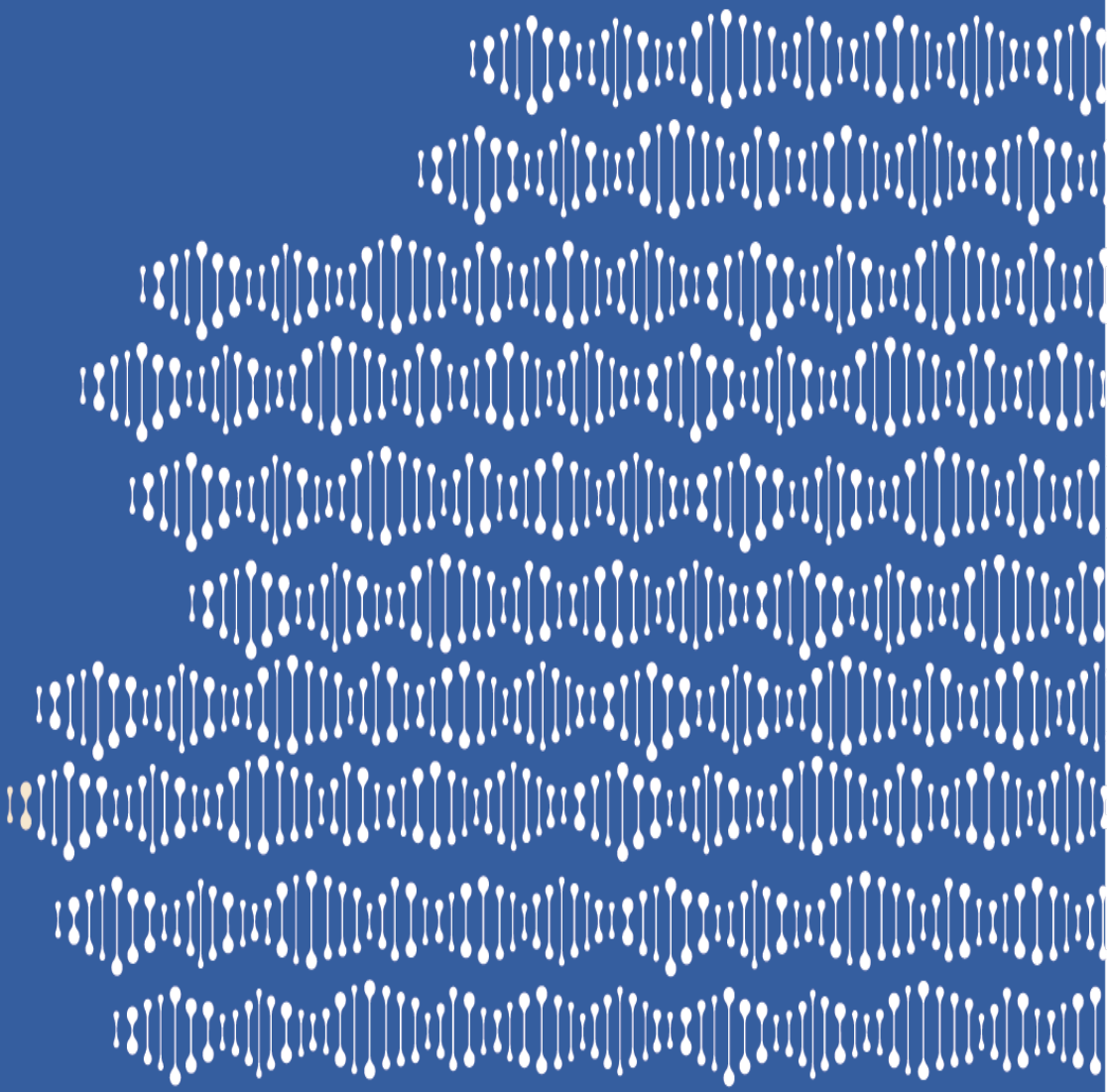
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

February 21, 2018



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Summary Overview of the February 21, 2018, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the February 21, 2018, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including new personnel, available grant funds, and other topics. Mr. Roberts will also present his annual report required by Tex. Health & Safety Code § 102.260(c).

Grantee Presentation – Asuragen, Inc.
Dr. Gary Latham will report on Asuargen's activities and achievements. Asuragen received a $6.8 million Commercialization/Product Development grant in 2012.

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

Chief Scientific Officer Report and Grant Award Recommendations
Dr. James Willson will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) award recommendations for Academic Research grant awards.

