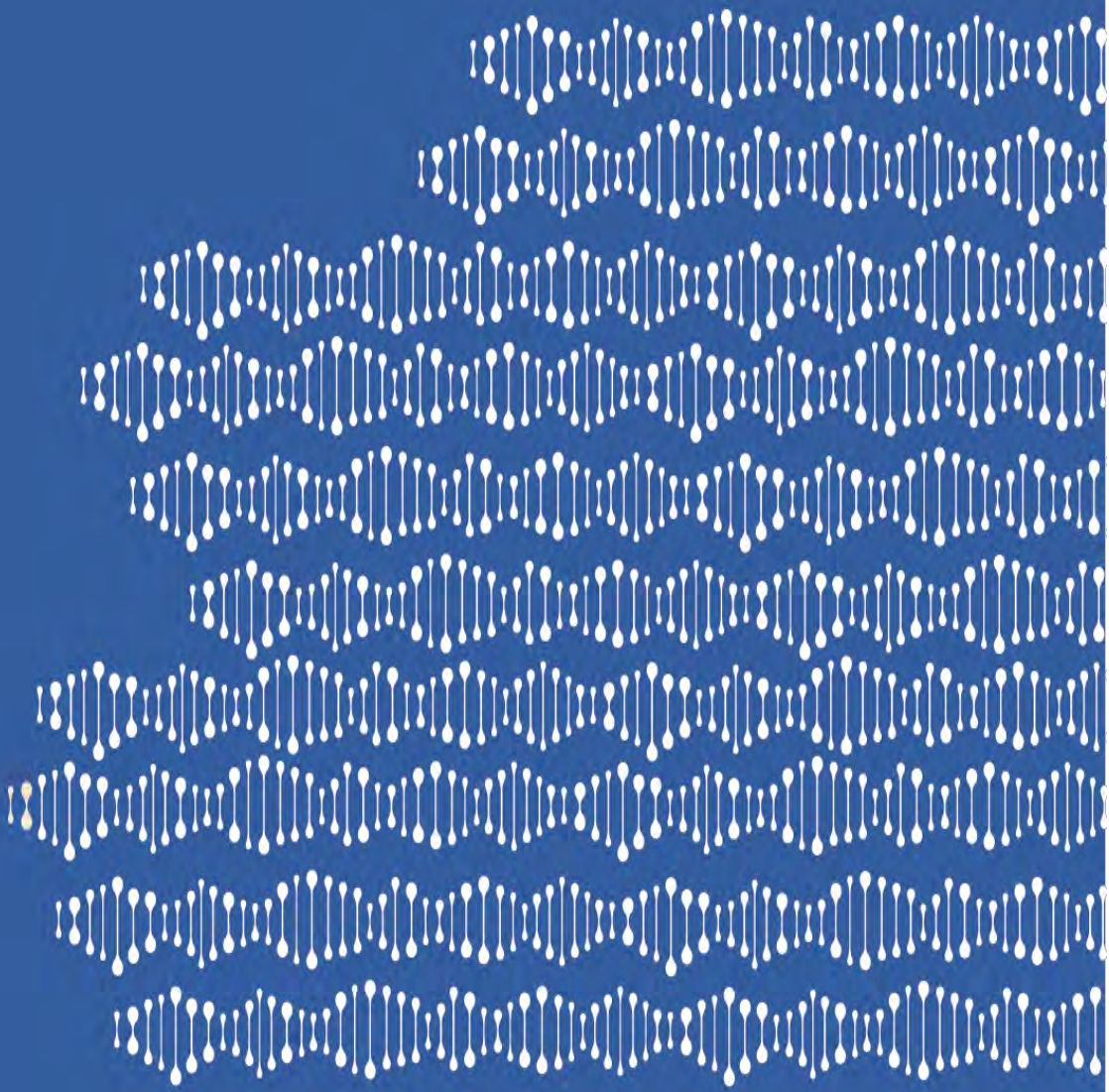
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

May 17, 2017



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Summary Overview of the May 17, 2017, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the May 17, 2017, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including a personnel update, legislative update, annual funding projections, report on FY 2017 Grant Award Funds Available, 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 ten award recommendations for Recruitment of Established Investigators; First-Time, Tenure-Track Faculty; and Rising Star grant recommendations totaling $25,104,127.

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
Dr. Becky Garcia will update the Oversight Committee on the Prevention Program activities as well as an update on the agency's communications activities.

Chief Product Development Officer Report
Mr. Mike Lang will provide an update on the Product Development Program.

Product Development Advisory Committee Report
The Chair of the Product Development Advisory Committee (PDAC) will present the PDAC annual report to the Oversight Committee.

Appointments - Scientific Research and Prevention Programs Committee and Product Development Advisory Committee
The Chief Executive Officer has provisionally appointed seven 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. In addition, Mr. Roberts has provisionally appointed 14 new members of the PDAC, which the Oversight Committee must approve. Biographical sketches for the PDAC appointees are included for the Oversight Committee's consideration.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and present two internal audit reports concerning internal agency compliance and training.

Amendments to 25 TAC Chapters 701 - 703
Ms. Eckel will present the final order approving amendments to Chapters 701 and 703 that the Oversight Committee provisionally approved at the February meeting. If approved, the amendments will become effective in June.

Ms. Eckel will also present one proposed change 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 August after the public has an opportunity to comment on the proposed rule changes.

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 second quarter of FY 2017. Ms. McConnell will present the FY 2018 Bond Issuance Resolution for approval by the Oversight Committee. She will also present recommendations for contract approvals for the following services: due diligence, grant management support, compliance monitoring, and outside legal services.

Election of Board Officers Process
Oversight Committee Chair Pete Geren will discuss the upcoming election of the Chair and Vice Chair. The Oversight Committee bylaws provide for an election at the last regular meeting of the Oversight Committee in each odd-numbered year. The Nominations subcommittee facilitates the election process by accepting nominations and recommending candidates for Oversight Committee consideration.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

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

May 17, 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 February 15, 2017, and April 17, 2017, meetings **TAB 1**
4. Public Comment
5. Grantee Presentations **TAB 2**
6. Chief Executive Officer Report **TAB 3**
   - CEO Report Pursuant to Health & Safety Code § 102.1063
7. Chief Compliance Officer Report **TAB 4**
8. Chief Scientific Officer Report and Grant Award Recommendations **TAB 5**
9. Chief Prevention and Communications Officer Report **TAB 6**
10. Chief Product Development Officer Report **TAB 7**
11. Product Development Advisory Committee Annual Report **TAB 8**
12. Scientific Research and Prevention Program Committee Appointments **TAB 9**
13. Product Development Advisory Committee **TAB 10**
    - Appointments
    - Charter
14. Internal Auditor Report **TAB 11**
    - Internal Audit Report Over Internal Agency Compliance
    - Internal Audit Report Over Training Program
15. Amendments to 25 T.A.C. Chapters 701 and 703 **TAB 12**
    - Final Order Approving Amendments to Chapters 701 and 703
    - Proposed Amendments to Chapter 703 and Authorization to Publish in *Texas Register*
16. Chief Operating Officer Report **TAB 13**
17. Contract Approvals **TAB 14**
    - Due Diligence Services
    - Grant Management Support Services
    - Compliance Monitoring Services
    - Outside Legal Services
18. FY 2018 Bond Issuance Resolution **TAB 15**
19. Election of Board Officers Process **TAB 16**

20. Subcommittee Business
21. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
22. Consultation with General Counsel
23. Future Meeting Dates and Agenda Items **TAB 17**
24. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting
February 15, 2017

1. Call to Order

A quorum being present, Presiding Officer Geren called the Oversight Committee to order at 11:03 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
Cynthia Mulrow, M.D.
Will Montgomery

3. Adoption of Minutes from November 17, 2016 meeting

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meeting November 17, 2106.

4. Public Comment

Presiding Officer Geren noted that Susan Dawson, a leader in the education reform community, had made a request for public comment. Ms. Dawson stated that CPRIT investments into preventing cancer could have a much greater impact if made in a way that more effectively leveraged the collective impact of multiple institutions in cancer research, treatment and prevention. Her suggestions included:

- Target grants/investments to focus on collaborative efforts of institutions (public and private) working together (not just multi-investigators)
- Target specific highly prevalent/low treatment efficacy cancer types as a platform for collaboration

There were no other requests for public comment.

5. Grantee Presentations

Presiding Officer Geren called on Dr. Rebecca Garcia, Chief Prevention and Communications Officer, to introduce Keith Argenbright, MD, MMM, Director of the Moncrief Cancer Center in Ft. Worth, part of The University of Texas Southwestern (UT Southwestern), Chief of the Division of Community Health Sciences at UT Southwestern, and a professor at the Harold C. Simmons Comprehensive Cancer Center.

Dr. Argenbright reported that the Moncrief Cancer Center provides education, early detection, patient navigation, and survivorship services to the medically underserved in 35 north Texas counties. The total population of underserved in those counties is estimated to be 3.45 million, and the Moncrief Cancer Center projects they will serve 1.29 million of that population with breast, cervical, and colorectal cancer screenings and patient navigation. Dr. Argenbright stated that the $800,000 CPRIT survivorship grant enabled the program to apply for and receive a federal grant valued at $21 million, which means they attracted about $26 for every dollar that CPRIT invested in that program.

The program provides cancer survivorship services to approximately 15,000 patients. Their services have resulted in a 31% increase in breast cancer screenings, 28% increase in colorectal screenings and a 17% aggregate increase in quality of life among survivors. Additionally, the program has a first-of-its-kind mobile clinic targeting underserved rural communities. The mobile clinic has 3-D mammography, telemedicine, an exercise area, nutrition education, consultation rooms, cervical screenings, and phlebotomy services. Dr. Argenbright stated that without CPRIT funding (over $17 million in multiple grants), the Moncrief Cancer Center would not be able to reach such a large service area.

An Oversight Committee member asked Dr. Argenbright about the number of men versus women served and whether the project provides lung cancer screenings. He responded that breast cancer is primarily, though not exclusively, a female cancer and that cervical cancer is only a female cancer. Colorectal screenings are divided evenly between men and women. Lung cancer screening is a relatively new screening and the program is contemplating a lung screening program. Additionally, the Moncrief Center held a prostate cancer awareness and education event.

In response to a question about how the "increase in quality of life" is measured, Dr. Argenbright stated that a survey is administered to patients when they enter the program and then again periodically throughout their time in the program. The 17% increase was statistically significant.

An Oversight Committee member asked why the program made the investment into a mobile clinic for screening. Dr. Argenbright discussed the difficulties rural residents encounter when having to miss work to drive hours into Ft. Worth for screening. Also, because trust often must be established with populations before they will accept the program's services, the mobile unit makes repeat trips to develop relationships with the rural communities.

Presiding Officer Geren called on Mr. Michael Lang, Chief Product Development Officer, to introduce the next grantee. Mr. Lang introduced Dr. Eric Poma, Founder and Chief Executive Officer, Chief Scientific Officer, and Director of Molecular Templates, Inc., with a doctorate degree in molecular biology and immunology and a master of business degree in finance. Molecular Templates is a biopharmaceutical company that has received multiple CPRIT grants.

Dr. Poma gave an overview of the drugs Molecular Templates is developing and the conduct of the clinical studies. He founded the company in 2009 with the goal of engineering a new class of oncology drugs. The medical community has largely optimized the benefits of chemotherapy and the genetic instability of cancer requires new ways of attacking tumor cells. Molecular Templates is having good success with treatment of elderly patients and patients who have failed or been unable to tolerate conventional treatment. He reports that the company would not have been able to reach this stage of clinical studies without CPRIT funding.

Presiding Officer Geren thanked the grantees for their work and for taking the time to make presentations to the Oversight Committee.

13. Internal Auditor Report

Presiding Officer announced that Agenda Item 13 – Internal Auditor Report would be taken up next out of agenda order.

Ms. Alyssa Martin, Internal Auditor, presented updates on the status of the 2017 Internal Audit Plan and Schedule, including the status of the internal audit of CPRIT training programs. There were no questions for Ms. Martin.

14. Advisory Committee on Childhood Cancer

Presiding Officer announced that Agenda Item 14 would be taken up next out of agenda order.

Dr. Willson introduced Dr. Susan Blaney, Chair of the Advisory Committee on Childhood Cancers (ACCC), to present the committee's annual report. He noted that Dr. Blaney is Deputy Director of the Texas Children's Cancer and Hematology Centers and Executive Vice Chair the Department of Pediatrics at Baylor College of Medicine.

Dr. Blaney reported that CPRIT expanded the committee recently to include representation of areas outside of the universities. She stated the success of CPRIT research applications focused on childhood cancers has continued to increase due in large part to focused RFA mechanisms resulting in the funding of more than 30 childhood and adolescent cancer research projects to date, an increase in the number of grant awards from 4% in 2014 to 16.7% in 2016. She noted that CPRIT-funded investigators have been able to garner an additional $17.5 million in follow-along funding. ACCC recommendations include:

- Issue RFAs for individual investigator grants specific to childhood and adolescent cancer on a continuous basis
- Release a RFA for multi-investigator research awards focused on childhood and adolescent cancer (with an emphasis on inter-institutional collaboration)
- Increase in the number of pediatric oncologists and laboratory investigators studying childhood cancer who serve on CPRIT grant review panels
- Consider setting aside at least one recruitment grant for pediatric oncology for each recruitment RFA
- Consider prioritizing recruitment of suitable candidates to underserved areas of Texas when appropriate research or clinical resources are available in those areas
- Continuation of the opportunity for institutions to submit an application for a shared resource to support research directed toward childhood and adolescent cancer in addition to an application to support another area of research
- Consider developing a grant funding mechanism to support the development of high-impact, multi-institutional shared resources that focus on childhood cancer
- Consider supporting childhood cancer research in Texas such as preclinical drug testing and/or model development cores, research or clinical (CLIA-certified) sequencing cores that define the genomic alterations in childhood cancers to more rapidly advance the field of precision medicine in pediatric oncology
- Explore innovative ways to facilitate and encourage commercial development of drugs and diagnostics for childhood cancer

15. University Advisory Committee – Annual Report

Presiding Officer announced that Agenda Item 15 would be taken up next out of agenda order.

Dr. Willson introduced Dr. Mary Ann Ottinger, Chair of the University Advisory Committee (UAC). Dr. Ottinger is Associate Vice Chancellor at the University of Houston System and Associate Vice President of Research at the University of Houston. Dr. Willson stated that the University Advisory Committee (UAC) meets quarterly with CPRIT staff. CPRIT staff consults the UAC before bringing project priority recommendations to the Oversight Committee.

As UAC chair, Dr. Ottinger presented the committee's annual report. She stated that the UAC members feel CPRIT is a critical catalyst, providing a focus on 1) understanding the underlying mechanisms and triggers that stimulate the onset and progression of cancer and cancer-related disease; 2) the efficacy of interventions; and 3) the testing of highly promising technologies and products. The committee feels recruitment grants continue to be highly effective in attracting talented cancer researchers to Texas institutions and they appreciate the interactive approach of the CPRIT staff with the cancer research community. UAC recommendations include:

- Consider funding programs that provide support for innovative clinical trials that incorporate translational studies involving biological/molecular correlates.

- Promote greater linkage between the Product Development Program and the research community, thereby enhancing the effectiveness of the Early Translational Research Awards.
- Monitor outcomes from Early Translational Research Programs, which are predicted to have high potential for impact.

In response to questions about the amount of paperwork required for CPRIT grants, Dr. Ottinger stated that a National Academy study showed that an investigator spends 42% of his or her time on administration, so anything to reduce paperwork allows more time for research. When asked if the UAC had any recommendations on how to streamline CPRIT's required paperwork, she stated the UAC would develop some recommendations during the coming year at the Oversight Committee's request.

7. Chief Compliance Officer Report

Presiding Officer announced that Agenda Item 7 would be taken up next out of agenda order.

Mr. Burgess presented the Chief Compliance Officer report on compliance activities over the last quarter.

Mr. Burgess highlighted the following activities:

Training & Support
CPRIT Oversight Committee members and CPRIT staff completed ethics and compliance training that was provided through an on-line module. Training covered the agency's Code of Conduct and Ethics, Conflict of Interest Policy, Non-Disclosure Agreement, and other required statements and certifications.

CPRIT has scheduled a grantee training webinar for March 9. The training fulfills an annual compliance training requirement for grantees' Authorized Signing Officials and other grantee staff. The training will focus on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process.

Mr. Burgess reported the following compliance activities that support the integrity and transparency of CPRIT's agency processes.

- FSR Reviews – 132 second-level reviews of grantee Financial Status Reports (FSRs) were performed during the month of January, of which 13 (10%) required resubmission due to insufficient or inaccurate documentation.
- Desk Reviews and On-site Reviews – 11 desk reviews and 2 on-site reviews were performed during the month of January.
- Annual Compliance Attestation (Self-Certification) – staff is currently working with three grantees to remediate attestation findings.

Mr. Burgess clarified that the grantee risk assessment, which assesses financial exposure, entity maturity and prior experience, is used to determine whether a grantee will receive a desk review, on-site review, or other type of compliance monitoring.

There were no questions for Mr. Burgess.

10. Chief Product Development Officer Report

Presiding Officer announced that Agenda Item 10 would be taken up next out of agenda order.

Mr. Michael Lang, Chief Product Development Officer, reported on the review cycle status, noting that of the three companies selected for due diligence in the FY 2017 Cycle 1, the Product Development Review Council did not recommend any applications for funding. For the FY 2017 Cycle 2, peer review will take place between March and July of 2017. He will present any recommendations for Oversight Committee consideration at the August 2017 meeting.

- Standard Revenue Sharing Terms

  Staff recommends a change to the standard revenue sharing terms for Product Development grants. The recommended change applies only to companies that are developing services, diagnostics, or devices. The standard revenue sharing terms for therapeutic companies receiving CPRIT grants remain the same as originally adopted in January 2015.

  The proposed change modifies the standard revenue sharing royalty rate to 2.5%, decreasing to 0.5% once the grantee has made revenue sharing payments totaling 2.5X the grant amount. The royalty obligation ceases when the governmental grant of exclusivity (e.g. patents) expires.

  The changed terms recognize the smaller profit margins for non-therapeutic companies. Revising the standard revenue sharing terms for services, diagnostics, and device firms may incentivize more companies to apply to CPRIT and diversify the Product Development portfolio.

- Matching Requirements for Second Awards

  Staff recommends that the Oversight Committee approve a change to the required amount of matching funds for Product Development grantees who are receiving their second CPRIT award. Grantees are currently required to dedicate to the grant project $1 of their own funds for every $2 of CPRIT grant award funds. The recommended proposal increases the Product Development grantee's matching fund obligation to $1 for every $1 contributed by CPRIT if the grantee is receiving a second Product Development grant.

Presiding Officer Geren asked the Chair of the Product Development Subcommittee to speak to the proposals for revenue sharing terms and matching requirements for second awards. Dr. Rosenfeld stated the subcommittee had considered both changes and recommended approval by the full Oversight Committee.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Holmes, the Oversight Committee unanimously voted to approve the recommended new revenue sharing terms for devices, diagnostics, services and other programs.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Holmes, the Oversight Committee unanimously voted to approve the recommended policy for increased matching fund requirements for Product Development grantees receiving a second Product Development grant.

Agenda Items 10, 19, 20

Presiding Officer Geren invoked Texas Open Meetings Act Section 551.071 and Health and Safety Code Section 102.2631 to move the Oversight Committee into closed session to take up Agenda Items 10, 19, and 20. Mr. Geren asked CPRIT staff Wayne Roberts (Chief Executive Officer), Kristen Doyle (Deputy Executive Officer and General Counsel), Michael Lang (Chief Product Development Research Officer), and Vince Burgess (Chief Compliance Officer) to join the Oversight Committee in the closed session.

Presiding Officer Geren convened the closed session at 12:55 p.m.

Presiding Officer Geren reconvened the open meeting at 2:49 p.m.

10. Chief Product Development Officer Report (continued)

Presiding Officer Geren called on Mr. Lang to present contract amendments for RP110508 and DP160057, awards to Bellicum Pharmaceuticals.

Mr. Lang reported that CPRIT awarded Bellicum contract RP110508 under revenue sharing terms in effect at the time of the award. CPRIT approved the award for DP160057 recently under current revenue sharing terms. For the convenience of both the company and CPRIT, the contract amendments would aggregate the total amount of both awards into the contract and apply current standard revenue sharing terms.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the recommended amendments for the Bellicum contracts RP110508 and DP160057 as presented by Mr. Lang.

Mr. Lang presented the contract amendment to CP120038 to Fujifilm Diosynth Biotechnologies (Fujifilm) for Oversight Committee approval. He explained that CPRIT made an award originally to a spinout from Texas A&M University called Kalon Biotherapeutics, a contract manufacturer of specialty pharmaceuticals. Since then, Fujifilm, a much larger international firm, acquired Kalon. The original award did not contain a royalty repayment because of the nature of the contract manufacturer, providing instead for payment through discounts offered to CPRIT awardees at Texas institutions. This process has not worked well for the parties. The proposed change requires the company to pay royalties, which CPRIT will credit differentially when earned from Texas institutions versus non-Texas institutions. This provides a return to CPRIT similar to the current standard structure of royalty-based returns, but incentivizes the company to continue to work with Texas institutions.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the recommended contract amendment for CP120038, Fujifilm Diosynth Biotechnologies as presented by Mr. Lang.

Presiding Officer Geren stated that the Oversight Committee would take no further action at this time on items discussed in closed session.

6. Chief Executive Officer Report

Wayne Roberts, Chief Executive Officer, presented his report including:

- The Senate Finance Committee budget held a hearing on February 1, 2017 related to CPRIT. CPRIT's budget hearing with the House Appropriations Subcommittee on Article I is scheduled for February 22, 2017.

  At the request of Presiding Officer Geren, a letter to the Legislative Leadership has been prepared for Oversight Committee consideration and signature during this meeting, which would add emphasis to CPRIT's budget request. Mr. Geren reported that CPRIT circulated the letter to Oversight Committee members at their desks. There were no questions from the Oversight Committee members.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve and sign the letter to legislative leadership showing support for CPRIT's legislative appropriations requested rider changes to enhance operational efficiencies and maximize available funds.

- Mr. Roberts stated the Sunset bills have been referred to committees in the House and Senate to extend CPRIT's sunset date from 2021 to 2023, along with the general operations bills that covers several topics. The most important element is giving CPRIT the ability to work with the Texas Treasury Safekeeping Trust Company.

- The American Cancer Society released the results of a poll in January related to CPRIT and cancer research. The poll indicates that 74% of the public believes that it is more important to fund cancer research through an entity such as CPRIT than to not spend the money.

- On February 7, 2017, the Texas Health Care and Biosciences Institute had its annual summit. One of the Institute's legislative priorities is to support CPRIT's legislative funding and agenda. On February 8, a number of the Institute's members visited legislators at the Capitol about a number of issues including support for CPRIT.

- CPRIT has three grant accountant vacancies, which are affected by Governor Abbott's freeze on state agency hiring. Staff has submitted a request for an exemption from the freeze for these positions which were approved by the last legislature to address State Auditor findings from January 2013.

- CPRIT has completed the 2016 Annual Report and hard copies will mailed to Oversight Committee members after printing.

- Sufficient funds are available for the awards being presented today. If the Oversight Committee approves all recommended awards, there will be a balance of $143.2 million available for the May and August meetings.

- Staff has created a "Significance Report" from responses gathered from closed CPRIT grants to identify what each grantee studied, what was learned, and what is the significance of the work to the taxpayers of Texas. CPRIT will continuously update and post this document on the agency's website.

There were no questions for Mr. Roberts.

8. Chief Scientific Officer Report and Grant Award Recommendations

Dr. James Willson, Chief Scientific Officer, reported on the impact of CPRIT's recruitment program. This program is unique to Texas and is nationally recognized as making it possible to do things in Texas "that are difficult or impossible to do in most other places" (*The Texas Brain Gain, J Clin Invest. 2012;12:424)*. Dr. Willson noted that of a total of 167 applications approved by the CPRIT Scientific Review Council, 74% have been accepted by the recruits.

Dr. Willson reported that CPRIT scholars include eight members of the National Academies of Science; Medicine, and Engineering; two members of the Howard Hughes Medical Institute; and two National Cancer Institute Outstanding Investigators. In addition to CPRIT funding, CPRIT Scholars received $195 million in follow-on research funding awards in national peer reviewed grants.

Academic Research Grant Award Recommendations

Dr. Willson presented five awards totaling $22,000,000 for Oversight Committee approval. He noted that the SRC approved application RR170007, Recruitment of Rising STAR Dr. Andrea Ventura, nominated by The University of Texas M.D. Anderson Cancer Center. Dr. Ventura declined the recruitment offer after the SRC made their recommendation.

Program Priorities Addressed:
Dr. Willson reported that all of the applications proposed to the Oversight Committee for funding this cycle address the Academic Research Program priority to recruit outstanding cancer researchers to Texas.

Academic Research Grant Award Recommendations

App ID	Candidate	Mech.	Organization	Budget
RR170013	Giuseppe Pelicci	REI	The University of Texas M.D. Anderson Cancer Center	$6,000,000
RR170011	Gerard Evan	REI	The University of Texas M.D. Anderson Cancer Center	$6,000,000
RR170008	Yair Reisner	REI	The University of Texas M.D. Anderson Cancer Center	$6,000,000
RR170010	Ram Madabhushi	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000
RR 170014	Han Xiao	RFTFM	Rice University	$2,000,000

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, presented his certification of the review process for the proposed grant awards recommended to the Oversight Committee at this meeting including Academic Research and Prevention awards. He stated he had reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the following mechanisms:

- Recruitment of Established Investigators
- Recruitment of First-Time, Tenure-Track Faculty Members
- Competitive Continuation/Expansion for Evidenced-Based Cancer Prevention Services
- Evidence-Based Cancer Prevention Services
- Dissemination of CPRIT-Funded Cancer Control Interventions

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 and

product development 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 Program Integration Committee's recommendations followed applicable laws and agency administrative rules. He certified the academic research and prevention award recommendations for the Oversight Committee's consideration.

Conflict of Interest Notification

Presiding Officer Geren noted for the record that no Oversight Committee member reported a conflict of interest with any recruitment application recommended for an award.

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

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

RP170259 Contract Amendment

Dr. Willson presented a proposed contract amendment for approval. He reported that he presented RP170259 to the Oversight Committee for approval in November 2016. The award approved by the Oversight Committee reflected the SRC's recommendations to reduce the number of Post-Doctoral trainees per year, to reduce the funding for the training program manager to 50% (from proposed 100% FTE), and to adjust the budget to reflect a reduction of 3 trainees per year. The award amount approved by the Oversight Committee on November 16, 2016, $2,071,403, reflected the reductions and adjustments recommended by the SRC.

However, when calculating the revised award amount for Oversight Committee approval, CPRIT staff did not include fringe benefit costs for six Post-Doctoral trainees. Fringe benefits are an authorized expense that may be included in grantee budgets. The exclusion was an inadvertent oversight.

Dr. Willson requested Oversight Committee approval to increase the funding for RP170259 by $576,748 to $2,648,151 to correct this omission. The revised amount is less than the budget originally requested in the grant application, but more than the amount originally approved by the Oversight Committee in November.

Research Training Award Recommendation

ID	Title	PI	Organization	Current Award	Recommended Award
RP170259	CPRIT Cancer Prevention Research Training Program	Chang, Shine	The University of Texas M. D. Anderson Cancer Center	$2,071,403	$2,648,151

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the recommended modification to the total award amount for RP170259 to $2,648,151, and to direct CPRIT staff to make the change to the award contract.

9. Chief Prevention and Communications Officer Report and Grant Award Recommendations

Presiding Officer Geren called Dr. Rebecca Garcia to report Communications and Prevention activities and to present the Prevention award recommendations.

Communications Report

Dr. Garcia reported on the Communications activities, including earned media, publicizing grant awards announcements, media coverage of CPRIT, ongoing projects, and events/meetings attended. She recognized Chris Cutrone for his work on CPRIT's 2016 Annual Report and Spencer Miller-Payne for his work on the Significance Report.

Dr. Garcia stated that in addition to the activities reported in the Oversight Committee meeting materials, staff had scheduled press meetings with new reporters to brief them on the background of the agency and its programs. The intent of the meetings was to educate, but ultimately the meetings resulted in some positive articles written about CPRIT.

Additionally, she reported that Communications staff will be using the various cancer awareness months to highlight the work of various grantees throughout the state. For example, January was Cervical Cancer Awareness Month and CPRIT's efforts resulted in seven broadcast stories and two online stories.

Prevention Program Report

Dr. Garcia presented an overview of the grant application cycle that produced the recommendations for consideration. She reported that five RFAs for Cycle 17.1 were released in May 2016. CPRIT received 36 applications. After administrative review, five were withdrawn and CPRIT assigned 31 applications requesting $36,684,532 to the review panels. Two peer review panels met in December 2016 in Dallas. The Prevention Review

Council (PRC) conducted a programmatic review January 20 and forwarded their recommendations to the Program Integration Committee (PIC). The PIC met January 31 and submitted its recommendations to the Oversight Committee for consideration today.

Dr. Garcia noted that CPRIT released five RFAs on November 17. Submissions are due March 2 with peer review meetings taking place in June. She will present recommendations to the Oversight Committee in August 2017.

Dr. Garcia reported that she and Ms. Magid held a webinar on January 11, 2017, to present the FY 2017 Cycle 2 funding opportunities and answer questions regarding the RFAs. More than 120 people participated in the webinar.

Prevention Grant Award Recommendations

Dr. Garcia presented nine projects totaling $12,024,696 for Oversight Committee consideration. The Program Integration Committee voted to defer one project, PP170037, until a future FY 2017 meeting, pending sufficient funding. Dr. Garcia presented the grant recommendations in three slates and noted the Prevention Program priorities addressed by the grant recommendations.

Number	Grant Type	Amount
5	Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services	$ 7,486,073
3	Evidence-Based Cancer Prevention Services	$ 4,238,623
1	Dissemination of CPRIT-Funded Cancer Control Interventions	$ 300,000

Number of Applications Addressing Priorities	
6	Prioritize populations disproportionately affected by cancer incidence, mortality or cancer risk prevalence
5	Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence
9	Prioritize underserved populations

Prevention Grant Awards

App ID	Mech.	Application Title	PD	Organization	Rec Budget
PP170036	CCE	Expansion and Continuation of Web-based Clinical Decision Support to Disseminate Tailored Screening Recommendations for Survivors of Pediatric Cancers	Poplack, David G	Baylor College of Medicine	$1,500,000
PP170046	EBP	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in high-risk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	$1,499,969
PP170004	CCE	DE Casa 2: Cervical Cancer Prevention in El Paso and West Texas	Shokar, Navkiran K	Texas Tech University Health Sciences Center at El Paso	$1,499,993
PP170023	CCE	Active Living After Cancer: Combining a Physical Activity Program with Survivor Navigation	Basen-Engquist, Karen M	The University of Texas M. D. Anderson Cancer Center	$1,494,530
PP170010	EBP	Cervical Cancer Screening and Patient Navigation (X-SPAN)	Argenbright, Keith E	The University of Texas Southwestern Medical Center	$1,499,816
PP170012	CCE	Building Bridges: Cancer Prevention Education and Screening for Refugees	Raines-Milenkov, Amy L	University of North Texas Health Science Center at Fort Worth	$1,491,550

App ID	Mech.	Application Title	PD	Organization	Rec Budget
PP170015	DI	Disseminating Evidence-Based Cancer Genomics Training to Community Health Workers	Chen, Lei-Shih	Texas A&M University	$300,000
PP170042	EBP	University Health System Hepatitis Viral Infection and Systematic Treatment Program (HepVISTA)	Villarreal, Roberto	University Health System	$1,238,838
PP170039	CCE	Nicotine Recovery Program (NRP)	Hollis, Gina	Mental Health Mental Retardation of Tarrant County	$1,500,000

CCE = Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services
EBP = Evidence-Based Cancer Prevention Services
DI = Dissemination of CPRIT-Funded Cancer Control Interventions

Presiding Officer Geren noted there were no reported conflicts of interest and that Mr. Burgess had previously certified these awards when he certified the Academic Research awards.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations for Evidence Based Cancer Prevention Services, Competitive Continuation/Expansion-Evidence Based Cancer Prevention Services, and Dissemination of CPRIT-Funded Cancer Control Intervention awards.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Margo, 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. Scientific Research and Prevention Program Committee Appointments

Mr. Roberts presented recommended appointments to the Scientific Research and Prevention Programs Committee.

Product Development Research Review Panels
- Leila Alland, M.D.

Academic Research Peer Review Panels
- Jean-Perre Issa, M.D.

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

12. Advisory Committee on Childhood Cancers Appointments

Mr. Roberts presented recommended appointments to the Advisory Committee on Childhood Cancers.

- Mohamad Al-Rahawan, M.D., MPH
- James Amatruda, M.D., Ph.D.
- Greg Aune, M.D.
- Juan Carlos Bernini, M.D.
- Stan Goldman, M.D.
- Meaghan Granger, M.D.
- Virginia Harod, M.D.
- Lisa Hartman, M.D.
- Barkat Hooda, M.D.
- Julie Luke, CPNP
- Cindy Schwartz, M.D., MPH
- Sheila Thampi, M.D

MOTION:
On a motion made by Mr. Holmes and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the nominations to the Advisory Committee on Childhood Cancers.

16. Amendments to 25 T.A.C. Chapters 701 and 703

Kristen Doyle, Deputy Executive Officer and General Counsel, presented the proposed administrative rule changes to Chapter 703 as originally considered at the November 2016 meeting. The first rule amendment, Section 703.13 (e), removes a reference to a superseded OMB Circular A-133. The second rule amendment, Section 703.25, explains that a request to carry forward unspent grant funds from one project year to the next requires CPRIT approval if the amount of unexpended budget line item balance is 25 percent or more of the line item amount for the year. After adoption, CPRIT will submit the proposed rule changes

to the Secretary of State. The rules are effective 20 days after submission.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Holmes, the Oversight Committee unanimously voted to approve the final order adopting rule changes to Texas Administrative Code Chapters 703.

Ms. Doyle then presented for Oversight Committee approval a request to publish proposed changes in the *Texas Register* for public comment as presented in the Oversight Committee meeting materials regarding Sections 701.3, 703.5, 703.6, 703.11, and 703.24. CPRIT will also announce the opportunity for public comment on the agency's website and via the CPRIT's electronic list serve. The proposed changes are to CPRIT's administrative rules setting policy guiding CPRIT's grant review and grant contracting processes. After the 30-day public comment period ends, legal staff will summarize all public comments for the Oversight Committee's consideration at the May 2017 meeting.

Ms. Doyle noted that staff withdrew the proposed change to Section 703.10. After internal discussion among all the CPRIT programs and with CPRIT Compliance staff, it was determined this change is not necessary since the information is available through CPRIT's Compliance Program.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the publication of the proposed changes to Texas Administrative Code Chapters 701and 703, with the exception of Section 703.10, for publication in the *Texas Register*.

17. Chief Operating Officer Report

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

- FY 2017, Quarter 1 Operating Budget
  CPRIT expended or obligated approximately $600,000 for Indirect Administration and $9.1 million for Grant Review and Award Operations. During the quarter, CPRIT collected $15,862 in revenue sharing payments.
- FY 2017, Quarter 1 Performance Measure Report
  CPRIT met or exceeded targets for its key prevention measures, but did not meet the performance target on the product development measure on company relocations to Texas because no companies relocated during the reporting period.
- Debt Issuance History
  The Texas Public Finance Authority issued $116.9 million in commercial paper notes on behalf of CPRIT since the beginning of FY 2017.
- Financial Audit for Year Ending August 31, 2016
  The audit performed by McConnell & Jones, LLP, was completed on December 5, 2016, with no audit findings.

There were no questions for Ms. McConnell.

18. Subcommittee Business

Presiding Officer Geren reported that he made interim subcommittee appointments to fill vacancies due to Oversight Committee member Cynthia Mulrow's resignation in November 2016. He requested final approval by Oversight Committee of the following subcommittee assignments:

- Prevention Subcommittee – Amy Mitchell and Dee Margo, with Mr. Margo as chair
- Audit Subcommittee – Will Montgomery will take over as chair of the subcommittee with Mr. Margo remaining as a member

MOTION:
On a motion made by Mr. Holmes and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the appointment of Amy Mitchell and Dee Margo to the Prevention Subcommittee, and to confirm Dee Margo as chair of the Prevention Subcommittee and Will Montgomery as chair of the Audit Subcommittee.

19. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
20. Consultation with General Counsel

Presiding Officer Geren reported that the Oversight Committee had already taken up Agenda Items 19 and 20 and no further action was necessary.

21. Future Meeting Dates and Agenda Items

Presiding Officer Geren announced the next regular Oversight Committee meeting for May 17, 2017, at 10:00 a.m.

22. Adjourn

MOTION:
There being no further business, the Oversight Committee unanimously approved a motion to adjourn made by Presiding Officer Geren and seconded by Dr. Rice.

Meeting adjourned at 3:57 p.m.

_____ _____

Signature Date

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting
April 17, 2017

1. Call to Order

A quorum being present, Presiding Officer Geren called the Oversight Committee to order at 8:00 a.m.

2. Roll Call/Excused Absences

Committee Members Present:
Angelos Angelou
Pete Geren
Amy Mitchell
Will Montgomery
Bill Rice, M.D.
Ned Holmes

Committee Members Absent:
Donald (Dee) Margo
Craig Rosenfeld, M.D.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to excuse the absence of Donald (Dee) Margo and Dr. Craig Rosenfeld.

3. Grant Nos. RP101219 and DP140067
4. Consultation with General Counsel

Closed Session

Pursuant to the Texas Open Meetings Act, Section 551.071, Presiding Officer Geren announced that the Oversight Committee would move into closed session to discuss Agenda Item 3 – Grant Nos. RP101219 and DP140067, and Agenda Item 4 – Consultation with General Counsel. The following staff were asked to join the Oversight Committee in the closed session: Wayne Roberts, Kristen Doyle, and Cameron Eckel. Also invited to join the closed session were Mollie Duckworth and Scott Powers, CPRIT's Outside Counsel with Baker & Botts LLP.

Presiding Officer Geren convened in closed session at 8:03 a.m.

Presiding Officer Geren reconvened the open meeting at 9:10 a.m.

MOTION:

On a motion made by Mr. Montgomery and seconded by Dr. Rice and Mr. Angelou, the Oversight Committee unanimously voted to authorize CPRIT's Chief Executive Officer and General Counsel to negotiate amendments to CPRIT Contract RP101219 Section 4.07 and any other contract sections necessary to CPRIT's contracts RP101219 and DP140067, consistent with our discussion in closed session, and to authorize CPRIT's Chief Executive Officer to execute the contract amendments.

Presiding Officer Geren called a recess at 9:12 a.m.

Presiding Officer Geren reconvened the open meeting at 9:23 a.m.

Closed Session

Pursuant to the Texas Open Meetings Act, Section 551.071, Presiding Officer Geren announced that the Oversight Committee would move into closed session for Agenda Item 4 – Consultation with General Counsel to include legal advice regarding Agenda Item 3 – Grant Nos. RP101219 and DP140067. The following staff were asked to join the Oversight Committee in the closed session: Wayne Roberts, Kristen Doyle, and Cameron Eckel. Also invited to join the closed session were Mollie Duckworth and Scott Powers, CPRIT's Outside Counsel with Baker & Botts LLP.

Presiding Officer Geren convened in closed session at 9:24 a.m.

Presiding Officer Geren reconvened the open meeting at 10:40 a.m.

5. Future Meeting Dates and Agenda Items

No discussion.

6. Adjourn

MOTION:

On a motion made by Dr. Rice and seconded by Montgomery the Oversight Committee unanimously voted to adjourn the meeting.
Meeting adjourned at 10:40 a.m.

_____ _____

Signature Date

Harpreet Singh, Ph.D

Chief Executive Officer

Dr Harpreet Singh co-founded Immatics Biotechnologies GmbH, the parent company of Immatics US, Inc. in 2000 during his PhD studies. Since then he has served over 15 years as Managing Director and Chief Scientific Officer of Immatics GmbH dedicated to the translation of science into highly innovative cancer immunotherapeutics as well as business concepts. At Immatics GmbH, he has led or significantly contributed raising more than $160m of venture capital in four financing rounds from 2004 to 2014 and is responsible for leading >50 FTEs dedicated to Target and TCR Discovery, Immunology, CMC and Translational Development.

Following creation of a business plan for development of adoptive cell therapies based on novel targets and T-cell receptors discovered by Immatics joined with cellular technologies developed by leading scientists at the MD Anderson Cancer Center, Harpreet Singh co-founded Immatics US, Inc. in 2015 raising approx. $20m public funding (CPRIT grant) by the State of Texas.

Trained in chemistry and biochemistry, Harpreet Singh completed his studies with his PhD in immunology at the University of Tuebingen with Hans-Georg Rammensee, a pioneering immunologist who discovered basic principles of all T-cell based immunotherapies – the presentation of peptides by HLA receptors – in the 1990s. Harpreet Singh is inventor on numerous patents and patent applications and has co-authored approx. 30 publications in peer-reviewed journals including Nature Medicine, Nature Biotechnology, Journal of Experimental Medicine, Brain and Blood.

Dean Edwards, Ph.D

Baylor College of Medicine

Professor

Mol & Cell Biology and Pathology & Immunology
Baylor College of Medicine
Houston, TX, US

Executive Director, Advanced Technology Cores

Baylor College of Medicine
Houston, Texas

Associate Director for Research Infrastructure

Baylor College of Medicine and Dan L. Duncan Cancer Center
Houston, Texas

Research Laboratory

Dr. Edwards' research laboratory has been funded by NIH grants for over 28 years in the areas of the biology and mechanism of action of steroid hormone receptors in normal mammary gland development and in breast cancer. Current studies include the role of progesterone as a risk factor in breast cancer through alterations of progesterone receptor (PR) signaling in early stages of breast tumorigenesis. Model systems have been developed to examine PR regulated transcriptional signaling pathways in normal mammary epithelial cells and how these pathways are dysregulated in pre-neoplastic lesions, including hyperplasias and ductal carcinoma in situ, and contribute to progression to invasive cancers. Also of interest are structure function studies of PR that have uncovered unique structural features of how coactivators interact to induce an active folded conformation of the intrinsically disordered amino terminal AF1 transcriptional activation domain. This structural information is being used for development of small molecules that interfere with PR AF1-coactivator interactions as a potential novel therapeutic target in breast cancer. Dr. Edwards also has extensive experience in Cancer Center leadership roles. Prior to joining BCM faculty in 2005, he was Director of a combined Cell Culture/ Monoclonal Antibody Shared Resource and was Program Leader of the Hormone Related

Malignancies Program of the University of Colorado NCI-designated Cancer Center. Since the inception of the NCI-designated Dan L. Duncan Cancer Center at BCM in 2006, Dr. Edwards has directed the Proteomics Shared Resource, has served as Associate Director for Research Infrastructure and is a member of the Cancer Center Executive Committee. As an Associate Director his role is to provide scientific guidance and oversight for all Cancer Center Shared Resources. In 2010, Dr. Edwards took on a new position as Executive Director of Institutional Advanced Technology Cores (ATC). This enabled a reorganization and centralization of Institutional Cores that included matching institutional support of Cancer Center Shared Resources as matrix Cores to fulfill the needs of both the Cancer Center and the Institution and minimize duplication of Cores. Dr. Edwards is also PI of a CPRIT (Cancer Prevention and Research Institute) supported Cancer Proteomics and Metabolomics Core Facility which provided funds for major expansion of the Cancer Center Proteomics Shared Resource and for start-up of the new Metabolomics Shared Resource.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 6, CHIEF EXECUTIVE OFFICER REPORT
DATE:	MAY 10, 2017

As of this writing the Chief Executive Officer Report for the May 17, 2017, Oversight Committee (OC) meeting will consist of the following items:

- Personnel update, including discussion of Governor Abbott's freeze on state agency hiring
- Legislative update
- Annual Funding Projections (update on funding ratio discussions)
- Report on "FY 2017 Grant Award Funds Available" (see following attachment)
- Other topics may be added as warranted

In addition, for your reference, copies of the CPRIT Activities Update for March and April 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 **1,123** grants totaling **$1.780 billion**

- 181 prevention awards totaling $181.1 million
- 942 academic research and product development research awards totaling $1.598 billion

Of the $1.598 billion in academic research and product development awards,

- 29.8% of the funding ($476.6 million) supports clinical research projects
- 27.0% of the funding ($431.6 million) supports translational research projects
- 24.6% of funding ($393.0 million) supports recruitment awards
- 14.9% of the funding ($237.3 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
- 5 Academic Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER

SUBJECT: ANNUAL FUNDING PROJECTIONS

DATE: MAY 10, 2017

Summary

Depending upon legislative action, CPRIT's sunset date of either 2021 or 2023 leaves an estimated $807-$842 million for research grant awards over its remaining authorized lifespan. Staff is preparing a working plan for use of these funds for Oversight Committee consideration at its August 2017 meeting to consider in the fall deliberations on the FY 2018 Program Priorities.

