oversight Committee will consider the recommendations at the February 2018 meeting. RFAs released June 8 include:

- Evidence-Based Cancer Prevention Services
- Tobacco Control and Lung Cancer Screening
- Dissemination of CPRIT-Funded Cancer Control Interventions (DI)

# Reposting of Dissemination (DI) RFA

To speed up the review and approval of applications to the Dissemination RFA, we are revising the submission and review process for this mechanism. The DI RFA will now be open continuously and reviewed by the Prevention Review Council quarterly. Recommendations of meritorious applications, if any, will be forwarded to the Oversight Committee for consideration at the quarterly meetings. The DI RFA was reposted August 1 with submissions due October 3.

# FY 2018 Cycle 2 Prevention RFAs

Conference calls with Prevention subcommittee members to discuss ideas for new RFAs for FY2018 cycle 2 occurred June 28 and 29. Ideas being explored include an RFA that would expand services to rural and medically underserved areas of the state. The draft concept will be discussed at the August 8 Prevention Subcommittee meeting. The plan is to release the 18.2

RFAs this fall with applications due in March, peer review in May/June, and consideration by Oversight Committee in August 2018.

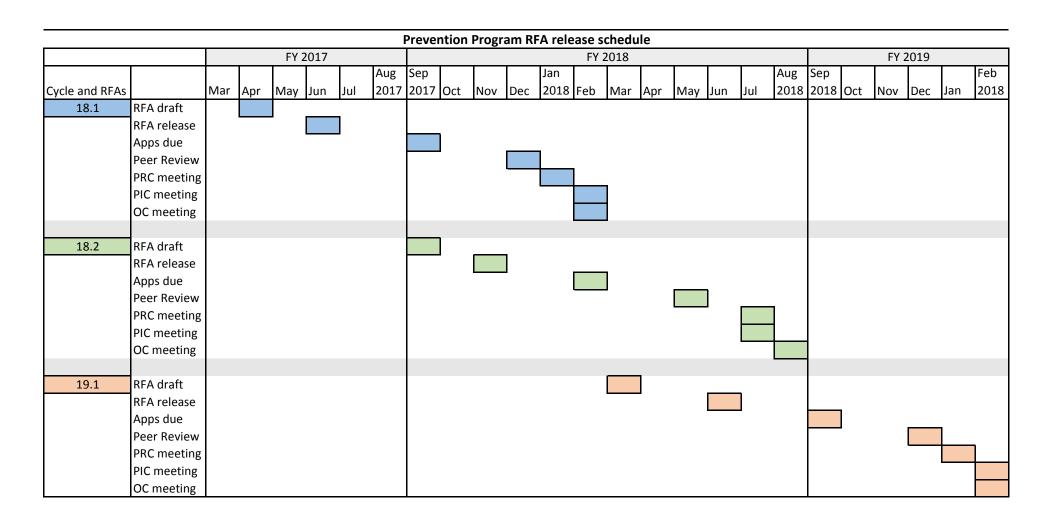
# Other activities

Prevention program staff are developing plans for updating the 2012 Texas Cancer Plan. The DSHS' Texas Comprehensive Cancer Control program, Texas Cancer Registry and Office of Surveillance, Epidemiology and Research are updating the statistics and providing input. We've contracted with Dr. Jennifer Redmond Knight, Assistant Professor, University of Kentucky College of Public Health and Co-Principal Investigator, Kentucky Cancer Consortium, to help with the revision.

The prevention program performance measures report for the Legislative Budget Board was submitted July 14.

As a member of the advisory board, Dr. Garcia participated in the July 17 Texas Health Improvement Network Advisory Meeting in Austin. The network was established to address the urgent health care challenges and improve the health care system in Texas.

Subject Page 2



# **Prevention Program RFA Descriptions for FY 2018**

# FY 2018 Cycle 1 Prevention RFAs

# **Evidence-Based Cancer Prevention Services**

This award mechanism seeks to fund projects that will deliver evidence-based cancer prevention and control clinical services. Priority will be given to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects. Award: Maximum of \$1.5M; Maximum duration of 36 months.

# Tobacco Control and Lung Cancer Screening

This award mechanism seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth. Award: Maximum of \$1.5M; Maximum duration of 36 months.

# Dissemination of CPRIT-Funded Cancer Control Interventions (DI)

This award mechanism seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be in a position to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding. Award: Maximum of \$300,000; Maximum duration of 24 months. The RFA will be open continuously and reviewed by the Prevention Review Council quarterly. Recommendations of meritorious applications, if any, will be forwarded to the Oversight Committee for consideration at the quarterly meetings.

# **Proposed FY 2018 Cycle 2 Prevention RFAs**

# <u>Draft concept for new RFA: Expansion of cancer prevention services to rural</u> (nonmetropolitan) and medically underserved areas

Currently or previously funded CPRIT projects would propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.

Other mechanisms under consideration for release include:

- Evidence-Based Cancer Prevention Services
- Tobacco Control and Lung Cancer Screening
- Dissemination of CPRIT-Funded Cancer Control Interventions (DI)

TO: **OVERSIGHT COMMITTEE MEMBERS** 

REBECCA GARCIA, PH.D. CHIEF PREVENTION AND FROM:

COMMUNICATIONS OFFICER

**COMMUNICATIONS UPDATE SUBJECT:** 

**DATE:** AUGUST 8, 2017

The following is an overview of the agency's communication activities from May 17, 2017 through August 16, 2017.

# **Earned Media**

The communications team conducted media outreach to secure positive coverage for CPRIT, including a print article in The Dallas Morning News on May 25 and an online article in Xconomy on May 31 regarding the Senate Bill 224 sunset extension.

**Grant Awards Announcement:** Following the Oversight Committee's approval of grant awards at its May meeting, CPRIT distributed a press release on May 17 to local, regional and national outlets announcing 10 grants through its Scholars program.

**Coverage:** (May 2, 2017 – July 31, 2017)

- 9 articles featured CPRIT
- 41 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

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

- May 12, 2017, Houston Business Journal, Biotech Company Names New CEO After Relocating to Houston
- May 19, 2017, 3D Printing Industry, Rice University Receives \$5 Million Grant for 3D Printed Cancer Research
- May 22, 2017, Duke University Newsroom, BME Postdoc Awarded Competitive CPRIT Grant for Cancer Research
- May 25, 2017, The Dallas Morning News, CPRIT Gets 2 More Years to Spend **Funds**
- May 29, 2017, *The Plano Leader*, Legislative Session Adjourns; 16 of Nelson's Bills Make it to Governor's Desk
- May 31, 2017, *Xconomy*, Texas Cancer Agency Poised to Receive Two-Year Extension
- June 5, 2017, The University of North Texas Health Science Center Newsroom, Conference to Focus on Health Disparities in Cancer

- June 7, 2017, *Texas Medical Association Newsroom*, Medicine's Big Winners as Legislature Wraps Up Regular Session
- June 23, 2017, *San Antonio Express-News*, Voelcker Fund Awards \$2.3M to UT Health for Research
- June 28, 2017, *Nasdaq*, Pelican Therapeutics, a Subsidiary of Heat Biologics, Receives First Tranche of \$15.2 Million CPRIT Grant Award

### **Communications Activities**

- The Communications team worked with the City of Houston Mayor's Office to secure a May 2018 proclamation and press conference for Cancer Research Month next year. The team also organized visits with CPRIT-funded Houston institutions and planned communication strategies to showcase the impact of CPRIT.
- Communications continues to be active on social media and earned media planning with our partners on cancer-related awareness events such as Childhood Cancer Awareness Month, Gynecologic Cancer Awareness Month, and National Breast Cancer Awareness Month.
- Spencer Miller-Payne coordinated social media with Baylor College of Medicine and University of Houston for World Lung Cancer Awareness Day, which was Tuesday, August 1.
- Work has begun on a video feature on the Texas Hepatocellular Carcinoma Consortium, which is a liver cancer research project involving four institutions – Baylor College of Medicine, MD Anderson, UT Southwestern and UTHealth San Antonio. The plan is to finishthe production in time for October, which is National Liver Cancer Awareness Month.
- Conference registration opened in July. A second call for abstracts was sent in mid-July. Planning meetings are taking place every three weeks and will be held biweekly starting in September. Calls with invited speakers to discuss logistics are being conducted. The preliminary schedule and other details can be found at <a href="http://cprit2017.org/">http://cprit2017.org/</a>.
- Communications staff have started CPRIT Enews, an internal email newsletter, sent to all staff and Oversight Committee members containing a daily roundup of CPRIT grantee and general cancer-related news coverage. This replaces the morning clipping service provided by Hahn Public Communications.
- Work on CPRIT's 2017 Annual Report will begin in mid-August.



MAY 12-18, 2017

# BIOTECH COMPANY NAMES NEW CEO AFTER RELOCATING TO HOUSTON

**Aravive Biologics**, a biopharmaceutical company that recently moved its headquarters to Houston, has named Dr. Stephen Eck as its president and CEO. Eck replaces Dr. Ray Tabibiazar, who remains chairman of the company's board of directors. Aravive, previously known as Ruga Corp., moved its headquarters to Houston from San Francisco in late 2016 after accepting a **\$20 million** grant from the Cancer Prevention and Research Institute of Texas. The company was awarded the grant in November 2015 to further the development of its myeloid leukemia treatment.



# RICE UNIVERSITY RECEIVES \$5 MILLION GRANT FOR 3D PRINTED CANCER RESEARCH

Rice University in Houston, Texas, has received a grant for \$5 million from the Cancer Prevention and Research Institute of Texas (CPRIT). The money is enabling the university to conduct research into creating patient-specific, digital and 3D printed, models used to predict and plan the outcome of invasive cancer surgeries.

The specific area of focus, for its critical position in relation to the spine and the hips, is in models of the pelvis, and will be conducted with the help of mechanical engineering researcher Professor B.J. Fregly.



Professor B.J. Fregly and a digram of skeletal computational modeling, key to his research. Image via: eng.ufl.edu

# Improving the outcome and recovery time of operations

In a statement from Rice University, Professor Fregly explains the utility of this specific research saying,

# CUSTOM PELVIC PROSTHESES HAVE THE POTENTIAL TO BOTH MAXIMIZE WALKING ABILITY AND MINIMIZE RECOVERY TIME, BUT THEY ARE NOT AVAILABLE CLINICALLY BECAUSE OF LOW RELIABILITY. THAT'S AN ENGINEERING PROBLEM THAT RICE IS IN A GOOD POSITION TO TACKLE.

Fregly's expertise is in building accurate 3D digital models of bones in the body. He says, "My research program has always had a heavy orthopedic, human movement prediction and computational treatment design focus". He then adds that collaboration with the surgeon Valerae Lewis, chair of the Department of Orthopedic Oncology at MD Anderson, has been key to linking his work to diagnosis of bone cancers.

# A 3 part digital approach

The overall hope of the program, according to Fregly, is "to improve the postsurgical functional outcome and recovery time for pelvic sarcoma patients in the Texas Medical Center, regardless of which surgical method a patient receives".

This will be made possible by the combined effort of three areas of expertise: patient-specific 3D imaging and data collection with Scott Tashman, director of the Biomotion Lab at the University of Texas Health Science Center; data-based 3D model creation on Fregly's part; and custom 3D printed prosthesis fabrication by Fred Higgs, director of the Particle Flow and Tribology Lab at Rice.

THIS PROJECT COULD NOT HAVE HAPPENED WITHOUT A COLLABORATIVE TEAM. I'M PULLING IT TOGETHER AND LEADING THE MODELLING, BUT WITHOUT VALERAE LEWIS WE WOULD HAVE NO CLINICAL PROBLEM TO ADDRESS AND NO PATIENTS. WITHOUT SCOTT TASHMAN, WE COULDN'T DO PRETREATMENT TESTING OR ASSESS HOW PATIENTS ARE PROGRESSING. AND WE NEED FRED HIGGS' EXPERTISE TO CREATE CUSTOM IMPLANTS USING ADDITIVE MANUFACTURING. IT REALLY WILL TAKE ALL OF US TO MAKE THIS PROJECT GO.

# A hub for 3D printing research

Rice University is also one participant in the National Institutes of Health's \$6.25 million center for 3D bioprinting and tissue engineering. In this specialist center, Rice will focus on 3D bioprinting of scaffold structures, and collaborate closely with the University of Maryland and the Wake Forest Institute for Regenerative Medicine.

https://3dprintingindustry.com/news/rice-university-receives-5-million-grant-3d-printed-cancer-research-113661/



# MAY 22, 2017 By Michaela Kane

# BME Postdoc Awarded Competitive CPRIT Grant for Cancer Research

BME's Isaac Hilton received a CPRIT grant to study innovative cancer research in his own lab at Rice University.

Isaac Hilton, a postdoctoral fellow in Duke University's Department of Biomedical Engineering (BME), recently received a grant to participate in the Cancer Prevention and Research Institute of Texas (CPRIT). As a CPRIT Scholar in Cancer Research, Hilton will work as an assistant professor of bioengineering at Rice University, where he will receive \$2 million in CPRIT start-up funds to work on innovative cancer research.

"This is a unique opportunity, because the funding was approved by Texas voters with the ultimate goal of changing and improving how we detect and treat cancer," says Hilton. "This particular award is geared towards recruiting cancer researchers who are seeking their first tenure-track appointment to Texas. This strategy is designed to position Texas as a leader in the fight against cancer well into the foreseeable future."

The CPRIT program began in 2007 after Texas voters passed a constitutional amendment authorizing the state to issue \$3 billion in bonds to fund cancer research. The initiative aims to recruit experienced researchers with a background in cancer who are then encouraged to study forms of cancer that are especially problematic for Texas healthcare, such as lung cancer and breast cancer.

Hilton, who earned his PhD in genetics and molecular biology from the University of North Carolina at Chapel Hill, has worked as a postdoctoral fellow in BME's <u>Charlie Gersbach's lab</u> since November 2013. During his time at Duke, he used epigenomic editing tools based on CRISPR-Cas9 to study the role that biochemical modifications play in controlling the expression of human genes.

"Isaac's work has been at the leading edge of the new field of epigenome editing," says Gersbach. "It's very encouraging to see the CPRIT program recognize the potential of Isaac's work to have a transformative effect on cancer research and treatment." Now, Hilton will bring his experience with cancer research and epigenome editing to his own lab at Rice, where he is planning to study the role of epigenetic modifications in regions of the genome that we suspect are associated with cancer onset and progression. "Emerging genome editing technologies provide us with the opportunity to address questions about cancer that we have been attempting to answer for decades," he said.

"This highly competitive award is not only a recognition of Isaac's research accomplishments, but it also attests to the world-class research that is going on in Duke BME labs," says Ashutosh Chilkoti, chair of the BME department.

Although Hilton looks forward to the new opportunities available to him, he is grateful for his time at Duke. "Charlie has been an amazing mentor to me, and his guidance is always insightful and helpful," he says. "The breadth of pioneering work that I have learned about during my time in Duke BME has helped to broaden my expertise."

https://bme.duke.edu/about/news/bme-postdoc-awarded-competitive-cprit-grant-cancer-research

# The Pallas Morning News

Thursday, May 25, 2017

# CPRIT gets 2 more years to spend funds

The House voted Wednesday to give the Cancer Prevention and Research Institute of Texas two more years to finish spending \$3 billion in bonds.

Voters in 2007 agreed to give the agency the bonds to invest in cancer research and prevention programs over 10 years, but agency leaders predicted there would still be \$150 million left to invest come 2020.

The bill also includes an amendment from Rep. Tan Parker, R-Flower Mound, that would make it easier for the agency to support clinical trials.

The bill passed 106-40.

Madlin Mekelburg



# Legislative session adjourns; 16 of Nelson's bills make it to governor's desk

The Texas Legislature adjourned sine die for the 85th Regular Session on Monday with hundreds of bills signed into law or on their way to the governor's desk, including 16 authored by Texas State Senator Jane Nelson, R-Flower Mound.

"It is a great privilege to represent the people of Tarrant and Denton counties in the Senate. Every day in Austin I fought to advance the priorities for our region, and I am grateful for the faith my constituents have placed in me," Nelson said. "We passed a responsible budget that meets our essential needs. It continues the policies of fiscal restraint that have shaped our success, and it positions Texas for a bright future. The budget was the most critical piece of legislation to get passed. I also succeeded in passing several local bills and legislation allowing general law cities to create child safety zones, protecting young girls from a horrible practice called FGM, and ensuring sexual assault victims do not have to co-parent with their assailant."

The Legislature also approved several bills co-authored by Nelson. Among those are bills to ban sanctuary cities; putting a stop the practice of fetal dismemberment; punishing teachers for misconduct with a student; strengthening voter identification and creation of a grant program to provide high caliber bullet proof vests for law enforcement officers.

Following are some highlights of Nelson's legislative package:

CPRIT: SB 81 clarifies that Cancer Prevention and Research Institute of Texas (CPRIT) Oversight Committee members must file financial disclosures with the Texas Ethics Commission. It gives CPRIT the tools it needs to exercise its fiduciary responsibility and protect the state's investment in cancer research. It also extends CPRIT's Sunset date to 2021 to ensure that it can fulfill its 10-year commitment under Proposition 15. "It is vitally important that CPRIT have the tools it needs to carry out its important mission in the most transparent, ethical and effective manner." Status: Sent to Governor

A few of Nelson's priorities did not make their way to the governor's desk. SB 17, phasing out the franchise tax, passed the Senate and never received a hearing in the House. "This tax is an impediment to Texas businesses and needs to be eliminated," Nelson said. SB 75 requiring parental consent for a minor to join a union, passed the Senate and the House Committee on Economic and Small Business Development but died in House calendars. "Parents should be involved in any contract their minor child signs, and it's disappointing that this bill did not make it through the process." SB 669 which would have reformed the property appraisal review process - making it more fair to taxpayers did not pass.

To search all legislation from the 85th Legislative Session visit the Texas Legislature online at capitol.state.tx.us.

http://starlocalmedia.com/theleader/news/legislative-session-adjourns-of-nelson-s-bills-make-it-to/article\_a2c0aed4-44a5-11e7-83ad-13f108b22ee3.html



# Texas Cancer Agency Poised to Receive Two-Year Extension

**Xconomy Texas** — *Austin*—The future of the Cancer Prevention and Research Institute of Texas (CPRIT) waits for Texas Gov. Greg Abbott's signature.

Texas lawmakers have passed legislation to expand the life of the agency, also known as CPRIT, which was created through a referendum a decade ago to issue \$3 billion in bonds to fund cancer research and treatment projects.

A letter to Abbott from the Texas Cancer Partnership argues that "Texas' investment in cancer research and programs through CPRIT is sound policy that makes economic sense." The partnership is an advocacy a group that includes the University of Texas MD Anderson Cancer Center and the Texas Association of Business.

"While we believe the private and non-profit sectors play an important role in funding cancer research and programs," the letter states, "we also firmly believe that investments by state and federal government institutions are critically important to leverage in the fight against cancer."

The bill before Abbott would push CPRIT's sunset date back from 2021 to 2023, in order to use about \$70 million in unexpired bond authority for cancer projects. The money is leftover, so to speak, because the agency **was temporarily shut down in 2012** following allegations of improperly awarded grants and misallocation of funds. The state imposed a series of reforms and, after a year-long hiatus, the agency reopened. At the time, some in the Texas biotech community wondered if CPRIT **could have the impact originally envisioned** for the agency.

Still, the agency has continued to make grants in three categories: research, prevention, and commercialization. CPRIT says that to date, it has awarded \$320.6 million in product development grants of a total \$1.79 billion.

As lawmakers debated CPRIT's future this spring, Mike Lang, the agency's head of product development, says he was traveling around the state meeting with various biotech networks in local communities. "We're of no value unless we're engaged with the companies that we support," he says.

While protocol naturally prevents any "game-time advice" for companies with outstanding proposals, Lang says CPRIT should be educating companies on what it takes to get state funding and the application process. "Only about 10 percent of applicants are ultimately funded," he adds.

The agency is currently in the middle of a funding cycle and Lang says new grants should be announced in August. In the meantime, he says agency officials are in regular contact with previous awardees. "We don't just write someone a large check," he says. "It's given in tranches. We observe the company, and they have to provide updates and status reports."

 $\frac{http://www.xconomy.com/texas/2017/05/31/texas-cancer-agency-poised-to-receive-two-year-extension/}{}$ 



June 5, 2017

By Alex Branch

# Conference to focus on health disparities in cancer

National experts, local officials, community leaders, faculty and students will come together June 8-9 to discover ways to reduce cancer disparities at UNT Health Science Center's 12<sup>th</sup> annual Texas Conference on Health Disparities, hosted by the Texas Center for Health Disparities.

The conference, "Evidence-Based Approaches to Reducing Cancer Health Disparities," will focus on breast, colorectal and prostate cancers.

African Americans and Hispanics in Texas are twice more likely to die from cancer than non-Hispanic whites.

"This disparity in cancer is seen not just in Tarrant County but across the country," said Jamboor K. Vishwanatha, PhD, Regents Professor and Director of the Texas Center for Health Disparities. "Each session will be very interdisplinary and interactive because those are the approaches it will take to make progress solving these disparities."

Mayor Betsy Price and Tarrant County Commissioner Roy C. Brooks will be among the local officials who will attend the conference. The keynote speaker is Rebecca Garcia, PhD, Chief Prevention and Communication Officer for the Cancer Prevention and Research Institute of Texas.



Rebecca Garcia, PhD

Between 400 to 450 people are expected to attend the conference. Attendees will learn about the latest basic, clinical, community and translational approaches to discover, develop, deliver and disseminate information to eliminating cancer health disparities, according to conference organizers.

Past conferences have focused on women's health, genomics, obesity, breast cancer and other major health disparities. The conferences are particularly impactful to UNTHSC students by exposing them to the many different health disparities that afflict underserved communities and inspiring students to serve those communities after graduation.

"Our students learn an incredible amount during these two days," Dr. Vishwanatha said. "It's a unique educational opportunity for everyone who attends."

For information about the conference, contact Rosalba Zamaguey at 817-735-0670

https://www.unthsc.edu/newsroom/story/conference-focus-health-disparities-cancer/



Action, June 1, 2017

Updated June 7, 2017

# Medicine's Big Winners as Legislature Wraps Up Regular Session

The 2017 regular session of the Texas Legislature gaveled to a close May 29. For medicine, the session was a mosaic of many richly colored tiles with some dark spots and quite a few shades of grey. The artists were shifting alliances and divisions of senators and representatives, Democrats and Republicans, and various factions of the GOP.

The final product includes one obvious empty space. Thanks to a long-brewing, House-Senate feud over unrelated issues, the legislature adjourned without passing a bill to reauthorize the Texas Medical Board (TMB) and the Medical Practice Act beyond their scheduled Aug. 31, 2017, demise.

"This is a fight that has nothing to do with the physicians or with the TMB, and everyone at the Capitol knows that," said TMA President Carlos J. Cardenas, MD. "The TMB serves a critical state function, licensing physicians and protecting the health and safety of Texans. We have no reason to believe that any of our state leaders want the TMB to go away, and we have every expectation that they will find a way to make sure that doesn't happen."

Gov. Greg Abbott is calling the legislature back for a special session beginning July 18. While his "call" for the session includes 20 different items, the governor clearly stated that lawmakers must reauthorize TMB and the Medical Practice Act – and similar legislation regarding a number of other state agencies – before moving on to the other 19 topics. "That will be the only legislation on the special session [agenda] until they pass out of the Senate in full," he said at a June 6 news conference.

Below is a comprehensive look at the bills that were of interest to TMA and its members.

# Medicine's Bills Signed by the Governor

Senate Bill 81, Sen. Jane Nelson's (R-Flower Mound) Cancer Prevention Research Institute of Texas sunset bill, extends the sunset date of the cancer research organization from 2021 to 2023, while also adding two years to its eligibility to allocate funds, to 2022. Its House sponsor was Rep. Sarah Davis (R-West University Place).

https://www.texmed.org/2017LegislativeWrapup/

# San Antonio Express-News

Friday, June 23, 2017

# Voelcker Fund awards \$2.3M to UT Health for research

# By Jesse Pound

STAFF WRITER

UT Health San Antonio has received more than \$2.3 million from the Max and Minnie Tomerlin Voelcker Fund to study treatments for cancer and heart disease.

Five UT Health researchers were chosen to receive the local fund's Young Investigator Award. Each will be awarded \$450,000 over the next three years.

UT Health also received

\$75,000 for a pilot study on the molecular mechanisms of anticancer drugs.

The Voelcker Fund has now given UT Health San Antonio more than \$21 million since 2007, UT Health San Antonio president William L. Henrich said in a statement.

The application process for the Voelcker Fund is often the first grant-writing experience for young researchers, Andrea Giuffrida, the vice president for research at UT Health San Antonio, said in a phone interview.

"If you look back at some of the previous awardees, most of them now have secured large grants from NIH (National Institute of Health), from CPRIT (Cancer Prevention Research Institute of Texas), from federal agencies. So the program works," Giuffrida said.

The Voelcker Fund provides funding for research on several diseases, including cancer, arthritis and heart disease,

Voelcker continues on B5

# **VOELCKER**

From page B1

according to its website. The award was first reported by the San Antonio Business Journal.

"UT Health San Antonio researchers are studying cancer and other diseases for which there are few answers," Banks Smith, Voelcker Fund trustee, said in a statement. "We want to see these quality research programs flourish and provide the answers society needs."

Four of the researchers
— Ann Griffith, Zhijie
"Jason" Liu, Gandadhara
Sareddy and Alexei Tumanov — are focusing on
cancer research, while
Andrew Pickering is
looking at heart disease.

All the recipients are from the Joe R. & Teresa Lozano Long School of Medicine at UT Health San Antonio.

UT Health San Antonio also received three of the four Young Investigator Awards in 2016.

Preference is given to scientists who completed their doctoral degree in the past 15 years, according to application information on the fund's website.

The research focus areas of the Voelcker Fund align with the medical school's strengths, Giuffrida said. He said UT Health had 23 submissions for the awards.

"They see this program as a way to promote and facilitate a path to an independent career as an

investigator," Giuffrida said.

The other trustees for the fund are David Berndt and Forrester M. Smith, III, according to the fund's website.

jpound@express-news.net @jesserpound



June 28, 2017,

# Pelican Therapeutics, a Subsidiary of Heat Biologics, Receives First Tranche of \$15.2 Million CPRIT Grant Award

DURHAM, NC / ACCESSWIRE / June 28, 2017 /Heat Biologics, Inc. ("Heat") (NASDAQ:HTBX), a leader in the development of novel therapies designed to activate a patient's immune system against cancer, reported that its Pelican Therapeutics subsidiary is on track to meet product development milestones and has received the first tranche of its \$15.2 millionCancer Prevention and Research Institute of Texas (CPRIT) grant award.

"We have made significant progress in advancing PTX-25, our lead antibody, towards the clinic, having completed key milestones, including epitope mapping, affinity maturation and antibody development studies," said Jeff Wolf, Founder and CEO of Heat. "We are pleased that Pelican has received the first tranche of its CPRIT award, which provides non-dilutive funding to cover costs of IND-enabling studies towards a comprehensive, 70-patient Phase 1 clinical trial combining PTX-25 with other immune-oncology drugs"

The recent acquisition of Pelican strengthens Heat's portfolio in the emerging T cell activation space. PTX-25 is a novel costimulatory antibody against TNFRSF25, an emerging costimulatory receptor on T cells. PTX-25 has the potential to improve clinical response in combination with Heat's ImPACT vaccine platform, as well as with other immunotherapy drugs, by stimulating the production of antigen specific "memory" CD8+ T cells - the immune cells critical in tumor eradication. T cell costimulatory therapy such as PTX-25, when combined with checkpoint inhibitors and other treatments, could significantly improve clinical responses for a broader range of patients.

# **About Heat Biologics, Inc.**

Heat Biologics, Inc. (NASDAQ:HTBX) is an immuno-oncology company developing novel therapies designed to activate a patient's immune system against cancer. Heat has generated highly specific T cell-stimulating therapeutic vaccine platform technologies, known as ImPACT and ComPACT. These technologies, in combination with other therapies such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms-of-action: robust activation of CD8+ "killer" T cells (one of the immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance a patient's immune response. Currently, Heat is conducting a Phase II trial with HS-110 (viagenpumatucel-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small, cell lung cancer (NSCLC).

In addition to Heat's recent portfolio expansion due to the acquisition of Pelican Therapeutics, the company's wholly-owned subsidiary, Zolovax, Inc., is developing therapeutic and preventative vaccines to treat infectious diseases based on Heat's gp96 vaccine technology Its current focus is on the development of a Zika vaccine in conjunction with the University of Miami.

For more information, please visit www.heatbio.com.

About the Cancer Prevention and Research Institute of Texas (CPRIT)

To date, CPRIT has awarded approximately \$1.8 billion in grants to Texas researchers, institutions and organizations. CPRIT provides funding through its academic research, prevention, and product development research programs. Programs made possible with CPRIT funding have reached all 254 counties of the state, brought more than 127 distinguished researchers to Texas, advanced scientific and clinical knowledge, and provided more than three million life-saving education, training, prevention and early detection services to Texans. Learn more at cprit.texas.gov. Follow CPRIT at twitter.com/CPRITTexas and facebook.com/CPRITTexas.

http://www.nasdaq.com/press-release/pelican-therapeutics-a-subsidiary-of-heat-biologics-receives-first-tranche-of-152-million-cprit-20170628-00234



# **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER

**SUBJECT:** PRODUCT DEVELOPMENT PROGRAM UPDATE

**DATE:** AUGUST 16, 2017

# FY 2017 Cycle 2 Product Development Research Applications

Twenty applications were submitted and accepted. Six of these were selected to present to the Peer Review Panel. The Peer Review Panel meeting was held April 25-26 where two applicants were recommended for due diligence. Based on the diligence findings, the Product Development Review Council recommended one project for funding. This project has been reviewed and approved by the PIC and is being presented to the Oversight Committee for their review.

# FY 2018 Cycle 1 Product Development Research Applications

The RFA for FY 2018 Cycle 1 was posted on June 29<sup>th</sup> to CARS. Eight applications have been started. Peer review is scheduled for October 23-26, 2017 with funding recommendations planned to be presented to the Oversight Committee on February 21, 2018.

# FY 2018 Cycle 2 Product Development Research Applications

Schedule for FY 2018 Cycle 2 has been finalized with the following milestones:

• RFA posting Dec 22, 2017 to Feb 7, 2018

Screening Telecon Mar 26-27, 2018
Peer review Apr 23-26, 2018
Oversight Committee review Aug 15, 2018

## NCI meeting

Wayne Roberts and Michael Lang traveled to Washington, DC to meet with the SBIR program staff at the National Cancer Institute. The NCI's SBIR program is similar to CPRIT's Product Development program as it supports early stage company product development projects. Both organizations use a peer review process to select awardees.

We learned about each other's programs and discussed best practices. NCI noted that many of their awardees later become CPRIT applicants.

# **Catalyzing Commercialization**

The Product Development Advisory Council recommended that CPRIT seek to stimulate more university research spinouts by collaborating with academic institutions to increase company formation and commercialization. The PDAC Chairman, Dr. Jonathan MacQuitty, spoke about this at the May Oversight Committee meeting.

CPRIT is actively planning two new or modified grant programs that would bridge between current academic and product development programs. We are evaluating restarting the CPRIT ETRA program, which would be renamed Early Translational Award (ETA). The program would be modified to include more focus on clinical and commercial objectives, and ensure support is available for this work. A new Seed Award program is being planned to provide startup funding to Newco spinouts from Texas research institutions. RFAs for both award mechanisms are being developed.

A presentation was made at the Product Development subcommittee meeting to provide additional context and details.

# Outreach and Diversity

Product Development maintains an active outreach program to build awareness and generate a pipeline of attractive applicants. We will increase our outreach efforts to both academic and company applicants to build their awareness and interest in the ETA and Seed Award programs noted above. Outreach to groups that have not been active CPRIT applicants will be prioritized.



# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

August 9, 2017

Oversight Committee Members,

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of grant contracts for one company that will be considered for a Product Development grant award at the August 16, 2017, Oversight Committee meeting. The company has been recommended for a grant award by the Program Integration Committee (PIC). The Oversight Committee will consider the PIC's recommendation at the August 16, 2017, Oversight Committee meeting.

Although CPRIT disburses the majority of grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.03(a). Typically, the grant amount to be paid in advance is based upon the project year budget or tranche amount. All grant recipients, including those that receive advance payment of grant funds, are required to submit quarterly financial status reports that are reviewed and approved by CPRIT's financial staff. Failure to submit the financial status reports on a timely basis will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

Advance payment of grant funds are needed for this award because it primarily funds a Phase 2 clinical trial. Most drug development firms engage the services of Clinical Research Organizations to conduct their clinical studies. The cost structure for these contracted services is highly front loaded. Hence the Clinical Research service providers typically require substantial upfront payments. Advancing grant funds allows these projects to begin work as quickly as possible.

Sincerely,

Wayne R. Roberts,

**CPRIT Chief Executive Officer** 



### **MEMORANDUM**

**TO:** OVERSIGHT COMMITTEE MEMBERS

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

**SUBJECT:** AGENDA ITEM 11: PROGRAM PRIORITIES IMPACT

**DATE:** AUGUST 7, 2017

In discussions with Presiding Officer Geren concerning the process for adopting FY 2018 Program Priorities he requested a status report on how program awards have aligned with the Oversight Committee's priorities since they were first adopted in FY 2015. The attached document is a tool to be used in setting the FY 2018 priorities and gauging agency success in addressing the priorities. This document will be revised annually leading into each year's priorities setting process.

The document was prepared by the Program Managers, Ramona Magid, Cathy Allen and Patty Moore, under the guidance of the Program Officers. The Program Officers will present the results at the August 16, 2017, Oversight Committee meeting.