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

Chief Prevention and Communications Officer Report and Grant Award Recommendations
Dr. Becky Garcia will report to the Oversight Committee on the Prevention Program activities and present the PIC's award recommendations for Prevention grant awards. She will also present the agency's communications update, including a review of CPRIT's 2017 Innovations Conference.

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

Chief Product Development Officer Report
Mr. Mike Lang will provide an update on the Product Development Program, including an overview of FY 2019 Requests for Applications.

Appointments - Scientific Research and Prevention Programs Committee
Mr. Roberts 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.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an amended FY 2018 Internal Audit Plan and present three internal audit and follow-up procedures reports.

Advisory Committee Reports
The University Advisory Committee (UAC) will present its annual report to the Oversight Committee. CPRIT's administrative rules and the committee's charter require the UAC to provide updates to the Oversight Committee annually.

Fiscal Year 2020 – 2023 Budget Scenarios
Mr. Roberts will report on his discussions with interested parties about the Oversight Committee's preferred funding projection for the remainder of CPRIT's statutory authority.

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

Ms. Eckel will also present proposed changes to the agency's administrative rules in Chapter 703. 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 proposed rule changes to the Oversight Committee for final approval in May after the public has an opportunity to comment on the proposed rule changes.

Chief Operating Officer Report
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the first quarter of FY 2018.

Subcommittee Business
At the January 17, 2018, special meeting, the Oversight Committee discussed creating a new subcommittee to address special issues that arise from time to time, including legislative issues. The Oversight Committee Chair will present the proposed charter for the Special Issues subcommittee and recommend members of the new subcommittee. If the Oversight Committee approves the Special Issues Subcommittee charter, the Board Governance Subcommittee charter should be amended to avoid overlapping duties. The Oversight Committee must vote to approve the changes to subcommittee charters and membership.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

Texas State Capitol Extension
1400 N. Congress Avenue, Austin, Texas 78701
Room E1.026

February 21, 2018
10:00 a.m.

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

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the November 29, 2017, and January 17, 2018, meetings
4. Public Comment
5. Grantee Presentation
6. Chief Executive Officer Report
   - CEO Report Pursuant to Health & Safety Code § 102.260(c)
7. Chief Compliance Officer Report
8. Chief Scientific Officer Report
   - Grant Award Recommendations
   - Proposed Request for Applications FY 2019 Cycle 2 Process and Timeline
9. Chief Prevention and Communications Officer Report
   - Grant Award Recommendations
   - Proposed Request for Applications FY 2019 Cycle 1 Process and Timeline
10. Chief Product Development Officer Report
    - Proposed Request for Applications FY 2019 Process and Timeline
11. Scientific Research and Prevention Program Committee Appointments
12. University Advisory Committee – Annual Report
13. Internal Auditor Report
    - Amended FY 2018 Internal Audit Plan
    - Internal Audit Report Over Post-Award Grant Contracting and Monitoring
    - Internal Audit Follow-Up Procedures Report Over Internal Agency Compliance
    - Internal Audit Follow-Up Procedures Report Over Training Program
14. Fiscal Year 2020 – 2023 Budget Scenarios
    - Fiscal Biennium 2020 – 2021 Budget Request
15. Amendments to 25 T.A.C. Chapters 701 – 703
    - 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
17. Subcommittee Business
    - Special Issues Subcommittee Charter
    - Board Governance Subcommittee Charter
18. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
19. Consultation with General Counsel
20. Future Meeting Dates and Agenda Items
21. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting
November 29, 2017

NOTE: Unless the information is confidential, the reports and presentations referenced in the minutes are available at http://www.cprit.state.tx.us/cprit-media/oc_packet_11-29-2017.pdf. Information regarding the recommended awards is available at http://www.cprit.state.tx.us/cprit-media/proposed_grant_awards_book_11292017.pdf.

Call to Order – Agenda Item 1

A quorum being present, Presiding Officer Montgomery called the Oversight Committee to order at 10:00 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present:
Dee Margo
Amy Mitchel
Will Montgomery
Mahendra Patel, M.D.
Bill Rice, M.D.

Dr. Craig Rosenfeld was not present at roll call but arrived at 10:01 a.m..

Absent:
Angelos Angelou

MOTION:
On a motion made by Ms. Mitchell and seconded by Mr. Margo, the Oversight Committee unanimously voted to excuse the absence of Mr. Angelou.