Background

Since January discussions have occurred at all agency levels about the funding ratio between Academic Research and Product Development Research.

Through February the cumulative ratio has been 79.5 percent Academic Research and 20.5 percent Product Development Research. At the May 2016 Special Work Session Oversight Committee members expressed an intent that the percent for Product Development should increase but a target was not specified. Based on that intent I established targets, or soft budgets for FY 2017 of 75 percent for Academic Research and 25 percent for Product Development Research. In doing so, I acknowledged that we would review this ratio with the Oversight Committee by the end of August 2017 for use in setting targets for FY 2018.

Based on preliminary reports from the peer reviews just concluded or underway it does not appear that the 75-25 split will be met this fiscal year. CPRIT peer review is rigorous—this year the Product Development Research reviewers did not forward a sufficient number of applications to increase the product development percent.

Discussion

As of May 10 the 85th Legislature has not adopted CPRIT's request to extend its Sunset date from August 2021 to August 2023. This decision will have a major effect on how much CPRIT has available for grant making and on how much CPRIT can award in each of its remaining years. Attachments 1 and 2 provide projections based upon 2021 or 2023 sunset. In short, if

CPRIT sunsets in 2021 the agency will have an estimated $806.6 million to award for research over three years. If we sunset in 2023 the estimate is $841.5 million over five years.

The difference between these 2021 and 2023 estimates is $34.9 million. This amount is lower than that previously articulated because these projections assume an aggressive spend down of the anticipated unexpended grant balances from awards of $56.2 million in CPRIT's remaining years. Previous estimates were less refined and assumed the $56.2 million would not be used between FY 2018 and whatever becomes the final sunset year. Furthermore, use of these balances in turn increases the amount of bond funds available for grants by $20-16.2 million per year which reduces the amount of unused bond authority previously projected.

Using these projections staff is developing a proposal for allocating funds for Oversight Committee consideration at its August 16, 2017, public meeting. It is likely that the funding projections will affect future annual Program Priorities adopted each November by the OC. Staff believes that the ratio and Program Priorities discussions are linked and can be combined for adoption by the Oversight Committee at its November 15, 2017, public meeting. This schedule allows time to analyze the Legislature's sunset decision and to review and modify a staff proposal by the Oversight Committee through the fall priorities setting process.

ATTACHMENT 1
ANNUAL FUNDING PROJECTIONS
2021 SUNSET DATE

	FY	Bonds	UB	Total		Less: Operations*	Amount Available for Awards	Less: 10% Prevention	Amount Available for Research	Academic Research**	Product Development Research**
Bonds committed thru 2-2017		2,009,231,008		2,009,231,008		174,805,567		181,098,812	1,598,491,032	1,269,805,384	328,685,648
Estimated May-Aug 2017								14,146,426	96,924,960	65,557,064	31,367,896
Less: Pro rata UB***									(56,235,789)	(44,988,631)	(11,247,158)
Subtotal thru 2017		2,009,231,008		2,009,231,008		174,805,567	1,834,425,441	195,245,238	1,639,180,203	1,290,373,817	348,806,386
	2018	300,000,000	20,000,000	320,000,000		20,000,000	300,000,000	30,000,000	270,000,000	202,500,000	67,500,000
	2019	300,000,000	20,000,000	320,000,000		20,000,000	300,000,000	30,000,000	270,000,000	202,500,000	67,500,000
	2020	300,000,000	16,235,789	316,235,789		20,000,000	296,235,789	29,623,579	266,612,210	199,959,158	66,653,053
	2021	12,000,000	0	12,000,000		12,000,000	0	0	0	0	0
	Totals 2018-21	**$2,921,231,008**	**$56,235,789**	**$2,977,466,797**		**$72,000,000**	**$896,235,789**	**$89,623,579**	**$806,612,210**	**$604,959,158**	**$201,653,053**
	Totals at Sunset 2021					246,805,567	2,730,661,230	284,868,817	2,445,792,413	1,895,332,974	550,459,439
	Program Percent							10.4%	89.6%	69.4%	20.2%
	Percent of Research									77.5%	22.5%
Unused Funding				**$22,533,203**							
	* Includes $2,969,554 / year transfer to DSHS										
	** 2018-2021 is 75-25 ratio										
	*** 2010-16 is 80-20 ratio										

ATTACHMENT 2
ANNUAL FUNDING PROJECTIONS
2023 SUNSET DATE

	FY	Bonds	UB	Total		Less: Operations*	Amount Available for Awards	Less: 10% Prevention	Amount Available for Research	Academic Research**	Product Development Research**
Bonds committed thru 2-2017		2,009,231,008		2,009,231,008		174,805,567		181,098,812	1,598,491,032	1,269,805,384	328,685,648
Estimated May-Aug 2017								14,146,426	96,924,960	65,557,064	31,367,896
Less: Pro rata UB***									(56,235,789)	(44,988,631)	(11,247,158)
Subtotal thru 2017		2,009,231,008		2,009,231,008		174,805,567	1,834,425,441	195,245,238	1,639,180,203	1,290,373,817	348,806,386
	2018	300,000,000	0	300,000,000		20,000,000	280,000,000	28,000,000	252,000,000	189,000,000	63,000,000
	2019	300,000,000	0	300,000,000		20,000,000	280,000,000	28,000,000	252,000,000	189,000,000	63,000,000
	2020	200,000,000	0	200,000,000		20,000,000	180,000,000	18,000,000	162,000,000	121,500,000	40,500,000
	2021	144,000,000	0	144,000,000		20,000,000	124,000,000	12,400,000	111,600,000	83,700,000	27,900,000
	2022	34,768,992	56,235,789	91,004,781		20,000,000	71,004,781	7,100,478	63,904,303	47,928,227	15,976,076
	2023	12,000,000	0	12,000,000		12,000,000	0	0	0	0	0
	Totals 2018-23	**$3,000,000,000**	**$56,235,789**	**$3,056,235,789**		**$112,000,000**	**$935,004,781**	**$93,500,478**	**$841,504,303**	**$631,128,227**	**$210,376,076**
	Totals at Sunset 2023					286,805,567	2,769,430,222	288,745,716	2,480,684,506	1,921,502,044	559,182,462
	Program Percent							10.4%	89.6%	69.4%	20.2%
	Percent of Research									77.5%	22.5%
Unused Funding				**$0**							
	* Includes $2,969,554 / year transfer to DSHS										
	** 2018-2023 is 75-25 ratio										
	*** 2010-16 is 80-20 ratio										

FY 2017 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	Prevention Percentage Based on Available Award Appropriations	Operating Budget	Total Appropriations
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	$ 300,000,000
Total Available for All Grants			$ 280,229,568		
Calculated 10% for Prevention Grants of Total Available Grant Funding			$ 28,022,957		
Adjustment for 10% Prevention Grants Limit	(296,355)	$ 296,355			
Adjustment to Address Avg Prevention Historical Limit	(1,851,835)	$ 1,851,835			
Revised Adjusted Appropriations	26,171,122	$ 254,058,446		$ 19,770,432	$ 300,000,000

	Prevention Grants	Academic Research Grants	PD Research Grants			
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 26,171,122	$ 190,543,834	$ 63,514,612			$ 280,229,568
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		$ 14,866,638				
11/16/16 AR Recruitment Awards		$ 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					
Announced Grant Award Subtotal	$ 12,024,696	$ 133,862,527	$ 32,146,716	$ -		$ 178,033,939
Grant Award Adjustments						
Declined Recruit Award (MDACC-Ye) 9/2016 Slate		$ (2,000,000)				$ (2,000,000)
Declined IIRA (BCM-Scott) 11/2016 Slate		$ (875,757)				$ (875,757)
Declined Recruit Award (MDACC-Clarke) 9/2016 Slate		$ (6,000,000)				$ (6,000,000)
Declined Recruit Award (MDA-Evan) 2/2017 Slate		$ (6,000,000)				$ (6,000,000)
Declined IIRA (MDACC-J. Chen) 11/2016 Slate		$ (900,000)				$ (900,000)
Reduction to IIRA (UTHSCSA-Aguiar) 11/2016 Slate		$ (267,840)				$ (267,840)
Declined Recruit Award (MDACC-Pelicci) 2/2017 Slate		$ (6,000,000)				$ (6,000,000)
Revised Grant Award Subtotal	$ 12,024,696	$ 111,818,930	$ 32,146,716			$ 155,990,342
Available Funds May 8, 2017	$ 14,146,426	$ 78,724,904	$ 31,367,896			$ 124,239,226
Pending Grants-PIC Recommendations						
Recruitment Awards		$ 25,104,127	$ -			
Pending Award Subtotal	$ -	$ 25,104,127	$ -			$ 25,104,127
Total Potential Grant Funding Committed	$ 12,024,696	$ 136,923,057	$ 32,146,716			$ 181,094,469
Potential Available Funds as of May 17, 2017	$ 14,146,426	$ 53,620,777	$ 31,367,896			$ 99,135,099
11/2016 PIC Deferred AR Grant Applications		$ 10,033,103				
2/2017 PIC Deferred PRV Grant Applications	$ 1,500,000					
PD Research Applications in Due Diligence (estimate)			$ 22,000,000			

Operating Budget Detail	
Indirect Administration	$ 3,030,652
Grant Review & Award Operations	$ 13,770,226
Subtotal, CPRIT Operating Costs	$ 16,800,878
Cancer Registry Operating Cost Transfer	$ 2,969,554
Total, Operating Costs	19,770,432

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2017

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			48			14							62	
New Grant Contracts Signed	9	15	6	4	21	11	10	20					96	
New Grant Contracts In Negotiation			41			15							56	
Grant Reimbursements Processed (#)	147	182	186	289	216	217	237	181					1,655	
Grant Reimbursements Processed ($)	$ 16,840,484	$ 13,844,271	$ 15,610,663	$ 25,547,229	$ 24,395,194	$ 35,405,089	$ 22,446,293	$ 17,441,664					$ 171,530,887	
Revenue Sharing Payments Received	$ 4,000	$ -	$ 11,862	$ -	$ -	$ 21,339	$ -	$ 5,728					$ 42,929	$ 3,178,132
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					$ 204,695,485	
Grants Awarded (#)/ Applications Rec'd (#)	12%	12%	13%	13%	13%	13%	13%	13%						
Debt Issued ($)/Funding Awarded ($)	64%	67%	64%	64%	67%	73%	73%	73%						
Grantee Compliance Trainings/Monitoring Visits	0	4	3	0	0	4	4	5					20	
Awards with Delinquent Reimbursement Submission (FSR)			1			0								63
Awards with Delinquent Matching Funds Verification			0			0								22
Awards with Delinquent Progress Report Submission			2			0								31
IA Agency Operational Recommendations Implemented	19	19	19	19	19	19	19	19						
IA Agency Operational Recommendations In Progress	19	19	19	19	19	19	19	19						
Open RFAs	11	3	5	10	10	10	13	8						
Prevention Applications Received	36	0	0	0	0	0	40	0					76	716
Product Development Applications Received	19	0	0	0	0	20	0	0					39	383
Research Applications Received	2	2	3	3	169	7	12	12					210	5,478
Help Desk Calls/Emails	230	247	167	110	254	254	163	195					1,620	
MISSION														
ACADEMIC RESEARCH PROGRAM														
Number of Research Grants Awarded (Annual)			46			6			0				52	
Recruited Scientists Announced														173
Recruited Scientists Accepted														127
Recruited Scientists Contracted														118
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														

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2017

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Patent Applications														
Number of Investigational New Drugs														
PRODUCT DEVELOPMENT RESEARCH PROGRAM														
Number of Product Development Grant Awarded (Annual)			2			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							9	
People Served by CPRIT-Funded Prevention and Control Activities			181,686			211,700							393,386	
People Served through CPRIT-Funded Education and Training			89,885			107,761							197,646	
People Served through CPRIT-Funded Clinical Services			91,801			103,939							195,740	
TRANSPARENCY														
Total Website Hits (Sessions)	5,975	5,618	7,019	5,137	8,089	7,798	6,805	5,577					52,018	
Total Unique Visitors to Website (Users)	4,485	4,009	4,768	3,608	5,563	5,673	4,978	3,848					36,932	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE – APRIL 2017
DATE:	MAY 3, 2017

Topics in the memo include preparation for the May Oversight Committee meeting, recent milestones in our fight against cancer, CPRIT staffing, legislative and related briefings, Compliance, Program, and Operations updates.

Preparation for the May 17 Oversight Committee Meeting

The Oversight Committee will meet May 17 at 10:00 a.m. in Board Room 1.170 of the Texas Higher Education Coordinating Board, 1200 E. Anderson Lane, Austin, Texas 78752. We have used this room previously when space at the Capitol was unavailable. We will post the final agenda for the Oversight Committee meeting by May 9, 2017; a tentative agenda is attached.

You will receive an email from CPRIT by May 5 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 ten 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 May 10. Hard copies of the agenda packet will be available at the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Congratulations to CPRIT grantee Dr. James Allison, Chair, Department of Immunology MD Anderson Cancer Center, upon his selection as one of TIME's 100 Most Influential People in 2017. Allison was one of six health care leaders on the list. The TIME article noted, "*It was Allison who figured out how to switch immune cells on to target malignant tumors. The drug he created is now spawning a new generation of immunotherapy treatments that experts hope will be less toxic and more aggressive than what's available now. His discoveries have already saved thousands of lives—and they're also forever changing what it means to have cancer.*"

National and international recognition continues to accumulate for Dr. Allison. He was elected to the 237th class of the American Academy of Arts and Sciences on April 12; he received the inaugural Sjöberg Prize from the Sjöberg Foundation and the Royal Swedish Academy of Sciences on March 31; and he will receive the 2017 Wolf Prize for Medicine in June during a ceremony at the Knesset, Israel's parliament. Dr. Allison was recruited to Texas with a CPRIT Established Investigator Recruitment Award.

- Jennifer Wargo, M.D., CPRIT grantee and associate professor of Surgical Oncology and Genomic Medicine, MD Anderson Cancer Center, was one of 10 early-career scientists to receive a $750,000, three-year grant from the Stand Up To Cancer (SU2C) Foundation on April 3, 2017. Dr. Wargo's team will use this award to expand studies of patient samples to build on her research to understand how the microbiome (collection of microorganisms living in or on the human body) affects response to immunotherapies. SU2C, a program of the Entertainment Industry Foundation, raises funds to accelerate the pace of cancer research to get new therapies to patients quickly and save lives.

- SU2C also recognized CPRIT grantee, Cassian Yee, M.D., at the University of Texas MD Anderson Cancer Center, with its Phillip A. Sharp Innovation in Collaboration Award on April 24. The award made provides $250,000 to reward distinctive collaborations that propose to accelerate current research and development models bringing therapeutic benefits for cancer patients. The award honors Dr. Phillip Sharp, who served as the original Chair of CPRIT's Scientific Review Council and is a strong advocate of team research. Dr. Yee was recruited to Texas with a CPRIT Established Investigator Recruitment Award

- Marc Cox, PhD, CPRIT grantee at the University of Texas at El Paso, received a $500,000 grant from the Department of Defense Prostate Cancer Research Program in March to develop more potent and effective drugs for the treatment of castration-resistant prostate cancer.

<u>Notable CPRIT Supported Research and Prevention Accomplishments</u>

- The Cyclotron and Radiochemistry Core at UT Southwestern Medical Center recently delivered its first radiotracer for human injection, launching a new era for nuclear medicine and molecular imaging in North Texas. CPRIT's $4.2 million instrumentation award from made it possible for UT Southwestern to acquire a cyclotron providing the sophisticated technology needed to create radiotracers. UT Southwestern is developing the core's initial radiotracer, Carbon–11 acetate, for clinical positron emission tomography (PET) imaging of brain tumors. After injecting a dose of Carbon–11 acetate into the bloodstream of a patient with brain cancer, the PET scan revealed a strikingly higher contrast in tumor masses compared with a conventional PET scans performed with radiolabeled glucose. UT Southwestern is developing Carbon–11 acetate to detect several other tumor types, including prostate, kidney, bladder, and lung cancers. Because Carbon-11 acetate has a short half-life, meaning the radioactivity level quickly diminishes, access to a cyclotron is required.

- Immune-Onc Therapeutics, a Palo Alto biopharmaceutical company developing innovative therapeutic antibodies for cancer treatment, has entered into an exclusive license and

collaboration agreement with UT Health Science Center at Houston and UT Southwestern. Immune-Onc will acquire the exclusive global rights to develop and commercialize novel biotherapeutics with applications in cancer immunotherapy. This collaboration will leverage the CPRIT-funded Therapeutic Monoclonal Antibody Lead Optimization and Development Core Facility at UT Health. The core advances lead antibodies from academic laboratories, and will utilize the preclinical and clinical drug development expertise of Immune-Onc to move lead candidates to clinical trials.

- Physicians at Baylor College of Medicine, Texas Children's Cancer Center, and Houston Methodist are conducting a CPRIT-supported clinical trial that provides access to a promising immune cell therapy for patients with glioblastoma. The clinical trial uses specially engineered T cells (known as CAR T cells) to target human glioblastoma cells. The CAR T cells are produced in the CPRIT-supported cell manufacturing facility of the Center for Cell and Gene Therapy at Baylor, which is one of the few academic institutions that has such a facility. Early results published in *JAMA Oncology* establish the safety of the CAR T cells and show a clinical benefit to patients. The study included 17 pediatric and adult patients with glioblastoma who received up to five escalating doses of the engineered T cells without significant side effects. Establishing the safety of this treatment is important, as other CAR T cell treatment approaches for solid tumors have resulted in significant side effects. Median survival of the patients who participated in the trial was 11.1 months following CAR T cell infusion and 24.5 months from diagnosis. Three patients in the trial have experienced no disease progression after more than two years of follow up.

- CPRIT grantee Padmanee Sharma, M.D., Ph.D., co-director of the Parker Institute for Cancer Immunotherapy at MD Anderson, recently reported in *Nature Medicine* on a CPRIT supported clinical study that appears to explain why prostate cancer is notoriously resistant to immunotherapy. Her team identified two pathways that "chill" the immune attack after treatment with the checkpoint inhibitor ipilimumab has fired up the immune system. Based on their findings, Dr. Sharma has launched a new clinical trial for patients with advanced prostate cancer that combines ipilimumab with a second checkpoint inhibitor to overcome the brakes on the immune system that follow ipilimumab. The new clinical trial, led by Dr. Sharma, will enroll 90 patients at nine centers nationally.

- Dr. Erez Lieberman Aiden, CPRIT grantee and director of the Center for Genome Architecture at Baylor College of Medicine, reported in *Science* on work by a high powered multi-institutional team that included Baylor College of Medicine, Rice University, Texas Children's Hospital, and the Broad Institute, that uses sophisticated computational methods to rapidly sequence genomes. They validated their approach through the de novo generation of a complete human genome and by generating the genome of *Aedes aegypti*, the mosquito vector of Zika virus. Click here to watch YouTube video by Dr. Aiden. Dr. Aiden was recruited to Texas with a CPRIT First Time, Tenure-Track Recruitment Award.

- CPRIT-funded researchers from UT Southwestern have developed a first-of-its-kind nanoparticle vaccine immunotherapy. Typical vaccines require immune cells to pick up tumor antigens and then travel to the lymphoid organs for T cell activation. Instead, nanoparticle vaccines package the tumor antigens to allow delivery directly to the body's

lymph nodes to activate tumor-specific immune responses. This research, published in *Nature Nanotechnology*, reported that the nanoparticle vaccine had anti-tumor efficacy in multiple tumor types in mice. The research was possible because of collaborations seeded by CPRIT awards to Dr. Jinming Gao, a bioengineer whose expertise is nanotechnologies, and Dr. Zhijian "James" Chen, an immunologist and Member of the National Academy of Science.

- DNAtrix Therapeutics announced results from four preclinical studies of new compounds based on their "armed virus" immunotherapies platform technology. DNAtrix's lead product, DNX-2401, an oncolytic (cancer killing) virus, is in clinical trials for recurrent glioblastoma, an incurable brain cancer. DNX-2401 sets off a chain reaction of tumor cell killing by selectively replicating within tumor cells for a period of weeks to months while sparing normal cells then secondarily triggering an anti-tumor immune response directed against the tumor. Patients with recurrent glioblastoma have tolerated DNX-2401 well and see prolonged survival compared to other therapies. The new compounds increase the company's probability of success and financial stability. DNAtrix received a Product Development Research grant in February 2014.

- ESSA Pharma Inc. announced updated Phase 1 clinical trial results showing their lead compound is safe and well tolerated at planned clinical doses. ESSA is developing novel drugs to treat prostate cancer. Their lead compound EPI-506 acts by disrupting the androgen receptor-signaling pathway, the primary pathway that drives prostate cancer growth. EPI-506 continues to be well tolerated through six escalating dose patient cohorts in the Phase 1 dose trial. The company plans to study an additional higher dose level. Higher dose levels increase probability of success in Phase 2 clinical trials. ESSA received a Product Development Research grant in February 2014.

- Medicenna Therapeutics Corp. announced that it treated the first patient in its Phase 2b clinical trial of MDNA55. The company is developing its lead candidate MDNA55 for the treatment of recurrent glioblastoma, the most common and incurable brain cancer. MDNA55 is a targeted immunotherapy with two mechanisms of action. It attacks the tumor cells and increases the therapeutic immune response to prevent tumor recurrence. The Phase 2b study will assess the safety and efficacy of MDNA55 on glioblastoma patients. Phase 2 clinical trials are a key inflection point in the drug development process. Therapies that show success in Phase 2 studies are likely to receive regulatory approval and are highly valued by the pharma industry. Medicenna received a Product Development Research grant in February 2015.

- Bellicum raised $6.4 million to support continued Phase 2 clinical studies on its lead compound BPX-501 and backup compounds. Bellicum is developing adjunctive T-cell therapies for blood cancers. Bellicum has developed cell therapies with "on and off switches" that can be used to control the potency of infused T-cells. This allows physicians to optimize dosage while mitigating potentially fatal side effects. The funds will also support a Phase 1 study of a backup compound. Bellicum received a Product Development Research grant in March 2011 to fund the development of BPX-501. CPRIT recently approved Bellicum for a second award in November 2016 to test a new combination therapy consisting

of BPX-501 along with donor stem cells that have been specially prepared to maintain certain beneficial cells that can work together with BPX-501.

- Texas is the first state in the country to provide cancer genomics training for health educators. This landmark is possible because of CPRIT grantee Dr. Lei-Shih Chen's Cancer Genomics Training program for a competent Texas health education workforce (Texas A&M University). The project has significantly increased Texans' cancer genomic literacy, adoption of personalized recommendations, and the ability to discuss their needs with specialists for further cancer genetic evaluation and testing. Dr. Chen received a CPRIT Prevention grant to fund this training program in February 2017.

- The CPRIT-funded Comprehensive Cervical Cancer Screening Program for Medically Underserved Women has developed a low-cost clinical platform that has screened and/or navigated more than 15,000 Harris County residents since 2012. These efforts have measurably reduced the incidence of cervical cancer and shifted the burden of this disease to earlier, more treatable stages. Preliminary results of a cost benefit analysis indicate that this CPRIT-funded project saves Harris County taxpayers more than $2 million annually in excess of program costs. This estimate does not take into consideration costs of time, lost productivity and other real-world expenses for the thousands of women the project has affected.

  The CPRIT project is a collaboration between Harris Health System and Baylor Medical Center, led by Dr. Matt Anderson. The findings have led to the implementation of system-wide organizational changes at the nation's third largest safety net health system. The changes have reduced the proportion of women lost to follow up from more than 40% to consistently less than 5%, increased the numbers of community health centers offering colposcopy from 4 to 14 and decreased the time to diagnostic resolution for an abnormal pap smear by more than half. The collaboration received CPRIT Prevention grants in January 2012 and November 2015 to develop and expand the program.

- Abbey Berenson, M.D., Ph.D., a CPRIT grantee at the University of Texas Medical Branch in Galveston, presented a poster in February 2017, at the 31st International Papillomavirus Conference in Cape Town, South Africa on "Postpartum HPV vaccination of young women delivering at a healthcare center in Southeast Texas, USA: A program assessment." Dr. Berenson displayed the poster for the full five days of the conference that drew 1,295 attendees from around the world. She reports very high interest in this approach to increasing initiation and completion among young women who did not receive the vaccine as adolescents. Dr. Berenson has received four CPRIT Prevention grants from CPRIT in 2012, 2014, 2015, and 2016 to increase HPV vaccination rates and low-income women and adolescents throughout Texas.

Legislative Update

Appropriations

CPRIT's proposed 2018-19 budget in the Senate and House versions of the General Appropriations Act remains unchanged from the bills introduced at the beginning of the session.

- The Senate Finance Committee did not take any action on agency requests to amend riders related to LBB approval of contracts worth $250,000 or more, LBB approval of agency transfers, and making the $2.9 million per year transfer to the Department of State Health Services (DSHS) for the Texas Cancer Registry sum certain to include Registry retiree health insurance payments. The Senate voted to approve the General Appropriations Act, SB 1, on March 28.

- The House Appropriations Committee, like the Senate, did not incorporate CPRIT's request to eliminate LBB contract approval or to make the DSHS transfer a sum certain. However, the House increased the contract amount threshold requiring LBB approval to $1,000,000 in the its introduced bill, so this difference between the House and Senate's threshold will be an issue for the budget conference committee to resolve. The House Appropriations Committee substituted its version of the budget for SB 1 on March 29 and the House adopted SB 1 on April 7.

- The Senate, as expected, failed to concur and named all budget conferees by close of business April 20. The Senate budget conferees are Jane Nelson, Juan Hinojosa, Joan Huffman, Lois Kolkhorst, and Charles Schwertner. The House budget conferees are John Zerwas, Oscar Longoria, Sarah Davis, Trent Ashby, and Larry Gonzales. In addition to deciding on the LBB contract approval rider the agency's request for an increase in the CEO salary will be determined at conference. The conferees began work April 24 and divided into small work groups that will meet privately to prepare recommendations for adoption at public meetings of the entire conference committee. As of this writing, there is no announced timeline for the final budget. However, the budget conference committee must distribute its report before midnight May 26 for approval in both chambers by May 28.

Funds Consolidation

Chairman Zerwas has filed HB 3849, the funds consolidation bill, which will be the vehicle for CPRIT's other request to exempt the statutorily authorized Interest and Sinking Fund from funds consolidation and thereby create the fund in the State Treasury. Creation of this fund means that the state will deposit grantee revenue sharing payments into it rather than the General Revenue Fund. House Appropriations reported the bill on April 18, but only as a "shell" with no funds listed yet. Assuming previous years serve as a guide; the bill will go over to the Senate late in the session when there is a better picture of the funds the two chambers want included. It will pass around the same time as the General Appropriations Act. We will continue monitoring this important bill.

CPRIT-Related General Legislation

As previously reported, we are monitoring six bills (three Senate bills and three House bills) that directly affect CPRIT:

- HB 63 (S. Davis) and SB 81 (Nelson) address CPRIT's operations. Other than the captions, these bills are identical. The bills add CPRIT to the list of major state agencies in the Government Code, fix the 10% cap on prevention by tying the cap to the appropriated amount for grants rather than the awarded amount, and authorize the Oversight Committee to

transfer management and decision making authority for CPRIT's revenue sharing assets to the Texas Treasury Safekeeping Trust Company. SB 81 passed the Senate on the Local and Uncontested Calendar on April 19 and sent over to the House. HB 63 was approved by the House on third reading April 25 by a record vote of 128-17-2.

- HB 84 (S. Davis) and SB 224 (Watson) change CPRIT's sunset date from August 31, 2021 to August 31, 2023. A fiscal note on the bills assessed a cost beginning in years 2022 of about $11 million per year. This is because, using fiscal note logic, continuing CPRIT two additional years allows the agency to issue $150 million that the state would otherwise not issue with a debt service payment of $11 million for 15-20 years. The fiscal note did not assess any costs for 2018-19. The Senate approved SB 224 on April 19 and sent it over to the House after a 23-8 vote. The House approved HB 84 on third reading April 25 by the House by a record vote of 105-40-2.

  The Texas Public Policy Foundation and Texas Conservative Coalition signaled their opposition to the CPRIT Operations and Sunset bills and support of the Self-Sufficiency bill (SB 1924, described below).

- SB 1924 (Schwertner) requires CPRIT to file annual reports, beginning in December 2018, detailing the agency's plan to transition to a self-sufficient entity after the $3 billion in constitutional authorization is expended. The plan must include the steps CPRIT will take to accomplish the transition, specify sources of funding other than state funds, and describe how CPRIT will structure state funded grants. Senator Schwertner filed a similar bill last legislative session that died on a point of order on the House floor. As of this writing, the bill does not have a House sponsor and the Speaker has not referred it to a House committee.

- HB 3721 (Parker) The "Improve Patient Access to Cancer Clinical Trials Act" establishes a program at CPRIT to encourage greater patient access to cancer clinical trials, including assisting patients facing financial barriers that inhibit participation by reimbursing direct patient incurred expenses and ensuring that trials are widely accessible. The bill also creates an ad hoc advisory committee addressing access to clinical trials. The House Committee on Public Health heard testimony on HB 3721 April 18 and voted it out of committee on April 27. As of this writing, the bill is not on the House calendar.

An unusual but not unprecedented situation exists with the operations and sunset bills in that they "crossed in the rotunda," meaning the two chambers each passed identical bills and forwarded them to the other chamber. Normally bill authors or parliamentarians and presiding officers hold or delay bill action to keep this from occurring to avoid having to repeat passage of the same bill in one chamber. This is not a normal session. Several scenarios exist to resolve this issue but are too complex to summarize in this memo. It is worth noting, however, that all four bills passed in their respective chamber by significant margins. We will report developments to the Oversight Committee.

CPRIT is also tracking other legislation that will affect state agency operations, including procurement, IT, and public information issues.

Personnel

As of April 30, 2017, CPRIT has 32 authorized full-time equivalent (FTE) positions, of which CPRIT has filled 31 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. The Governor's Office responded to my February waiver request indicating that it would not take action on the request at this time. Due to the importance of this compliance activity, we have contracted for two temporary accountants. The third is taking longer to fill than hoped because of high demand from other state agencies needing similar temporary expertise due to the hiring freeze.

Legislative Briefings and CPRIT Outreach

- Kristen Doyle, Heidi McConnell, and I briefed key legislative staff on CPRIT's remaining fiscal issues in meetings between April 4 and April 26.

- Dr. Becky Garcia, Chris Cutrone, Ramona Magid, Mike Lang, Ms. McConnell, and I attended luncheon presentations hosted by Representative Toni Rose in recognition of Minority Cancer Awareness Day.

- Ms. Doyle and I met with Susan Dawson to discuss her vision for facilitating collaborative cancer research initiatives. Ms. Dawson presented an overview at the February Oversight Committee meeting.

- Dr. Jim Willson, Dr. Garcia, and Michael Lang attended the annual American Association of Clinical Research meeting in Washington D.C. April 2 - 5.

- Ms. Magid participated in the teleconference meeting of the steering committee of the Texas HPV coalition on April 3.

- As a member of the advisory board, Dr. Garcia participated in the April 19 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.

- Dr. Garcia and Ms. Magid attended the steering committee meeting of the Texas Alliance for Colorectal Cancer Testing on April 20 in Austin.

- I discussed CPRIT rider issues that the budget conference committee will address with Representative Oscar Longoria on May 1.

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 the most recent CGMS report (April 24, 2017), two required grantee reports from two entities have not been filed in the system by the set due date; one is an Academic Research grant and one is a Product Development grant. Of the two delinquent reports, one is the result of a technology issue with CPRIT's grant management system. This issue should be resolved by May 15, allowing grantee submission of these reports. 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.

Grantees submitted two Financial Status Reports (FSRs) late; as a result, the grantees waived reimbursement for these two FSRs. 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 106 second-level reviews of grantee Financial Status Reports (FSRs) during the month of April. Nine 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 nineteen desk reviews during the month of April. So far this fiscal year, CPRIT has completed 157 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, subcontracting monitoring, and timeliness of required grantee report submission. Grant Compliance Specialists are working with 14 grantees to remediate desk review findings.

On-Site Reviews

Grant Compliance staff performed five on-site reviews during the month of April. 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 are required to 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. Grantees must submit an independent audit report, including any findings, 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 four grantees to remediate audit findings. CPRIT gives grantees 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 report 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 submitted a request for additional time on or before the due date of the required audit that CPRIT's CEO subsequently approved.

Academic Research Program Update

17.2 Academic Research Peer Review
Peer Review panels met in Dallas from April 19, 2017 through April 27, 2017 to conduct an evaluation of applications submitted in response to 17.2 RFAs for Core Facility Support Awards and Hi-Impact/Hi-Risk Research Awards. Oversight Committee member Will Montgomery attended several of the Peer Review panel meetings. Dr. Willson will present the grant applications recommended by the Scientific Review Council (SRC) to the Program Integration Committee and Oversight Committee in August 2017.

Recruitment 17.9 Update
The table below displays the number of applications by recruitment mechanism and total requested funding that the Scientific Review Council (SRC) will review. Dr. Willson will present the SRC recommended grant applications to the Program Integration Committee and Oversight Committee in May 2017.

Table 1: 17.9 Recruitment Summary Dashboard

Mechanism	# Applications	Total Requested Funding
Recruitment of Established Investigator	0	0
Recruitment of Rising Star	1	$4,000,000
Recruitment of First-Time Tenure Track Faculty Member	10	$20,000,000
Total	11	$24,000,000

Research Residency Rotation

CPRIT entered into a Letter of Agreement with the Texas Department of State Health Services Preventative Medicine Residency Program to provide a cancer research educational rotation for a Preventative Medicine Resident. The first Preventative Medicine Resident under this agreement, Dr. Emilie Prot, successfully completed a 30-day rotation within the Academic Research Program in March.

Product Development Research Program Update

FY 2017 Cycle 2 Product Development Research Applications

Applicants submitted twenty proposals for the second cycle of Product Development Research awards. CPRIT held Peer Review screening teleconferences March 28-29. At the meetings, the Peer Review panels selected six applicants to present their proposals to Peer Review panels in April. Following the Peer Review panels held April 25-26, The Product Development Review Council (PDRC) recommended two applicants for due diligence. Michael Lang will present the PDRC's recommendations to the Oversight Committee in August for approval.

FY 2018 Cycle 1 Product Development Research Applications

The RFA for the first award cycle of FY 2018 is under development. CPRIT plans to begin accepting applications for review by the end of June.

Advisory Committee Meetings

CPRIT convened the Product Development Advisory Council (PDAC) meeting on March 30 to discuss the Product Development Research program, including how to best utilize remaining CPRIT funding. The PDAC will present its annual report and recommendations to the Oversight Committee at its May meeting.

Prevention Program Update

FY 2017 Cycle 2 Prevention Applications

CPRIT released five RFAs for Cycle 17.2 in November 2016. CPRIT received 40 applications by the March 2, 2017 deadline. After administrative review, CPRIT withdrew three applications and assed the remaining 37 applications requesting $52,906,830 to the Peer Review panels. The

two panels will meet May 31 – June 2 in Dallas. Dr. Garcia will present the Prevention Review Council's recommendations to the Program Integration Committee and the Oversight Committee in August.

FY 2018 Cycle 1 Prevention RFAs

Prevention Program staff are currently preparing RFAs for the first cycle of FY 2018 with a projected release date in June. CPRIT expects to release the following RFAs:

- 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

Other activities

CPRIT submitted the Prevention Program performance measures report for the Legislative Budget Board on April 3.

Prevention Program staff discussed updating the Texas Cancer Plan with the DSHS' Texas Comprehensive Cancer Control program, Texas Cancer Registry and Office of Surveillance, Epidemiology and Research.

Communications

- Communications staff worked with the office of Representative Toni Rose, the UT Southwestern Moncrief Cancer Center and UT Health Northeast on promoting Minority Cancer Awareness Day at the Capitol (April 6). CPRIT produced a series of four videos featuring the UT Southwestern Moncrief Cancer Institute mobile screening unit and the UT Health Northeast inflatable colon that were set up at the Capitol. The videos feature interviews with Representative Rose, Dr. Keith Argenbright and Dr. Assal Rahimi of UT Southwestern, and UT Health Northeast Colorectal program manager Carlton Allen. CPRIT will distribute the videos via social media.

- Dr. Garcia and Chris Cutrone traveled to Dallas to interview Dr. James Brugarolas about UT Southwestern's SPORE grant from NCI on kidney cancer and CPRIT's crucial role in securing the grant. CPRIT will release the videotaped interview via social media in early May for National Cancer Research Month. You can read more about the SPORE grant at http://www.utsouthwestern.edu/research/kidney-cancer/awards/spore.html.

- Communications staff is working with the City of Houston and CPRIT partner institutions on a mayoral proclamation recognizing National Cancer Research Month. Plans include a presentation event prior to a City Council meeting with CPRIT Scholars from each institution in attendance. CPRIT is helping to draft proclamation language and working with partner institutions on the media strategy.

- CPRIT will open the abstract and registration system for the *2017 Innovations in Cancer Prevention and Research Conference* in May. CPRIT sent a listserv email message

providing information about registration and abstract submission as well as conference speaker and hotel information. The conference website was soft-launched at http://www.cprit2017.org/ in April.

- CPRIT's Twitter account recorded 9,000 impressions in April, approximately 345 per day. More than 1,180 accounts follow CPRIT on Twitter, with 10 new followers added in April. CPRIT was mentioned on Twitter 34 times in April, a 62% increase over March. CPRIT's Facebook account saw a 25% increase in April, reaching 28,000 people and receiving 14% more "likes" than the previous month.

Operations and Finance Update

- The Weaver audit team has completed reports for the training programs and agency compliance audits and is finalizing the report for the information security audit. The audit team also completed fieldwork for the internal audit over pre-award grant management.

- Two competitive solicitations for services closed in April. CPRIT solicited proposals for an IT risk assessment and for an accounting firm to perform CPRIT's annual financial audit. CPRIT staff is completing evaluations of the vendors who submitted proposals to each of the solicitations. We also completed FY 2018 pricing for several service contract renewals, including grants management support services, due diligence services, compliance-monitoring services and outside counsel services.

Upcoming Subcommittee Meetings

Listed below are upcoming May Oversight Committee subcommittee meetings.

Subcommittee	Date & Time
Board Governance	May 4 at 10:00 a.m.
Audit	May 8 at 10:00 a.m.
Prevention	May 9 at 10:00 a.m.
Scientific Research	May 10 at 10:00 a.m.
Product Development	May 11 at 10:00 a.m.
Nominations	May 12 at 10:30 a.m.

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

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CPRIT has awarded **1,123** grants totaling **$1.780 billion**

- 181 prevention awards totaling $181.1 million
- 942 academic research and product development research awards totaling $1.598 billion

Of the $1.598 billion in academic research and product development awards,

- 29.8% of the funding ($476.6 million) supports clinical research projects
- 27.0% of the funding ($431.6 million) supports translational research projects
- 24.6% of funding ($393.0 million) supports recruitment awards
- 14.9% of the funding ($237.3 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
- 5 Academic Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE – MARCH 2017
DATE:	APRIL 3, 2017

Topics in the memo include recent milestones in our fight against cancer; a legislative update, CPRIT staffing; legislative briefings and CPRIT outreach; Compliance; Program; and Operations updates.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Prevention grantees who made the news for Colorectal Cancer Awareness Month include Texas A&M Health Science Center, Texas Tech Health Sciences Center, and UT Health Northeast.

- Congratulations to CPRIT grantee Professor Jonathan Sessler who was named The University of Texas's inventor of the year. Dr. Sessler is Professor of Chemistry at UT Austin and a 40-year cancer survivor. The award recognizes his 75 patents including the development of Texaphyrin, an MRI imaging agent, and his role in co-founding Pharmacyclics, a biotech company sold in 2015 to AbbVie for $21 billion.

- CPRIT Scholar Kevin Pruitt, Ph.D., associate professor in the Department of Immunology and Molecular Microbiology at Texas Tech University Health Sciences Center (TTUHSC), was selected as the inaugural recipient of the Childers-Fralick Basic Cancer Research Endowed Chair. His work focuses on how specific proteins create epigenetic "footprints" in cancer cells that enable them to overproduce estrogen within tumors. Dr. Pruitt completed his Ph.D. training as a National Science Foundation pre-doctoral fellow in the Department of Pharmacology at the University of North Carolina at Chapel Hill and continued postdoctoral training at the Johns Hopkins University School of Medicine's Department of Oncology. During this period, Dr. Pruitt was recognized as an American Cancer Society postdoctoral fellow. After receiving the CPRIT Recruitment of Rising Stars award, he relocated his lab to TTUHSC.

- CPRIT grantee Hagop Kantarjian, M.D., chair of the Department of Leukemia at MD Anderson Cancer Center, reported results from a large multi-center clinical study that he led involving over 400 patients with heavily pretreated acute lymphocytic leukemia. The findings reported in the *New England Journal of Medicine* indicate that patients treated with an immune-based therapy, blinatumomab, had significantly longer survival and lower adverse effects than those getting standard chemotherapy. Blinatumomab, developed by Amgen, binds simultaneously to specific cytotoxic T-cells and B-cells to allow the patient's healthy T-cells to recognize and eliminate cancer stem cells.

- Two Texas medical schools, The University of Texas Southwestern Medical Center and Baylor College of Medicine, appeared on the *U.S. News and World Report* annual listing of the best and most innovative medical schools in the country. The *U.S. News and World Report* bases its list on surveys, student data, and research funding provided to schools from the National Institutes of Health.

Notable CPRIT Supported Research and Prevention Accomplishments

- The Department of State Health Services grant, *Tobacco Cessation Services for High Risk Populations*, has enhanced Texas smoking cessation efforts. About 18,000 individuals enrolled in cessation services through the quit line that included counseling and nicotine replacement therapy. During the grant period, the quit rate for those who enrolled in counseling was about 27 percent, resulting in 4,860 fewer tobacco users. A 2012 return on investment study of the Texas tobacco program activities by Kaiser Permanente's Center for Health Research indicate that for each person quitting results in an initial savings of $7,886 in health care costs and lost productivity during the initial five years. Using these data, during the three years of CPRIT funding for quit line services, Texas saw a return of $38.3 million.

- Dr. David Poplack's Baylor College of Medicine project, *Passport for Care* (PFC), has been successfully engaging childhood cancer survivors and their clinicians and providing them with information on follow-up screening/preventive services for the late effects of treatment. The PFC Clinician's Website now provides information used in the care of 4,830 survivors throughout Texas. The 2,717 survivors enrolled in the Survivor Website can access their cancer treatment history, follow up guidelines, and health information. The project has national impact - more than 27,000 survivors in more than 125 clinics are receiving tailored, accurate follow up guidelines and health information. In addition, national research studies in collaboration with the Children's Oncology Group are being developed using the PFC modules that have been used by 1,984 healthcare professionals.

- CPRIT grantees Lawrence Lum, Ph.D., associate professor of Cell Biology and Eric Olson, Ph.D., professor of Molecular Biology at UT Southwestern, unexpectedly discovered that an anticancer agent in clinical development with CPRIT funding promotes regeneration of damaged heart muscle and may help prevent congestive heart failure following heart attacks. For several years Dr. Lum has worked to develop a cancer drug that targets a cell signaling pathway (Wnt) crucial for tissue regeneration and frequently contributing to cancer. He designed an anticancer agent to inhibit an enzyme that is essential to the production of Wnt pathway proteins in humans. In testing the inhibitor in animals, he noted a curiosity. After further testing, Dr. Lum and Dr. Olson, an expert in heart muscle biology, determined that the heart's ability to pump blood in mice treated with the inhibitor improved nearly twofold compared to untreated animals. In addition to the improved pumping ability of hearts, the researchers noticed a reduction in fibrosis, or scarring, in the hearts of the treated mice. Collagen-laden scarring that occurs following a heart attack can cause the heart to inappropriately increase in size, and lead to heart failure. The *Proceedings of the National Academy of Sciences* published the findings and Dr. Lum hopes to advance the inhibitor into clinical testing as a regenerative agent for heart disease within the next year.

- CPRIT Scholar Andrew Futreal, Ph.D. and CPRIT grantee Jennifer Wargo, M.D., both at MD Anderson Cancer Center, identified patient characteristics that predict response to the immune checkpoint inhibitors. Their work, published in *Science Translational Medicine*, found that the presence of immune infiltrates in a patient's tumor after immune checkpoint inhibitor treatment is a strong predictor of a response. They also presented provocative evidence that the composition of a patient's gut bacteria affects response to the immune checkpoint inhibitors as well. Their findings are important because the immune checkpoint inhibitors help 20-30 percent of patients – with some complete responses lasting for years – but do not work for others. These findings provide new predictive indicators for success and suggest reasons for failure in those patients who do not benefit.

- In a cross-state collaboration supported in part by CPRIT grants, UT Dallas and Rice University scientists developed a computer model to predict mutations that adversely affect the interaction of proteins that have co-evolved to work together. Knowledge of these hot spots for protein-protein interface could aid in design of therapeutic drugs to intervene at that point. *Molecular Biology and Evolution* and the *Proceedings of the National Academy of Science* reported the research, led by Dr. Faruk Morcos, assistant professor of biologic sciences at UT Dallas, and conducted with CPRIT-funded computational scientists at Rice.