# ACADEMIC RESEARCH PROGRAM PRIORITIES FY2015 - FY2017

				Priorities - FY2015, FY2016 and FY2017																										
			Recruit o	Recruit outstanding cancer researchers to Texas  Investment						•	A broad range of innovative, investigator- initiated academic research projects				1 Prevention and Early Detection				Childho	ood Cancers		-	-	ities and cance ce in Texas	rs of	Computational biology and analytic methods			ytic	
	#		#								#				#				#				#				#			
	funded		Addressing	%			# addressing	%		%	addressing				addressing	%			addressing	%		%	addressing	%		%	addressing	%		%
Cycle	awards	\$ awarded	Priority	Awards	\$ Awarded	% Funds	priority	Awards	\$ Awarded	Funds	priority	% Awards	\$ Awarded	% Funds	priority	Awards	\$ Awarded	% Funds	priority	Awards	\$ Awarded	Funds	priority	Awards	\$ Awarded	Funds	priority	Awards	\$ Awarded	Funds
FY2015	112	\$188,180,000	17	15%	\$49,000,000	26%	6	5%	\$30,950,000	16%	69	62%	\$92,319,999	49%	13	12%	\$22,100,000	12%	10	9%	\$17,900,000	10%	ND	0%	ND	0%	2	2%	\$6,450,000	3%
FY2016	109	\$197,590,000	20	18%	\$62,520,000	32%	6	6%	\$30,340,000	15%	72	66%	\$51,970,000	26%	17	16%	\$23,272,828	12%	20	18%	\$26,984,209	14%	38	35%	\$32,982,826	17%	9	8%	\$24,600,567	12%
FY2017	* 122	\$212,911,662	39	32%	\$113,100,000	53%	11	9%	\$46,562,278	22%	67	55%	\$53,986,327	25%	14	11%	\$21,260,046	10%	23	19%	\$48,478,271	23%	21	17%	\$40,896,125	19%	14	11%	\$39,983,177	19%
Total	343	\$598,681,662	76	22%	\$224,620,000	38%	23	7%	\$107,852,278	18%	208	61%	\$ 198,276,326	33%	44	13%	\$ 66,632,874	11%	53	15%	\$ 93,362,480	16%	59	17%	\$73,878,951	12%	25	7%	\$71,033,744	12%

Note: Projects may address more than one priority

July 13, 2017

<sup>\*</sup>Assumes adoption of August 1, 2017 PIC recommendations

# PREVENTION PROGRAM PRIORITIES FY2015 - FY2017

			ties - FY20	15 and FY2016										
							Prioritize popu	alations and	geographic areas	of greatest	-		entive efforts to	
Focus on underserved population						ns	need	d, greatest po	otential for impac	t		in the	state exist	
			#								#			
	# funded		addressing	% of total		% of \$	# addressing	% of total		% of \$	addressing	% of total		% of \$
Cycle	awards	\$ awarded	priority	awards	\$ awarded	awarded	priority	awards	\$ awarded	awarded	priority	awards	\$ awarded	awarded
FY2015	16	\$27,890,646	16	100%	\$27,890,646	100%	15	94%	\$26,627,304	95%	12	75%	\$18,920,485	68%
FY2016	26	\$26,938,196	26	100%	\$26,938,196	100%	18	69%	\$18,650,900	69%	14	54%	\$13,464,820	50%
TOTAL	42	\$54,828,842	42	100%	\$54,828,842	100%	33	79%	\$45,278,204	83%	26	62%	\$32,385,305	59%

NOTE: Projects may address more than one priority

	Prioritie Prioritie													
													hic areas of the	
							Prioritize pop	oulations dis	proportionately a	ffected by	dispropo	rtionately affe	cted by cancer in	ncidence,
			Prio	ritize unders	served population	ns	cancer incide	nce, mortali	ty or cancer risk p	orevalence	me	ortality or can	cer risk prevalen	ce
			#								#			
	# funded		addressing	% of total		% of \$	# addressing	% of total		% of \$	addressing	% of total		% of \$
Cycle	awards	\$ awarded	priority	awards	\$ awarded	awarded	priority	awards	\$ awarded	awarded	priority	awards	\$ awarded	awarded
FY 2017	17	\$26,043,832	17	100%	\$26,043,832	100%	11	65%	\$14,229,009	55%	10	59%	\$15,068,341	58%

NOTE: Projects may address more than one priority

<sup>\*</sup>Assumes adoption of August 1, 2017 PIC recommendations

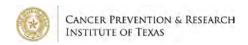
# PRODUCT DEVELOPMENT PROGRAM PRIORITIES FY2015 - FY2017

						Prioriti	es - FY2015 a	nd FY201	16						
				exas companies ar likely to bring imp the market			t promotes transla to new companies ne marketplace		Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment and prevention						
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Crolo	# funded awards	\$ awarded	# addressing priority	% of total awards	\$ awarded	% of \$ Awarded	# addressing priority	total awards	\$ awarded	% of \$ Awarded	addressing priority	total awards	\$ awarded	% of \$ Awarded	
Cycle	awaius	5 awaiueu	priority	awaius	ş awaiucu	Awaiueu	priority	awaius	5 awaiucu	Awarucu	priority	awaius	5 awaiucu	70 01 3 Awarded	
FY2015	6	\$69,509,265	6	100%	\$69,509,265	100%	1	17%	\$2,000,000	3%	6	100%	\$69,509,265	100%	
FY2016	4	\$66,060,655	4	100%	\$66,060,655	100%	1	25%	\$16,946,716	26%	4	100%	\$66,060,655	100%	
TOTAL	10	\$135,569,920	10	100%	\$135,569,920	100%	2	20%	\$18,946,716	14%	10	100%	\$135,569,920	100%	

NOTE: Projects may address more than one priority

													Priorities - FY20	17*												
	Funding novel projects that offer therapeutic or diagnostics not currently available, i.e., disruptive technologies			Funding proj		ssing large or ch dical needs	allenging unmet	Investing in	n early stag	e projects when pri available	vate capital is least			rcialization of tec t Texas institutio		attracting recruit sta experience	ng new company promising compa ff with life science of C-level staff to e expertise at varie	es expertise, es lead seed clust	that will especially ters of lfe	Providing a	appropriate retu investm		xpayer			
	# funded		# addressing	% of total		% of \$	# addressing	% of total		% of \$	# addressing	% of total			# addressing	% of total		% of \$	# addressing	% of total		% of \$	# addressing	% of total		% of \$
Cycle	awards	\$ awarded	priority	awards	\$ awarded	Awarded		awards	\$ awarded	Awarded	priority	awards	\$ awarded	% of \$ Awarded		awards	\$ awarded		priority	awards	\$ awarded		0	awards	\$ awarded	Awarded
FY2017	1	\$8,998,067	1	100%	\$8,998,067	100%	1	100%	\$8,998,067	100%	0	0%	\$0	0%	1	100%	\$8,998,067	100%	1	100%	\$8,998,067	100%	1	1	8998067	1

<sup>\*</sup> Assumes adoption of August 1, 2017 PIC recommendation



# **Priorities across CPRIT's Three Programs: FY2015 – FY2017 Cumulative\***

	Prevention and Early Detection Initiatives	Early Translational Research	Enhance Texas' Research Capacity and Life Science Infrastructure
Academic Research Program Implementation	\$63,068,424 39 awards	\$37,830,000 24 awards	\$294,380,000 76 awards
Prevention Program Implementation	\$80,872,674 59 awards	N/A	\$80,872,674 59 awards
Product Development Research Program Implementation	N/A	N/A	\$135,569,920 10 awards

<sup>\*</sup>Assumes adoption of PIC recommendations



#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS FROM: CAMERON ECKEL, STAFF ATTORNEY

**SUBJECT:** APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND

PREVENTION PROGRAMS COMMITTEE

**DATE: AUGUST 3, 2017** 

## **Summary and Recommendation**

The Chief Executive Officer has appointed four experts to the 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 July 28, 2017, 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.



# **Recommendations for Academic Research Peer Review Panels**

- Alex A Adjei, MD, PhD, FACP
- Lee J. Helman, MD
- Keith D. Robertson, Ph.D.
- Jen Jen Yeh, MD

#### **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: Alex A. Adjei, MD, PhD

eRA COMMONS USER NAME (credential, e.g., agency login): adjei001

POSITION TITLE: Professor of Oncology

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 Ghana Medical School, Accra, Ghana	M.D.	06/82	Medicine
University of Alberta, Edmonton, Canada	Ph.D.	10/89	Pharmacology

#### A. Personal Statement

I have spent my career in drug development, focusing on evaluating mechanisms of drug action and synergistic drug combinations in the laboratory, while performing phase I clinical trials in the clinic. In addition, I have applied my expertise in cancer pharmacology and drug development specifically to treating lung cancer, focusing on phase II developmental trials, biomarkers and pharmacogenetics. I have built research teams to translate in vitro and in vivo preclinical findings utilizing cultured cell lines, in vivo models including PDXs to define drug combinations and biomarkers that are then tested in the clinic. I have taken promising preclinical molecules, overseen their preclinical IND-enabling studies, arranged pre-IND FDA meetings, written INDs, and performed initial first-in-human studies. In recognition of my drug development activities, I was the first recipient of the American Society of Clinical Oncology Drug Development Research Professorship (2012-2017). I am currently the Principal Investigator of the NCI UM1 and phase II supplements at Mayo Clinic, and director of the early cancer therapeutics program, which is able to efficiently translate preclinical findings into phase I, phase I/II and phase II studies in all solid tumors and hematologic malignancies. In addition to drug development activities. I have been involved in conducting and overseeing a number of multi-institutional clinical trials and have been active in the ETCTN. As a former Group Vice-Chair and the Lung Program Chair of the North Central Cancer Treatment Group (NCCTG), I have had experience and involvement in coordinating and strategizing for lung cancer research nationally. As PI of several co-operative studies, I have expertise in running national multi-institutional studies. I have also previously overseen all aspects of clinical trials at Roswell Park Cancer Institute- as the senior vice-president for clinical research, setting strategic goals. facilitating development, implementation and conduct of all trials. I am currently co-Chair of the Thoracic Malignancies Steering Committee of NCI, and co-leader of the Experimental Therapeutics program at Mayo Clinic.

#### B. Positions and Honors Positions and Employment

i Ositions an	<u>a Employment</u>
1982-1983	Rotating Intern, University of Ghana Medical School, Accra, Ghana, West Africa.
1983-1984	Medical Officer, Department of Medicine, University of Ghana Medical School, Accra, Ghana
1984-1989	Graduate Student, Department of Pharmacology, University of Alberta, Edmonton, Alberta, Canada
1987-1989	Honorary Clinical Research Fellow, Dept of Medicine, University of Alberta, Edmonton, Canada
1989-1990	Intern, Internal Medicine Howard University and Affiliated Hospitals, Washington, DC
1990-1991	Resident, Internal Medicine Howard University and Affiliated Hospitals, Washington, DC
1991-1992	Chief Resident, Dept of Medicine Howard University and Affiliated Hospitals, Washington, D.C
1992-1995	Clinical and Research Fellow in Oncology, Johns Hopkins University School of Medicine
	Hospital, Baltimore, Maryland
1995-1998	Senior Associate Consultant, Oncology Mayo Clinic and Foundation, Rochester, Minnesota
1998-2006	Consultant in Oncology, Mayo Clinic and Foundation, Rochester, Minnesota
1995-2001	Assistant Professor of Oncology, Mayo Medical School, Rochester, Minnesota
2002-2004	Associate Professor of Oncology, Mayo College of Medicine, Rochester, Minnesota
2004-2006	Professor of Oncology, Mayo College of Medicine, Rochester, Minnesota
2006-2016	Professor of Oncology, Roswell Park Cancer Institute (RPCI), Buffalo, NY
2006-2016	Senior Vice President for Clinical Research; Chairman, Department of Medicine,

	Katherine Anne Gioia Chair in Cancer Medicine, RPCI, Buffalo, NY
2007-2016	Professor of Medicine, State University of New York, Buffalo, NY
2007-2016	Academic Scholar in Medicine, State University of New York, Buffalo, NY
2016	Consultant, Medical Oncology, Mayo Clinic, Rochester, MN
2016	Director, Early Cancer Therapeutics Program, Mayo Clinic, Rochester, MN
2016	Director, Global Oncology, Mayo Clinic, Rochester, MN
2016	Professor of Oncology, Mayo Clinic College of Medicine
	Other Professional Activities
1979	Best Student Award, University of Ghana Medical School
1985-1989	Alberta Heritage Foundation for Medical Research Scholarship
1988	National Cancer Institute (Canada) Travel Fellowship
1991	Resident of the Year, Howard University and Affiliated Hospitals Washington, D.C.
1993	Travel Award, American Society of Hematology
1995	Merit Award, American Society of Clinical Oncology
1999	Co-Chair, North Central Cancer Treatment Group (NCCTG) Lung Committee
1999	Member, Lung Cancer Concept Evaluation Panel, National Cancer Institute (NCI)
2000	Member, Lung Cancer Progress Review Group, NCI
2002	Member, Signal Transduction Working Group, NCI
2003 2003-2006	Chair, American Association for Cancer Research Minorities in Cancer Research Council
2003-2006	Director, Mayo Clinic Phase I Program Leader, Mayo Clinic Lung Cancer Program
2003-2000	Member, NIH Study Section: National Center for Research Resources (NCRR) Clinical
2001 2001	Research Review Committee (GCRC – CTSA)
2004	Co-Chairperson, 96th Annual Meeting of the American Association for Cancer Research
2005	Member, NCI Special Emphasis Panel, Lung Cancer SPORE reviews
2005	Member, NCI Special Emphasis Panel, Program Project Grant Reviews
2005-2012	Chair, North Central Cancer Treatment Group Lung Committee
2005-2007	Group Vice-Chair, North Central Cancer Treatment Group
2005-2012	Senior Editor, Molecular Cancer Therapeutics
2005 2005	Member, American Society of Clinical Oncology Translational Research Task Force
2006-2008	Member, Scientific Leadership Council in Lung Cancer, Coalition of Cancer Cooperative Groups Co-Chair, Clinical Trials Design Task Force, Investigational Drugs Steering Committee, NCI
2006-2013	Section Editor, Cancer Journal
2006	Co-Chairperson, 98 <sup>th</sup> Annual Meeting of the American Association for Cancer Research
2007-2013	Chair, NIH Study Section: NCRR Clinical Research Review Committee (CTSA)
2008-2011	Member, Editorial Board, Journal of Clinical Oncology
2008	Member, Cancer Research Committee, American Society of Clinical Oncology
2009	Member, Grants Selection Committee, American Society of Clinical Oncology
2009	Member, Review Panel NCI Intramural Program – Medical Oncology Branch
2009	Member, Scientific Advisory Board, Ontario Institute of Cancer Research, Clinical Trials
2010	Program and Chemistry Group Member, Clinical Oncology Study Center (CONC), Center for Scientific Review, NCI
2010	Member, Editorial Advisory Panel for Treatment Strategies, US Oncology
2011-2012	Member, Steering Committee, ASCO/ASTRO/IASLC Multidisciplinary Thoracic Oncology Mtg
2011	Member, Board of Directors, Academic and Community Cancer Research United (AACRU)
2011	Member, Board of Directors, International Association for the Study of Lung Cancer (IASLC)
2012	Co-Chairperson, 104 <sup>th</sup> Annual Meeting of the American Association for Cancer Research
2012	Member, Gastrointestinal Steering Committee, NCI Colon Cancer Task Force
2012	Member, Executive Advisory Board, Mitchell Cancer Institute, Mobile, Alabama
2013	Editor-in-Chief, Journal of Thoracic Oncology
2013	Member, NCI IRG Subcommittee A – Cancer Centers.  Member, External Advisory Board, University of Miami CTSI.
2013 2014	Member, External Advisory Board, University of Miami CTSI Member, SWOG/Cold Spring Harbor/Jackson Labs Translational Science Center Advisory
201 <del>4</del>	Board
2015	Co-Chair, Thoracic Malignancies Steering Committee, NCI
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#### **C. Contribution to Science** (selected from 243 peer-reviewed manuscripts)

# 1. Development of Pharmacodynamic Biomarkers for Early Cancer Drug Development

Working with farnesyltransferase inhibitors in the early days of "targeted therapies", I was one of the first investigators to incorporate biomarkers into clinical trials. Our group developed a buccal mucosa cell assay to allow for the evaluation of the inhibition of prelamin in patient cells after treatment with farnesyltransferase inhibitors. Continuing from our work with farnesyltransferase inhibitors where we

evaluated drug effects in normal tissue, we incorporated tumor biomarkers into phase I drug development. In a series of studies, we developed an assay for ERK phosphorylation in cells and incorporated them into phase I studies of MEK inhibitors, paving the way for the routine incorporation of PD biomarkers in phase I and phase II clinical trials. We also contributed significantly to the understanding of these compounds and performed a number of single-agent and hypothesis based cpmbination studies

- a. **Adjei AA**, Davis JN, Erlichman C, Svingen PA, Kaufmann SH. Comparison of potential markers of farnesyltransferase inhibition. Clin Cancer Res 2000 Jun; 6(6):2318-25.
- b. **Adjei AA**, Erlichman C, Davis JN, Cutler DL, Sloan JA, Marks RS, Hanson LJ, Svingen PA, Atherton P, Bishop WR, Kirschmeier P, Kaufmann SH. A Phase I trial of the farnesyl transferase inhibitor SCH66336: evidence for biological and clinical activity. Cancer Res 60(7):1871-7, 2000.
- c. **Adjei AA**, Croghan GA, Erlichman C, Marks RS, Reid JM, Sloan JA, Pitot HC, Alberts SR, Goldberg RM, Hanson LJ, Bruzek LM, Atherton P, Thibault A, Palmer PA, Kaufmann SH. A phase I trial of the farnesyl protein transferase inhibitor R115777 in combination with gemcitabine and cisplatin in patients with advanced cancer. Clin Cancer Res 2003; 9:2520-26.
- d. Adjei AA, Cohen RB, Franklin W, Morris C, Wilson D, Molina JR, Hanson LJ, Gore L, et al. Phase I Pharmacokinetic and Pharmacodynamic Study of the Oral, Small-Molecule Mitogen-Activated Protein Kinase Kinase 1/2 Inhibitor AZD6244 (ARRY-142886) in Patients With Advanced Cancers. J Clin Oncol. 26(13):2139-46, 2008.
- e. McShane LM, Hunsberger S, **Adjei AA**. Effective incorporation of biomarkers into phase II trials. Clin Cancer Res: 15(6):1898-905, 2009.

# 2. Clinical development of novel combinations based on preclinical mechanistic studies.

Another focus of my group over the years has been evaluating mechanisms of preclinical synergy of novel compounds and translating findings into clinical trials.

- a. **Adjei AA**, Davis JN, Bruzek LM, Erlichman C, Kaufmann SH. Synergy of the protein farnesyltransferase inhibitor SCH66336 and cisplatin in human cancer cell lines. Clin Cancer Res 2001 May; 7(5):1438-45.
- b. **Adjei AA**, Croghan GA, Erlichman C, Marks RS, Reid JM, Sloan JA, Pitot HC, Alberts SR, Goldberg RM, Hanson LJ, Bruzek LM, Atherton P, Thibault A, Palmer PA, Kaufmann SH. A phase I trial of the farnesyl protein transferase inhibitor R115777 in combination with gemcitabine and cisplatin in patients with advanced cancer. Clin Cancer Res 2003; 9:2520-26.
- c. Yu C, Friday BB, Lai JP, Yang L, Sarkaria J Kay NE, Carter CA, Roberts LR, Kaufmann SH, **Adjei AA.** Cytotoxic synergy between the multikinase inhibitor sorafenib and the proteasome inhibitor bortezomib in vitro: induction of apoptosis through Akt and c-Jun NH2-terminal kinase pathways. Mol Cancer Ther. 5(9):2378-87. 2006.
- d. Yu C, Friday BB, Yang L, Atadja P, Wigle D, Sarkaria J, **Adjei AA.** Mitochondrial Bax translocation partially mediates synergistic cytotoxicity between histone deacetylase inhibitors and proteasome inhibitors in glioma cells. Neuro Oncol. 10, 309-319, 2008.

#### 3. Phase I Clinical Trials of Novel Anticancer Agents

We have performed the first-in-human studies of a number of compounds and have contributed to an understanding of their mechanism of action in a series of preclinical and clinical studies. We have also further developed a number of promising compounds and combinations in phase II studies

- a. Dy GK, Thomas JP, Kaufmann SH, Wilding G, Bruzek L, Erlichman C, Mandrekar S, Pitot HC, Alberts SR, Hanson LJ, **Adjei AA**. A Phase I and Pharmacologic Trial of two schedules of the Proteasome Inhibitor, PS-341, in Patients with Advanced Cancer. Clin Cancer Res.;11:3410-6, 2005.
- b. Markovic SN, Geyer SM, Dawkins F, Sharfman W, Albertini M, Maples W, Fracasso PM, Fitch T, Lorusso P, **Adjei AA**, Erlichman C. A phase II study of bortezomib in the treatment of metastatic malignant melanoma. Cancer. 15;103(12):2584-9, 2005.
- c. Zhao Y, Foster NR, Meyers JP, Thomas SP, Northfelt DW, Rowland KM Jr, Mattar BI, Johnson DB, Molina JR, Mandrekar SJ, Schild SE, Bearden JD 3rd, Aubry MC, **Adjei AA.** A Phase I/II Study of Bortezomib in Combination with Paclitaxel, Carboplatin and Concurrent Thoracic Radiation Therapy for Non-Small Cell Lung Cancer: NCCTG-N0321.J Thorac Oncol. 10:172-180, 2015.
- d. Lorusso PM, **Adjei AA**, Varterasian M, Gadgeel S, Reid J, Mitchell DY, Hanson L, Deluca P, et al. Phase I and pharmacodynamic study of the oral MEK inhibitor CI-1040 in patients with advanced malignancies. J Clin Oncol; 23(23):5281-93, 2005.

- e. **Adjei AA**, Mauer A, Bruzek L, Marks RS, Hillman S, Geyer S, Hanson LJ, Wright JJ, Erlichman C, Kaufmann SH, Vokes EE. Phase II study of the farnesyl transferase inhibitor R115777 in patients with advanced non-small-cell lung cancer. J Clin Oncol 2003, May 1; 21(9):1760-6.
- f. **Adjei AA**, Erlichman C, Sloan JA, Reid JM, Pitot HC, Goldberg RM, Peethambaram P, Hanson LJ, Alberts SR, Jett J. Phase I and pharmacologic study of sequences of gemcitabine and the multitargeted antifolate agent in patients with advanced solid tumors. J Clin Oncol ;18:1748-57, 2000.
- g. Ma CX, Nair S, Thomas S, Mandrekar S, Nikcevich DA, Rowland KM, Fitch TR, Windschitl HE, Hillman S, Schild S, Jett JR, Obasaju C, **Adjei AA.** Pemetrexed and Gemcitabine as Front-line Therapy for Advanced NSCLC: A Randomized, Phase II NCCTG Trial of Three Schedules. J Clin Oncol, 23: 5929-5937, 2005.

#### 4. Preclinical Pharmacology and Mechanism of action of signal transduction inhibitors

We have delineated the mechanism of action of a number of novel anticancer agents that have contributed to their subsequent development. We demonstrated a feedback loop between ERK and RAF, and predicted that a combination of MEK inhibitors and raf inhibitors would be synergistic. We demonstrated this in vitro and in vivo with a combination of the MEK inhibitor, rafemitinib and the pan-raf inhibitor sorafenib. These and other such data underlie the use of MEK inhibitors and BRAF inhibitors in the therapy of melanoma.

- a. Friday BB, Yu C, Dy GK, Smith PD, Wang L, Thibodeau SN, **Adjei AA.** BRAF V600E disrupts AZD6244- induced abrogation of negative feedback pathways between extracellular signal-regulated kinase and Raf proteins. Cancer Res. 2008 Aug 1; 68(15):6145-53.
- b. Schmieder R, Puehler F, Neuhaus R, Kissel M, Adjei AA, Miner JN, Mumberg D, Ziegelbauer K, Scholz, A.Allosteric. MEK1/2 Inhibitor Refametinib (BAY 86-9766) in Combination with Sorafenib Exhibits Antitumor Activity in Preclinical Murine and Rat Models of Hepatocellular Carcinoma. Neoplasia 15:1147-1157, 2013.
- c Bruzek LM, Meng XW, Gores GJ, Carter C, Kaufmann SH, **Adjei AA**. The Role of Mcl-1 Down-regulation in the Pro-apoptotic activity of the Multi-Kinase Inhibitor BAY43-9006. Oncogene, 24: 6861-6869, 2005.
- d **Adjei AA**, Charron M, Rowinsky EK, Svingen PA, Miller J, Reid JM, Sebolt-Leopold J, Ames MM, Kaufmann SH. Effect of pyrazoloacridine (NSC 366140) on DNA topoisomerases I and II. Clin Cancer Res 1998 Mar; 4(3):683-91.

#### 5. Translational Pharmacogenetics

We have performed basic and translational pharmacogenetic studies aimed at understanding the determinants of toxicity of investigational anticancer agents. We resequenced and characterzed functional polymorphisms of aromatase and folyl polyglutamate synthase and studied the pharmacogenetics of aromatase inhibitors and the antifolate pemetrexed in a number of clinical trials.

- a. Ma CX, Adjei AA, Salavaggione OE, Coronel J, Pelleymounter L, Wang L, Schaid D, Eckloff, BW., Wieben, ED., **Adjei, AA.**, Weinshilboum, RM. Human Aromatase (CYP19). Pharmacogenomics: Gene Resequencing and Functional Genomics. Cancer Research, 65: 11071-82, 2005.
- b. Leil TA, Endo C, Adjei AA, Dy GK, Salavaggione OE, Reid JR, Ames MM, **Adjei AA.** Identification and characterization of genetic variation in the folylpolyglutamate synthase gene. Cancer Res. 67(18):8772-82, 2007.
- c. **Adjei AA**, Mandrekar SJ, Dy GK, Molina JR, Adjei AA, Gandara DR, Ziegler KL, Stella PJ, Rowland KM Jr, Schild SE, Zinner RG. Phase II trial of pemetrexed plus bevacizumab for second-line therapy of patients with advanced non-small-cell lung cancer: NCCTG and SWOG study N0426. J Clin Oncol. 2010 Feb 1; 28 (4):614-619. Epub 2009 Oct 19.
- d. Adjei AA, Salavaggione OE, Mandrekar SJ, Dy GK, Ziegler KL, Endo C, Molina JR, Schild SE, Adjei AA. Correlation between polymorphisms of the reduced folate carrier gene (SLC19A1) and survival after pemetrexed-based therapy in non-small cell lung cancer: A North Central Cancer Treatment Group-Based Explatory Study. J Thorac Oncol. 2010 Sep; 5(9):1346-53.
- e. Dy GK, Molina JR, Qi Y, Ansari R, Thomas S, Ross HJ, Soori G, Anderson D, Aubry MC, Meyers J, Adjei AA, Mandrekar S, **Adjei AA.** NCCTG N0821 (Alliance): A Phase II First-Line Study of Pemetrexed, Carboplatin, and Bevacizumab in Elderly Patients with Advanced Nonsquamous Non-Small-Cell Lung Cancer With Good Performance Status. J Thorac Oncol. 9:1146-1153, 2014.

#### Complete List of Published Work in MyBibliography:

https://www.ncbi.nlm.nih.gov/pubmed/?term=alex+a+adjei

# D. Research Support

**ACTIVE** 

ASCO Drug Development Research Professorship (Adjei)

07/01/12 - 06/01/17

**Conquer Cancer Foundation** 

Provides support for mentoring junior colleagues in the areas of drug development, clinical trial design and regulatory science

UM1 CA186686-03 Adjei (PI) National Institutes of Health 04/01/13 - 03/31/18

NCI Experimental Therapeutics - Clinical Trials Network with Phase I Emphasis

The major goals of this project are: Phase I trials of novel anticancer agents and laboratory correlates. This cooperative agreement contains funding for protocol development, data management and statistical analysis performed in conjunction with CTEP-approved trials as well as a small amount of funds for pharmacokinetic and pharmacogenetic analysis.

UM1 CA186686-03S1 Adjei (PI) National Institutes of Health 04/01/13 - 03/31/18

Phase 2 Clinical Trials Program for Experimental Therapeutics Clinical Trials

The major goals of this project are: Phase II trials of novel anticancer agents and laboratory correlates. This cooperative agreement contains funding for protocol development, data management and statistical analysis performed in conjunction with CTEP-approved trials and is a supplement to the Phase I grant

DOD/CDMRP BC140507 (Gudkov)

02/01/15 - 01/31/18

Prevention of Metastatic Breast Cancer with a TLR5 Agonist

Our main objective is to determine the feasibility and decipher the mechanisms of metastasis suppressor activity of TLR5 agonist Entolimod to facilitate its development into a cancer immunotherapeutic drug.

#### **COMPLETED**

1 U10 CA 180866 (Levine, Adjei, Lele, Singh)

05/06/14 - 02/28/16

NIH/NCI

Network Lead Academic Participating Site Grant from the Roswell Park Cancer Institute
The aim of inter-Institutional cooperative clinical research is to advance our understanding of malignant diseases and; thereby improve our ability to treat people afflicted with them. These aims are accomplished by resolving scientific questions of importance regarding cancer biology and therapy through the cooperation of selected Institutions that can pool their intellectual, technical, and patient resources. The rapid accumulation of clinical data and experience through cooperative research expedites progress in cancer therapy.

#### **BIOGRAPHICAL SKETCH**

NAME: Lee J. Helman

Senior Investigator, Pediatric Oncology Branch, National Cancer Institute, National Institutes of Health

#### **EDUCATION/TRAINING**

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
George Washington University	B.A. with distinction	06/76	Biology
University of Maryland School of Medicine, Baltimore, MD	M.D. magna cum laude	1980	Medicine
Barnes Hospital, St. Louis, MO		1980-1983	Residency in Internal Medicine
Washington University Medical Service, St. Louis, MO Veterans Administration Medical Center, St. Louis, MO		7/82-12/82	Chief Resident
Pediatric Branch and Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD		1983-1984	Medical Staff Fellow
Molecular Genetics Section, Pediatric Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD		1984-1986	Medical Staff Fellow

#### A. Personal Statement

After completing my residency in Internal Medicine at Washington University where I served as Chief Resident of the VA my senior year, I came to the National Cancer Institute as a fellow in Medical Oncology in 1983. During my first clinical year, I spent 6 months training in the Medicine Branch and 6 months training in the Pediatric Branch. I then joined the Molecular Genetics Section of the Pediatric Branch to study the molecular control of normal and aberrant differentiation using neuroblastoma as a model system. Using cDNA cloning techniques, I cloned IGFII and found it was markedly overexpressed in neuroblastoma compared to normal adrenal medulla. I became an independent investigator in the Pediatric Branch in 1990 and elected to study pediatric sarcomas. I found that IGFII was also overexpressed in rhabdomyosarcomas compared to normal skeletal muscle, and then studied the role of IGFII in normal skeletal muscle development and in the pathogenesis of rhabdomyosarcoma. I have continued to study the role of IGF signaling in a variety of pediatric sarcomas and used these insights in clinical studies of human IGF1R antibodies. My laboratory now studies mechanisms of resistance to IGF1R blockade and are also pursues functional genomics and matrix drug screening to identify new targets for the treatment pediatric sarcomas. I have also developed an interest in pediatric GIST tumors that lack the KIT or PDGFRA mutations (as is common in adult GIST tumors) and have, with others, identified SDH mutations as the driver in these tumors. We recently published results of a large series of these rare GIST patients, dividing them into categories with implications for treatment and prognosis. Over the years I have assumed increasing levels of responsibility at the NCI, serving as the Chief of the Pediatric Oncology Branch from 1997-2007, Scientific Director for Clinical Research in the Center for Cancer Research at the NCI from 2007-2016, and as Acting Director of the Center for Cancer Research from 2007-2016. Over my years at NCI, I have trained 12 post-doctoral fellows who have all continued to be involved in research, several at academic institutions. I currently serve as the Director of the Cancer and Blood Diseases Research Program at The Saban Research Institute at Children's Hospital Los Angeles as well as the Section Head for Basic and Translational Research for the Division of Children's Center for Cancer and

Blood Diseases and Professor of Pediatrics and Medicine at the Keck School of Medicine at the University of Southern California. I also serve as a member of the Executive Committee of the USC Norris Comprehensive Cancer Center.

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

2007

1986-1987	Biotechnology Fellow, Molecular Genetics Section, Pediatric Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD
1987-1990	Senior Staff Fellow, Molecular Genetics Section, Pediatric Branch, NCI, NIH, Bethesda, MD
1990-1992	Medical Officer, Molecular Genetics Section, Pediatric Branch, NCI, NIH, Bethesda, MD
1993-present	Head, Molecular Oncology Section, Pediatric Oncology Branch, NCI, NIH, Bethesda, MD
1994-1998	Associate Professor of Pediatrics, Uniformed Services of the Health Sciences, F. Edward
	Herbert School of Medicine, Bethesda, MD
1995-1996	Acting Deputy Chief, Pediatric Oncology Branch, NCI, NIH, Bethesda, MD
1996-1997	Acting Chief, Pediatric Oncology Branch, NCI, NIH, Bethesda, MD
1999-2017	Professor of Pediatrics/Oncology (par-time), Johns Hopkins University, Baltimore, MD
1997-2007	Chief, Pediatric Oncology Branch, NCI, NIH, Bethesda, MD
2001-2015	Deputy Directory, Center for Cancer Research, NCI, NIH, Bethesda, MD
2005-2007	Acting Scientific Director for Clinical Research, CCR, NCI, NIH, Bethesda, MD
2005-2007	Acting Chief, Medical Oncology, CCR, NCI, NIH, Bethesda, MD
2007-2016	Scientific Director for Clinical Research, CCR, NCI, NIH, Bethesda, MD
2008-2009	Acting Clinical Director, NCI, NIH, Bethesda, MD
2015-2016	Acting Director, CCR, NCI, NIH, Bethesda, MD
2017-present	Professor of Pediatrics and Internal Medicine, Children's Hospital Los Angeles and
	University of Southern California. Director Pediatric Cancer Research Program

# Other Experience and Professional Memberships 2005-present

Other Experienc	e and i foressional memberships 2005-present
1998-present	Intramural Advisory Board, NIH
1999-present	Israel Canc Res Fund Scientific Advisory Board
2000-present	Amer Joint Comm on Cancer Bone Task Force
2000-present	Scientific Review Board, Can Res Found of America's Hope Street Kids
2001-present	Scientific Advisory Board, Children's Cancer Research Institute, Vienna, Austria
2000-present	Children's Oncology Group – Ewing's Biology Comm
2001-present	Bone Sarcoma Disease Comm & Scientific Advisory Committee
2001-present	Cancer Research UK, Grant Reviewer
2002-present	Sarcoma Foundation of America Medical Advisory Board
2003-2006	ASCO Board of Directors
2003-present	AACR Pediatric Oncology Task Force
2003-present	NCI Sarcoma Progress Review Group, Executive Director
2003-2008	Board of Governors, Warren Grant Magnuson Clinical Center, NIH (Restructured and
	Renamed Advisory Board for Clinical Research 2004)
2005	AACR Pediatric Cancers-Basic Science and Pediatric Cancer-Clinical Investigations
	Sections, Program Committee
2003-present	Ireland-Northern Ireland-National Cancer Institute Cancer Consortium, Implementation Group
	Member
2006	Scientific Committee Member
2005	European Commission's 6th Framework Programme for Research and Demonstration
	Activities, Major Diseases Unit for Cancer-Evaluation of European Projects on Cancer
	Research
2005-present	Coaches Curing Kids' Cancer, Co-Chair Medical Advisory Board
2006	MD Anderson Cancer Center, External Advisory Board for the Department of Sarcoma
	Medical Oncology
2006	Samuelsson Foundation Grant Reviewer
2006	Cincinnati Children's Hospital Medical Center Research Foundation, Scientific
	Advisory Council

Maine Institute for Human Genetics & Health, Founding Member

2007-2010 2007-2010	Maine Institute for Human Genetics & Health, Chair, Scientific Advisory Board Children's Research Institute at Children's National Medical Center, Scientific Advisory Committee
2008-present	Alex's Lemonade Stand Fund Grant Program Grant Reviewer
2008-present	Foster Foundation Advisory Board
2009-2011	EuroBoNeT Consortium, External Advisory Board
2009-2010	8th International Symposium on Targeted Anticancer Therapies (TAT 2010),
	Organizing Committee
2010	Irish Cancer Society, Grant Reviewer
2010	Irish Medicines Board, Expert Panel of the Clinical Trials Subcommittee
2010-2013	Clinical Trials Network of Texas, CTNet, External Advisory Board
2010-2015	Baylor College of Medicine, External Advisory Board, Project: Targeted Therapies for Metastatic Osteosarcoma
2014-2015	MD Anderson Cancer Center, External Advisory Board

Phi Beta Kappa, George Washington University

#### Honors/Awards

1976

2016

1070	Thi Beta Kappa, George Washington Chiveroity
1979	Alpha Omega Alpha, University of Maryland School of Medicine
1986/1987	ASCO Travel Award
1996	American Society of Clinical Investigation
1999	Israel Cancer Research Fund's Elliott Osserman Award for Distinguished Service in
	Support of Cancer Research
2002	NIH Merit Award
2003	Association of American Physicians
2005	NCI Director's Award
2005, 2006, 2010	Federal Technology Transfer Award
2006, 2009	NIH Director's Award
2008	The Life Raft Group Humanitarian Award
2011	ASCO Pediatric Oncology Award and Lecture: Pathways to New Targets for
	Pediatric Sarcomas
2011	ASCO Statesman Award
2012	NCI Women Scientists Advisors Mentoring and Leadership Award
2012	The Arielle Anacker Cancer Foundation Man of the Year Award for Outstanding
	Work in Research of Pediatric Bone Cancers
2012	British Association for Cancer Research Tom Connors Lecturer Award at the
	National Cancer Research Institute Cancer Conference, Liverpool, United Kingdom

#### C. Contributions to Science

**NIH Directors Award** 

#### Identification and Characterization of IGF Signaling Activation in Pediatric Sarcomas

During my work as a post-doctoral fellow, I cloned a cDNA for human IGFII. Using this clone as a probe, I confirmed that IGFII was very highly expressed in human fetal skeletal muscle as well as in human rhabdomyosarcomas (RMS), an embryonal tumor thought to be of skeletal muscle origin. Based on these data, I elected to pursue the role of IGFII in this tumor. I first demonstrated that IGFII functioned as an autocrine growth factor in RMS (Cell Growth Differ. 1: 325-331,1990). I subsequently demonstrated that while there were no mutations in IGFII in these tumors, there was loss of imprinting (LOI) of the IGFII gene in RMS (JCI 94:445-448, 1994). I demonstrated that a mouse monoclonal antibody directed against the IGFI receptor blocked growth of RMS cell lines and xenografts. I also showed that Ewing's sarcomas had LOI of the IGFII gene, and that human fibroblasts required the IGFI receptor for the Ewing's oncogene, EWS-FLI-1

to transform them (J. Biol. Chem. 272:30822-30827, 1997). This work laid the foundation for the clinical testing of several fully human monoclonal antibodies directed against the IGFIR in Ewing's sarcoma and RMS. I played a major role in one such study showing that while there was a relatively low overall response rate, some responses in Ewing's sarcoma were dramatic, suggesting that efforts to maximize the role of such therapy in Ewing's sarcoma are warranted (J. Clin. Oncol. 29:4541-4547, 2011).