Oath of Office for Newly Appointed Oversight Committee Members – Agenda Item 3

Presiding Officer Montgomery welcomed two Speaker of the House appointees, Dr. Mahendra Patel and Dr. Bill Rice.

Presiding Officer Montgomery administered the Oath of Office to both Drs. Patel and Rice.

Adoption of Minutes from the August 16, 2017, Meeting – Agenda Item 4

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meeting of August 16, 2017, as presented.

Public Comments – Agenda Item 5

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

Grantee Presentation – Agenda Item 6

Dr. Rebecca Garcia, Chief Prevention and Communications Officer, introduced Dr. Jane Bolin, Professor at Texas A&M School of Public Health, Director at Southwest Rural Health Research Center. She noted that Dr. Bolin is the Project Director (PD) or Co-PD on five CPRIT Prevention Grants.

Dr. Bolin reported on the work and outcomes of the Texas C-STEP colorectal cancer program; the Texas C-STEP program focused on breast cancer, cervical cancer, and HPV vaccination; and a Dissemination grant award on community health worker (CHW) training programs. These programs concentrate on rural, underserved areas of Texas and are designed using the effective statewide county extension agent model. The grants for clinical services originally served 17 mostly rural counties but have since expanded to 21 counties.

Texas C-STEP colorectal cancer program results include approximately 2,000 colonoscopy screenings – 25% of these revealed cancer precursors and 18 people were diagnosed with colorectal cancer. More than 1,850 students and professionals received training, including 46 family medicine residents trained in endoscopy.

The women's health clinical services awards resulted in 993 mammograms and 474 Pap tests with an additional 510 diagnostic procedures.

Dr. Bolin's Dissemination grant award engages CHWs and partner organizations and communities to deliver more effective cancer education, training, and navigation. The Department of State Health Services approved the 41 continuing education hours as a prerequisite to maintaining state certification. Over 1,000 CWSs have completed training modules and 45 instructors have completed the 'Train the Trainer' module.

Dr. Bolin responded to an Oversight Committee member's question about program sustainability, explaining that the institution has embedded graduate medical education and nursing education in these curricula. She reports that they are working on establishing a permanent fund through private philanthropy and the A&M Foundation to cover the cost of screening and diagnostic services to those who are uninsured or underinsured.

A member asked if providers charged this program less for their services than the standard fee; Dr. Bolin responded that the providers charged substantially less than the standard.

In response to a question about tracking where the graduate students become employed, Dr. Bolin said that the project is tracking the information and that many of the students do go to rural or underserved areas. She clarified that the training provided by the grants is for students, not practicing physicians.

Dr. Bolin explained that through the CPRIT program CHWs are trained to provide only education and navigation and that expanding the scope of practice would need to be addressed through legislation to allow other professionals to be credentialed at rural hospitals. Dr. Bolin also responded to questions about the number of and salary of CHWs. She will provide the Oversight Committee with information on the number of CHWs in Texas.

An Oversight Committee member asked about interaction between the county extension agents and community health workers. Dr. Bolin responded that the agents and CHWs do interact, especially on Texas A&M's Healthy South Texas Initiative project. CHWs are also closely aligned with the Federally Qualified Health Centers and local clinics.

Another member asked how the project selected counties to offer the training; Dr. Bolin explained that the state CHW leadership contacts specific counties to put on programs.

In response to the question regarding Texas A&M working with Texas Tech University Health Sciences Center in El Paso to host the training, Dr. Bolin responded that Texas A&M and Texas Tech Health Sciences Center in El Paso did not collaborate on this training.

An Oversight Committee member asked if there was any research conducted in conjunction with the Prevention grant and if there was any plan to do prevention research on the outreach program. Dr. Bolin responded that they do not conduct clinical trials but do report on and publish the data. They have discussed access to clinical trials and the most effective ways to do preventative clinical trials.

In response to a question about whether the Texas A&M model was provided to other grantees, Dr. Garcia explained that goal of the Dissemination grants like the one awarded to the CHW program is to package and disseminate the materials so that others can replicate effective programs in other areas of the state. The Dissemination RFAs are open continuously and reviewed quarterly to speed up the dissemination of models of successful projects.

Chief Executive Officer Report – Agenda Item 7

Presiding Officer Montgomery called Mr. Wayne Roberts, Chief Executive Officer to give his report.