- Dr. Theodora Ross, CPRIT grantee and Director of the Cancer Genetics Program at Southwestern, reported in *Cell Reports* on findings that begin to explain one of the great mysteries in cancer research: why inherited mutations, such as those in BRCA1, cause cancer only in specific tissues such as the breast and ovaries, rather than in all tissues. She found

that the BRCA1 gene is required for the survival of blood forming stem cells, which explains why breast cancer patients carrying a BRCA1 mutation do not have elevated risk for leukemia. In contrast to breast cells, blood stem cells with a BRCA1 mutation die before they can transform into a cancer. This finding suggests a "die or transform" hypothesis to explain this tissue specificity. It is important because the BRCA1 gene predisposes women to breast and ovarian cancer when it is abnormal. BRCA1 and BRCA2 genetic mutations affect 10-15 percent of breast cancers. In addition to her cancer prevention and research programs, Dr. Ross authored a go-to guide for people facing a genetic predisposition for cancer**,** *A Cancer in the Family: Take Control of Your Genetic Inheritance*.

- Xiaobing Shi, Ph.D., associate professor of Epigenetics and Molecular Carcinogenesis at MD Anderson, reported in the journal *Nature* on CPRIT-funded research that opens new possibilities for treating acute myeloid leukemia, the second most common type of leukemia. He found that a protein called ENL "unlocks" leukemia-boosting signals and explained how a class of experimental drugs now in clinical trial called bromodomain and extra-terminal (BET) inhibitors may be effective in treating leukemia.

- Dr. Sandra Schmid, chair of Cell Biology at Southwestern, is an internationally renowned authority on how cells move molecules across the cell membrane. CPRIT awards have allowed her to apply this basic knowledge of normal cell behavior to cancers. In articles in the *Proceedings of the National Academy of Sciences* and *Developmental Cell,* she shows how cancer cells can repurpose tools of normal nerve cell communication to fuel aggressive tumor growth and spread. She found that dynamin1 (Dyn1) – a protein once thought to be present only in nerve cells – is also found in aggressive cancer cells. The cancer cells use Dyn1 for rapid uptake and recycling of the growth factors that allow cancer cells to multiply faster than noncancerous cells. She has also found that aggressive cancer cells have adapted these same nerve cell processes to thwart a key cancer-killing pathway triggered by activating "death receptors" on cancer cells. This research promises to improved strategies to fight the most aggressive cancers by targeting Dyn1. Currently, the Schmid laboratory is conducting research to identify Dyn1 inhibitors as potential anticancer drugs.

- Investigators working at the MD Anderson's Institute for Applied Cancer Science identified a gatekeeper protein called SMARCB1 that prevents pancreatic cancer cells from transitioning into a particularly aggressive cell type and found therapies capable of thwarting those cells when the gatekeeper is depleted. This NIH and CPRIT-supported research, recently reported in the journal *Nature*, relied upon preclinical experiments using patient-derived tumor xenografts and mouse models that point to potential treatments for patients with a rapidly progressing and resistant subgroup of tumor cells. These findings suggest a potential new strategy for treating pancreatic cancer.

- CPRIT grantee Cell Medica completed a $74 million financing round to support immunotherapy clinical research. The company is advancing two immunotherapy compounds originally developed at Baylor College of Medicine. Cell Medica's lead compound, CMD-003 is cell therapy used to treat advanced lymphomas. A Phase II clinical study is ongoing. Cell Medica, which established its U.S. headquarters in Houston as a condition of the CPRIT grant, collaborates closely with Baylor College of Medicine on a strong pipeline of novel immunotherapy compounds in development. Cell Medica received a Product Development Research grant in 2012.

- CPRIT grantee Pelican Therapeutics announced that Heat Biologics has agreed to buy an 80 percent controlling stake in the company in a strategic acquisition. Pelican is developing PTX-25, a novel drug to stimulate further T-cell response. Heat Biologics is a leader in the development of immunotherapies designed to activate a patient's immune system against cancer. The two companies plan to develop and use Pelican's drug together with ImPACT, Heat Biologics' technology that induces live human T- cells to secrete cancer antigens that stimulate the patient's immune system to destroy cancer cells. The objective of the combination is to enhance the durability of the T-cell response. Immunotherapy drugs have shown dramatic improvements in survival, but only for a portion of patients. Enhancing the durability of the patient's T-cell response may enlarge the target population. Pelican will operate as a Texas-based subsidiary of Heat Biologics. CPRIT approved Pelican for a CPRIT Product Development Research grant in 2016.

- Medicenna Therapeutics announced a strategic collaboration with MD Anderson Cancer Center on March 17. Medicenna, a CPRIT grantee, is a clinical stage immunotherapy company developing treatments for brain cancers affecting adults and children. The company's novel Interleukin-4 Empowered Cytokines fuse to cell-killing payloads and act as molecular Trojan horses targeting tumors that over-express the IL-4 receptor. The lead compound, MDNA55, has completed three clinical trials with promising results in more than 70 patients, including more than 60 adults with recurrent Glioblastoma, the most common and aggressive form of brain cancer. Medicenna executed a multi-year sponsored research agreement with MD Anderson to design, optimize, and advance preclinical development of Empowered Cytokines. Medicenna received a Product Development grant in 2015 to support clinical trials.

- The FDA approved CPRIT grantee Salarius Pharmaceuticals its lead compound, SP-2577, for orphan drug status to treat Ewing's sarcoma. The FDA also designated SP-2577 as a drug for a "rare pediatric disease." The designation means that SP-2577 is eligible for a Pediatric Priority Review Voucher (PRV) upon FDA approval. Both of these endorsements are important since orphan drug status qualifies SP-2577 for an expedited FDA regulatory review and approval. A PRV designation is a valuable transferable right to expedited FDA

review, which the company may sell to another company. Salarius specializes in developing novel drugs for rare pediatric cancers and other cancers by focusing on treatments that interrupt the final steps of the signaling cascade. Ewing's sarcoma is a rare devastating pediatric, adolescent, and young adult bone cancer with no approved treatment. Nearly half of patients diagnosed with Ewing's sarcoma fail to respond to chemotherapy, radiation, and surgical treatment and face 70%-80% mortality. If successful, a treatment for Ewing's Sarcoma represents hope for thousands of patients and their families where current treatments are often woefully inadequate. The company plans to begin Phase I clinical trials for Ewing's sarcoma and for late stage prostate cancer in 2017. Salarius received a Product Development Research grant in 2016.

- In a strategic move, CPRIT grantee Molecular Templates, Inc. merged with San Francisco-based Threshold Pharmaceuticals, a clinical stage biopharmaceutical company developing novel therapies for cancer. The merged company will be known as Molecular Templates and continue to be based in Austin. Following the merger, Molecular Templates will be listed on the NASDAQ (NASDAQ: MTEM). Molecular Templates' proprietary technology creates a new class of biologic drug candidates known as Engineered Toxin Bodies (ETBs) that deliver foreign class I antigens into tumor cells to boost immune recognition of the tumor. The company's lead drug candidate treats non-Hodgkin's Lymphoma. The Molecular Templates technology has the advantage of being able to generate "off the shelf" therapeutics that do not require patient cell harvesting or transplantation. Molecular Templates will have two clinical-stage compounds and a unique biological platform with a differentiated mechanism of action in oncology. Longitude Capital, a U.S.-based venture capital firm, will invest $20 million at the close of the merger, a commitment that is a strong testament to the promise inherent in the combined companies' clinical assets and technology platform. Molecular Templates received Product Development grants in 2012 and 2016.

Legislative Update

Appropriations

CPRIT's 2018-19 budget in the Senate and House versions of the General Appropriations Act remains unchanged from the bills introduced at the beginning of the session.

- The Senate Finance Committee did not take any action on agency requests to amend riders related to LBB approval of contracts worth $250,000 or more, LBB approval of agency transfers, and making the $2.9 million per year transfer to the Department of State Health Services for the Texas Cancer Registry sum certain to include Registry retiree health insurance payments. The Senate voted to approve the General Appropriations Act, SB 1, on March 28.

- Ms. McConnell and I testified on February 22 before the House Committee on Appropriations' Subcommittee on Articles I, IV and VII regarding CPRIT's biennial budget request. The full House Appropriations Committee accepted the subcommittee's report without changes on March 10. Like the Senate, the House Appropriations Committee did not incorporate CPRIT's request to eliminate LBB contract approval or to make the DSHS transfer a sum certain. Because the contract amount threshold requiring LBB approval was increased to $1,000,000 in the House's introduced bill, this difference between the House and Senate versions of the bill ($250,000 threshold) will be an issue for the budget conference committee to resolve. The agency's request for an increase in the CEO salary will be determined in the conference committee decisions on the budget.

Funds Consolidation

Chairman Zerwas has filed HB 3849, the funds consolidation bill, which will be the vehicle for CPRIT's other request to exempt the Interest and Sinking Fund from funds consolidation and thereby create the fund in the State Treasury. Creation of this fund will allow grantee revenue sharing payments to be deposited into it rather than the General Revenue Fund. The bill currently is a shell with no funds listed yet, so we will be monitoring it as it moves forward.

CPRIT-Related General Legislation

As of March 10, the last day that legislators could file new bills for consideration during the 85th legislative session without special permission, six bills (three Senate bills and three House bills) are filed that directly affect CPRIT:

- HB 63 (S. Davis) and SB 81 (Nelson) address CPRIT's operations. With expected committee substitutes, these bills will be nearly identical. The bills add CPRIT to the list of major state agencies in the Government Code, fix the 10% cap on prevention by tying the cap to the appropriated amount for grants rather than the awarded amount, and authorize the Oversight Committee to transfer management and decision making authority for CPRIT's revenue sharing assets to the Texas Treasury Safekeeping Trust Company.

- HB 84 (S. Davis) and SB 224 (Watson) change CPRIT's sunset date from August 31, 2021 to August 31, 2023. A fiscal note on the bill assessed a cost beginning in years 2022 of about $11 million per year. This is because, using fiscal note logic, continuing CPRIT two additional years allows the agency to issue $150 million that otherwise would not be issued with a debt service payment of $11 million for 15-20 years. The fiscal note did not assess any costs for 2018-19.

- SB 1924 (Schwertner) requires CPRIT to file annual reports, beginning in December 2018, detailing the agency's plan to transition to a self-sufficient entity after the $3

billion in constitutional authorization is expended. The plan must include the steps CPRIT will take to accomplish the transition, specify sources of funding other than state funds, and describe how CPRIT will structure state funded grants. Senator Schwertner filed this bill last legislative session. After passing the Senate and a House committee, a point of order on the bill was sustained during House debate and it was not enacted.

- HB 3721 (Parker) The "Improve Patient Access to Cancer Clinical Trials Act" establishes a program at CPRIT to encourage greater patient access to cancer clinical trials, including assisting patients facing financial barriers that inhibit participation by reimbursing direct patient incurred expenses and ensuring that trials are widely accessible. The bill also creates an ad hoc advisory committee addressing access to clinical trials.

Ms. Doyle and I provided resource testimony on HB 63 and HB 84 when the House Public Health committee considered the bills on March 21. We also served as resource witnesses when the Senate Health and Human Services committee took up the SB 81, SB 224, and SB 1924 on March 29. Many witnesses, including representatives for the American Cancer Society, the Leukemia & Lymphoma Society, the Texas Healthcare and Bioscience Institute, The Rose, the Texas Association of Business, Bellicum Pharmaceuticals, and Aeglea testified in favor of extending CPRIT's sunset date on behalf of the sunset bills. Principal investigators representing prevention and research projects at universities across the state also testified on the sunset bill (state law prevents state entities from advocating for legislation, so these witnesses served as a resource to the committee.) No one registered opposition to any CPRIT bills. The committee chairs left the bills pending in the committees, which is standard. We expect the committees to vote on the pending legislation this week. Speaker Straus has not yet referred HB 3721 to a House committee.

CPRIT is also tracking other legislation that will affect state agency operations, including procurement, IT, and public information issues.

Personnel

As of March 31, 2017, 30 FTEs of CPRIT's authorized 32 FTEs are filled.

Governor Abbott imposed an immediate hiring freeze at all state agencies and institutions of higher education on January 31 to last through the end of the 2017 fiscal year. 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 hiring freeze. On February 22, 2017, I requested a waiver from the hiring freeze to fill these three positions. The State Auditor identified the failure to have these positions as a weakness in his January 2013 *Audit Report on Grant Management at the Cancer Prevention and Research Institute of Texas and Selected*

Grantees and the Legislature specifically authorized the positions in the 2014-15 General Appropriations Act.

The Governor's Office notified CPRIT on March 21 that it is taking "no action at this time" on the request. Due to the importance of this activity to our compliance program, we are contracting for these services on a temporary basis. One temporary accountant began on March 27. However, high demand from other state agencies needing similar expertise due to the hiring freeze is making contracting for all three positions more difficult and taking significantly longer than desired.

Legislative Briefings and CPRIT Outreach

Kristen Doyle, Heidi McConnell, and I briefed Representative Stephanie Klick on CPRIT's activities and legislative issues on February 21.

Chris Cutrone, Mike Lang, Dr. Jim Willson and Dr. Becky Garcia and I met with a delegation of local officials from El Paso to discuss CPRIT funding opportunities on February 21.

Ms. McConnell, Ms. Doyle, and I briefed Senator Dawn Buckingham's staff on CPRIT's activities and legislative issues on February 28.

Ms. Doyle and Mr. Lang participated in a panel discussion about CPRIT at the 2017 Texas Life Science CEO Summit on February 28.

Drs. Garcia and Willson, Ms. Doyle, Mr. Cutrone and I attended a Childhood Cancer Awareness Day breakfast meet and greet hosted by Representative J.M. Lozano on March 1.

On March 1 and 7 Ms. Doyle, Ms. McConnell, Dr. Willson (March 1 only) and I discussed proposed clinical trials legislation with Representative Tan Parker's staff.

Dr. Willson, Mr. Lang, and I met with representatives of Texas Biomedical Research Institute from San Antonio on March 2 to discuss changes in their executive management and CPRIT funding opportunities.

I met with Representative Geanie Morrison on March 6 to discuss CPRIT activities and legislative issues.

At the invitation of the Governor's Office of Economic Development's Texas One, I presented information about CPRIT on March 10 to the Select USA Delegation, a group of European medical device companies looking to relocate in the United States.

Ms. Doyle and I met with Representative Nicole Collier to discuss CPRIT activities and legislative issues on March 29.

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 550+ grants that are either active or wrapping up grant activities and receives an average of 570 grantee reports each month.

As of the most recent CGMS report (March 20, 2017), seven required grantee reports from six entities have not been filed in the system by the set due date; five (71%) are Academic Research grants, one (14%) is a Prevention grant, and one (14%) is a Product Development grant. Of the seven delinquent reports, three are the result of a technology issue with CPRIT's grant management system. This issue should be resolved by the end of March, allowing grantee submission of these reports. 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 156 second-level reviews of grantee Financial Status Reports (FSRs) during the month of March. Sixteen FSRs (10%) 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 twelve desk reviews during the month of March. So far this fiscal year, CPRIT has completed 108 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, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee

report submission. Grant Compliance Specialists are working with 14 grantees to remediate desk review findings.

On-Site Reviews

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

Annual Compliance Attestation (Self-Certification)

Grantees are required to 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.

Training & Support

On February 8, 2017, CPRIT staff conducted a training for the new Authorized Signing Official (ASO) for The University of Texas Health Science Center at Houston. CPRIT's rules require that in the event of a change in the ASO designated by the Grant Recipient on or after November 1, 2016, the new ASO must complete the annual compliance training program within 60 days of the change. Failure to do so may result in withholding of Grant Award funds until the training is completed.

CPRIT staff conducted a grantee training webinar on March 9, 2017, with about 150 grantee staff in attendance. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process. This webinar was in support of the annual compliance training requirement, which states that the ASO and at least one other employee from each grantee organization must attend an annual compliance training by November 1 of each year. CPRIT has scheduled a second grantee training webinar tentatively for June 7, 2017.

Academic Research Program Update

FY 2017 Cycle 2 Academic Research Review Cycle

More than 160 applications submitted in response to Cycle 17.2 RFAs for Core Facility Support Awards and High Impact/High-Risk Research Awards will undergo peer review in Dallas from April 19 through April 27, 2017. Core Facilities Support Awards (RFA R-17.2- CFSA) support an institution's efforts to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs. Grantees may receive up to $3 million (total costs) for the first two years and up to $1 million per year for up to three additional years. High Impact/High-Risk Research Awards (RFA R-17.2-HIHR) provides short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. The maximum award is $200,000 (total costs) to fund a project lasting no more than two years.

The table below displays the number of applications under review and total requested funding.

17.2 Peer Review Summary Dashboard

Mechanism	# Applications	Total Requested Funding
Core Facility Support Awards	24	$116,224,521
Hi-Impact/Hi-Risk Awards	143	$28,496,610
Total	167	$144,721,131

Product Development Research Program Update

FY 2017 Cycle 2 Product Development Research Applications

Twenty applicants submitted applications by the February 9 deadline. Peer reviewers met by conference call for screening teleconferences on March 28 and 29 to select companies for in person peer review meetings. The peer review committees selected six companies for in-person presentations that will take place April 25 in Dallas. Following due diligence, any company award recommendations will come to the Program Integration Committee and the Oversight Committee for consideration in August.

FY 2018 Cycle 1 Product Development Research Applications

The RFAs for the first cycle of awards in FY 2018 is under development. CPRIT expects to release the RFAs in late May/early June and begin accepting applications in late June.

Advisory Committee Meetings

The University Advisory Council (UAC) met on March 21, 2017. UAC Chair Dr. Ottinger led the meeting. The Committee provided input to CPRIT as related to Academic Research Programmatic Planning. Three new members to the committee, Carrie Byington, M.D., Texas A&M University System appointee; David Niesel, Ph.D., University of Texas System appointee, and Peter S. Rotwein, M.D., Texas Tech University System appointee, attended the meeting. The University of North Texas System member remains to be appointed.

The Product Development Advisory Committee (PDAC) met on March 30, 2017. Dr. Jonathan MacQuitty and Dr. David Lowe were appointed chair and vice chair, respectively. The PDAC discussed Product Development priorities, including translational and clinical research, and how to best use remaining Product Development grant funds. The PDAC will present its annual report to the Oversight Committee at the May 17th meeting.

Prevention Program Update

FY 2017 Cycle 2 Prevention Applications

CPRIT released the following RFAs on November 17, 2017:

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

Forty applications were received by the March 2 due date. CPRIT is assigning applications to panels and reviewers this month with peer review in June. The Program Integration Committee and the Oversight Committee Recommendations will consider grant recommendations in August.

Other activities

CPRIT rolled out the new Prevention Program grantee quarterly reporting tool on February 4. Prevention Program Senior Program Manager Ramona Magid held three training webinars to demonstrate use of the tool and initial reports using it were due March 15. CPRIT is reviewing the reports and preparing data for submission to the Legislative Budget Board as part of the required quarterly report on April 3.

Communications

2017 Innovations Conference

Selection of topics and faculty for the program is underway. To date, CPRIT has confirmed seven faculty (presenters). There has been a delay in selecting a vendor for the registration and abstract system due to new audit reporting requirements imposed on potential vendors. The audit reporting requirement not only adds about $22,500 in cost but also delays by 4-6 weeks registration and abstract submissions.

Cancer Awareness Months Activities

Communications plans for 2017 include working with CPRIT grantees to promote their work in conjunction with national cancer awareness months. February was National Cancer Prevention month. Dr. Garcia and Dr. Argenbright from UT Southwestern Medical Center provided video interviews that CPRIT released via social media.

During March, CPRIT received substantial broadcast media coverage for Colorectal Cancer Awareness Month. CPRIT social media activity continues to increase this month with almost daily posts highlighting colorectal cancer awareness. During the first 21 days of March, CPRIT earned 7.4K impressions (number of times users saw a Tweet on Twitter), about 375 per day. CPRIT's Facebook page saw its average hits increase to 195 in March from 161 in February.

Colorectal Cancer Awareness Month is one of the busiest for the advocate community, which gave CPRIT and grantees multiple opportunities for earned media. We worked with three of our grantee institutions to secure earned broadcast media in their local markets.

- Chris Cutrone went to Lubbock to assist with earned media efforts for CPRIT grantee Dr. Theresa Byrd and her program *Accion for Rural West Texas*, a Texas Tech Health Sciences Center colorectal cancer screening program. Earned media centered on a proclamation ceremony recognizing Colorectal Cancer Awareness Month during a session of the Lubbock City Council. Coverage was on Fox 34 and Telemundo (Spanish).

- Colorectal Cancer Awareness Month coverage included Texas A&M Health Science Center's Texas C-STEP program. Janet Helduser and Dr. David McClellan of Texas C-STEP were interviewed on KBTX CBS.

- CPRIT was the center of coverage on UT Health Northeast's colorectal screening programs. There were five airings, three on the NBC affiliate, KETK, and two on the FOX affiliate, KFXK/ FOX 51.

In addition, Spencer Miller-Payne, Communications Specialist, participated in a "Tweetchat" via CPRIT's Twitter site (@CPRITTexas) that was hosted by Texas A&M University Health Sciences Center. Participants included NCI, UTHSC-San Antonio, Colon Cancer Alliance and Baylor College of Medicine, Scott & White among others. CPRIT also provided video of Dr. Jim Willson discussing colorectal cancer prevention and research.

Other Activities

- CPRIT communications staff worked with UT Southwestern communications staff on a story for the Fort Worth Business Press on CPRIT Prevention grantee Dr. Keith Argenbright. We are now working with them on a short video for social media focusing on UTSW's SPORE grant from NCI on kidney cancer and CPRIT's role in securing that grant.

- The Communications team is developing a short video for social media focusing on CPRIT Product Development Research grantee Molecular Templates.

- The Achievements Report was redesigned for 2017 with the new version released immediately after the February Oversight Committee meeting.

- Staff continues to respond to requests for information and prepare legislative briefing materials.

Operations and Finance Update

The Weaver audit team is completing reports on several internal audit reports including training programs, information security, and agency compliance. On March 20, the audit team began field work for the internal audit over pre-award grant management.

Upcoming Subcommittee Meetings

Upcoming May Oversight Committee subcommittee meetings are listed below.

Subcommittee	Date & Time
Board Governance	May 4 at 10:00 a.m.
Audit	May 8 at 10:00 a.m.
Prevention	May 9 at 10:00 a.m.
Scientific Research	May 10 at 10:00 a.m.
Product Development	May 11 at 10:00 a.m.
Nominations	May 12 at 10:30 a.m.

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

*****

CPRIT has awarded **1,123** grants totaling **$1.780 billion**

- 181 prevention awards totaling $181.1 million
- 942 academic research and product development research awards totaling $1.598 billion

Of the $1.598 billion in academic research and product development awards,

- 29.8% of the funding ($476.6 million) supports clinical research projects
- 27.0% of the funding ($431.6 million) supports translational research projects
- 24.6% of funding ($393.0 million) supports recruitment awards
- 14.9% of the funding ($237.3 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
- 5 Academic Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	MAY 8, 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.

The CGMS report on April 24, 2017 identified two required grantee reports from two entities that were not filed in the system by the set due date; one was an Academic Research grant and one was a Product Development Research grant. Of the two delinquent reports, one was the result of a technology issue with CPRIT's grant management system. This issue should be resolved by May 15, allowing grantee submission of this report. 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 the month of April two Financial Status Reports (FSRs) were submitted late and 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 118 second-level reviews of grantee Financial Status Reports (FSRs) during the month of April. Ten 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 compliance staff has performed 157 desk reviews so far this fiscal year. 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, subcontracting monitoring, and timeliness of required grantee report submission. Grant Compliance Specialists are working with 14 grantees to remediate desk review findings.

On-Site Reviews

Grant Compliance staff performed five on-site reviews during the month of April. Thirteen on-site reviews have been performed so far this fiscal year. 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 are required to 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.

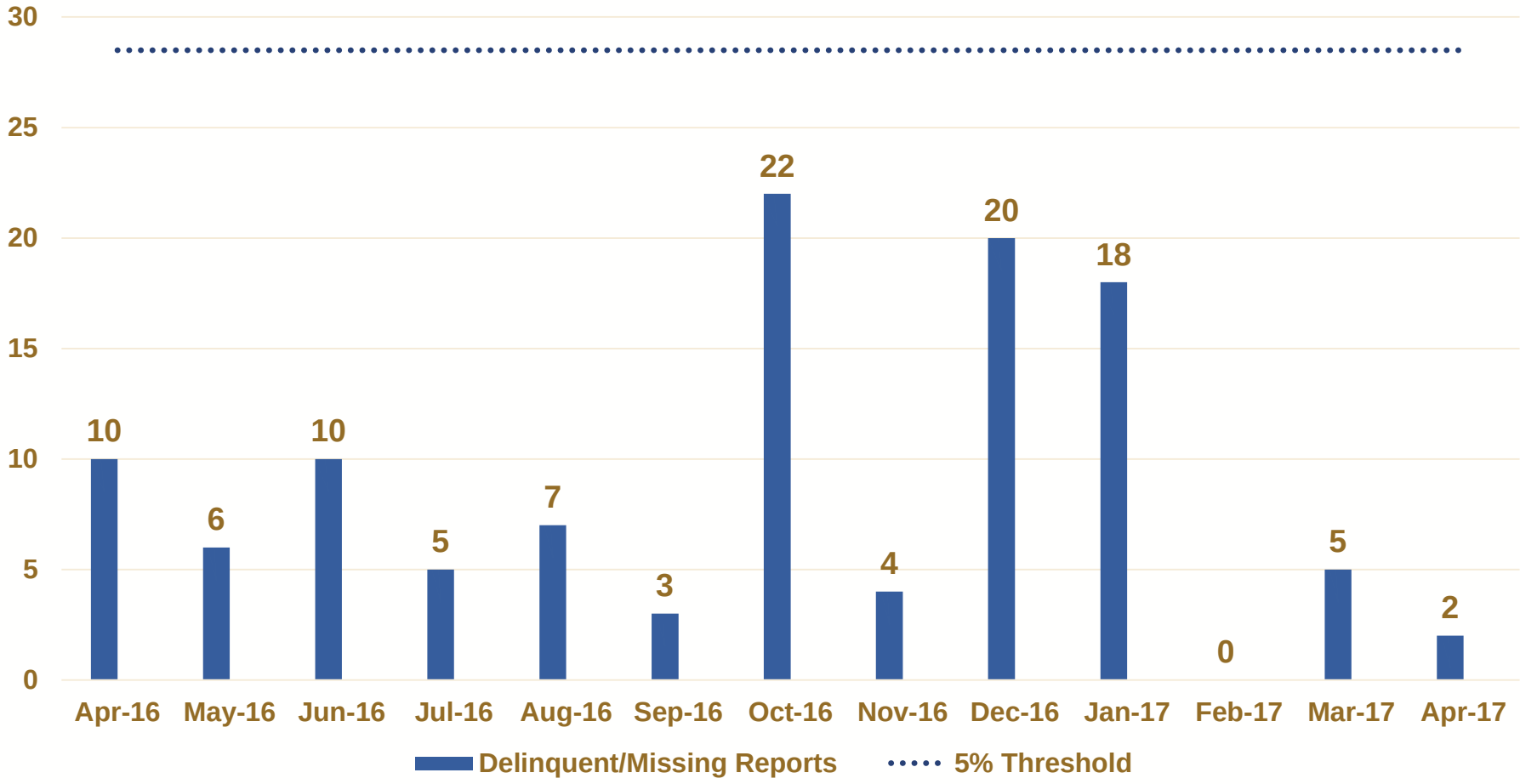
Grant Compliance Specialists are working with four grantees to remediate audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. There are currently no grantees with a delinquent audit report or a delinquent Corrective 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 a request for additional time was submitted on or before the due date of the required audit and subsequently approved by CPRIT's CEO.

Training & Support

CPRIT staff conducted a grantee training webinar on March 9, 2017 with approximately 150 grantee staff in attendance. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process. This webinar was in support of the annual compliance training requirement which states that the Authorized Signing Official (ASO) and at least one other employee from each grantee organization must attend an annual compliance training by November 1 of each year. A second grantee training webinar is tentatively scheduled for June 7, 2017.

CPRIT staff conducted a new grantee training for Pelican Therapeutics, Inc., on May 3, 2017. In addition to a brief overview of CPRIT's history and mission, the training covered grantee reporting requirements, an overview of the compliance program, and a hands-on navigation of CGMS. Also, on May 3, 2017, CPRIT staff conducted a separate training for three new Authorized Signing Officials (ASOs). CPRIT's rules require that in the event of a change in the ASO designated by the Grant Recipient on or after November 1, 2016, the new ASO must complete the annual compliance training program within 60 days of the change. Failure to do so may result in withholding of Grant Award funds until the training is completed.

Grant Recipient Report Monitoring – 4-16 thru 4-17 Delinquent/Missing Reports



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

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: MAY 2, 2017

Recruitment Impact

As displayed in table 1, to date CPRIT has recruited 127 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	103	82	80%
Rising Stars	22	13	59%
Established Investigators	42	29	69%
Missing Links	6	3	50%
Total	**173**	**127**	**73%**

FY17 Academic Research Grant and Recruitment Applications Under Review

FY17 Academic Research Cycle 2 are currently under review. *Table 2* displays data by applications received for two Requests for Applications (RFAs) which closed for application receipt on January 17, 2017. Full scientific reviews were conducted April 19-26 in Dallas. The Scientific Review Council and Program Integration Committee recommendations will be presented at the August 16, 2017 Oversight Committee meeting.

Table 2: 17.2 Academic Research RFA Submission Data

Funding Mechanism	Applications Submitted
Core Facilities Support Awards	25
High-Impact /High Risk Awards	159
Total	184

FY 2018 Cycle 1 Request for Academic Research Applications

CPRIT announced and posted five Requests for Applications (RFAs) on January 5, 2017. Application receipt opening date is March 15, 2017 with a closing date of June 8, 2017. Grant recommendations for FY2018 Cycle 1 awards are expected to be presented to the Oversight Committee in February 2018. The five RFAs are as follows:

- **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.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: MAY 4, 2017

FY 2017 Cycle 2 Prevention Applications

Five RFAs for Cycle 17.2 were released in November 2016. CPRIT received 40 applications by the March 2, 2017 deadline. After administrative review, 3 were withdrawn and 37 applications requesting $52,906,830 were assigned to the peer review panels. The two panels are scheduled to meet May 31 – June 2 in Dallas. The Program Integration Committee and the Oversight Committee will consider grant recommendations 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

Prevention Program staff are currently preparing RFAs for FY2018 Cycle 1 with a projected release date in June. The following RFAs are expected to be released:

* 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

Other activities

The prevention program performance measures report for the Legislative Budget Board was submitted April 3.

Prevention program staff has begun discussions of updating the Texas Cancer Plan with the DSHS' Texas Comprehensive Cancer Control program, Texas Cancer Registry and Office of Surveillance, Epidemiology and Research.

Meetings

Dr. Garcia attended the annual American Association of Clinical Research meeting in Washington D.C. April 2 - 5.

Ramona Magid participated in the teleconference of the steering committee of the Texas HPV Coalition on April 3.

As a member of the advisory board, Dr. Garcia participated in the April 19 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.

Dr. Garcia and Ramona Magid attended the steering committee meeting of the Texas Alliance for Colorectal Cancer Testing on April 20 in Austin.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

TO: OVERSIGHT COMMITTEE MEMBERS

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

SUBJECT: COMMUNICATIONS UPDATE

DATE: MAY 17, 2017

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

Earned Media

The communications team conducted individual media outreach to secure positive coverage for CPRIT, including a feature in the San Antonio Business Journal on Feb. 16 and D Magazine on Feb. 21 following the grant awards announcement. The Austin American-Statesman, Houston Chronicle and San Antonio Express-News also featured CPRIT in articles following the Senate Bill 224 vote regarding sunset extension.

In addition, the team executed the 2017 media plan highlighting CPRIT's impact in relation to corresponding cancer awareness months. CPRIT-funded programs and researchers were featured, and broadcast stories included an interview excerpt featuring CPRIT Chief Scientific Officer. This work resulted in a total number of 12 broadcast and eight online story placements.

During March, CPRIT received substantial broadcast media coverage for Colorectal Cancer Awareness Month. CPRIT social media activity continues to increase this month with almost daily posts highlighting colorectal cancer awareness. Colorectal Cancer Awareness Month is one of the busiest for the advocate community, which gave CPRIT and grantees multiple opportunities for earned media. We worked with three of our grantee institutions to secure earned broadcast media in their local markets.

Grant Awards Announcement: Following the Oversight Committee's approval of grant awards at its February meeting, CPRIT distributed a press release on Feb. 15 to local, regional and national outlets announcing 14 grants through its academic research and prevention programs.

Coverage: (Feb. 7, 2017 – May 1, 2017)

- 27 articles featured CPRIT
- 68 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- February 16, 2017, *KSAT (ABC, San Antonio)*, University Health System Awarded $1.2M to Help Combat Hepatitis C
- February 21, 2017, *D Magazine*, Cancer Prevention and Research Institute of Texas Awards $34 Million in Grants
- February 26, 2017, *Fort Worth Star-Telegram*, UTA Raises Cancer Research Profile with $6 Million in Grants
- March 2, 2017, *The Lufkin News*, Guest Column: Texas a Leader in Cancer Prevention, Research
- March 10, 2017, *KJTV (FOX, Lubbock)*, City Council Recognizes Colorectal Cancer Awareness
- March 14, 2017, *KFOX (FOX, El Paso)*, TTUHSC El Paso Grant Aimed at Helping Fight Cervical Cancer
- April 19, 2017, *Houston Chronicle*, Senate Votes to Extend Life of State Cancer Institute
- April 19, 2017, *San Antonio Express-News*, Senate Votes to Extend Life of State Cancer Institute
- April 21, 2017, *Austin American-Statesman*, Senate Agrees to Give CPRIT two more years
- April 28, 2017, *The Katy News*, Chairman Sarah Davis Passes Sunset Extension For The Cancer Prevention Institute of Texas

Video Production

CPRIT communications has stepped up the production of short videos for social media distribution. Much of the video production has revolved around cancer awareness months and has been used in media releases noted above. In addition, video interviews of grantees and CPRIT program officers have been produced. Videos are distributed via social media.

- A series of four videos featuring Dr. Garcia discussing cancer prevention was produced in late February for National Cancer Prevention Month.
- Also in February, a video was produced featuring Dr. Keith Argenbright discussing the CPRIT's impact on his prevention work.
- A short video was produced of CPRIT Product Development Research grantee, Molecular Templates CEO, Eric Poma.
- Working with the office of State Rep. Toni Rose, the UTSW Moncrief Cancer Center and UT Health Northeast, CPRIT produced a series of four videos on promoting Minority Cancer Awareness Day at the Capitol (April 6). These featured the UTSW Moncrief Cancer Institute mobile screening unit and the UT Health Northeast inflatable colon that were set-up at the Capitol. The videos feature interviews with Rep. Rose, Dr. Keith Argenbright and Dr. Assal Rahimi of UTSW and UT Health Northeast Colorectal program manager Carlton Allen.
- Dr. Garcia and Chris Cutrone traveled to Dallas to interview Dr. James Brugarolas for a video on UTSW's SPORE grant from NCI on kidney cancer and CPRIT's crucial role in securing the grant. The video will be released via social media in early May for National Cancer Research Month. http://www.utsouthwestern.edu/research/kidney-cancer/awards/spore.html

Social Media

Tailoring our social media content to mirror the cancer awareness months has allowed CPRIT to piggyback trending topics with our target audience. Coupled with posting original content, such as videos of Eric Poma of Molecular Templates or Keith Argenbright of the Moncrief Cancer Institute, and actively promoting CPRIT-related content from other institutions has greatly increased our social media reach.

The following are April metrics for CPRIT's social media profiles:

- Twitter
  - 10.8K impressions in April—more than 350 per day
  - 35 mentions—60% more than March
  - 1,187 followers— 10 more than last month
- Facebook
  - 3,880 people reached in April—157% more than March
  - 450% more likes
  - 85% more post engagement
  - 22% more page views

National Cancer Research Month

Communications is working with the City of Houston and CPRIT partner institutions on a proclamation signing event recognizing National Cancer Research Month during May. Plans include a presentation event prior to a City Council meeting with CPRIT Scholars from each Houston institution in attendance. Proclamation language has been submitted to the city and we will work with partner institutions on the media strategy.

Conference Update

TMI was selected as the vendor to develop the abstract and registration system for the *2017 Innovations in Cancer Prevention and Research Conference*. Both sites are expected to open in May. A listserv email was sent providing information about registration and abstract submission as well as conference speaker and hotel information. The conference website was soft-launched - http://www.cprit2017.org/

Website activities

The communications team continues to design and develop content for CPRIT's soon-to-be-launched digital newsroom; a multi-channel platform for posting, curating and distributing CPRIT and related content.

By Dawn Jorgenson - Web - News Editor

Posted: 6:59 PM, February 16, 2017
Updated: 6:59 PM, February 16, 2017

University Health System awarded $1.2M to help combat hepatitis C

Officials aim to prevent development of liver cancer

SAN ANTONIO - The Cancer Prevention and Research Institute of Texas awarded the University Health System with $1.2 million Wednesday to increase screening for hepatitis C and prevent the development of liver cancer.

According to UHS, South Texas has the highest incidence of liver cancer in the nation, largely due to hepatitis C.

Researchers said they have found that the baby boomer population -- born from1945 to 1965 -- had more than twice the rate of hepatitis C in the nation, with Hispanics also at higher risk.

Officials said the program will expand screening for hepatitis C, provide education to both patients and health care providers and develop culturally and linguistically tailored patient navigation that will work to eliminate barriers to care, preventing many new cases of liver cancer, thereby reducing health care costs.

The grant was one of only 14 awarded by CPRIT on Wednesday, with UHS being the only San Antonio organization to be on the receiving end. This grant marks the eighth awarded to the UHS for cancer prevention since 2010, for a total of nearly $9 million. Other projects included breast and cervical cancer education and colorectal cancer screening.

UHS officials said a 2007 passage of Proposition 15 created CPRIT, authorizing the sale of bonds to fund up to $3 billion in cancer research in Texas over a 10-year period.

http://www.ksat.com/health/university-health-system-awarded-12m-to-help-combat-hepatitis-c

D CEO HEALTHCARE

Cancer Prevention and Research Institute of Texas Awards $34 Million in Grants

02/21/2017 | by Olivia Nguyen | Share Post

The Cancer Prevention and Research Institute of Texas awarded 14 grants totaling $34 million for funding research and solutions in the fight against cancer. All 14 grants were made through CPRIT's academic research and prevention programs.

Including the latest awards, UT Southwestern Medical Center researchers have been awarded a cumulative total of more than $334 million from CPRIT, which have helped attract additional awards in basic science research, translational research and outreach and prevention programs.

CPRIT started giving grants in 2009 after Texas voters approved a 2007 constitutional amendment committing $3 billion to further cancer research. To date, CPRIT has awarded 1,123 grants totaling more than $1.78 billion.

Nine of the 14 projects awarded are geared toward helping Texans "prevent and reduce their risk of cancer." The projects will provide education and screenings for breast, cervical, colorectal cancer, the hepatitus virus, and vaccinations for HPV. The funds will also provide support for cancer survivors. According to CPRIT, the 172 prevention programs implemented have delivered over three million services across the state.

Wayne Roberts, CEO of CPRIT, says the new grants allows CPRIT to push Texas into the forefront of cancer research and prevention.

"CPRIT helps bring the best and brightest researchers in the world to Texas, while continuing to invest in promising programs with our partners," Roberts said in a statement.

http://healthcare.dmagazine.com/2017/02/21/cancer-prevention-and-research-institute-of-texas-awards-34-million-in-grants/

Star-Telegram

UTA raises cancer research profile with $6 million in grants

BY ROBERT CADWALLADER
rcadwallader@star-telegram.com
FEBRUARY 26, 2017

Baohong Yuan, an associate professor of bioengineering at UTA, received a $900,000 grant for his work on deep-tissue imaging technologies. **Paul Moseley** - pmoseley@star-telegram.com

ARLINGTON — Baohong Yuan was a biomedical researcher in Washington, D.C., when he saw a recruiting advertisement that prompted him to uproot his life and head for the University of Texas at Arlington.

UTA's bioengineering department was investing heavily in biomedical imaging and looking for a researcher who could take the technology to another level — combining light with ultrasound for deep-tissue, high-resolution imaging.

For years, Yuan had been developing that technology for monitoring tumors. He knew it was a perfect fit when he arrived for his interview.

"I met a lot of colleagues. They were so research active, which really surprised me," said Yuan, an associate professor of bioengineering. "I really wanted to join this environment to develop this technology."

During the past seven years, Yuan's research has coincided with UTA's emergence as an important player in cancer research. Last year, the university was awarded $6 million in new grants for developing cancer-fighting technologies — its most ever for that purpose.

The total included a $900,000 grant from the Cancer Prevention and Research Institute o Texas for Yuan to continue his own mission, which includes putting the power of an MRI machine in a hand-held device.

"Certainly, 2016 is a high-water mark for us," said Duane Dimos, UTA's vice president fo research. "I would say the combination of the existing faculty experts along with a lot of really great new faculty hires — that has led to our assertion that we're becoming a major cancer research institution."

UTA has more than 25 cancer researchers in its biology, bioengineering and computer science colleges and has 13 cancer-related patents issued in the past five years.

Last year, UTA joined the ranks of top research universities listed by the Carnegie Classification of Institutions of Higher Education, joining an elite group of 115 R1 doctora universities including MIT, Harvard and Johns Hopkins.

UTA also is investing in research infrastructure, the centerpiece being its $125 million, 220,000-square-foot Science and Engineering Innovation and Research building, which wi be the university's signature site for multidisciplinary life and health science teaching and research. Construction started in October and the building is expected to open in August 2018.

Dimos said the university is positioning itself as "the innovation hub around cancer for the North Texas region."

Entrepreneur partners

UTA has also begun partnering with entrepreneurs to fast track development of faculty and researcher innovations for commercial markets. Universities license their patents either to existing companies or to small startups they help create.

"It's not new, but I'm seeing more of it," said Darlene Boudreaux, executive director of TECH Fort Worth, a nonprofit incubator that matches innovators with entrepreneurs and helps them launch operations. Founded in 1998, it provides startup space in a 17,000-square-foot building through a joint venture with the city of Fort Worth, UTA and the University of North Texas Health Science Center.

> **THE MORE RESEARCH GRANTS A UNIVERSITY HAS, THE MORE OPPORTUNITY IT HAS TO DISCOVER SOMETHING PATENTABLE.**
>
> Darlene Boudreaux, executive director of the business incubator TECH Fort Worth

In collaboration with TECH Fort Worth, the Health Science Center also operates an Acceleration Lab Program in Fort Worth, which offers six leasable labs for startup companies and two core laboratories where scientists can share expensive equipment such as microscopes and chemical analyzers. The program helps new companies move their technologies from the laboratory to the marketplace.

"The more research grants a university has, the more opportunity it has to discover something patentable," Boudreaux said. "And the more patents a university has, the more opportunity to license technology to private companies. ... And the money that comes into startups goes into the community to build and launch their products."

So far, UTA has two private enterprises working on cancer research — AbeXXa Biologics, which opened last year in the school's Nano Technology Research Center, and Tuevol Therapeutics, which was founded in 2014 and is in an off-campus lab. Both were created by professors wanting to advance their own research.

AbeXXa founder Jon Weidanz, UTA's associate vice president for research and a biology professor, said nurturing spin-off businesses to develop technologies is a model that has proven successful around the country.

"It drives the success of the local economies in those areas," said Weidanz, whose research focus is on an emerging field of therapies and treatments aimed at using a patient's immune system to fight cancer. UTA recruited him partly for his experience starting research companies.

"By having successful startups on campus or around the Arlington and Fort Worth area," he said, "we begin to create a new sense of awareness that UTA is not only doing great things — which it has been doing for years — but it's able to have an impact on our community in terms of providing medical solutions, creating economic opportunity, recruiting new money into the area.

"Venture funds would be looking at UTA in a different way," he added.

Grant funding

Cancer research has deep support through federal, state and private grant sources. UTA officials are optimistic that funding will continue rolling in, and in even bigger numbers this year, despite nationwide belt-tightening.

Congressional funding for the National Cancer Institute, the largest provider of cancer research funding, has not kept up with inflation for more than a decade.

THE ANNUAL BUDGET OF THE NATIONAL CANCER INSTITUTE, THE LARGE FUNDING SOURCE FOR CANCER RESEARCH, GREW FROM $2.55 BILLION IN FISCAL 1998 TO $5.21 BILLION IN 2016. BUT THAT AMOUNTED TO JUST $2.997 BILLION IN INFLATION-ADJUSTED DOLLARS OVER THAT PERIOD.