#### Identification of SDH Alterations in Pediatric GIST that Lack KIT or PDGFRA Mutations

Gastrointestinal stromal tumors (GIST) provide an example of the benefit of applying targeted therapy aimed at tumor-specific mutations identified by sequencing. In the case of GIST, most adult tumors harbor a CKIT or PDGFRA mutation and are successfully treated with kinase inhibitors that target these activated kinases. Pediatric GISTs are very rare tumors that almost never harbor these activating kinase mutations. After seeing cases of pediatric GIST that did not respond to standard treatments for adult tumors, it became clear that pediatric GIST, while histologically similar to adult GIST, had a distinct biology. Because of the rarity of pediatric GIST, I founded the NIH Pediatric and Wild-Type GIST clinic in June 2008. We brought both patients and physicians from around the country to the NIH to establish a large database of patients and to study the tumor biology with the hope of developing more effective treatment. We have held 10 such clinics to date and have seen more than 100 patients from around the USA and several patients from Europe. We first determined that a subset of these tumors had SDH deficiency by IHC staining and found numerous SDH mutations (PNAS, 108:314-308, 2011). We subsequently identified a large subgroup of tumors that had mutations in SDH A, B, C or D, and all of these tumors displayed massive global genomic hypermethylation presumably due to loss of TET2 demethylase activity secondary to accumulation of succinate (Cancer Discov. 3:648-657, 2013). The majority of these SDH mutations occurred in the germline, but a substantial minority of patients has been found to have SDH deficiency by IHC staining but no discernable SDH mutation. We have published results using clinical and molecular data to categorize pediatric GIST into 3 distinct groups with differing prognoses and management strategies (JAMA Oncology 2:922-928, 2016). We will continue to explore other therapies aimed at overcoming the SDH deficiency that drives these tumors.

# Identification of mTOR Signaling as a Target in Metastatic Pediatric Sarcomas

Metastatic disease represents the major cause of morbidity and mortality for pediatric sarcoma patients, and little progress has been made in improving the outcome of patients who present with metastases. We therefore sought to develop models of metastatic behavior to help us identify new approaches to treatment. Using a mouse model of highly metastatic osteosarcoma, we identified the membrane-cytoskeletal linker, ezrin, as necessary for metastatic behavior (Nat. Med. 10:182-186, 2004). Using this same murine metastatic model, we then determined that blockade of mTOR using rapamycin could abrogate the metastatic behavior (Cancer Res. 65:2406- 2411, 2005). This led us to explore whether mTOR inhibition might be of benefit to treat pediatric sarcomas that are not curable using current chemotherapeutic approaches. We elected to analyze Stage III human rhabdomyosarcoma tumors, because approximately 50% of patients who present with Stage III tumors recur with metastatic disease. We used phosphoprotein pathway mapping to study primary tumor samples obtained at diagnosis in cases where long-term outcome was known. We determined that activation of mTOR signaling in tumors at diagnosis predicted poor outcome (Cancer Res. 67:3431-3440, 2007). Overall, these findings have strongly implicated mTOR activation in metastatic behavior of pediatric sarcomas. Based in part on our work, the Children's Oncology Group recently completed a randomized study comparing standard chemotherapy with or without the addition of a rapalog in the treatment of high-risk rhabdomyosarcoma. The study demonstrated a clear survival advantage for the patients treated with chemotherapy plus rapalog treatment, confirming the potential of mTOR inhibition to improve the outcome of patients at high risk of developing overt metastatic disease.

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

ZIA SC006891 \$475,000 per year This was an NCI intramural funded project entitled *Solid Tumors*. The project encompassed basic and clinical studies of osteosarcoma, Ewing's sarcoma, rhabdomyosarcoma, and pediatric SDH-deficient GIST. This funding supported all of Dr. Helman's laboratory studies and partial funding for resulting clinical studies (research nurse support). It was active for 16 years up until the time of his departure from the NCI, and reviewed every 4 years but external Board of Scientific Counselors.

#### **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: Robertson, Keith D.

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

POSITION TITLE: Professor of Pharmacology

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
Cornell University, Ithaca, NY	B.S.	05/1992	Biochemistry
The Johns Hopkins University, Baltimore, MD	Ph.D.	10/1996	Pharmacology
The Johns Hopkins University, Baltimore, MD	Postdoctoral	06/1997	Pharmacology
Norris Comprehensive Cancer Center, University of Southern California, Los Angeles, CA	Postdoctoral	06/1999	Molecular Biology
National Institutes of Health / Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, MD	Postdoctoral	06/2000	Biochemistry

#### A. Personal Statement

I am an established investigator with expertise in cancer epigenetics. I have led a productive NIH-funded laboratory focused on basic and translational aspects of cancer epigenetics for 17 years. The long-term goal of my laboratory is to determine how epigenetic marks on the DNA are targeted throughout the genome under normal conditions and how this regulatory network goes awry in cancer and other human diseases. We address this goal using traditional and cutting edge methods in molecular biology, biochemistry, cell biology, and pharmacology. I have trained 12 postdoctoral fellows and 7 of them are now in independent academic or industry positions. Five of my trainees have successfully competed for NIH (F31/F32) or foundation fellowships. I have a broad background in cancer biology and substantial specific expertise in epigenetic mechanisms that are key to the successful completion of this project. As a postdoctoral fellow at the University of Southern California and NIH/NICHD, I studied DNA methylation of tumor suppressor genes and biochemically characterized the DNA methyltransferases. As PI on several NIH funded grants, I laid the groundwork for the proposed studies by developing assays to quantify DNA and histone modifications, characterizing the interplay between histone epigenetic marks and DNA methylation/hydroxymethylation, and defining how environmental factors impact the epigenome. In addition, I successfully administered the research projects (e.g. staffing, training, interactions with federal funding agencies, budgets), collaborated with other researchers, and published peer-reviewed manuscripts in quality journals. As a result of these experiences, I am aware of the importance of careful planning, communication with my staff and collaborators, and publishing research findings in a timely manner. In summary, I have demonstrated a record of directing productive research projects in basic and translational epigenetics.

- 1. Putiri EL, Tiedemann RL, Thompson JJ, Liu C, Ho T, Choi J-H, **Robertson KD**. Distinct and overlapping control of 5-methylcytosine and 5-hydroxymethylcytosine by the TET proteins in human cancer cells. *Genome Biol.* 15(6): R81, 2014. PMCID: PMC4197818
- 2. Tiedemann RL, Putiri EL, Lee J-H, Hlady RA, Kashiwagi K, Ordog T, Zhang Z, Liu C, Choi J-H, **Robertson KD**. Acute depletion redefines the division of labor among the DNA methyltransferases in methylating the human genome. *Cell Rep.* 9(4):1554-66, 2014. PMCID: PMC4254561
- 3. Zhou D, Hlady RA, Schafer MJ, White TA, Liu C, Choi J-H, Miller JD, Roberts LR, LeBrasseur NK, **Robertson KD**. High fat diet and exercise lead to a disrupted and pathogenic DNA methylome in mouse liver. *Epigenetics*. 12(1): 55-69, 2017. PMCID: PMC5270632
- 4. Hlady RA, Puszyk W, Wu Q, Cabrera R, Choi JH, Liu C, **Robertson KD**. Initiation of aberrant DNA methylation patterns and heterogeneity in precancerous lesions of human hepatocellular carcinoma. *Epigenetics*. 12(3): 215-2252017, 2017. PMCID: PMC5406211

### Selected from a total of 90 manuscripts.

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

<b>Positions</b>	and	<b>Employ</b>	yment:

2000-2004	NCI Cancer Scholar/Principal Investigator, National Institutes of Health, Bethesda, MD
2004-2009	Assistant Professor, Department of Biochemistry and Molecular Biology and Shands Cancer
	Center, University of Florida, College of Medicine, Gainesville, FL
2009-2013	Associate Professor (tenured), Cancer Center and Department of Biochemistry and Molecular
	Biology, Georgia Regents University, Augusta, GA (now Augusta University)
2013-present	Professor of Pharmacology, Mayo Clinic College of Medicine and Science, Rochester, MN
2015-present	Consultant, Department of Molecular Pharmacology and Experimental Therapeutics, Mayo
-	Clinic, Rochester, MN

# Other Experience and Professional Memberships:

1999-present	American Association for Cancer Research
2002-present	American Society for Biochemistry and Molecular Biology
2003-2006	Epigenetics Society Board of Directors
7/2006	Ad-hoc reviewer for NIH SEP 'Epigenetics' ZAA1 DD (72)
9/2006	Ad-hoc reviewer for NIH Program Project P01 ES11624-05
2006-2008	President, Epigenetics Society (formerly the DNA Methylation Society)
2006-present	Editorial Board, Epigenetics
2008-present	American Society for Microbiology
6/2009	Ad-hoc reviewer, NIH Genetics of Human Disease (GHD) Study Section
6/07,10/09	Ad-hoc reviewer, NIH Cancer Genetics (CG) Study Section
2/2010	Ad-hoc reviewer, NIH SEP 'Epigenetic Processes in Development' Study Section
3/2011	Ad-hoc reviewer, NIH SEP 'Epigenomics of Human Health and Disease' ZRG1 GGG-M(50)
6/2011	Ad-hoc reviewer, NIH/NCI SEP 'Barrett's Esophagus Translational Research Network' U54
9/2011	Ad-hoc reviewer, NIH Molecular Genetics B (MGB) Study Section
3/2012	Ad-hoc reviewer, NIH/NCI SEP 'Provocative Questions ZCA1 SRLB-9 (M1)' Study Section
11/12, 2/13	Ad-hoc reviewer, NIH/NCI SEP 'NCI Omnibus R21/R03 FOA' Study Section
2/14,6/14,10/14	Ad-hoc reviewer, NIH Cancer Genetics (CG) Study Section
2/15, 2/16	Ad-hoc reviewer, NIH Genetics of Human Disease (GHD) Study Section
2016-	Vice President, Cancer Epigenetics Society

#### Honors:

1997	Stop Cancer, The Next Generation - Seed Grant Award
1999	American Cancer Society Postdoctoral Fellowship
1999	AACR-Pharmacia and Upjohn Young Investigator Award
2000	National Cancer Institute, Cancer Scholar Program (K22 Grant Award)
2009	Georgia Cancer Coalition Distinguished Cancer Scholar

7/16,11/16,2/17 Ad-hoc reviewer, NIH F09A Fellowships Study Section

#### C. Contributions to Science

- 1. Defining the function of the DNA methylation machinery in normal and diseased states. A key unanswered question in the field is exactly how epigenetic defects, such as aberrant DNA hypo- or hypermethylation, occur at the molecular and biochemical level. A number of publications throughout my career have contributed to a better understanding of this process, largely in the context of cancer-methylation defects, with an emphasis on function and targeting of the DNA methyltransferases (DNMTs) and more recently, the Tet-eleven-translocation (TET) hydroxymethylases. Key findings to arise from these studies are the non-redundant functions of the DNMTs and TETs and that the TETs protect certain features in the genome from aberrant DNA hypermethylation.
  - a. Van Emburgh BO and **Robertson KD**. Modulation of Dnmt3b function *in vitro* by interactions with Dnmt3L, Dnmt3a, and Dnmt3b splice variants. *Nucleic Acids Res.* 39(12): 4984-5002, 2011. PMCID: PMC3130282

- b. Jin B, Ernst J, Tiedemann RL, Xu H, Kellis M, Dalton S, Liu C, Choi J-H, **Robertson KD**. Linking DNA methyltransferases (DNMTs) to epigenetic marks and nucleosome structure genome-wide in human tumor cells. *Cell Rep.* 2(5): 1411-1424, 2012. PMCID: PMC36259459.
- c. Putiri EL, Tiedemann RL, Thompson JJ, Liu C, Ho T, Choi J-H, **Robertson KD**. Distinct and overlapping control of 5-methylcytosine and 5-hydroxymethylcytosine by the TET proteins in human cancer cells. *Genome Biol.* 15(6): R81, 2014. PMCID: PMC4197818
- d. Tiedemann RL, Putiri EL, Lee J-H, Hlady RA, Kashiwagi K, Ordog T, Zhang Z, Liu C, Choi J-H, and **Robertson KD**. Acute depletion redefines the division of labor among DNA methyltransferases in methylating the human genome. *Cell Rep.* 9(4):1554-66, 2014. PMCID: PMC4254561
- 2. Interactions between DNA methylation and other epigenetic marks. There are four epigenetic marks on the DNA but many more marks on the histones (multiple modification sites and many more marks). It is clear that these different marks do not work in isolation, rather the components of the machinery interact (e.g., DNA methyltransferases (DNMTs)/TETs with histones and histone modifiers), and different marks influence each other positively and negatively. Early in my career I was among the first to show that DNMTs interact with HDACs and pRb. We have since built on this substantially by identifying numerous DNMT-histone modifier interactions and studied their function and mechanism.
  - a. Jin B, Yao B, Li J-L., Fields CR, Delmas AL, Liu C, Robertson KD. DNMT1 and DNMT3B modulate distinct polycomb-mediated histone modifications in colon cancer. *Cancer Res.* 69(18): 7412-7421, 2009. PMCID: PMC2745494
  - b. Gopalakrishnan S, Sullivan BA, Trazzi S, Della Valle G, **Robertson KD**. DNMT3B interacts with constitutive centromere protein CENP-C to modulate the histone code and DNA methylation at centromeres. *Hum. Mol. Genet.* 18(17): 3178-3193, 2009. PMCID: PMC2722982
  - c. Putiri EL, Tiedemann RL, Liu C, Choi JH, **Robertson KD**. Impact of human MLL/COMPASS and polycomb complexes on the DNA methylome. *Oncotarget*. 5(15): 6338-52. 2014. PMCID: PMC4171634
  - d. Tiedemann RL, Hlady RA, Hanavan PD, Lake DF, Tibes R, Choi J-H, Ho TH, Robertson KD. Dynamic reprogramming of DNA methylation in SETD2-deregulated renal cell carcinoma. *Oncotarget*. 7(2): 1927-46. 2016. PMCID: PMC4811507
- 3. DNA epigenetic marks in human disease. DNA methylation and hydroxymethylation patterns are disrupted in many human diseases, and this is probably no more studied than in the context of cancer. Yet a key unanswered question is how and when these defects arise and how they contribute to cancer initiation and progression. There is also an emerging appreciation that environmental factors, such as diet, influence the epigenome in a way that may predispose to certain diseases; we have made contributions in this area by showing that alcohol and viral infection leave unique signatures on the epigenome. We have also contributed significantly to identifying and characterizing the molecular defects in ICF Syndrome, a rare genetic disease caused by mutations in *DNMT3B*.
  - a. Jin B, Tao Q, Peng J, Soo HM, Wu W, Ying J, Fields CR, Delmas AL, Liu X, Qiu J, **Robertson KD**. DNA methyltransferase 3B (DNMT3B) mutations in ICF syndrome lead to altered epigenetic modifications and aberrant expression of genes regulating development, neurogenesis, and immune function. *Hum. Mol. Genet.* 17(5): 690-709, 2008.
  - b. Hlady RA, Tiedemann RL, Puszyk W, Zendejas I, Roberts RL, Choi J-H, Liu C, **Robertson KD**. Epigenetic signatures of alcohol abuse and hepatitis infection during human hepatocarcinogenesis. *Oncotarget*. 5(19): 9425-43, 2014. PMCID: PMC4253444
  - c. Zhou D, Hlady RA, Schafer MJ, White TA, Liu C, Choi J-H, Miller JD, Roberts LR, LeBrasseur NK, **Robertson KD**. High fat diet and exercise lead to a disrupted and pathogenic DNA methylome in mouse liver. *Epigenetics*. 12(1): 55-69, 2017. PMCID: PMC5270632
  - d. Hlady RA, Puszyk W, Wu Q, Cabrera R, Choi JH, Liu C, **Robertson KD**. Initiation of aberrant DNA methylation patterns and heterogeneity in precancerous lesions of human hepatocellular carcinoma. *Epigenetics*. 12(3): 215-2252017, 2017. PMCID: PMC5406211
- **4**. *Links between DNA methylation and genome stability*. A major function of epigenetic marks in the genome is to regulate structure and stability of the DNA. DNA methylation generally results in more condensed DNA structures, but the role of DNA methylation in genomic stability and/or DNA repair, has remained unclear. We have made several key contributions in this area by showing that DNMT1 plays an important role in the DNA damage response and that aza-nucleoside DNA methylation inhibitors like 5-aza-2'-deoxycytidine, used

clinically, act in part by inducing DNA double strand breaks.

- a. Palii SS, Van Emburgh BO, Sankpal UT, Brown KD, Robertson KD. DNA methylation inhibitor 5-aza-2'-deoxycytidine (5-azadC) induces reversible genome-wide DNA damage that is distinctly influenced by DNA methyltransferases (DNMTs) 1 and 3B. *Mol. Cell. Biol.* 28(2): 752-771, 2008. PMCID: PMC2223421
- b. Ha K, Lee GE, Palii SS, Brown KD, Takeda Y, Liu K, Bhalla KN, **Robertson KD**. Rapid and transient recruitment of DNMT1 to DNA double strand breaks is mediated by its interaction with multiple components of the DNA damage response machinery. *Hum. Mol. Genet.* 20(1): 126-140, 2011. PMCID: PMC3000680
- c. Yun S, Vincelette ND, Abraham I, **Robertson KD**, Fernandez-Zapico ME, Patnaik MM. Targeting epigenetic pathways in acute myeloid leukemia and myelodysplastic syndrome: A systematic review of DNA hypomethylating agents trials. *Clin. Epigenetics*. 8(1): p. 68, 2016. PMCID: PMC4908810
- d. Patnaik M, Zahid M, Lasho T, Finke C, Ketterling R, Gangat N, **Robertson KD**, Hanson C, and Tefferi A. Number and type of TET2 mutations in chronic myelomonocytic leukemia and their clinical relevance. *Blood Cancer J*. 6(9):e472, 2016. PMCID: PMC5056973

#### Complete List of Published Works in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/keith.robertson.1/bibliography/41154125/public/?sort=date&direction=ascending.

#### D. Research Support

### **Ongoing Research Support**

R01 CA114229 Robertson (PI) 7/1/2004-6/30/2018

De novo methyltransferase function in chromatin and cancer.

**The major goal of this project** is to study the function and regulation of *de novo* methyltransferase DNMT3B using *in vitro* and *in vivo* assay systems, and determine how it is targeted to specific DNA regions in normal and cancerous cells.

Role: PI

R01 AA019976 Robertson (PI) 9/1/2011-6/30/2016 (NCE)

Developmental pathways, environmental agents, and epigenetics in liver disease.

The major goal of this project is to define changes to the epigenome and transcriptome in hepatocellular cancers (HCC) and HCC cell lines arising in the setting of chronic alcohol exposure and then examine how these changes contribute to HCC development and whether they possess prognostic utility.

Role: PI

#### **Completed Research Support (within the last three years)**

None

#### **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: Jen Jen Yeh

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

#### POSITION TITLE: Associate Professor of Surgery

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
Wesleyan University, Middletown, CT	BA	05/1991	Biology
Johns Hopkins Univ Sch of Medicine, Baltimore, MD	MD	06/1996	Medicine

#### A. Personal Statement

I am a physician-scientist with an active surgical oncology practice of patients with pancreatic and endocrine tumors. In addition to one and half days a week dedicated to patient care, we also have recurring multidisciplinary oncology conferences for each of the tumor groups to provide useful sounding boards for the extension of basic findings. I have leadership roles in the Department of Surgery as the Vice Chair for Research where I have established infrastructure to promote surgeon research and promote collaborations with other departments. In addition, I have a leadership role as a member of the Program Planning Committee for the Lineberger Comprehensive Cancer Center and am a member of the Faculty Search Committee. The remainder of my time is focused on research. Since starting my research group in 2008, I have mentored (past/present) 8 predoctoral trainees and 15 postdoctoral trainees, many supported by training grant awards such as the NIDDK Student Research Training Program, Surgical Oncology, Cancer Biology and Genetics and Molecular Biology and LCCC Post-doctoral T32 Training Programs, NIH F32s and the HHMI Graduate Training Program in Translational Medicine. I am Director of the clinical shadowing program for the pre-doctoral Cancer Biology T32 as well as the Integrated Training in Model Systems post-doctoral T32. One of my postdoctoral trainees is completing a K award. Two hold academic positions at universities.

The goal of my laboratory is to identify novel therapeutic targets in pancreatic cancer using a combination of bioinformatics, molecular and translational approaches including patient-derived tissues and innovative mouse model studies. I have identified and validated prognostic molecular signatures for patients with localized pancreatic cancer (Stratford, PLoS Medicine). More recently, my group has expanded our computational approaches to focus on deconvoluting the complexity of different tissue compartments that influences genomic analyses of patient samples (Moffitt, Nature Genetics). We have successfully performed this "virtual microdissection" and by doing so have identified two distinct tumor subtypes in patients associated with patient outcome. One subtype is similar to the basal breast and bladder cancer subtypes. In addition, both subtypes exhibit differences in their kinase activation profiles. We are now advancing our findings and evaluating our subtypes in relation to treatment response in both preclinical and clinical trials.

For preclinical trials, we have established a Patient Derived Xenograft (PDX) Program where we have successfully passaged and expanded 65 pancreatic PDX to date. We have performed pharmacokinetic studies for several cytotoxic drugs. With the increasing recognition, PDXs and GEMMs are more accurate predictors of drug response and better models for biomarker and therapeutic discovery, these models are an exciting first step for the translation of our laboratory studies into clinical trials. These models have been shown to capture the heterogeneity of human tumors, but are renewable and can be expanded as biological replicates. We have shown that these models recapture tumor-specific subtypes and are currently studying the tumor microenvironment in these modes. As part of our initiative to develop novel strategies for treatment and using my surgical oncology expertise, we have many long-standing collaborations with groups at UNC to develop technology towards new diagnostic and therapeutic approaches for pancreatic cancer.

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

#### **Positions and Employment**

- 1996-1997 Intern, General Surgery, Boston University Medical Center, Boston, MA
- 1997-2003 Resident, General Surgery, Boston University Medical Center, Boston, MA
- 1998-2002 Research Fellow, Department of Adult Oncology, Dana-Farber Cancer Institute and Department of Medicine, Harvard Medical School, Boston, MA
- 2003-2005 Fellow, Surgical Oncology, Memorial-Sloan Kettering Cancer Center, New York, NY
- 2005-2011 Assistant Professor, Division of Surgical Oncology, Department of Surgery, University of North Carolina, Chapel Hill, NC
- 2010-2011 Assistant Professor, Department of Pharmacology, University of North Carolina, Chapel Hill, NC
- 2011-2017 Associate Professor, Division of Surgical Oncology, Department of Surgery, University of North Carolina, Chapel Hill, NC
- 2011-2017 Associate Professor, Department of Pharmacology, University of North Carolina, Chapel Hill, NC
- 2015- Vice Chair of Research, Department of Surgery, University of North Carolina, Chapel Hill, NC
- 2017- Professor, Division of Surgical Oncology, Department of Surgery, University of North Carolina, Chapel Hill, NC
- 2017- Professor, Department of Pharmacology, University of North Carolina, Chapel Hill, NC

#### **National Committees**

- 2017 Cancer Prevention and Research Institute of Texas (CPRIT) Clinical Translational Research Panel
- 2017-2019 American College of Surgeons Surgical Forum Abstract Review Committee
- 2017 Senior Appointment Committee Cancer Research UK, Manchester Institute
- 2016- Center for Cancer Genomics Working Groups
- 2013-2017 TCGA Pancreas Workgroup
- 2013-2014 Stand Up to Cancer- Lustgarten Foundation Joint Scientific Advisory Committee (JSAC)
- 2006-2011 Cancer and Leukemia Group B, GI surgery and correlative science committee
- 2009 NCI Colon Cancer Task Force, junior investigator

#### **Awards and Honors**

- 2005 Gorin Fellow Award, Memorial Sloan-Kettering Cancer Center
- 2005 ASCO Foundation Merit Award
- 2005 UNC GI SPORE Faculty Career Development Award
- 2006 ASCO Young Investigator Award
- 2006 Emerald Foundation Award
- 2007 UNC GI SPORE Faculty Career Development Award
- 2007 Lineberger Comprehensive Cancer Center (LCCC) Clinical/Translational Research Award
- 2007 University Research Council Award
- 2008 Franklin H. Martin, MD, FACS, Faculty Research Fellowship of the American College of Surgeons
- 2008 Kimmel Translational Scholar Award
- 2008 North Carolina University Cancer Research Fund Innovation Award
- 2009 American Surgical Association Foundation Fellowship Award
- 2017 Castle Connolly Exceptional Women in Medicine

#### **Professional Societies, Honor Societies:**

- 2000 Sigma Xi Scientific Honor Society
- 2002 Alpha Omega Alpha Honor Medical Society
- 2004 Society of Surgical Oncology
- 2005 American College of Surgeons
- 2005 American Society of Clinical Oncology
- 2006 American Association for Cancer Research
- 2006 Cancer and Leukemia Group B
- 2008 Association of Academic Surgeons
- 2012 Society of University Surgeons
- 2013 Surgical Biology Club
- 2014 Society of Clinical Surgery

#### C. Contributions to Science

**I.** I have used translational approaches to understand the molecular underpinnings of pancreatic cancer to tailor therapies. My work evaluating differences in primary tumor biology has led to the identification of rigorous tumor-specific subtypes that have now been validated in multiple large cohorts. We have hypothesized that these may have therapeutic implications and have promising data in patients that strongly support this.

- 1. Moffitt RA, Marayati R, Volmar KE, Hoadley, KA, Anderson J, Bentrem DJ, Talamonti MS, Iacobuzio-Donahue CA, Hollingsworth MA, **Yeh JJ** Virtual microdissection of pancreatic ductal adenocarcinoma reveals tumor and stroma subtypes. *Nature Genetics September 47(10):1168-78, 2015.* NIHMS716599 PMC4912058
  - \*\*Through digital microdissection of tissue compartments this work classified pancreatic cancer into tumor and stroma subtypes with clinical and biologic implications that may be leveraged to tailor the choice and timing of therapies for patients.
- 2. Stratford JK, Bentrem DJ, Anderson JM, Fan C, Volmar KA, Marron JS, Routh ED, Caskey LS, Samuel JC, Der CJ, Thorne LB, Calvo BF, Kim HJ, Talamonti MS, Iacobuzio-Donahue CA, Hollingsworth MA, Perou CM, Yeh JJ A six-gene signature predicts survival of patients with localized pancreatic ductal adenocarcinoma. PLoS Medicine 13;7(7):e1000307 2010. PMC2903589 \*\*Pancreatic cancer patients undergoing surgical resection have a median survival of 26 months. However postoperative complications and hospital readmission rates are high diminishing quality of life after surgery. This work was the first development of a progonostic signature, validated in multiple external datasets, associated with patient survival after resection to help guide operative decision making for patients who may not benefit as much from surgery.

The multidisciplinary nature of my work shows that I have the insight and ability to meld seemingly disparate disciplines for pancreatic cancer research. I have built a PDX Program that has provided the infrastructure for evaluation of novel therapies and biomarkers (see II and III).

II. We have shown that effective delivery of existing chemotherapeutic regimens will be key in converting patients who are borderline resectable/unresectable to resectable tumors. The below work showed that local iontophoretic delivery of cytotoxic agents may be a promising neoadjuvant and palliative therapy for pancreatic cancer. Nearly 30% of patients with pancreatic cancer do not have metastatic disease but yet due to local anatomical issues, are not surgical candidates. Neoadjuvant chemotherapy and radiation therapy has been used in an attempt to shrink tumors locally to convert unresectable and borderline resectable tumors to resectable. However results have been mixed and toxicity high. Our studies using orthotopic pancreatic cancer patient-derived xenografts showed that local iontophoretic administration was able to shrink tumors compared to systemic administration with negligible systemic delivery. We are now moving this technology towards the clinic.

- Byrne JD, Jajja MR, O'Neill AT, Schorzman AN, Keeler AW, Luft JC, Zamboni WC, DeSimone J\*, Yeh JJ\*. Iontophoretic device delivery for the localized treatment of pancreatic ductal adenocarcinoma. Proc Natl Acad Sci USA 2016 PMC4776454. \*co-corresponding
- Byrne JD, Jajja MR, O'Neill AT, Bickford LR, Keller AW, Hyder N, Wagner K, Deal AM, Little RE, Moffit RM, Stack C, Nelson M, Brooks CR, Lee W, Luft JC, Napier ME, Darr D, Anders CK, Stack RS, Tepper J, Wang AZ, Zamboni WC, Yeh JJ\*, DeSimone J\* Local Iontophoretic Administratin of Cytotoxic Therapies to Solid Tumors. Science Translational Medicine 7(273):273ra14, 2015. PMC4545246 \*co-corresponding

**III.** We have shown that PDX models may also be used in the evaluation of biomarkers such as rare circulating tumor cells and stem cells.

- Torphy RJ, Tigananelli CJ, Kamande JW, Moffitt RA, Herrera Loeza SG, Soper SA, Yeh JJ.
   Circulating Tumor Cells as a Biomarker of Response to Treatment in Patient-Derived Xenograft
   Mouse Models of Pancreatic Adenocarcinoma. PLoS One 2014 Feb 19; 9)2:389474. PMC3929698
- 2. Gach PC, Attayek PJ, Herrera G, **Yeh JJ**, Allbritton NL. Isolation and in vitro culture of rare cancer stem cells from patient-derived xenografts of pancreatic ductal adenocarcinoma. *Anal Chem* 2013 Aug 6;85(15):7271-8. PMC3754897

We have shown that PDX models are important preclinical tools to predicting therapy response. Lack of response in these models, sometimes contrary to other preclinical studies, has since been borne out in clinical trials.

- 1. Lipner M, Marayati R, Deng Y, Wang X, Raftery L, O'Neil BH, **Yeh JJ.** Metformin treatment does not inhibit growth of pancreatic cancer patient-derived xenografts. *PLoS One 2016,* PMC4711922.
- 2. Neel NF, Stratford JK, Shinde V, Ecsedy JA, Martin TD, Der CJ, **Yeh JJ (2)**. Response to MLN8237 in pancreatic cancer is not dependent on RalA phosphorylation. *Mol Cancer Ther.* 13(1):122-33, 2014. PMC3910332

#### Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/myncbi/collections/bibliography/40525522/

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

1-R01-CA199064-01-A1 (MPI Yeh (contact), Johnson, Graves) 09/1/2016-07/31/2021

National Cancer Institute Role: PI

#### Tumor subtypes and therapy response in pancreatic cancer

This research will use *baseline* kinome characteristics that have been identified in combination with new gene expression subtypes to predict therapies *a priori* with the long-term goal that treatment of patients will not be limited to existing standards of care, but rather the ability to identify treatment strategies based on an individual tumor subtype knowledge.

1-R01-CA193650-01 (MPI Yeh (contact), Johnson) 06/1/2015-05/31/2020

National Cancer Institute Role: PI

#### Adaptive kinome in pancreatic cancer

This proposal seeks to develop rational combinations of existing cytotoxic drugs with targeting agents and develop and apply computational methods for predicting these combinations through a systems-based approach of understanding how the kinome *adapts or reprograms* to a panel of 6 pre-designated treatments.

U24-CA211000 (MPI Raphael (contact), Yeh) 10/1/16-9/30/21

National Cancer Institute Role: PI

Pathway and network integration of cancer genomics and clinical data

1-R01-CA157738-01A1 (Liu) 12/9/2011-11/30/17
National Inst. of Health Role: Co-Investigator
Novel Single Domain Antibodies with Multivalency and Multispecificity

This project addresses a critical need for developing cost-effective targeting ligands that recognize and bind

HER family members with desired avidity and multispecificity.

1-R01-CA177993-A1 (Allbritton) 8/1/14-7/31/18

National Cancer Institute Role: Co-Investigator

#### Single-Cell Measurement of Lipid Signaling in Colorectal Cancer

PI3 kinase activity and metabolites of phosphatidyl inositide 4,5-bisphosphate will be measured in single tissue-cultured colorectal cancer cells.

5-P01-CA142538-02 (Kosorok) 06/1/2015-03/31/2020

National Cancer Institute Role: Co-Investigator

#### Statistical Methods for Cancer Clinical Trials - Project 5

This research will study cancer treatment formally as an overall, individualized strategy so that the entire series of decisions leading to the best outcomes can be determined, promoting a paradigm shift in the way cancer therapies are evaluated.

R01CA190717-01 (Bogdanov)/UCincinnati subcontract 3/31/2015-3/31/2020 National Cancer Institute Role: Co-investigator Alternatively spliced tissue factor and pathobiology in pancreatic cancer.

Study of alternatively spliced Tissue Factor (asTF) as a therapeutic target.

Not Applicable (MPI Linehan, Wolpin)

American Association of Cancer Research

Targeting macrophages to improve chemotherapy in metastatic pancreas cancer

**OVERLAP: None** 

#### Completed (Recent)

1U01CA151455-01 (MPI Lin, Yeh) 9/3/10-7/31/16 National Cancer Institute 9/3/10-7/31/16

Nanoscale Metal-organic Frameworks for Imaging and Therapy of Pancreatic Cancer This research focuses on the development and implementation of nanoscale metal-organic

frameworks as diagnostic and therapeutic tools for pancreatic cancer.

Not Assigned (MPI Soper, Yeh) 9/30/14-8/31/16

National Institute of Health – SBIR Role: PI

(subcontract)

#### **Low-cost Microfluidic System for Detection of CTCs**

This is a project to evaluate circulating tumor cell burden and characteristics in pancreatic cancer patients.

05/1/2013-04/30/2015

Not Assigned (Yeh)

Lustgarten Foundation Role: PI

#### Kinome landscape of pancreatic cancer

This is a pilot study to determine the kinome landscape of pancreatic cancer in predominantly patient primary tumors.

1-R01-CA13599-01 (Allbritton) 3/1/09 – 1/31/15
National Cancer Institute Role: Co-Investigator

Multiplexed Measurement of Kinase Activity in Single Cells

A collaborative interdisciplinary research program is proposed to create the instrumental and chemical tools needed to directly assess the catalytic activity of protein kinases in living cells from disease models and cancer patients.

Not assigned (Der) 2/1/12-1/31/15 Lustgarten Foundation 2/1/12-1/31/15

# Mechanisms of ERK inhibition resistance and identification of K-Ras effector signaling components essential for ERK-dependent pancreatic cancer growth

This project centers on the SCH772984 ERK1 and ERK2 selective protein kinase inhibitor, coupled with an RNA interference library targeting components of the K-Ras effector signaling networks, to identify inhibitors of pancreatic ductal adenocarcinoma (PDAC) cell growth.



# Cancer Prevention & Research Institute of Texas

# Product Development Review Council

• Sandra Silberman, M.D., Ph.D.



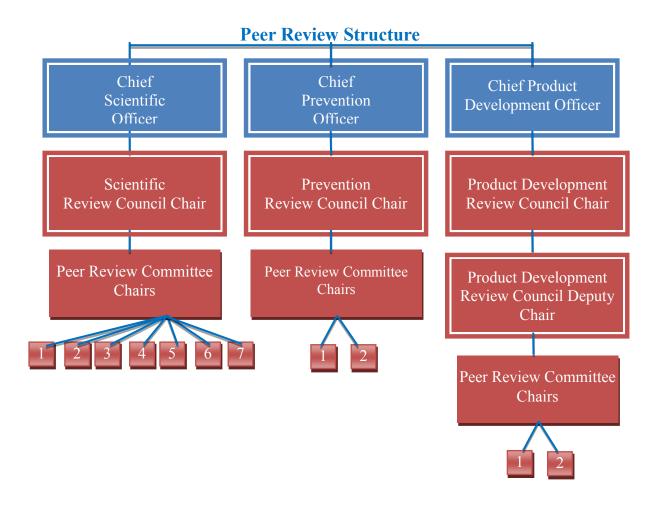
#### Sandra Silberman, M.D., Ph.D.

Dr. Silberman is a Hematologist/Oncologist who earned her B.A., Sc.M. and Ph.D. from the Johns Hopkins University School of Arts and Sciences, School of Public Health and School of Medicine, respectively, in Baltimore, MD. She received her M.D. from Cornell University Medical College in New York City, and then completed both a clinical fellowship in Hematology/Oncology as well as a research fellowship in tumor immunology at the Brigham & Women's Hospital and the Dana Farber Cancer Institute in Boston, MA. She continued to do basic research in Boston after being granted a Clinical Investigator Award from the National Institutes of Health and was an Instructor in Medicine at Harvard Medical School. She subsequently served as an attending physician at Yale University Hospital in New Haven, CT.

Her career in clinical development began at Pfizer, Inc., where she oversaw the first clinical trials of Tarceva™. She left Pfizer after having the opportunity to lead the global development of Gleevec™ at Novartis, resulting in the submission of a New Drug Application (NDA) and then several supplemental NDAs. Dr. Silberman then became the first Vice President and Global Therapeutic Area Head in Oncology at Eisai, a role in which she advanced five original, proprietary compounds into Phases I through III, gaining the first oncology approval for Eisai, with an NDA for Halavan™. She then served as a senior advisor to a number of biopharmaceutical companies, including Bristol-Myers Squibb, AstraZeneca, Imclone, Roche, and numerous biotech companies as an independent industry consultant, initiating and leading numerous INDs and NDAs. She has also been a consultant for several non-profit organizations, including the Chordoma Foundation and ABC2. She joined Quintiles (Durham, NC) as the Vice President of Oncology and Global Head of Translational Medicine in the newly formed Innovation division, overseeing how changes in clinical drug development using novel technologies could lead to better and more effective trial designs as well as new partnerships with the pharmaceutical and biotechnology industries. She is currently the managing partner in a consulting company providing guidance for biotechnology and pharmaceutical companies in the advancement of new and pioneering cancer therapies through translational research, clinical trial designs, as well as later development programs. Throughout her career in industry she has continued to work part time in active clinical practice, and is currently an attending physician in the Hematology/Oncology clinic at the Veteran's Administration Medical Center in Durham, NC.