<u>Personnel Update</u>

Mr. Roberts introduced CPRIT's new staff members: Stephen Nance, Compliance Program Manager; Melanie Jamison, Grant Compliance Specialist; Rosemary French, Product Development Program Manager; Joan Thomas, Grant Accountant; Robert Lansdowne, Grant Accountant; Debra McHenry, Grant Accountant; and Claudia Leal, on temporary basis as the vacant Executive Assistant positions are filled.

FY 2018 Grant Award Funds Available

Mr. Roberts confirmed there will be sufficient FY 2018 funds available for today's recommended awards.

Preparation for the January 17, 2018, Special Meeting

Mr. Roberts summarized the preparations and expectations for the January 17, 2018 special Oversight Committee meeting.

Mr. Roberts also informed the Oversight Committee that the program subcommittees will meet before the January meeting; those meetings will be arranged by each program officer.

There were no questions for Mr. Roberts.

Chief Compliance Officer Report – Agenda Item 8

Mr. Vince Burgess, Chief Compliance Officer, presented his report highlighting several compliance activities and initiatives. He noted that the number of grantee delinquent/missing reports have risen due to the aftermath of Hurricane Harvey. He said the agency has allowed an extra 30 days to submit reports.

Mr. Burgess also noted the overall decline of delinquent/missing reports. He credited the training provided for Authorized Signing Officials (ASOs) and grantee trainings. He completed his report by highlighting that compliance staff have conducted 275 desk and onsite reviews in FY 2017, representing half of the approximately 560 active grants.

Mr. Burgess responded to an Oversight Committee member's question about whether 50% was the right amount of coverage. Mr. Burgess noted that the 50% grant coverage was comparable to the coverage level last year, with similar findings that are generally decreasing. He added that the annual risk assessment is performed at the grantee level, based on financial exposure, entity maturity, and prior experience. The findings determine which grants to monitor, and as a result some will be reviewed multiple times during the 3-year life of the grant. The 27 on-site reviews in FY 2017 covered every Prevention and Product Development grantee.

Chief Scientific Officer Report and Grant Award Recommendations – Agenda Item 9

FY 2017 Grants Overview

Dr. James Willson, Chief Scientific Officer discussed table 3 in the materials provided in Tab 5, which illustrates the targeted priorities as addressed by the Academic Research Program grants awarded in FY 2017.

He responded to an Oversight Committee's question regarding the success rate for computational biology grant awards, explaining that computational biology is a relative new discipline for cancer biologists and presents a learning and cultural shift along with the opportunity for new collaborations and research methodologies/technology. Dr. Willson also reported that several awardee presentations at the recent CPRIT Innovations Conference demonstrate that grantees are successfully incorporating computational biology and analytic methods into other Academic Research RFAs and grant submissions.

Dr. Willson responded to a question about Core Facilities Support Awards remaining an Academic Research program priority in FY 2019. He explained the Oversight Committee will discuss this topic at the January 17, 2018, Oversight Committee meeting.

In response to an Oversight Committee member's question about the possibility of CPRIT collecting and measuring the productivity and citation impact of publications resulting from CPRIT awards, Dr. Willson indicated that his program has been collecting productivity measures including follow-on funding, publication numbers, and patent filings for the different funding mechanisms. He explained that an assessment of the citation impact of publications from CPRIT awards will require additional time and funds.

Academic Research Award Recommendations

Dr. Willson presented three proposed recruitment awards recommended by the CPRIT Scientific Review Council (SRC) and the Program Integration Committee (PIC). The awards for this review cycle (18.1 and 18.2) included two Recruitment of First-Time, Tenure Track Faculty Members grants and one Recruitment of Established Investigators grant totaling $10,000,000.

Academic Research Recruitment Grant Awards				
App ID	**Candidate**	**Award Mechanism**	**Organization**	**Budget**
RR180005	Karras, Georgios	RFTFM	The University of Texas M.D. Anderson Cancer Center	$2,000,000
RR180007	Agathocleous, Michalis	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000
RR180006	Skok, Jane	REI	The University of Texas M.D. Anderson Cancer Center	$6,000,000

REI: Recruitment of Established Investigators
RFTFM: Recruitment of First-Time Tenure Track Faculty Members

There were no questions for Dr. Willson.

Compliance Certification

Mr. Burgess certified the review process for the Recruitment and Prevention award recommendations for the Oversight Committee's consideration. He reported that he was satisfied that the application review process that resulted in the three Academic Research and one Prevention grant awards recommended by the PIC followed applicable laws and agency administrative rules.