"Federal investment in cancer research has been stagnant since 2003," Douglas Lowry, acting director of the National Cancer Institute, said in the agency's budget plan and proposal for fiscal year 2017. He recommends an annual increase of 7 percent for 10 years to "restore the NCI's purchasing power and accelerate scientific discovery."

The NCI's annual budget grew from $2.55 billion in fiscal 1998 to $5.21 billion in 2016. But that amounts to only $2.997 billion in inflation-adjusted dollars over that period, according to an agency funding chart.

Many other public and private grant sources for cancer research exist, including the American Cancer Society, a nonprofit that invested more than $95 million in research grants in 2015, and $4.5 billion since 1946. The ACS is funding 54 grants in Texas worth $30.3 million, and 748 grants totaling $406.9 million nationwide.

"We have funded, at least some point in their careers, 47 Nobel Prize winners," said Evelyn Barella, ACS director of media relations. "There's not another nonprofit organization that can touch that."

But the Cancer Prevention and Research Institute of Texas funding has been "critical" during this period of grant uncertainty, said Michael Cho, chairman of bioengineering at UTA.

"National funding has been lacking, but then a program like CPRIT kicks in, specifically designed for diagnosis and treatment of cancer," Cho said. "The bioengineering department has been a beneficiary of this very targeted investment."

CPRIT was created by a voter-approved constitutional amendment in 2007 that authorized the state to issue $3 billion in bonds to fund Texas-based cancer research and prevention services.

In 2016, it funded not only Yuan's $900,000 grant but also an $823,000 grant to cell biology researcher Mark Pellegrino, an assistant biology professor at UTA.

Yuan, who came to America from China 14 years ago to explore his imaging technology concept, is using nano-particles that attach to various types of molecules on tumors and the blood vessels the tumor creates to feed itself. The particles, activated by ultrasound, help focus and sharpen the imaging, and in the future they could be used to carry drugs to precise targets, leaving healthy tissue alone.

He's been awarded five grants totaling $2.9 million since 2010 for his research. And he plans to apply for a $100,000 grant from the National Institutes of Health to help start up a business to commercialize his technology.

He's nearing the end of a long journey, he said, but there's much more more work to do.

"When you have some idea, you really push it forward. If you don't do anything, the idea is just an idea," Yuan said. "The progress, that's why I'm excited. We still have a lot of challenges to overcome, but at this level, I feel we are successful."

http://www.star-telegram.com/news/local/community/arlington/article134856139.html

THE LUFKIN NEWS

GUEST COLUMN: Texas a leader in cancer prevention, research

March 2, 2017

Last May the Cancer Prevention and Research Institute of Texas, created by Texans in 2007, celebrated the halfway point in its historic $3 billion investment in cancer research and prevention. No other state has undertaken a cancer initiative of this magnitude, and within a short eight years, CPRIT has accelerated the pace of discoveries and created cancer research infrastructure at Texas universities beyond what many thought possible.

On average, the National Cancer Institute provides $204 million per year in cancer research to Texas-based institutions. With its 911 university research awards totaling $1.3 billion, CPRIT has doubled this research funding in Texas.

Before CPRIT, Texas had just one NCI Comprehensive Cancer Center. Now Texas boasts three comprehensive centers and a fourth that is a designated center. As a result of the work at these and other Texas higher education institutions, our state plays an integral role in the national effort to study and control cancer, and Texas is able to attract both talent and research funding. All of this is due to CPRIT's investments.

CPRIT's role in recruiting the best minds in cancer research to Texas reverberates across the country. Since its inception, CPRIT has supported the recruitment of 127 premier cancer researchers to our Texas institutions from around the world. Often these recruits come with 15 to 30 years remaining in their careers, meaning CPRIT has already brought nearly 3,000 research years to Texas. We will benefit for years from the work done by these recruits, but Texas must continue the kind of support CPRIT offers compared to other states to make the most of our investment.

The benefit of CPRIT-supported initiatives is significant. Texas is now a leader in fighting adolescent and childhood cancer, and has a national center of excellence in immunological cancer research. We also have leading stem cell transplant programs with treatments for effectively targeting cancer tumors. Many academic research awards have led to CPRIT product development projects that move new cures from the lab into clinical trials. And the 27 CPRIT-funded core facilities assure that Texas' cancer researchers have shared access to the most up-to-date technology needed for cutting edge research.

CPRIT is saving the lives of Texans every day through its prevention grants. Many Texas universities have had a role in providing over 3 million cancer risk reduction and screening services in every Texas county. Through these grants, CPRIT has especially made an enormous difference in rural Texas and along the border among populations with previously limited access to cancer education and screening services. This is life-saving work.

We unequivocally support a fully funded CPRIT, a CPRIT that can continue its visionary mission started less than 10 years ago. By doing so, lawmakers will ensure the remaining $1.2 billion authorized by Texans for this historic mission is fully utilized. We must also think beyond 2023 to capitalize fully on the investment CPRIT has made in research talent and to maintain our current momentum in this monumental undertaking. Texans knew we could conquer cancer when they created CPRIT. Let's finish the job we've started.

http://lufkindailynews.com/news/community/article_b02e667a-fecc-11e6-a025-ff7d229a0803.html

City Council recognizes Colorectal Cancer Awareness

By Marcos Ortiz

Posted: Mar 10, 2017 8:17 PM CST

LUBBOCK, Texas - Colon cancer is considered a silent killer because often there are no symptoms until its too late to cure. The city council recognized multiple survivors, just like district one councilman Juan Chadis. "I was part of the 10%. I was 42 when I was diagnosed with cancer", said Chadis.

Ramon Butler Martinez said he's cancer free now and is going through remission including regular checks. "If you start getting any type of symptoms go and get checked out you know you never know cancer was the last thing that I had ever going to diagnose from just feeling faint and not being able to do those few things", said Martinez. Cancer researcher Theresa Byrd is the director of a group called Accion or Against Colo-rectal cancer in our Neighborhoods." The disease can be prevented if it's found at an early stage.

"So a lot of cancers when we screen we just find early cancer hopefully with colo-rectal cancer we can find changes that might become cancer and get rid of them before the cancer ever happens. I think it's very rewarding plus it's one of the major cancer killers in the United States", said Byrd.

C-PRIT the Cancer Prevention and Research Institute of Texas funds prevention efforts and cancer research."C-PRIT has committed about 10% of its overall funding to colon cancer, it's interesting that colon cancer represents 10% of all cancers that affect all Texans so it's important to know that CPRIT is really quite invested in the fight",said Dr. Jim Willson. The Texas cancer registry reports Hispanics will develop Colo-rectal cancer at a higher rate than others and the numbers are far higher in Floyd and Terry counties.

http://www.fox34.com/story/34727716/city-council-recognizes-colorectal-cancer-awareness

KFOX14

TTUHSC El Paso grant aimed at helping fight cervical cancer

by Marcel Clarke | Tuesday, March 14th 2017

EL PASO, Texas — A new grant is allowing local doctors to fight cervical cancer in the borderland.

Texas Tech University Health Science Center El Paso recently received a grant of $1.5 million from the Cancer Prevention and Research Institute of Texas.

According to the Texas Tech University Health Science Center El Paso, the grant will help expand "De Casa en Casa," a program that helps uninsured Latinas.

The grant will help educate women in the area about regular checkups and will help provide free Pap smears.

El Pasoans to whom KFOX14 spoke reacted positively to the news.

"I think it is great that El Paso is getting the attention that it deserves, especially for people that can go ahead and overlook a lot of these important aspects of their health simply because there is no access to it," said Andy Faris.

Melissa Folson agreed.

"I think that is great. I think that it is something very important," she said.

http://kfoxtv.com/news/local/ttuhsc-el-paso-grant-aimed-at-helping-fight-cervical-cancer

HOUSTON CHRONICLE

By Mike Ward Wednesday, April 19, 2017

Senate votes to extend life of state cancer institute

AUSTIN — The Texas Senate, after debating whether cancer research is paying enough dividends, on Wednesday agreed to continue the operations of the Cancer Prevention and Research Institute of Texas for another two years.

By a 23-8 vote, Senate Bill 224 was approved to give the Austin-based agency two more years before it faces a top-to-bottom review on whether it should be continued in business — a so-called "sunset" process that all state agencies undergo periodically.

CPRIT was created in 2007 to explore the causes and cures for cancer, at a time when federal funding was declining. Texas voters overwhelmingly approved a constitutional amendment to create the agency, which officials touted as a way to eventually conquer cancer and put Texas on the map for bio-medical research that could create thousands of jobs.

State Sen. Kirk Watson, D-Austin, said the agency's groundbreaking research initiatives are set to expire in 2021, at which time there will be more than $70 million of unused bond authority by that date.

At the time the institute was created, the state issued more than $3 billion in bonds to get research programs started.

Watson said an extension of the sunset date "is crucial to try to prevent the estimated $156.8 billion cost of cancer to the Texas economy annually."

Sen. Charles Schwertner, a Georgetown Republican and orthopedic surgeon, said while he supports extending the sunset date by two years, he questioned whether the institute has lived up to expectations that it would by now be self-sufficient through licensing agreements and patents.

Watson said the agency has made great progress in realizing its goals of finding a cure for various cancers. Sen. Jane Nelson, a Flower Mound Republican who has clout because she is the Senate's chief budget writer, noted that she authored the original bill establishing the agency and supports the extension.

"I don't think there is a better investment of our money than this," she said, noting that she is a strong fiscal conservative.

The measure was then passed and was sent to the House, where approval is expected.

San Antonio Express-News

By Mike Ward Wednesday, April 19, 2017

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http://www.mysanantonio.com/news/politics/texas/article/Senate-votes-to-extend-life-of-state-cancer-11083996.php

Austin American-Statesman
Friday
April 21, 2017

TEXAS LEGISLATURE

Senate agrees to give CPRIT two more years

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THE Katy News
Katy's ONLY Locally Owned Newspaper
Apr 28, 2017

Chairman Sarah Davis Passes Sunset Extension For The Cancer Prevention Institute Of Texas

AUSTIN, TX- Today, Chairman Sarah Davis passed House Bill 84 and House Bill 63 which extends the expiration date of the Cancer Prevention Institute of Texas (CPRIT) and ensures adequate management of related equity and royalties derived from agency grant disbursements.

"Voters overwhelmingly approved the establishment of the Cancer Prevent Institute of Texas dedicated to the eradication of cancer. I could not be more proud to ensure the will of the voters will be executed to its full extent," said Davis.

Chairman Sarah Davis introduced both House Bill 84 and House Bill 63 during the early filing period for the 85th Legislature due to the vital importance of continuing Texas' fight against cancer. The passage of this critical legislation allows for maximum use of the $3 billion bond authority.

"We are grateful for the passage of House Bill 63 and House Bill 84 and the confidence the House has shown in CPRIT," Wayne Roberts, CEO of CPRIT commented. "The swift approval is a testament to Representative Davis' tireless work on behalf of the 117,000 Texans who are diagnosed with cancer every year."

The Cancer Prevention Institute's continuance is essential due to the significant impacts the agency has produced for Texans and beyond. Of the three grant types offered, for every dollar granted to product development research, there has been nearly four dollars of private sector follow-on investment, which now totals $1.33 billion. For every screening and or preventative dollar that is spent, $22 in savings to the healthcare system is produced in cost avoidance. Numerous award winning scientists have been recruited with the academic research grants who have both grown research in rare cancers and are responsible for a thriving spin-off bio-sciences community. CPRIT grants and follow on funding have created and maintained over 11,000 direct jobs, and when factoring in secondary effects, Texas has gained over 79,000 new jobs. The continuance of this agency is good for Texans and good for the Texas economy.

http://thekatynews.com/2017/04/28/chairman-sarah-davis-passes-sunset-extension-for-the-cancer-prevention-institute-of-texas/

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	PRODUCT DEVELOPMENT OVERSIGHT COMMITTEE MEMBERS
FROM:	MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT:	PRODUCT DEVELOPMENT PROGRAM REPORT
DATE:	MAY 1, 2017

FY 2017 Cycle 2 Product Development Research Applications

Twenty applications were submitted and accepted. Screening teleconferences were held March 28-29 where six of these applicants were selected to present at peer review. These six applicants presented at Peer Review Panel meetings April 25-26 in Dallas where two firms were selected to progress to due diligence. Due diligence has commenced and results are scheduled to be reviewed by the Product Development Review Council on July 17. Applications recommended by PDRC and PIC will be presented to the Oversight Committee in August for approval.

FY 2018 Cycle 1 Product Development Research Applications

18.1 RFA is being edited for planned June 29th opening of CARS system to accept applications.

Product Development Advisory Council

The Product Development Advisory Council meeting was held March 30th to discuss how to best utilize remaining CPRIT funding. CPRIT estimates approximately $210 million is available for awards if the current 75/25 split between academic research and product development awards remains in place. The committee unanimously recommended increasing CPRIT's investment in product development, specifically by focusing on providing grant money to support clinical studies and trials.

The PDAC also recommends that the Product Development Research Program and the Academic Research Program collaborate to award grants to Texas institutions that support advancing promising research into the product development pipeline. A more detailed presentation on these issues will be provided at the May 17 meeting.

Company Contract Negotiations

Negotiations with Fuji to amend revenue sharing terms have been concluded. Agreement has been reached on modified revenue sharing terms and contract amendment is in process.

Product Development Research Advisory Committee
Annual Report

Submitted to CPRIT Oversight Committee May 17, 2017

The members of the Product Development Advisory Committee (PDAC) appreciate the opportunity to provide the PDAC's annual report and recommendations to the Oversight Committee regarding CPRIT's Product Development Research Program. We welcome a continuing dialogue with the Oversight Committee and CPRIT staff to enhance and improve Texas' position as a leader in cancer prevention, cancer research, and cancer product development.

Texas is recognized around the country for its commitment to prevent and cure cancer. Along with its world-renowned academic medical centers such as M.D. Anderson Cancer Center and UT Southwestern Medical Center, the formation and funding of CPRIT established Texas as a top destination for the advance of innovative, cutting-edge research and the development of products targeting cancer.

CPRIT's Product Development Research Program has the potential to be at the forefront of new, game changing cancer drugs, diagnostics, and tools. The Product Development Research Program is attracting some of the very best cancer-focused technologies to Texas for company formation and relocation. Companies funded by CPRIT have the potential for a lasting economic and medical benefit through the resulting healthcare innovation and biotechnology ecosystem that otherwise would not exist.

CPRIT has awarded 31 grants totaling more than $300 million to 28 companies since 2010. These companies have raised more than $1.3 billion in follow-on funding after receiving CPRIT awards.

Product Development Advisory Committee Background and Membership

The PDAC is an *ad hoc* advisory committee that offers guidance to the Oversight Committee on issues related to CPRIT's Product Development Research Program. CPRIT's Product Development Research Program reduces the burden of cancer by bringing improved products to market, and growing the Texas life sciences ecosystem.

Members of the Oversight Committee and representatives from the life science industry trade association, CPRIT staff, and Texas venture capital companies nominated members of the PDAC. Listed below are the current PDAC members (asterisks identify CPRIT grantees):

Jonathan MacQuitty, Ph.D., **Chair** *Venture Partner, Lightspeed Venture Partners*	David Lowe, Ph.D.,* **Vice Chair** *President and CEO, Aeglea Biotherapeutics*

David Arthur* *CEO and Director, Salarius Pharmaceuticals*	Bruce Butler, Ph.D. *Vice President, Research and Technology, Director, Office of Technology Management UT Health Sciences Center at Houston*
Paul Lammers, M.D.* *CEO and President, Mirna Therapeutics*	Gary Latham, Ph.D.* *Sr. V.P., Research and Development, Asuragen*
Kevin LaLande *Managing Director, Santé Ventures*	Martin Lindenberg, M.D. *Director, The McNair Center for Free Enterprise and Entrepreneurship, University of St. Thomas*
Brenton Scott, Ph.D.* *President and COO, Pulmotect*	Greg Stein, M.D.* *CEO, Curtana Pharmaceuticals*
Ilia Tikhomirov* *President and CEO, Formation Biologics*	James Topper, M.D., Ph.D. *Managing General Partner, Frazier Healthcare Partners*
Matt Winkler, Ph.D.* *Founder, Asuragen and Mirna Therapeutics*	

The Oversight Committee reactivated the current PDAC in 2014. The PDAC's first project was to provide advice when the Oversight Committee and CPRIT staff were considering adoption of uniform revenue sharing terms for the Product Development Research Program. The Oversight Committee recognized the PDAC's contribution to the discussion as largely responsible for reaching a consensus policy for CPRIT's current standard revenue sharing terms. The PDAC met twice in the past year to discuss issues related to the Product Development Program. The PDAC's recommendations from those meetings are included in this report.

Product Development Research Program Priorities

The Oversight Committee's 2017 program priorities for the Product Development Research Program are:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available; i.e., disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early stage projects when private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions;

- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead and seed clusters of life science expertise at various Texas locations; and
- Providing appropriate return on Texas taxpayer investment.

The Product Development Research Program may achieve the Oversight Committee's priorities for other CPRIT programs, including:

- Populations disproportionately affected by cancer incidence, mortality or cancer risk prevalence (Prevention Program Priority);
- Recruitment of outstanding cancer researchers to Texas (Academic Research Program Priority);
- Investment in core facilities (Academic Research Program Priority);
- Prevention and early detection (Academic Research Program Priority);
- Computational biology and analytic methods (Academic Research Program Priority);
- Childhood cancers (Academic Research Program Priority); and
- Population disparities and cancers of importance in Texas (Academic Research Program Priority).

New PDAC Policy Recommendations – For OC Review

To fulfill its statutory mandate and to achieve the Oversight Committee's Program Priorities, the PDAC makes the following recommendations.

Recommendation 1: CPRIT should increase its investment in Product Development Research.

At its March meeting, the PDAC discussed how to best utilize remaining CPRIT Product Development Research grant funding, which CPRIT estimates to be approximately $210 million if the current 75/25 split between academic research and product development awards remains in place. The committee unanimously recommended increasing CPRIT's investment in product development, specifically by focusing on providing grant money to support clinical studies and trials.

PDAC members noted that the California Institute of Regenerative Medicine (CIRM), an agency similar to CPRIT in many respects, has received recent criticism for not emphasizing clinical trials and product development over constructing research buildings and funding basic research. Cures, or at least documented progress towards advancing cures to approval, have been very limited in the California experience.

Unlike CIRM, CPRIT has not used its funds to construct buildings. CPRIT has funded more product development than CIRM, as well as more clinical trial support. However, CPRIT's historical funding weight of 78% towards academic research and recruitment versus 22% for Product Development

Research may subject CPRIT to criticism similar to CIRM. This will become increasingly important as CPRIT approaches the end of its funding authorization. CPRIT should place significantly greater emphasis on clinical studies and Phase I and II clinical trials when investing CPRIT's remaining grant funds. Clinical trials are the best evidence that the cures many Texans expected when creating CPRIT are under development.

The PDAC recommends CPRIT emphasize funding clinical projects that will demonstrate human proof of principle in an appropriate period, preferably before the agency's closure, currently set at August 31, 2021. Doing so prioritizes direct patient needs. Currently CPRIT invests approximately $60 - $70 million per year for product development. This means that CPRIT awards two or three major Product Development grants annually, typically in the $12 - $20 million range. The PDAC recommends increasing the total amount CPRIT awards for Product Development by 50% annually ($90 - $100 million). This will increase the number of major awards to five or six grants per year. Doing so increases the probability that the grantees will develop useful cancer products in the period remaining for CPRIT. Continuing at the current level increases the risks that useful cancer products will not be generated before CPRIT ends.

Recommendation 2: Collaborate with CPRIT's Academic Research Program to support translational work at academic centers with the goal of increasing the number and quality of university spinouts.

The PDAC recommends that the Product Development Research Program and the Academic Research Program collaborate to award grants to Texas institutions that support moving promising research into the product development pipeline. Texas represents almost 10 percent of the US economy but gets only 5 percent of NCI funding and 4 percent of venture capital health care investment. Very little translational research funding is available, which means that many projects demonstrating early potential never progress beyond university laboratories. Some PDAC members pointed to recent media reports highlighting the difficulties companies are confronting when trying to reproduce announced academic research results. This industry perception of irreproducibility, along with higher education's traditional emphasis on publication over commercialization (development) of promising findings, also contributes to the difficulty early stage university projects encounter when trying to move downstream into product development and the establishment of viable spinout companies. The use of grants from the Academic Research Program to support activities such as GMP production of active agents, confirmation of in-vivo findings, and toxicology testing would allow a stronger base of information and materials to be available to help start a company.

Furthermore Texas is not creating enough "investor ready" companies. Experienced leadership at an early stage is a vital part of the successful development process. Often, young companies make poor decisions in the early stages of their development that turn out to be fatal, ending the promising idea before it can fulfill its potential. Examples of uninformed decision-making include failing to design a clinical trial that is robust enough to derive definitive answers, preclinical work that fails to provide

adequate results to attract next-stage investors, and naïve intellectual property decisions. Working with the inventor at the academic institution when the company is forming around a good idea and continuing to provide advice at critical junctures increases the potential for a strong investor-ready company.

The PDAC recommends that CPRIT actively promote additional university company spinouts through an enhanced Early Translational Research Award (ETRA) program. Specific suggestions include:

- Provide dedicated grants for translational research at academic institutions in the $2-3m range.
- Provide seed awards to support new company formation from Texas research institutions.
- Insure academic researchers have access to industry expertise for translational research studies.
- Engage industry expertise to lead commercialization of companies that show promising translational research findings.

Prior PDAC Policy Recommendations – Have Been Implemented

The PDAC previously provided the following recommendations to the Oversight Committee, through CPRIT's Chief Product Development Officer Mike Lang. These recommendations have been implemented.

Recommendation 3: CPRIT should fund only the very best projects without arbitrary limits or restrictions on who can apply. The agency should permit and encourage companies to apply to CPRIT for follow-on funding after successfully completing a CPRIT-funded project.

Companies that received grants several years ago are now starting to apply for additional grant funding. CPRIT permits academic research and prevention grantees to receive multiple grants, with some principal investigators holding up to four CPRIT grants. However, CPRIT released Product Development Research Program RFAs in June 2016 that limited the applicant pool to only those companies that have not received a CPRIT award.

The PDAC recommends that the agency continue to accept all submissions, including those from applicants who have received an award previously, and to consider an application on its merits regardless of the size or status of the company. Doing so maximizes the opportunities to meet CPRIT's Product Development Program priorities, such as funding disruptive technologies and projects addressing large or challenging unmet medical needs. CPRIT should not be solely an incubator of new companies.

One can argue that prohibiting repeat awards would diversify CPRIT's investment portfolio and add more firms to the Texas ecosystem. The PDAC discussed this point, but concluded that access to capital to fund innovative projects is always limited until human proof of concept has been demonstrated regardless of the size of the company or status of the company. Some PDAC members contend that

raising capital to fund a novel project may be an even greater challenge at a small public biotechnology company because the "lead" value-creating program is typically the investors' singular focus.

Building on this point, CPRIT should encourage companies to apply for follow-on funding upon the successful completion of a CPRIT-funded project. Follow-on funding is the bedrock of product development. CPRIT is already familiar with the company and its CPRIT-funded project; therefore, the subsequent application is de-risked compared to a new application. The standard for awarding all grants must be high; all applications should go through the same meritorious technical review.

For companies receiving second CPRIT awards, the PDAC recommended the Oversight Committee increase the matching requirement from the current 2:1 ratio of CPRIT funds/investor funds to 1:1 or 1:2.

Status: Following the PDAC's discussion, subsequent RFAs have not included a restriction against CPRIT grantees from applying for a second award. The Oversight Committee adopted the PDAC's recommendation to increase the matching requirement to 1:1 for companies receiving a second CPRIT award.

Recommendation 4: Maintain grant funding up to $20 million per grant, even if it means that CPRIT awards fewer Product Development grants.

The PDAC discussed whether CPRIT should lower the maximum amount of awards for a Product Development grant at both of the PDAC meetings during this fiscal year. Reducing the award cap would increase the total number of awards CPRIT can make, which may diversify CPRIT's investment portfolio and add more firms to the Texas ecosystem.

Awarding more grants at smaller amounts prevents CPRIT from being truly impactful. Grants at smaller amounts will not attract disruptive technologies that have the potential to be game changing. It will mean more and smaller virtual companies, which creates a heavy administrative and compliance burden on CPRIT.

More importantly reduced awards may be insufficient to support Phase 1 (and Phase 2) clinical studies and to induce firms to relocate to Texas. The pathway to successfully launching a cancer drug will be much riskier because CPRIT will be funding only early pre-clinical work. Decreasing the size of grants means that CPRIT will not provide the operating capital necessary for companies to achieve milestones that will attract additional investment. This means that a critical part of the funding "Valley of Death" will not be covered. Maintaining the $20 million award cap is important for achieving meaningful drug development advancement.

The PDAC recommended maintaining the $20 million award cap so that CPRIT may continue to be at the forefront of funding the development of breakthrough cancer drugs, diagnostics, and tools. We note that some PDAC members support increasing the award cap.

Status: Following the PDAC's discussion, no changes were made to $20 million award limit.

Recommendation 5: Establish separate standard revenue sharing terms for projects developing diagnostics and devices.

CPRIT has standard revenue sharing terms based on paying royalties. Royalty rates range from 3% to 5% depending upon the amount of product revenues. The CPRIT agreement caps the total royalty amount at 4X the award amount after which the royalty rate declines to 0.5 percent until the right to exclusivity expires.

The PDAC discussed whether it was appropriate to have a different set of royalty terms for non-therapeutic products such as cancer diagnostics and medical devices. High development costs, a longer time to market, and greater risks characterize drug development; consequently, industry profit margins are high. The cumulative CPRIT royalty makes up less than 10% of the cumulative revenue for a typical successful oncology drug. This is typical of other royalty agreements and attractive to pharma startups as evidenced by the high number of applicants.

The development costs, time to market, and risks are considerably less for the cancer diagnostic and medical device sectors. Profit margins are lower, about one-half to one-third that of drug development. Given the smaller profit margins for diagnostics and devices, CPRIT's fixed royalty structure is a much larger burden on these sectors – up to one-third of the revenue of a typical device or diagnostic. The greater impact may make a CPRIT award less attractive to device and diagnostic startups, as evidenced by fewer CPRIT applicants with diagnostic and device projects.

After discussion, the PDAC recommended reducing royalty rates for device and diagnostic companies to 2.5% with a cap at 2.5X the award amount. The 0.5 percent continuing royalty remains in place and will last until the right of government exclusivity ends.

Status: The Oversight Committee adopted this recommendation on February 15, 2017.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	MAY 12, 2017

Summary and Recommendation

The Chief Executive Officer has appointed seven 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 May 12, 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.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Scientific Research and Prevention Program Committee Appointments

Dr. Gregory S. Cooper, M.D.

Dr. David Gius, M.D., Ph.D.

Dr. Iva Greenwald, Ph.D.

Dr. Mickey Hu, Ph.D.

Dr. Garth Powis, D. Phil.

Dr. Mario Shootman, Ph.D.

Dr. David Uehling, Ph.D.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

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: Gregory S. Cooper

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

POSITION TITLE: Professor

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Pennsylvania, Philadelphia, PA	BA	05/1982	Sociology
University of Pennsylvania, Philadelphia, PA	MA	05/1982	Sociology
University of Pennsylvania, Philadelphia, PA	MD	05/1986	Medicine
University Hospitals of Cleveland, Cleveland, OH		06/1989	Internal Medicine Residency
University Hospitals of Cleveland, Cleveland, OH		06/1991	Gastroenterology Fellowship
University Hospitals of Cleveland, Cleveland, OH		06/1992	Chief Medical Resident
University Hospitals of Cleveland, Cleveland, OH		06/1993	Clinical Epidemiology and Gastroenterology Fellow

A. Personal Statement

I am a practicing gastroenterologist and health services researcher with a major interest in cancer prevention and control research, primarily through the use of large databases. My work has included studies with Medicare claims data, the linked SEER-Medicare database, Medicaid data, regional hospital data and health plan claims. I also serve as Co-Project Leader in the Case GI SPORE for a prospective study of stool DNA testing for detection of advanced adenomas that recruited patients from a screening population, including 40% minorities, and thus have experience in leading large clinical trials.

My primary research focus has been on colorectal cancer screening and approaches to increase its overall use and effectiveness. We have identified the impact of changes in reimbursement on screening uptake, important racial disparities in acceptability and uptake of screening, patient subgroups that appear to be underserved, and provided data on the prevalence of complications of colonoscopy with anesthesia

assistance. I currently serve as primary mentor for two junior faculty career development awardees and provide oversight in several trainee research projects through my roles as Director of Clinical Research for the Cleveland Digestive Disease Research Core Center and Director of a program in Comparative Effectiveness Research at the Case CTSC.

As Co-Program Leader for the Cancer Prevention and Control Program at the Case Comprehensive Cancer Center, I provide oversight for more than 30 researchers at the institutions and schools that comprise our matrix Cancer Center. I coordinate programmatic meetings, mentor junior faculty, and engage researchers from our Program and others in collaborative research. I also direct monthly focus group meetings related to cancer screening and surveillance.

B. Positions and Honors

B. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

1993-1994 Assistant Professor of Medicine, CWRU and UHC, Cleveland, OH
1994-1996 Assistant Professor of Medicine and General Medical Sciences (Oncology), CWRU and UHC, Cleveland, OH
1994- Member, Case Comprehensive Cancer Center, Cleveland, OH
1996-1999 Assistant Professor, Medicine and Epidemiology & Biostatistics, CWRU and UHC, Cleveland, OH
1999-2005 Associate Professor of Medicine-Gastroenterology, General Medical Sciences (Oncology) and Epidemiology & Biostatistics, CWRU and UHC, Cleveland, OH
2005- Professor of Medicine-Gastroenterology, General Medical Sciences (Oncology) and Epidemiology & Biostatistics, CWRU and UHC, Cleveland, OH
2006- Co-Leader, Cancer Prevention, Control and Population Research Program, Case Comprehensive Cancer Center, Cleveland, OH
2011- Director, Office of Comparative Effectiveness Research, Case Clinical Translational Science Collaborative (CTSC), Cleveland, OH
2015- Director, Clinical Component, Cleveland Digestive Disease Research Core Center

Honors and Awards: 2005 John Peter Minton Hero of Hope Research Medal of Honor from the American Cancer Society, Ohio Division
2016 Research Mentor Award, Department of Medicine, Case Western Reserve University

Study Sections

2006- 2012 American Cancer Society: Cancer Control and Prevention: Health Policy and Health Services Research
2009- 2015 American College of Gastroenterology: Research Committee
2009- Ad Hoc Reviewer, National Cancer Institute
2010- Ad Hoc Reviewer, Department of Veterans Affairs, Health Services Research and Development

Advisory Boards

2002- State of Ohio Cancer Incidence Surveillance System Scientific Advisory Board
2006 American Cancer Society: Health Policy Advisory Committee
2005 Co-Chair: Ohio Department of Health and Cancer Research Prevention Foundation Dialogue for Action, Current Concepts in Colorectal Cancer Screening and Control,
2012- 2015 Columbia University Cancer Center External Scientific Advisory Board

C. Contributions to Science

1. We have evaluated the impact of health policy and economic factors on the uptake of cancer screening procedures. Data have shown an increased uptake of mammography but not colonoscopy following Affordable Care Act implementation, favorable breast cancer outcomes associated with the CDC's Breast and Cervical Cancer Program, as well as an association of HMO penetration with lower pricing of colon cancer resection.
Dor A, Koroukian SM, Xu F, Stulberg JJ, Delaney CP, **Cooper GS**: Pricing of surgeries for colon cancer: patient severity and market factors. Cancer 2012; 118:5741-8 (PMID 22569703).

Cooper GS, Kou TD, Schluchter MD, Dor A, Koroukian SM: Changes in receipt of cancer screening in Medicare beneficiaries following the Affordable Care Act. J Natl Cancer Inst 2015; 108(5). pii: djv374. doi: 10.1093/jnci/djv374. (PMID 26640244).
Koroukian SM, Bakaki P, Schluchter M, Owusu C, **Cooper GS**, Flocke SA: Comparing breast cancer outcomes between Ohio's Medicaid and the Breast and Cervical Cancer Prevention Program. J Oncology Practice 2015;11:478-85 (PMID 26374859).
Koroukian SM, Bakaki P, Han X, Schluchter M, Owusu C, **Cooper GS**, Flocke SA: Lasting effects of the Breast and Cervical Cancer Early Detection Program (BCCP) on breast cancer detection and outcomes. Prev Chron Dis 2015 Jul 23;12:E116. doi: 10.5888/pcd12.140491 (PMID 26203184).
Cooper GS, Kou TD, Dor A, Koroukian SM, Schluchter MD: Cancer preventive services, socioeconomic status and the Affordable Care Act. Cancer 2017 (E pub ahead of print) (PMID 28067955).

2. We have conducted a series of studies to document practice patterns for colonoscopy, including the miss rate for detection of cancer, underuse and overuse for follow up after polypectomy, outcomes with different sedation models, and its role in treatment of malignant polyps. These studies have identified important gaps in the current technology.
Cooper GS, Xu F, Barnholtz Sloan JS, Koroukian SM, Schluchter MD: Management of malignant colon polyps: a population-based analysis of colonoscopic polypectomy versus surgery. Cancer 2012; 118:651-9. (PMCID PMC3193545).
Cooper GS, Xu F, Barnholtz Sloan JS, Schluchter MD, Koroukian SM: Prevalence and predictors of interval colorectal cancers in Medicare beneficiaries. Cancer 2012; 118:3044-52. (PMCID PMC3258472)
Cooper GS, Kou TD, Barnholtz-Sloan JS, Koroukian SM, Schluchter MD: Use of colonoscopy for polyp surveillance in Medicare beneficiaries. Cancer 2013; 119:1800-7 (PMCID PMC3648624)
Cooper GS, Kou TD, Rex DK: Complications following colonoscopy with anesthesia assistance: a population-based analysis. JAMA Intern Med 2013; 173:551-6. (PMCID PMC3987111)

3. Our group performed a series of studies to validate the accuracy of claims data in the identification of incident cancer cases, cancer stage, initial course of treatment and follow up care. These studies provided the basis for future work by our group and others in the use of this data source.
Cooper GS, Yuan Z, Stange KC, Amini SB, Dennis LK, Rimm AA: The utility of Medicare claims data for measuring cancer stage. Med Care 1999; 37:706-11. (PMID 10424641)
Cooper GS, Virnig B, Klabunde CN, Schussler N, Freeman J, Warren JL: Use of SEER-Medicare data for measuring cancer surgery. Med Care 2002; 40 (Suppl): 43-8. (PMID 12187167)
Cooper GS, Johnson CC, Lamerato L, Poisson LM, Schultz L, Simpkins J, Wells K, Ulcickas Yood M, Chase G, Nathanson SD, Elston Lafata J: Use of guideline recommended follow up care in cancer survivors: routine or diagnostic indications? Med Care 2006; 44:590-4. (PMID 16708008)

4. In collaboration with investigators at Case Western Reserve University, Virginia Commonwealth University and the Henry Ford Health System, we have evaluated the context of primary care visits and its relation to subsequent colon cancer screening uptake.
Elston Lafata J, **Cooper G**, Divine G, Oja-Tebbe N, Flocke SA: Patient-physician colorectal cancer screening discussion content and patients' use of colorectal cancer screening. Patient Education and Counseling 2014; 94:76-82. (PMCID PMC3865022)
Elston Lafata J, **Cooper GS**, Divine G, Flocke SE, Oja-Tebbe N, Stange KC, Wunderlich T: Patient-physician colorectal cancer screening discussions: delivery of the 5A's in practice. Am J Prev Med 2011; 41:480-6 (PMCID PMC4657138)
Flocke SE, Stange KC, **Cooper GS**, Wunderlich T, Oja-Tebbe N, Divine G, Lafata JE: Patient-rated importance and receipt of information for colorectal cancer screening. Cancer Epidemiol Biomarkers Prev 2011; 20:2168-73 (PMCID PMC3189279).

5. As a research mentor, I have collaborated with trainees at the resident, fellow and junior faculty level in studies related to cancer screening and surveillance and clinical epidemiology.
Wells BJ, Kattan MW, **Cooper GS**, Jackson L, Koroukian S: Creation of an online colorectal cancer risk calculator using data from the Multiethnic Cohort Study. J Am Board Family Medicine 2014; 27:42-5 (PMID 24390885).

Rose J, Augestad KM, **Cooper GS**: Colorectal cancer surveillance: What's new and what's next. World J Gastroenterol 2014; 20:1887-97 (PMID 24587668).
Rose J, Augestad KM, Kong C-Y, Meropol NJ, Kattan MW, Hong Q, An X, **Cooper GS**: A simulation model of colorectal cancer surveillance and recurrence. BMC Med Inform Decis Mak 2014;14:29 (PMID 24708517).
Cummings LC, Kou TD, Schluchter MD, Chak A, **Cooper GS**: Outcomes after endoscopic versus surgical therapy for early esophageal cancers in an older population. Gastrointest Endosc 2016; 84:232-240 (PMID 26801375).
Mansoor E, **Cooper GS**: Burden of eosinophilic esophagitis in the United States: a population-based study. Dig Dis Sci 2016; 61: 2928-34 (PMID 27250980).

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/gregory.cooper.3/bibliography/41145309/public/?sort=date&direction=ascending

D. Research Support

ACTIVE
1P50CA150964 (Markowitz, PI; Cooper, Co-Project Leader) 9/1/12-8/31/17
NIH/NCI
Case GI SPORE
Detection of Advanced Adenomas via Stool DNA (sDNA) Methylation Testing
The goal of this project is to evaluate the accuracy of a panel of stool DNA methylation markers in detection of advanced polyps in a screening population, including the management of apparent false positive tests.

5P30 CA043703-22 (Gerson, PI) 09/30/91-03/31/18
NIH/NCI
Comprehensive Cancer Center Support Grant
The objectives of the Center are: 1) to improve the prevention, diagnosis, and therapy of cancer through research; 2) to stimulate and support innovative, coordinated, interdisciplinary research on cancer diagnosis, treatment, and control; 3) to develop clinical applications of research discoveries and to make these applications available as quickly as possible; and 4) to develop cancer prevention and control activities to contribute to the reduction of cancer morbidity and mortality in Northeast Ohio and the surrounding region and nation. Role: Co-leader of Cancer Prevention, Control and Population Research Program

UL1TR000439 (Davis, PI) 6/29/12-5/31/17
NIH/NCATS
Clinical and Translational Science Collaborative of Cleveland
The CTSC coordinates the existing resources relevant to translational and clinical research at CWRU and 3 of its hospital affiliates, Cleveland Clinic, MetroHealth Medical Center and University Hospitals Case Medical Center, including GCRC facilities, a successful multidisciplinary institutional K12 program, technological and statistical core facilities and practice-based research networks, as well as creates new resources. The support will establish the Office of Comparative Effectiveness Research at the Case CTSC and serve as a resource for education and research support.
Role: Director, Office of Comparative Effectiveness Research

MRSG-13-315-01-CPHPS (Rose, PI) 7/1/13-6/30/18
American Cancer Society
Modeling Colorectal Cancer Recurrence and Surveillance
The aim of this career development award is to use data to determine optimal surveillance strategies after initial treatment of nonmetastatic colorectal cancer and develop research skills in cancer prevention and control.
Role: Primary Mentor

Career Development Award (Cummings, PI) 7/1/14-6/30/17
American College of Gastroenterology

Medication and Perioperative Effects on Esophageal Cancer Outcomes
The aim of this career development award is to examine the impact of specific medications including metformin on risk of esophageal cancer and the effect of regional anesthesia and blood transfusion on survival after cancer diagnosis.
Role: Primary Mentor

1P30DK097948-01 (Cominelli, PI) 2/15/15 – 1/31/20
NIH/NIDDK

The Cleveland Digestive Diseases Research Core Center
The major goal of this program is to promote digestive diseases related research in an integrated, collaborative and multidisciplinary fashion by supporting 3 scientific cores and a well-organized administrative core. The overall objective of the Cleveland DDRCC is to increase the availability of core resources for Center members, with the goal of fostering research, collaborations, and new directions in digestive and liver disease research.
Role: Clinical Component Director

RECENTLY COMPLETED

RSGI-12-218-01-CPHPS (Cooper, PI) 7/1/12-6/30/14 (NCE through 12/31/14)
American Cancer Society
Healthcare Reform and Cancer Screening
The goals of this proposal are to evaluate the use of screening mammography, colonoscopy and PSA testing in Medicare beneficiaries before and after the Affordable Care Act legislation and to determine variation in procedure use according to patient and regional characteristics.

Research Scholar Grant (Koroukian, PI) 1/1/12-12/31/13 (NCE through 12/31/14)
American Cancer Society
Multilevel Evaluation of Breast Cancer Prevention Efforts in Ohio
The study will specifically examine transitions between the Breast and Cervical Cancer Early Detection Program, Medicare and Medicaid, will include surveys of BCCEDP Directors, and will consider both county-specific factors and individual factors on stage of breast cancer diagnosis, treatment received and survival. Role: Co-Investigator

1R01 CA132862-01 (Cooper, PI) 01/01/09-12/31/11 (NCE through 12/31/13)
NIH/NCI
Colonoscopy: Practice Patterns and Limitations
Colorectal cancer, the second most fatal cancer in the U.S., is largely preventable through the removal of polyps. However, there is only limited knowledge about the treatment and outcome of colorectal polyps in routine clinical practice. Using data from a large number of Medicare patients, we will study practice patterns for polyp removal via colonoscopy, evaluate its effectiveness in the treatment of early stage colorectal cancer, and estimate the potential failed detection rate at colonoscopy.

Medtronic, Inc. (Cooper, PI) 8/1/14-7/31/15
Investigator Initiated Research Contract
Recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) and Risk of Benign and Malignant Tumors: A Retrospective Cohort Study in Privately Insured Patients
The aim of this study is to determine risk of cancer and benign tumors among younger patients administered rhBMP-2 at the time of lumbar spinal fusion surgery.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Gius, David MD, PhD	Zell Family Scholar Professor, Department of Radiation Oncology, Northwestern University, Feinberg School of Medicine
eRA COMMONS USER NAME (credential, e.g., agency login) Giusd33	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Illinois, at Chicago, Chicago, IL	BS	05/83	Chemistry
The University of Chicago, Chicago, IL	PhD	05/90	Virology
Loyola University of Chicago, Maywood, IL	MD	05/92	Medicine

A. Personal Statement

The central theme of the laboratory is the potential relationship of intracellular pro-proliferative/pro-survival and/or adaptive signaling pathways and how tumor cells respond to a wide array of endogenous and exogenous stress, including that induced by cytotoxic anticancer agents. Over the years my research group has focused this idea on signaling proteins and pathways that direct how cells defend themselves against the damaging effects of oxidative molecules that can result in significant transient or cytotoxic damage. These proteins and biochemical pathways are potential targets for chemoprevention. Compounds targeting them could be used alone or as adjunct therapies to improve the cytotoxic effects of existing anti-cancer agents. In this regard, our laboratory concentrates its efforts on the investigation of the mechanistic connection between aging, cellular and/or mitochondrial metabolism, and carcinogenesis, focusing on the sirtuin gene family. To address this idea, over the past 5 years, we have constructed mice that have the 3 primary (*Sirt1-3*) sirtuins genetically deleted. We have shown that the mice lacking *Sirt2* (Kim et al., 2011, *Cancer Cell*) and *Sirt3* (Kim et al., 2010, *Cancer Cell*) each develop breast cancer, as well as other types of malignancies to varying degrees, and that the levels of SIRT2-3 are also decreased in human cancer samples, as compared to normal tissues. In addition, a mechanism connecting the tumor-permissive phenotype and the aberrant regulation of mitochondrial ROS in the Sirt3 knockout mouse has recently been published (Tao et al., 2010, *Molecular Cell*). Thus, based on these results it seems clear that the primary sirtuins are tumor suppressors in several breast cancers as well as, to a lesser extent, in several other human malignancies.