# CPRIT PEER REVIEW FY 2018 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

CPRIT FY 2018 Honoraria Policy

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

<sup>&</sup>lt;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>

All of CPRIT's expert peer reviewers live and work outside Texas, which is an uncommon requirement among grant-making organizations. CPRIT implemented this peer reviewer qualification to ensure an impartial review, minimize conflicts of interest, and provide the opportunity to select the best projects without regard for self-interest.

#### Honoraria

In recognition of the work undertaken by CPRIT peer reviewers, state law authorizes CPRIT to pay honoraria to its peer reviewers. 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 considerably more effort and expertise than simply chairing a committee. Having panel chairs of this caliber distinguishes CPRIT's peer review process from all others.

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<sup>&</sup>lt;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>&</sup>lt;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 2018. 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 – 2017 review cycle information and the projected workload for FY 2018.

NOTE: In addition to the regular Council Chair duties in FY 2018, 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 2018.

<u>Hourly Rate Proxy</u>: 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 considerably 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 2018, 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 – 2017 review cycle information and the projected workload for FY 2018.

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<sup>&</sup>lt;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. The hourly rate used by CPRIT is also likely to be less than rates used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is considerably greater than the \$28,000 - \$46,000 honoraria paid to CPRIT Review Committee Chairs.

#### **Review Committee Members**

The number of peer review committees varies by program, generally based on the volume of grant applications submitted. Peer reviewers are responsible for individually reviewing, scoring and critiquing 6-10 applications per cycle, as well as participating in panel discussions about grant applications assigned to the peer review committee. A full review of a single application generally takes a reviewer 6-8 hours, but substantially more time may be required for complex, highly technical applications. A typical CPRIT grant application averages about 40 pages in length with additional supporting documentation. Applications for multi-million dollar collaborative research projects and product development project may be much more extensive.

Estimated Time Commitment per Review Cycle: Peer reviewer activity varies by program and number of applications assigned. Academic research peer reviewers are expected to commit approximately 85 hours per review cycle. Prevention peer reviewers will commit 55-70 hours per cycle. Product Development peer reviewers will commit 100 hours per cycle. **Table 3** provides a detailed analysis of the activities, hours, and units used to project the peer review workload. The information in Table 3 reflects 2009–2016 review cycle information and the projected workload for FY 2018.

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

<u>Hourly Rate Proxy</u>: 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

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<sup>&</sup>lt;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.

reviewers must have both academic research and product development backgrounds and are more difficult to recruit. While the hourly rates are significantly less than those paid to professionals of this caliber, the rate is appropriate given the workload and responsibilities compared to Review Council and Committee chairs.

#### **Comparison to other Grant Making Organizations**

Grant-making organizations use various models and methods for compensating peer review committee members. A survey of 21 cancer granting organizations reported wide variation among programs such that an average compensation scheme for panel members was not possible. The disparity among organizations makes it difficult to devise a benchmark compensation method or amount. Reported compensation practices may fail to include intangible benefits available to reviewers in addition to monetary compensation, which further complicates the ability to make a meaningful comparison between CPRIT and other grant-making organizations. As discussed earlier, these non-monetary incentives are largely unavailable to CPRIT reviewers because of CPRIT's policy to use highly qualified, experienced, out-of-state reviewers.

- International Cancer Research Partners (ICRP) surveyed 31 of its partner organizations and 21 responded. The report found that organizations commonly paid different honoraria depending on the role of the reviewer. Chairs often received more than committee members did, and teleconference or online reviewers typically received less compensation than those members who participated in-person. An average could not be computed 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>&</sup>lt;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 5 for an explanation of the correlation between units and hours.)

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

**Table 2. Committee Chair Activities** 

		Table 2	2 - Committee Chair Activities, Hours, Uni	ts			
	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  Prepare and participate in quarterly Review Council teleconferences	11	Review annual and final progress reports, including milestone achievement reports, advise on activities of funded product development grants.		
20	Review recruitment applications	3					
3	Participate in quarterly review of recruitment applications						
52		32		45			
\$875	Unit cost	\$875	Unit cost	\$875	Unit cost		
\$200	Hourly	\$200	Hourly	\$200	Hourly		
\$45,500	\$46K Annual honoraria	\$28,000	\$28 K Annual honoraria	\$39,375	\$40K Annual honoraria		

See Table 5 for an explanation of the correlation between units and hours.

Table 3. Peer Reviewer Activities per Cycle

	Table 3 - Pe	er Revi	ewers Activity by Program			
Pr	oduct Development Review:~30 reviewers	Prevei	ntion Review:~ 33 reviewers	Acad	emic 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		\$250 Unit cost		\$250 Unit cost	
	\$65 avg. hourly rate		\$50 avg. hourly rate		\$50 avg. hourly rate	
	\$6,500 per cycle		\$4,000 in person per cycle		\$4,250 per cycle	

<sup>\*</sup> 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 5 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 rom the honorarium paid to the reviewer. In the event a Review Council chair, Committee chair, or peer reviewer is not able to complete a full review cycle due to unforeseen circumstances, the CPRIT Program Officer may approve, in his or her discretion, a partial payment of the honorarium.

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

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

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

**Table 5. Hours and Units Calculation** 

PARTICIPATION (HOURS)	UNITS	Council Chairs	Committee Chairs	Peer reviewers
1-5	1		Unit Cost	
6-10	2	\$1200	\$875	\$250-\$325
11-15	3		Average Hourly Rate	
16-20	4	\$250	\$200	\$50-\$65
21-25	5		Honoraria	
26-30	6	\$64,000 - \$75,000 annually	\$28,000 - \$46,000 annually	\$4,000 - \$6,500 per cycle
31-35	7			
36-40	8			
41-45	9			
46-50	10			
51-55	11			
56-60	12			
61-65	13			
66-70	14			
71-75	15			



**TO:** OVERSIGHT COMMITTEE MEMBERS

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

**SUBJECT:** SECTION 102.1062 WAIVER – DR. BECKY GARCIA

**DATE:** AUGUST 11, 2017

#### **Waiver Request and Recommendation**

I request that the Oversight Committee approve a conflict of interest waiver for FY 2018 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 2017.

#### **Background**

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

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

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

#### **Exceptional Circumstances Requiring Dr. Garcia's Participation**

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

#### **Proposed Waiver and Limitations**

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

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

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

#### **Important Information Regarding this Waiver and the Waiver Process**

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



To: OVERSIGHT COMMITTEE MEMBERS

From: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER

Subject: SECTION 102.1062 WAIVER—DONALD BRANDY

**Date:** AUGUST 11, 2017

#### **Waiver Request and Recommendation**

I request that the Oversight Committee approve a conflict of interest waiver for FY 2018 for Mr. Donald Brandy, CPRIT's Purchaser and HUB Coordinator, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The Oversight Committee approved the same waiver for Mr. Brandy in FY 2015, FY 2016, and FY 2017.

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 considered vendor or outside service contracts.

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

CPRIT employees may engage in outside employment so long as the employment does not detract from the employee's ability to reasonably fulfill his or her responsibilities to CPRIT. Employees must receive written approval from the CEO to engage in outside employment and I am required to notify the Audit Subcommittee regarding any approvals and to annually report all approved outside employment. I notified the Audit Subcommittee regarding my approval for Mr. Brandy's outside employment and it was discussed at the December 18, 2014, subcommittee meeting.

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

In order to approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process or other expenditure of CPRIT funds.<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, during the course of his official duties there may be circumstances requiring Mr. Brandy to procure goods or services on CPRIT's behalf from a university that has also employed him as a tennis referee. This is unlikely to occur; to date, CPRIT has only one services contract with an academic institution, Texas Tech University. However, as CPRIT's lead contact for agency purchases, Mr. Brandy should be allowed to perform his official duties to the fullest extent possible. Any involvement with university athletic department personnel resulting from his outside employment is unlikely to be the same individuals at the university responsible for contracting with CPRIT.

#### **Proposed Waiver and Limitations**

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

Section 102.1062 Waiver—Brandy FY2018

<sup>&</sup>lt;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.
- This waiver is limited to the conflict of interest specified in this request. To the extent that Mr. Brandy has a conflict of interest not address in this waiver, then Mr. Brandy will follow the required notification and recusal process.



To: OVERSIGHT COMMITTEE CHAIR DR. WILLIAM RICE

From: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

**Subject:** SECTION 102.1062 WAIVER - DR. JOHN HELLERSTEDT

Date: **AUGUST 11, 2017** 

#### Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2018 for Program Integration Committee (PIC) member DSHS Commissioner Dr. John Hellerstedt, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Commissioner Hellerstedt to participate in CPRIT's review process as a PIC member. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria. The waiver is the same as approved by the Oversight Committee for FY 2017.

#### **Background**

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

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

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

#### **Exceptional Circumstances Requiring Commissioner Hellerstedt's Participation**

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

#### **Proposed Waiver and Limitations**

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

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

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

#### Important Information Regarding this Waiver and the Waiver Process

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

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



To: **OVERSIGHT COMMITTEE MEMBERS** 

From: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

**Subject:** SECTION 102.1062 WAIVER - AMY MITCHELL

Date: **AUGUST 11, 2017** 

#### Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2018 for Ms. Amy Mitchell, CPRIT Oversight Committee member, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Ms. Mitchell to fully participate in the grant award approval process. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria. This waiver is the same as the waiver approved for Ms. Mitchell in FY 2017.

#### **Background**

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

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

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

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

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

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

#### **Exceptional Circumstances Requiring Ms. Mitchell's Participation**

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

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

#### **Proposed Waiver and Limitations**

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

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

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

#### Important Information Regarding this Waiver and the Waiver Process

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



To: OVERSIGHT COMMITTEE CHAIR DR. WILLIAM RICE

From: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

**Subject: SECTION 102.1062 WAIVER – WILL MONTGOMERY** 

**Date:** AUGUST 11, 2017

#### **Waiver Request and Recommendation**

I request that the Oversight Committee approve a conflict of interest waiver for FY 2018 for Mr. Will Montgomery, CPRIT Oversight Committee member, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Mr. Montgomery's waiver is the same as the one approved by the Oversight Committee for FY 2017. The waiver is necessary for Mr. Montgomery to fully participate in the grant award approval process. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

#### Background

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

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

- UT Health Science Center at Houston
- 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

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

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

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

#### Exceptional Circumstances Requiring Mr. Montgomery's Participation

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

Committee members that are able to perform the critical task of reviewing information about potential grantees and the review process associated with the grant recommendations.

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

#### **Proposed Waiver and Limitations**

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

- Rice University
- Texas A & M University System
- Texas A & M System Technology Commercialization
- Texas A & M Institute for Biosciences & Technology
- Methodist Hospital System (Houston)
- UT Southwestern
- UT School of Public Health
- UT Medical Branch, Galveston
- Children's Medical Center Research Institute
- UT San Antonio
- UT Austin
- UT Health Science Center at Houston
- 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.
- This waiver is limited to the conflict of interest specified in this request, Health & Safety Code Section 102.106(c)(4). To the extent that Mr. Montgomery has a conflict of interest

- with an application submitted by an entity listed herein that is not the conflict identified in Section 102.106(c)(4), then Mr. Montgomery will follow the required notification and recusal process.
- The waiver is limited to the entities specified in the request and based upon the circumstances stated herein. If circumstances change such that Mr. Montgomery is required to personally represent one of the entities listed herein or to supervise the work of someone representing the entity, he will notify the Chief Executive Officer and the presiding officer of the Oversight Committee.



TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN DOYLE, GENERAL COUNSEL

**SUBJECT:** TRANSFER OF ASSET MANAGEMENT AUTHORITY TO THE TEXAS

TREASURY SAFEKEEPING TRUST COMPANY

**DATE:** JULY 27, 2017

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

Governor Abbott signed legislation into law earlier this summer permitting the Oversight Committee to transfer the management and final disposition authority for assets generated by CPRIT's grant award projects to the Texas Treasury Safekeeping Trust Company (Trust Company). CPRIT has identified four equity assets to transfer to the Trust Company on or after the September 1, 2017, effective date of the legislation. The proposed resolution approves the transfer of these four assets and delegates authority to the Chief Executive Officer to take all actions necessary to complete the transfer of the assets, including negotiating a fee for the Trust Company's reasonable and necessary expenses involved with managing the transferred assets. I recommend that the Oversight Committee vote to approve the resolution.

#### **Background:**

CPRIT's statute requires all grant award contracts to include a revenue sharing provision allowing the state to collect royalties, income, and other benefits, including interest or proceeds resulting from securities and equity ownership realized because of CPRIT grant projects. CPRIT has more than 1,100 award contracts. The vast majority of CPRIT-funded grant projects that ultimately generate revenue will fulfill the contractual revenue sharing requirements through royalty payments to CPRIT. However, CPRIT has taken an equity interest in two companies, Cell Medica and Mirna Therapeutics, through its Product Development grant contracts. CPRIT also holds equity in two companies, Codiak Biosciences and Coregon, Inc., resulting from revenue sharing agreements with academic institutions.<sup>1</sup>

The Legislature created the Trust Company as a special purpose entity to efficiently and economically manage, invest, and safeguard funds for the state and its political subdivisions. According to the Trust Company, it is first and foremost a fiduciary organization, and as such, it is held to the highest standard of care imposed in either law or equity and is obligated to subordinate its own interests to those of its beneficiaries. The Trust Company's mission is to

<sup>&</sup>lt;sup>1</sup> CPRIT's standard revenue sharing agreement with academic institutions requires the institution to give CPRIT ten percent of the amount the institution receives from the CPRIT-funded project. In some cases, the institution takes equity in a newly formed company. In those cases, CPRIT receives ten percent of the institution's equity allotment.

preserve and grow the State's financial resources by competitively managing and investing them in a prudent, ethical, innovative, and cost-effective manner while focusing on client needs. The Trust Company invests, manages, and oversees over \$50 billion in assets. Investments include cash-equivalent funds such as the Texas Treasury Pool, separately managed portfolios for various Texas state agency clients, and endowment monies invested across a broad spectrum of asset classes, including hedge, private equity, and real estate funds.

#### **CPRIT's Need for Asset Management Expertise**

Cancer research projects in CPRIT's growing portfolio are progressing through the phases of research and development, with some early investments generating revenue through licensing and market sales. In its fiduciary role, the Oversight Committee will need to make decisions regarding the management and disposition of CPRIT-controlled assets as the portfolio continues to mature. There are near term and longer-term issues that CPRIT must address to ensure the state also benefits monetarily from its investment in cancer research. These include decisions on whether to convert royalty obligations to equity holdings, when to sell equity, and the bundling and sale of potential royalty obligations.

CPRIT staff identified the need for investment expertise to assist the Oversight Committee and the agency in making decisions associated with asset management. Investment management is a specialized field. The Trust Company investment staff are skilled in statistical analysis, economics, portfolio management, trading, portfolio transition management, risk management, and accounting. Additionally, the Trust Company has experience managing assets like those generated by CPRIT grants. The Trust Company took over the management and control of the state's equity positions and other investments in the Emerging Technology Fund's ("ETF") portfolio in 2015. The ETF is comprised of approximately 100 investments in early stage companies, about two-thirds of which are life sciences ventures. The Trust Company will leverage its experience managing the ETF's equity investments and draw from the relationships it has developed investing in private equity for over a decade to provide additional resources to aid in the successful completion of projects and grant awards.

CPRIT initiated a working relationship with the Trust Company more than a year ago. Over the course of several meetings, we explored ways that the Trust Company may provide CPRIT with portfolio management and expertise. These discussions laid the groundwork for the statutory amendment authorizing CPRIT to leverage the Trust Company's expertise via transfer of the Oversight's asset management and disposition authority to the Trust Company.

#### **Process for Transferring Management and Disposition Authority to the Trust Company**

The newly adopted statutory amendment is clear that the decision to transfer asset management and disposition authority to the Trust Company is at the discretion of the Oversight Committee. Accordingly, initiating the transfer requires an affirmative vote of the Oversight Committee. Rather than propose a blanket transfer of all assets and potential assets associated with CPRIT-funded projects, I recommend that the Oversight Committee transfer its authority on an asset-by-asset basis at this time. Doing so allows CPRIT and the Trust Company the opportunity to work through preliminary issues in this new arrangement as well as time for the Trust Company to

assess any staffing or resource needs. CPRIT identified the initial assets in the proposed resolution because CPRIT is a shareholder in each of the companies and will most likely require near term decision making.

The resolution proposed for the Oversight Committee's consideration memorializes the intent of the Oversight Committee to transfer management and disposition authority for the specific assets named in the resolution. The resolution also authorizes CPRIT's CEO to act on the Oversight Committee's behalf for all activities necessary to complete the full transfer of authority for each asset, including the execution of required legal documents and approval of a negotiated fee CPRIT will pay to the Trust Company. The statutory amendment permits the Trust Company to charge CPRIT to recover the costs associated with managing any transferred assets. CPRIT staff and Trust Company representatives are negotiating an appropriate fee and payment structure, which we will memorialize through an inter-agency agreement. <sup>2</sup> Mr. Roberts will report the final fee agreement to the Oversight Committee.

Another outstanding issue CPRIT and Trust Company representatives are discussing is how the Trust Company will update the Oversight Committee regarding CPRIT assets under its management, as well as the frequency of those updates. At this time, we anticipate that the Trust Company will update the Oversight Committee annually, but may be available more frequently at the Oversight Committee's request.

#### **Recommendation:**

I recommend that the Oversight Committee approve the proposed resolution.

Transfer of Asset Management Authority to Texas Treasury Safekeeping Trust Company

<sup>&</sup>lt;sup>2</sup> We do not anticipate that the management and disposition fee associated with these four assets will exceed \$100,000. In the event that it does, Mr. Roberts will bring the contract to the Oversight Committee for approval consistent with the Oversight Committee's bylaws.



### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# A RESOLUTION AUTHORIZING THE TRANSFER OF MANAGEMENT AND DISPOSITION AUTHORITY FOR CERTAIN ASSETS TO THE TEXAS TREASURY SAFEKEEPING TRUST COMPANY AND THE PAYMENT OF A FEE FOR MANAGEMENT OF THE ASSETS

Whereas, Texas Health & Safety Code § 102.256 authorizes the Cancer Prevention and Research Institute of Texas ("CPRIT") to collect royalties, income, and other benefits, including interest or proceeds resulting from securities or equity, realized because of projects undertaken with CPRIT grant awards;

Whereas, CPRIT owns equity in publicly traded and privately held companies pursuant to contractual agreements authorized by Texas Health & Safety Code § 102.256;

Whereas, the 85<sup>th</sup> Session of the Texas Legislature adopted an amendment to Texas Health & Safety Code § 102.256, signed into law by the Governor on June 9, 2017, and effective September 1, 2017, ("Authorizing Law") permitting CPRIT to transfer to the Texas Treasury Safekeeping Trust Company ("Trust Company") CPRIT's management and disposition authority over the state's interest in securities, equities, royalties, income, and other benefits realized as a result of projects undertaken with CPRIT grant awards;

Whereas, in managing the assets transferred by CPRIT through procedures and subject to restrictions that the Trust Company considers appropriate, the Trust Company may acquire, exchange, sell, supervise, manage, or retain any kind of investment that a prudent investor, exercising reasonable care, skill, and caution, would acquire, exchange, sell, or retain in light of the purposes, terms, distribution requirements, and other circumstances then prevailing pertinent to each investment, including the requirements prescribed by Texas Health & Safety Code § 102.256(b) and the purposes described by Texas Health & Safety Code § 102.002;

Whereas, the CPRIT Oversight Committee desires and intends to transfer its management and disposition authority over specific equity interests realized as a result of certain CPRIT grant awards as permitted by Authorizing Law; and

**Whereas,** Authorizing Law permits the Trust Company to charge CPRIT a fee to recover the reasonable and necessary costs incurred in managing the assets transferred by CPRIT.

#### **NOW, THEREFORE, BE IT RESOLVED** by the CPRIT Oversight Committee that:

Section 1. The CPRIT Oversight Committee intends to transfer its management and disposition authority for, the assets listed below to the Trust Company effective on or after September 1, 2017, in accordance with applicable local law and relevant constitutional documents of the companies whose shares are to be transferred. Accordingly and pursuant to the Authorizing Law, the CPRIT Oversight Committee hereby ratifies, approves, and confirms the transfer of the following assets listed below:

- a. All shares held by CPRIT in Cell Medica Limited (approximately 1,822,437 A Preference Shares)
- b. All shares held by CPRIT in Mirna Therapeutics (approximately 2,395,010 shares of common stock);
- c. All shares held by CPRIT in Codiak Biosciences, Inc. (approximately 112,500 shares of Series A Preferred Stock and 432,750 shares of Class A Common Stock); and
- d. All shares held by CPRIT in Coregon, Inc. (approximately 333,333 shares of common stock).

Section 2. In the event that the shares of one or more companies listed herein is exchanged for shares in another company through a merger or acquisition on or after the date of this resolution, the CPRIT Oversight Committee affirms that the transfer of management and disposition authority as described in this resolution and approved by the CPRIT Oversight Committee specifically applies to the shares of the new company without further action by the CPRIT Oversight Committee.

Section 3. The CPRIT Oversight Committee hereby delegates authority to CPRIT's Chief Executive Officer, and any designee of the Chief Executive Officer, to take all action in conformity with the Authorizing Law necessary to effect the transfer of CPRIT's management and disposition authority for, the specific assets named herein to the Trust Company on or after September 1, 2017. CPRIT's Chief Executive Officer, and any designee of the Chief Executive Officer, may take all action necessary or desirable in conformity with the Authorizing Law for carrying out, giving effect to, and consummating the transactions required to complete the transfer. Such authority includes, without limitation, the execution and delivery of any documents in connection with the transfer and the negotiation and payment of a fee paid by CPRIT to the Trust Company for the reasonable and necessary costs incurred in managing the transferred assets.

Section 4. The CPRIT Oversight Committee hereby empowers, authorizes, and directs CPRIT's Chief Executive Officer to:

- sign and deliver any and all documents necessary or desirable to effect the transfer of authority to the Trust Company. Such documents may include but not limited to a Memorandum of Understanding and Fee Agreement between CPRIT and the Trust Company;
- b. cooperate with the named companies, including their successors, the Trust Company and its consultants to effectuate the transfer; and
- c. to take any other action necessary to assist in such transfer.

Section 5. The CPRIT Oversight Committee hereby ratifies, approves, and confirms all actions consistent with provisions of this Resolution heretofore taken by CPRIT and its Chief

Executive Officer or designee thereof and the other officers of, or consultants to CPRIT, directed toward the transfer of the specific assets named herein.

Section 6. The CPRIT Oversight Committee adopted this Resolution at a meeting open to the public, and CPRIT provided public notice of the time, place, and purpose of said meeting, all as required by Ch. 551, Texas Government Code.

Adopted by the affirmative vote of a majority of the CPRIT Oversight Committee present and voting on August 16, 2017.

Cancer Prevention and Research In	stitute
of Texas Oversight Committee	Attested:
<u>-</u>	
Chairman	Secretary

## August 2017 Oversight Committee Internal Audit Status Report As of August 7, 2017

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.

#### 2017 Internal Audit Plan and Schedule

Weaver has completed fieldwork or has issued reports for all projects on the 2017 Internal Audit Plan.

SERVICE MALON	NEW INTERNAL AUDITS	
Internal Audit	Description	Timing
Training	Fieldwork for the Training Program audit was completed on February 6, 2017. We issued the report on March 10, 2017. The audit resulted in an overall assessment of "Strong" with two total findings.  Moderate Risk Findings:  Monitoring Evidence of Timely Completion of Oversight	Complete
	Committee Required Training  • Employee Civil Rights Training Updates  Follow-up procedures on the remediation of the findings will be included in the proposed audit plan for fiscal year 2018.	
Internal Agency Compliance	Fieldwork for the Internal Agency Compliance audit was completed on February 24, 2017. We issued the report on April 17, 2017. The audit resulted in an overall assessment of "Strong" with one total finding.  Moderate Risk Finding:  Missing Annual Conflict of Interest Form for PIC Member from DSHS  Follow-up procedures on the remediation of the findings will be included in the proposed audit plan for fiscal year 2018.	Complete
Pre-Award Grant Management	Fieldwork for the Pre-Award Grant Management audit was completed April 19, 2017. We issued the report on May 30, 2017. The audit resulted in an overall assessment of "Satisfactory" with three total findings.  High Risk Finding:  Available Grant Funds Monitoring  Moderate Risk Findings:  Missing Post-Review Statement  Separated Employee User Access  Follow-up procedures on the remediation of the findings will be	Complete

	FOLLOW-UP PROCEDURES	
Follow-Up	Description	Timing
	Fieldwork for the Procurement and P-Cards audit was complete on June 21, 2017. We issued the report on August 4, 2017. The audit resulted in an overall assessment of "Satisfactory" with nine total findings.	
Procurement and P-Cards	Moderate Risk Findings:  Purchase Requisition Creation and Approval  Missing RFP Approval  Required Disclosures, Certifications, and Reviews  Monitoring Split Purchases and Consolidation of Purchases  Travel Requisition Approval  Timeliness of P-Card and Travel Card Reconciliations  Low Risk Findings  Financial Interest Disclosure  Travel Card Usage Authorization  Follow-up procedures on the remediation of the findings will be	Complete
T Security Follow- Jp	included in the proposed audit plan for fiscal year 2018.  Fieldwork for these follow-up procedures was completed on March 9, 2017. The report was issued May 30, 2017.	Complete
devenue Follow- Jp 2 Low Findings	Fieldwork for these follow-up procedures was completed on June 21, 2017. The report was issued July 8, 2017. Both findings from the prior year's audit were remediated	Complete
Cash Management follow-Up 1 Moderate Finding	Fieldwork for these follow-up procedures was completed on June 21, 2017. The report was issued July 13, 2017. The one finding from the prior year's audit was remediated	Complete
Commodity and service Contracts follow-up 3 Moderate Findings 2 Low Findings	Fieldwork for these follow-up procedures was completed on June 21, 2017. The report was issued July 13, 2017. Four findings were remediated. One finding was not remediated, however, management has accepted the risk and closed the finding.  Low Risk Finding Closed by Management:  Invoice Approval	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.

In addition, the annual update of the Internal Audit Risk Assessment was performed August 7, 2017, resulting in no recommended change to the Fiscal Year 2018 Internal Audit Plan. The results of the updated Internal Audit Risk Assessment will be incorporated into the required Annual Internal Audit Report, due November 1, 2017.

Alyssa G. Martin, CPA, MBA, Internal Auditor

**Executive Partner** 

Weaver and Tidwell L.L.P

# Cancer Prevention and Research Institute of Texas FY 2018 Internal Audit Plan August 2017

Audit Area	Risk	Summary Procedures
		2018 Planned New Infernal Audits
Post Award Grant Monitoring	High	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Grants Management, Monitoring and Contracting
Grant Contracting	Moderate	practices. Activities to be evaluated will include Contract Terms, Fund Availability, Certifications, Grant Contract Execution, Grantee Monitoring, Sub-Contractor Monitoring, Grantee Reporting and Scientific Review.
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 evaluated will include Annual Report, Research and Analytical Support, Texas Cancer Plan, State Reporting, Public Information Act Requests, and Ad Hoc Reporting.
Information Technology Services	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Information Technology practices. Activities to be evaluated will include Network Operations, Help Desk, Change Management, Website Maintenance, Intranet Content Management, Third-Party Services, Disaster Recovery and Business Continuity Planning.
Communications	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Communications practices. Activities to be evaluated will include Website Content Compliance, Newsletter and Listserv, Grantee Communications, Achievement Report, Media Relations, and Publicly Available Information.
		2018 Planned Internal Audit Follow-up
Procurement and P-Cards	High	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.
Pre-Award Grant Management	Moderate	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.
Training	Moderate	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.
Internal Agency Compliance	Moderate	Internal Audit will perform follow-up procedures on 2017 Internal Audit findings to ensure corrective action has been taken.
Information Security	High	
A CONTRACT OF THE PARTY OF THE		2018 Planned Annual Requirements
Project Management	Ϋ́	Track overall internal audit procedures, coordinate audit activities, and reporting to management.
Update Risk Assessment	¥ X	Perform required annual update of risk assessment.
Annual and Quarterly Board Reports	A A	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Subcommittee and Oversight Committee of internal audit activities.

Cancer Prevention and Research Institute of Texas Schedule of Audits, Status, and Findings Summary

As of August 7, 2017

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The state of the s	MOID
A th	The nine findings from the 2015 Grant Management internal audit were closed as part of the 2016 Internal Audit Follow-up procedures.
B Sul	At the conclusion of the audit, no follow-up procedures were recommended to be performed by Internal Audit based on the nature and risk rating of the findings in the report. Internal Audit has recommended that Management perform their own follow-up procedures to validate remediation has occurred. Management has agreed to report the confirmation of the remediation to the Audit Subcommittee separately.
C T	The prior internal auditor did not provide risk ratings for the individual findings in the final report. Therefore the number of findings and the findings remediated are shown in total.
D Pro	At the conclusion of the audit, follow-up procedures were recommended to be performed by CPRIT's Compliance group, which is occurring. Internal Audit does not plan to perform follow-up procedures on these open findings. Management has agreed to report the confirmation of the remediation to the Audit Subcommittee separately.
E the	The 2015 Governance and IT Follow-up procedures closed all the outstanding Governance findings. We incorporated the remaining open information Technology Services follow-up procedures into the Information Security Internal Audit. The two open findings are information security related, and the audit procedures included in the audit included the evaluation of the conditions related to the open findings have been consolidated into the 2016 IT Security Internal Audit.

### **CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS**

IA # 03-17 INTERNAL AUDIT REPORT OVER PRE-AWARD GRANT MANAGEMENT

**REPORT DATE: APRIL 19, 2017** 

**ISSUED: MAY 30, 2017** 

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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 procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period March 20, 2017 through April 19, 2017 relating to the Pre-Award Grant Management processes.

The objectives of the internal audit were to evaluate the design and effectiveness of CPRIT's Pre-Award Grant Management processes. The objectives were organized as follows:

- A. Confirm the design of internal controls over Pre-Award Grant Management processes ensure that consistent processes are implemented and designed effectively to manage the grant application and evaluation process.
- B. Ensure that controls over selected critical processes within Pre-Award Grant Management processes are operating effectively and that required grant application documentation is obtained and reviewed.
- C. Ensure that access to view, process or modify data in the CPRIT Application Receipt System (CARS), CSRA SharePoint, and CPRIT Portal is restricted to appropriate personnel.

To accomplish these objectives, we conducted interviews with CPRIT personnel responsible for Pre-Award Grant Management. We also reviewed documentation and performed specific testing procedures to assess controls. Procedures were performed at CPRIT's office and completed on April 19, 2017.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Siduell, L.L.P.

WEAVER AND TIDWELL, L.L.P. Austin, Texas May 30, 2017

#### **BACKGROUND**

The Cancer Prevention and Research Institute of Texas (CPRIT) was established in 2007 as a result of a Texas constitutional amendment. CPRIT's goal is to expedite innovation in cancer research and product development, and to enhance access to evidence-based prevention programs throughout the state. As part of achieving that goal, CPRIT awards grants for cancer research and prevention.

In 2015, Internal Audit performed an audit over Grants Management, which included the grant cycle from the initiation of a grant application, through the grant application evaluation and award, completing with grant monitoring, and close-out. As part of the update of the Internal Audit Risk Assessment in 2015, the grants cycle was split into three distinct cycles to better depict how the process occurs: Pre-Award Grant Management, Grant Contracting, and Post-Award Grant Monitoring. This internal audit focused on the Pre-Award Grant Management processes.

CPRIT awards three types of grants, including academic research, prevention, and product development research grants.

Since June 1, 2015, CPRIT pre-award grant activity included:

- 43 RFA Solicitations (17 FY16; 26 FY17)
- 216 Grant Awards
- \$ 467,386,581 Funds Awarded

5 Product Development Research Grants
 35 Prevention Grants
 176 Academic Research Grants
 342,363,034

As part of granting funds for cancer academic research, prevention, and product development research, the agency conducts an extensive review process for all grant applications. The grant process begins with the issuance of a Request for Applications (RFA) to invite academic institutions, companies, or other organizations to submit applications for CPRIT grant funds. The Program Managers and Program Officers are responsible for ensuring that the RFAs align with CPRIT goals and priorities.

As part of the grant application review and approval process, grant applications are subject to many levels of review, including an administrative review to ensure completeness of the application, as well as programmatic reviews by the Scientific Research and Prevention Programs Committee (SRPPC), a program review council, the Program Integration Committee (PIC), and the Oversight Committee. The Oversight Committee holds the ultimate responsibility to approve and grant awards.

SRPPC members are selected and vetted by the CEO and approved by the Oversight Committee. SRPPC members perform the first level of review and score the applications. The highest-scoring applications are recommended to a program review council for review and finalization of recommendations. Product development research applications also receive a due diligence and intellectual property review prior to review by the Product Development Review Council. Once an application has gone through SRPPC review, the Review Council performs a review of the application and selects the highest-scoring applications to recommend to the PIC. The PIC then completes a review of the applications and submits recommendations to the Oversight Committee for grant award. During the quarterly Oversight Committee meetings, the Oversight Committee performs the final review and approval of grant applications for CPRIT grant funds.

**ISSUED: MAY 30, 2017** 

As part of the grant application review process, all SRPPC members, PIC members, and Oversight Committee members are required to complete a conflict of interest disclosure for all grant applications reviewed. The conflict of interest disclosure must be completed prior to accessing any applications and identifies any independence issues or certifies that the SRPPC member, PIC member, or Oversight Committee member does not have a conflict of interest with any of the applications reviewed. CPRIT's third-party observer vendor monitors the grant application evaluation meetings to ensure that SRPPC members do not participate in the discussion of applications with which a conflict of interest has been identified. SRPPC members who have identified a conflict of interest are tracked and are not allowed to be present or participate in discussions of the grant application.

Additionally, SRPPC members, review council members, and PIC members are required to complete a post-review statement after their respective application review meeting to indicate that they understand the CPRIT Conflict of Interest Policy and have identified any relevant conflicts of interest. SRPPC Chairs, who make up the respective review council, are not required to complete a conflict of interest form prior to review of applications and identify any conflicts of interest during the meeting. SRPPC Chairs are required to complete a post-review statement after the relevant review meeting to indicate that they understand the CPRIT Conflict of Interest Policy and have identified any relevant conflicts of interest.

As part of the grant award process, CPRIT management is responsible for monitoring available grant funds and ensuring that prevention grant awards remain within the statutory limit of 10% of all grant awards. The Chief Operating Officer monitors available grant funds prior to and following each oversight committee meeting to ensure that grants awards are only awarded within available grant funds, and to ensure that prevention grant awards are within the 10% statutory limit.

#### **AUDIT OBJECTIVE AND SCOPE**

The audit focused on CPRIT's Pre-Award Grant Management processes to solicit and evaluate grant applications and make grant awards. Activities that were evaluated include the Request for Application (RFA) Review Process, Conflicts of Interest, Scientific Research and Prevention Programs Committee (SRPPC) including travel coordination, Grant Application Approval and Awarding Grant Funds. Key functions and sub-processes within the Pre-Award Grant Management process that were reviewed include:

- RFA Review Process
  - Academic Research
  - Product Development Research
  - Prevention
- Conflict of Interest Disclosure
- Scientific Research and Prevention Programs Committee Review Process
- Grant Application Approval
- Grant Award Approval

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

#### **RFA Review Process**

- RFA solicitations align with Program Priorities and the Texas Cancer Plan
- RFA solicitations are reviewed and approved prior to posting and distribution
- Administrative review is performed on applications to ensure completeness and compliance with RFA requirements

#### Conflict of Interest Disclosure

- Scientific Research and Prevention Programs Committee (SRPPC) members disclose conflicts of interest
- SRPPC members confirm understanding of conflict of interest policies
- Program Integration Committee members disclose conflicts of interest
- Oversight Committee members disclose conflicts of interest
- Any individuals with conflicts of interest are recused from evaluation
- CPRIT staff do not substantively participate in SRPPC meetings

#### Scientific Research and Prevention Programs Committee Review Process

- Available grant funds allocation thresholds are monitored by management
- · Prevention grants awards are within statutory limits
- SRPPC members are appropriately vetted and selected by the CEO
- SRPPC members are approved by the Oversight Committee prior to beginning service
- SRPPC members are assigned to appropriate panels based on expertise
- SRPPC scores are appropriately tabulated and validated
- High-scoring product development research applications receive due diligence and intellectual property review prior to approval for award recommendation
- Recommended applications are reviewed and approved by a review council

#### **Grant Application Approval**

- Applications are reviewed and approved by the Program Integration Committee
- Application Pedigrees are completed for approved awards
- CEO Affidavits are completed for approved awards
- CCO Compliance Certifications are completed for approved awards

#### **Grant Award Approval**

- Available grant funds are monitored by management
- Prevention grants awards are within statutory limits
- Oversight Committee approves all awards
- Applicants of approved grant awards are notified with a Notice of Funding Recommendation

The audit did not include the following Grant Contracting or Post-Award Monitoring processes in the scope:

- Grant Contract Terms and Execution
- Funds Availability
- Grantee Certification and Reporting
- Grantee and Sub-contractor Compliance Monitoring
- · Grantee Reporting and Scientific Review
- Annual Progress Reports
- External Reporting

Our procedures included interviewing key personnel within the agency to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the process. We evaluated the existing policies, procedures, and processes in their current state. Our coverage period was from June 1, 2015, through February 28, 2017.