Conflict of Interest Notification

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

Vote on Recommended Awards

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the PIC's recommendation for one Recruitment of Established Investigators award and two Recruitment of First-Time, Tenure-Track Faculty Members awards.

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

Budget Modification

Dr. Willson presented a request to increase funds for the approved grant award RP170691 by $943,570. The change rectifies an inadvertent calculation error made by CPRIT staff when adjusting the requested budget for RP170691 to reflect a reduction proposed by the SRC. The revised total grant amount, $4,766,430, corrects the calculation error and accurately reflects the SRC's recommendation.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the budget modification for RP170691 to increase the award amount by $943,570 to $4,766,430.

Chief Prevention and Communications Officer Report and Grant Award Recommendation – Agenda Item 10

Prevention Program Awards Recommendations

Dr. Rebecca Garcia, Chief Prevention and Communications Officer, discussed the prevention program update and presented the prevention award recommendation.

Dr. Garcia explained that the CPRIT Prevention Review Council (PRC) and the PIC recommended one project totaling $294,804 for approval. She provided an overview of the recommended project and a brief description of the *Dissemination of CPRIT-Funded Cancer Control Interventions (DI)* mechanism and review process.

Prevention Program Awards Recommendations					
App ID	**Mech.**	**Application Title**	**PD**	**Organization**	**Rec Budget**
PP180063	DI	STOP HCC-HCV Prevention Program Dissemination Project	Turner, Barbara	The University of Texas Health Science Center at San Antonio	$294,804

There were no questions for Dr. Garcia.

Compliance Certification
Presiding Officer Montgomery noted that Mr. Burgess previously certified compliance of the Prevention awards process.

Conflict of Interest Notification
Presiding Officer Montgomery noted that no Oversight Committee member reported a conflict of interest with the application under consideration.

Vote on Recommended Award

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the PIC's award recommendation for PP180063 to The University of Texas Health Science Center at San Antonio.

MOTION:
On a motion made by Dr. Rice 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.

Communications Program Update

Dr. Garcia reported on the recent *CPRIT Innovations In Cancer Prevention and Research Conference*. She thanked staff that worked to make the conference a success, recognizing Chris

Cutrone, Spencer Miller-Payne, Ramona Magid, and Therry Simien for their efforts. Dr. Garcia noted that more than 800 people attended. She asked Mr. Chris Cutrone, Senior Communications Specialist, to present a video recap of the conference. He explained that CPRIT streamed Facebook Live sessions of the conference, reaching 1,400 people on Facebook, with an additional 4,700 Twitter impressions. The communications team created 11 videos highlighting the work of the grantees that CPRIT will place on social media throughout the year. Regarding statewide media coverage of the conference, Mr. Cutrone noted that 11 media markets, including Spanish language media in Austin, ran interviews.

Mr. Roberts and Presiding Officer Montgomery thanked Dr. Garcia and her team for all their hard work.

In response to an Oversight Committee member's question, Dr. Garcia reported that some legislative staffers were in attendance. Mr. Roberts added that he was satisfied with representation of legislative staff, given that several other legislative activities were concurrent with the conference. The board commented on the use of social media by grantees to promote their grant and results; the social media hits can be sent to their legislator's office so they can see the results in their region.

Chief Product Development Officer Report – Agenda Item 11

Mr. Michael Lang, Chief Product Development Officer, presented his Product Development Program report, which is included in the member's packet at Tab 7.

There were no questions for Mr. Lang.

Internal Auditor Report – Agenda Item 14

Ms. Alyssa Martin, CPRIT's contracted Internal Auditor, presented the Internal Auditor Report on the Internal Audit Plan approved for FY 2018, included in the meeting packet at Tab 10. She indicated that audits have been scheduled with CPRIT staff, with the first one beginning in early December.

There were no questions for Ms. Martin.

Scientific Research and Prevention Program Committee Appointments – Agenda Item 12

Mr. Roberts presented the list of three appointees to CPRIT review panels for Oversight Committee approval, noting that their biographical information was included in the meeting packet at Tab 8. He stated the Nominations Subcommittee discussed the appointments and recommended approval. There were no questions for Mr. Roberts.

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

FY 2018 Program Priorities – Agenda Item 13

Mr. Roberts presented the FY 2018 Program Priorities for the Oversight Committee's consideration. He explained that the FY 2018 Program Priorities, included at Tab 9, are the same priorities approved for FY 2017. He noted that each of the program subcommittees discussed the FY 2018 program priorities and recommended approval.