B. Positions and Honors

Positions and Employment

1989 - 1991 Research Fellow, The University of Chicago, Chicago, IL, Advisor Ralph Weichselbaum
1992 - 1993 Transitional Resident, Weiss Memorial Hospital, the University of Chicago, Chicago, IL
1993 - 1997 Resident, Radiation Oncology, Washington University School of Medicine, St. Louis, MO

1997 - 2001	Assistant Professor, Department of Radiation Oncology, Washington School of Medicine, Washington University, St. Louis, MO
2001 - 2009	Chief, Molecular Radiation Oncology, National Cancer Institute, Bethesda, MD
2010 - 2011	Associate Professor, Department of Cancer Biology, Pediatrics, and Radiation Oncology, Vanderbilt Medical School, Vanderbilt University, Nashville, TN
2011 - 2012	Professor and Thoracic Radiation Oncology Clinical Chief, Department of Cancer Biology, Pediatrics, and Radiation Oncology, Vanderbilt Medical School, Vanderbilt University, Nashville, TN
2012 - Present	Zell Family Scholar Professor, Director, Women's Cancer Program, Robert H. Lurie Comprehensive Cancer Center, Department of Radiation Oncology and Pharmacology, Feinberg Northwestern School of Medicine, Northwestern University, Chicago, IL

National Committees and Review Boards

2016 – 2018	Chair, Radiation Science and Medicine Working Group Steering Committee, American Association for Cancer Research.
2015- 2017	Permanent member Congressionally Directed Medical Research Programs (CDMRP) Lung and Peer Reviewed (LCRP) grant award Integration Panel (IP). 2015 – 2017.
2010 - 2012	Chair, ASTRO Research Evaluation Committee, Fairfax, Virginia
2007 - 2010	Councilor-Medicine, Radiation Research Society Governing Board
2007 - 2009	Committee Member, ASTRO Radiation Biology Committee, Fairfax, Virginia
2004 - 2009	Member, ASTRO Radiation & Cancer Biology Committee
2003 - 2005	Chair, Planning Committee, NCI Radiation Young Investigator Workshop, Bethesda, MD
2001 - 2004	Permanent Member IRB committee, National Cancer Institute, Bethesda, MD
2001 - 2003	Member, CTEP committee, National Cancer Institute, Bethesda, MD
2001 – 2002	Committee Member, Grand Rounds Selection Committee, National Cancer Institute, Bethesda, MD
2001 – 2002	Member, Gyn Cancers Progress Review Group National Cancer Institute, Bethesda, MD

Editorial Boards

1999	Cancer Investigation, Associate Editor
2002	International Journal of Radiation Oncology, Biology, and Physics, Associate Editor
2002 - 2004	Toxicology Letters, Associate Editor
2006	Cancer Research, Associate Editor
2006	Guest Editor for February 2006 Edition, Antioxidants & Redox Signaling

Awards

1987 - 1989	Graduate Training Fellowship, The Department of Molecular Genetics and Cell Biology, and the Committee on Virology, The University of Chicago, Chicago, IL
1998	Radiation Oncology Teacher of the Year, Radiation Oncology Center, Mallinckrodt Institute of Radiology, Washington University School of Medicine, St. Louis, MO
2014	Member, Alpha Omega Alpha (AOA) Medical Honor Society, 2014

Study Section Reviewer

- Chair, Special emphasis Panel, Radiation Therapeutics, and Biology, 10/2015 – 10/2017
- National Cancer Institute, Radiation Therapeutics, and Biology Study Section – Ad Hoc from 6/2005 to 2/2010 as a NCI tenure track faculty and a permanent Member from 10/2011 to 6/2015
- DOD, Chair, Collaborative Innovators and Transformative Vision Breast Cancer Study Section, 11/2011
- Member, Integration Panel, Lung Cancer Research Program, DOD, Congressionally Directed Medical Research Programs, 06/2014 to 05/2017
- Chair, DOD Breast Cancer, Collaborative Innovators and Transformative Vision Awards, 09/2011 to 09/2013.
- National Cancer Institute, NCI Directors Provocative Questions (PQ) Ad Hoc reviewer, 09/2013
- Department of Defense, Chair, PIM Study section, Breast Cancer Program, 04/2009 to 01/2010
- National Cancer Institute, Special Emphasis Panel, 10/2008, 2/2009, and 6/2009

- Department of Defense, Chair, PIM/RON Study section, Prostate Cancer Program, 9/2008
- National Cancer Institute, Radiation Study Section, Ad Hoc, 07/2006, 02/2007, 07/2007, 02/2008, 02/2008, 07/2008, 06/2009, 10/2009, 06/2010, 02/2011, and 06/2011
- Department of Defense, Breast Cancer Research Program, 2003, 2006, and 2009
- Department of Defense, Prostate Cancer Research Program, 2000, 2001, 2002, 2004, and 2005

C. Contributions to Science

http://www.ncbi.nlm.nih.gov/sites/myncbi/12yBsmjmg1RkN/bibliography/46175078/public/

(I) My research career started as a graduate student at the University of Chicago where I worked in the laboratory of Dr. Lou Laimins investigating the pathways directing gene expression (i.e., the identification of cis- and trans- enhancer elements) in oncogenic HPV-18. I also spent just over one year doing a dual postdoctoral fellowship between the laboratories of Vikas Sukhatme, M.D., Ph.D. and Tom Curran, Ph.D. working on FOS signaling in the regulation of the Egr gene family. It was during this time (1989 to 1991) that I focused my research interests on signaling pathways and the subsequent dys-regulation of signaling in carcinogenesis. When I finished my clinical radiation oncology training / residency and started at Washington University as an instructor I was encouraged to I began working on the relationship between oxidative stress and the DNA binding transcription factors, and Dr. Curran recommended I pursue this idea in regards to how cells respond to the stress of ionizing radiation (IR). As such, my early research as a junior faculty at Washington University focused on the role of small molecular metabolites and/or reactive oxygen species (ROS) that result in oxidative damage to the cells exposed to the damaging effects of IR and how changes in gene expression play a protective role in how cells respond to the damaging and cytotoxic effects of ROS.

1. **Gius D**, Cui H, Bradbury CM, Cook J, Smart DK, Zhao S, Young L, Brandenburg SA, Hu Y, Bisht KS, Ho AS, Mattson D, Sun L, Munson PJ, Chuang EY, Mitchell JB, Feinberg AP. Distinct Effects on Gene Expression of Chemical and Genetic Manipulation of Cancer Epigenome Revealed by a Multimodality Approach. ***Cancer Cell*** 6:361-371 2004 PMID: 15488759.
2. Smart, D., Ortiz, K., Mattson, D., Bradbury, C.M., Bisht, K., Sieck, L.K., Brechbiel, M.W., and **Gius, D**. Thioredoxin Reductase as a Molecular Target for Anti-Cancer Agents that induce Oxidative Stress. ***Cancer Research*** 64:6716-6724, 2004. PMID: 15374989
3. Wei SJ, Botero A, Hirota K, Bradbury CM, Markovina S, Laszlo A, Spitz DR, Goswami PC, Yodoi J, **Gius D**. Thioredoxin nuclear translocation and interaction with redox factor-1 activates the activator protein-1 transcription factor in response to ionizing radiation. ***Cancer Research*** 60:6688-6695, 2000 Dec 1;. PMID: 11118054
4. Yu W, **Gius D**, Onyango P, Muldoon-Jacobs K, Karp J, Feinberg AP, Cui H. Epigenetic silencing of tumour suppressor gene *p15* by its antisense RNA. ***Nature*** 451:202-206, 2008. PMCID: 2743558

(II) When I moved to the National Cancer Institute in 2001, I began the process of expanding my research into how tumor cells respond to and defend against ROS in *in vivo* murine models to investigate this idea in a more physiologically relevant fashion. I hypothesized that these models would provide a more physiologically relevant system in which to address the role of oxidative damage in carcinogenesis, and/or tumor cell resistance. In addition, since medical school, I was intrigued by the statistical correlative connection between increasing age and the risk of human malignancies. In this regard, our laboratory hypothesized that there might be a mechanistic relationship between the sirtuin anti-aging gene family, ROS, metabolism, and carcinogenesis. In the last several years, ours has been one of several research groups driving the field of aging, sirtuins, and murine models for carcinogenesis. In this regard, our laboratory was the first to show that a sirtuin (SIRT3) was an *in vivo* tumor suppressor protein.

5. Jacobs KM, Pennington JD, Bisht KS, Aykin-Burns N, Kim HS, Mishra M, Sun L, Nguyen P, Ahn BH, Leclerc J, Deng CX, Spitz DR, **Gius D.** SIRT3 interacts with the daf-16 homolog FOXO3a in the Mitochondria, as well as increases *FOXO3a* Dependent Gene expression. ***Int. J. Biol. Sci.*** 4:291-299, 2008. PMCID: 2532794
6. Kim HS, Patel K, Muldoon-Jacobs K, Bisht KS, Aykin-Burns N, Pennington JD, van der Meer R, Nguyen P,

Savage J, Owens KM, Vassilopoulos A, Ozden O, Park SH, Singh KK, Abdulkadir SA, Spitz DR, Deng CX, **Gius D.** *SIRT3* is a Mitochondria-Localized Tumor Suppressor Required for Maintenance of Mitochondrial Integrity and Metabolism during Stress. ***Cancer Cell*** 17:41-52, 2010. PMID: 22014574

7. Baur JA, Chen D, Chini EN, Chua K, Cohen HY, de Cabo R, Deng C, Dimmeler S, **Gius D**, Guarente LP, Helfand SL, Imai S, Itoh H, Kadowaki T, Koya D, Leeuwenburgh C, McBurney M, Nabeshima Y, Neri C, Oberdoerffer P, Pestell RG, Rogina B, Sadoshima J, Sartorelli V, Serrano M, Sinclair DA, Steegborn C, Tatar M, Tissenbaum HA, Tong Q, Tsubota K, Vaquero A, Verdin E. Dietary Restriction: Standing Up for Sirtuins. ***Science*** 329:1012-1013, 2010. Letter to the editor. PMID: 20798296.
8. Bao J, Scott I, Lu Z, Pang L, Dimond CC, **Gius D,** Sack MN. Sirt3 is regulated by nutrient excess and modulates hepatic susceptibility to lipotoxicity. ***Free Radic. Biol. Med.*** 49:1230-7, 2010. PMCID: 2943385.

(III) We also hypothesized that the cytoplasmic sirtuins (e.g., SIRT2) would also function as fidelity proteins that connect ROS, aging, metabolism, and carcinogenesis and as such, Sirt2 knockout mice were constructed. Experiments with this *in vivo* model showed that SIRT2 also was a tumor suppressor and further suggested that sirtuins are a family of fidelity proteins. In addition, their loss of function in mice, via genetic deletion, results in a permissive phenotype for age-related illness, including the development of tumors. Since the publication of these 2 manuscripts in *Cancer Cell* showing that SIRT2 and SIRT3 are TS proteins, it has been shown that SIRT4 (Csibi et al., 2013, *Cancer Cell*, from the Haigis laboratory) and SIRT6 (Sebastián et al., 2014, *Cell*, from the Mostoslavsky laboratory) are also sirtuins proteins that can function as tumor suppressors, suggesting that sirtuins are a family of cellular, nutrient dependent fidelity proteins that when genetically deleted results in an in vivo murine tumor permissive phenotype.

9. Kim HS, Vassilopoulos A, Wang RH, Lahusen T, Xiao Z, Xu X, Li C, Veenstra TD, Li B, Yu H, Ji J, Wang XW, Park SH, Cha YI, **Gius D**, Deng CX. Sirt2 Maintains Genome Integrity and Suppresses Tumorigenesis through Regulating APC/C Activity. ***Cancer Cell*** 20:487-499, 2011. PMID: 22100505
10. Zhang H, Park SH, Pantazides BG, Hardy CW, Duong DM, Seyfried NT, **Gius D**, and Yu DS. SIRT2 Directs the Replication Stress Response through CDK9 Deacetylation. ***Proc. Natl. Acad. Sci.*** **USA** 110:13546-13551, 2013. PMID: 23898190
11. Park SH, Ozden O, Liu G, Song HY, Zhu Y, Yan Y, Zou X, Kang HJ, Jiang H, Principe DR, Cha YI, Roh M, Vassilopoulos A, **Gius D**. SIRT2-mediated deacetylation and tetramerization of pyruvate kinase directs glycolysis and tumor growth. ***Cancer Res***. Apr 27, (Epub ahead of print), 2016. PMID: 27197174
12. Zhang H, Li X, Daddacha W, Pan Y, Madden WZ, Park S-H, Duong DM, Xie M, Yu, B, Warren M.D, Liu EA, Deng X, Seyfried NT, **Gius D**, and Yu DS. ATRIP Deacetylation by SIRT2 Drives ATR Checkpoint Activation by Promoting Binding to RPA-ssDNA. ***Cell Reports*** 14:1435-47. 2016. PMID: 26854234

(IV) We are also pursuing research to attempt to determine the upstream pathways and mechanism that direct (i.e., activate or repress) SIRT3 enzymatic activity. In addition, we are also beginning to focus on translational research to determine if human tumors exhibit a specific loss of SIRT3-MnSOD acetylation signature as well as identify new small chemicals that will active this pathway. This may lead to new therapeutic strategies, with the overarching goal of translation of this research from the bench to the bedside. In this regard, we have shown that two agents, GC4419, which chemically removes superoxide, and Honokiol, which directly binds to and increases SIRT3 deacetylation activity, are new, potentially therapeutic opportunities..

13. Peek CB Affinati AH, Moynihan-Ramsey K, Kuo H-Y, Yu W, Sena L, Ilkayeva O, Marcheva B, Kobayashil Y, Omura C, Levi DC, Bacsik DJ, **Gius D**, Newgard CB, Goetzma E, Chandel N, Denu JM, and Bass, J. Circadian Clock NAD+ Cycle Drives Mitochondrial Oxidative Metabolism in Mice. ***Science*** 342:1243417, 2013. PMID: 24051248
14. Desouki MM, Doubinskaia I, **Gius D**, Abdulkadir SA. Decreased mitochondrial SIRT3 expression is a potential molecular biomarker associated with poor outcome in breast cancer. ***Hum Pathol*****.** 45:1071-1077, 2014. PMID: 24746213
15. Vassilopoulos A, Pennington JD, Andresson T, Rees DM, Bosley AD, Fearnley IM, Ham A, Flynn CR, Hill S, Rose KL, Kim HS, Deng CX, Walker JE, **Gius D**. SIRT3 deacetylates ATP synthase F1 complex

proteins in response to nutrient- and exercise-induced stress. ***Antioxid Redox Signal***. 21:551-64, 2014. PMID: 24252090

16. Vinodkumar K, Pillai VB,1, Samant S,, Sundaresan NR, Raghuraman H, Kim G, Hail DB, Bonner M, Arbiser J, Jones DP, **Gius D**, and Mahesh P. Gupta. Honokiol is an activator of SIRT3 that promotes mitochondrial function and blocks cardiac hypertrophy in mice. ***Nat. Commun.*** 6:6656, 2015. PMID: 25871545

(V) After demonstrating that SIRT3 is a tumor suppressor, we investigated the mechanism that might connect the aberrant increase in cellular ROS and metabolism to the development of a tumor-permissive phenotype. In this regard, we showed that SIRT3 directs the acetylation status and function of MnSOD detoxification activity. We has also shown that there is an Loss of SIRT3-MnSOD-Ac-ROS mitochondrial axis that promotes both carcinogenesis but also a tumor resistance phenotype. These manuscript listed strongly suggest that SIRT3 is a fidelity or tumor suppressor and its dysregulation, either as a result of increasing age or other physiological states, promotes breast carcinogenesis, at least in some part, via dysregulated detoxification proteins..

17. Tao R, Coleman MC, Pennington JD, Ozden O, Park SH, Jiang H, Kim HS, Flynn CR, Hill S, Hayes McDonald W, Olivier AK, Spitz DR, **Gius D.** Sirt3-Mediated Deacetylation of Evolutionarily Conserved Lysine 122 Regulates MnSOD Activity in Response to Stress. ***Molecular Cell*** 40:893-904, 2010. PMCID: 3266626
18. Haigis MC, Deng C-X, Finley LWS, Kim H-S, and **Gius D.** SIRT3 is a Mitochondrial Tumor Suppressor: A Scientific Tale that Connects Aberrant Cellular ROS, the Warburg Effect, and Carcinogenesis. ***Cancer Research*** 72:2468-2472, 2012. PMID: 22589271
19. Vassilopoulos A, Pennington JP, Andresson T, Rees D, Bosley AD, Fearnley IM, Ham A, Flynn CR, Jones K, Kim H-K, Deng C-X, Walker J, and **Gius, D**. SIRT3 Deacetylates ATP Synthase F1 Complex Proteins in Response to Nutrient and Exercise-Induced Stress in Muscle. ***Antioxid. Redox Signal*** 21(4):551-564, 2014. PMID: 24252090
20. Ozden O, Park SH, Wagner BA, Yong Song H, Zhu Y, Vassilopoulos A, Jung B, Buettner GR, **Gius D**. SIRT3 deacetylates and increases pyruvate dehydrogenase activity in cancer cells. ***Free Radic Biol Med***. 76:163-172, 2014. PMID: 25152236

D. Research Support

NIH/NCI R01CA152601 (Gius - PI) 08/01/10 – 06/30/20 1.80 Calendar
Loss of Mitochondrial Sirt3, Decreased MnSOD Activity, and IR Induced Genomic Instability
The goal of this proposal is to determine a mechanistic connection between CLOCK signaling factors, SIRT3, mitochondrial metabolism (specifically superoxide levels), and IR-induced genomic instability as well as carcinogenesis.

NIH/NCI R01CA152799 (Gius - PI) 09/01/11 – 08/31/16 1.80 Calendar
SIRT3 is a Mitochondrial Tumor Suppressor in ER/PR Positive Mammary Tumors
The goal of this proposal is to determine the genetic and biochemical relationship between the mitochondrial sirtuin, SIRT3, metabolism, and ER/PR positive breast cancers.

NIH/NCI 1R01CA168292 (Gius - PI) 09/01/12 – 08/31/17 1.80 Calendar
ROS and HIF-1α as molecular targets for chemoprevention in Sirt3$^{-/-}$ breast cancers
The goal of this proposal is to determine if mice lacking *Sirt3* are a novel *in vivo* model in which to investigate the well established connection between decreased SIRT3 levels and ROS, HIF-1α, the Warburg effect, and breast malignancies. We hypothesize that agents thought to scavenge or decrease cellular ROS (O2-.) and/or inhibit HIF-1α activity will prevent tumors in Sirt3 knockout mice.

NIH/NCI P30CA60553 (Platanias) 03/01/14 - 07/31/18 1.20 Calendar
Program Leader, Women's Cancer Program

The goals of this Cancer Center Support Grant are to conduct and support cancer research and to integrate cancer-related research throughout the university; to coordinate and integrate cancer-related activities of the University including community outreach initiatives; to develop and conduct cancer education programs; to promote and participate in state-of-the-art care of cancer patients at the affiliated hospitals of the McGaw Medical Center of Northwestern University; and to develop and implement the initiatives in cancer prevention and control research. These goals are accomplished through the activities of the 9 established programs and 15 shared resources. 01-2013-029A (Gius – Project 2)

Avon Foundation 10/01/13 - 09/30/17 1.20 Calendar
Center of Excellence Project 2: Therapeutic intervention of SIRT3 driven luminal B tumors with SOD mimetics
In this grant application we propose that loss of *Sirt3* is a novel mechanism for carcinogenesis in which to investigate our hypothesized connection between decreased SIRT3 levels, ROS, and breast malignancies.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Iva Greenwald	Professor of Biochemistry and Molecular Biophysics Professor of Genetics and Development
eRA COMMONS USER NAME (credential, e.g., agency login) IVAGREENWALD	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Cornell University, Ithaca, NY	B.S.	1977	Biological Sciences
M.I.T., Cambridge, MA	Ph.D.	1982	Biology
MRC Lab. of Molecular Biology, Cambridge, UK	Postdoctoral	1983-1986	Molecular Biology

Positions and Honors

Positions:

1977-1982 Graduate Student, Department of Biology, M.I.T., Cambridge, MA
Thesis advisor: H. R. Horvitz
Thesis title: Genetic analysis of muscle structure and cell lineage in *Caenorhabditis elegans*

1983-1986 Postdoctoral Fellow, MRC Laboratory of Molecular Biology, Cambridge, U.K.
Sponsor: J. Hodgkin

1986-1993 Assistant and Associate Professor (with tenure), Dept. of Molecular Biology (formerly Biology), Princeton University, Princeton, NJ

1993-present Associate Professor (with tenure) and Professor (1995), Department of Biochemistry and Molecular Biophysics, Columbia University, College of Physicians and Surgeons, NY, NY

1994-2015 Associate Investigator and Investigator (1999), Howard Hughes Medical Institute

2009-2015 Professor, Dept. of Genetics and Development, Columbia University, College of Physicians and Surgeons, NY, NY

2016-present Professor, Dept. of Biological Sciencies, Columbia University

Awards and Honors:

1973 National Merit Scholar and New York State Regents Scholar
1983 Jane Coffin Childs Memorial Fund Postdoctoral Fellow
1986 NIH Postdoctoral Fellow
1987 Searle Scholar
1988 DuPont Young Faculty Award
1998 Promising Investigator Award, Metropolitan Life Foundation
2005 Elected to the American Academy of Arts and Sciences
2005 Elected to the U.S. National Academy of Sciences
2012 Senior Scholar Award, Ellison Medical Research Foundation

Academic service:

Editorial:

1994-1999	Associate Editor, *Genetics*
1995-1999	Editorial Board, *Developmental Biology*
1998-2001	Editorial Advisory Board, *Development*
2001-2011	Editor, *Development*
2004-2016	Section Editor, Signal Transduction, *WormBook*
2008-present	Editorial Board, *Proceedings of the National Academy of Sciences (USA)*
2013-present	Editorial Advisory Board, *Development*
2015-present	Editor-in-Chief, *WormBook* in *Genetics*

National/International advisory or review activities:

1986-present	ad hoc reviewer for NIH, reviewer for many journals
1994-1997	American Cancer Society Developmental Biology Study Section
1996-present	Caenorhabditis Genetics Center Advisory Committee (Chair 2016)
1997-2001	Scientific Advisory Committee, Damon Runyon-Walter Winchell Cancer Research Fund
2002-2004	Scientific Review Panel, Israel Cancer Research Fund
2009-2014	International Scientific Advisory Board, Israel Cancer Research Fund
2015-present	Committee on Publications, PNAS
2016-present	WormBoard

Contributions to Science

(1) Fundamental aspects of the LIN-12/Notch signaling system: role and mechanism. Key contributions include the demonstration of binary regulation of cell fate, the importance of feedback mechanisms in lateral specification, the sequence and potential function of LIN-12/Notch as a receptor, the novel mechanism of signal transduction.

reviewed in: Greenwald, I. (2012) Notch and the awesome power of genetics. Genetics 191, 655-69.

Greenwald, I.S., Sternberg, P.W. and Horvitz, H.R. (1983) The *lin-12* locus specifies cell fates in Caenorhabditis elegans. Cell *34*: 435-444.

Greenwald, I. (1985) *lin-12*, a nematode homeotic gene, is homologous to a set of mammalian proteins that includes epidermal growth factor. Cell *43*: 583-590.

Seydoux, G. and Greenwald, I. (1989) Cell autonomy of *lin-12* function in a cell fate decision in *C. elegans*. Cell *57*: 1237-1245.

Wilkinson, H.A., Fitzgerald, K., and Greenwald, I. (1994) Reciprocal changes in expression of *lin-12* (receptor) and *lag-2* (ligand) prior to commitment in a *C. elegans* cell fate decision. Cell 79, 1187-1198.

Struhl, G., Fitzgerald, K. and Greenwald, I. (1993) Intrinsic activity of the *lin-12* and *Notch* intracellular domains *in vivo*. Cell 74, 331-345.

(2) γ-secretase topology and role in Notch signaling: Key contributions include the essential role of γ-secretase in Notch signal transduction and the first topological evidence that a key catalytic aspartyl residue resided in a transmembrane domain.

Levitan, D. and Greenwald, I. (1995) Facilitation of *lin-12*-mediated signalling by *sel-12*, a *C. elegans* S182 Alzheimer's disease gene. Nature 377, 351-354.

Li, X. and Greenwald, I. (1997) HOP-1, a *C. elegans* presenilin, appears to be functionally redundant with SEL-12 presenilin and to facilitate LIN-12 and GLP-1 signalling. Proc. Natl. Acad. Sci. (USA) 94, 12204-12209.

Li, X. and Greenwald, I. (1998) Additional evidence for an eight-transmembrane-domain topology for *Caenorhabditis elegans* and human presenilins. Proc. Natl. Acad. Sci. (USA) 95, 7109-7114.

Struhl, G. and Greenwald, I. (1999) Presenilin is required for activity and nuclear access of Notch in Drosophila. Nature 398, 522-525.

Struhl, G. and Greenwald, I. (2001) Presenilin-mediated transmembrane cleavage is required for Notch signal transduction in Drosophila. Proc. Natl. Acad. Sci. (USA) 98, 229-234.

(3) Crosstalk between other signaling pathways and LIN-12/Notch in development: endocytosis of LIN-12/Notch in response to EGFR activation, negative regulation of EGFR signaling in response to LIN-12/Notch activation, negative regulation of LIN-12/Notch to maintain cell fate plasticity multipotency when Insulin signaling is low. These efforts are ongoing.

Shaye, D.D. and Greenwald, I. (2002) Endocytosis-mediated downregulation of LIN-12/Notch upon Ras activation in *C. elegans*. Nature 420, 686-690.

Yoo, A.S., Bais, C., and Greenwald, I. (2004) Cross-talk between the EGF receptor-MAP kinase and LIN 12/Notch pathways in *Caenorhabditis elegans* vulval development. Science 303, 663-666.

Yoo, A.S. and Greenwald, I. (2005) LIN-12/Notch activation leads to microRNA-mediated downregulation of Vav in *C. elegans*. Science 310, 1330-1333.

Karp, X. and Greenwald, I. (2013) Control of cell fate plasticity and maintenance of multipotency by DAF-16/FoxO in quiescent *C. elegans.* Proc Natl Acad Sci (USA), www.pnas.org/cgi/doi/10.1073/pnas.1222377110.

(4) Directed cancer-relevant studies: *C. elegans* genetic analysis established missense ligand-independent activating mutations in LIN-12/Notch and negative regulation by SEL-10/Fbw7 as a paradigm for T-cell acute lymphoblastic leukemia; ongoing efforts include identifying novel regulators of LIN-12/Notch activity and exploring other potential targets for the tumor suppressor Fbw7.

Greenwald, I. and Seydoux, G. (1990) Analysis of gain-of-function mutations of the *lin-12* gene of *C. elegans*. Nature *346*: 197-199.

Hubbard, E.J.A., Wu, G., Kitajewski, J. and Greenwald, I. (1997) *sel-10*, a negative regulator of *lin-12* activity in *C. elegans*, encodes a member of the CDC4 family of proteins. Genes Dev. 11, 3182-3193.

de la Cova, C. and Greenwald, I. (2012) SEL-10/Fbw7-dependent negative feedback regulation of LIN-45/Braf signaling in C. elegans via a conserved phosphodegron Genes Dev. 26, 2524-2535.

Sallee, M.D. and Greenwald, I. (2015) Dimerization-driven degradation of *C. elegans* and human E proteins. Genes Dev. 29, 1356-1361.

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: HU, MICKEY

eRA COMMONS USER NAME (agency login): MICKEYHU

POSITION TITLE: Associate Professor (University tenure line)

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
National Taiwan University, Taipei	BS	06/1978	Chemistry
National Taiwan University, Taipei	MS	06/1982	Biological Sciences
California Institute of Technology, Pasadena, CA	PHD	06/1988	Chemical Biology
California Institute of Technology, Pasadena, CA	Postdoctoral Fellow	08/1989	Molecular Biology
Stanford University Medical Center, Stanford, CA	Postdoctoral Fellow	06/1993	Molecular Immunology

A. Personal Statement

I have the expertise, leadership, training and motivation essential for successfully carrying out the proposed project. I have a broad background in breast cancer (BCa) biology, with expertise in cell biology, signal mechanisms, small-molecule (SM) anticancer drugs and therapeutic treatments. My research includes the FOXO3-dependent remedying the malignant properties of metastatic BCa (MBC) cells by low-dose therapy with SM anticancer drugs, and pharmacological activation of FOXO3 in regulating tumor suppression in MBC. The proposed research will be strongly supported by our discovery in novel combination immunotherapies that blend immunotherapy (e.g., anti-PD-1) and targeted SM “immune receptor inhibitors” (IRIs) on suppressing MBC progression and *boosting the efficacy of immunotherapy*. I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result these experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work as documented in the following publications.

1. Hu MC, Lee DF, Xia W, Golfman LS, Ou-Yang F, Yang JY, Zou Y, Bao S, Hanada N, Saso H, Kobayashi R, Hung MC. IkappaB kinase promotes tumorigenesis through inhibition of forkhead FOXO3a. Cell. 2004 Apr 16;117(2):225-37. PubMed PMID: 15084260.
2. Tsai WB, Chung YM, Takahashi Y, Xu Z, Hu MC. Functional interaction between FOXO3a and ATM regulates DNA damage response. Nat Cell Biol. 2008 Apr;10(4):460-7. PubMed PMID: 18344987; PubMed Central PMCID: PMC2674111.
3. Chung YM, Park SH, Tsai WB, Wang SY, Ikeda MA, Berek JS, Chen DJ, Hu MC. FOXO3 signalling links ATM to the p53 apoptotic pathway following DNA damage. Nat Commun. 2012;3:1000. PubMed PMID: 22893124; PubMed Central PMCID: PMC3589124.
4. Hu T, Chung YM, Guan M, Ma M, Ma J, Berek JS, Hu MC. Reprogramming ovarian and breast cancer cells into non-cancerous cells by low-dose metformin or SN-38 through FOXO3 activation. Sci Rep. 2014 Jul 24;4:5810. PubMed PMID: 25056111; PubMed Central PMCID: PMC4108946.

B. Positions and Honors

Positions and Employment

1983 - 1988 Graduate Research Assistant, California Institute of Technology, Pasadena, CA
1988 - 1989 Postdoctoral Fellow, California Institute of Technology, Pasadena, CA
1989 - 1993 Postdoctoral Fellow, Stanford University Medical Center, Stanford, CA
1993 - 1999 Principal Investigator, Amgen Center, Amgen Inc., Thousand Oaks, CA
1999 - 2001 Assistant Professor (NTRA), University of Texas M.D. Anderson Cancer Center, Houston, TX
2001 - 2008 Assistant Professor (tenure-track), M.D. Anderson Cancer Center, Houston, TX2008 - present Associate Professor (University tenure line), Stanford University School of Medicine, Stanford,

Other Experience and Professional Memberships

2000 - 2009 Review member, CDMRP BCRP Review Panel: Clinical and Experimental Therapeutics
2004 - 2009 Review member, USAMRMC CDMRP, BCRP Review Panel: Concept Award
2004 - 2009 Review member, USAMRMC CDMRP, Prostate Cancer Research Program Review Panel: Clinical and Experimental Therapeutics
2009 - 2009 Review member, NIH RFA OD-09-003 Challenge Grants Study Section Panel 10
2009 - 2009 Review member, NIH Challenge Grants in Health and Science Research (RC1) Review Panel
2009 - 2010 Review member, USAMRMC CDMRP, BCRP IDEA Award Review Panel
2010 - 2010 Review member, Susan G. Komen for the Cure Postdoctoral Fellowship review committees
2010 - 2015 Review member, Scientific Review Committee, Stanford Cancer Center, Stanford University
2011 - 2011 Review member, NIH Grant Review Panel, 2011/05 ZRG1 IMM Scientific Review Group
2012 - 2015 Review member, USAMRMC CDMRP BCRP Review Panels: TRN and TRN2
2015 - present Review member, NIH, the Cancer Drug Development & Therapeutics (CDDT) study section

Honors

1983 - 1988 Graduate Scholarship, California Institute of Technology
1987 Li-Ming Research Award, Li-Ming Foundation, Los Angeles, CA
1987 The Herbert Newby McCoy Award, California Institute of Technology
1988 - 1989 Amgen Postdoctoral Research Fellowship, Amgen, Inc.
1989 - 1991 Leukemia Society of America Postdoctoral Fellowship, Leukemia Society of America
1991 - 1993 Howard Hughes Medical Institute Postdoctoral Fellowship, Howard Hughes Medical Institute

C. Contribution to Science

a. My early publications directly addressed the fact that the E. coli *lac* repressor can be utilized to generate a genetic switch for regulating gene expression in mammalian cells. For the first time, I established a novel inducible promoter, a genetic switch, in mammalian cells by using the lac repressor-operator system (PMID: 3028641). In fact, this invention was accomplished a few years before the next inducible Tet (Tet- on) promoter was established. I served as the primary investigator in these studies.

   a. Hu MC, Davidson N. The inducible lac operator-repressor system is functional in mammalian cells. Cell. 1987 Feb 27;48(4):555-66. PubMed PMID: 3028641.
   b. Hu MC, Davidson N. A combination of derepression of the lac operator-repressor system with positive induction by glucocorticoid and metal ions provides a high-level-inducible gene expression system based on the human metallothionein-IIA promoter. Mol Cell Biol. 1990 Dec;10(12):6141-51. PubMed PMID: 2247053; PubMed Central PMCID: PMC362889.

b. I applied a novel strategy to isolate and clone the gut mucosal (Peyer's patch) homing receptor, integrin α4/β7, using a mouse mAb. I documented that the expression of integrin α4/β7 in lymphocytes played a key and essential role in the regulation of lymphocyte migration and binding to Peyer's patches (PMID: 1518854). Our findings suggest that the mechanism underlying the homing receptor-mediated lymphocyte migration and extravasation from blood into subcutaneous tissue is probably shared by malignant tumor metastasis. Strikingly, this receptor has been highlighted as a novel receptor for HIV entry through the gut [Nat. Immunol. 9:301-309 (2008)]. I served as the primary investigator in these studies.

a. Neuhaus H, Hu MC, Hemler ME, Takada Y, Holzmann B, Weissman IL. Cloning and expression of cDNAs for the alpha subunit of the murine lymphocyte-Peyer's patch adhesion molecule. J Cell Biol. 1991 Nov;115(4):1149-58. PubMed PMID: 1840602; PubMed Central PMCID: PMC2289944.

b. Hu MC, Crowe DT, Weissman IL, Holzmann B. Cloning and expression of mouse integrin beta p(beta7): a functional role in Peyer's patch-specific lymphocyte homing. Proc Natl Acad Sci U S A. 1992 Sep1;89(17):8254-8. PubMed PMID: 1518854; PubMed Central PMCID: PMC49896.

c. Hu MC, Holzmann B, Crowe DT, Neuhaus H, Weissman IL. The Peyer's patch homing receptor. Curr Top Microbiol Immunol. 1993;184:125-38. PubMed PMID: 8313716.

c. I employed a novel strategy to discover that FOXO3 is a key tumor suppressor. Our data indicated that nuclear exclusion of FOXO3 significantly contributed to cancer pathogenesis. We discovered a new mechanism whereby the IKKβ regulates FOXO3 access to the nucleus and thus, tumorigenesis. Notably, we found a striking inverse correlation between cytoplasmic FOXO3 and survival rate in patients with breast cancer (PMID: 15084260). Indeed, the significance of this finding in breast cancer was highlighted in Nature Rev. Cancer 4:421 (2004). I served as either the primary or senior investigator in these studies.

a. Hu MC, Lee DF, Xia W, Golfman LS, Ou-Yang F, Yang JY, Zou Y, Bao S, Hanada N, Saso H, Kobayashi R, Hung MC. IkappaB kinase promotes tumorigenesis through inhibition of forkhead FOXO3a. Cell. 2004 Apr 16;117(2):225-37. PubMed PMID: 15084260.

b. Yang JY, Xia W, Hu MC. Ionizing radiation activates expression of FOXO3a, Fas ligand, and Bim, and induces cell apoptosis. Int J Oncol. 2006 Sep;29(3):643-8. PubMed PMID: 16865280; PubMed Central PMCID: PMC2632978.

d. I led research to discover that FOXO3 controls ATM-mediated DNA damage response in genomic stability maintenance (PMID: 18344987). This finding is important because understanding cellular responses to DNA damage can provide invaluable insight into the pathogenesis of cancer and suggest new therapeutic interventions, and recent gene knockout experiments reveal vital functions of FOXO in tumor suppression and stem cell maintenance. Our recent results show that FOXO3 controls the formation of ATM-containing signaling complexes at sites of DNA damage that induce apoptosis (PMID: 22893124). Moreover, we established a new paradigm of low-dose therapy-induced rectification or reprogramming of cancer cells in a FOXO3-dependent manner, and may allow patients to overcome these cancers with minimal side effects (PMID: 25056111). I served as the senior investigator in all of these studies.

a. Tsai WB, Chung YM, Takahashi Y, Xu Z, Hu MC. Functional interaction between FOXO3a and ATM regulates DNA damage response. Nat Cell Biol. 2008 Apr;10(4):460-7. PubMed PMID: 18344987; PubMed Central PMCID: PMC2674111.

b. Chung YM, Park SH, Tsai WB, Wang SY, Ikeda MA, Berek JS, Chen DJ, Hu MC. FOXO3 signalling links ATM to the p53 apoptotic pathway following DNA damage. Nat Commun. 2012;3:1000. PubMed PMID: 22893124; PubMed Central PMCID: PMC3589124.

c. Hu T, Chung YM, Guan M, Ma M, Ma J, Berek JS, Hu MC. Reprogramming ovarian and breast cancer cells into non-cancerous cells by low-dose metformin or SN-38 through FOXO3 activation. Sci Rep. 2014 Jul 24;4:5810. PubMed PMID: 25056111; PubMed Central PMCID: PMC4108946.

d. Park SH, Chung YM, Ma J, Yang Q, Berek JS, Hu MC. Pharmacological activation of FOXO3 suppresses triple-negative breast cancer in vitro and in vivo. Oncotarget. 2016 Jun 7. doi: 10.18632/oncotarget.9881. [Epub ahead of print] PubMed PMID: 27283899

5. I led research to examine BPA's mechanisms of action and discover that low-dose BPA exerts c-Myc-dependent genotoxic and mitogenic effects on mammary cells. I served as the senior investigator.

a. Pfeifer D, Chung YM, Hu MC. Effects of Low-Dose Bisphenol A on DNA Damage and Proliferation of Breast Cells: The Role of c-Myc. Environ Health Perspect. 2015 Dec;123(12):1271-9. PubMed PMID: 25933419; PubMed Central PMCID: PMC4671234

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/myncbi/mickey.hu.1/bibliography/41149943/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

2016/09/01-2018/08/31
1R21CA201940-01A1, National Cancer Institute (NCI) HU, MICKEY C-T (PI)
Stem cell-adrenomedullin therapy for cancer linked lymphedema
Role: PI

2016/07/01-2018/06/30
02-2016-033, Avon Breast Cancer Crusade Research Program
Hu, Mickey (PI)
Targeting metastatic breast cancer with novel EMT-inhibiting drugs
Role: PI

Completed Research Support

2013/10/01-2016/09/30
02-2013-051, Avon Foundation for Women
Hu, Mickey (PI)
Exposure to tobacco smoke and BPA together augments the risk of developing breast cancer
Role: PI

2014/10/01-2015/09/30
1R41CA183335-01, NCI Hsu, Sheau Yu (PI)
Developing Novel Therapies for Treating Breast Cancer Related Lymphedema
Role: Co-PI

2012/09/01-2013/08/31
Stanford Cancer Institute Developmental Cancer Research Award, Stanford Cancer Institute
Hu, Mickey (PI)
Activation of FOXO tumor suppressor for triple-negative breast cancer therapy
Role: PI

2012/03/01-2013/02/28
The Ann Schreiber Research Training Programs of Excellence 2012, The Ovarian Cancer Research Fund
Park, See-Hyoung (PI)
Targeting Ovarian Cancer with Combination of Olaparib and Bepridil
Role: Faculty

2006/03/10-2012/12/31
R01 CA113859-05, National Cancer Institute (NCI) HU, MICKEY C-T (PI)
The Role of Regulation of FOXO3a in Tumor Suppression
Role: PI

2010/07/01-2012/06/30
02-2010-063, Avon Foundation for Women
Hu, Mickey (PI)
Roles of BPA and FOXO in DNA damage response in breast cancer development
Role: PI

2011/04/01-2012/03/31
The Scientific Scholar Award, The Marsha Rivkin Center for Ovarian Cancer Research
Chung, Young Min (PI)
Targeting Ovarian Cancer with Combination of Olaparib and Trifluoperazine
Role: Faculty

2006/03/10-2011/02/28
R01 CA113859-01A1, National Cancer Institute (NCI) HU, MICKEY C-T (PI)
The Role of Regulation of FOXO3a in Tumor Suppression
Role: PI

2006/03/10-2011/01/31
R01 CA113859-02, National Cancer Institute (NCI) HU, MICKEY C-T (PI)
The Role of Regulation of FOXO3a in Tumor Suppression
Role: PI

2006/03/10-2010/12/31
R01 CA113859-04, National Cancer Institute (NCI) HU, MICKEY C-T (PI)
The Role of Regulation of FOXO3a in Tumor Suppression

Role: PI

2005/07/01-2010/04/30
1R01CA111479 , NCI Lin, Sue-Hwa (PI)
Bone Metastasis Factor-1 in Prostate Cancer/Bone Interaction
Role: CPI

2006/06/01-2009/05/31
BCTR0504415, The Susan G. Komen Breast Cancer Foundation
Hu, Mickey (PI)
Activation of FOXO Tumor Suppressor for Breast Cancer Therapy and Prevention
Role: PI

2005/09/01-2008/08/31
BC045295 , DOD USAMRMC Breast Cancer Research Program Concept Award
Hu, Mickey (PI)
Targeting Malignant Breast Cancer Cells with A Tumor-specific Neurotropic Peptide-toxin
Role: PI

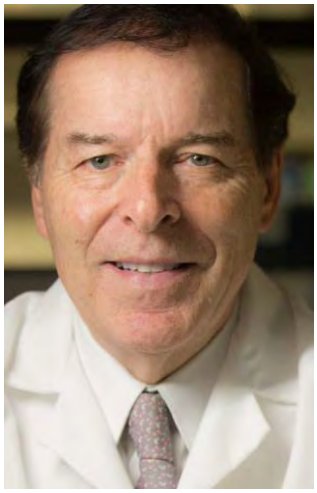
2006/03/10-2008/08/31
R01 CA113859-03, National Cancer Institute (NCI) HU, MICKEY C-T (PI)
The Role of Regulation of FOXO3a in Tumor Suppression
Role: PI

2006/09/01-2008/08/30
003657-0012-2006, ARP-Biological Sciences, the Texas Advanced Research Program
Hu, Mickey (PI)
FOXO Signaling in DNA Damage and Repair Responses
Role: PI

2006/08/01-2007/03/31
P50 CA116199-01, NCI Hortobagyi, Gabriel
(PI)
Suppressing Breast Cancer with FOXO Gene Therapy
Role: Co-Investigator

2003/07/01-2006/06/30
BCTR0201848, The Susan G. Komen Breast Cancer Foundation
Hu, Mickey (PI)
Cyclin D1 as a therapeutic target in human breast cancer
Role: PI

2002/07/01-2006/06/30
DK62248-01, NIH Bedford, Mark (PI)
The Functional Analysis of the Coactivator CARM1
Role: Co-Investigator



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: Powis, Garth

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

POSITION TITLE: Professor/Director

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
Birmingham University, England, United Kingdom	B.Sc., Hons. (1st Class)	05/73	Biochemistry and Pharmacology
Merton College, Oxford, United Kingdom	D. Phil.	05/76	Biochemistry and Pharmacology

A. Personal Statement

I am a molecular pharmacologist and my research interests are the targeting of signaling pathways for cancer drug discovery. My current research interests include studies of the mechanisms, and discovery of novel targets for inhibition of tumor hypoxia and redox stress signaling, mechanisms of PI3K/RAS signaling, discovery and validation of novel targets for the development of inhibitors of mutant KRAS, development of biomarkers for patent selection, and overall molecular target assessment in translational research. I believe in an integrated approach new agent discovery from novel target discovery and validation, small molecule probe development and biomarker discovery, carried through from very basic studies in model organisms, cell and molecular biology, tumor tissue validation of potential targets, small molecule inhibitor discovery and development with *in vivo* studies in appropriate animal models. My experience in drug discovery and development has led to 3 novel targeted agents, a HIF-1 inhibitor, a PI3K inhibitor and a thioredoxin inhibitor currently in clinical testing as anti-cancer agents. I have been continuously RO1 funded by NCI since 1985 and I continue to be a frequent reviewer for NCI grant study sections.

B. Positions and Honors

Positions and Employment

1976-1978 Lecturer, Department of Pharmacology, Glasgow University, Glasgow, United Kingdom
1978 Visiting Associate Professor, Department of Pharmacology, Yale University, New Haven, CT
1978-1992 Professor of Pharmacology, Department of Pharmacology, Division of Developmental Oncology Research, Mayo Clinic & Foundation, Rochester, MN
1992-2005 Professor of Pathology and Pharmacology, and Director of Research, Arizona Cancer

Center, Tucson, AZ
2005-2013 Professor and Chair, Department of Experimental Therapeutics, Division of Cancer Medicine, Director Center for Targeted Therapy, The University of Texas MD Anderson Cancer Center, Houston, TX
2013–current Professor and Director, Sanford-Burnham-Prebys NCI-designated basic research Cancer Center, Sanford-Burnham Prebys Medical Discovery Institute, La Jolla, CA.

C. Contribution to Science

Total publications 355, review articles 31. Patents 20.