#### **EXECUTIVE SUMMARY**

Through our interviews, observations, evaluation of internal control design, and testing of controls, we identified three findings. The listing of findings includes items that have been identified and are considered to be non-compliance issues with documented CPRIT policies and procedures, with rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover significant risks to CPRIT. These issues could have significant financial or operational implications.

A summary of our results, by audit objective, is provided in the table below. See the Appendix for an overview of the Assessment and Risk Ratings.

**OVERALL ASSESSMENT** 

SCOPE AREA	RESULT	RATING
Objective A: Confirm the design of internal controls over Pre-Award Grant Management processes ensure that consistent processes are implemented and designed effectively to manage the grant application and evaluation process.	We identified 29 controls to be in place in the process, and identified the following opportunity for improvement:  • Perform secondary review of Available Grant Funds monitoring spreadsheet	SATISFACTORY
Objective B: Ensure that controls over selected critical processes within Pre-Award Grant Management processes are operating effectively and that required grant application documentations is obtained and reviewed.	Controls in place were generally operating as designed. We identified the following opportunities for improvement:  • Verify that all Post-Review Statements are completed	STRONG
Objective C: Ensure that access to view, process or modify data in the CARS, CSRA SharePoint, and	Access to CARS, CSRA SharePoint, and the CPRIT Portal was generally appropriate. We identified the following opportunity for improvement:	STRONG

Through our interviews, evaluation of internal control design and control testing we did not identify any additional observations or opportunities for improvement.

Monitor access to CSRA's SharePoint to

ensure access is removed timely upon departure of CPRIT and CSRA employees

CPRIT Portal is restricted to

appropriate personnel.

SATISFACTORY

#### CONCLUSION

Based on our evaluation, the Pre-Award Grant Management process has procedures and controls in place to conduct effective management of the significant processes within CPRIT. However, we identified opportunities to improve the processes and effectiveness of the controls within the Pre-Award Grant Management process.

CPRIT should ensure that a secondary review of the Available Grant Funds monitoring spreadsheet is performed to verify that data points included in the schedule are complete. CPRIT should also ensure that all Post-Review Statements are completed for the evaluation of the grant applications. CPRIT should ensure that access to the CSRA SharePoint is appropriately removed upon termination of CPRIT and CSRA employees.

Follow-up procedures will be conducted as part of the 2018 Internal Audit Plan to validate the effectiveness of the steps taken to address the findings identified.

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

ISSUED: MAY 30, 2017

### DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

Our procedures included interviewing key agency personnel to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the process. We evaluated the existing policies, procedures and processes in their current state.

#### **Objective A: Design of Internal Controls**

Confirm the design of internal controls over Pre-Award Grant Management processes ensure that consistent processes are implemented and designed effectively to manage the grant application and evaluation process.

**Procedures Performed:** We conducted interviews with key personnel throughout CPRIT and examined existing documentation to confirm our understanding of the internal controls for the Pre-Award Grant Management processes. We confirmed the design of controls within the following critical sub processes:

- RFA Review Process
- Conflict of Interest Disclosure
- Scientific Research and Prevention Programs Committee Review Process
- Grant Application Approval
- Grant Award Approval

We evaluated whether the design of the confirmed internal controls sufficiently mitigates the critical risks associated with the Pre-Award Grant Management processes. We identified any unacceptable risk exposures due to control design inadequacy or any opportunities to strengthen the effectiveness of the existing control design.

Results: We identified 29 controls in place over the significant activities within the Pre-Award Grant Management processes. We identified one finding where an improvement in the process and procedures can be made.

Process Area	Controls	Control Gaps
Pre-Award Grant Management Processes		
RFA Review Process	4	-
Conflict of Interest Disclosures	10	-
Scientific Research and Prevention Programs Committee Review Process	11*	-
Grant Application Approval	4*	-
Grant Award Approval	4*	Finding 1
Total	29	1

<sup>\*</sup> Duplicate Control: The total number of controls identified is 29. However, based on their design, controls address risks in multiple processes. We have mapped the 29 identified controls to the processes in which they mitigate the risks within the processes.



**ISSUED: MAY 30, 2017** 

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 Operations 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.

**Recommendation:** CPRIT should assign the responsibility to perform a detailed review of the Available Grant Funds monitoring spreadsheet against the award slates and declined awards when the spreadsheet is updated. The detailed review could be performed by the Operations Specialist or Operations Manager, and should be performed prior to providing the spreadsheet to the program officers and managers, the PIC, and the Oversight Committee.

**CPRIT Management Response:** CPRIT management agrees with the finding and has developed a process by which the Operations Manager verifies the grant award slate and grant declination amounts in the Available Grant Funds monitoring spreadsheet each time it is updated.

Responsible Party: Chief Operating Officer, Operations Manager

Implementation Date: May 5, 2017

#### **Objective B: Effectiveness of Controls**

Ensure that controls over selected critical processes within Pre-Award Grant Management processes are operating effectively and that required grant application documentation is obtained and reviewed.

- 1. Procedures Performed: We selected a sample of 10 from the population of 48 Request for Applications that were released between June 1, 2015, and February 28, 2017, and verified the following:
  - Solicitations were approved prior to posting
  - Solicitations aligned with CPRIT's Program Priorities and the Texas Cancer Plan

Results: No findings identified.

- 2. Procedures Performed: We selected a sample of 40 from the population of 255 Scientific Research and Prevention Programs Committee (SRPPC) members that were active on at least one review panel between June 1, 2015, and February 28, 2017, and verified the following:
  - SRPPC members were appropriately vetted and selected by the CEO
  - SRPPC members were approved by the Oversight Committee
  - SRPPC members were assigned to appropriate panels based on experience

Results: No findings identified.



- **3. Procedures Performed:** We selected a sample of 35 from the population of 150 grant applications approved and awarded between June 1, 2015, and February 28, 2017, and verified the following:
  - High-scoring product development research applications were subjected to due diligence and intellectual property review
  - Approved applications were reviewed by a program review council, Program Integration Committee, and Oversight Committee
  - Approved applications had completed application pedigrees, CEO affidavits, and CCO compliance certifications
  - Applicants of approved grant awards were notified via a Notice of Funding recommendation
  - Conflict of Interest disclosures were completed
  - Third Party Observer Reports were completed for program review council meetings

Results: No findings identified.

- **4. Procedures Performed:** We reviewed the Available Grant Funds monitoring spreadsheet for FY16 and verified the following:
  - · Available grant funds were monitored by management
  - Validated mathematical accuracy of Available Grant funds
  - Correct source of documentation was used to calculate available grant funds
  - · Prevention grant awards were within statutory limits

**Results:** We verified that available grant funds were monitored by management. However, we identified a discrepancy between the grant funds awarded by the Oversight Committee and the awards identified in the Available Grant Funds monitoring spreadsheet.

#### Finding 1 – HIGH – Available Grant Funds Monitoring

- **5. Procedures Performed:** We selected a sample of 40 from the population of 928 grant applications that were received between June 1, 2015, and February 28, 2017, and verified the following:
  - Applications were complete prior to SRPPC review
  - Administrative review was performed on accepted applications
  - SRPPC steps were completed for approved applications
  - SRPPC members disclosed conflicts of interest
  - SRPPC scores were appropriately tabulated and validated
  - Third-party observer reports were completed for SRPPC meetings

**Results:** We verified that applications were complete prior to SRPPC review, administrative review was performed on accepted applications, SRPPC steps were completed for approved applications, SRPPC scores were appropriately tabulated and validated, and third-party observer reports were completed. However, we identified one missing Post-Review Statement related to two of the 40 applications tested.

**ISSUED: MAY 30, 2017** 

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.

**Recommendation:** CPRIT should ensure that Conflict of Interest disclosures are completed by all SRPPC panelists, including panel chairs. CPRIT should work with CSRA to implement a process where panel chairs must confirm that they do not have any conflicts with the applications prior to participating in the evaluation process. This could be accomplished by the panel chairs providing a Conflict of Interest statement during the process to assign the applications to the panels for evaluation.

**CPRIT Management Response:** CPRIT management agrees with this finding and will work with CSRA to implement a formal process where panel chairs must confirm that they do not have any conflicts with the applications prior to participating in the evaluation process.

Responsible Party: Chief Compliance Officer

Implementation Date: September 1, 2017

#### **Objective C: System Access**

Ensure that access to view, process or modify data in the CARS, CSRA SharePoint, and the CPRIT Portal is restricted to appropriate personnel.

 Procedures Performed: We obtained the user access permissions for the CPRIT Application Receipt System (CARS) from CSRA. We evaluated the user permissions to verify that only CSRA employees have access to the CARS system.

Results: No findings identified.

2. Procedures Performed: We obtained the user access permissions for the CSRA SharePoint from CSRA. We evaluated the user permissions for all CPRIT and CSRA employees with access to the CSRA SharePoint to verify system access is appropriate.

**Results:** We identified two CPRIT employees and one CSRA employee that had active user IDs in the CSRA SharePoint after they separated employment from their respective organization.

ISSUED: MAY 30, 2017

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.

**Recommendation:** CPRIT should perform a review of user access of the CSRA SharePoint portal and request that CSRA remove access from CSRA employees who have separated employment with CSRA. This review should include the review of CPRIT employee access to ensure that access for CPRIT employees is appropriate. (See the August 2016 Information Security Internal Audit - Finding 11).

CPRIT should also continue to enforce the requirement that CSRA obtain a SOC report for the services provided to CPRIT (See the August 2016 Information Security Internal Audit - Finding 6).

**CPRIT Management Response:** CPRIT management agrees with this finding and will develop a process that CSRA provides formal notification to CPRIT that CSRA IT system accounts of separated employees from either organization are deactivated. Timely deactivation of separated employee access to CSRA IT systems will be verified through the documentation required for completion of the SOC 2 report due from CSRA.

Responsible Party: Chief Operating Officer, Operations Manager, Information Technology Manager

Implementation Date: February 28, 2018

3. Procedures Performed: We obtained and tested the user access permissions for the CPRIT Portal from CPRIT IT personnel. We evaluated the user permissions for all CPRIT employees, PIC members, and Oversight Committee members with access to the CPRIT portal to verify system access is appropriate.

Results: No findings identified.

### **APPENDIX**

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

#### **REPORT RATINGS**

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- · Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
  - o Reliability and integrity of financial and operational information
  - Effectiveness and efficiency of operations and programs
  - Safeguarding of assets
  - o 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:

The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.

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.

The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.



**ISSUED: MAY 30, 2017** 

#### **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**

IA # 04-17 INTERNAL AUDIT REPORT OVER PROCUREMENT AND P-CARDS

**REPORT DATE: JUNE 21, 2017** 

**ISSUED: AUGUST 4, 2017** 

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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 procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period May 15, 2017 through June 21, 2017 relating to the procurement and P-Card processes.

The objectives of the internal audit were to evaluate the design and effectiveness of CPRIT's procurement and P-Card processes. The objectives were organized as follows:

- A. Determine whether internal controls over procurement and P-Card processes 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 selected critical processes within procurement and P-Card processes are operating efficiently and effectively.
- C. Determine whether access to the purchasing and P-Card systems is restricted to appropriate individuals and that access is reviewed periodically.

To accomplish these objectives, we conducted interviews with CPRIT personnel responsible for procurement and P-Cards. We also reviewed documentation and performed specific testing procedures to assess controls. Procedures were performed at CPRIT's office and were completed on June 21, 2017.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Tiduell, L.L.P.

WEAVER AND TIDWELL, L.L.P. Austin, Texas August 4, 2017

#### **BACKGROUND**

The Cancer Prevention and Research Institute of Texas (CPRIT) was established in 2007 as a result of a Texas constitutional amendment. CPRIT's goal is to expedite innovation in cancer research and product development, and to enhance access to evidence-based prevention programs throughout the state.

Throughout the fiscal year, the agency purchases goods and services for the operation of the agency to accomplish its goals. The State of Texas Procurement Manual, CPRIT's Administrative Rules, and CPRIT's Procurement Plan and Contract Management Handbook establish CPRIT's purchasing requirements for the procurement of goods and services through the issuance of a purchase order, or the use of a P-Card or Travel Card.

The Purchaser holds the primary responsibility for ensuring that the purchasing method and documentation follow state and CPRIT requirements. Purchases under \$5,000 do not require a specific procurement method. Purchases between \$5,000 through \$25,000 require an informal solicitation process, and purchases \$25,000 and above require a formal solicitation process. Purchases from state cooperative contracts can be used in place of other purchasing methods.

A purchase order is required for all purchases, and each one is reviewed and approved by the Chief Operating Officer or Chief Executive Officer. Additionally, each purchase order must have a completed budget verification by the Operations Specialist prior to issuing the purchase order to a vendor. From June 1, 2015 through March 31, 2017, 154 purchase orders were issued by CPRIT.

Purchases can also be paid with a P-Card. The Purchaser is the P-Card administrator and is the only person at CPRIT with access to the agency's P-Card. The P-Card is used for general agency purchases including general office supplies, information technology service subscriptions, and other operational items. From June 1, 2015 through March 31, 2017, 400 purchases were made with the P-Card.

CPRIT utilizes a Travel Card for booking hotel and airfare for employee or Oversight Committee member travel. The agency Travel Card is administered by the Accountant. Travel requisitions must have a completed budget verification and executive approval prior to using the card to purchase travel. From June 1, 2015 through March 31, 2017, 251 purchases for travel were made with the central billed Travel Card.

The agency P-Card and Travel Card are available to be used for purchases that are \$2,000 or less. A monthly P-Card reconciliation is performed by the Purchaser and a monthly Travel Card reconciliation is performed by the Accountant to ensure that all charges to the cards are appropriate, contain a valid invoice or receipt, and to verify that there are no fraudulent or inappropriate charges. The Chief Operating Officer reviews the reconciliations for appropriateness and accuracy.

ISSUED: AUGUST 4, 2017

#### **AUDIT OBJECTIVE AND SCOPE**

The audit focused on CPRIT's procurement and P-Card processes to obtain goods and services for the agency. 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 Procurement and P-Card process that were reviewed include:

#### **Procurement**

- Purchase Requests
- Purchase Method Determination
- Interlocal and Cooperative Agreement Purchases
- Vendor Selection and Award
- Vendor Acceptance and Setup
- Purchase Orders
- Vendor Monitoring and Reporting

#### P-Card (P-Card & Central Travel Card)

- Governance
- Request and Approval
- Usage
- Administration
- Reconciliation
- Monitoring and Tracking

The scope of the audit did not include the processes for contract initiation, execution and management.

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

#### Procurement:

#### Purchase Requests

- Budgets are verified and funds are encumbered prior to purchase requisition approval
- Purchases are within buyer limits
- Items requested for purchase are accurate
- Segregation of duties in the initiation and approval of purchase requests is present
- Purchase requisitions are properly approved prior to initiating procurement activities

#### Purchase Method Determination

- Appropriate purchase method is selected
- Appropriate purchase methods are followed
- Justification to support the determination of purchase method is documented

#### **Bidding**

- Qualified vendors are identified and notified
- Smaller dollar purchases are procured from reputable and approved vendors
- An appropriate bidding process is used for the type and value of the purchase
- Scope of work descriptions contain specific deliverables and timeframes
- Conflicts of interest are identified and avoided



#### Interlocal and Cooperative Agreement Purchases

- · Consolidated purchasing or purchasing power is utilized for similar purchases
- Vendors used through Interlocal and Cooperative Agreements are qualified and meet the agency's requirements
- Vendors used through Interlocal and Cooperative Agreements are procured competitively and appropriately
- Interlocal and Cooperative Agreements provide best value compared to open market purchasing
- Pricing related to Interlocal and Cooperative purchasing is accurate and within pre-approved contract rates
- Interlocal and Cooperative Agreements have an appropriate term and duration
- Interlocal and Cooperative contracts are properly reviewed and approved
- Contracts on the Interlocal and Cooperative Agreement list are current and accurate

#### Vendor Selection and Awards

- Multiple vendors providing similar products or services are identified, reviewed, and eliminated
- Sole-source and single source purchases are limited and do receive pre-approval
- Purchases are properly approved by Management
- Conflicts of interest are managed and monitored

#### Vendor Acceptance and Setup

- New vendors are properly authorized for entry into the system and that the data is entered
  accurately into the system
- Sensitive vendor information is properly safeguarded
- · Changes to the vendor master file are authorized
- Fictitious or duplicate vendors are not set-up
- A complete and accurate list of vendors is maintained

#### **Purchase Orders**

- Purchases of goods and services are authorized prior to placing the order with the vendor
- Quantity and pricing on the purchase order is properly reflected and entered in the system
- Purchase orders are based on correct information
- Purchase order modifications are properly authorized
- Open purchase orders are monitored and closed in a timely manner

#### Vendor Monitoring and Reporting

- · Aggregate spending with a non-contract vendor is monitored
- Serial, sequential, or split purchasing is detected
- Vendors comply with CPRIT requirements
- Vendor rebates or reimbursements are received in a timely manner
- Active vendors are periodically reviewed for stability and financial viability
- Vendor reporting under Senate Bill 20 is completed timely and accurately

#### P-Card:

#### P-Cards Governance

- Employees are aware of policies and procedures for using P-Cards
- The number of P-Cards issued is appropriate for the size of the agency
- · Cardholder and transactional data from P-Cards is secure
- P-Card transaction data is maintained in accordance with required record retention laws

#### P-Card Request and Approval

- P-Cards are adequately authorized to employees
- Purchase limits exist and/or are not appropriately authorized
- Employees have adequate training regarding the use of P-Cards

#### P-Card Usage

- P-Card purchases are properly authorized by the employee's supervisor
- Contract vendors are being utilized for purchases, when available
- Purchases using P-Cards are appropriately restricted by merchant code category
- MCC setup is appropriate and up to date
- Overrides to purchase restrictions are appropriately reviewed and approved
- Overrides to purchase restrictions are appropriately documented and supported
- Transaction overrides expire

#### P-Card Administration

- Stolen P-Cards are appropriately deactivated in a timely manner
- P-Cards are appropriately deactivated upon termination of employees
- Changes to P-Card (i.e. Profile) are properly approved
- Increases and decreases in purchasing limits are appropriate
- P-Cards are canceled or suspended for non-compliant cardholders
- Fraudulent transactions or incorrect transactional information are disputed

#### P-Card Reconciliation

- Employees conduct periodic P-Card reconciliations
- Employee's supervisor or department head reviews and approves the employee's monthly P-Card reconciliation
- P-Card transactions are appropriately reconciled on a periodic basis by an independent source
- P-Card transactions are being charged to the correct budget, project, and account
- P-Card payment transactions to vendors are not duplicated by other payment methods
- · P-Card transaction reconciliation is completed in a timely manner

#### P-Card Monitoring and Tracking

- Inappropriate and/or unauthorized P-Card transactions are identified
- Inappropriate and/or unauthorized P-Card Transactions are adequately reported
- Emergency purchases are appropriate and meet requirements
- P-Card transactions are not processed with restricted vendors
- Excessive spending from a non-contract vendor is identified and reported
- P-Card transaction and profile data is routinely reported to management for review
- P-Card transactions are being monitored for fictitious payments, personal purchases, purchases of food and alcohol and other unallowable expenses
- · Split purchasing is monitored

Our procedures included interviewing key personnel in Purchasing and Finance to gain an understanding of the current processes in place, examining existing documentation, evaluating the internal controls over the process, and testing the effectiveness of the controls in place. We evaluated the existing policies, procedures and processes in their current state. Our coverage period was from June 1, 2015 through March 31, 2017.

#### **EXECUTIVE SUMMARY**

Through our interviews, observations, evaluation of internal control design, and testing of controls, we identified nine findings. These findings includes items that have been identified and 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 financial or operational implications.

A summary of our results, by audit objective, is provided in the table below. See the Appendix for an overview of the Assessment and Risk Ratings.

OVERALL ACCECOMENT	CATICEACTORY
OVERALL ASSESSMENT	SATISFACTORY

SCOPE AREA
Determine whether internal controls over procurement and P-Card processes ensure that consistent processes are implemented and designed effectively to address the risks within the associated subprocesses and to ensure effective operations.

SCOPE AREA	RESULT	RATING
Objective B: Ensure that controls over selected critical processes within procurement and P-Card processes are operating efficiently and effectively.	Controls in place were not always operating as designed. We identified the following opportunities for improvement:  Require purchase requisitions to be completed for all purchases and ensure they are appropriately approved  Verify that the purchasing method is appropriately determined, documented, and utilized  Consistently document the approval of RFPs  Monitor vendors to ensure that "No Financial Interest Disclosure" documents are completed prior to executing vendor contracts  Verify travel requisitions received budget certification and approval by the CEO or COO  Ensure that P-Card and Travel Card Reconciliations are completed in a timely manner	SATISFACTORY
Objective C: Determine whether access to the Purchasing and P-Card systems is restricted to appropriate individuals and that access is reviewed periodically.	Access to CITI, TINS, and USAS were appropriate. We did not identify any areas for improvement.	STRONG

Other opportunities for improvement were identified through our interviews, evaluation of internal control design and transactional testing. These observations include those items that are not considered to be non-compliance issues with regulatory requirements or 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 procurement and P-Card functions have procedures and controls in place to conduct effective management of the significant processes within CPRIT. However, we identified opportunities to improve the processes and effectiveness of the controls within the procurement and P-Card processes.

CPRIT should consistently enforce their requirements to document procedures throughout the procurement and P-Card processes, including implementing procedures to ensure approvals of purchase requisitions, travel requisitions, and RFPs are documented. The agency should also implement procedures to periodically perform a structured review of purchases to ensure that purchases have not been split into multiple purchase requisitions to avoid the more formal purchasing methods required by state law.

Further, CPRIT should ensure that all disclosures, certifications, and reviews are completed. A Financial Interest Disclosure document should be completed by vendor proposal evaluators prior to participating in a proposal evaluation and the Certificate of Interested Parties (Form 1295) should be completed by vendors prior to CPRIT entering into a contract with a vendor.

Follow-up procedures will be conducted as part of the 2018 Internal Audit Plan to validate the effectiveness of the steps taken to address the findings identified.



DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

**ISSUED: AUGUST 4, 2017** 

### DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

Our procedures included interviewing key agency personnel to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the process. We evaluated the existing policies, procedures and processes in their current state.

#### **Objective A: Design of Internal Controls**

Determine whether internal controls over procurement and P-Card processes ensure that consistent processes are implemented and designed effectively to address the risks within the associated subprocesses and to ensure effective operations.

**Procedures Performed:** We conducted interviews with key personnel throughout CPRIT and examined existing documentation to gain an understanding of the current procurement and P-Card processes. We identified controls within the following critical sub processes:

#### **Procurement**

- Purchase Requests
- Purchase Method Determination
- Bidding
- Interlocal and Cooperative Agreement Purchases
- Vendor Selection and Award
- Vendor Acceptance and Setup
- Purchase Orders
- Vendor Monitoring and Reporting

#### P-Card (P-Card & Central Travel Card)

- Governance
- Request and Approval
- Usage
- Administration
- Reconciliation
- · Monitoring and Tracking

We evaluated whether the identified internal controls are sufficiently designed to mitigate the critical risks associated with the procurement and P-Card processes. We identified any unacceptable risk exposures due to control design inadequacy or any opportunities to strengthen the effectiveness of the existing control design.

**Results:** We identified 52 controls in place over the significant activities, 28 controls within the procurement process, and 24 controls within the P-Card process. We identified nine findings where an improvement in the process and procedures can be made.

Significant Process	Identified Controls	Control Gaps
Procurement		
Purchase Requests	2	Finding 1
Purchase Method Determination	2	Finding 2
Bidding	8	Finding 3 Finding 4 Finding 5
Interlocal and Cooperative Agreement Purchases	2	-
Vendor Selection and Awards	3	Finding 2
Vendor Acceptance and Setup	5	-
Purchase Orders	4	-
Vendor Monitoring and Reporting	2	Finding 6
Sub Total – Procurement	28	6
P-Card (P-Card & Central Travel Card)	(Maanie 10	
P-Cards Governance	4	
P-Card Request and Approval	2	-
P-Card Usage	9	Finding 1 Finding 7 Finding 8
P-Card Administration	5	-
P-Card Reconciliation	3	Finding 9
P-Card Monitoring and Tracking	1	-
Sub Total – P-Card	24	3
TOTAL	52	9

#### **Purchasing**

#### 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.

Recommendation: The Purchaser should require a purchase requisition to be submitted and approved prior to each purchase according to CPRIT's Procurement Plan and Contract Management Handbook to ensure that the purchase is appropriately and has the required budget available. Prior to executing the purchase, the Purchaser should ensure that a purchase requisition has received one of the appropriate approvals and certification of budget availability. For purchases that are anticipated to reoccur multiple times throughout the year, an annual purchase request for the anticipated annual expenditure could be utilized to obtain approval and budget certification in order to avoid additional paperwork, unnecessary delays and inefficient workflow.

Alternately, CPRIT should consider revising their Procurement Plan and Contract Management Handbook. Revisions to the handbook could include identifying thresholds where the submission and approval of a purchase request is not required prior to the approval of a purchase order. Additionally those revisions could include instances where a single purchase request is acceptable to make multiple purchases, such as recurring purchases.

Management Response: CPRIT management agrees that the purchasing documentation should match the written process. With CPRIT's deployment of the state's Centralized Accounting and Payroll/Personnel System (CAPPS) on September 1, 2017, the agency's purchasing and accounts payable processes will be integrated. Purchases cannot be initiated until a purchase order is generated by the system based on the Chief Operating Officer's approval recorded in the system. The purchaser will be able to initiate blanket purchase requisitions for recurring services such as online information technology services that will be linked to P-Card payments through the accounts payable processes. CPRIT will be revising its procedures in the Procurement Plan and Contract Management Handbook in conjunction with implementing the CAPPS processes.

Responsible Party: Chief Operating Officer, Purchaser

Implementation Date: October 31, 2017

#### Finding 2 - MODERATE - Purchase Method Was Not Appropriate

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.

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.

**Recommendation:** The Purchaser must follow the appropriate purchase method as stated in the Texas Procurement Manual. A secondary review of the purchase should be implemented to ensure purchases were procured appropriately.

ISSUED: AUGUST 4, 2017

Management Response: CPRIT management agrees that all of the supporting information was not recorded for the two purchases identified in the audit. CPRIT will ensure that the evaluation criteria for procurement decisions are documented on all purchases and that state purchasing guidelines are followed. All purchase orders will include a statement about the evaluation of best value.

Responsible Party: Chief Operating Officer, Purchaser

Implementation Date: September 1, 2017

#### 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.

**Recommendation:** CPRIT should implement procedures to formally document and retain the approval of RFPs by the Chief Operating Officer. For email approvals, the Purchaser should print the email approval and include the printed approval in the procurement file for the contract. For signature approvals, the Purchaser should ensure that the signed version of the RFP is included in the procurement file for the contract. For verbal approvals, the Purchaser should document approvals on the solicitation document or via a negative confirmation email to the Chief Operating Officer.

**Management Response:** CPRIT management agrees that the Chief Operating Officer must approve solicitations before they are distributed or advertised. The Purchaser will ensure that the signed version of an RFP is included in the procurement file for the contract or that a note to the file is recorded if verbal approval is provided.

Responsible Party: Purchaser

Implementation Date: August 1, 2017

#### 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 toprated vendors based on the evaluation, which includes input from subject-matter experts.

**Recommendation:** CPRIT should implement procedures to ensure all employees involved in vendor proposal evaluations submit a Financial Interest Disclosure document prior to participating in the evaluation. CPRIT should ensure that conflict of interest is disclosed by evaluators of vendor proposals submitted in response to a formal solicitation and should require evaluators to sign a Financial Interest Disclosure prior to performing an evaluation of vendor proposals. Any disclosed conflict of interest should be adequately addressed. Evaluators that have a conflict of interest or an appearance of conflict should not participate as evaluators in that particular vendor proposal evaluation. This requirement should be included in CPRIT's formal procurement procedures.

**Management Response:** CPRIT management agrees with the finding and will add a financial interest disclosure statement to the Non-Disclosure Agreement that evaluators have to complete to address any possible risks of conflicts of interest in the evaluation process. The Procurement Plan and Contract Management Handbook will be updated to incorporate this new procedure.

Responsible Party: Chief Operating Officer, Purchaser

Implementation Date: October 31, 2017

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

**Recommendation:** The Purchaser should ensure that all required disclosures, certifications, and reviews have been submitted and are in the purchasing file prior to executing a contract with the selected vendor. The Purchaser should verify that the purchasing checklist developed after the audit includes all required documentation. Once the checklist is finalized, it should be utilized to ensure that all required forms and documents have been submitted and are in the procurement file before completing the purchasing process.

**Management Response:** CPRIT management agrees that it should document that all required disclosures, certifications, and reviews are submitted prior to executing service contracts. The Purchaser has developed a checklist which will be used to verify that all purchasing steps have been completed.

Responsible Party: Purchaser

Implementation Date: August 1, 2017

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.



**ISSUED: AUGUST 4, 2017** 

Recommendation: CPRIT purchasing should implement routine, structured procedures to monitor purchases for the opportunity to consolidate purchases and to identify potential split purchases. The Purchaser should modify the existing purchase order log to include attributes about the purchase, such as purchase method and contract number. On a quarterly basis, the Purchaser should use the log to review and analyze purchase orders not related to a state contract, to identify whether there is an opportunity to consolidate the buying power of the agency to leverage better pricing and/or delivery terms. This process would also assist CPRIT in identifying any purchases that have been potentially split to avoid more formal purchasing methods required by state law and CPRIT's procurement requirements.

CPRIT should consider implementing a monthly procurement checklist to ensure that regular, recurring tasks are completed in a timely manner. The review and evaluation of non-contract purchases to identify potential split purchases and opportunities for consolidating purchases should be included in the checklist as a procedure to be completed quarterly, in addition to the other monthly procedures.

Management Response: CPRIT management agrees that commodity purchases should not be intentionally split to avoid meeting the thresholds for formal bidding requirements. Given the small volume of CPRIT's recurring commodity purchases, which are primarily office supplies, as well as the agency's adherence to the principle of conservation of funds, the Purchaser does not make volume purchases of these items. Instead, purchases of these items are made on an as needed basis often through existing state contracts negotiated by the Comptroller's Statewide Procurement Division. CPRIT is implementing the state's Centralized Accounting and Payroll/Personnel System (CAPPS) financials module which includes purchasing processes on September 1, 2017. CPRIT will evaluate how CAPPS could be used to monitor these purchases.

Responsible Party: Chief Operating Officer, Purchaser

Implementation Date: February 1, 2018

#### P-Cards

#### 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.

**Recommendation:** CPRIT should update the agency's Procurement Plan and Contract Management Handbook to revise the requirement restricting the authorized use of a payment card to the holder of the card. The handbook should be amended to allow authorized, designated employees to utilize the agency's central billed Travel Card. As part of the revisions, the handbook should also include specific requirements for the authorized individuals to provide the approved, budget certified travel requisition to the Travel Card Administrator when the card is used.

**Management Response:** CPRIT management agrees with the finding and will revise the agency's Procurement Plan and Contract Management Handbook to conform to the procedures that are in practice for CPRIT's central billed Travel Card administered by the Accountant.

Responsible Party: Chief Operating Officer, Accountant

Implementation Date: October 31, 2017



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

**Recommendation:** CPRIT should reinforce the requirements to receive authorization and budget certification on a travel requisition with all personnel responsible for booking travel on a Travel Card to ensure that required processes and procedures are followed in accordance with CPRIT's Procurement Plan and Contract Management Handbook. The Travel Card Administrator would then be accountable for enforcing the requirements to obtain the necessary approvals and budget certifications prior to booking travel.

Management Response: CPRIT management agrees that travel authorization and budget verification should be approved on a travel requisition. With the implementation of the state's Centralized Accounting and Payroll/Personnel System (CAPPS) financials module on September 1, 2017, travel requisitions will be initiated and processed through budget certification and authorization in this system. A travel requisition will not be finalized without these steps being completed in CAPPS. Travel Card transactions will be paid against budgeted expenses recorded in an approved travel requisition.

Responsible Party: Chief Operating Officer, Accountant

Implementation Date: October 31, 2017

#### 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.

**Recommendation:** CPRIT should ensure that P-Card and Travel Card reconciliations are completed and reviewed in a timely manner.

CPRIT should consider implementing a monthly procurement checklist to ensure that regular, recurring tasks are completed in a timely manner. The reconciliation of P-Card and Travel Card transactions should be incorporated into the checklist to ensure that the reconciliations are completed in a timely manner.

Management Response: CPRIT management agrees that P-Card and Travel Card reconciliations should be performed in a timely manner. With CPRIT's implementation of the state's Centralized Accounting and Payroll/Personnel System (CAPPS) financials module on September 1, 2017, reconciliation of both the P-Card and Travel Card will be automated in the system upon receipt of a statement for either central billed card. Transactions reflected on the statements can be efficiently processed for payment against outstanding purchase orders or travel requisitions. Any exceptions to processing transactions outside the 30-day prompt payment requirement will be noted in the comments section of CAPPS. The agency should be able to effectively monitor unpaid transactions through the reporting feature of the system but will evaluate whether other methods should be employed.

Responsible Party: Chief Operating Officer Implementation Date: February 1, 2018

### **Objective B: Effectiveness of Controls**

Ensure that controls over selected critical processes within procurement and P-Card processes are operating efficiently and effectively.

- 1. Procedures Performed: We selected a sample of 30 out of 154 purchase orders processed between June 1, 2015 through March 31, 2017 and verified that:
  - Purchase requisitions were properly reviewed and approved prior to being processed
  - The initiation and approval of purchase requests and purchase orders are appropriately segregated
  - Purchase requisitions and/or purchase orders were not serial, sequential or split purchases to avoid procurement thresholds
  - The appropriate purchase method was selected, followed and documented
  - Purchases exempt from bidding were appropriate based on state purchasing guidelines
  - The purchasing source used was appropriate and complied with CPRIT's internal policies and procedures
  - Interlocal and Cooperative Agreement Purchases were the best value and obtained from active agreements
  - Interlocal and Cooperative Agreement Purchases were appropriately and timely reported
  - Vendors selected had complete contract files, including all required forms and supporting documentation
  - Vendors were not debarred
  - Purchase orders contained the required information and included available budgets
  - Purchase orders were properly reviewed and approved prior to being processed
  - Purchase order modifications were properly authorized
  - · Total vendor spending (including P-Cards) was monitored and reported

**Results:** We identified 18 exceptions within the 30 purchases where CPRIT did not consistently enforce CPRIT's Procurement Plan and Contract Management Handbook procedures requiring an approved purchase requisition for the purchases. We also identified two exceptions where the purchase method did not have the required documentation for the purchase method.

Finding 1 – MODERATE – Purchase Requisition Creation and Approval

Finding 2 - MODERATE - Purchase Method Was Not Appropriate



- 2. Procedures Performed: We selected a sample of 5 out of 19 contracts initiated between June 1, 2015 through March 31, 2017 and verified that:
  - The bidding process was conducted as prescribed in CPRIT's internal policies and procedures along with applicable State of Texas requirements
  - Requests for Proposal (RFP's) were approved prior to their release
  - The appropriate number of bids were received and evaluated prior to selecting a vendor for award
  - Defined criteria was used to evaluate bids
  - · Contract awards were based on best value
  - Vendor performance was monitored and documented
  - · Conflicts of interest were identified and disclosed
  - Vendors were properly set-up in USAS

**Results:** We identified that the approval of RFPs is not consistently documented. Additionally, we identified four instances where required disclosures, certifications and required reviews were not consistently documented.