Mr. Roberts indicated that consideration of the FY 2019 Programs Priorities will occur at the January 17, 2018 meeting. He explained that FY 2019 would be the last year for full funding for grant awards; the Oversight Committee will discuss annual projections of funds available for grants through FY 2022 at the January meeting.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the FY 2018 Program Priorities.

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

Chapter 703 Rule Change Proposed for Final Adoption and Chapter 701 and 703 Proposed Rule Changes

Ms. Cameron Eckel, Staff Attorney, presented the proposed rule changes, which were included at Tab 11. She reported that that the Board Governance subcommittee recommends final approval of the proposed change to rule 703.13. Ms. Eckel noted that CPRIT staff is not recommending that the Oversight Committee consider the change proposed at the August 2017 meeting for rule 703.26. She also presented the subcommittee's recommendation to approve two proposed rule changes, Rule 703.26 and new Rule 701.37, for publication in the *Texas Register*. Ms. Eckel explained these proposed rule amendments will be considered for final adoption at the February 2018 meeting.

There were no questions for Ms. Eckel.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the final order adopting a rule change to the Texas Administrative Code Chapter 703 and the proposed changes to Texas Administrative Code Chapters 701 and 703 for publication in the *Texas Register*.

Chief Operating Officer Report – Agenda Item 16

Ms. McConnell presented several reports in the board packet at Tab 12, including:

- Annual Financial Report for the Year Ended August 31, 2017, due November 20th – submitted November 15, 2017;
- Audited Financial Statements for the Year Ending August 31, 2017, due December 20th – McConnell & Jones LLP is finalizing the audit report. CPRIT has scheduled a special

Audit Subcommittee meeting on December 4, 2017, for the audit team to present the final report. McConnell & Jones LLP has informed Ms. McConnell that there are no findings;
- FY 2018 Operating Budget due December 1st – in progress;
- Historically Underutilized Business (HUB) Biennial Report for 2018-19 due December 1st – in progress; and
- FY 2018 State Agency Procurement Plan due December 1st – in progress

Responding to an Oversight Committee member's question, Ms. McConnel indicated that the Financial Audit was a clean audit with no findings.

Answering a question about the CPRIT interest and sinking fund, Ms. McConnell reported that CPRIT has deposited $38,695 into the newly created state treasury account. She reminded the Oversight Committee that only the legislature may appropriate from the fund to pay debt service.

Special Resolution Honoring Outgoing Oversight Committee Members Ned Holmes and Pete Geren

Presiding Officer Mr. Montgomery presented two honorary resolutions for the Oversight Committee's approval. The resolutions recognize Mr. Ned Holmes and Mr. Pete Geren for their numerous years of service as Oversight Committee members.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve and sign the resolutions for Mr. Geren and Mr. Holmes.

Subcommittee Business – Agenda Item 17

Presiding Officer Montgomery presented for Oversight Committee approval the Board Governance Subcommittee's proposed subcommittee assignments for the 2018-2019 biennium.

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the new subcommittee assignments for the 2018-2019 biennium.

Personnel – Chief Executive Officer – Agenda Item 18
Texas Open Meeting Act and Public Information Act Update – Agenda Item 19

At 12:01 p.m. Presiding Officer Montgomery called the Oversight Committee into closed session to discuss agenda items 18 and 19 pursuant to the Texas Open Meeting Act section 551.074, personnel matters related to the Chief Executive Office, and section 551.071, consultation with CPRIT's attorney. Mr. Montgomery asked Ms. Kristen Doyle, CPRIT's General Counsel, to join the Oversight Committee in the closed Session.

Mr. Montgomery reconvened the open meeting at 12:35 p.m.

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Ms. Mitchell, the Oversight Committee unanimously voted to increase the base salary of Chief Executive Officer Wayne Roberts to the legislatively authorized amount of $256,250 per year and for the Presiding Officer to take all the necessary actions to effectuate this increase.

Compliance Investigation Pursuant to Health & Safety Code 102.2631 – Agenda Item 20
Consultation with General Counsel - Item 21

Agenda items 20 and 21 were not taken up.

Future Meeting Dates and Agenda Items - Item 22

Presiding Officer Montgomery reminded Oversight Committee members that CPRIT has scheduled a special Oversight Committee meeting on January 17, 2018. The Oversight Committee will hold their next regular meeting on February 21, 2018.

Adjourn - Item 23

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

Meeting adjourned at 12:37 p.m.