1. Cell Signaling Targets for Cancer Therapy and first-in-class PI3-kinase inhibitor PX-866. In 1991 I was among of the first investigators to propose that cell signaling offered targets that could be used for cancer drug discovery (1) based upon our observation that a D-3-deoxy-3-substituted-myoinositol analogue inhibited PI3-kinase signaling and blocked cancer cell growth (2). As PI of a NCI National Cooperative Drug Discovery Grant (NCDDG) at that time working in collaboration with the Eli Lilly Company I assisted them setting up their first high throughput chemical library cancer drug screen, and my lab working on PI3-kinase as a target identified and patented the fungal metabolite wortmannin as the first selective kinase inhibitor (3). Wortmannin was a breakthrough chemical probe at the time exhibiting nanomolar potency and it was instrumental in enabling many of the early studies of PI-3-kinase and related signaling pathways. As PI of a subsequent NCDDG grant working this time with a biotech company I co-founded, ProlX Pharmaceuticals, I developed PX-866, an analogue of wortmannin with drug-like properties, through IND as a pan-PI3-Kinase/ m-TOR inhibitor (4). PX-866 was licensed by the Oncothyreon company, and it has been through Phase I clinical trial, and is just completing the last of 6 Phase II clinical trials. PX-866 was unusual at the time in being an irreversible inhibitor, which although not in vogue at the time is increasingly used for new generation kinase and other cancer drug target inhibitors.

a. **Powis G,** Kozikowski A. Growth factor and oncogene signaling pathways as targets for rational anticancer drug development. Clin Biochem 24:385-97, 1991. PMID: 1760877
b. **Powis G**, Aksoy IA, Melder DC, Aksoy S, Eichinger H, Fauq AH, Kozikowski AP. D-3-deoxy-3-substituted myo-inositol analogues as inhibitors of cell growth. Cancer Chemother Pharmacol 29:95-104, 1991. PMID: 1760864
c. US Patent 5,378,725, Rosanne Bonjouklian, and **Garth Powis**. Inhibition of phosphatidylinositol 3-kinase with wortmannin and analogs thereof, University of Arizona, issued 1/1/1995,
d. Ihle NT, Williams R, Chow S, Chew W, Berggren MI, Paine-Murrieta G, Minion DJ, Halter RJ, Wipf P, Abraham R, Kirkpatrick L, **Powis G**. Molecular pharmacology and antitumor activity of PX-866, a novel inhibitor of phosphoinositide-3-kinase signaling. Mol Cancer Ther 3:763-72, 2004. PMID: 15252137

2. Redox signaling and first-in-class thioredoxin redox inhibitor PX-12. I was the first investigator to identify in 1994 that thioredoxin-1, the human orthologue of the small cytosolic bacterial protein thioredoxin, was elevated in a number of human cancers and that redox signaling played an important role in its growth stimulating activity (1). I also was first to clone thioredoxin reductase responsible for thioredoxin-1 reduction, and mitochondrial thioredoxin-2, and with collaborators to determine the dimeric crystal structure of reduced and oxidized thioredoxin-1(2). Subsequent studies by my group showed that thioredoxin-1 was associated with decreased patient survival (3), observations later confirmed by other investigators in a number of human tumors. In 1998 I developed the thioredoxin inhibitor PX-12 as a potential anticancer agent and showed it blocked the action of thioredoxin-1 in stimulating tumor HIF-1 and VEGF production. Through ProlX Pharmaceuticals I obtained a number of Phase 1 and Phase 2 Small Business Research Innovation(SBRI) grants to get PX-12 into Phase I clinical trial in 2006. A Phase 2 clinical trial in pancreatic cancer supported by a PO1 grant showed limited antitumor activity. However, recent studies of PX-12 administered orally to the APC /min+ mouse, which has a point mutation at the Apc gene and is considered a model for human familial adenomatous polyposis. (FAP), showed PX-12 to be a potent inhibitor of intestinal tumor formation by decreasing β-catenin levels through a non-canonical degradation pathway. Oral PX-12 is being developed as a low toxicity alternate treatment to celecoxib for patients with FAP.

a. Oblong JE, Berggren M, Gasdaska PY, **Powis G**. Site-directed mutagenesis of active site cysteines in human thioredoxin produces competitive inhibitors of human thioredoxin reductase and elimination of mitogenic properties of thioredoxin. J Biol Chem 269:11714-20, 1994: PMID. 8163468

b. Weichsel A, Gasdaska JR, **Powis G**, Montfort WR. Crystal structures of reduced, oxidized, and mutated human thioredoxins: evidence for a regulatory homodimer. Structure 4:735-51, 1996. PMID: 8805557
c. Raffel J, Bhattacharyya AK, Gallegos A, Cui H, Einspahr JG, Alberts DS**, Powis G**. Increased expression of thioredoxin-1 in human colorectal cancer is associated with decreased patient survival. J Lab Clin Med 142:46-51, 2003. PMID: 12878985
d. Kirkpatrick DL, Kuperus M, Dowdeswell M, Potier N, Donald LJ, Kunkel M, Berggren M, Angulo M, **Powis G**. Mechanisms of inhibition of the thioredoxin growth factor system by antitumor 2-imidazolyl disulfides. Biochem Pharmacol 55:987-94, 1998. PMID: 9605422

3. Hypoxia an Achilles heel of tumor growth and a first-in-class HIF-1 inhibitor PX478.

The effect of hypoxia in cancer has been a long standing interest of mine . In 2004 I published the results of study with a first-in-class inhibitor of the hypoxia inducible factor 1α (HIF-1α) by a small molecule inhibitor PX-478 I developed (1). The compound showed remarkable antitumor activity in animal models with a 5 day course of treatment leading to progressive tumor regression for several weeks, and in some cases complete cure of the animals. However, it was not until 2008 that we were able to publish the mechanism for the compound as an inhibitor of HIF-1α translation (2). A patent was issued in 2006 and PX-478 was licensed by the pharma company Oncothyreon who started a Phase I clinical trial in 2008. Continued study of PX-478 in my lab has shown that it is a potent inhibitor of the tumor stromal vascular response to radiation therapy and a potent radiosensitizer (3). My lab has also shown that hypoxia induced HIF-1α is an inducer of hedgehog production by pancreatic cancer cells causing tumor fibroblast deposition of collagen and fibronectin as a cause of the extensive desmoplasia seen in pancreatic cancer (4). PX-478 is an inhibitor of hedgehog signaling. My interest in tumor hypoxia and the stroma has continued and current work in the lab is focused on the role of the stroma supporting cancer cell growth through cell contact interactions and metabolic support, under conditions of hypoxia to which both stroma as well as tumor are exposed, and the effects of HIF-1α.

a. Welsh S, Williams R, Kirkpatrick L, Paine-Murrieta G, **Powis G**. Antitumor activity and pharmacodynamic properties of PX-478, an inhibitor of hypoxia-inducible factor-1alpha. Mol Cancer Ther. 2004 Mar;3(3):233-44. PMCID: PMC2935253
b. Koh MY, Spivak-Kroizman T, Venturini S, Welsh S, Williams RR, Kirkpatrick DL, **Powis G.** Molecular mechanisms for the activity of PX-478, an antitumor inhibitor of the hypoxia-inducible factor-1alpha. Mol Cancer Ther. 2008 Jan;7(1):90-100**.** PMID: 1820201
c. Schwartz DL, Bankson JA, Lemos R Jr, Lai SY, Thittai AK, He Y, Hostetter G, Demeure MJ, Von Hoff D, **Powis G**. Radiosensitization and stromal imaging response correlates for the HIF-1 inhibitor PX-478 given with or without chemotherapy in pancreatic cancer. Mol Cancer Ther. 2010 Jul;9(7):2057-67. PMCID: PMC2935253
d. Spivak-Kroizman TR, Hostetter G, Posner R, Aziz M, Hu C, Demeure MJ, Von Hoff D, Hingorani SR, Palculict TB, Izzo J, Kiriakova GM, Abdelmelek M, Bartholomeusz G, James BP, **Powis G**. Hypoxia triggers hedgehog-mediated tumor-stromal interactions in pancreatic cancer. Cancer Res. 2013 April. PMCID: PMC3782107

4. Drugging undruggable cancer targets: PH domains

Based on the observation I had made that 3-D3-deoxyinositiols inhibited PI-3-kinase signaling, I discovered in 2003 that an analogue, DPIEL, bound to and inhibited the pleckstrin homology (PH) phosphoinositide binding domain of AKT (1). The PH domain is a 3 dimensional protein fold known to occur over 40 high value signaling targets but it had previously been considered to be undruggable My report was the first demonstration that a small molecule could inhibit a PH domain. DPIEL had weak antitumor activity but it was clear that there was the potential for developing cancer drugs this way. In fact the clinically successful Merck allosteric inhibitor MK-2206 PH domain binding drug was developed based on the work in this publication. I also initiated a research program to exploit the PH domain for the development of novel cancer therapeutics. Working with collaborators were able to show that because of low sequence homology between PH domains it is possible to obtain good selectivity among PH domain inhibitors (2) and have developed selective PH domain inhibitors of AKT (3), PDK1 (4) and more recently PH domain proteins that are necessary for the activity of mutant KRas (see below). The PDK1 PH domain inhibitor PHT-425 is currently being developed as a treatment for mutant NRas melanoma which other investigators have shown is supsceptible to PDK1 inhibition, and as a topical treatment for skin cancer and cancers metastasizing to the skin such as inflammatory breast cancer. A biotechnology company PHusis Therapeutics has been established to carry out the commercialization of these agents.

a. Meuillet EJ, Mahadevan D, Vankayalapati H, Berggren M, Williams R, Coon A, Kozikowski AP, **Powis G**. Specific inhibition of the Akt1 pleckstrin homology domain by D-3-deoxy-phosphatidyl-myo-inositol analogues. Mol Cancer Ther 2003; 2:389-99. PMID: 12700283
b. Du-Cuny L, Zuohe S, Moses S, **Powis G**, Mash EA, Meuillet EJ, Zhang S. Computational modeling of novel inhibitors targeting the Akt pleckstrin homology domain. Bioorg Med Chem 17(19):6893-6992, 10/2009. e-Pub 8/2009. PMCID: PMC2808703.
c. Mash EA, Meuillet EJ, **Powis G**. In vitro and In vivo activity of novel small-molecule inhibitors targeting the Pleckstrin Homology Domain of Protein Kinase B/AKT. Cancer Res 69(12):5073-5081, 6/2009. e-Pub 6/2009. PMCID: PMC2914301.
d. Meuillet EJ, Zuohe S, Lemos R, Ihle N, Kingston J, Watkins R, Moses SA, Zhang S, Du-Cuny L, Herbst R, Jacoby JJ, Zhou LL, Ahad AM, Mash EA, Kirkpatrick DL, **Powis G**. Molecular pharmacology and antitumor activity of PHT-427, a Novel AKT/PDPK1 pleckstrin homology domain inhibitor. Mol Cancer Ther 9(3):706-717. PMCID: PMC2837366.

5. Translational studies on KRAS and KRAS inhibitors

While working at MD Anderson Cancer Center I became involved in the first ever biopsy driven personalized medicine clinical trial in refractory NSCLC patients called BATTLE-1 . This was a large 250 patient trial and a rich source of clinical material for translational hypothesis generation. Analyzing the data it became apparent to me that different KRas mutations activate specific downstream signaling pathways with lab based studies confirming the observation, and influence patient response to therapy(1). The work on KRas stimulated my interest in this elusive cancer target that has been known for over 40 years, but for which there is no effective therapy (2). Employing a global siRNA screen I identified genes that when inhibited block the growth of mutant KRas, but not isogenic wild type KRas cells. The top hit was CNK1, a PH domain protein present in the KRas membrane signaling nanocluster. After extensive molecular validation of CNK1 as a target for inhibiting mutant KRas I have been able to convincingly demonstrate that CNK1's PH domain is critical for correctly positioning the KRas nanocluster on the cell membrane allowing KRas to activate downstream signaling (3). I am now developing small molecule inhibitors of the CNK1 domain PH domain with lead compounds have shown selective inhibition of mutant KRas signaling, cell growth and invasion and with antitumor activity against mutant KRas tumors (4). Lead compounds are in late preclinical development. Full reports of the work have not yet been published because of patent issues.

a. Ihle N, Byers L, Kim E, Saintigny P, Lee J, Blumschein G, Tsao A, Liu S, Larsen L, Wang J, Diao L, Coombes K, Chen L, Zhang S, Abdelmelek M, Tang X, Papadimitrakopoulou V, Mina J, Lippman S, Hong W, Herbst R, Wistuba I, Heymach J, **Powis G.** Effect of KRAS oncogene subsititutions on protein behaviour: Implications for signaling and clinical outcome. J Natl Cancer Inst 104(3):228-239, 2/2012. PMCID: PMC3274509.
b. Bailey AM1, Zhan L, Maru D, Shureiqi I, Pickering CR, Kiriakova G, Izzo J, He N, Wei C, Baladandayuthapani V, Liang H, Kopetz S, Guo GL, **Powis G,.** FXR silencing in human colon cancer by DNA methylation and KRAS signaling Am J Physiol Gastrointest Liver Physiol. 2014;306:G48-58. PMCID: PMC3920083
c. Kirkpatrick D, Triana-Baltzer G,Indarte M, Scott M, Lemos R, **Powis G**. Potent and selective inhbitors of the KRAS-signaling nanocluster protein CNKSR1, blocks oncogenic KRAS signaling and mut-KRAS cell growth. Eur. J. Cancer. 2014. 50,160.
d. US Patent, 2009/040575. Gokhale VA, Mahadevan M, Meuillet E, Mash E, **Powis G** and Zhang S,. Small molecule inhibitors of the pleckstrin homology domain and methods for using same, University of Arizona 4/14/2009, Issued.

A complete list of published work is available in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/garth.powis.1/bibliography/40449454/public/?sort=date&direction=ascending

D. Research Support

Ongoing:

5 R01 CA163541-03 Powis (PI) 04/16/2012-04/30/2017
NIH/NCI
Exploiting tumor stroma interactions for cancer therapy. Major goals: 1) to investigate the mechanisms of HIF-1's regulation of pancreatic cancer growth and desmoplasia; 2) to investigate the role of the tumor-stroma interaction in the response to radiation, 3) to exploit a novel target for breaking the tumor-stroma interaction.

Overlap: None

1 R01 CA160398-03 Powis (PI) 04/01/2012-04/30/2017
NIH/NCI
Inhibiting oncogenic KRAS for cancer therapy. Major goals: 1) to investigate which of multiple KRAS downstream signaling pathways are activated by different mut-KRAS amino acid substitutions; 2) to investigate which signaling pathways are essential for mut-KRAS oncogene addiction and/or resistance to therapy; 3) To investigate the regulation of mut-KRAS signaling by the RAS nanocluster protein CNK1. Overlap: None

5 R01 CA155196-04 Herbst/Powis (MPI) 08/01/213-07/31/2016
NIH/NCI
Personalizing NSCLC Therapy: Exploiting KRAS activated pathways. Major goals: 1) to identify predictive biomarkers from selected targeted therapies for patients with advanced, refractory NSCLC, 2) elucidate the role of mutant KRAS signaling in NSCLC, and 3) identify new targets and potential therapies that will mitigate the effects of mutant KRAS in NSCLC patients. Overlap: None

1 R01 CA172670-01 Kopetz (PI) 02/01/2012-12/31/2017
NIH/NCI

Stress signaling pathways and resistance in colorectal cancer. Major goals: 1)To develop an understanding of the mechanisms of resistance to therapy for CRC so that we can design more effective therapies, 2) identify new drug targets for treatment, and develop biomarkers that identify CRC patients most likely to have responses to specific therapies. Overlap: None
Role: Co-PI

2 P30CA030199-34 Powis (PI) 05/01/2013-04/30/2020
NIH/NCI
Cancer Center Support Grant. The Sanford Burnham Medical Research Institute's Cancer Center is dedicated to revealing the fundamental molecular causes of cancer and to applying this knowledge to the health of humans. Through continued commitment to collaborative and multidisciplinary research, our plans seek to propel our scientific activities onward to deliver results that will have a transformational impact in cancer research and medicine.

Completed:
5 R01 CA098920-11 Powis (PI) 04/01/2009-01/31/2015
NIH/NCI
Hypoxia and Anticancer Drug Action
Major goals: The goals of this project are: 1) To investigate novel mechanisms of HIF-1a and stress protein synthesis regulated by the endoplasmic reticulum unfolded protein response (UPR); 2) To investigate novel mechanisms of HIF-1a regulation through degradation and synthesis; 3) To investigate the mechanism(s) of HIF-1 an independent tumor growth to provide targets for therapeutic intervention.

5 R01 CA077204-15 Powis (PI) 04/01/2009-01/31/2015
NIH/NCI
Redox Signaling and Cancer Drug Action
Major goals: The goals of this project are: 1) to investigate and validate in mammalian cancer cells novel pathways of redox signaling discovered through forward genetic studies site Drosophila melanogaster; 2) to investigate and validate novel pathways of redox signaling discovered through genome wide siRNA screening in mammalian cancer cells; 3) to investigate the redox control of the endoplasmic reticulum (ER) unfolded protein response (UPR) on stress protein translation; and 4) to investigate the mechanisms of action of the antitumor Trx signaling inhibitors PX-12 and pleurotin.

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: Schootman, Mario

POSITION TITLE: Professor of Epidemiology; Associate Dean for Research

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

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
Vrije Universiteit Faculty of Human Movement Sciences, Amsterdam, The Netherlands	M.S.	12/1990	Health science
The University of Iowa, Iowa City, Iowa	Ph.D.	12/1993	Epidemiology

A. Personal Statement

I have extensive experience in designing and conducting clinical and public health studies focusing on various adverse outcomes as a function of where individuals live. I have published over 200 peer-reviewed manuscripts, many of which are focused on various aspects of neighborhood-based research using advanced epidemiological methods (e.g., bias correction, propensity scores), a geographic information system, and spatial statistics. Having been the principal investigator of 5 R01 grants, 3 R21 grants, and 1 R03 during the past 10 years, I have the necessary expertise to serve as an investigator on this EPA grant.

B. Positions and Honors

Positions and Employment

1993–1999	Chronic Disease and Injury Epidemiologist, Iowa Department of Public Health, Iowa
1999–2013	Professor of Medicine, Division of Health Behavior Research, Department of Internal Medicine, Washington University (Instructor: 1999-2000; Assistant Professor: 2001-2007; Associate Professor: 2007-2012).
2005–2006	Interim Associate Director for Prevention and Control of the Alvin J. Siteman Cancer Center at Washington University and Barnes-Jewish Hospital
2005–2011	Co-Program leader, Prevention and Control Program, Alvin J. Siteman Cancer Center at Washington University and Barnes-Jewish Hospital
2005–2013	Chief, Division of Health Behavior Research, Department of Internal Medicine, Washington University
2007–2013	Adjunct Associate Professor, Department of Community Health, School of Public Health, Saint Louis University (Adjunct Assistant Professor: 1999-2006)
2008–	Adjunct Associate Professor, Department of Epidemiology, College of Public Health, University of Iowa (Adjunct Assistant Professor: 1995-2008)

2013– Professor of Epidemiology, Health Services Research, and Medicine, James R. Kimmey Endowed Chair of Public Health, College for Public Health and Social Justice, Saint Louis University.

2014– Associate Dean for Research, co-director Doctoral Program in Public Health Studies, Saint Louis University.

Other Experience and Professional Memberships

2003- Member, various NIH study sections (charter member, Community-Level Health Promotion study section: 2005-2009).

2011- Member, Editorial Board, J Primary Care & Community Health, Biomed Research International.

2012-2015 Member, Editorial Board, BMC Cancer.

C. Contribution to Science

1. A geographic information system (GIS) is a powerful tool to help describe the neighborhood of the population. I have used a GIS and related multilevel and spatial methodologies for various purposes, showing how adverse neighborhood conditions affect various health outcomes. In addition, I have done methodologic research to measure various aspects of neighborhoods.

a. **Schootman M**, Sterling DA, Struthers J, Yan Y, Laboube T, Emo B, Higgs G. Positional accuracy and geographic bias of four methods of geocoding in epidemiologic research. Ann Epidemiol 17, 464-470, 2007.
b. Pruitt SL, Jeffe DB, Yan Y, **Schootman M**. Reliability of perceived neighborhood conditions and the effects of measurement error on self-rated health across urban and rural neighborhoods. J Epidemiol Community Health 66, 342-351, 2012. PMCID: PMC3151345
c. Hoehner C, **Schootman M**. Concordance of commercial data sources for neighborhood-effects studies. J Urban Health 87, 713-725, 2010. PMCID: PMC2900563
d. Thompson T, Rodebaugh TL, Perez M, Struthers J, Sefko JA, Lian M, **Schootman M**, Jeffe DB. Influence of neighborhood-level factors on social support in early-stage breast cancer patients and controls. Soc Science Medicine 2016; 156: 55-63.

2. We have conducted methodologic research to measure various aspects of neighborhoods. For example, we showed that Google Street View can be used to reliably and validly measure key aspects of neighborhoods.

a. Pruitt SL, Jeffe DB, Yan Y, **Schootman M**. Reliability of perceived neighborhood conditions and the effects of measurement error on self-rated health across urban and rural neighborhoods. J Epidemiol Community Health 66, 342-351, 2012. PMCID: PMC3151345
b. Wilson JS, Kelly CM, **Schootman M**, Baker EA, Banerjee A, Clennin M, Miller D. Assessing the built environment using omnidirectional imagery. Am J Prev Med 42, 193-199, 2012. PMCID: PMC3263366
c. Kelly CM, Wilson J, Baker EA, Miller DK, **Schootman M**. Using Google Street View to audit the built environment: Inter-rater reliability results. Ann Beh Med 45, S108-112, 2013. PMCID: PMC3549312
d. Andresen EM, Malmstrom TK, **Schootman M**, Wolinsky FD, Miller JP, Miller DK. Observer ratings of neighborhoods: Comparison of two methods. BMC Public Health 13, 1024, 2013. PMCID: PMC3840667

3. Adverse neighborhood conditions affect various colorectal cancer outcomes. We have shown that extensive variation exists in 30-day mortality following a colorectal cancer diagnosis that is much larger across geographic areas (census tracts) than across hospitals. Thirty-day mortality is a key outcome measure in colorectal cancer. In addition, we have shown extensive geographic variation in incidence and prognosis of colorectal cancer.

a. Lian M, **Schootman M**, Doubeni CA, Park Y, Major JM, Torres Stone RA, Laiyemo AO, Hollenbeck A, Graubard BI, Schatzkin A. Geographic variation in colorectal cancer survival and the role of small-area socioeconomic deprivation: A multilevel survival analysis of the NIH-AARP Diet and Health Cohort. Am J Epidemiol, 174, 828-838, 2012. PMCID: PMC3203377
b. Doubeni CA, Major JM, Laiyemo AO, **Schootman M**, Zauber AG, Hollenbeck AR, Sinha R, Allison J. Contribution of behavioral risk factors and obesity to socioeconomic differences in colorectal cancer incidence. J Natl Cancer Inst, 104(18), 1353-62, 2012. PMCID: PMC3529596

c. **Schootman M**, Lian M, Pruitt SL, Hendren S, Deshpande AD, Jeffe DB, Davidson NO. Hospital and geographic variability in 30-day mortality following colorectal cancer surgery. Health Serv Res 49, 1145-1164, 2014. PMCID: PMC4111769
d. **Schootman M**, Lian M, Pruitt SL, Hendren S, Mutch M, Deshpande AD, Jeffe DB, Davidson NO. Hospital and geographic variability in two colorectal cancer surgery outcomes: complications and mortality after complications. Ann Surg Oncol 21, 2659-2666, 2014. PMCID: PMC4090776

Complete List of Published Work:
https://www.ncbi.nlm.nih.gov/sites/myncbi/mario.schootman.1/bibliography/40557002/public/?sort=date&direction=descending

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
David Uehling	Scientific Advisor and Group Leader

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Harvard University	Post-doctoral	1988-1989	Organic Chemistry
Yale University	Post-doctoral	1987-1988	Organic Chemistry
University of California, Berkeley	PhD	1983-87	Organic Chemistry
University of California, San Diego	BA	1979-83	

NOTE: The Biographical Sketch may not exceed four pages. Follow the formats and instructions on the attached sample.

A. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

1983-1987: Research assistant, University of California, Berkeley.
1987-1989: Postdoctoral research associate, Yale and Harvard University.
1989-1990: Senior Scientist, Glaxo, Inc.
1991-1995: Research Investigator I, Glaxo, Inc.
1995-2000: Research Investigator II, Glaxo Wellcome, Inc.
2001-2008: Manager, GlaxoSmithKline
January, 2009-2012: Senior Chemist, OICR
January, 2015-Present: Group Leader and Scientific Advisor, Drug Discovery Group, OICR

B. Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.

Harding, M. W.; Galat, A.; Uehling, D. E.; Schreiber, S. L. **"A Receptor for the Immunosuppressive Agent FK-506 Is a Cis-trans Peptidyl-prolyl Isomerase"** *Nature* **1989**, *341*, 758.

Uehling, D. E.; Nanthakumar, S. S.; Emerson, D. L.; Croom, D.; Leitner, P. P.; Luzzio, M. J.; McIntire, G.; Morton, B.; Profeta, S.; Sisco, J.; Sternbach, D. D; Tong, W.-Q. Vuong, A.; Besterman, J. M. "**Synthesis, Topoisomerase I Inhibitory Activity, and *In Vivo* Evaluation of 11-Azacamptothecin Analogs**" *J. Med. Chem.* **1995**, *38(7)*, 1106-18.

Uehling, David E.; Shearer, Barry G.; Donaldson, Kelly H.; Chao, Esther Y.; Deaton, David N.; Adkison, Kim K.; Brown, Kathleen K.; Cariello, Neal F.; Faison, Walter L.; Lancaster, Mary E.; Lin, Jasmine; Hart, Robert; Milliken, Tula O.; Paulik, Mark A.; Sherman, Bryan W.; Sugg, Elizabeth E.; Cowan, Conrad. **"Biarylaniline Phenethanolamines as Potent and Selective β 3 Adrenergic Receptor Agonists."** *Journal of Medicinal Chemistry* **2006**, 49(9), 2758-2771.

Cobb, J.E., Nanthakumar, S. S.; Rutkowske, R., Uehling, D. E. **"Functionalized 2,5-Disubstituted Benzazepines: Stereoselective Synthesis of 3-Methyl-5-phenyl-2,3,4,5-tetrahydro-1H-3-benzazepine-2-carbonitrile and Related Derivatives."** *Synlett*; **2004** (8), 1394-1398

Uehling, David E.; Donaldson, Kelly H.; Deaton, David N.; Hyman, Clifton E.; Sugg, Elizabeth E.; Barrett, David G.; Hughes, Robert G.; Reitter, Barbara; Adkison, Kim K.; Lancaster, Mary E.; Lee, Frank; Hart, Robert; Paulik, Mark A.; Sherman, Bryan W.; True, Timothy; Cowan, Conrad. **"Synthesis and Evaluation of Potent and Selective β3 Adrenergic Receptor Agonists Containing Acylsulfonamide, Sulfonylsulfonamide, and Sulfonylurea Carboxylic Acid Isosteres."** *J. Med. Chem.* **2002**, *45(3)*, 567-583.

Wood, Edgar R.; Shewchuk, Lisa M.; Ellis, Byron; Brignola, Perry; Brashear, Ronald L.; Caferro, Thomas R.; Dickerson, Scott H.; Dickson, Hamilton D.; Donaldson, Kelly H.; Gaule, Michael; Griffin, Robert J.; Hassell, Anne M.; Keith, Barry; Mullin, Robert; Petrov, Kimberly G.; Reno, Michael J.; Rusnak, David W.; Tadepalli, Sarva M.; Ulrich, John C.; Wagner, Craig D.; Vanderwall, Dana E.; Waterson, Alex G.; Williams, Jon D.; White, Wendy L.; Uehling, David E.. **6-Ethynylthieno[3,2-d]- and 6-ethynylthieno[2,3-d]pyrimidin-4-anilines as tunable covalent modifiers of ErbB kinases.** *Proceedings of the National Academy of Sciences of the United States of America* **2008**, 105(8), 2773-2778.

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Small molecule epigenetic screen identifies novel EZH2 and HDAC inhibitors that target glioblastoma brain tumor-initiating cells. Oncotarget, **2016**, *7*:59360-59376

C. Research Support. List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Principal Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.

Chemistry program leader, Oncology, GSK. Coordinator of chemistry strategy and compound progression for the B-Raf kinase project. Helped initiate new oncology targets in lead optimization or post-candidate selection stage. Program successfully identified high quality development candidate dabrafenib progressing through Phase III. Four patent applications filed in area in past year.

Currently leading various early stage chemistry projects related to kinases, unfolded protein response, apoptosis and stem cells, Protein-protein interactions

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	MEMBERS OF THE PRODUCT DEVELOPMENT ADVISORY COMMITTEE
DATE:	MAY 12, 2017

Summary and Recommendation

The Chief Executive Officer has nominated 13 experts to serve on the Product Development Advisory Committee (PDAC). The Nominations Subcommittee discussed the nominations at its meeting on May 12, 2017, and recommends that the Oversight Committee vote to approve the nominated members.

Discussion

Texas Health & Safety Code § 102.155 allows the Oversight Committee to create ad hoc committees of experts to advise the Oversight Committee on issues relating to cancer. The PDAC will advise the Oversight Committee on issues related to the Product Development Research program. The proposed membership is comprised of industry experts, including current and former grantees. Each member will serve a two-year term that may be renewed by the Oversight Committee.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Product Development Advisory Committee

- Jonathan MacQuitty, Ph.D., Chair
  Venture Partner, Lightspeed Venture Partners
- David Lowe, Ph.D.,* Vice Chair
  President and CEO, Aeglea Biotherapeutics
- David Arthur*
  CEO and Director, Salarius Pharmaceuticals
- Bruce Butler, Ph.D.
  Vice President, Research and Technology, Director, Office of Technology Management UT Health Sciences Center at Houston
- Paul Lammers, M.D.*
  CEO and President, Mirna Therapeutics
- Gary Latham, Ph.D.*
  Sr. V.P., Research and Development, Asuragen
- Kevin LaLande
  Managing Director, Santé Ventures
- Martin Lindenberg, M.D.
  Director, The McNair Center for Free Enterprise and Entrepreneurship, University of St. Thomas
- Brenton Scott, Ph.D.*
  President and COO, Pulmotect
- Greg Stein, M.D.*
  CEO, Curtana Pharmaceuticals
- Ilia Tikhomirov*
  President and CEO, Formation Biologics
- James Topper, M.D., Ph.D.
  Managing General Partner, Frazier Healthcare Partners
- Matt Winkler, Ph.D.*
  Founder, Asuragen and Mirna Therapeutics

* = former or current grantee

JONATHAN MACQUITTY

Jonathan is a Venture Partner at Lightspeed Venture Partners (LSVP) advising them on life science and healthcare investments. He was most recently the founding CEO of Forty Seven Inc, a Lightspeed investment which he helped start up in early 2015. Forty Seven is developing immuno-oncology therapeutics to treat various types of cancer. The company's lead product is now in four different clinical studies in the US and the UK. Jonathan is also Chairman of another Lightspeed investment, Personalis, which is commercializing human genomic analysis for cancer research and diagnosis.

Jonathan has spent 35 years in life science companies and in the venture capital sector that finances them. He was formerly a partner at Abingworth, a trans-Atlantic life science venture capital firm, heading up the firm's West Coast office. He joined Abingworth in 1999 as President of the firm's US subsidiary based in Menlo Park, CA. From its founding in 1988 until its acquisition in 1997, he was CEO of GenPharm International, a Bay Area biotech company developing a human sequence antibody platform. Pharming BV, a wholly owned European subsidiary of GenPharm was spun off and went public on Euronext in 1996. Prior to GenPharm Jonathan did business development at Genencor and Genentech.

His directorships have included Acorda (now NASDAQ), Dicerna (now NASDAQ), Guava (acquired), Gynesonics, Labcyte, Myelos (acquired), Palo Alto Health Sciences, ParAllele BioScience (acquired), Quantum Dot (acquired), SFJ Pharma, Sosei (now listed in Tokyo), and Sunesis (now NASDAQ).
He has also served on the Board of the Biotechnology Industry Organization (BIO).

Jonathan has an MA in Chemistry from Oxford University, a PhD in Chemistry from the University of Sussex, and an MBA from Stanford University.

David G. Lowe, Ph.D., is Co-Founder, President & Chief Executive Officer of Austin TX based Aeglea BioTherapeutics. Dr. Lowe earned a B.S. and a Ph.D. in Biochemistry from the University of Toronto, Ontario, Canada. In 1985 he joined Genentech, Inc., South San Francisco CA, as a post-doctoral fellow in molecular biology. At Genentech, Inc., he ultimately became a Senior Scientist and Director where he was responsible for a department of 50 researchers with expertise in protein biochemistry, molecular & cellular biology, *in vivo* pharmacology & physiology, and MRI bioimaging. He was directly responsible for small molecule and protein drug discovery programs across a variety of disease areas. A major emphasis for this research effort was tumor angiogenesis, pursuing an anti-cancer strategy based on the metabolic dependence of growing tumors for neovascularization. In eight years, the department put seven molecules into the clinic, two of which became products. After Genentech in 2002 Dr. Lowe joined Skyline Ventures, a Palo Alto, CA based life science venture capital firm. Initially as a Kauffman Fellow in Entrepreneurship and Venture Capital and ultimately as Managing Director Dr. Lowe led financings in raw start up and mid stage companies developing drugs, research tools and diagnostics, with exits from 10 companies generating positive returns. In addition to Aeglea he sits on the Board of Austin TX based Shattuck Labs.

David J. Arthur
Chief Executive Officer

Mr. Arthur is a senior life sciences executive with 25+ years of US and global experience building and leading medical and marketing organizations in product development; launching and managing pharmaceutical and device brands. Prior to accepting the role as Chief Executive Officer Salarius Pharmaceuticals, David was Managing Director Dacon Pharma, LLC. Additionally, David spent 20+ years with Eli Lilly and Boehringer-Ingelheim in executive roles managing product development, business development, US business, global commercialization, European regional marketing and financial planning/analysis.

Mr. Arthur earned a BS in Chemical Engineering from North Carolina State University, a Masters of Business Administration from the Duke University Fuqua School of Business, is a licensed Professional Engineer and Six Sigma Green Belt.

Offce of Technology Management

OTM Team

Bruce D. Butler, Ph.D.

Vice President, Research and Technology

Director, Offc e of Technology Management

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Fax: +1 (713) 500-0331

Email: Bruce.D.Butler@uth.tmc.edu

Dr. Bruce D. Butler is Vice President Research and Technology, and directs the Off ce of Technology Management at the University of Texas Health Science Center at Houston (UTHealth). The off ce handles the technology transfer activities including the creation of new start-ups for the six UTHealth schools and the UTHealth faculty at the Texas Heart Institute. Dr. Butler also holds an academic position as Professor in the Department of Anesthesiology at the Medical School and managed a research program in collaboration with NASA, U.S. Navy and several international pharmaceutical companies. He has over 200 published papers, abstracts and book chapters. Other positions he holds include VP for the Off ce of Global Health Initiatives, Associate Director of the UTHealth / MD Anderson Cancer Center-Center for Advanced Biomedical Imaging Research (CABIR). Dr. Butler is an inventor on numerous U.S. and associated foreign patents; several of which have been commercialized through UTHealth that include respiratory healthcare products and bio-pharmaceuticals. He has been involved with product development for medical and home-care devices, including FDA regulatory approvals and clinical trials. Dr. Butler has been personally involved in the creation of 5 life-science start-ups and numerous other business development partnerships.

KEVIN M. LALANDE

MANAGING DIRECTOR

Prior to founding Santé Ventures, Kevin spent seven years with Austin Ventures, a prominent venture firm with $3.9 billion under management. Before joining Austin Ventures, he was a management consultant with McKinsey & Company. Previously, Kevin co-founded and sold three successful start-up companies: NetProfit, sold to a privately held advertising agency in 1996; Serus, sold to Netopia (Nasdaq: NTPA) in 1998; and TimeMarker, sold to PrimeHoldings (OTCBB: PRIM) in 2001. Kevin received an MBA with highest distinction (Baker Scholar) from the Harvard Business School and holds a BS in Electrical and Computer Engineering.

Why Venture Capital Doesn't Scale

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Management

Management

Mirna has assembled an experienced management team with leaders in microRNA and cancer research, and all aspects of drug and business development.

Paul Lammers, M.D., M.Sc.
President & Chief Executive Officer

Dr. Paul Lammers has served as a member of Mirna's board of directors and as President and Chief Executive Officer since November 2009. Previously, Dr. Lammers was the President of Repros Therapeutics Inc., a biopharmaceutical company. Dr. Lammers has also served as the Chief Medical Officer for EMD Serono, Inc., a biopharmaceutical division of Merck KGaA, Senior Vice President of clinical and regulatory affairs at Zonagen, Inc., which later became Repros Therapeutics, and Organon International, a pharmaceutical company, spending eight years in the commercial and clinical operations in Europe and the United States. Dr. Lammers received an M.Sc. and M.D. from the Catholic University (Radboud University) in Nijmegen, The Netherlands.

Gary J. Latham, PhD

Sr. VP, Research and Development

Dr. Latham joined in March 2006 when Asuragen was founded. Gary has significant R&D leadership experience spanning protein engineering, assay development, and sample prep development at Ambion, Inc., where he launched multiple life science products. During his tenure at Asuragen, he has led the company's bioinformatics and research groups and was responsible for developing Asuragen's AmplideX® PCR technology for fragile X syndrome and QuantideX® NGS products for oncology applications. Gary is an inventor on 10 issued and multiple pending patents and has received >$13M in research grants. Dr. Latham received his Ph.D. in Biochemistry from Vanderbilt University, and was an American Cancer Society Postdoctoral Fellow at the University of Oregon's Institute for Molecular Biology.

UNIVERSITY of ST. THOMAS HOUSTON

The McNair Center for Free Enterprise & Entrepreneurship

Meet the Director

Growing up in South Africa, when Martin Lindenberg headed to the University of Witwatersrand in Johannesburg, he decided to study Computer Science and Mathematical Statistics. Graduating with honors, he went to medical school at his alma mater. Handling the course load of a medical student during the day, he started taking MBA courses at night. When he graduated with an M.B.B.Ch. (equivalent to a U.S. M.D.), Dr. Lindenberg came to the proverbial fork in the road. He could go further with his medical studies, a path he was familiar with, or go down the unknown road and finish his MBA. After watching his father, a businessman and entrepreneur, build a family-owned clothing business from 20 to 500 employees, he chose the path that led to completing his MBA in Marketing, Strategy and General Management at the University of Witwatersrand.

In July 2016, Dr. Martin Lindenberg joined the University of Saint Thomas, Houston as the Director of The McNair Center for Free Enterprise & Entrepreneurship. With 30 plus years history of business and leadership experience domestically & internationally, Lindenberg has an impressive track record in the entrepreneurial arena. He has personally grown 11 businesses, and invested in and consulted to over a dozen. He has been a key player in starting six medical technology companies: two becoming public and three profitably sold later to larger companies. He has a proven track record in executive and board leadership, varying from family enterprises to Fortune 300 corporations.

From 1997 to 1998, Dr. Lindenberg was the Founding Chairman and then continued as a Board member until 2014 of the Houston Technology Center, noted by Forbes as "One of the Ten Incubators Changing the World." From 2004 to 2010, he was a Co-founder & President of Fannin Innovation Studio, which is an early-stage life sciences development group focused on commercializing innovations developed in the Texas Medical Center institutions. From 2014 to 2016, he was a Professor of Entrepreneurship at The Bauer College of Business at The University of Houston.

Martin Lindenberg has been a door-to-door salesman, a student leader, a camp counselor, a computer scientist, physician, teacher, mentor, developer of medical products and pharmaceuticals, businessman, non-profit leader and board member. Besides the accomplishment of delivering a baby on a 747 flying from Johannesburg to London, he believes his greatest achievements and blessings have been raising his children and being married to his best friend for over 36 years.

Principal Investigator/Program Director (Last, First, Middle):	Scott, Brenton L.

BIOGRAPHICAL SKETCH

NAME Brenton L. Scott	POSITION TITLE
eRA COMMONS USER NAME hbscott	President and PI of Past and Proposed CPRIT Proposals

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Southern Utah University - Cedar City UT	B.S.	2000	Chemistry
Rice University - Houston TX	Ph.D.	2005	Biochemistry
University of Houston - Houston TX	M.B.A.	2005	Business
MD Anderson Cancer Center - Houston TX	Fellow	2005-07	Pulmonary Medicine

A. Personal Statement

The goal of the proposed research is to advance the development of PUL-042 by completing key clinical studies to demonstrate drug activity. While at MD Anderson Cancer Center we first established a practical method of stimulating lung epithelium with mixtures of innate immune ligands to induce a high level of resistance to microbial infections. We have since elucidated many of the cellular and molecular mechanisms of inducible resistance, and based upon this knowledge, identified a formulation of chemically defined small molecules that induce effective resistance that can be developed as a clinical therapeutic. With the lead inventors, I co-founded Pulmotect and was originally the Chief Operating Officer prior to becoming the President in 2011. I have been the PI of seven Phase I and II SBIRs and the PI for the previous award from the Cancer Prevention Research Institute of Texas. I have worked with many institutions and proposed team for a number of years, I am familiar with the experimental methods and business requirements necessary to complete the Aims of this proposal. We are enthusiastic about the ongoing collaboration and efforts to transition this clinical stage technology into the market to better help those at risk of pneumonia.

B. Positions and Honors

Positions and Employment

2011 – Present	Pulmotect, Inc.	President
2007-2011	Pulmotect, Inc.	Chief Operating Officer
2008-2010	AlphaDev, LLC	Sr. Associate
2005-2007	MD Anderson	Odyssey Postdoctoral Fellow
2005	MD Anderson	Life Science Entrepreneurship/Mentoring Course
2000-2005	Rice University	Doctoral Student
2001-2002	Rice University	Teaching Assist for Cellular Biology and Advanced Genetics
1998-2000	OMG Apex	Analytical Chemist

Honors and Consultancies

- 2008 - 2016: Raised >$22 M in equity and grant financing, completing two clinical trials
- 2012: Awarded First Place at SE BIO Shootout
- 2012: PI on $7.2M Cancer Prevention Research Institute of Texas Award
- 2008 - 2011: $1M "Texas Emerging Technology Fund" award
- 2007: Two time awardee of a "Most Promising" company at Rice Alliance for Technology and Entrepreneurship forum
- 2007: Selection for ASCB "2007 Press Book"
- 2006: NIH Loan Repayment Program Award
- 2005: Odyssey Fellowship Award from MD Anderson Cancer Center
- Academic scholarship and full funding throughout undergraduate and graduate education
- 2004: First Outstanding Graduate Student Award – Rice University
- 2004: Texas Life Science Scholarship – One of three recipients from BioHouston
- 2003: Houston Live Stock and Rodeo Scholarship

C. Selected Peer-Reviewed Publications (in chronological order)

1. Alfaro VY, Goldblatt DL, Valverde GR, Munsell MF, Quinton LJ, Walker AK, Dantzer R, Varadhachary A, Scott BL, Evans SE, Tuvim MJ, Dickey BF. Safety, tolerability, and biomarkers of the treatment of mice with aerosolized Toll-like receptor ligands. Front Pharmacol 2014 Feb 6;5:8 (PMID 24567720).
2. Kim K, Petrova YM, Scott BL, Nigam R, Agrawal A, Evans CM, Azzegagh Z, Gomez A, Rodarte EM, Olkkonen V, Bagirzadeh R, Piccotti L, Ren B, Yoon JH, McNew JA, Adachi R, Tuvim M, Dickey BF. Munc18b Is an Essential Gene in Mice Whose Expression Is Limiting for Secretion by Airway Epithelial and Mast Cells. *Biochem J.* 2012 Jun 14.
3. Evans SE, Clement CG, Pawlik, Gilbert BE, Bowden G, Hook M, Hawke D, Kobayashi R, Reynolds PR, Scott BL, Kontoyiannis, Lewis RE, LaSala R, Peterson JW, Chopra, AK, Klimpel G, Tuvim MJ, Dickey BF. Stimulation of lung innate immunity protects broadly against bacterial, fungal and viral pneumonia. *Am J Respir Cell Mol Biol* 2010, 42:40-50
4. Clement CG, Evans SE, Evans CM, Hawke D, Reynolds PR, Moghaddam SJ, Scott BL, Melicoff E, Adachi R, Dickey BF, Tuvim MJ. Stimulation of lung innate immunity protects against lethal pneumococcal pneumonia in mice. *American Journal of Respiratory and Critical Care Med* 2008, 177:1322-30
5. Van Komen, J.S., Bai, X., Scott, B.L., McNew, J.A. An intramolecular t-SNARE complex functions in vivo without the syntaxin N-terminal regulatory domain. *Journal of Cell Biology*, 2006 Jan:172(2):295-307.
6. Scott, B.L., J.S. Van Komen, H. Irshad, S. Liu, K.A. Wilson, and J.A. McNew. Sec1p directly stimulates SNARE-mediated membrane fusion *in vitro*. *Journal of Cell Biology,* 2004 Oct:167(1)75-85.
7. Scott, B.L., J.S. Van Komen, S. Liu, T. Weber, and J.A. McNew. A liposome fusion assay to monitor membrane fusion machines. *Methods in Enzymology,* 2003:372:274-300.
8. Brock, D.A., R.D. Hatton, D.V. Giurgiutiu, B.L. Scott, W. Jang, R. Ammann, and R.H. Gomer. CF45-1 a secreted protein which participates in Dictyostelium group size regulation. *Eukaryotic Cell*, 2003 Aug:2(4):788-97.
9. Brock, D.A., R.D. Hatton, D.V. Giurgiutiu, B.L. Scott, R. Ammann, and R.H. Gomer. The different components of a multisubunit cell number-counting factory have both unique and overlapping functions. *Development*, 2002 Aug;129(15):3657-68.