Finding 3 – MODERATE – Missing RFP Approval

Finding 5 - MODERATE - Required Disclosures, Certifications, and Reviews

- **3. Procedures Performed:** We selected a sample of 30 out of 400 P-Card transactions processed between June 1, 2015 through March 31, 2017. We verified that:
  - P-Card transaction data was maintained in accordance with required record retention laws
  - P-Card purchases were properly authorized by the employee's supervisor
  - Contract vendors were being utilized for purchases when available
  - Excessive spending from a non-contract vendor was identified and reported
  - P-Card transactions were not processed with restricted vendors
  - P-Card purchases represented the best purchase method for the agency, if multiple purchase methods were available
  - P-Card transactions were being charged to the correct budget, project, and account
  - P-Card payment transactions to vendors were not duplicated by other payment methods
  - P-Card transactions were monitored to identify split transactions to avoid purchase limit amounts
  - Emergency purchases were appropriate and met requirements

**Results:** We identified 15 instances where purchase requisitions for P-Card transactions were not created to document the approval and verification of budget availability.

Finding 1 - MODERATE - Purchase Requisition Creation and Approval

- **4.** We selected a sample of 30 out of 251 Travel Card transactions processed between June 1, 2015 through March 31, 2017. We verified that:
  - Travel Card transaction data was maintained in accordance with required record retention laws
  - Travel Card purchases were properly authorized
  - Travel Card transactions were being charged to the correct budget, project, and account
  - Travel Card payment transactions to vendors were not duplicated by other payment methods
  - Emergency purchases were appropriate and met requirements

Results: We identified nine exceptions where appropriate approvals and/or budget certifications were not documented on travel requisition forms.

### Finding 8 – MODERATE – Travel Requisition Approval

- **5. Procedures Performed**: We selected a sample of six out of 22 monthly P-Card reconciliations and six out of 22 monthly Travel Card reconciliations performed between June 1, 2015 through March 31, 2017. We verified that:
  - Fraudulent transactions or incorrect transactional information was disputed
  - The COO reviewed and approved the employee's monthly P-Card reconciliation
  - P-Card and Travel Card transactions were appropriately reconciled on a periodic basis by an independent source in a timely manner
  - Inappropriate and/or unauthorized P-Card and Travel Card transactions were identified and reported

**Results:** We identified one instance where the P-Card reconciliation was not performed in a timely manner and four instances where Travel Card reconciliations were not performed in a timely manner.

Finding 9 – MODERATE – Timeliness of P-Card and Travel Card Reconciliations

### **Objective C: System Access**

Determine whether access to the purchasing and P-Card systems is restricted to appropriate individuals and that access is reviewed periodically.

1. Procedures Performed: We obtained the user access permissions for USAS from the Operations Manager. We evaluated the permissions for all users with access to USAS to verify system access is appropriate.

Results: No findings identified.

2. Procedures Performed: We obtained the user access permissions for TINS from the Operations Manager. We evaluated the permissions for all users with access to TINS to verify system access is appropriate.

Results: No findings identified.



3. Procedures Performed: We obtained CITI's "Program Administrator/Non Cardholder Setup/Maintenance Form" for each employee with access to P-Card and Travel Card accounts at the CITI Bank. We evaluated the permissions of the users within the CITI Bank accounts to verify that access is appropriate.

Results: No findings identified.

### **APPENDIX**

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

#### REPORT RATINGS

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- · Operating or program objectives and goals conform with those of the agency
- · Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
  - Reliability and integrity of financial and operational information
  - Effectiveness and efficiency of operations and programs
  - Safeguarding of assets
  - o 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:

The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.

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.

The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

ISSUED: AUGUST 4, 2017

#### **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 # 06-17 — INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR REVENUE FINDINGS

**REPORT DATE: JUNE 21, 2017** 

**ISSUED: JULY 13, 2017** 

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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 May 8, 2017 through June 21, 2017 relating to the findings from the 2016 Internal Audit Report over Revenue, dated July 8, 2016.

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 2016 Internal Audit Report over Revenue.

To accomplish this objective, we conducted interviews with key personnel responsible for Revenue. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the Cancer Prevention and Research Institute of Texas office and were completed on June 21, 2017.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Siduell, L.S.P.

WEAVER AND TIDWELL, L.L.P. Austin, Texas July 13, 2017

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 06-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR REVENUE FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

#### BACKGROUND

In 2016, internal audit procedures over CPRIT's revenue process were completed and reported to the Oversight Committee. The internal audit report over CPRIT's revenue procedures and activities identified two areas for improvement related to grantee revenue sharing payments, as well as a formal process to document the Accountant's reconciliation of bond issuance proceeds.

The 2017 Internal Audit Plan included performing procedures to validate that CPRIT management has taken steps to address the internal audit findings.

#### FOLLOW-UP PROCEDURES OBJECTIVE AND SCOPE

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the findings included in the 2016 Internal Audit Report over Revenue, and to validate that appropriate corrective action had been taken. The 2016 report identified the following findings:

- 1. CPRIT does not have a process to proactively monitor triggering events that require grantee revenue sharing payments
- 2. CPRIT does not have a formal process to document the Accountant's reconciliation of bond issuance proceeds to ensure they are received by CPRIT and agree to the amounts requested.

Our follow-up procedures included the following:

- Review of a Revenue Sharing Report
- Testing revenue sharing payments
- Examination of reconciliations from September 1, 2016 through April 30, 2017

### **EXECUTIVE SUMMARY**

The findings from the 2016 revenue internal audit included non-compliance issues with CPRIT policies and procedures, rules and regulations required by law, or where these is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have financial or operational implications.

In the 2016 internal audit, we identified two findings, both of which were risk rated as Low.

Through our interviews, review of documentation, observations, and testing, we determined that both of the 2016 revenue findings were remediated.

Risk Rating	Finding	Remediated	Partially Remediated	Open
High	-	-	-	_
Moderate	-	_	-	_
Low	2	2	-	_
Total	2	2	-	•

# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 06-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR REVENUE FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

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		
SCOPE AREA	RESULT	RATING
Objective: Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2016 Internal Audit Report over Revenue.	We identified that procedures implemented by management adequately addressed and remediated the prior open findings.	STRONG

### CONCLUSION

Based on our evaluation, CPRIT management has made satisfactory effort to remediate the findings from the 2016 Internal Audit Report. We recommend continued diligence in maintaining internal controls of revenue processes.

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 06-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR REVENUE FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

### 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 2016 Internal Audit Report over Revenue.

**Finding 1 – LOW – Monitoring of Revenue Sharing Obligations:** CPRIT does not have procedures in place to proactively monitor triggering events that require grantee revenue sharing payments to occur. In addition, CPRIT does not have a process to validate that revenue sharing obligations are received. Revenue is recognized and recorded when revenue sharing checks are received from grantees. CPRIT received a total of \$98,074.07 in revenue sharing payments from grantees during the audit period of September 1, 2014, through May 31, 2016.

Revenue sharing is self-reported by grantees through submission of an annual Revenue Sharing Report in the CGMS system. Revenue Sharing Reports are reviewed and approved by Grant Accountants, but no analysis is performed on the self-reported revenue to determine whether it is accurately calculated and there is no tracking process to ensure revenue payments received match reported obligations.

CPRIT's grant compliance monitoring procedures do not include steps to review non-financial grantee reports, such as the Annual Progress Report and any required Tranche Report, to identify grantee revenue subject to revenue sharing requirements in the grant contract. CPRIT's compliance group performs onsite and desk reviews which include a review of a grantee's program income and reported revenue sharing, but they do not have a process to determine the existence of all obligations. Grantees are selected for review based on an annual risk assessment, and the likelihood for revenue sharing is not a component of the risk assessment.

For two revenue sharing payments totaling \$3,529 out of 10 payments that were tested, the grantee did not provide supporting documentation to evidence occurrence and validate that the shared revenues were accurately calculated.

**Procedures Performed:** We reviewed the Revenue Sharing Report and verified that CPRIT implemented changes to the Revenue Sharing Report in the CPRIT's Grant Management System (CGMS) to include, among other changes, a required field for the payment calculation and information about timing of anticipated payments.

We reviewed a Revenue Sharing Report for a product development grant in CGMS and verified that the updated version of the report was submitted by the grantee.

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 06-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR REVENUE FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

Senate Bill 81 of the 85<sup>th</sup> Texas Legislature will allow CPRIT to contract with the Texas Safekeeping Trust Company to actively monitor the revenue sharing obligations of grantees. We reviewed the draft of the bill and verified that monitoring of revenue sharing obligations is included. The bill was passed by the legislature and signed by the Governor on June 9, 2017, to be effective starting September 1, 2017.

Results: Finding remediated.

Finding 2 – LOW – Reconciliation of Bond Issuance Proceeds: CPRIT does not formally document the Accountant's reconciliation of bond issuance proceeds to ensure they are received by CPRIT and agree to the amounts requested. Receipts of bond issuance proceeds are informally monitored by the Accountant, but there is no documented evidence of reconciliation of the amounts received to the amounts requested.

**Procedures Performed:** We verified that all reconciliations of bond proceed receipts from general obligation bond and commercial paper note issuances from September 1, 2016 through April 30, 2017 were appropriately performed and documented.

Results: Finding remediated.

### **APPENDIX**

# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 06-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR REVENUE FINDINGS JUNE 21, 2017

ISSUED: JULY 13, 2017

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:
  - o Reliability and integrity of financial and operational information
  - o Effectiveness and efficiency of operations and programs
  - Safeguarding of assets
  - o 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:

The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.

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# 06-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR REVENUE FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

#### **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 # 07-17 – INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR CASH MANAGEMENT FINDINGS

**REPORT DATE: JUNE 21, 2017** 

**ISSUED: JULY 13, 2017** 

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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 May 8, 2017 through June 21, 2017 relating to the findings from the 2016 Internal Audit Report over Cash Management, dated August 26, 2016.

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 2016 Internal Audit Report over Cash Management.

To accomplish this objective, we conducted interviews with key personnel responsible for Cash Management. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the Cancer Prevention and Research Institute of Texas office and were completed on June 21, 2017.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Siduell, L.S.P.

WEAVER AND TIDWELL, L.L.P. Austin, Texas July 13, 2017

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 07-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR CASH MANAGEMENT FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

#### **BACKGROUND**

In 2016, internal audit procedures over CPRIT's cash management process were completed and reported to the Oversight Committee. The internal audit report over CPRIT's cash management procedures and activities identified one area for improvement related to the review and approval of the cash forecasting workbook.

The 2017 Internal Audit Plan included performing procedures to validate that CPRIT management has taken steps to address the internal audit findings.

### FOLLOW-UP PROCEDURES OBJECTIVE AND SCOPE

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the findings included in the 2016 Internal Audit Report over Cash Management, and to validate that appropriate corrective action had been taken. The 2016 report identified the following finding:

1. The CPRIT cash forecasting workbook is not reviewed and approved for accuracy and completeness by another CPRIT employee.

Our follow-up procedures included the following:

- Inquiry with the COO to validate that a secondary review of the cash forecasting workbook has been implemented
- Review of cash forecasting workbook updates from February 2017 and April 2017

### **EXECUTIVE SUMMARY**

The findings from the 2016 cash management internal audit included non-compliance issues with CPRIT policies and procedures, rules and regulations required by law, or where these is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have financial or operational implications.

In the 2016 internal audit, we identified one finding, which was risk rated as Moderate.

Through our interviews, review of documentation, observations, and testing, we determined that the 2016 cash management finding was remediated.

Risk Rating	Finding	Remediated	Partially Remediated	Open
High	-	-	-	-
Moderate	1	1		_
Low	_	-	-	-
Total	1	1	-	-

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 07-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR CASH MANAGEMENT FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

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		
SCOPE AREA	RESULT	RATING
Objective: Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2016 Internal Audit Report over Cash Management.	We identified that procedures implemented by management adequately addressed and remediated the prior open findings.	STRONG

### CONCLUSION

Based on our evaluation, CPRIT management has made satisfactory effort to remediate the findings from the 2016 Internal Audit Report. We recommend continued diligence in maintaining internal controls of cash management processes.

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 07-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR CASH MANAGEMENT FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

### 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 2016 Internal Audit Report over Cash Management.

Finding 1 – MODERATE – Cash Forecasting Segregation of Duties: The CPRIT cash forecasting workbook, including critical inputs, assumptions, and calculations, is not reviewed and approved for accuracy and completeness by another CPRIT employee. The Chief Operating Officer (COO) manually enters data into the workbook, which is used to plan the timing of bond issuance to meet the needs of the agency.

**Procedures Performed:** CPRIT has implemented a secondary review of updates to the cash forecasting workbook. Updates are prepared by the COO and reviewed by the Chief Executive Officer (CEO).

COO prepared the following two updates since the implementation date of December 1, 2016:

- February 2017 update
- April 2017 update

We verified the CEO reviewed the April 2017 cash forecasting workbook with the COO on May 4, 2017. We also verified that the workbook included the critical inputs and assumptions and was mathematically accurate.

Results: Finding remediated.



### **APPENDIX**

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA# 07-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR CASH MANAGEMENT FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

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:
  - o Reliability and integrity of financial and operational information
  - o Effectiveness and efficiency of operations and programs
  - o 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:

The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.

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.

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# 07-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR CASH MANAGEMENT FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

### **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**

IA # 08-17 — INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER COMMODITY AND SERVICE CONTRACTS

**REPORT DATE: JUNE 21, 2017** 

**ISSUED: JULY 13, 2017** 

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

This report presents the results of the internal audit follow up procedures performed for the Cancer Prevention and Research Institute of Texas (the Institute) during the period May 15, 2017 through June 21, 2017 related to the findings from the Internal Audit Report over Commodity and Service Contracts dated May 13, 2016.

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 2016 Internal Audit Report over Commodity and Service Contracts.

To accomplish this objective, we conducted interviews with key personnel responsible for the commodity and service contracts process. 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 an exit meeting was conducting on June 21, 2017.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Siduell, L.S.P.

WEAVER AND TIDWELL, L.L.P. Austin, Texas July 13, 2017

# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA # 08-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR COMMODITY AND SERVICE CONTRACTS FINDINGS JUNE 21, 2017

ISSUED: JULY 13, 2017

#### **BACKGROUND**

In fiscal year 2016, an internal audit over the CPRIT's commodity and service contracts process was completed. The internal audit report identified five areas of improvement related to the centralized listing of active contracts, vendor on-boarding documentation, review and approval of commodity invoices, budget certifications, and vendor performance tracking.

The 2017 Internal Audit Plan included performing follow up procedures to validate that CPRIT management has taken steps to address the prior internal audit findings.

### FOLLOW-UP PROCEDURES OBJECTIVE AND SCOPE

The follow up procedures focused on the remediation efforts taken by CPRIT management to address the findings included in the 2016 Internal Audit Report over Commodity and Service Contracts, and to validate that appropriate corrective action had been taken. The 2016 report identified the following findings:

- 1. CPRIT's centralized listing of active contracts is not updated upon the execution of new contracts.
- 2. Vendor and contractor on-boarding is not formally documented.
- 3. Commodity invoices are not consistently reviewed and approved by appropriate personnel.
- 4. CPRIT does not consistently follow its procedures to ensure that the budget certification sign-off on the purchase order and/or purchase request is completed consistently.
- 5. CPRIT does not consistently report vendor performance for contracts greater than \$25,000.

Our follow-up procedures included the following:

- Interviewing key personnel to identify corrective actions taken to address prior findings
- Reviewing policies, procedures, and other documentation
- Performing test procedures to ensure that policies and procedures are appropriately implemented to address prior findings

We evaluated the corrective action of four of the five internal audit findings. The remaining one internal audit finding was not evaluated. CPRIT management indicated that no corrective actions have been taken to address this finding.

#### **EXECUTIVE SUMMARY**

The findings from the 2016 Internal Audit Report over Commodity and Service Contracts 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.

In the 2016 Internal Audit, we identified five findings, of which three were risk rated as Moderate and two were risk rated as Low.

Through our interviews, review of documentation, observations and testing we determined that of the four findings where corrective action was evaluated, all four have been fully remediated. The remaining one internal audit finding was not evaluated since CPRIT management indicated that no corrective actions have been taken to address the finding, and made the determination to accept the risk associated with the low risk finding.

### **CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS** IA # 08-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR COMMODITY AND SERVICE CONTRACTS FINDINGS

**JUNE 21, 2017 ISSUED: JULY 13, 2017** 

A summary of our results is provided in the table below.

Risk Rating	Findings	Remediated	Closed – Management Accepted Risk	Open
High	-	-	-	-
Moderate	3	3	-	-
Low	2	1	1	-
Total	5	4	1	-

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  SCOPE AREA RESULT		

### CONCLUSION

Based on our evaluation, personnel responsible for commodity and service contracts made efforts to remediate the findings from the 2016 Internal Audit Report over Commodity and Service Contracts. However, additional efforts should be made to remediate the remaining open finding.

We recommend that CPRIT continue to remediate the commodity and service contracts findings and strengthen the existing processes. CPRIT should ensure all invoices are reviewed and approved by an individual with sufficient authority and knowledge of the purchase and delivery of goods or services.

Based on management's acceptance of the risk, no additional internal audit follow-up procedures are recommended.

DETAILED FOLLOW-UP RESULTS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

## CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA # 08-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR COMMODITY AND SERVICE CONTRACTS FINDINGS

JUNE 21, 2017 ISSUED: JULY 13, 2017

### DETAILED FOLLOW-UP RESULTS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

Our procedures included interviewing key personnel responsible for the commodity and service contracts process to gain an understanding of the corrective actions taken in order to address the findings identified in the 2016 Internal Audit over Commodity and Service Contracts 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 2016 Internal Audit Report over Commodity and Service Contracts.

Finding 1 – MODERATE – Contract Listing: CPRIT's centralized listing of active contracts is not updated upon the execution of new contracts. Two contracts that were approved by the Oversight Committee in November of 2015 for Award Year 16 (AY16) were not added to the listing until May 2016. Further, the Health and Human Services Commission contract is not on the contract listing. The Purchaser uses the list to identify contracts that need to be removed or closed. This listing is also used to identify contracts that are nearing expiration and need to be closed out, contract renewals and extensions, add contract term to the list, start and end date.

The Accountant receives and logs all invoices for contracted services and keeps track of the service expenditures against all known contract amounts. We determined that the Accountant had not been notified of all existing contracts and consequently did not monitor the contract expenses against the contracted amount for the following contracts:

- Spencer Stuart expenditures in AY15 and AY16
- The Perryman Group expenditures in AY16
- Andrews Kurth no expenditures at the time of procedures

**Procedures Performed:** Based on our interviews with the Purchaser and the COO and review of contract list updates, we verified that timely updates to the contract list are being performed by the Purchaser. We reviewed the following contract list updates:

- November 9, 2016
- November 21, 2016
- o December 2, 2017
- o January 24, 2017
- o February 2, 2017
- o April 19. 2017
- o April 26, 2017

Results: Finding remediated.

# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA # 08-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR COMMODITY AND SERVICE CONTRACTS FINDINGS JUNE 21, 2017

ISSUED: JULY 13, 2017

**Finding 2 – LOW – Vendor On-Boarding:** Vendor and Contractor on-boarding is not formally documented. The vendors and contractors are contacted informally by the designated CPRIT Contract Administrator who discusses the contract, expected services, and any on-boarding needs directly with the vendor/contractor.

**Procedures Performed:** We verified that CPRIT implemented a vendor onboarding checklist for new vendors/contractors. We verified that the vendor onboarding checklist was completed and signed by the Contract Administrators for the following new vendors:

- Business & Financial Management Solutions
- Tradeshow Multimedia, Inc.

Results: Finding remediated.

**Finding 3 – LOW – Invoice Approval:** Commodity invoices are not consistently reviewed and approved by appropriate personnel. This can create a segregation of duties issue in which a purchase is initiated, executed, and the invoice is approved by the same individual. For two out of 30 commodity expenditures tested, the Purchaser provided approval for the invoice and was also responsible for initiating the purchase. The COO approved the associated purchase order and payment.

For one out of 30 commodity expenditures tested, we were unable to verify that the invoice was reviewed and approved prior to the payment. We were able to verify that the purchase order and the payment were approved by the COO.

**Procedures Performed:** Management has not implemented procedures to remediate the finding. No follow-up procedures were performed.

Results: Closed – Management accepted risk.

**Recommendation:** CPRIT should ensure all invoices are reviewed and approved by an individual with sufficient authority and knowledge of the purchase and delivery of goods or services. Payment should not be processed without a corresponding approved invoice.

Further, CPRIT should document and retain all purchase requests with the voucher packet to complete the purchase documentation and demonstrate appropriate segregation of duties.

**Updated Management Response:** CPRIT management evaluated having one of the administrative assistants verify the general office supply commodities match the goods invoiced as explained in the prior management response. However, the administrative assistants in the agency do not have "sufficient authority and knowledge" of the specifications and requirements for these purchases. Being a small state agency and given the relatively low volume and small dollar amount of office supply commodities the agency purchases in which the Purchaser initiates the purchase, verifies receipt of the items and approves the invoices that risks are minimized given the approvals of the initial purchase requisition as well as the payment release of these purchases. Based on these factors, CPRIT management accepts the low risk of the potential lack of segregation of duties.

# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA # 08-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR COMMODITY AND SERVICE CONTRACTS FINDINGS JUNE 21, 2017

ISSUED: JULY 13, 2017

Finding 4 – MODERATE – Budget Certification: CPRIT does not consistently follow its procedures to ensure that the budget certification sign-off on the purchase order and/or purchase request is completed consistently. The Chief Operating Officer monitors the budget on an ongoing basis and is the final signatory authority on Purchase Orders. Purchases of goods and services are considered as part of the annual operating budget. However, CPRIT policy also requires sign-off on purchases to verify budget availability.

For two out of 23 commodity expenditures tested that had purchase orders, Accounting did not sign-off verifying the budget prior to the purchase.

For purchases made through a P-Card that were not monthly re-occurring fees, one out of 23 purchase requests did not have Accounting personnel sign-off on the form verifying the budget prior to the purchase.

**Procedures Performed:** We tested eight out of 33 purchase orders that occurred from September 1, 2016 through March 31, 2017 and verified that budget was certified by the Operations Specialist.

Results: Finding remediated.

**Finding 5 – MODERATE – Vendor Performance Tracking:** Contract Administrators are not consistently aware of the Vendor Performance Tracking System reporting requirement of the Comptroller of Public Accounts. Contract Administrators do not submit Vendor Performance Forms for contracts that are greater than \$25,000 as required by the Comptroller of Public Accounts. Currently, the Purchaser is responsible for completing the vendor performance reporting during the performance of the contract closeout procedures.

Vendor Performance Evaluations are inconsistently performed. We identified three contracts closed out during the period with expenditures exceeding \$25,000. For the three identified contacts:

- One of the contracts, the closeout checklist was marked "N/A" for vendor performance evaluation completed.
- Two of the contracts, the closeout checklist did not have the step "vendor performance evaluation completed" on the form.
- For all three contracts, we searched the VPTS database and were unable to find any instances of a vendor performance evaluation completed by CPRIT.

**Procedures Performed:** We reviewed the Vendor Performance Tracking System form and verified that it includes instructions and information needed to record the vendor performance in the Texas Comptroller of Public Accounts Vendor Performance Tracking System.

We obtained the Vendor Performance Report for the one contract closed out since September 1, 2016 and determined that the evaluation was completed and submitted in the Comptroller's Vendor Performance Tracking System.

Results: Finding remediated.

**APPENDIX** 

# CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS IA # 08-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR COMMODITY AND SERVICE CONTRACTS FINDINGS JUNE 21, 2017

ISSUED: JULY 13, 2017

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:
  - o Reliability and integrity of financial and operational information
  - o Effectiveness and efficiency of operations and programs
  - Safeguarding of assets
  - o 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 # 08-17 INTERNAL AUDIT FOLLOW-UP PROCEDURES REPORT OVER PRIOR YEAR COMMODITY AND SERVICE CONTRACTS FINDINGS JUNE 21, 2017

ISSUED: JULY 13, 2017

#### **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 2017 ANNUAL INTERNAL AUDIT REPORT

**AUGUST 31, 2017** 

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**DRAFT - For Discussion Purposes Only** 

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 2018 Internal Audit Plan on its website at <a href="https://www.cprit.state.tx.us">www.cprit.state.tx.us</a> by August 31, 2017. CPRIT's Oversight Committee reviewed and approved the Annual Internal Audit Report as part of their regular meeting held on August 16, 2017.

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 2017

The internal audits planned and performed for fiscal year 2017 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 2017 are listed below.

Internal Audit	Report #	Report Date	Current Status
Internal Audit over Training	IA #01-17	February 6, 2017	The report was issued March 10, 2017.  Follow-up procedures to verify that corrective action has been performed are included in the proposed 2018 Internal Audit Plan.
Internal Audit over Internal Agency Compliance	IA #02-17	February 24, 2017	The report was issued April 17, 2017.  Follow-up procedures to verify that corrective action has been performed are included in the proposed 2018 Internal Audit Plan.
Internal Audit over Pre-Award Grant Management	IA #03-17	April 19, 2017	The report was issued May 30, 2017.  Follow-up procedures to verify that corrective action has been performed are included in the proposed 2018 Internal Audit Plan.
Internal Audit over Procurement and P-Card	IA #04-17	June 21, 2017	The report was issued August 4, 2017.  Follow-up procedures to verify that corrective action has been performed are included in the proposed 2018 Internal Audit Plan.

**DRAFT – For Discussion Purposes Only** 

Internal Audit	Report #	Report Date	Current Status
Internal Audit Follow-Up over Information Security	IA #05-17	March 9, 2017	The report was issued May 30, 2017.  Follow-up procedures to verify that corrective action has been performed on the remaining open findings are included in the proposed 2018 Internal Audit Plan.
Internal Audit Follow-Up over Revenue	IA #06-17	June 21, 2017	The report was issued July 13, 2017.  All prior findings were remediated.
Internal Audit Follow-Up over Cash Management	IA #07-17	June 21, 2017	The report was issued July 13, 2017.  All prior findings were remediated.
Internal Audit Follow-Up over Commodity and Service Contracts	IA #08-17	June 21, 2017	The report was issued July 13, 2017.  All prior findings were remediated or closed.

#### 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 2017:

Weaver consulted with CPRIT to update the agreed upon procedures issued in 2016 that detail the required audit steps to be completed for CPRIT grant recipients by an independent auditor to satisfy the State Single Audit requirements and CPRIT policies and procedures.

Other consulting and nonaudit services were provided by Grant Thornton, Business and Financial Management Solutions, LLC (BFMS), and CohnReznick LLP. CPRIT engaged Grant Thornton and BFMS as the third parties to observe each in-person and telephone conference Peer Review Panel meeting and ensure compliance with conflict of interest and staff participation requirements. CohnReznick LLP was engaged by CPRIT to perform grant compliance monitoring services to ensure that CPRIT grant recipients are in compliance with Texas Uniform Grant Management Standards and CPRIT policies and procedures.

Grant Thornton and BFMS issued the following reports during fiscal year 2017:

FY2017 Third Party Observer Reports						
Review Panel	Observer	Status				
	Product D	evelopment				
17.1 PDP-1 Screening	2016-09-22-PDEV	September 28, 2016	Grant Thornton	Complete		
17.1 PDP-2 Screening	2016-09-23-PDEV	September 28, 2016	Grant Thornton	Complete		
16.2 PDRC/due diligence	2016-10-17-PDEV	October 25, 2016	Grant Thornton	Complete		
17.1 PDP-1 in person	2016-10-25-PDEV	November 3, 2016	Grant Thornton	Complete		
17.1 PDP-2 in person	2016-10-26/27-PDEV	November 4, 2016	Grant Thornton	Complete		
17.1 Due Diligence/PDRC	2016-09-22-PDEV	January 20, 2017	BFMS	Complete		

Review Panel	Report #	Report Date	Observer	Status
		Research		
17.2 DDD 1 personing	2017-01-17-	March 28, 2017	BFMS	Complete
17.2 PDP 1 -screening	DD_PDR_17.1	IVIAICIT 20, 2017	DI WIO	Complete
17.2 PDP 2-screening	2017-03-28-	March 29, 2017	BFMS	Complete
	DD_PDR_17.2.1	100000000000000000000000000000000000000		
17.2 PDP 1-in person	2017-03-29-	April 25, 2017	BFMS	Complete
review 17.2 PDP 2-in person	DD_PDR_17.2.2 2017-04-25-			
review	DD PDP 17.2.1	April 26, 2017	BFMS	Complete
	2017-04-26-	7 1 10 0017	DEMO	Commission
17.2 Due Diligence/PDRC	DD_PDP_17.2.2	July 12, 2017	BFMS	Complete
17.1 and 17.2 SRC	2016-09-15-RES	September 20, 2016	Grant Thornton	Complete
recruitment	2010-09-13-ICE3	September 20, 2010	Grant mornton	Complete
SRC (16.10-12 recruits and	2016-09-01-RES	September 4, 2016	Grant Thornton	Complete
17.1 CRSA-CR)			Crant Thornton	Complete
17.1 BCR-1	2016-09-21-RES	September 28, 2016	Grant Thornton	<del></del>
17.1 BCR-2	2016-09-22-RES	September 28, 2016	Grant Thornton	Complete
17.1 Cancer Biology	2016-09-23-RES	September 28, 2016	Grant Thornton	Complete
17.1 Imaging and Technology	2016-09-26-RES	October 5, 2016	Grant Thornton	Complet
17.1 Cancer Prevention	2016-09-28-RES	October 5, 2016	Grant Thornton	Complet
17.1 Clinical and				•
Translational Research	2016-09-27-RES	October 5, 2016	Grant Thornton	Complet
SRC 17.1 Research	2016 10 12 DES	Ostobor 24 2016	Grant Thornton	Complet
applications	2016-10-13-RES	October 24, 2016		Complet
17.34 Recruits/SRC	2016-11-10-RES	November 14, 2016	CPRIT Chief	Complete
			Compliance Officer	
17.5-6 Recruits/SRC	2017-01-12-REC_17.5-6	January 17, 2017	BFMS	Complet
17.78 Recruits/SRC	2017-03-22-REC_17.7-8	March 22, 2017	BFMS	Complet
17.9 Recruits/SRC	2017-04-22-REC_17.9	April 22, 2017	BFMS	Complet
17.2 BCR-1	2017-04-20_BCR_17.2	April 20, 2017	BFMS	Complet
17.2 BCR-2	2017-04-24_BCR_17.2	April 24, 2017	BFMS	Complete
17.2 Cancer Biology	2017-04-19_CB_17.2	April 19, 2017	BFMS	Complet
17.2 Imaging and	2017-04-27_ITI_17.2	April 27, 2017	BFMS	Complete
Technology 17.2 Clinical and		1 ,		'
Translational Research	2017-04-25_C/TCR_17.2	April 25, 2017	BFMS	Complet
SRC 17.10 Recruits	2017-05-11_SRC_17.10	May 11, 2017	BFMS	Complet
17.2 SRC	2017-07-13_SRC_17.2	July 13, 2017	BFMS	Complet
17.11 SRC Recruits	2017-06-15_REC_17.11	June 15, 2017	BFMS	Complet
17.12 SRC recruits	2017-07-13_REC_17.12	July 13, 2017	BFMS	Complete
17.12 ONO IGUIUIS		ention	D. HO	Complete
17.1 Panel 1	2016-12-05- PREV	December 13, 2016	BFMS	Complete
17.1 Panel 2	2016-12-07- PREV	December 13, 2016	BFMS	Complete
17.1 PRC	2017-01-2 PRC 17.1	January 23, 2017	BFMS	Complete
17.2 Panel 1	2017-06-1- PREV	June 1, 2017	BFMS	Complete
17.2 Panel 2	2017-06-02- PREV	June 2, 2017	BFMS	Complete
17.2 PRC	2017-07-06 PRC 17.2	July 6, 2017	BFMS	Complete

**DRAFT – For Discussion Purposes Only** 

CohnReznick issued the following reports during fiscal year 2017:

### **CohnReznick FY2017 Grant Compliance Monitoring Reports**

Report Name	Report #	Report Date	Current Status
Asian American Health Coalition of Greater Houston (dba Hope Clinic)	PP140205	October 4, 2016	Six findings identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	DP150069	October 7, 2016	Completed. No findings identified.
Baylor College of Medicine	DP150083	January 30, 2017	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	PP130070	October 7, 2016	Completed. No findings identified.
Baylor College of Medicine	PP130084	October 26, 2016	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	PP140028	January 9, 2017	Completed. No findings identified.
Baylor College of Medicine	RP130315	November 16, 2016	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP130368	November 16, 2016	Completed. No findings identified.
Baylor College of Medicine	RP130485	November 16, 2016	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP130573	November 16, 2016	Completed. No findings identified.
Baylor College of Medicine	RP130588	November 16, 2016	Completed. No findings identified.
Baylor College of Medicine	RP130651	November 16, 2016	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP140001	December 20, 2016	Completed. No findings identified.
Baylor College of Medicine	RP140179	January 9, 2017	Two findings identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP140181	October 5, 2016	Completed. No findings identified.

Report Name	Report #	Report Date	Current Status
Baylor College of Medicine	RP140223	November 28, 2016	Completed. No findings identified.
Baylor College of Medicine	RP140252	February 17, 2017	Completed. No findings identified.
Baylor College of Medicine	RP140258	December 22, 2016	Completed. No findings identified.
Baylor College of Medicine	RP140350	November 28, 2016	Completed. No findings identified.
Baylor College of Medicine	RP140456	January 9, 2017	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP140469	December 22, 2016	Completed. No findings identified.
Baylor College of Medicine	RP140553	January 9, 2017	Completed. No findings identified.
Baylor College of Medicine	RP140616	December 20, 2016	Completed. No findings identified.
Baylor College of Medicine	RP140767	December 22, 2016	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP140784	February 6, 2017	Two findings identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP150032	April 19, 2017	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP150081	June 12, 2017	Completed. No findings identified.
Baylor College of Medicine	RP150129	June 16, 2017	Completed. No findings identified.
Baylor College of Medicine	RP150197	March 1, 2017	Completed. No findings identified.
Baylor College of Medicine	RP150232	March 22, 2017	Completed. No findings identified.
Baylor College of Medicine	RP150292	March 3, 2017	Completed. No findings identified.
Baylor College of Medicine	RP150334	June 16, 2017	Completed. No findings identified.

Report Name	Report #	Report Date	Current Status
Baylor College of Medicine	RP150440	March 13, 2017	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP150451	March 14, 2017	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RP160192	July 14, 2017	Completed. No findings identified.
Baylor College of Medicine	RP160345	June 28, 2017	Completed. No findings identified.
Baylor College of Medicine	RP160384	June 16, 2017	Completed. No findings identified.
Baylor College of Medicine	RP160451	June 28, 2017	One finding identified. Remediation testing will occur in FY 2018.
Baylor College of Medicine	RR150106	July 14, 2017	Completed. No findings identified.
Baylor Research Institute	RP110553- P5	November 28, 2016	Four findings identified. Remediation testing will occur in FY 2018.
Baylor University	R1309	April 3, 2017	Two findings identified. Remediation testing will occur in FY 2018.
CerRx, Inc.	CP130023	April 19, 2017	Two findings identified. Remediation testing will occur in FY 2018.
ESSA Pharma Inc.	CP130020	October 7, 2016	Three findings identified. Remediation testing will occur in FY 2018.
Formation Biologics	DP150039	October 28, 2016	Four findings identified. Remediation testing will occur in FY 2018.
Immatics Biotechnologies	DP150029	March 16, 2017	Three findings identified. Remediation testing will occur in FY 2018.
Kalon Biotherapeutics, LLC	CP120038	December 2, 2016	One finding identified. Remediation testing will occur in FY 2018.
Legacy Community Health Services	PP140208	October 4, 2016	Completed. No findings identified.

Report Name	Report #	Report Date	Current Status
MHMR of Tarrant County	PP120216	October 7, 2016	Three findings identified. Remediation testing will occur in FY 2018.
MHP, Inc. Promoviendo Vidas Saludables	PP150078	October 7, 2016	Completed. No findings identified.
Mirna Therapeutics, Inc.	DP140067	July 10, 2017	One finding identified. Remediation testing will occur in FY 2018.
Nuviant Medical Inc.	DP150005	February 17, 2017	Five findings identified. Remediation testing will occur in FY 2018.
OncoNano Medicine	DP140072	June 13, 2017	Five findings identified. Remediation testing will occur in FY 2018.
Pulmotect, Inc.	CP120014	January 10, 2017	Four findings identified. Remediation testing will occur in FY 2018.
Rice University	R1226	January 10, 2017	Completed. No findings identified.
Rice University	R1226	July 12, 2017	One finding identified. Remediation testing will occur in FY 2018.
Rice University	RP160460	June 16, 2017	Completed. No findings identified.
Texas A&M Engineering Experiment Station	RP150421	March 10, 2017	Five findings identified. Remediation testing will occur in FY 2018.
Texas A&M University Health Science Center Institute of Biosciences and Technology	RP110532- P2	February 17, 2017	One finding identified. Remediation testing will occur in FY 2018.
Texas A&M University System Health Science Center	DP150086	June 12, 2017	Five findings identified. Remediation testing will occur in FY 2018.
Texas Department of State Health Services	PP120029	September 15, 2016	Two findings identified. Remediation testing will occur in FY 2018.
Texas Tech University	RP130624	October 28, 2016	Two findings identified. Remediation testing will occur in FY 2018.