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Signature Date

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting
January 17, 2018

NOTE: Unless the information is confidential, the reports and presentations referenced in the minutes are available at http://www.cprit.state.tx.us/cprit-media/oc_packet_01-17-2018.pdf.

Call to Order – Agenda Item 1

A quorum being present, Presiding Officer Montgomery called the Oversight Committee to order at 10:02 a.m.

Roll Call/Excused Absences – Agenda Item 2

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

Mahendra Patel, M.D., was not present at the roll call, but arrived at 10:25 a.m.

Public Comment

Ms. Susan Dawson addressed the Oversight Committee regarding Agenda Item 7, New Initiatives. Ms. Dawson indicated that she would follow up with staff after the meeting to address additional ideas for consideration in the event the Oversight Committee decides to move forward with the staff proposal.

Special Meeting Overview – Agenda Item 3

Presiding Officer Montgomery and Chief Executive Officer Wayne Roberts reviewed the material behind Tab 1 in the meeting books concerning the meeting's purposes and expectations.

Budget Preparation – Agenda Item 4

Presiding Officer Montgomery asked Mr. Roberts and Heidi McConnell, Chief Operating Officer, to explain the three budget projection scenarios for fiscal years 2020 through 2023 for consideration by the Oversight Committee. The budget scenarios and supporting information are located behind Tab 2.

Mr. Roberts addressed the future budget constraints resulting from declining constitutional bond funds available for agency grant making and operations. He explained that after Fiscal Year 2019 the amount of bond funding remaining will not be sufficient to sustain the agency's operations and grant awards at the current level of $300 million each year, the maximum allowed by law.

The Oversight Committee and agency senior staff discussed pros and cons to each budget scenario. Dr. James Willson, Chief Scientific Officer; Dr. Rebecca Garcia, Chief Prevention Officer; and Mr. Michael Lang, Chief Product Development Officer, recommended Scenario 4 that divides the available grant funds between fiscal years 2020 and 2021 with CPRIT making no awards in fiscal year 2022.

After discussion, the Oversight Committee indicated a preference for Scenario 4 and instructed staff to discuss this option with advocates, the grantee community, and legislators with an interest in CPRIT activities. Presiding Officer Montgomery asked Mr. Roberts to report back to the Oversight Committee at the next meeting for additional discussion and public comment. The Oversight Committee did not act on the budget scenarios.

An Oversight Committee member asked Mr. Roberts and Ms. McConnell about whether CPRIT may request an exceptional item from the General Revenue Fund to make up the expected shortfalls after Fiscal Year 2019 to sustain agency operations and grant making activities at $300 million per year. Mr. Roberts responded that no legal or statutory impediment prevents the request from being made.

Fiscal Year 2018 Program Priorities and FY 2015 – 2017 Program Impact – Agenda Item 5

Presiding Officer Montgomery recognized Mr. Roberts to summarize the material in the meeting books behind Tab 3 related to previously approved Fiscal Year 2018 Program Priorities and how CPRIT's awards align with program priorities in effect each fiscal year between 2015 – 2017.

Fiscal Year 2019 Program Priorities – Agenda Item 6

Dr. Garcia, Dr. Willson, and Mr. Lang summarized their recommendations for Fiscal Year 2019 Program Priorities. Each of their presentations are in the meeting books behind Tab 4 concerning.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously approved the staff recommendations for the Fiscal Year 2019 Program Priorities.

New Initiatives – Agenda Item 7

Presiding Office Montgomery asked Wayne Roberts to introduce the discussion on a proposed new initiative. Mr. Roberts summarized the report in the meeting books behind Tab 5. Drs. Willson and Garcia responded to questions on the new initiative, "Collaborative Action Program to Reduce Liver Cancer Mortality in Texas," including how the proposed project relates to a new Fiscal Year 2019 Program Priority, Hepatocellular cancer, approved earlier in the meeting. The staff recommended approval to develop a Request for Applications for the new project.

> **MOTION:**
> On a motion made by Mr. Angelou and seconded by Dr. Rosenfeld, the Oversight Committee unanimously approved the staff recommendation to develop a Request for Applications for "Collaborative Action Program to reduce liver cancer mortality in Texas" for an estimated release during the summer of 2018.