Gregory Stein, M.D., M.B.A.

Chief Executive Officer

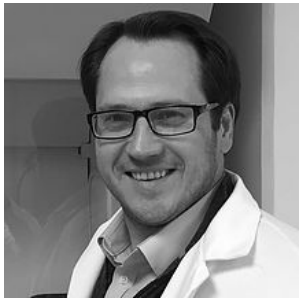
Dr. Stein co-founded Curtana Pharmaceuticals and became the company's Chief Executive Officer in April, 2013. During hi professional career of over 20 years, he has been a clinician and a life sciences executive with experience in the areas of diagnostics, medical devices, pharmaceuticals and biotechnology.

Prior to co-founding Curtana, Dr. Stein served as the Vice President, Operations and Medical Affairs at Sova Pharmaceuticals, Inc., a venture-backed company he c founded in March, 2010. The company is focused on the development of novel therapeutic drugs for the treatment of inflammatory and

neuropathic pain. Prior to Sova, he was the Senior Director of Product Marketing at Genoptix, which was recently acquired by Novartis. Genoptix is a specialized laboratory service provider focused on delivering personalized and comprehensive diagnostic services to community-based hematologists and oncologists. Prior to joining Genoptix, Dr. Stein was an entrepreneur with a focus on identifying innovative technology for commercial development in the medical therapeutic, device and diagnostic areas. He has been the founder of two other early-stage drug development companies, Opus Pharmaceuticals and Uzima Bioscience.

Before pursuing a career in the business world, Dr. Stein practiced Emergency Medicine in a busy urban hospital on the west side of Chicago where he served as the Assistant Medical Director of the department and Associate Emergency Medical Services Director for the regional EMS system.

Dr. Stein is board certified in Emergency Medicine. He completed his residency at the University of Illinois Affiliated Hospitals in Chicago and is a graduate of the 3-year accelerated Independent Study Program at the Ohio State University School of Medicine. Dr. Stein received a B.A. in Psychology from UC San Diego and an M.B.A. from The Rady School of Management at UC San Diego.



Ilia Tikhomirov

Director

Ilia is an entrepreneur and inventor of several products under development by Formation Biologics. At Formation Biologics, Ilia built a strong leadership and advisory teams, raised a multiple rounds of financing, and in-licensed additional drug candidates. Prior to Formation Biologics, Ilia occupied positions of increasing responsibility at YM BioSciences Inc. (YM), a publicly traded oncology drug development company that was acquired by Gilead Sciences in a $500 million transaction. His findings at YM led to the creation of an antibody technology and ultimate spin-out of Formation Biologics from YM prior to the Gilead acquisition. Ilia completed undergraduate and graduate scientific training at the University of Toronto and also holds an MBA from Rotman School of Business.

Close Previous | Next

JAMES N. TOPPER, M.D., PH.D.

Managing General Partner

Jamie co-leads Frazier's Life Sciences team and has over 25 years of experience working with entrepreneurs to found and build successful therapeutics-focused companies.

Jamie is a Managing General Partner of Frazier Healthcare Partner's Life Sciences team. He joined Frazier in 2003 and opened Frazier's Menlo Park office in the same year. Throughout his 12 years as a General Partner, Jamie has invested across over 20 companies encompassing a broad spectrum of Life Science and Biopharmaceutical companies.

Jamie has led and served as a board member for many of Frazier's successful life sciences investments, including Acerta Pharma BV (sold to AstraZeneca), Calistoga Pharmaceuticals (co-founder, sold to Gilead), Rempex (sold to The Medicines Company), Incline (co-founder, sold to The Medicines Company), Alnara (sold to Lilly), Portola (co-founder, NASDAQ: PTLA), CoTherix (sold to Actelion), and Threshold (NASDAQ: THLD). He currently represents Frazier on the boards of Alcresta, Allena Pharmaceuticals, Alpine Immune Sciences, AnaptysBio, Aptinyx, Entasis Therapeutics, and Millendo Therapeutics (formerly Atterocor). He is also a board observer for Gristone Oncology.

LOCATION

Menlo Park

CONTACT

Phone: 650.325.5156

Email

EDUCATION

University of Michigan (B.S.)

Stanford University (M.D., Ph.D.)

YEAR JOINED

2003

Prior to joining Frazier, Jamie served as head of the cardiovascular research and development franchise at Millennium Pharmaceuticals and ran Millennium San Francisco (formerly COR Therapeutics). Before the merger of COR and Millennium, he served as the Vice President of Biology at COR and was responsible for all research activities. He served on the faculties of Stanford Medical School and Harvard Medical School prior to joining COR.

Jamie received his M.D. and Ph.D. in Biophysics from Stanford University School of Medicine and holds a B.S. from the University of Michigan. He did his postgraduate training in Internal Medicine and Cardiovascular Disease at the Brigham and Women's Hospital in Boston. He has authored over 50 publications and was the recipient of a Howard Hughes Scholars Award while on the faculty at Stanford University. In 2011 and 2016, Jamie was named to the Midas List of leading venture capitalists, and in 2013 was recognized by Forbes as one of the top 10 healthcare investors.

SELECT INVESTMENTS

Acquired by AstraZeneca in 2016

Acquired by Eli Lilly & Co. in 2010

Matt Winkler, Ph.D.
Chairman & Founder
Asuragen
(512) 681-5210
mwinkler@asuragen.com

Matt Winkler is Founder and Chairman of Asuragen. Asuragen is a growing (2016 $31M revenue), global *in vitro* diagnostic product provider, with on-market tests serving unmet medical needs in oncology and genetics. In July 2016 Asuragen received FDA clearance for its QuantideX® qPCR BCR-ABL IS Kit for Monitoring Minimal Residual Disease in Chronic Myeloid Leukemia. This is the first and only test cleared for managing patients with leukemia.

Matt received a B.S. degree in Genetics and a Ph.D. in Zoology from the University of California at Berkeley. He joined the Zoology Department of the University of Texas in 1983. In 1988, as an Associate Professor, he started Ambion, Inc. a molecular biology "tools" company. He is the author of over 30 publications and has 19 issued patents. Ambion became the preeminent" molecular biology tools company" focused on RNA with almost 400 employees located in Austin, Cambridge, England and Tokyo, Japan. In March of 2006 he sold the research products division of Ambion to Applied Biosystems and with about 100 employees started Asuragen. The high quality of its scientific environment has allowed Asuragen to be one of the largest recipients of National Institutes of Health, Small Business Innovation Research (SBIR) grants in Texas as well as developing highly innovative commercial products.

In December of 2007 Asuragen created Mirna Therapeutics, as a "carve out" of Asuragen, to develop cancer therapeutics based on miRNA. Mirna has been the recipient of a Texas Emerging Technology Fund (ETF) investment in 2009, and has received two significant CPRIT grant awards (2010 and 2015). Mirna (MIRN) went public in October 2015.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, GENERAL COUNSEL CAMERON L. ECKEL, STAFF ATTORNEY
SUBJECT:	PROPOSED ADOPTION OF CHARTER FOR THE PRODUCT DEVELOPMENT ADVISORY COMMITTEE
DATE:	MAY 9, 2017

Summary and Recommendation

The Board Governance subcommittee recommends that the Oversight Committee vote to approve the Product Development Advisory Committee (PDAC) charter. The Board Governance subcommittee is responsible for providing guidance to the Oversight Committee regarding approval of organizational documents. The Board Governance Subcommittee discussed the proposed PDAC charter with CPRIT's General Counsel, Kristen Doyle, at its meeting on May 4, 2017.

Background

Texas Health & Safety Code § 102.155(a) allows the Oversight Committee to create ad hoc committees of experts to advise the Oversight Committee on issues relating to cancer. The primary purpose of the PDAC is to advise the Oversight Committee on important issues of the Product Development Research program. The PDAC submitted its charter for approval earlier this month.

THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS PRODUCT DEVELOPMENT ADVISORY COMMITTEE CHARTER

BACKGROUND

Texas Health and Safety Code § 102.155 allows for the establishment of an ad hoc committee of experts to advise the Oversight Committee of the Cancer Prevention and Research Institute of Texas ("Oversight Committee"), and to advise the Cancer Prevention and Research Institute of Texas ("CPRIT" or "Institute"). The Product Development Advisory Committee ("PDAC") was created to advise the Oversight Committee regarding the Product Development Research program. This Charter ("PDAC Charter"), adopted by the PDAC members and approved by the Oversight Committee on May 17, 2017, supersedes any other documents relating to the PDAC.

PURPOSE

The primary purpose of the PDAC is to advise the Oversight Committee on important issues of the Product Development Research program. The PDAC shall give their expert opinion on the program's current policies and guidance for improving those policies.

COMPOSITION

The PDAC shall be composed of at least nine members appointed by the Oversight Committee. PDAC members shall serve two-year terms, at the end of which the Oversight Committee may renew the appointment of the PDAC member or appoint a new member. The two-year terms of the PDAC already constituted at the time the PDAC Charter is approved shall begin on the day after approval of the charter.

If a PDAC member is unable to complete his or her term, the Oversight Committee shall appoint someone to fulfill the remainder of the term.

ELECTION OF OFFICERS

The Institute's Chief Executive Officer shall appoint the first PDAC Chairperson and Vice-Chairperson. Thereafter, the PDAC Chairperson and Vice Chairperson shall be elected to serve a two-year term by a majority of PDAC members present and able to vote at the first meeting held on or after September 1, 2018, and thereafter for every even-numbered year. The term of an officer shall not extend longer than the officer's term on the PDAC.

MEETINGS AND QUORUM

The PDAC shall meet as often as deemed necessary by the PDAC Chairperson. At a minimum, the PDAC shall meet annually to compose a report to send to the Oversight Committee and to conduct any other business required by this Charter, statutes, or administrative rules.

A meeting of the PDAC requires a quorum of members. Such meeting may take place in person or by teleconference. A quorum exists when at least a majority of appointed members of the PDAC is present or available via telephone. If there is an even number of currently appointed members, then half that number plus one member constitutes a quorum.

The Vice-Chairperson or his/her designate shall record the minutes for each PDAC meeting. The Vice-Chairperson shall forward the final meeting minutes to the Institute's Chief Executive Officer for retention and distribution to the Oversight Committee members.

An office copy of the PDAC meeting minutes will be retained at Institute headquarters and available to the public on request.

DUTIES AND RESPONSIBILITIES

The PDAC shall submit a written report, at least annually, to the Oversight Committee regarding the work undertaken by the PDAC for the previous year and the PDAC's recommendations for the Institute. The PDAC shall submit the report by May of each calendar year to the Institute's Chief Executive Officer for distribution to the Oversight Committee.

The PDAC Chairperson shall present the report at the first regular meeting of the Oversight Committee following the submission of the written report. If the Chairperson is unable to attend, then the Vice-Chairperson or other designee may present the report.

The report shall inform the Oversight Committee regarding:

- Revenue sharing provisions that provide a fair return for the state of Texas while not discouraging follow-on funding from other sources;

- Analysis of the current portfolio mix of Product Development Research awards by stage of company and size of award;

- Strategies to expand and encourage relocation of high quality companies to Texas;

- The influence of Product Development Research program awards, including suggestions for improvements of the various award mechanisms;

The PDAC may provide on-going advice to the Oversight Committee that will advance or improve the Product Development Research program and aid the mission of the Institute.

OTHER DUTIES

In addition to duties and responsibilities stated herein, the Oversight Committee's Presiding Officer may authorize additional, official duties of the PDAC.

AMENDING OR REPEALING THE CHARTER

The PDAC retains the ability to make, alter, amend, or repeal the PDAC Charter. The PDAC shall make changes to the PDAC Charter pursuant to a majority vote of the PDAC members. Proposed changes are final once approved by a vote of the Oversight Committee.

CHARTER APPROVAL

As reflected by the signatures of the PDAC Chairperson and Oversight Committee's Presiding Officer, the PDAC Charter was adopted and approved in compliance with the process specified herein on the dates stated below.

Adopted by the PDAC	**Approved by the Oversight Committee**
_____	_____
Jonathan MacQuitty, Ph.D. Chair, PDAC	Pete Geren Presiding Officer, Oversight Committee
Date: _____	Date: May 17, 2017

STATEMENT OF REVISIONS: None

May 2017 Oversight Committee
Internal Audit Status Report
As of April 30, 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, Sr. Manager.

2017 Internal Audit Plan

Weaver has completed or initiated planning activities for all projects on the 2017 Internal Audit Plan.

Internal Audit	Description	Status / 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 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.	Complete
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	Internal Audit included an evaluation of risks and internal controls in place related to CPRIT's Pre-Award Grant Management process. Activities evaluated included the RFA Review Process, Conflicts of Interest, Peer Review (including travel coordination), and Grant Application Approval. Fieldwork has been completed. An exit meeting with Management was held on April 17, 2017. The Findings and Observation Matrix was delivered to CPRIT Management on April 21, 2017 outlining the preliminary results. Management Responses are expected by May 5, 2017 with a Final Report expected to be issued mid-May.	Fieldwork Complete

Procurement and P-Cards	Internal Audit will include an evaluation of risks and internal controls in place related to the CPRIT's Procurement and P-card practices. Activities to be evaluated will include Purchase Orders, Bidding and Awards, Contract Negotiation and Approval, Vendor Management and Selection, Vendor Acceptance, Vendor Set-up, P-card Program, P-card Purchases, and Central Travel Card. A planning meeting with Management was held on April 17, 2017. Fieldwork is scheduled to begin on May 15, 2017.	May and June 2017
IT Security Follow-Up • 4 High Findings • 6 Moderate Findings • 1 Low Finding	Internal Audit performed follow-up procedures on the 11 findings from the 2016 Internal Audit to ensure corrective action was taken. Fieldwork has been completed. The Findings and Observation Matrix was delivered to CPRIT Management on March 31, 2017 outlining the preliminary results.	Fieldwork Complete
Revenue Follow-Up • 2 Low Findings	Internal Audit will perform follow-up procedures on the two findings from the 2016 Internal Audit to ensure corrective action has been taken. A planning meeting with Management was held on April 17, 2017. Fieldwork is scheduled to begin on May 1, 2017.	May 2017
Cash Management Follow-Up 1 Moderate Finding	Internal Audit will perform follow-up procedures on the one finding from the 2016 Internal Audit to ensure corrective action has been taken. A planning meeting with Management was held on April 17, 2017. Fieldwork is scheduled to begin on May 1, 2017.	May 2017
Commodity and Service Contracts Follow-Up • 3 Moderate Findings • 2 Low Findings	Internal Audit will perform follow-up procedures on the five findings from the 2016 Internal Audit to ensure corrective action has been taken. A planning meeting with Management was held on April 17, 2017. Fieldwork is scheduled to begin on May 8, 2017.	May 2017

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, we have provided ongoing consultation with CPRIT Management for SOC 2 report for CSRA. We have reviewed the preliminary control list provided to CPRIT by CSRA and provided feedback regarding the initial control inventory for CSRA in order to assist management in ensuring that the coverage of CSRA's SOC 2 report provides the coverage required by CPRIT.

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

Cancer Prevention and Research Institute of Texas
Internal Audit of Pre-Award Grant Management
Internal Audit Risk Coverage
March 2017

Scope: The audit focused on CPRIT's Pre-Award Grant Management processes to solicit and evaluate grant applications and make grant awards. Activities evaluated included the Request for Application (RFA) Review Process, Conflicts of Interest, Scientific Research and Prevention Program Committee (SRPP) including travel coordination, Grant Application Approval and Awarding Grant Funds. Key functions and sub-processes within the Pre-Award Grant Management process reviewed included:

- RFA Review Process
  - o Research
  - o Product Development
  - o Prevention
- Conflict of Interest Disclosure
- Scientific Research and Prevention Program Review (including travel coordination)
- Grant Application Approval
- Grant Award Approval

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

Monitored Risks

Pre-Award Grant Management		
Process Area	**Risks Monitored**	
RFA Review Process	1	RFA solicitations align with State Plan goals
	2	RFA solicitations are not reviewed nor approved prior to posting and distribution
	3	Administrative review is not performed on applications to ensure completeness and compliance with RFA requirements
Conflict of Interest Disclosure	4	Scientific Research and Prevention Program Committees (SRPP) members do not disclose conflicts of interest
	5	SRPP members do not confirm understanding of conflict of interest policies
	6	Program Integration Committee members do not disclose conflicts of interest
	7	Oversight Committee members do not disclose conflicts of interest
	8	Any individuals with conflicts of interest are not recused from evaluation
	9	CPRIT staff do not substantively participate in SRPP meetings
Scientific Research and Prevention Program Review Process	10	Available grant funds allocation thresholds are not monitored by management
	11	Prevention grants awards are not within statutory limits
	12	SRPP members are not appropriately vetted and selected by the CEO
	13	SRPP members are not approved by the Oversight Committee prior to beginning service
	14	SRPP members are not assigned to appropriate panels based on expertise
	15	SRPP scores are not appropriately tabulated and validated
	16	High-scoring Product Development applications do not receive due diligence and intellectual property review prior to approval
	17	Recommended applications are not reviewed nor approved by the Program Review Council
Grant Application Approval	18	Applications are not reviewed nor approved by the Program Integration Committee
	19	Application Pedigrees are not completed for approved awards
	20	CEO Affidavits are not completed for approved awards
	21	CCO Compliance Certifications are not completed for approved awards
Grant Award Approval	22	Available grant funds are not monitored by management
	23	Prevention grants awards are not within statutory limits
	24	Oversight Committee does not approve all awards
	25	Approved applicants are not notified with a Notice of Funding Recommendation

Cancer Prevention and Research Institute of Texas
Internal Audit of Procurement and P-Cards
Internal Audit Risk Coverage
April 2017

Scope: The audit will focus on CPRIT's Procurement and P-Card processes to obtain goods and services for the agency. We will review 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 to be reviewed include:

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

The scope of the audit will not include the processes for contract initiation, execution and management. However, a follow-up of the Commodity and Service Contracts Audit will be included in this audit to reperform testing on the following findings:
- Contract Listing
- Vendor On-Boarding
- Invoice Approval
- Budget Certification

Monitored Risks

Procurement		
Process Area	**Risks Monitored**	
Purchase Requests	1	Budgets are not verified and funds are not encumbered prior to purchase requisition approval
	2	Purchases are not within buyer limits
	3	Items requested for purchase are inaccurate
	4	Segregation of duties in the initiation and approval of purchase requests is not present
	5	Purchase requisitions are not properly approved prior to initiating procurement activities
Purchase Method Determination	6	Appropriate purchase method was not selected
Bidding	7	Qualified vendors are not identified and notified
	8	Smaller dollar purchases are not procured from reputable and approved vendors
	9	An appropriate bidding process was not used for the type and value of the purchase
	10	Scope of work descriptions do not contain specific deliverables and timeframes
	11	Conflicts of interest are not identified and avoided
Interlocal and Cooperative Agreement Purchases	12	Consolidated purchasing or purchasing power is utilized for similar purchases
	13	Vendors used through Interlocal and Cooperative Agreements are not qualified and meet the agency's requirements
	14	Vendors used through Interlocal and Cooperative Agreements were not procured competitively and appropriately
	15	Interlocal and Cooperative Agreements do not provide best value compared to open market purchasing
	16	Pricing related to Interlocal and Cooperative purchasing is not accurate nor within pre-approved contract rates
	17	Interlocal and Cooperative Agreements do not have an appropriate term and duration
	18	Interlocal and Cooperative contracts are not properly reviewed and approved
	19	Contracts on the Interlocal and Cooperative Agreement list are not current nor accurate
Vendor Selection and Awards	20	Multiple vendors providing similar products or services are not identified, reviewed, and eliminated
	21	Sole-source and single source purchases are not limited and do not receive pre-approval
	22	Purchases are not properly approved by Management
	23	Conflicts of interest are not managed and monitored
Vendor Acceptance and Setup	24	New vendors are not properly authorized for entry into the system and that the data is entered accurately into the system
	25	Sensitive vendor information is not properly safeguarded
	26	Changes to the vendor master file are not authorized
	27	Fictitious or duplicate vendors are set-up
	28	A complete and accurate list of vendors is not maintained

Cancer Prevention and Research Institute of Texas
Internal Audit of Procurement and P-Cards
Internal Audit Risk Coverage
April 2017

Procurement		
Process Area	**Risks Monitored**	
Purchase Orders	29	Purchases of goods and services were not authorized prior to placing the order with the vendor
	30	Quantity and pricing on the purchase order is not properly reflected and entered in the system
	31	Purchase orders are not based on correct information
	32	Purchase order modifications are not properly authorized
	33	Open purchase orders are not monitored and closed in a timely manner
Vendor Monitoring and Reporting	34	Aggregate spending with a non-contract vendor is not monitored
	35	Serial, sequential, or split purchasing is not detected
	36	Vendors do not comply with CPRIT requirements
	37	Vendor rebates or reimbursements are not received in a timely manner
	38	Active vendors are not periodically reviewed for stability and financial viability
	39	Vendor reporting under Senate Bill 20 is not completed timely and accurately

P-Cards		
Process Area	**Risks Monitored**	
P-Cards Governance	40	Employees are not aware of policies and procedures for using P-Cards
	41	The number of P-Cards issued is not appropriate for the size of the agency
	42	Cardholder and transactional data from P-Cards is not secure
	43	P-Card transaction data is not maintained in accordance with required record retention laws
P-Card Request and Approval	44	P-Cards are not adequately authorized to employees
	45	Purchase limits do not exist and/or are not appropriately authorized
	46	Employees do not have adequate training regarding the use of P-Cards
P-Card Usage	47	P-Card purchases are not properly authorized by the employee's supervisor
	48	Contract vendors are not being utilized for purchases, when available
	49	Purchases using P-Cards are not appropriately restricted by merchant code category
	50	MCC setup is not appropriate and up to date
	51	Overrides to purchase restrictions are not appropriately reviewed and approved
	52	Overrides to purchase restrictions are not appropriately documented and supported
	53	Transaction overrides do not expire
P-Card Administration	54	Stolen P-Cards are not appropriately deactivated in a timely manner
	55	P-Cards are not appropriately deactivated upon termination of employees
	56	Changes to P-Card (i.e. Profile) are not properly approved
	57	Increases and decreases in purchasing limits are not appropriate
	58	P-Cards are not canceled or suspended for non-compliant cardholders
	59	Fraudulent transactions or incorrect transactional information are not disputed
P-Card Reconciliation	60	Employees do not conduct periodic P-Card reconciliations
	61	Employee's supervisor or department head does not review and approve the employee's monthly P-Card reconciliation
	62	P-Card transactions are not appropriately reconciled on a periodic basis by an independent source
	63	P-Card transactions are not being charged to the correct budget, project, and GL
	64	P-Card payment transactions to vendors are duplicated by other payment methods
	65	P-Card transaction reconciliation is not completed in a timely manner
P-Card Monitoring and Tracking	66	Inappropriate and/or unauthorized P-Card transactions are not identified
	67	Inappropriate and/or unauthorized P-Card Transactions are not adequately reported
	68	Emergency purchases are inappropriate and do not meet requirements
	69	P-Card transactions are processed with restricted vendors
	70	Excessive spending from a non-contract vendor is not identified and reported
	71	P-Card transaction and profile data is not routinely reported to management for review
	72	P-Card transactions are not being monitored for fictitious payments, personal purchases, purchases of food and alcohol and other unallowable expenses
	73	Split purchasing is not monitored

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of April 30, 2017

					Open Findings				Closed Findings				Total Findings				
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	
Fiscal Year 2015																	
Grant Management	2015	Complete	July 27, 2015	Satisfactory	-	8	1	9					-	8	1	9	Note A
Expenditures Internal Audit	2015	Complete	August 24, 2015	Strong	-	-	2	2					-	-	2	2	Note B
2014 Governance and IT Follow-Up	2015	Complete	August 14, 2015	Satisfactory				9				7	-	1	1	2	Note C, Note E
2014 Grantee Monitoring Follow-Up	2015	Complete	July 31, 2015	Satisfactory				14				11	1	-	2	3	Notes C, D
Fiscal Year 2015 Subtotal					-	8	3	34	-	-	-	18	1	9	6	16	
Fiscal Year 2016																	
Commodity and Service Contracts Internal Audit	2016	Complete	May 13, 2016	Satisfactory	-	3	2	5	-	-	-	-	-	3	2	5	
Revenue Internal Audit	2016	Complete	July 8, 2016	Strong	-	-	2	2	-	-	-	-	-	-	2	2	
Information Security Internal Audit	2016	Complete	August 3, 2016														
Cash Management Internal Audit	2016	Complete	August 12, 2016	Strong		1		1					-	1	-	1	
2015 Grant Management Follow-Up	2016	Complete	June 9, 2016	Strong	-	8	1	9	-	8	1	9	-	-	-	-	Note A
2015 Information Technology Follow-Up	2016	Complete	N/A	N/A	-	1	1	2	-	1	1	2	-	-	-	-	Note E
Fiscal Year 2016 Subtotal					-	13	6	19	-	9	2	11	-	4	4	8	
Fiscal Year 2017																	
Training Program Internal Audit	2017	January 2017	March 10, 2017	Strong	-	2	-	2					-	2	-	2	
Internal Agency Compliance	2017	February 2017	April 17, 2017	Strong	-	1	-	1					-	1	-	1	
Pre-award Grant Management	2017	Fieldwork Complete			Fieldwork is complete. Exit meeting was held on April 17, 2017.												
Procurement and P-Card Internal Audit	2017	May 2017			Planning meeting was held on April 17, 2017. Fieldwork is scheduled to begin on May 15, 2017.												
2016 Information Security Follow-Up	2017	Fieldwork Complete			Fieldwork is complete. Findings and Observation Matrix was delivered on March 31, 2017.												
2016 Commodity and Service Contracts Follow-Up	2017	May 2017			Planning meeting was held on April 17, 2017. Fieldwork is scheduled to begin on May 8, 2017.												
2016 Revenue Follow-Up	2017	May 2017			Planning meeting was held on April 17, 2017. Fieldwork is scheduled to begin on May 1, 2017.												
2016 Cash Management Follow-Up	2017	May 2017			Planning meeting was held on April 17, 2017. Fieldwork is scheduled to begin on May 1, 2017.												
Fiscal Year 2017 Subtotal						3		3						3		3	
Fiscal Year 2018																	
Post Award Grant Monitoring Internal Audit Grant Contracting Internal Audit	2018																
Information Technology Services Internal Audit	2018																
Communication	2018																
State Reporting	2018																
2017 Procurement Follow-Up	2018																
2017 Non-Grant Expenditures Follow-Up	2018																
2017 Training Follow-Up	2018																
2017 External Affairs Follow-Up	2018																
Fiscal Year 2018 Subtotal																	

FISCAL YEAR 2017 SUMMARY																	
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**Findings**				**Closed Findings**				**Total Open Findings**				**Timing of Follow-Up Procedures by IA**
					High	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	
Training Program Internal Audit	2017	Complete	March 10, 2017	Strong	-	2	-	2	-	-	-	-	-	2	-	2	FY 2018
Internal Agency Compliance	2017	Complete	April 17, 2017	Strong	-	1	-	1	-	-	-	-	-	1	-	1	FY 2018
Information Security Internal Audit	2016	Fieldwork Complete	August 3, 2016														February 2017
Revenue Internal Audit	2016	Fieldwork May 1, 2018	July 8, 2016	Strong	-	-	2	2	-	-	-	-	-	-	2	2	May 2017
Cash Management Internal Audit	2016	Fieldwork May 1, 2019	August 12, 2016	Strong	-	1	-	1	-	-	-	-	-	1	-	1	May 2017
Commodity and Service Contracts Internal Audit	2016	Fieldwork May 8, 2017	May 13, 2016	Satisfactory	-	3	2	5	-	-	-	-	-	3	2	5	May 2017
Total Findings For Internal Audit Follow-Up					-	4	4	8	-	-	-	-	-	4	4	8	

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Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of April 30, 2017

NOTES	
A	The nine findings from the 2015 Grant Management internal audit were closed as part of the 2016 Internal Audit Follow-up procedures.
B	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	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	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 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. The two prior open findings have been consolidated into the 2016 IT Security Internal Audit.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

INTERNAL AUDIT REPORT OVER INTERNAL AGENCY COMPLIANCE

REPORT DATE: FEBRUARY 24, 2017

ISSUED: APRIL17, 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 February 13, 2017 through February 24, 2017 relating to the admissions and registration processes.

The objectives of the internal audit were to evaluate the design and effectiveness of CPRIT's Internal Agency Compliance processes. The objectives were organized as follows:

A. Determine whether internal controls over the Internal Agency Compliance processes are implemented and designed effectively to manage and monitor internal agency compliance with statutory and agency requirements.
B. Ensure that controls over critical requirements within the Internal Agency Compliance processes are operating efficiently and effectively.

To accomplish these objectives, we conducted interviews with CPRIT personnel responsible for Internal Agency Compliance. We also reviewed documentation and performed specific testing procedures to assess controls. Procedures were performed at CPRIT's offices and were completed on February 24, 2017.

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

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.
Austin, Texas
April 17, 2017

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
INTERNAL AUDIT REPORT OVER INTERNAL AGENCY COMPLIANCE
REPORT DATE: FEBRUARY 24, 2017
ISSUED: APRIL 17, 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 granting funds for cancer research, prevention, and product development, the agency has the responsibility to ensure that the individuals participating in the grant awards process do not have conflicts of interest with those receiving the grant funds. State Government Code, CPRIT's Administrative Rules, Code of Conduct and Ethics, Policies and Procedures, and Compliance Handbook establish the compliance requirements for CPRIT's Oversight Committee, employees and other stakeholders.

The Deputy Executive Officer and Chief Compliance Officer share the responsibilities within CPRIT to monitor and manage internal compliance requirements for the agency. Through their efforts, updates and changes in agency compliance requirements are identified, integrated into agency Administrative Rules (where applicable), and communicated to agency employees, peer reviewers, and Oversight Committee Members.

Through the compliance management processes, CPRIT is responsible for ensuring that their Oversight Committee, Program Integration Committee (PIC), and employees complete annual acknowledgements of CPRIT's Conflict of Interest Policy. Oversight Committee members are also required to complete political contribution disclosures annually, and agency employees are required to complete outside employment disclosure forms to report possible conflicts with other employment.

CPRIT management reports any identified conflicts of interest to the Oversight Committee through the course of the Oversight Committee meetings. The Oversight Committee has the ability to grant waivers for conflicts, as deemed appropriate by the Committee. The Oversight Committee is responsible for ensuring that individuals with reported conflicts of interest do not participate in restricted activities, and rely on the compliance reports provided by the Chief Compliance Officer to ensure that participation in grant application and award activities is appropriate.

AUDIT OBJECTIVE AND SCOPE

The audit focused on CPRIT's internal processes and programs to manage and monitor agency personnel and Oversight Committee compliance with statutory and agency requirements. 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 Internal Agency Compliance processes that were reviewed include:

- Compliance Requirement Identification
- Internal Policy Development
- Conflict of Interest and Disclosures
- Internal Compliance Monitoring
- Non-Compliance Identification and Reporting

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

Compliance Requirement Identification
- New compliance requirements are identified and evaluated
- Changes to existing compliance requirements are identified and evaluated
- Legislative and regulatory requirements are communicated to appropriate levels of management

Internal Policy Development
- Agency administrative rules are updated to be in compliance with new and/or changes in compliance requirements in a timely manner and communicated to all relevant parties
- Policies and procedures are regularly evaluated to ensure alignment with requirements
- Policies and procedures are approved by management prior to implementation

Conflict of Interest and Disclosures
- Oversight Committee members complete Conflict of Interest forms timely and accurately
- Chief Executive Officer completes Conflict of Interest forms timely and accurately
- Oversight Committee members disclose political contributions timely and accurately
- Employees disclose outside employment on a timely basis
- Required forms and disclosures are monitored to ensure completion and submission

Internal Compliance Monitoring
- Compliance with policy and regulatory requirements is monitored and managed on an ongoing basis
- Employee compliance is monitored

Non-Compliance Identification and Reporting
- Potential non-compliance is identified and evaluated
- Non-compliance is reported to appropriate management
- Non-compliance is reported externally as required
- Corrective action is implemented and monitored

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. In addition, we observed the February 15, 2017 Oversight Committee meeting. Our coverage period was from August 1, 2015 through January 31, 2017.

EXECUTIVE SUMMARY

Through our interviews, observations, evaluation of internal control design, and testing of controls, we identified one finding. The finding includes the item that was identified and considered to be a non-compliance issue 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. This issue 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.*

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
INTERNAL AUDIT REPORT OVER INTERNAL AGENCY COMPLIANCE
REPORT DATE: FEBRUARY 24, 2017
ISSUED: APRIL 17, 2017

OVERALL ASSESSMENT	STRONG

SCOPE AREA	RESULT	RATING
Objective A: Determine whether internal controls over the Internal Agency Compliance processes are implemented and designed effectively to manage and monitor internal agency compliance with statutory and agency requirements.	We identified 12 controls to be in place in the process, and did not identify any gaps or unacceptable risk exposures. We identified that the agency had policies and procedures in place covering the 60 compliance requirements identified across six relevant authoritative statutes, rules and codes evaluated.	**STRONG**
Objective B: Ensure that controls over critical requirements within the Internal Agency Compliance processes are operating efficiently and effectively.	The critical controls over Internal Agency Compliance processes are operating effectively. We identified one instance where a required, annual conflict of interest form was not completed in accordance with CPRIT requirements.	**STRONG**

Through our interviews, evaluation of internal control design and control testing we did not identify any additional observations or opportunities for improvement.

CONCLUSION

Based on our evaluation, the Internal Agency Compliance functions have procedures and controls in place to conduct effective management of the significant processes within CPRIT. However, we identified an opportunity to improve the processes and effectiveness of the controls within the Internal Agency Compliance process, which was independently identified by agency management. Management has already identified a solution to remediate the finding and has begun the process to implement the necessary changes.

CPRIT should continue to monitor the revised review checklist to ensure that all Oversight Committee members, PIC members, and CPRIT employees complete and return their required disclosure statements.

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

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
INTERNAL AUDIT REPORT OVER INTERNAL AGENCY COMPLIANCE
REPORT DATE: FEBRARY 24, 2017
ISSUED: APRIL 17, 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, evaluating the internal controls over the process, and observing an Oversight Committee meeting. We evaluated the existing policies, procedures and processes in their current state.

Objective A: Design of Internal Controls

Determine whether internal controls over the Internal Agency Compliance processes are implemented and designed effectively to manage and monitor internal agency compliance with statutory and agency requirements.

1. **Procedures Performed:** We conducted interviews with key personnel throughout CPRIT and examined existing documentation to gain an understanding of the current Internal Agency Compliance processes. We identified controls within the following critical sub processes:

   - Compliance Requirement Identification
   - Internal Policy Development
   - Conflict of Interest and Disclosures
   - Internal Compliance Monitoring
   - Non-Compliance Identification and Reporting

   We evaluated whether the identified internal controls are sufficiently designed to mitigate the critical risks associated with the Internal Agency Compliance processes. We identified any unacceptable risk exposures due to control design inadequacy or any opportunities to strengthen the effectiveness of the existing control design.

   In addition, we evaluated the existing control design to verify that CPRIT's processes are designed to be in compliance with relevant guidance and regulations.

   Results: We identified 12 controls in place over the significant activities within the Internal Agency Compliance processes. We identified one finding where an improvement in the process and procedures can be made.

Significant Process	Controls	Control Gaps
Compliance Requirement Identification	3	-
Internal Policy Development	3*	-
Conflict of Interest and Disclosure	3*	Finding 1-
Internal Compliance Monitoring	4	-
Non-Compliance Identification and Reporting	2	-
TOTAL	**12**	**1**

* **Duplicate Control:** The total number of controls identified is 12. However, based on their design, controls address risks in multiple processes. We have mapped the 12 identified controls to the processes in which they mitigate the risks within the processes.

Finding 1 – MODERATE – **Missing Annual Conflict of Interest Form for PIC Member from DSHS**

CPRIT does not have a process in place to ensure that all required annual conflict of interest forms are completed. In accordance with CPRIT's Code of Conduct and Ethics, Conflict of interest forms are required to be completed by all CPRIT Oversight Committee members, Program Integration Committee (PIC) members, and employees must sign, date and file a conflicts of interest statement on an annual basis.

We identified that the PIC member representing the Department of State Health Services (DSHS) did not complete the required annual conflict of interest statement for fiscal years 2016 and 2017. One position of the PIC is filled by a representative of DSHS. Although the PIC member from DSHS changed from FY 2016 to FY 2017, neither PIC member completed the annual conflict of interest statement.

Although the annual conflict of interest statement was not signed, we did identify that all PIC members completed the Conflict of Interest PIC Statements (Certification of No Communication with Applicants, Certification of No Financial Interest and Certification of No Communication between PIC members and Oversight Committee members) required to be completed at each PIC meeting, as well as a Post Review Statement for every meeting. Both PIC members were granted waivers while they were on the PIC and had no conflicts of interest reported during our testing period.

Additionally, upon identification of the issue by Internal Audit, the current PIC member from DSHS completed the missing form for FY 2017 and additional procedures were added to the Chief Compliance Officer's review checklist to ensure that all required disclosures are received in the future.

Recommendation: The Chief Compliance Officer should continue to utilize the updated review checklist to verify the submission of the annual conflict of interest statements by all Oversight Committee members, PIC members and CPRIT employees to ensure that all required disclosure statements are completed and returned to CPRIT, as required.

Management Response: CPRIT management agrees with this finding. The Chief Compliance Officer will utilize the updated review checklist to verify submission of the annual conflict of interest statements by all Oversight Committee members, PIC members, and CPRIT employees to ensure that all required disclosure statements are completed and returned to CPRIT by the due date.

Responsible Party: Chief Compliance Officer
Implementation Date: February 24, 2017

2. **Procedures Performed**: We evaluated the CPRIT controls identified against the 60 compliance requirements identified in the following authoritative statues, codes and agency rules:

Statutes/Rules/Codes	# Requirements
Health and Safety Code, Title 2. Health, Subtitle E. Health Care Councils and Resource Centers, Chapter 102. Cancer Prevention and Research Institute of Texas	13
Texas Government Code, Title 5. Open Government; Ethics	3
Texas Administrative Code, Title 25 Health Services, Part 11 Cancer Prevention and Research Institute of Texas	20
CPRIT Code of Conduct and Ethics	21
Oversight Committee Bylaws	3
Total	**60**

Results: No findings identified.

Objective B: Effectiveness of Controls

Ensure that controls over critical requirements within the Internal Agency Compliance processes are operating efficiently and effectively.

1. **Procedures Performed:** We reviewed all administrative rule changes that occurred from August 1, 2015 through January 31, 2017. This period covered a total of nine Oversight Committee meetings. For each meeting, we verified that:

   - Administrative rule changes caused by changes in state statutes, grant administration procedures, and/or grant monitoring procedures were identified and proposed to the Oversight Committee
   - Changes were published in a timely manner
   - Changes were communicated to CPRIT management
   - Changes to administrative rules were communicated to CPRIT staff and other relevant stakeholders in a timely manner

   Results: No findings identified.

2. **Procedures Performed:** We reviewed the annually required conflict of interest policy acknowledgement forms for the 55 total CPRIT employees, Oversight Committee members, and Program Integration Committee (PIC) members during the coverage period of August 1, 2015 through January 31, 2017, including

   This period included:
   - 44 CPRIT employees
   - 9 Oversight Committee members
   - 2 Program Integration Committee (PIC) members from DSHS

We examined the conflict of interested policy acknowledgement forms to verity that CPRIT employees, Oversight Committee members, and PIC members completed their forms in a timely manner. We also verified that any conflicts of interest were disclosed to the Oversight Committee and, for employees and PIC members, waivers were approved by the Oversight Committee.

Results: We identified that there were 2 PIC members who did not complete the required annual conflict of interest statement for fiscal years' 2016 or 2017.

Finding 1 – MODERATE – Missing Annual Conflict of Interest Form for PIC Member from DSHS

3. **Procedures Performed:** We reviewed the annually required political contribution disclosure forms for the nine Oversight Committee members during the coverage period of August 1, 2015 through January 31, 2017. We verified that each of the Oversight Committee members completed a political disclosure form, as required.

   Results: No findings identified.

4. **Procedures Performed**: We reviewed the annually required outside employment disclosure forms for all 44 staff employed by CPRIT during the coverage period of August 1, 2015 through January 31, 2017. We verified that all staff completed an outside employment disclosure form and each form was reviewed by the employee's supervisor and the Chief Executive Officer.

   Results: No findings identified.

5. **Procedures Performed:** We reviewed the minutes for all Oversight Committee meetings that occurred from the coverage period of August 1, 2015 through January 31, 2017. This period covered a total of nine Oversight Committee meetings. For each meeting, we verified that:

   - CPRIT has procedures embedded into Oversight Committee meetings and operational processes to monitor employee and Oversight Committee compliance
   - Oversight Committee members, PIC members or CPRIT employees did not participate in any restricted activity where conflicts of interest have been identified
   - Identified instances of non-compliance were reported appropriately and corrective action was implemented timely

   Results: No findings identified.

6. **Procedures Performed:** We attended the February 15, 2017 Oversight Committee meeting to verify that CPRIT has procedures embedded into the Oversight Committee meeting procedures and processes to monitor Oversight Committee compliance with agency requirements.

   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
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

RISK RATINGS

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

IA # 01-17 INTERNAL AUDIT REPORT OVER TRAINING PROGRAM

REPORT DATE: FEBRUARY 6, 2017

ISSUED: MARCH 10, 2017

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weaver
Assurance · Tax · Advisory

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

This report presents the results of the internal audit procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period January 9, 2017 through February 6, 2017 relating to the Training Program of CPRIT.

The objectives of the internal audit were to evaluate the design and effectiveness of CPRIT's training program process as follows:

A. Determine whether internal controls over the Training Program processes ensure that consistent processes are implemented and designed effectively to manage the training Program.
B. Ensure that controls over critical requirements within the Training Program processes are operating efficiently and effectively.
C. Ensure that compliance and professional development training requirements are completed in a timely manner by the required individuals.

Our procedures included interviewing key 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. Our coverage period was from July 1, 2015 through December 31, 2016.

The scope of the audit did not include evaluating the content of the training materials for sufficiency, adequacy and accuracy. The scope also did not include processes and activities related to grantee compliance monitoring, human resources, compliance, and IT security.

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

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.
Austin, Texas
March 10, 2017

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
INTERNAL AUDIT REPORT OVER TRAINING PROGRAM
FEBRUARY 6, 2017
ISSUED: MARCH 10, 2017

BACKGROUND

The goal Cancer Prevention & Research Institute of Texas (CPRIT) is to expedite innovation in cancer research and product development, and to enhance access to evidence-based prevention programs throughout the state. Under the guidance of its governing body, the Oversight Committee, CPRIT accepts applications and awards grants for a wide variety of cancer-related research and for the delivery of cancer prevention programs and services by public and private entities located in Texas.

Training is required to ensure that the agency's Oversight Committee, employees, and grant recipients are knowledgeable of the requirements of the state, CPRIT's administrative rules, codes of conduct, ethics requirements and responsibilities of administering and receiving grant funds. CPRIT's Operating Budget for FY 2017 includes a professional development budget of $20,000 to administer training Program to the agency's 29 employees, the Oversight Committee, and the agency's grant recipients.

CPRIT annually provides Compliance and Ethics training to employees and Oversight Committee Members to meet the Texas Administrative Code §701.7 requirement. Grant recipients also receive annual training to provide updates and information related to their requirements as recipients of grant funds.

Oversight Committee members receive initial training upon being appointed to the Committee. This training consists of ethics training, as well as, Open Meetings Act, Public Information Act, and contract oversight responsibilities. After the initial trainings, the Oversight Committee members are trained on CPRIT goals, legislative and compliance information, administrative rules, and grants on an annual basis.

CPRIT employees also receive onboarding training that includes code of conduct and ethics, grant compliance and legislative requirements. Annually the Chief Compliance Officer provides ongoing training to CPRIT staff to ensure that agency employees are knowledgeable of CPRIT grant compliance requirements. After every legislative session, the General Counsel provides training to CPRIT employees regarding legislative changes that affect the agency.

On an annual basis, CPRIT's Chief Compliance Officer provides a compliance training program for grant recipients addressing applicable financial, administrative, and programmatic requirements related to proper stewardship over grant award funds, including grant reporting to meet the CPRIT's grant requirements.