Report Name	Report #	Report Date	Current Status
Texas Tech University Health Science Center at El Paso	PP140164	September 19, 2016	Two findings identified. Remediation testing will occur in FY 2018.
Texas Tech University Health Science Center at El Paso	PP140164	May 8, 2017	Two findings identified. Remediation testing will occur in FY 2018.
Texas Tech University Health Sciences Center	PP140033	July 14, 2017	Completed. No findings identified.
The Bridge Breast Network	PP140026	October 4, 2016	Completed. No findings identified.
The Methodist Hospital Research Institute	DP150099	June 29, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The Methodist Hospital Research Institute	RP160501	October 7, 2016	Completed. No findings identified.
The University of North Texas Health Science Center at Fort Worth	DP150091	March 29, 2017	Four findings identified. Remediation testing will occur in FY 2018.
The University of Texas at Austin	DP150061	November 9, 2016	Completed. No findings identified.
The University of Texas at Austin	RP130219	October 28, 2016	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas at Austin	RP130372	November 9, 2016	Completed. No findings identified.
The University of Texas at Austin	RP130412	November 9, 2016	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas at Austin	RP130702	November 16, 2016	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas at Austin	RP140108	November 9, 2016	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas at Austin	RP140648	January 9, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas at Austin	RP140842	February 7, 2017	One finding identified. Remediation testing will occur in FY 2018.

Report Name	Report #	Report Date	Current Status
The University of Texas at Austin	RR160005	July 27, 2017	Completed. No findings identified.
The University of Texas at Dallas	RP120717- P4	April 27, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas at Dallas	RP140517	January 30, 2017	Three findings identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at Houston	DP150065	January 30, 2017	Three findings identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at Houston	DP150093	January 30, 2017	Four findings identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at Houston	PP130075	November 9, 2016	Three findings identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at Houston	PP160051	February 17, 2017	Three findings identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at Houston	R1215	January 9, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at Houston	RP130059	November 14, 2016	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at Houston	RP150230	March 10, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at San Antonio	DP150055	March 1, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at San Antonio	DP150096	<b>M</b> arch 23, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at San Antonio	PP150079	March 17, 2017	One finding identified. Remediation testing will occur in FY 2018.

Report Name	Report #	Report Date	Current Status
The University of Texas Health Science Center at San Antonio	RP120867	December 6, 2016	Three findings identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at San Antonio	RP140105	November 9, 2016	Completed. No findings identified.
The University of Texas Health Science Center at San Antonio	RP140452	February 17, 2017	Completed. No findings identified.
The University of Texas Health Science Center at San Antonio	RP150166	March 1, 2017	Completed. No findings identified.
The University of Texas Health Science Center at San Antonio	RP150445	June 13, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at San Antonio	RP150574	November 28, 2016	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas Health Science Center at San Antonio	RP160124	June 13, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	DP150052	March 30, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	DP150059	March 30, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	PP130079	December 27, 2016	Three findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	PP150012	March 30, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	PP150077	April 27, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	PP160027	April 3, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP110471- AC	October 25, 2016	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP110471- C2	October 25, 2016	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP110471- P1	October 25, 2016	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP110486- P1	October 31, 2016	Completed. No findings identified.

Report Name	Report #	Report Date	Current Status
The University of Texas M.D. Anderson Cancer Center	RP110532- P3	March 17, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP110553- P3	November 8, 2016	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP110562- C2	April 24, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP110562- P2	April 24, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP110595- AC	March 20, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP110595- C1	April 24, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP110595- C2	March 24, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP110595- P1	December 21, 2016	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP110595- P2	December 5, 2016	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP120713- AC	July 7, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP120713- C3	July 6, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP120713- P1	July 7, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP120732- C1	July 7, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP130020	February 17, 2017	Two findings identified. Remediation testing will occur in FY 2018.

Report Name	Report #	Report Date	Current Status
The University of Texas M.D. Anderson Cancer Center	RP130054	February 17, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP130078	February 17, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP130123	February 17, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP130276	February 17, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP130310	February 17, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP130397	June 23, 2014	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP130432	July 7, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP130502	February 28, 2017	Three findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP130516	October 13, 2016	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP140106	December 27, 2016	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP140218	April 5, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP140222	April 5, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP140224	April 3, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP140244	May 8, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP140262	May 9, 2017	Completed. No findings identified.

Report Name	Report #	Report Date	Current Status
The University of Texas M.D. Anderson Cancer Center	RP140271	July 28, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP140522	March 16, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP140556	March 22, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP140563	March 22, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP140606	March 22, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP140609	<b>M</b> arch 22, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP140612	April 4, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP150030	March 30, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP150079	December 29, 2016	Three findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP150093	December 21, 2016	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP150094	December 21, 2016	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP150102	March 13, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP150148	March 13, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP150179	March 13, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP150195	December 29, 2016	One finding identified. Remediation testing will occur in FY 2018.

Report Name	Report #	Report Date	Current Status
The University of Texas M.D. Anderson Cancer Center	RP150235	April 4, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP150245	April 4, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP150282	April 4, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP150293	April 4, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP150319	April 18, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP150403	April 24, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP150405	April 24, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP160013	April 18, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP160019	April 18, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP160023	April 18, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP160121	April 4, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP160145	April 4, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RP160150	April 18, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP160183	April 18, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP160188	April 18, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP160229	April 18, 2017	One finding identified. Remediation testing will occur in FY 2018.

Report Name	Report #	Report Date	Current Status
The University of Texas M.D. Anderson Cancer Center	RP160232	April 18, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP160237	April 18, 2017	Two findings identified. Remediation testing will occur in FY 2018.
The University of Texas M.D. Anderson Cancer Center	RP160739	July 7, 2017	Completed. No findings identified.
The University of Texas M.D. Anderson Cancer Center	RR140012	July 7, 2017	Completed. No findings identified.
The University of Texas Medical Branch at Galveston	DP150074	June 12, 2017	Four findings identified. Remediation testing will occur in FY 2018.
The University of Texas Southwestern Medical Center	R1225	January 9, 2017	One finding identified. Remediation testing will occur in FY 2018.
The University of Texas Southwestern Medical Center	RP150053	April 27, 2017	Three findings identified. Remediation testing will occur in FY 2018.
The University of Texas Southwestern Medical Center	RP160622	April 4, 2017	Completed. No findings identified.
The University of Texas Southwestern Medical Center	RP160713	July 27, 2017	Completed. No findings identified.
The University of Texas Southwestern Medical Center	RR150074	April 5, 2017	Completed. No findings identified.
The University of Texas Southwestern Medical Center	RR150076	April 5, 2017	Completed. No findings identified.
University Health System	PP150064	October 5, 2016	One finding identified. Remediation testing will occur in FY 2018.
University of Houston	RP140113	November 28, 2016	Five findings identified. Remediation testing will occur in FY 2018.
University of Houston	RR150088	June 16, 2017	Four findings identified. Remediation testing will occur in FY 2018.
Val Verde Regional Medical Center	PP150071	October 7, 2016	Completed. No findings identified.
Val Verde Regional Medical Center	PP150071	May 24, 2017	Eight findings identified. Remediation testing will occur in FY 2018.

**DRAFT - For Discussion Purposes Only** 

#### 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 <a href="https://www.aicpa.org/prsummary">www.aicpa.org/prsummary</a>.

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

Est Sally LLP

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#### 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 7, 2017, and the Oversight Committee subsequently approved the plan on August 16, 2017. Below is the Fiscal Year 2018 Internal Audit Plan submitted to the agency's Oversight Committee based on the results of the 2016 Internal Audit Risk Assessment Update. The approved internal audit plan was submitted to the State Auditor's Office prior to November 1, 2017.

Fiscal Year 2018 Into	ernal Audit Plan		
Audit Area	2016 Risk Rating	Estimated Hours	
Post-Award Grant Monitoring	High	240,200	
Grant Contracting	Moderate	240-260	
State Reporting	Moderate	220-250	
Information Technology Services	High	230-250	
Communications	Moderate	220-250	

Planned follow-up procedures for fiscal year 2017 to verify and communicate with Management the remediation efforts of prior Internal Audit Recommendations.

Fiscal Year 2018 Follo	w-up Procedures	
Audit Area	2016 Risk Rating	Estimated Hours
Procurement and P-Cards	High	60-80
Pre-Award Grant Management	High	60-80
Training	Moderate	60-80
Internal Agency Compliance	Moderate	40-60
Information Security	High	80-100

The 2016 Internal Audit Risk Assessment Update resulted in nine Significant Activities rated as "High" risk. Three of the nine Significant Activities are not included in the Fiscal Year 2018 Internal Audit Plan. Those risks are as follows:

- 1. Commodity and Service Contracts Commodity and Service Contracts was not included in the 2018 Internal Audit Plan. Commodity and Service Contracts was included in the 2016 Internal Audit Plan, and was included in 2017 Follow-Up Procedures.
- 2. Disaster Recovery and Business Continuity Planning Disaster Recovery and Business Continuity Planning was not included in the 2018 Internal Audit Plan.
- **3. Governance** Governance was not included in the 2018 Internal Audit Plan. Governance was included in the 2014 Internal Audit Plan, and was included in 2015 Follow-Up Procedures.

#### VI. External Audit Services Procured in FY 2017

CPRIT engaged McConnell & Jones, LLP, a certified public accounting and consulting firm, as their external auditors for FY 2017. McConnell & Jones, LLP is registered with the Public Company Auditor Oversight Board (PCAOB).

DRAFT - For Discussion Purposes Only

#### 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 <a href="www.cprit.state.tx.us">www.cprit.state.tx.us</a> and also has a dedicated page to fraud prevention and reporting on its website at <a href="http://www.cprit.state.tx.us/about-cprit/fraud-prevention/">http://www.cprit.state.tx.us/about-cprit/fraud-prevention/</a>.
- 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.



#### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: KRISTEN PAULING DOYLE, GENERAL COUNSEL

**CAMERON L. ECKEL, STAFF ATTORNEY** 

**CHAPTER 703 RULE CHANGE PROPOSED FOR FINAL Subject:** 

**ADOPTION** 

Date: **AUGUST 3, 2017** 

#### **Summary and Recommendation**

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule change to Chapter 703 as originally considered at the May 2017 meeting. Once the Oversight Committee approves the final order adopting the rule change, CPRIT will submit the amendment to the Secretary of State and the change will be considered final and 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.

CPRIT published the proposed rule in the June 23rd edition of the *Texas Register*, as well as solicited public comment via CPRIT's website. No public comments were received

The Board Governance Subcommittee met on August 3rd to review the final order with CPRIT's General Counsel. The Subcommittee recommends the Oversight Committee approve the final order adopting the proposed rule change.

#### **Next Steps**

After the Oversight Committee adopts the proposed rule change, CPRIT will submit the final order to the Secretary of State. The rule change 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 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendment to § 703.24. The proposed change would allow grant awards with contract initiation dates in the last quarter of the state fiscal year to have an initial financial reporting period beginning the following fiscal year. The proposed amendments were published in the June 23, 2017, issue of the *Texas Register* (42 TexReg 3249).

#### **Reasoned Justification**

The proposed amendment addresses a procedural issue for Institute grant contracts with an effective date in the fourth quarter of the state fiscal year, typically August 31. Oversight Committee action on grant awards recommended by a Review Council Chair in a particular fiscal year must have a contract effective date in the same fiscal year to be funded with general obligation bond proceeds appropriated in that fiscal year. For awards approved by the Oversight Committee in the last quarter of a fiscal year, the contract effective date results in a partial quarter, often only one day. The Institute's electronic grant management system generates a financial status report that covers the partial fiscal quarter. The system maintains the partial financial status report filing requirement for the remainder of the grant. As a result, these grants appear to have five quarters in the Institute's electronic grant management system for financial reporting purposes. This "fifth quarter" issue creates confusion and imposes a logistical burden on grantees. The proposed rule change addresses the fifth quarter issue by allowing grant awards with a contract effective date in the last quarter of a state fiscal year to have an initial financial reporting period beginning September 1 of the following state fiscal year. Grantees may submit any expenses for the partial quarter in the initial reporting period beginning September 1.

#### **Summary of Public Comments and Staff Recommendation**

CPRIT received no public comments regarding the proposed amendments.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, 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 18, 2017.



#### **MEMORANDUM**

To: OVERSIGHT COMMITTEE MEMBERS

From: CAMERON L. ECKEL, STAFF ATTORNEY

KRISTEN PAULING DOYLE, GENERAL COUNSEL

SUMMARY OF PROPOSED RULE CHANGES TO BE PROPOSED **Subject:** 

**AUGUST 2017** 

**AUGUST 3, 2017** Date:

#### **Summary and Recommendation**

The Board Governance Subcommittee recommends that the Oversight Committee approve the proposed administrative rule changes. The proposed changes affect Texas Administrative Code Chapter 703. After approval, CPRIT will publish the proposed changes in the *Texas Register* for public comment.

#### **Discussion**

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes. State law requires agencies to set policy using 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 3rd to discuss the proposed rule changes with legal staff. The first proposed change affects § 703.13 and specifies that grantees must retain records related to their CPRIT grant for a period of three years following the date of the last disbursement of grant funds made by CPRIT or when all reports are submitted to and approved by CPRIT, whichever date is later. Currently, CPRIT's administrative rules are silent on the grantee record retention period. The second proposed change to § 703.26 prohibits payment by a grantee to a subcontractor if the subcontractor employs an individual who is a relative of the grantee. A relative is defined as "a person related within the second degree by consanguinity or affinity determined in accordance with §§ 573.021 - 573.025, Texas Government Code." A grantee may request from CPRIT's Chief Executive Officer an exception to the proposed restriction. If approved, the CEO must notify the Oversight Committee in writing. The subcommittee voted to recommend approval and publication to the Oversight Committee.

## **Next Steps**

Once approved by the Oversight Committee, CPRIT will publish the proposed rule changes in the *Texas Register*. The publication date begins the 30-day period soliciting public comment. CPRIT staff 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 (Institute) proposes amendments to §§ 703.13 and 703.26. The proposed changes clarify how long a grant recipient must maintain grant records, how long a grant recipient must allow inspection of grant records, and expand the list of unallowable costs to include payments by a grant recipient to a subcontractor that employs a relative of the grant recipient.

### **Background and Justification**

The proposed change to § 703.13(a) clarifies that a grant recipient must maintain records related to a grant project for a period of three years following the date of the last disbursement of grant funds made by the Institute or when all reports are submitted to and approved by the Institute, whichever is later. Currently, the Institute's administrative rules are silent on the grant recipient's record retention obligations and the rule provides needed guidance for grant recipients. Section 703.13 is further amended to require a grant recipient to allow inspection of grant records for a period of three years following the date the last disbursement of grant funds is made by the Institute and all reports are submitted to and approved by the Institute, whichever is later. Currently, the audit period is up to three years following the end of the grant recipient's fiscal year during which the grant contract was terminated. This proposed change will provide uniformity between the inspection period and the proposed term for grant recipient's records retention obligations.

The proposed change to § 703.26(e) prohibits payment by a grant recipient to a subcontractor if the subcontractor employs an individual who is a relative of the grant recipient as defined by Texas Administrative Code § 701.3(57). A grant recipient may request that the Institute's Chief Executive Officer allow an exception to allow payment to a subcontractor that employs a relative. If the Chief Executive Officer grants an exception, he must notify the Oversight Committee in writing. If a grant recipient has stricter internal policies concerning this issue then this proposed amendment will not supersede those policies. The purpose of this proposed rule change is to reduce potential conflicts of interest between a grant recipient and a subcontractor.

#### **Fiscal Note**

Kristen Pauling Doyle, General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule changes are 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 changes are in effect the public benefit anticipated due to enforcing the rules will be clarification of policies and procedures the Institute will follow to implement its statutory duties.

#### **Small Business and Micro-business Impact Analysis**

Ms. Doyle has determined that the rule changes shall not have an effect on small businesses or on micro businesses.

Written comments on the proposed rule changes may be submitted to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711 no later than October 2, 2017. CPRIT asks parties filing comments to indicate whether or not 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. Comments may be submitted by facsimile transmission to 512/475-2563.

#### **Statutory Authority**

The rule changes are proposed under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provide the Institute with broad rule-making authority to administer the chapter. Kristen Pauling Doyle, the Institute's General Counsel, 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.

#### 703.13 Audits and Investigations

- (a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the 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 it later [end of the Grant Recipient's fiscal year during which the Grant Contract was terminated].
- (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 it 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 within 60 days of the anniversary date of the Grant Contract effective date. 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

#### **RULE §703.26** Allowable Costs

- (a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.
  - (1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.
  - (2) A cost is allocable if the cost:
    - (A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;
    - (B) Is assigned the Grant Award in accordance with the relative benefit received;

- (C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;
- (D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and
- (E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.
- (3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with §703.24.
- (b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, Texas Health and Safety Code, the Institute's administrative rules, and the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from the Uniform Grant Management Standards on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.
- (c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.
- (d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.
- (e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:
  - (1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.
  - (2) Contributions to a contingency reserve or any similar provision for unforeseen events.
  - (3) Contributions and donations made to any individual or organization.
  - (4) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.
  - (5) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

- (6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.
- (7) An honorary gift or a gratuitous payment.
- (8) Interest and other financial costs related to borrowing and the cost of financing.
- (9) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.
- (10) Liability insurance coverage.
- (11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.
- (12) Professional association fees or dues for the Grant Recipient or an individual.
- (13) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.
- (14) Fees for visa services.
- (15) Payments to a subcontractor if the subcontractor employs an individual that is a Relative of the Grant Recipient. For exceptional circumstances, the Institute's Chief Executive Office may grant an exception to allow payment of Grant Award funds to a subcontractor who employs a Relative of a Grant Recipient if the Grant Recipient notifies the Institute prior to finalizing a subcontract with such a circumstance. The Chief Executive Officer must notify the Oversight Committee in writing of his decision to allow reimbursement for the otherwise unallowable expense. Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.
- (f) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.



#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN DOYLE, GENERAL COUNSEL

VINCE BURGESS, CHIEF COMPLIANCE OFFICER

CAMERON ECKEL, STAFF ATTORNEY

**SUBJECT:** NEW MEMBER TRAINING PROPOSAL

**DATE:** JULY 27, 2017

# **Summary and Recommendation:**

Consistent with the Board Governance Subcommittee's charge to assess the internal policies and processes of the Oversight Committee annually, the subcommittee has identified proposed changes to Oversight Committee bylaws regarding new member training. The proposed changes clarify the topics addressed with the new member, specify the amount of time to complete the training, and establish a policy limiting the new member's participation until training is completed. The Board Governance subcommittee recommends that the Oversight Committee approve the proposed changes to the bylaws related to new member training.

### **Background:**

Although CPRIT's statute does not address new member training, Texas Government Code §§ 551.005 and 552.012 require newly appointed governing board members to complete at least one hour of training devoted to Open Meetings and one hour devoted to Open Records. Governing board members are also required by Texas Government Code § 2262.0535 to complete a course of training related to state contracting.<sup>1</sup> The new member may fulfill all statutorily required training requirements on their own schedule by watching on-line videos made available by the Texas Attorney General and the Texas Comptroller.

The Oversight Committee Bylaws § 3.15 direct the General Counsel and the Chief Compliance Officer to "provide training to all new members of the Oversight Committee and shall provide ongoing or continuing training to all members of the Oversight Committee at least once a year." Other than a reference to the statutorily required Open Meetings training, the bylaws defer to the discretion of the General Counsel and the Chief Compliance Officer to establish the form and substance of the training.

<sup>&</sup>lt;sup>1</sup> Unlike the Open Meetings and Open Records training, the statute does not link the contract training specifically to new members and provides no deadline for completing the training. Since all current Oversight Committee members have already completed contract training, we recommend that the member complete the contract training as part of the new member onboarding.

### **Discussion:**

While training in open meetings, open records, and government contracting is necessary for new Oversight Committee members, these topics are not sufficient to prepare the new member to govern CPRIT. We recommend that the new member training provide a high-level overview of CPRIT's mission, grants review process, the compliance program, and CPRIT's funding projections through 2023. Training will also include a discussion of CPRIT's conflict of interest, non-disclosure, and ethics policies in sufficient depth so that the new member can complete the associated certifications at the conclusion of the training. Given the breadth of the proposed onboard training topics, we do not recommend that in-depth presentations of each of the three programs be a required part of the new member training. The new member will be encouraged to schedule individual meetings with each of the program officers.

We suggest that the Oversight Committee allow new members to participate in Oversight Committee meetings and subcommittee meetings prior to completing the required training (including the statutorily required open meetings, open records, and contract training) with two caveats. First, a new member should not participate in the discussion or vote on an award recommendation until the member has completed the CPRIT new member training component. Second, a new member should not participate in the discussion or vote on a contract approval request until the member has completed the statutorily required contract training.

Our proposed training process and timeline are described below.

<u>Training Process and Onboarding Materials</u> – Upon notice of appointment, the CEO will send a welcome email to the new member. The email will include information about:

- Filing the Personal Financial Disclosure form with the Ethics Commission within 30 days of the member's appointment
- How to access and complete the required Open Meetings, Open Records, and Government Contracting training
- Scheduling an in-person new member training

One week prior to the scheduled new member training, CPRIT will deliver an Oversight Committee Member Manual to the new member, which includes the following documents:

- Constitutional Amendment establishing CPRIT
- Health & Safety Code Chapter 102
- CPRIT's Administrative Rules T.A.C. Chapters 701, 702, 703
- Grants Policies and Procedures Manual
- Oversight Committee Bylaws
- Code of Conduct.
- CPRIT's Grant Review Process
- Program Priorities for the fiscal year
- Most recent CPRIT Annual Report
- Non-Disclosure Policy
- Conflict of Interest Policy
- Oversight Committee Members and Subcommittee Assignments

The CEO, General Counsel, Chief Compliance Officer, and Chief Operating Officer will provide the new member training in person, unless the CEO determines that a conference call is more appropriate. If necessary, the Deputy CEO may substitute for the CEO and/or CPRIT's staff attorney may substitute for the General Counsel.

To document a new member's completion of training, the General Counsel will complete the onboarding checklist. The CEO will sign the checklist and provide it to the Chief Compliance Officer for CPRIT's records. The Chief Compliance Officer will notify the Presiding Officer and Vice Presiding Officer that the new member has completed the required CPRIT new member-training component.

Deadline for Completing Training – We propose a deadline of 30 business days (approximately 6 weeks) to complete the CPRIT new member training component.<sup>2</sup> This amount of time should be sufficient to allow CPRIT representatives and the new member to find a half-day for training. If the Oversight Committee agrees to the 30-business day deadline, we recommend a change to the due dates listed in the Code of Conduct for the initial Conflict of Interest Compliance Statement, the Non-Disclosure Agreement, and the Ethics Compliance Statement. Currently, these agreements and compliance statements are due within 30 days of appointment to the Oversight Committee.

In the event that the new member has not completed the CPRIT new member training component by the established deadline, the Chief Compliance Officer will notify the Presiding Officer, Vice Presiding Officer, CEO and General Counsel. With the advice of the Presiding Officer and the Vice Presiding Officer, the CEO may extend the deadline for completing the training. Based upon the circumstances, the Presiding Officer may inform the new member's appointing office of the member's failure to complete the CPRIT new member training component.

# **Next Steps:**

Proposed changes to the Oversight Committee Bylaws (including changes to the Code of Conduct) are attached for the Oversight Committee's consideration. The Board Governance subcommittee supports the proposed changes and recommends that the Oversight Committee approve the proposed bylaw changes. CPRIT will implement the updated policy beginning with the training for the first new member appointed following approval of the bylaw changes.

New Member Training Proposal

<sup>&</sup>lt;sup>2</sup> The statute allows new members to complete the Open Meetings and Open Records training within 90 days of assuming the responsibilities as an Oversight Committee member.



# THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

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# CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS OVERSIGHT COMMITTEE BYLAWS

# ARTICLE 1 ESTABLISHMENT AND PURPOSES

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

# Section 1.2 Purposes. The Institute is established to:

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

# ARTICLE 2 AUTHORITY, AMENDMENT, AND INTERPRETATION

- Section 2.1 <u>Rulemaking Authority</u>. These Bylaws ("<u>Bylaws</u>") have been adopted by the Oversight Committee (as defined herein) pursuant to the authority granted to the Oversight Committee in Section 102.108 of the Health and Safety Code.
- Section 2.2 <u>Amendment</u>. These Bylaws may be amended or modified only with the approval of a simple majority of the members of the Oversight Committee as set forth in Section 3.13; <u>provided</u>, that no amendment or modification to these Bylaws may be made if such amendment or modification would cause these Bylaws to conflict with applicable law. All approved amendments or modifications shall be noted in a "Statement of Revisions" at the end of these Bylaws.
- Section 2.3 <u>Interpretation</u>. These Bylaws are adopted subject to any applicable law, including, but not limited to, Chapter 102 of the Health and Safety Code and Title 25, Chapters 701–704, of the Texas Administrative Code. Whenever these Bylaws may conflict with applicable law, the conflict will be resolved in favor of the applicable law. If at any time the Oversight Committee determines that these Bylaws conflict with applicable law, then the Oversight Committee shall promptly act to amend these Bylaws to cause them to conform to applicable law.

# ARTICLE 3 THE OVERSIGHT COMMITTEE

- Section 3.1 <u>General Powers</u>. The Oversight Committee of the Institute (the "<u>Oversight Committee</u>") is the governing body of the Institute. The Oversight Committee may adopt such policies and practices, consistent with applicable law, as it may deem proper for the conduct of its meetings and the management of the Institute.
- Section 3.2 <u>Number</u>. The Oversight Committee is composed of the following nine (9) members:
  - (a) three members appointed by the Governor of the State of Texas;
- (b) three members appointed by the Lieutenant Governor of the State of Texas; and
- (c) three members appointed by the Speaker of the House of Representatives of the State of Texas

# Section 3.3 Composition; Disqualification.

- (a) The members of the Oversight Committee must represent the geographic and cultural diversity of the State of Texas. In making appointments to the Oversight Committee, the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas shall each appoint at least one person who is a physician or a scientist with extensive experience in the field of oncology or public health and should attempt to include cancer survivors and family members of cancer patients if possible.
- (b) A person may not be a member of the Oversight Committee if the person or the person's spouse: (i) is employed by or participates in the management of a business entity or other organization receiving money from the Institute; (ii) owns or controls, directly or indirectly, an interest in a business entity or other organization receiving money from the Institute; or (iii) uses or receives a substantial amount of tangible goods, services, or money from the Institute, other than reimbursement authorized by law for Oversight Committee membership, attendance, or expenses.
- Section 3.4 <u>Term.</u> Each member of the Oversight Committee will hold office for such member's term or until such member's earlier death, resignation, disqualification, or removal. Members of the Oversight Committee appointed by the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas serve at the pleasure of the appointing office for staggered six-year terms, with the terms of three members expiring on January 31 of each odd-numbered year. Not later than the 30th day after the date an Oversight Committee member's term expires, the appropriate appointing authority shall appoint a replacement.
- Section 3.5 <u>Vacancy</u>. If a vacancy occurs on the Oversight Committee, then the appropriate appointing authority shall appoint a successor, in the same manner as the original appointment, to serve for the remainder of the unexpired term. The appropriate appointing authority shall appoint the successor not later than the 30th day after the date the vacancy occurs.

- Section 3.6 <u>Resignation</u>. Any appointed or designated member of the Oversight Committee may resign at any time by notice given in writing to the appropriate appointing authority and to the Chair of the Oversight Committee or to the Vice Chair if the Chairman is resigning. The resigning member will continue to serve until such time that the appropriate appointing authority appoints a successor.
- Section 3.7 Removal. It is a ground for removal from the Oversight Committee that a member: (a) is ineligible for membership of the Oversight Committee under Section 3.3(b) of these Bylaws; (b) cannot, because of illness or disability, discharge the member's duties for a substantial part of the member's term; or (c) is absent from more than half of the regularly scheduled Oversight Committee meetings that the member is eligible to attend during a calendar year without an excuse approved by a majority vote of the Oversight Committee. If the Chief Executive Officer has knowledge that a potential ground for removal exists, then the Chief Executive Officer shall notify the Chairperson of the potential ground. The Chairperson shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. If the potential ground for removal involves the Chairperson, then the Chief Executive Officer shall notify the next highest ranking officer of the Oversight Committee, who shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. Notwithstanding, the foregoing, the validity of an action of the Oversight Committee is not affected by the fact that it is taken when a ground for removal of a committee member exists.
- Section 3.8 <u>Strategic Partnerships</u>. To the fullest extent permitted by applicable law, the Oversight Committee retains the authority and power to approve strategic partnerships, alliances, and coalitions of the Institute subject to vote of the simple majority of the members of the Oversight Committee as set forth in Section 3.13.
- Section 3.9 <u>Regular Meetings</u>. The Oversight Committee shall hold a public meeting at least once in each quarter of the calendar year, with appropriate notice and with a formal public comment period.
- Section 3.10 <u>Special Meetings</u>. Special meetings of the Oversight Committee may be held upon the call of the Chairperson of the Oversight Committee, or the Vice Chairperson of the Oversight Committee when performing the duties of the Chairperson, as he or she may deem necessary, with appropriate notice and with a formal public comment period. Emergency meetings and telephonic meetings may be held only as provided under applicable law.
- Section 3.11 Notice of Open Meetings. All meetings of the Oversight Committee are subject to the terms of the Open Meetings Act, Chapter 551 of the Texas Government Code (the "Open Meetings Act"). The Open Meetings Act provides that the public must be given notice of the time, place, and subject matter of meetings of governmental bodies. In absence of an emergency, notice of a meeting must be posted at a place that is readily accessible to the public at all times at least seven (7) days preceding the scheduled time of the meeting. In case of an emergency of urgent public necessity, which shall be clearly identified in the notice, it shall be sufficient if the notice is posted two hours before the meeting is convened.

- Section 3.12 <u>Quorum</u>. The presence of a simple majority of the members of the Oversight Committee present is necessary and sufficient to constitute a quorum for the transaction of business at any meeting of the Oversight Committee.
- Section 3.13 <u>Action By Simple Majority Vote</u>. Except as otherwise provided by these Bylaws or applicable law, the vote of a simple majority of the members of the Oversight Committee present at a meeting at which a quorum is present will be the prevailing action of the Oversight Committee.
- Section 3.14 <u>Expenses</u>. A member of the Oversight Committee is not entitled to compensation, but is entitled to reimbursement for actual and necessary expenses incurred in attending meetings of the Oversight Committee or performing other official duties authorized by the Chairperson.
- Section 3.15 <u>Training</u>. The Institute's General Counsel and Chief Compliance Officer shall provide training to all new members of the Oversight Committee and shall provide ongoing or continuing training to all members of the Oversight Committee not less than once a year.
- (a) The form and substance of such training will be in the discretion of the Institute's General Counsel and Chief Compliance Officer.
- (b) A new member shall also complete a course of training regarding the function and operation of the Institute, including his or her responsibilities pursuant to CPRIT's Conflict of Interest, Non-Disclosure, and Ethics Compliance policies. The new member shall complete the CPRIT training component within 30 business days of the new member's appointment.
- (c) Each A new member of the Oversight Committee shall also complete a course of training regarding his or her responsibilities under the Open Meetings Act, the Open Records Act, and Government Contracting within 90 days of becoming a member of the Oversight Committee.
- (d) A new member that has not completed the required training may participate in any meeting of the Oversight Committee or its subcommittees, subject to the following restrictions: (1) the new member shall not participate in the discussion or vote on any award recommendation until the new member has completed the CPRIT training component; and (2) the new member shall not participate in the discussion or vote to approve a contract until the new member has completed the Government Contract training.

# ARTICLE 4 SUBCOMMITTEES OF THE OVERSIGHT COMMITTEE

Section 4.1 <u>Generally</u>. The Oversight Committee may designate one or more subcommittees of the Oversight Committee, each subcommittee to consist of three or more of the members of the Oversight Committee. The Oversight Committee shall appoint and approve members of the subcommittees specifically listed in Section 4.2, except for the members of the Executive Committee, which shall be comprised of the designated members as set forth below in Section 4.3. The Oversight Committee may designate one or more members of the Oversight Committee as alternate members of any subcommittee, who may replace any absent or disqualified

member at any meeting of the subcommittee. If a member of a subcommittee is absent from any meeting, or disqualified from voting thereat, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of a subcommittee, a majority of the then authorized members of the subcommittee will constitute a quorum, and the vote of a majority of the members of the subcommittee present at any meeting at which there is a quorum will be the act of the Unless the Oversight Committee provides otherwise, each subcommittee subcommittee. designated by the Oversight Committee shall adopt a subcommittee charter and may make, alter, and repeal rules and procedures for the conduct of its business. The Subcommittee charter shall be approved by a vote of a simple majority as set forth in Section 3.13. In the absence of a subcommittee charter, each subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business. Each subcommittee will have a chairperson, who will be selected by the Oversight Committee at large.

- Section 4.2 <u>Certain Subcommittees</u>. Without limiting in any way the previous Section, the following are subcommittees of the Oversight Committee (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):
  - (a) Executive Subcommittee;
  - (b) Audit Subcommittee;
  - (c) Board Governance and Ethics Subcommittee;
  - (d) Nominations Subcommittee;
  - (e) Product Development Subcommittee;
  - (f) Scientific Research Subcommittee:
  - (g) Prevention Subcommittee; and
  - (h) Diversity Subcommittee.
- Section 4.3 <u>Executive Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Executive Subcommittee (the "<u>Executive Subcommittee</u>").
- (a) The purpose of the Executive Subcommittee is to transact all normal business referred to it by the Oversight Committee and to conduct the Chief Executive Officer's annual performance review.
- (b) The Executive Subcommittee will be composed of no more than four (4) members of the Oversight Committee. Members of the Executive Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal from their positions by action of the Oversight Committee.

- (c) The Executive Subcommittee shall meet as often as the Chair deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- (d) Meetings of the Executive Subcommittee shall be conducted in accordance with the Texas Open Meetings Act.
- Section 4.4 <u>Audit Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Audit Subcommittee (the "<u>Audit Subcommittee</u>").
- (a) The purpose of the Audit Subcommittee is to review and make recommendations to the Oversight Committee with respect to the following:
  - (i) The annual operating budget and strategic plan;
  - (ii) Policies for monitoring grant performance;
- (iii) Variances in the operating budget of the Institute of more than 5% or \$25,000;
  - (iv) Non-grant contracts exceeding \$100,000; and
  - (v) Any variance of more than 10% in any announced grant award.
- (b) The members of the Audit Subcommittee will be appointed by the Oversight Committee. The Audit Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Audit Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Audit Subcommittee.
- (c) The Audit Subcommittee shall meet as often as the Chairperson of the Audit Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.5 <u>Board Governance and Ethics Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Board Governance and Ethics Subcommittee (the "Board Governance and Ethics Subcommittee").
- (a) The purpose of the Board Governance and Ethics Subcommittee is to review and recommend proposed changes for approval to the Oversight Committee with respect to the following:
  - (i) These Bylaws;
  - (ii) Any policies or administrative rules of the Institute;
  - (iii) Legislation regarding or affecting the Institute;
  - (iv) The delegation of authority to the Chief Executive Officer;
  - (v) The ethics policies of the Institute and their administration; and

- (vi) An annual review of the internal policies and processes of the Oversight Committee.
- (b) The members of the Board Governance and Ethics Subcommittee will be appointed by the Oversight Committee. The Board Governance and Ethics Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Board Governance and Ethics Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Board Governance and Ethics Subcommittee.
- (c) The Board Governance and Ethics Subcommittee shall meet as often as the Chairperson of the Board Governance and Ethics Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.6 <u>Nominations Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Nominations Subcommittee (the "Nominations Subcommittee").
- (a) The purpose of the Nominations Subcommittee is to identify members for the Institute's advisory committees and to accept nominations for and recommend candidates to serve as Oversight Committee officers.
- (b) The members of the Nominations Subcommittee will be appointed by the Oversight Committee. The Nominations Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Nominations Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Nominations Subcommittee.
- (c) The Nominations Subcommittee shall meet as often as the Chairperson of the Nominations Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.7 <u>Product Development Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Product Development Subcommittee (the "<u>Product Development Subcommittee</u>").
- (a) The purpose of the Product Development Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer. In addition, the Product Development Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT product development research grants.
- (b) The members of the Product Development Subcommittee will be appointed by the Oversight Committee. The Product Development Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Product Development Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Product Development Subcommittee.

- (c) The Product Development Subcommittee shall meet as often as the Chairperson of the Product Development Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.8 <u>Scientific Research Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Scientific Research Subcommittee (the "<u>Scientific Research Subcommittee</u>").
- (a) The purpose of the Scientific Research Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT scientific research grants. The purpose of the Scientific Research Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for research into the causes of and cures for all types of cancer in humans and to create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT research grants.
- (b) The members of the Scientific Research Subcommittee will be appointed by the Oversight Committee. The Scientific Research Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Scientific Research Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Scientific Research Subcommittee.
- (c) The Scientific Research Subcommittee shall meet as often as the Chairperson of the Scientific Research Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.9 <u>Prevention Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Prevention Subcommittee (the "<u>Prevention Subcommittee</u>").
- (a) The purpose of the Prevention Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants. The purpose of the Prevention Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for cancer prevention and control programs to mitigate the incidence of all types of cancers in humans and to implement the Texas Cancer Plan. In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants.