AUDIT OBJECTIVE AND SCOPE

The audit focused on the Cancer Prevention and Research Institute of Texas (CPRIT) Training Program as they are deployed to employees, the CPRIT Oversight Committee and CPRIT grant recipients. 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 Training Program processes reviewed included:

Employee Technical Training

- Training Requirement Identification
  - Continuing Education
- Training Plan Development and Budgeting
- Delivery and Completion
- Training Completion Monitoring

Oversight Committee Training

- Member Onboarding
  - Code of Conduct and Ethics
  - Conflict of Interest
- Governance Training
- Legislative and Compliance Update Training

Employee Compliance and Ethics Training

- New Employee Onboarding
- Code of Conduct and Ethics Training
- Grant Compliance Training
- Legislative and Compliance Updates
- Training Completion Monitoring

Grantee Training and Onboarding

- Training Material Review and Update
- Training Scheduling and Planning
- New Grantee Onboarding Training
- Grantee Compliance Trainings
- Grantee Compliance Updates
- Training Completion Monitoring

The scope of the audit did not include grantee compliance monitoring, internal compliance programs, human resource requirements, or information technology security related to training records and programs.

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

Employee Technical Training

- Employee training needs are identified and tracked
- Employee certification and continuing education requirements are met
- Training plans address all necessary courses
- Attendance is recorded and monitored
- Training content addresses technical needs
- Training budgets are appropriate

Oversight Committee Training

- New Oversight Committee members receive onboarding training
- Oversight Committee members are aware of governance responsibilities
- Oversight Committee members are notified of legislative and compliance updates
- Oversight Committee members receive contract oversight training

Employee Compliance and Ethics Training

- Employees receive onboarding training
- Employees receive training related to the Code of Conduct and Ethics
- New compliance requirements are identified and communicated to employees
- Employees receive updated ethics training
- Employees receive policy compliance and civil rights training

Grantee Training and Onboarding

- Grantees receive onboarding training
- Grantees receive required compliance training
- Grantee attendance is tracked and monitored
- Grantee training content addresses all necessary compliance topics
- Appropriate representatives from the grantee organization attend required training

The scope of the audit did not include evaluating the content of the training materials for sufficiency, adequacy and accuracy. The scope also did not include processes and activities related to grantee compliance monitoring, human resources, compliance, and IT security.

Our procedures included interviewing key 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. Our coverage period was from July 1, 2015 through December 31, 2016.

EXECUTIVE SUMMARY

Through our interviews, evaluation of internal control design and testing of transactions we identified two findings. The listing of findings include those items that have been identified and are considered to be non-compliance issues with documented CPRIT policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover significant risks to the agency. These issues potentially 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	STRONG

SCOPE AREA	RESULT	RATING
Objective A: Determine whether internal controls over the Training Program processes ensure that consistent processes are implemented and designed effectively to manage the training Program.	We identified 18 controls to be in place in the training program process. We identified the following opportunity for improvement: • Monitor, verify, and obtain evidence of timely Oversight Committee training completion.	STRONG
Objective B: Ensure that controls over critical requirements within the Training Program processes are operating efficiently and effectively.	We determined that the controls over critical requirements within the Training Program processes are operating efficiently and effectively.	STRONG

SCOPE AREA	RESULT	RATING
Objective C: Ensure that compliance and professional development training requirements are completed in a timely manner by the required individuals.	We determined that required trainings are completed timely for active employees. We identified the following opportunities for improvement: • Monitor completion of Oversight Committee trainings • Monitor due dates and completion of employee State Civil Rights Training	STRONG

Other opportunities for improvement were identified through our interviews, evaluation of internal control design and transactional testing. These observations include those items that are not considered to be non-compliance issues with documented CPRIT policies and procedures. These are considered process improvement observations and the intent for the recommendations are to strengthen current CPRIT processes and controls. These observations were provided to management separately.

CONCLUSION

Based on our evaluation, the training program function has procedures and controls in place that are designed to mitigate risks with the significant processes. However, we identified several opportunities to improve the processes and effectiveness of the controls within the training program process.

We recommend CPRIT management monitor, verify and retain documentation of the timely completion of required Oversight Committee member training sessions. Additionally, CPRIT should ensure that recurring employee training is completed within the required timeframes.

Follow-up procedures should be conducted in Fiscal Year 2018 to validate the effectiveness of the remediation efforts taken to address the findings identified.

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

DETAILED PROCEDURES PERFORMED, FINDINGS, RECOMMENDATIONS AND MANAGEMENT RESPONSE

Our procedures included interviewing key personnel involved with the training Program to gain an understanding of the current processes in place, examining existing documentation, evaluating the internal controls over the process, and testing the effectiveness of the controls in place. We evaluated the existing policies, procedures and processes in their current state.

Objective A: Design of Internal Controls

Determine whether internal controls over the Training Program processes are designed to ensure that consistent processes are implemented and designed effectively to manage the training Program.

Procedures Performed: We conducted interviews of key personnel and examined existing documentation to gain an understanding of the current Training Program process. We identified internal controls that address risks over the critical sub processes:

- Employee Technical Training
- Oversight Committee Training
- Employee Compliance and Ethics Training
- Grantee Training and Onboarding

We evaluated whether the identified internal controls were sufficiently designed to comply with CPRIT policies and procedures and mitigate the critical requirements of the Training Program 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 18 controls in place over the significant activities within the Training Program process. We identified one finding where an improvement in the process, policies and procedures can be made.

Significant Process	Controls	Control Gaps
Employee Technical Training	3	-
Oversight Committee Training	5	Finding 1
Employee Compliance and Ethics Training	5	-
Grantee Training and Onboarding	5	-
TOTAL	**18**	**1**

Finding 1 – MODERATE - Monitoring Evidence of Timely Completion of Oversight Committee Required Training:
CPRIT does not have processes in place to ensure it obtains and retains evidence that newly appointed Oversight Committee members complete required trainings related to the Public Information Act, Open Meetings Act, and contract oversight within the required 90 day timeframe.

Of the eight Oversight Committee Members active during the audit scope period, one was appointed and required to complete training within the scope period. CPRIT was unable to provide documented evidence that Public Information Act training was completed for the appointed Committee Member within the 90 day timeframe.

After internal audit identified the issue, CPRIT contacted the Oversight Committee member who subsequently completed the required training and provided evidence of completion.

Recommendation: CPRIT Management should implement procedures to ensure that it obtains and maintains evidence that new Oversight Committee appointees complete their state required training within the 90 day timeframe. This could be achieved by periodically reviewing the status of completion of trainings throughout the 90 day timeframe to ensure that the state required training is completed in a timely manner. CPRIT should ensure that the agency retains documentation that training has been completed.

Management's Response: CPRIT management agrees with this finding and will adjust its processes so that the General Counsel provides to the Chief Compliance Officer a copy of the written communication sent to new members explaining the training requirements and associated deadlines. The Chief Compliance Officer will regularly follow up with new members throughout the 90-day period until members provide documentation that the training is complete. The Chief Compliance Officer will retain documentation of completed training for each Oversight Committee member.

Responsible Party: General Counsel, Chief Compliance Officer

Implementation Date: March 1, 2017

Objective B: Effectiveness of Internal Controls

Ensure that controls over critical requirements within the Training Program processes are operating efficiently and effectively.

1. **Procedures Performed:** We identified all CPRIT employees active during the scope period of July 1, 2015 through December 31, 2016. For each, we obtained evidence to verify the following:

   - Employee training requirements are identified
   - Employee training plans are reviewed and approved
   - Training plan is adequately budgeted
   - Training completion is tracked and logged

   Results: No findings identified.

2. **Procedures Performed:** We identified all Oversight Committee members active during the scope period of July 1, 2015 through December 31, 2016. For each, we obtained evidence to verify the following:

   - Oversight Committee members received onboarding training
   - Oversight Committee members received Code of Conduct and Ethics training
   - Oversight Committee members received ongoing governance and legislative update training

   Results: No findings identified.

3. **Procedures Performed:** We identified all CPRIT employees active during the scope period of July 1, 2015 through December 31, 2016. For each, we obtained evidence to verify the following:

   - Employees received Code of Conduct and Ethics training
   - Employees received training on key grant compliance requirements
   - Employees received legislative update training, where relevant
   - Training completion is monitored

   Results: No findings identified.

4. **Procedures Performed:** We selected a sample of 15 grantees active during the scope period of July 1, 2015 through December 31, 2016. For each, we obtained evidence to verify the following:

   - Grantees received onboarding and ongoing training
   - Grantees received annual compliance training
   - Training was attended by appropriate personnel
   - Grantees have adequate opportunities to attend training
   - Grantee attendance is tracked and monitored.

   Results: No findings identified.

Objective C: Compliance

Ensure that compliance and professional development training requirements are completed in a timely manner by the required individuals.

1. **Procedures Performed:** We identified the active CPRIT employees with certifications and training requirements during the period of July 1, 2015 through December 31, 2016. For each, we obtained evidence to verify the following:

   - Employee training plans are reviewed and approved
   - Employees attended required professional development courses

   Results: No findings identified.

2. **Procedures Performed:** We identified all Oversight Committee members active during the scope period of July 1, 2015 through December 31, 2016. For each, we obtained evidence to verify the following:

   - Oversight Committee members complete Public Information Act and Open Meetings training
   - Oversight Committee members receive contract oversight training

   Results: We identified one Oversight Committee member for which CPRIT could not provide evidence of completion of Public Information Act training within the required 90-day timeframe.

   Finding 1 – MODERATE – Monitoring Evidence of Timely Completion of Oversight Committee Required Training

3. **Procedures Performed:** We identified all CPRIT employees who had been active during the scope period of July 1, 2015 through December 31, 2016. For each, we obtained evidence to verify that they had completed required civil rights training.

   Results: We determined that all current employees received the required training. We identified three former employees who had not completed the training within the required timeframe at the time of their separation from CPRIT.

   Finding 2 – MODERATE - **Employee Civil Rights Training Updates:**
   We identified that three employees did not complete the required update of their state Civil Rights Training every two years.

   Of the 39 active employees throughout the in scope period, three did not maintain current Civil Rights Training as required by state law. The three employees training updates were between 3-14 months delinquent. All three separated employment from CPRIT prior to December 2016 when CPRIT implemented a tracking spreadsheet to monitor the completion of Civil Rights Training.

   Recommendation: CPRIT should continue its efforts to monitor the upcoming due dates for Civil Rights Training renewal through the its tracking spreadsheet. CPRIT should also continue its efforts to automate the reminders to inform employees of upcoming training requirements. CPRIT Senior Management should be notified if any employee has not completed training updates in the required timeframe.

   Management Response: CPRIT management agrees with the finding and has implemented a tracking spreadsheet to monitor employee training due dates. Employees will receive reminder emails of upcoming training requirements. If an employee becomes delinquent in completing training requirements, the employee's supervisor and the Chief Executive Officer will be notified of the delinquent training requirement for appropriate action.

   Responsible Party: Operations Manager, Chief Operating Officer

   Implementation Date: December 1, 2016

APPENDIX

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
INTERNAL AUDIT REPORT OVER TRAINING PROGRAM
FEBRUARY 6, 2017
ISSUED: MARCH 10, 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:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and Program
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

RISK RATINGS

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**KRISTEN PAULING DOYLE, GENERAL COUNSEL** **CAMERON L. ECKEL, STAFF ATTORNEY**
Subject:	**CHAPTERS 701 AND 703 RULE CHANGES PROPOSED FOR FINAL ADOPTION**
Date:	**MAY 8, 2017**

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule changes to Chapters 701 and 703 as originally considered at the February 2017 meeting. Once the Oversight Committee approves the final orders adopting the rule changes, CPRIT will submit the amendments to the Secretary of State and the changes 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. A summary of the final rule amendments is located on the following page.

CPRIT published the proposed rules in the December 23rd edition of the *Texas Register*, as well as solicited public comment via CPRIT's website. One comment was received related to the proposed change to 701.36 that corrects the definition of "relative." As explained in the final order, CPRIT declines to make a change to the rule as proposed.

The Board Governance Subcommittee met on May 4th to review the public comments and final orders with CPRIT's General Counsel. The Subcommittee recommends the Oversight Committee approve the final orders adopting the proposed rule changes.

Next Steps

After the Oversight Committee adopts the proposed rule changes, CPRIT will submit the final order to the Secretary of State. The rule changes become effective 20 days after the date CPRIT files the order with the Secretary of State.

Final Rule Amendments – May 2017

§ 701.3 Definitions

Proposed Change - § 701.3(57) is amended to correct the explanation of a relationship by second-degree consanguinity. Second-degree consanguinity does not include aunts, uncles, nieces, or nephews. The amendment also updates the characterization of affinity for clarity.

§ 703.5 Scientific Research and Prevention Programs Committees

Proposed Change - § 703.5(g) is amended to expand the existing one-year restriction against a peer review panel member providing professional services in excess of $5000 to grantees reviewed by the member's panel. The restriction now applies to all grant applicants reviewed by the member's panel.

§ 703.6 Grant Review Process

Proposed Change – § 703.6(e)(4)(B) is amended to reflect that the Product Development Review Council decides the applications moving forward to due diligence. The Review Council decision is based on the applications recommended for due diligence by the Peer Review Panel(s).

§ 703.11 Requirement to Demonstrate Available Funds for Cancer Research Grants

Proposed Change - § 703.11(a)(4) is added to clarify that CPRIT may require a grantee to commit to a matching funds obligation that is greater than the 2:1 ratio set by the statute. Research grantees are required to contribute $1 for every $2 CPRIT pays toward the project. The Product Development Subcommittee recently recommended a policy change for Oversight Committee consideration to increase the amount contributed by a Product Development grantee who has previously received a CPRIT award. If the Oversight Committee approves the policy change, this rule amendment is necessary to carry out the new requirement. CPRIT will notify grant applicants of the increased matching fund commitment via the request for applications.

§ 703.24 Financial Status Reports

Proposed Change - § 703.24(a) is amended to add a new paragraph (4) that sets a deadline for grantees to submit supporting documentation associated with the quarterly financial status report (FSR). Occasionally, supporting documentation will be deficient or incorrect. CPRIT may request additional information and leave the FSR submission open while waiting for the additional information (rather than disapproving the FSR). The proposed amendment sets a uniform deadline for the grantee to submit the requested documentation. Failure to submit the documentation within 21 days will result in an automatic disapproval of the FSR.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 701. Policies and Procedures

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendment § 701.3(57) to clarify the definition of relative. The proposed amendment appeared in the March 3, 3017, issue of the *Texas Register* (42 TexReg 997).

Reasoned Justification

The proposed amendment removes "uncle, aunt, niece, or nephew," which the Institute listed inaccurately as examples of relatives related within the second degree by consanguinity or affinity. Texas Government Code §§ 573.021-.025 characterizes uncles, aunts, nieces, and nephews as relatives within the third degree of consanguinity.

Summary of Public Comments and Staff Recommendation

CPRIT received one comment in response to this proposed rulemaking. Dr. Richard Luduena from University of Texas Health San Antonio requested that the definition of "relative" be "expanded to include sons-in law, daughters-in law, brothers-in-law sisters-in-law, fathers-in-law, mothers-in-law, uncles, aunts, nephews, nieces and first cousins…A compromise might be to allow conflicts in this degree (uncles, aunts, in-laws, etc.), but to make certain that they are disclosed and perhaps the degree of the relationship described."

According to the statutory descriptions of consanguinity and affinity in Texas Government Code §§ 573.021-.025, CPRIT's rule already includes some of the relationships identified by Dr. Luduena (sons-in law, daughters-in law, brothers-in-law, sisters-in-law, fathers-in-law, and mothers-in-law) within the first or second degree of consanguinity or affinity; therefore no change is necessary. However, CPRIT declines to make the requested change to include uncles, aunts, nephews, nieces, and cousins. The amendment as proposed is consistent with Texas Health & Safety Code Annotated § 102.106, which establishes the second degree of consanguinity and affinity civil standard for determining prohibited conflicts of interest. Uncles, aunts, nieces, nephews, and cousins are related via third or fourth degrees of consanguinity and outside the statutory direction in Texas Health & Safety Code § 102.106.

The Institute adopts the rule change 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 the Institute's General Counsel has reviewed the adoption 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 May 19, 2017.

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 amendments §§ 703.5, 703.6, 703.11, and 701.24. The proposed changes affect conflicts of interest prohibitions of Scientific Research and Prevention Program Committee Members, Product Development Review Council role in due diligence, the matching fund requirements of Academic Research and Product Development Research grantees, and disapproval of Financial Status Reports for untimely supporting documentation. The proposed amendments were published in the March 3, 3017, issue of the *Texas Register* (42 TexReg 1001).

Reasoned Justification

The proposed amendment to § 703.5(g) prohibits a Scientific Research and Prevention Programs Committee Member from providing professional services to a grant applicant that results in compensation of more than $5,000. The restriction would be in place for one year beginning from the due date of the Grant Application or the effective date of the Grant Award, whichever is later.

The proposed amendment to § 703.6(c)(4)(B) reflects that the Product Development Review Council decides the applications moving forward in the review process for due diligence. The Review Council's bases their decision on the Grant Applications recommended by the Peer Review Panel(s).

The proposed amendment to § 703.11(a) clarifies that the Institute may require a research grant recipient to demonstrate a matching funds obligation greater than one-half of the grant award amount. In the event that the Institute increases the matching funds obligation, the proposed language requires the Institute to include the obligation in the Request for Applications. Texas Health and Safety Code § 102.0255 requires research grant recipients to dedicate an amount of matching funds equal to one-half of the grant award.

The proposed amendment to § 703.24 allows the Institute to disapprove a Financial Status Report (FSR) if a Grant Recipient does not timely respond to a written request by the Institute for more information or backup documentation. If the Institute submits a request in writing for more information or backup documentation regarding an FSR, the Grant Recipient has 21 days to respond to the request. If there is no response by the Grant Recipient within that timeframe, the Institute will disapprove the FSR. The proposed amendment is not intended to restrict the Institute's ability to disapprove an FSR or to extend the Grant Recipient's FSR due date.

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 May 19, 2017.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**KRISTEN PAULING DOYLE, GENERAL COUNSEL** **CAMERON L. ECKEL, STAFF ATTORNEY**
Subject:	**SUMMARY OF PROPOSED RULE CHANGE TO BE PROPOSED MAY 2017**
Date:	**MAY 8, 2017**

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 May 4th to discuss the proposed rule change with legal staff. The proposed rule change would allow 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. Within CPRIT's Grant Management System (CGMS) this causes those grant awards to have a partial quarter or "fifth quarter" that remains in CGMS for the life of the grant and often provides confusion and reporting difficulties for grantees. The proposed rule amendment would address 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. 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 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.

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 an 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.

Background and 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 on 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.

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 July 24, 2017. Parties filing comments are asked 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 and 102.251, which provide the Institute with broad rule-making authority to administer the chapter and to issue rules regarding the procedures for awarding grants. 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.

703.24

(a) Grant Recipients shall report expenditures to be reimbursed with Grant Award funds on the quarterly Financial Status Report form.

(1) Expenditures shall be reported by budget category consistent with the Grant Recipient's Approved Budget.

(2) All expenditures must be supported with appropriate documentation showing that the costs were incurred and paid. A Grant Recipient that is a public or private institution of higher education as defined by §61.003, Texas Education Code is not required to submit supporting documentation for an individual expense totaling less than $750 in the "supplies" or "other" budget categories.

(3) The Financial Status Report and supporting documentation must be submitted via the Grant Management System, unless the Grant Recipient is specifically directed in writing by the Institute to submit or provide it in another manner.

(4) The requirement to report and timely submit quarterly Financial Status Reports applies to all Grant Recipients, regardless of whether Grant Award funds are disbursed by reimbursement or in advance of incurring costs.

(b) Quarterly Financial Status Reports shall be submitted to the Institute within 90 days of the end of the state fiscal quarter (based upon a September 1 - August 31 fiscal year). The Institute shall review expenditures and supporting documents to determine whether expenses charged to the Grant Award are:

(1) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(2) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(c) A Grant Award with a Grant Contract effective date within the last quarter of a state fiscal year (June 1-August 31) will have an initial financial reporting period beginning September 1 of the following state fiscal year.

(1) A Grant Recipient that incurs Authorized Expenses after the Grant Contract effective date but before the beginning of the next state fiscal year may request reimbursement for those Authorized Expenses.

(2) The Authorized Expenses described in paragraph (c)(1) must be reported in the Financial Status Report reflecting Authorized Expenses for the initial financial reporting period beginning September 1.

(d) [~~(c)~~] Except as provided herein, the Grant Recipient waives the right to reimbursement of project costs incurred during the reporting period if the Financial Status Report for that quarter is not submitted to the Institute within 30 days of the Financial Status Report due date. Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.

(1) For purposes of this rule, the "Financial Status Report due date" is 90 days following the end of the state fiscal quarter.

(2) The Chief Executive Officer may approve a Grant Recipient's request to defer submission of the reimbursement request for the current fiscal quarter until the next fiscal quarter if, on or before the original Financial Status Report due date, the Grant Recipient submits a written explanation for the Grant Recipient's inability to complete a timely submission of the Financial Status Report.

(3) A Grant Recipient may appeal the waiver of its right to reimbursement of project costs.

(A) The appeal shall be in writing, provide good cause for failing to submit the Financial Status Report within 30 days of the Financial Status Report due date, and be submitted via the Grant Management System.

(B) The Chief Executive Officer may approve the appeal for good cause. The decision by the Chief Executive Officer to approve or deny the grant recipient's appeal shall be in writing and available to the Grant Recipient via the Grant Management System.

(C) The Chief Executive Officer's decision to approve or deny the Grant Recipient's appeal is final, unless the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision by the Oversight Committee.

(D) The Grant Recipient may request that the Oversight Committee reconsider the Chief Executive Officer's decision regarding the Grant Recipient's appeal. The request for reconsideration shall be in writing and submitted to the Chief Executive Officer within 10 days of the date that the Chief Executive Officer notifies the Grant Recipient of the decision regarding the appeal as noted in subparagraph (C) of this paragraph.

(E) The Chief Executive Officer shall notify the Oversight Committee in writing of the decision to approve or deny the Grant Recipient's appeal. The notice should provide justification for the Chief Executive Officer's decision. In the event that the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision, the Chief Executive Officer shall provide the Grant Recipient's written request to the Oversight Committee at the same time.

(F) The Grant Recipient's request for reconsideration is deemed denied unless three or more Oversight Committee members request that the Chief Executive Officer add the Grant Recipient's request for reconsideration to the agenda for action at the next regular Oversight Committee meeting. The decision made by the Oversight Committee is final.

(G) If the Grant Recipient's appeal is approved by the Chief Executive Officer or the Oversight Committee, the Grant Recipient shall report the project costs and provide supporting documentation for the costs incurred during the reporting period covered by the appeal on the next available financial status report to be filed by the Grant Recipient.

(H) Approval of the waiver appeal does not connote approval of the expenditures; the expenditures and supporting documentation shall be reviewed according to subsection (b) of this section.

(I) This subsection applies to any waivers of the Grant Recipient's reimbursement decided by the Institute on or after September 1, 2015.

(4) Notwithstanding subsection (c) of this section, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding Financial Status Report(s). The approval shall be in writing and maintained in the Grants Management System. The Chief Program Officer's approval may cover more than one Financial Status Report and more than one fiscal quarter.

(5) In order to receive disbursement of grant funds, the most recently due Financial Status Report must be approved by the Institute.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER** **CHIEF OPERATING OFFICER REPORT**
Subject:	**CHIEF OPERATING OFFICER REPORT**
Date:	**MAY 9, 2017**

CPRIT Financial Overview for FY 2017, Quarter 2

FY 2017, Quarter 2 Operating Budget

CPRIT expended or obligated approximately $1.2 million in Indirect Administration during the year. The agency has also expended or obligated $10.8 million in Grant Review and Award Operations. The obligations 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 $21,339 in revenue sharing payments, bringing the total payments received through February 2017 to $37,201.

FY 2017, Quarter 2 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 September 2016 through February 2017.

Debt Issuance History

In February 2017, the Texas Public Finance Authority (TPFA) issued on CPRIT's behalf $106 million in general obligation bonds. This money comprises the remaining quarterly commercial paper issuances CPRIT had planned in FY 2017 covering agency operating costs, grant reimbursement payments, and transfer to the Department of State Health Services for Texas Cancer Registry operations.

In conjunction with the issuance of this new money, TPFA also refunded as general obligation bonds $269 million of outstanding commercial paper notes issued on CPRIT's behalf for the previous four quarters. Of the $269 million in outstanding commercial paper notes, $116.9 million had been issued in the first two quarters of FY 2017.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of February 28, 2017

Indirect Administration (B.1.1.)

		2017 Appropriated	2017 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,432,617	$ 1,417,617		$ 630,625	786,992	44%	$ 630,625	$ 786,992
1002	Other Personnel Costs	52,785	67,785		31,687	36,098	47%	31,687	36,098
2001	Professional Fees and Services	807,317	807,317		385,322	421,995	48%	385,322	421,995
2003	Consumable Supplies	27,584	27,584		7,015	20,569	25%	7,015	20,569
2004	Utilities	58,577	58,577		6,440	52,137	11%	6,440	52,137
2005	Travel	45,000	45,000		18,227	26,773	41%	18,227	26,773
2006	Rent-Building	-	18,408		18,408	0	0%	18,408	0
2007	Rent-Machine and Other	32,172	34,207		15,380	18,827	45%	15,380	18,827
2009	Other Operating Expenses	574,600	554,157		127,341	426,816	23%	127,341	426,816
	Subtotal - Indirect Administration (B.1.1.)	**$ 3,030,652**	**$ 3,030,652**	**1.02%**	**$ 1,240,446**	**$ 1,790,206**	**41%**	**$ 1,240,446**	**$ 1,790,206**

Grant Review and Award Operations (A.1.3.)

		2017 Appropriated	2017 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 2,730,580	2,681,233		$ 1,495,027	$ 1,186,206	56%	$ 1,495,027	$ 1,186,206
1002	Other Personnel Costs	3,856	53,203		71,484	(18,281)	0%	71,484	(18,281)
2001	Professional Fees and Services	10,809,493	10,809,493		9,585,934	1,223,559	89%	9,585,934	1,223,559
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities		10,000		5,316	4,684	53%	5,316	4,684
2005	Travel	65,000	65,000		34,578	30,422	53%	34,578	30,422
2009	Other Operating Expenses	201,297	191,297		40,792	150,505	21%	40,792	150,505
	Conference		20,481		-	20,481	0%	-	20,481
	Subtotal - Grant Operations (A.1.3.)	**$ 13,810,226**	**$ 13,830,707**	**4.66%**	**$ 11,233,132**	**$ 2,597,575**	**81%**	**$ 11,233,132**	**$ 2,597,575**

Grants

		2017 Appropriated	2017 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,334,312	$ 28,334,312		$ 12,024,696	$ 16,309,616	42%	$ 12,024,696	$ 16,309,616
4000	Grants - Research (A.1.1.)	251,780,562	$ 251,780,562		157,133,486	$ 94,647,076	62%	157,133,486	94,647,076
	Subtotal - Grants	**$ 280,114,874**	**$ 280,114,874**	**94.32%**	**$ 169,158,182**	**$ 110,956,692**	**60%**	**$ 169,158,182**	**$ 110,956,692**
	Grand Totals	**$ 296,955,752**	**$ 296,976,233**	**100.00%**	**$ 181,631,760**	**$ 115,344,473**	**61%**	**$ 181,631,760**	**$ 115,344,473**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of February 28, 2017

	02/01/2017-02/28/2017	AY 17 Year to Date as of 02/28/2017
Beginning Balance : 02/01/2017		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 02/28/2017		**$ 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 February 28, 2017

	02/01/2017-02/28/2017	AY 17 Year to Date as of 02/28/2017
Beginning Balance : 02/01/2017		**$ -**
Increases:		
(1) License Plate Revenue Received	$ 615.98	$ 4,992.06
Total Increases	**$ 615.98**	**$ 4,992.06**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	-	-
	-	-
Total Reductions	**$ -**	**$ -**
Ending Balance, 02/28/2017		**$ 4,992.06**

Note:

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of February 28, 2017

		02/01/2017-02/28/2017	AY 17 Year to Date as of 02/28/2017
Beginning Balance : 02/01/2017			**$ 96,416.49**
Increases:			
(1)	Product Development Application Fees Received	$ 20,000.00	$ 20,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ -	$ 64.80
(4)	Conference Registration Fees-Credit Card	$ -	$ -
Total Increases		**$ 20,000.00**	**$ 20,064.80**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended		$ -
	Legal Services Expenses (Application Fees)	$ -	$ (41,000.00)
Total Reductions		**$ -**	**$ (41,000.00)**
Ending Balance, 02/28/2017			**$ 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 February 28, 2017

		02/01/2017-02/28/2017	AY 17 Year to Date as of 02/28/2017
Beginning Balance : 02/01/2017			**$ -**
Increases:			
(1)	Revenue Sharing / Royalties	$ 21,339.02	$ 37,200.83
Total Increases		**$ 21,339.02**	**$ 37,200.83**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
	Sweep Account	$ (21,339.02)	$ (37,200.83)
		$ -	$ -
Total Reductions		**$ (21,339.02)**	**$ (37,200.83)**
Ending Balance, 02/28/2017			**$ -**

Note:

Cancer Prevention and Research Institute of Texas
FY 2017, Quarter 2 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			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.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable		
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable		
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable		
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,800,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable		
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable		
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable		
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable		
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable		
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable		
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable		
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable		
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable		
2016		August 29, 2016	$ 60,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 277,300,000				
2017	$300,000,000	October 19, 2016	$ 58,000,000		Commercial Paper Notes	Series A, Taxable		
2017		January 5, 2017	$ 58,900,000		Commercial Paper Notes	Series A, Taxable		
2017		February 8, 2017	$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded $269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				$ 222,900,000				
TOTAL ISSUED TO DATE				**$ 1,293,800,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE**
From:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER**
Subject:	**FY 2018 SERVICE CONTRACT APPROVALS**
Date:	**MAY 9, 2017**

Recommendation

CPRIT staff recommends 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.

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 unit cost.

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

Background

Contract Renewal with ICON Clinical Research (ICON) for Due Diligence Services

Each year CPRIT receives approximately fifty product development grant applications. These applications are evaluated by peer review panels which evaluate submitted applications to select a subset of applications for due diligence evaluation.

Due diligence is a comprehensive assessment of the company prior to investment. ICON assesses diligence topics to assess likelihood of program success including:

- Discovery Science
- Preclinical Research
- Manufacturing

- Clinical Research
- Regulatory Approval
- Management and Financial
- Commercial

The Product Development Review Council provides a fund/not fund recommendation based largely on the diligence reports addressing these key issues.

CPRIT only pays ICON for a completed company diligence report at a unit cost of $25,750. This unit cost remains the same from FY 2017. With the need for an estimated eight due diligence reports, the contract cost for FY 2018 will be $206,000. This would be the third and final renewal option in ICON's contract.

Contract Renewal with SRA International, Inc., a CSRA Company (CSRA) for Grant Management Support Services

CSRA provides:

- Logistical support for in-person and virtual peer review meetings;
- Summarized evaluation reports for each grant application including peer review chair consensus statements, budget recommendations, and noted issues in clinical trials with human subjects or animal research;
- Scientific expertise for the evaluation of the annual and final progress reports for academic research grants;
- A Software as a Service (SaaS) subscription to their Grants Management Platform (GMP) software including the application receipt module, program and peer review module, and grant management module;
- Enhancements to their GMP grants management module to increase protections over the data in that module as well as provide CPRIT the ability to reset workflows for certain reports when they are incorrectly submitted;
- Enhancements to their GMP program and peer review module to increase protections over the data in that module
- Incorporation of grant request for application requirements in the GMP application receipt module for electronic application submission; and
- Administration of electronic grant pedigrees.

CSRA has subcontracts with two Texas-based Historically Underutilized Business (HUB) vendors for some support services. One subcontractor, Innovation Event Management, provides meeting support services for the in-person peer review meetings held in Dallas or Houston. The other, The Alamo Travel Group, makes air travel arrangements for peer reviewers attending in-person meetings.

The contract also includes requirements for CSRA to provide to CPRIT certain reports related to the information technology platform operations on a regular and ad hoc basis.

The increase in contracted costs from FY 2017 to FY 2018 can be attributed to increases in labor category rates generally by one percent with a few labor category rates increasing by 25 percent

due to increased responsibilities for those positions. Other cost increases are attributed to the completion of the first Service Organization Control (SOC) 2, type 2 report about processes and controls over the CSRA information technology platforms which will cover May 2017 through October 2017 and a second report covering November 2017 through May 2018 to achieve the ongoing coverage required for information security compliance and the increased protections over data in the GMP program and peer review module as well as the grants management module.

CPRIT awarded a new contract to CSRA beginning in FY 2017 with a cost of $8,265,446 for the year. The contract has four one-year renewal options.

Contract Renewal with CohnReznick for Compliance Monitoring Services

Currently, there are approximately 585 active CPRIT grants that require ongoing compliance monitoring. In addition to monitoring grant recipient required reporting, CPRIT's compliance program conducts second-level reviews of all Financial Status Reports (FSRs), tracks submission of grant recipient single audits, performs grant desk reviews and onsite monitoring reviews, and provides annual compliance training to all grant recipients.

CPRIT initially awarded CohnReznick the contract in FY 2015. The FY 2018 contract renewal will allow CPRIT to strategically phase down contracted compliance support services and increase newly authorized CPRIT compliance personnel. As part of CPRIT's FY 2018 Compliance Monitoring Plan, CohnReznick will reduce their desk and onsite reviews, continue to provide information technology support for the compliance workflow module, and provide limited assistance with the grantee risk assessment process.

Contract Renewals with Vinson & Elkins and Baker Botts and New Contract with Yudell Isidore for Outside Counsel Services

CPRIT relies on outside legal counsel with IP expertise to conduct a review of companies' IP estate as part of the due diligence process. The IP due diligence is not a re-review of the grant application but serves as an independent analysis of the IP and associated licenses underlying the company's planned drug, device, diagnostic, technology, or service proposed for CPRIT funding. The Product Development Review Council uses information gained through the IP due diligence process to finalize their grant award recommendations.

These contract extensions and new contract are the result of CPRIT's request for proposals issued in September 2017 and FY 2018 Needs Assessment. The request for proposals included an option to renew the three outside counsel contracts for up to four additional one-year periods. The option to extend the contract(s) provides service continuity, particularly when review cycles cross fiscal years.

CPRIT pays each firm based solely on the number of hours worked; there is no guaranteed minimum payment. Generally, the price per IP due diligence company project ranges from $10,000 - $20,000. The cost of each assessment varies based upon the complexity of the IP information and issues presented, as well as the volume of documents counsel must review. The outside counsel contracts use an hourly rate, which the Attorney General caps at $525/hour.

Contracting with multiple firms allows CPRIT to balance the workload and avoid potential conflicts of interest between the firms and the companies under review.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

A RESOLUTION
AUTHORIZING A REQUEST FOR FINANCING
AND THE EXECUTION AND DELIVERY OF DOCUMENTS
REQUIRED TO EFFECT SUCH FINANCING

Whereas, the Texas Public Finance Authority (the "Authority") is authorized to issue general obligation bonds to finance the grant program for cancer research and prevention and control for the use and benefit of the Cancer Prevention & Research Institute of Texas (the "Agency") pursuant to Article III, Section 67, Texas Constitution; Texas Health & Safety Code, Chapter 102, as amended; and Texas Government Code, Chapter 1232, as amended, (collectively, the "Authorizing Law");

Whereas, the Agency desires and intends to request the Authority to finance the costs of the program as permitted by the Authorizing Law; and

Whereas, the Agency recognizes that in order to finance the cost of the program, the Authority may issue short term obligations, general obligation bonds, either or both ("Obligations") in an aggregate principal amount sufficient to finance program costs in the estimated amount of $300,000,000, plus the costs of issuance and related administrative costs, if any, which will be determined at the time of issuance; and

Whereas, the form of a Request for Financing, dated as of May 17, 2017, (the "Request for Financing") from the Agency to the Authority, which includes a detailed description of the program to be financed for the Agency ("program" herein) and a proposed expenditure schedule is presently before the CPRIT Oversight Committee.

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

Section 1. The purpose of the financing is to provide funds sufficient to make grant awards for cancer research and prevention and control and for the operations of the Agency, and the financing thereof is appropriate at this time. Accordingly, the execution and delivery of the Request for Financing to the Authority pursuant to the Authorizing Law is hereby ratified, approved and confirmed.

Section 2. The Chief Executive Officer of the Agency is hereby empowered, authorized and directed to:

a. sign and deliver any and all documents necessary or desirable to effect the financing and provide the projects, which may include but not be limited to a Memorandum of Understanding and a Financing Agreement between the Agency and the Authority;

b. cooperate with the Authority and its consultants to prepare an Official Statement in connection with the sale of the Obligations;
c. and to take any other action necessary to assist in such sale.

Section 3. All actions not inconsistent with provisions of this Resolution heretofore taken by the Institute and the Executive Director or designee thereof and the other officers of, or consultants to the Institute, directed toward the financing of the Program, and the issuance of the Obligations are hereby ratified, approved and confirmed.

Section 4. The officers and employees of the Agency shall take all action in conformity with the Authorizing Law and the provisions of the General Appropriations Act, 85th Legislature, R.S. (2017) to effect the issuance of the Obligations and complete the Program as provided in the Agreement and take all action necessary or desirable or in conformity with the Authorizing Law for carrying out, giving effect to, and consummating the transactions contemplated by the Memorandum of Understanding, the Agreement, the Obligations, and this Request for Financing, including without limitation, the execution and delivery of any closing documents in connection with the closing of the Obligations.

Section 5. This Resolution was adopted at a meeting open to the public, and public notice of the time, place and purpose of said meeting was given, all as required by Ch. 551, Texas Government Code.

Adopted by the affirmative vote of a majority of the Cancer Prevention and Research Institute of Texas Oversight Committee present and voting on this 17th day of May, 2017.

Cancer Prevention and Research Institute
of Texas Oversight Committee

Attested:

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Chairman

Secretary

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Fiscal Year 2018 Request for Financing Program Description

Purpose

The Cancer Prevention and Research Institute of Texas (CPRIT) is the state agency mandated to:

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

Powers and Duties

CPRIT will make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and make grants to institutions of learning and to advanced medical research facilities and collaborations in this state for:

1) research into the causes of and cures for all types of cancer in humans;
2) facilities for use in research into the causes of and cures for cancer;
3) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans; and
4) cancer prevention and control programs in this state to mitigate the incidence of all types of cancer in humans.

Implementation Plan

CPRIT estimates that $233.4 million in bonds proceeds must be issued on an as-needed basis consistent with Texas Government Code, Chapter 1232 to cover grant award obligations from fiscal years 2011, 2012, 2013, 2014, 2015, 2016, and 2017; new grant award obligations made during fiscal year 2018; and operating costs for general agency administration and pre- and post-award grants management processes. During fiscal year 2018, CPRIT will use the bond proceeds to disburse grant funds for grants awarded by CPRIT during the last three months of fiscal year 2011 as well as during fiscal years 2012, 2013, 2014, 2015, 2016, 2017, and 2018. CPRIT is currently authorized to obligate approximately $283.3 million for cancer prevention and research grant awards in fiscal year 2018.

CPRIT announces grant awards for cancer prevention education and service programs and academic and product development cancer research programs four times per year. CPRIT anticipates that it will obligate all of the available $283.3 million for cancer prevention, product development research, and academic research.

Grant funds are generally disbursed quarterly on a reimbursement basis to grant recipients. For certain types of grant awards, limited to product development, CPRIT advances funds in order to provide those specific types of recipients with working capital to meet their research milestones or objectives.

CPRIT is authorized to use bond proceeds to fund its grant review and award operations and indirect administration costs. At this time, the total budgeted amount of these two categories is $16.7 million in bond proceeds for fiscal year 2018 based on the authorized appropriations in General Appropriation Act, 85th Legislature. CPRIT must transfer $2.9 million in bond proceeds to the Texas Department of State Health Services (DSHS) for the operating costs associated with the Texas Cancer Registry. From the total of all of the agency's operating costs, CPRIT requires half of the proceeds to be available at the beginning of the state fiscal year to be able to cover the operating expenses for six months. CPRIT also requires proceeds at the beginning of each state fiscal quarter to pay for award costs reimbursed to grant recipients for the previous state fiscal quarter.

The scientific research program provides awards in the following areas: cancer biology, cancer genetics, immunology, imaging, therapeutics, prevention/epidemiology, and informatics/ computation. The product development research program focuses awards on the development of cancer drugs, diagnostics, and devices based on discoveries made in one of the seven areas described above. Prevention program grants are awarded for cancer prevention information and services, early detection and treatment, professional education and practice, cancer data acquisition and utilization, or survivorship (the areas of the Texas Cancer Plan). Awards for all programs are issued for multiple years, ranging from two to five years.

CPRIT has established a grant process that allows grant proposals for cancer prevention, scientific research, and product development research to be submitted through requests for applications (RFA) issued throughout each fiscal year. All proposals are reviewed by multiple experts in the appropriate area. CPRIT has approximately 200 national experts in cancer prevention, research and product development to review proposals and provide funding recommendations to CPRIT.

The award recommendations developed by the peer review committees are forwarded to the Program Integration Committee (PIC) for consideration. The five members of the PIC are statutorily defined as the Chief Executive Officer (CEO), Chief Scientific Officer, Chief Prevention Officer, Chief Product Development Officer, and DSHS Commissioner. The PIC finalizes award recommendations across all programs prior to every Oversight Committee meeting. When those proposed awards are forwarded to the Oversight Committee, each recommended award is accompanied by an affidavit signed by the CEO to affirm that the award followed all required pre-award grant procedures. The Oversight Committee considers these recommendations and votes to approve the awards.

Cancer Prevention and Research Institute of Texas

Estimated Expenditure Schedule, Fiscal Year 2018

Fiscal Year 2018	September	October	November	December	January	February	March	April	May	June	July	August	Total
Bond proceeds for Indirect Administration	$ 1,515,326	$ -	$ -	$ -	$ -	$ -	$ 1,515,326	$ -	$ -		$ -	$ -	$ 3,030,652
Bond proceeds for Grant Review and Award Operations	$ 6,853,541	$ -	$ -	$ -	$ -	$ -	$ 6,853,541	$ -	$ -	$ -	$ -	$ -	$ 13,707,082
Bond proceeds for Texas Cancer Registry (GAA 2017-18, Art. I, CPRIT Rider 5)	$ 1,484,777	$ -	$ -	$ -	$ -	$ -	$ 1,484,777	$ -	$ -	$ -	$ -	$ -	$ 2,969,554
Bond proceeds for Prevention and Research Grants	$ 58,346,356	$ -	$ -	$ 59,000,000	$ -	$ -	$ 54,046,356	$ -	$ -	$ 59,300,000	$ -	$ -	$ 230,692,712
Debt Issuance Subtotal, Fiscal Year 2018	$ 68,200,000	$ -	$ -	$ 59,000,000	$ -	$ -	$ 63,900,000	$ -	$ -	$ 59,300,000	$ -	$ -	$ 250,400,000
Cumulative Debt Total, Fiscal Year 2018	**$ 68,200,000**	**$ 68,200,000**	**$ 68,200,000**	**$ 127,200,000**	**$ 127,200,000**	**$ 127,200,000**	**$ 191,100,000**	**$ 191,100,000**	**$ 191,100,000**	**$ 250,400,000**	**$ 250,400,000**	**$ 250,400,000**	**$ 250,400,000**

Excerpted from Oversight Committee Bylaws

ARTICLE 5

CHAIRPERSON AND VICE CHAIRPERSON

Section 5.1 Election. 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 Election, Term of Office and Removal. At the first regular Oversight Committee meeting following the adoption of these bylaws, the members of the Oversight Committee shall 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 Chairperson. The Chairperson is the presiding officer of the Oversight Committee. The Chairperson shall preside at each meeting of the Oversight Committee. The Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by applicable law or recommended by the Board Governance and Ethics Subcommittee and approved by the Oversight Committee. The Chairperson may authorize official duties of members of the Oversight Committee, the University Advisory Committee, or any Ad Hoc Advisory Committee in accordance with applicable law. The Chairperson may not serve as the presiding officer for any other foundation or organization created to specifically benefit the Institute.

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

Governance and Ethics Subcommittee or applicable law and approved by the Oversight Committee.

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

Excerpted from the Nominations Subcommittee Charter

DUTIES AND RESPONSIBILITIES

The Subcommittee has the following duties and responsibilities:

- Annually review and report to the Oversight Committee regarding the composition and effectiveness of the Institute's advisory committees;
- Identify qualified individuals for appointment as members of advisory committees;
- 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; and
- Facilitate the Oversight Committee's officer election process by accepting nominations and recommending candidates for Oversight Committee consideration. The Subcommittee may work together with the outgoing Oversight Committee Chair to fulfill duties related to board elections.

Oversight Committee Meetings and Standing Subcommittees Meetings 2018

November 2017

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
10/29	10/30	10/31 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

February 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

August 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.