- (b) The members of the Prevention Subcommittee will be appointed by the Oversight Committee. The Prevention Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Prevention Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Prevention Subcommittee.
- (c) The Prevention Subcommittee shall meet as often as the Chairperson of the Prevention Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.
- Section 4.10 <u>Diversity Subcommittee</u>. There is a subcommittee of the Oversight Committee to be known as the Diversity Subcommittee (the "<u>Diversity Subcommittee</u>").
- (a) The purpose of the Diversity Subcommittee is to ensure that the Institute makes every effort to outreach to all communities about the cancer research and prevention funding opportunities in the State of Texas.
- (b) The members of the Diversity Subcommittee will be appointed by the Oversight Committee. The Diversity Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Diversity Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Diversity Subcommittee.
- (c) The Diversity Subcommittee shall meet as often as the Chairperson of the Diversity Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

# ARTICLE 5 CHAIRPERSON AND VICE CHAIRPERSON

- Section 5.1 <u>Election</u>. The Oversight Committee shall elect from among its members a Chairperson and a Vice Chairperson in accordance with the selection provisions of these Bylaws. Nothing herein restricts the ability of the Oversight Committee to elect additional officers from among its members by a vote of a simple majority of the members of the Oversight Committee.
- Section 5.2 <u>Election, Term of Office and Removal</u>. At the first regular Oversight Committee meeting following the adoption of these bylaws, the members of the Oversight Committee shall elect the Chairperson and Vice Chairperson by a vote of a simple majority as set forth in Section 3.13. Thereafter, the members of the Oversight Committee shall elect the Chairperson and Vice Chairperson by a vote of a simple majority of as set forth in Section 3.13 at the last regular Oversight Committee meeting of the state fiscal year in each odd-numbered year. The Nominations Subcommittee may recommend candidates for the Oversight Committee's consideration prior to the vote by the Oversight Committee. The Chairperson and the Vice Chairperson will hold office until death, resignation, or removal from office, or the election and qualification of a successor, whichever occurs first; provided, however, that neither the Chairperson nor the Vice Chairperson may hold office for two consecutive terms. If the person holding the office or Chairperson or Vice Chairperson holds office for one term, and a successor has not been elected by the Oversight Committee to take office at the expiration of the term, then the person holding the office of Chairperson or Vice Chairperson, as applicable, shall continue to

hold the office until such time that a quorum of the Oversight Committee can meet and elect a successor. The Chairperson or the Vice Chairperson may be removed at any time, with or without cause, by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13. If the office of the Chairperson or the Vice Chairperson becomes vacant for any reason, including by the expiration of the term, then the vacancy must be filled by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13.

- Section 5.3 <u>Chairperson</u>. The Chairperson is the presiding officer of the Oversight Committee. The Chairperson shall preside at each meeting of the Oversight Committee. The Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by applicable law or recommended by the Board Governance and Ethics Subcommittee and approved by the Oversight Committee. The Chairperson may authorize official duties of members of the Oversight Committee, the University Advisory Committee, or any Ad Hoc Advisory Committee in accordance with applicable law. The Chairperson may not serve as the presiding officer for any other foundation or organization created to specifically benefit the Institute.
- Section 5.4 <u>Vice Chairperson</u>. The Vice Chairperson shall, in the absence of the Chairperson, preside at each meeting of the Oversight Committee. The Vice Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by the Board Governance and Ethics Subcommittee or applicable law and approved by the Oversight Committee.
- Section 5.5 <u>Presiding Officers in the Absence of the Chairperson and Vice Chairperson.</u> In the absence of the Chairperson and Vice Chairperson, the Chairperson of the Scientific Research Subcommittee shall preside at each meeting of the Oversight Committee. In the absence of Scientific Research Subcommittee Chairperson, then the Chairperson of the Product Development Subcommittee shall preside. In the absence of the Chairpersons of the Scientific Research and Product Development Subcommittees, then the Chairperson of the Prevention Subcommittee shall preside.

# ARTICLE 6 THE CHIEF EXECUTIVE OFFICER

- Section 6.1 <u>General Powers</u>. There will be one Chief Executive Officer of the Institute (the "<u>Chief Executive Officer</u>"). The Chief Executive Officer has such powers as are delegated to the Chief Executive Officer by the Oversight Committee and such powers as are vested in the Chief Executive Officer pursuant to applicable law.
- Section 6.2 <u>Selection by the Oversight Committee</u>. The Oversight Committee shall hire the Chief Executive Officer.
- Section 6.3 <u>Performance of Duties</u>. The Chief Executive Officer shall perform the duties of the Chief Executive Officer as provided by these Bylaws, applicable law, or the Oversight Committee. In performance of such duties, the Chief Executive Officer is authorized to execute contracts on behalf of CPRIT. Such authority is limited when CPRIT's enabling statute specifically authorizes the Oversight Committee to enter into a written contract. In that event, the Chief Executive Officer may execute contract(s) pursuant to a specific delegation by the Oversight Committee. Subject to prior authorization by the Chief Executive Officer, CPRIT's Chief Operating Officer may execute contracts on behalf of CPRIT. The Chief Executive Officer must

notify the Oversight Committee in writing prior to authorizing the Chief Operating Officer to execute contracts on behalf of CPRIT; such notification shall specify the time period the Chief Operating Officer is authorized to do so. The Oversight Committee Chairperson and Vice Chairperson may authorize the Chief Operating Officer to execute contracts on behalf of CPRIT and waive prior notification by the Chief Executive Officer upon a finding that an emergency exists preventing such prior notification. The emergency authorization shall be in writing.

- Section 6.4 <u>Grant Review</u>. The Chief Executive Officer shall oversee the grant review process and may terminate grants that do not meet contractual obligations.
- Section 6.5 <u>Quarterly Report</u>. Each quarter, the Chief Executive Officer shall report to the Oversight Committee on any new grant awards and the progress and continued merit of scientific research and prevention programs previously awarded funding. The report must include a summary of the allocation of funding among scientific research and prevention programs and details regarding the final results of completed projects under these programs.
- Section 6.6 <u>Duties Regarding Foundations or Organizations Created to Specifically Benefit CPRIT</u>. The Chief Executive Officer shall annually report to the Oversight Committee on guidelines for the governance of any foundation or organization created specifically to benefit CPRIT and the relationship between the Institute and the foundation or organization. The Chief Executive Officer shall also annually solicit a report from the foundation or organization created specifically to benefit the Institute regarding the funds the foundation or organization holds, the pledges it has received, and the identities of contributors.

# ARTICLE 7 OTHER OFFICERS OF THE INSTITUTE

- Section 7.1 <u>Creation and Selection of Other Officers of the Institute</u>. The Oversight Committee may direct the Chief Executive Officer to create other officer positions of the Institute and to hire individuals to fill such positions.
- Section 7.2 <u>Certain Officers</u>. Without limiting in any way the previous Section, the following officer positions of the Institute have been created (each of which has the duties and authority set forth in this Article in addition to any other duties and authority as may be delegated to such officer by the Oversight Committee):
- (a) Chief Operating Officer, whose duties include oversight of the Institute's daily operations, including financial administration, grants management administration, communications, governmental relations, and information technology services;
- (b) Chief Compliance Officer, whose duties include reporting to the Oversight Committee on the agency's compliance with applicable law, administrative rules, and policies, and building, developing, and maintaining a compliance program that fosters ethical business behavior and includes requirements for risk assessments, program governance, metrics, and reporting;
- (c) Chief Scientific Officer, whose duties include oversight of the scientific research application submission process, coordinating the review of research proposals,

monitoring grant progress, and fostering collaboration among the cancer and disease scientific research community to maximize the Institute's impact

- (d) Chief Product Development Officer, whose duties include oversight of the cancer research development application submission process, coordinating review of the cancer research product development proposals, monitoring grant progress and fostering collaboration among the bioscience community to maximize the Institute's impact;
- (e) Chief Prevention Officer, whose duties include oversight of the prevention application submission process, coordinating the review of prevention proposals, monitoring grant progress, and fostering collaboration among the cancer and disease prevention community to maximize the Institute's impact; and
- (f) General Counsel, whose duties include oversight of the legal issues that arise as part of the Institute's operations.

# ARTICLE 8 COMMITTEES OF THE INSTITUTE

- Section 8.1 <u>Creation of Committees of the Institute</u>. Pursuant to applicable law and in accordance with this Article, the Oversight Committee may create Committees of the Institute and appoint and approve members of such committees.
- Section 8.2 <u>Scientific Research and Prevention Program Committee</u>. There will be one or more scientific research and prevention programs committees of the Institute (each, a "<u>Scientific Research and Prevention Programs Committee</u>"). Each Scientific Research and Prevention Programs Committee has such powers as are vested in it pursuant to applicable law. The Chief Executive Officer, with approval by simple majority of the members of the Oversight Committee as set forth in Section 3.13, shall appoint as members of one or more Scientific Research and Prevention Programs Committees experts in the field of cancer research, prevention, and patient advocacy to serve for terms as determined by the Chief Executive Officer. Individuals appointed to a Scientific Research and Prevention Programs Committee may be residents of another state. A member of a Scientific Research and Prevention Programs Committee may receive an honorarium according to a policy developed by the Chief Executive Officer in consultation with the Oversight Committee.
- Section 8.3 <u>University Advisory Committee</u>. There will be one university advisory committee of the Institute (the "<u>University Advisory Committee</u>"). The University Advisory Committee has such powers as are vested in it pursuant to applicable law. The University Advisory Committee shall advise the Oversight Committee and each Scientific Research and Prevention Programs Committee regarding the role of institutions of higher education in cancer research. The University Advisory Committee is composed of the following members to serve for the term as determined by the appropriate appointing authority appointing such member:
- (a) two members appointed by the chancellor of The University of Texas System to represent:
  - (i) The University of Texas Southwestern Medical Center at Dallas;

- (ii) The University of Texas Medical Branch at Galveston;
- (iii) The University of Texas Health Science Center at Houston;
- (iv) The University of Texas Health Science Center at San Antonio;
- (v) The University of Texas Health Center at Tyler; or
- (vi) The University of Texas M. D. Anderson Cancer Center;
- (b) one member appointed by the chancellor of The Texas A&M University System to represent:
  - (i) The Texas A&M University System Health Science Center; or
- (ii) the teaching hospital for The Texas A&M Health Science Center College of Medicine;
- (c) one member appointed by the chancellor of the Texas Tech University System to represent the Texas Tech University Health Sciences Center;
- (d) one member appointed by the chancellor of the University of Houston System to represent the system;
- (e) one member appointed by the chancellor of the Texas State University System to represent the system;
- (f) one member appointed by the chancellor of the University of North Texas System to represent the system;
  - (g) one member appointed by the president of Baylor College of Medicine;
  - (h) one member appointed by the president of Rice University; and
- (i) members appointed at the Chief Executive Officer's discretion by the chancellors of other institutions.
- Section 8.4 Ad Hoc Advisory Committee on Childhood Cancers. The Oversight Committee shall create an ad hoc committee of experts to address childhood cancers. Members of the Ad Hoc Advisory Committee on Childhood Cancers shall be appointed by the Oversight Committee and serve for terms determined by the Oversight Committee. The Ad Hoc Advisory Committee on Childhood Cancers has the duties and authority set forth in the advisory committee's charter in addition to any other duties and authority as may be delegated by the Oversight Committee.
- Section 8.5 Other Ad Hoc Advisory Committees of the Institute. The Oversight Committee, as necessary, may create additional ad hoc committees of experts to advise the Oversight Committee on issues relating to cancer. The number of members of each Ad Hoc Committee will be determined by the Oversight Committee. Ad Hoc Advisory Committee members are appointed by the Oversight Committee and serve for terms determined by the Oversight Committee.

- Section 8.6 <u>Certain Ad Hoc Advisory Committees of the Institute</u>. Without limiting in any way the previous Section, the following are the Ad Hoc Advisory Committees of the Institute (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):
  - (a) Scientific and Prevention Advisory Council; and
  - (b) Product Development Advisory Committee;
- Section 8.7 <u>Annual Report to the Oversight Committee</u>. Each Committee of the Institute shall report to the Oversight Committee at least annually regarding the work undertaken by such committee pursuant to a schedule and format dictated by the Oversight Committee.

# ARTICLE 9 CODE OF CONDUCT AND ETHICS POLICY

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

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#### STATEMENT OF REVISIONS

### Approved November 1, 2013

Changes made to Sections 2.2, 3.2, 3.3(a) and (b), 3.4, 3.7, 3.15, 4.1, 4.2, 4.3(a) and(b), 4.4(a)(iii), 4.5(a)(iv), 4.6, 4.7, 4.8(a) and(b), 4.9(a) and(b), 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 7.1, 7.2(b) and (d), 8.2, 8.3(i), 8.4, 9.1, Article 6 (title), and Article 9 (title) and text.

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

### Approved May 21, 2014

Changes made to Sections 4.4(a)(ii), 8.6(b)

Reason for change(s): Revision made to reflect statutory changes adopted in 2013 legislative session and to change name of certain ad hoc advisory committees.

# Approved May 20, 2015

Changes made to Section 4.6(a) and Section 5.2

Reason for change(s): Revision made to assign Nominations Subcommittee the responsibilities associated with officer elections.

# Approved September 10, 2015

Nonsubstantive changes made to Article 9 to correct typographical errors.

# Approved November 19, 2015

Change made to Section 6.3.

Reason for change: Clarifies the Chief Executive Officer's contract execution authority and process for delegating such authority to the Chief Operating Officer.

Approved August 16, 2017

# Change made to Section 3.15 and Article 9, Section V.

Reason for change: Specifies new member training requirements, including deadlines for training and required forms, and clarifies participation in Oversight Committee meetings prior to completing required training.



### 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;
- (<u>5</u>) 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. Unless otherwise specified, 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 member's or employee's appointment or 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.



#### **MEMORANDUM**

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN DOYLE, GENERAL COUNSEL AND DEPUTY EXECUTIVE

**OFFICER** 

**SUBJECT:** DELEGATION OF AUTHORITY TO VOTE MIRNA SHARES

**DATE:** AUGUST 8, 2017

### **Summary and Recommendation:**

I recommend that the Oversight Committee delegate authority to CPRIT's Chief Executive Officer to vote CPRIT's shares in Mirna at the company's upcoming annual shareholder meeting. The delegation includes the power for Mr. Roberts to authorize a proxy to vote on CPRIT's behalf. CPRIT is a shareholder of Mirna via the revenue sharing agreement in Mirna's award contract. Mirna discontinued development of its lead compound MRX34 after halting its clinical trial in September 2016. In May, Mirna announced that it plans to merge with Synlogic, Inc., via a reverse merger arrangement to maximize value for its shareholders. The boards of directors for both companies recommend shareholder approval of the merger. Mirna will hold an annual meeting of its shareholders on August 24, 2017, to approve the merger.

# **Background – Mirna's CPRIT Grant Awards**

Mirna began operations in 2007 to develop a new class of cancer treatments based on naturally occurring tumor suppressor microRNAs. Mirna was one of the first companies to receive a CPRIT grant when the Oversight Committee ratified an award (grant ID #RP101219) for a \$10.3 million grant in June 2010 for the optimization of its lead compound, MRX34, with liver cancer applications. The Oversight Committee approved a second Product Development Research grant of \$16.7 million (grant ID #DP140067) in May 2014 for further development of MRX34. CPRIT owns 2,395,010 shares of Mirna's publicly traded stock via CPRIT's revenue sharing agreement, representing ownership of approximately 11 percent of the company.

The company voluntarily halted its ongoing Phase I clinical study of MRX34 in September 2016 following multiple immune-related severe adverse events. The FDA subsequently notified Mirna that the agency was placing its Investigational New Drug application for MRX34 on full clinical hold. Mirna announced in November 2016 that it was discontinuing development of MRX34 and initiated a plan to reduce personnel and expenses while exploring strategic alternatives with the goal of enhancing stockholder value.

# Mirna's Reverse Merger with Synlogic

According to the company, Mirna's management team pursued a reverse merger rather than liquidating the company as an option for maximizing value for its shareholders. In a reverse merger, shareholders of a private company purchase control of the public shell company -- in this case, Mirna -- to merge it with the privately held company. The private company becomes a publicly held company once the merger is complete. A reverse merger minimizes the cost and time associated with taking a private company public. The shareholders of the shell company own a portion the merged entity but the merger dilutes their ownership of the merged company.

Mirna representatives indicate that the reverse mergers are common in the biotech space, particularly when there is significant additional value in the ongoing listing. Given the amount of cash on hand and Mirna's public listing, the Mirna board of directors agreed that a reverse merge was the best way to maximize value for shareholder.

Mirna engaged Wedbush, Inc. as its financial advisor. With their assistance, the company narrowed the field of more than 40 interested private and public companies to five merger candidates that met with an investment committee. On May 16, 2017, Mirna and Synlogic publicly announced their definitive merger agreement. Synlogic also reported closing a \$42 million Series C fundraising round at the time of the merger.

Synlogic, based in Cambridge, MA, will focus on advancing its drug discovery and development platform for Synthetic Biotic medicines, which are designed using synthetic biology to reprogram beneficial microbes to treat metabolic and inflammatory diseases and cancer. According to the company, Synlogic is pioneering the development of a novel class of living medicines, Synthetic Biotics<sup>TM</sup>, based on its proprietary drug discovery and development platform. Synlogic's initial pipeline includes Synthetic Biotic medicines for the treatment of rare genetic diseases, such as Urea Cycle Disorder (UCD) and Phenylketonuria (PKU). In addition, the company indicates that it is leveraging the broad potential of its platform to create Synthetic Biotic medicines for the treatment of more common diseases, including liver disease, inflammatory and immune disorders, and cancer. Synlogic reports a collaboration with AbbVie to develop Synthetic Biotic-based treatments for inflammatory bowel disease.

According to the company, following the completion of the merger no employees of Mirna will transition to Synlogic.

#### **Shareholder Approval Necessary to Complete Merger**

The boards of directors for both companies have approved the merger, but it will not move forward unless the shareholders of both companies agree. Mirna has called an annual meeting of its shareholders for August 24, 2017, at the office of the company's attorneys in Menlo Park, California. Mirna's board of directors recommends that its shareholders vote to approve the May 15, 2017, Agreement and Plan of Merger and Reorganization, to approve an amendment to the Certificate of Incorporation to effect the reverse stock split of Mirna's common stock, and to

change the corporate name to Synlogic, Inc.. CPRIT may authorize specific Mirna representatives to vote CPRIT's shares as designated by CPRIT via a proxy.

Mirna stockholders will own approximately 17 percent of the combined company, based on Mirna's expected cash at the time of the close.

### Delegation of Authority to Vote Mirna Shares to CPRIT Chief Executive Officer

In order for CPRIT's CEO to vote or authorize Mirna representatives to vote by proxy CPRIT's outstanding Mirna shares, the Oversight Committee must delegate authority to him. The Oversight Committee can accomplish this by voting to approve the delegation of authority, including the power to permit the shares to be voted by proxy.



To: **OVERSIGHT COMMITTEE MEMBERS** 

From: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

**Subject:** CHIEF OPERATING OFFICER REPORT

Date: **AUGUST 8, 2017** 

### **CPRIT Financial Overview for FY 2017, Quarter 3**

### FY 2017, Quarter 3 Operating Budget

CPRIT expended or obligated approximately \$1.9 million in Indirect Administration during the year and approximately \$12.2 million in Grant Review and Award Operations, which is a little more than 75% of the overall administrative budget used nine months into the fiscal year. The obligations and expenditures reflected in the Professional Fees and Services category are primarily for service contracts for pre- and post-award grants management support services, legal due diligence services, business and regulatory due diligence services, and compliance and audit services.

During this quarter, the agency received \$18,617 in revenue sharing payments, bringing the total payments received through May 2017 to \$55,818.

### FY 2017, Quarter 3 Performance Measure Report

CPRIT reported on its two key quarterly performance measures to the Legislative Budget Board. It met or exceeded the prevention measure but did not meet performance on the product development measure on company relocations to Texas because no company recipients of a CPRIT grant award relocated to Texas during the reporting period from March through May 2017.

### **Debt Issuance History**

CPRIT has not requested any additional debt issuances since February 2017 when TPFA issued \$269 million of general obligation bonds on CPRIT's behalf. This was the total amount of funding that CPRIT required for operating expenses and grant award obligations for the year.

### **FY 2018 Operating Budget**

The 2018 budget is based on the state budget approved by the Texas Legislature in May and reflects a reduction of \$63,144 to the Grant Review and Award Operations line item. The adjustment was made because there is a savings from allowing the agency to hire 3 additional FTEs for the compliance program and transitioning out of the compliance support services contract for desk reviews and onsite monitoring visits. The FY 2017 budget is provided for comparison.

### Cancer Prevention and Research Institute of Texas Quarterly Financial Report As of June 30, 2017

	Indirect Administration (B.1.1.)											
		Ар	2017 propriated	20:	17 Budgeted	% of Total Budget	tual Expenditures & ant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse	e/Overspent
1001	Salaries and Wages	\$	1,432,617	\$	1,347,500		\$ 952,108	395,392	71%	\$ 952,108	\$	395,392
1002	Other Personnel Costs		52,785		67,785		37,612	30,173	55%	37,612		30,173
2001	Professional Fees and Services		807,317		877,434		700,012	177,422	80%	700,012		177,422
2003	Consumable Supplies		27,584		27,584		9,857	17,727	36%	9,857		17,727
2004	Utilities		58,577		58,577		11,407	47,170	19%	11,407		47,170
2005	Travel		45,000		45,000		24,445	20,555	54%	24,445		20,555
2006	Rent-Building		-		18,408		18,408	0	0%	18,408		0
2007	Rent-Machine and Other		32,172		34,207		21,977	12,230	64%	21,977		12,230
2009	Other Operating Expenses		574,600		554,157		201,935	352,222	36%	201,935		352,222
	Subtotal - Indirect Administration (B.1.1.)	\$	3,030,652	\$	3,030,652	1.02%	\$ 1,977,761	\$ 1,052,891	65%	\$ 1,977,761	\$	1,052,891

						Act	tual Expenditures &			Estimated		
			2017		% of Total	Gr	ant Encumbrances	Remaining	Percent	Expenditures		
		ΑĮ	propriated	2017 Budgeted	Budget		(FYTD)	Budget	Expended	(YTD)	Lapse	e/Overspent
1001	Salaries and Wages	\$	2,730,580	2,666,233		\$	2,219,814	\$ 446,419	83%	\$ 2,219,814	\$	446,419
1002	Other Personnel Costs		3,856	83,203			79,437	3,766	0%	79,437		3,766
2001	Professional Fees and Services		10,809,493	10,809,493			9,734,509	1,074,984	90%	9,734,509		1,074,984
2003	Consumable Supplies		-	-			-	-	0%	-		-
2004	Utilities			10,000			8,674	1,326	87%	8,674		1,326
2005	Travel		65,000	65,000			44,238	20,762	68%	44,238		20,762
2009	Other Operating Expenses		201,297	176,297			70,610	105,687	40%	70,610		105,687
	Conference			20,481			-	20,481	0%	-		20,481
	Subtotal - Grant Operations (A.1.3.)	\$	13,810,226	\$ 13,830,707	4.66%	\$	12,157,282	\$ 1,673,425	88%	\$ 12,157,282	\$	1,673,425

### Grants

		А	2017 ppropriated	2	2017 Budgeted	% of Total Budget	tual Expenditures & rant Encumbrances (FYTD)		Remaining Budget	Percent Expended	E	Estimated xpenditures (YTD)	La	pse/Overspent
4000 4000	Grants - Prevention (A.1.2) Grants - Research (A.1.1.)	\$	28,334,312 251,780,562	\$ \$	28,334,312 251,780,562		\$ 12,024,696 132,923,057	\$ \$	16,309,616 118,857,505	42% 53%	\$	12,024,696 132,923,057	\$	16,309,616 118,857,505
	Subtotal - Grants	\$	280,114,874	\$	280,114,874	94.32%	\$ 144,947,753	\$	135,167,121	<b>52</b> %	\$	144,947,753	\$	135,167,121
	Grand Totals	\$	296,955,752	\$	296,976,233	100.00%	\$ 159,082,796	\$	137,893,437	54%	\$	159,082,796	\$	137,893,437

## Cancer Prevention and Research Institute of Texas Cancer Prevention and Research Institute Fund Account - 5136 As of June 30, 2017

	1/2017- 0/2017	AY 17 Year to Date as of 06/30/2017		
Beginning Balance : 06/01/2017		\$	600,506	
Increases:				
(1) (2)	\$ 	\$	-	
Total Increases	\$ -	\$	600,506.00	
Reductions:				
Expenditures - Appropriated	\$ -	\$	-	
	\$ -	\$	-	
	\$ -	\$	-	
Total Reductions	\$ -	\$		
Ending Balance, 06/30/2017		\$	600,506.00	

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds (\$303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

## Cancer Prevention and Research Institute of Texas License Plate Trust Fund Account - 0802 As of June 30, 2017

	6/01/2017- 6/30/2017	AY 17 Year to Date as of 06/30/2017		
Beginning Balance : 06/01/2017		\$	-	
Increases: (1) License Plate Revenue Received	\$ 1,055.98	\$	8,159.99	
Total Increases	\$ 1,055.98	\$	8,159.99	
Reductions:  Expenditures - Appropriated	\$ -	\$	(250.00)	
Total Reductions	\$ -	\$	(250.00)	
Ending Balance, 06/30/2017		\$	7,909.99	

Note:

# Cancer Prevention and Research Institute of Texas Appropriated Receipts - 666 As of June 30, 2017

		1/2017- 0/2017	ear to Date as of 06/30/2017
Beginning	g Balance : 06/01/2017		\$ 96,416.49
Increases	:		
(1)	Product Development Application Fees Received	\$ -	\$ 20,000.00
(2)	Appropriated Receipts applied to payments	\$ -	\$ -
(3)	Conference Registration Fees	\$ -	\$ 64.80
(4)	Conference Registration Fees-Credit Card	\$ -	\$ -
Total Incr	eases	\$ -	\$ 20,064.80
Reduction	ns:		
	Conference Expenditures - Appropriated	\$ -	\$ -
	Credit Card Fees Expended		\$ -
	Legal Services Expenses (Application Fees)	\$ -	\$ (41,000.00)
Total Red	uctions	\$ -	\$ (41,000.00)
Ending Ba	alance, 06/30/2017		\$ 75,481.29

Begin balance is \$76,000 for application fees and \$20,416.49 for conference fees

## Cancer Prevention and Research Institute of Texas General Revenue Fund Account - 0001 As of June 30, 2017

		1/2017- 0/2017	/ear to Date as of 06/30/2017
Beginnin	g Balance : 06/01/2017		\$ -
Increases	s:		
(1)	Revenue Sharing / Royalties	\$ -	\$ 42,929.17
Total Incr	reases	\$ -	\$ 42,929.17
Reductio	ns:		
	Expenditures - Appropriated	\$ -	\$ -
	Sweep Account	\$ -	\$ (42,929.17)
		\$ -	\$ -
Total Rec	ductions	\$ -	\$ (42,929.17)
Ending B	alance, 06/30/2017		\$ <u>-</u>

Note:

### Cancer Prevention and Research Institute of Texas FY 2017, Quarter 3 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	800,000	175,441	206,098	207,730		589,269	73.66%
Number of Entities Relocating to TX for Cancer Research Related Projects	2.00	0.00	0.00	0.00		0.00	0.00%
Annual Age-adjusted Cancer Mortality Rate	152.5	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT- Funded Research Projects	450	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	315	N/A	N/A	N/A	N/A		0.00%

### **Variance Explanations**

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

This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

### Cancer Prevention and Research Institute of Texas FY 2017, Quarter 2 Performance Measure Report

		<b>6-5</b> 4				•	0/ 685 1/
Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	800,000	175,441	206,098			381,539	47.69%
Number of Entities Relocating to TX for Cancer Research Related Projects	2.00	0.00	0.00			0.00	0.00%
Annual Age-adjusted Cancer Mortality Rate	152.5	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT- Funded Research Projects	450	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	315	N/A	N/A	N/A	N/A		0.00%

### **Variance Explanations**

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

This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

### Cancer Prevention and Research Institute of Texas FY 2017, Quarter 1 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	800,000	175,441				175,441	14.26%
Number of Entities Relocating to TX for Cancer Research Related Projects	2.00	0.00				0.00	0.00%
Annual Age-adjusted Cancer Mortality Rate	152.5	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT- Funded Research Projects	450	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	315	N/A	N/A	N/A	N/A		0.00%

### **Variance Explanations**

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

This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

## Cancer Prevention and Research Institute of Texas FY 2018 Operating Budget

	2018	2017
Institute Operations (Indirect Administration)		
Salaries and Wages	\$ 1,617,425	\$ 1,347,500
Other Personnel Costs	52,785	67,785
Professional Fees and Services:	826,175	885,399
Consumable Supplies	27,584	27,584
Utilities	58,577	48,577
Travel	45,000	45,000
Rent-Machine and Other	32,172	34,207
Other Operating Expenses	370,934	574,600
Subtotal - Institute Operations	\$ 3,030,652	\$ 3,030,652
Grant Review and Award Operations		
Salaries and Wages	\$ 2,991,208	\$ 2,666,233
Other Personnel Costs	3,856	83,203
Professional Fees and Services:	10,443,893	10,681,494
Utilities	1,628	10,000
Travel	87,500	65,000
Other Operating Expenses	218,997	324,777
Subtotal - Grant Review and Award Operations	\$ 13,747,082	\$ 13,830,707
Grants		
Grants - Prevention	\$ 28,037,956	\$ 28,334,312
Grants - Research	252,272,756	251,780,562
Subtotal - Grants	\$ 280,310,712	\$ 280,114,874
Grand Total	\$ 297,088,446	\$ 296,976,233



To: **OVERSIGHT COMMITTEE** 

HEIDI MCCONNELL, CHIEF OPERATING OFFICER From:

**Subject:** FY 2018 SERVICE CONTRACT APPROVALS

Date: **AUGUST 7, 2017** 

### 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 \$243,750 to provide internal audit services; and
- Contract renewal with Hahn Public Communications for \$149,975 to provide strategic communication services.

The contracts being considered are not-to-exceed amounts, and payment is based on the delivery of actual services from the vendor, either time and materials 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 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;
- estimate 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 provide internal audit services to the agency based on an annual audit plan. The proposed FY 2018 audit plan includes audits over post award grant monitoring and grant contracting, state reporting, information technology services and communications. The plan includes follow-up on the procurement and P-cards, pre-award grant management, training, internal agency compliance and information security audits completed in FY 2017.

CPRIT awarded the initial contract to Weaver and Tidwell in FY 2016 and would exercise the second renewal option for services in FY 2018.

Contract Renewal with Hahn Public Communications for Strategic Communications Services Hahn Public Communications provides communications strategy services, media relations support, digital media advisory services, and communications program evaluation and assessment.

CPRIT awarded the initial contract to Hahn in FY 2015 and would exercise the third and final one-year renewal option in FY 2018.



OVERSIGHT COMMITTEE MEMBERS TO:

FROM: KRISTEN P. DOYLE, GENERAL COUNSEL

OVERSIGHT COMMITTEE SUBCOMMITTEE ASSIGNMENTS **SUBJECT:** 

AUGUST 8, 2017 DATE:

### **Summary and Recommendation**

Oversight Committee members submitted requests for subcommittee reassignments to the Chair of the Nominations Subcommittee. The Nominations Subcommittee discussed the subcommittee assignments at its meeting on July 28, 2017, and recommends that the Oversight Committee vote to approve the assignments.

### Discussion

The Oversight Committee Bylaws require the Oversight Committee to appoint and approve members of each subcommittee. Subcommittee assignments were last reviewed and changed in 2015. Prior to the July 28<sup>th</sup> meeting, Oversight Committee members submitted their preferences to the Chair of the Nominations Subcommittee who worked to balance out membership and chair assignments. A list of the recommended subcommittee assignments is on the following page.

The Nominations Subcommittee considered the proposed subcommittee assignments for FY 2018 – 2019 and recommends Oversight Committee approval.

### **Subcommittee Assignments**

CURRENT	Audit	Brd Gov	Nom	Prev	Aca Res	Prod Dev	Contract
Angelou	X		X			X	
Geren		X		X			Χ
Holmes		X	X	X			Χ
Margo	X	X		X		X	
Mitchell			X	X	X		
Montgomery	X				X		X
Rice	X	X			X	X	
Rosenfeld						X	Χ

X = Chair

PROPOSED	Audit	Brd Gov	Nom	Prev	Aca Res	Prod Dev	Contract
Angelou			X			X	
Geren		Х		Х			X
Holmes			X	Х			Χ
Margo	Х		Х	X		X	
Mitchell		X		Х	X		
Montgomery	Х	Х			Х		Χ
Rice	Х	Х			X	X	
Rosenfeld			Х			X	Х

X = Chair

	<b>Committee Assignments</b>		Chair		
	Current	Proposed	Current	Proposed	
Angelou	3	2	0	0	
Geren	3	3	0	1	
Holmes	4	3	2	1	
Margo	4	4	1	1	
Mitchell	3	3	0	1	
Montgomery	3	4	2	0	
Rice	4	4	1	2	
Rosenfeld	2	3	1	1	



TO: OVERSIGHT COMMITTEE MEMBERS

NED HOLMES, NOMINATIONS SUBCOMMITTEE CHAIR FROM:

INTENTION TO RECOMMEND APPROVAL OF SLATE OF OFFICER **SUBJECT:** 

**CANDIDATES** 

JULY 28, 2017 **DATE:** 

### **Summary and Recommendation:**

The Nominations Subcommittee intends to present the following slate of officer candidates for approval by the Oversight Committee: Will Montgomery, Presiding Officer (Chair), Dee Margo, Assistant Presiding Officer (Vice Chair), and Amy Mitchell, Secretary. The Oversight Committee must vote to approve the slate of officer candidates at its meeting on August 16, 2017.

#### Discussion:

Texas Health and Safety Code § 102.104 requires the Oversight Committee to elect a presiding officer and assistant presiding officer from among its members every two years. Although the Oversight Committee may elect additional officers, the presiding officer and assistant presiding officer may not serve in the position to which the officer was elected for two consecutive terms. CPRIT's Bylaws set the officer election at the last regular meeting of the state fiscal year in each odd-numbered year.

The Bylaws were amended at the May 20, 2015, Oversight Committee meeting to provide that the Nominations Subcommittee may recommend candidates for the Oversight Committee's consideration. The Nominations Subcommittee, working with Mr. Geren, the outgoing Oversight Committee presiding officer, has identified qualified members that are willing to serve in CPRIT's three officer positions: Will Montgomery, Presiding Officer (Chair), Dee Margo, Assistant Presiding Officer (Vice Chair), and Amy Mitchell, Secretary. The Nominations Subcommittee recommends Oversight Committee approval of the slate of candidates.

### Oversight Committee Meetings and Standing Subcommittees Meetings 2018

					Nove	mber 2017
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
10/29	10/30	10/31	1	2 Board Governance	3	4
5	6 Audit	7 Prevention	8 Academic Scientific Research	9 Product Development	10 Nominations	11
12	13 Bi-Annual Conference Day 1	14 Bi-Annual Conference Day 2		16	17	18
19	20	21	22	23	24	25
26	27	28	29 Oversight Committee Meeting	30	12/1	12/2

<sup>\*</sup> Pic Meeting Date (CPRIT Staff Only) - TBD

<sup>\*</sup> Portal Opening - TBD

					Feb	ruary 2018
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 Scientific Research	15 Product Development	16 Nominations	17
18	19	20	21 Oversight Committee Meeting	22	23	24

						May 2018
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
4/29	4/30	1 PIC Meeting CPRIT Staff Only	2 Portal Opens	3 Board Governance	4	5
6	7 Audit	8 Prevention	9 Academic Scientific Research	10 Product Development	11 Nominations	12
13	14	15	16 Oversight Committee Meeting	17	18	19

Note: Unless the subcommittee members agree to a different time, all subcommittee meetings will begin at 10:00 a.m. with the exception of Diversity and Nominations that will begin at 10:30 a.m. Members of the Audit and Program subcommittees should allocate 1.5 hours for a meeting. All others subcommittee meetings require one hour.

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### Oversight Committee Meetings and Standing Subcommittees Meetings 2018

					А	ugust 2018
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
7/29	7/30	7/31 PIC Meeting CPRIT Staff Only	1 Portal Opens	2 Board Governance	3	4
5	6 Audit	7 Prevention	8 Academic Scientific Research	9 Product Development	10 Nominations	11
12	13	14	15 Oversight Committee Meeting	16	17	18

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.