Post Fiscal Year 2019 Program Priorities and Program Budgeting – Agenda Item 8

Presiding Officer Montgomery recognized Mr. Roberts to discuss future annual program priority processes. Mr. Roberts explained that due to today's decisions, no additional Oversight Committee action is necessary at this time. The Fiscal Year 2020 Program Priorities process will occur in the spring of 2019 for adoption at the February or May 2019 Oversight Committee meeting. This will allow the program priorities to continue guiding the requests for applications released by CPRIT.

Adjourn – Agenda Item 9

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

Meeting adjourned at 12:57 p.m.

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Signature Date

February 20, 2018

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

Dear CPRIT Oversight Committee Members,

Thank you for your continued leadership of the Cancer Prevention & Research Institute of Texas, which has given new hope to cancer patients and their families – and has placed Texas at the forefront of the fight against cancer.

As organizations that are committed to pressing forward in this fight, we are concerned about the projected funding reductions for CPRIT in the next budget cycle and beyond.

As voter-approved bond authority begins to run out in the next biennium, the funds available to continue CPRIT's work will drop precipitously. Not only does this pending funding cliff jeopardize the ongoing work of the groundbreaking research happening in Texas, but it also places at risk the many Texans who are benefitting from lifesaving prevention and early detection services.

We know we don't have to convince you of the importance of the work CPRIT is doing. Where we need your support is in giving Texans the opportunity to have a

debate about whether this work should continue, rather than simply allowing funding to come to an end.

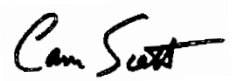
This debate must happen in the next session of the Texas Legislature if we hope to address the pending funding cliff before we reach the bottom.

The ability to secure level funding for CPRIT next session (or to even have the debate in any substantial way) is dependent upon CPRIT's Legislative Appropriations Request (LAR) including an exceptional item to request the difference between the reduced bond-backed amount available and the amount needed to maintain CPRIT's current annual budget of $300 million.

We consider it imperative that CPRIT include this exceptional item in its LAR, and we urge you to take this necessary action to give advocates the opportunity to earnestly address this issue with lawmakers.

Again, thank you for your lifesaving work on behalf of all Texans, and for your consideration of this request.

On behalf of the Texas Cancer Partnership,



Cam Scott
Senior Director, Government Relations – Texas
American Cancer Society Cancer Action Network
512-573-5356

cc: Wayne Roberts, CEO

BIOGRAPHICAL SKETCH

Gary Joseph Latham, PhD

Sr. Vice President

Research and Development

Asuragen

As the SVP of R&D at Asuragen, I direct >50 scientists in technology creation, assay feasibility, diagnostic product development, and bioinformatics/software development teams that are charged with creating molecular diagnostic assays. One of our most important advances for patients has been the invention of PCR reagents that can amplify the full spectrum of fragile X triplet repeat expansions, thereby providing a solution to a technical problem that eluded the field for nearly 20 years. Commercially branded as AmplideX® PCR reagents, these tools enable a rapid PCR-only workflow for fragile X screening and testing, from genotyping to epityping, and are used by >150 laboratories in >40 countries through a menu of successful RUO, ASR/GPR, and CE-IVD and country-specific IVD products. The underlying technology has also resulted in a high-complexity risk stratification test implemented in Asuragen's CLIA laboratory and on-market kits that resolve repeat expansions associated with ALS and Alzheimer's Disease. Other noteworthy tests that we've developed include an expanded ethnic Cystic Fibrosis carrier panel that was incorporated into the state of California's newborn screening program, and a commercial thyroid cancer diagnostic built from a novel miRNA signature that can help reduce unnecessary patient surgeries.

I was also the PI for a successful $6.8M CPRIT product development grant that resulted in the development and launch of multiple next-generation sequencing (NGS) products. These products include kits that integrate both wet-bench reagents and bioinformatic software to interrogate a wide range of clinically-actionable DNA mutations in solid tumors, and a product that queries >130 RNA variants important in non-small cell lung cancer and that can guide targeted therapies. A third product, based on the reagent and informatics backbone my group created, is being advanced as a US-IVD test for a highly druggable gene. Each of these products greatly simplifies the NGS process while providing accurate information for challenging FFPE tumor biopsies to lower the barrier for less sophisticated laboratories to implement this breakthrough technology for precision medicine.

My scientific output is represented in 41 peer-reviewed publications (h-index=27; i10-index=42), 14 issued and more than a dozen pending US patents, 10 NIH research and CPRIT product development grants totaling >$13M, and the development and launch of several multimillion dollar products and services at both Ambion and Asuragen. These accomplishments reflect my commitment to deliver forward-thinking, market-ready technologies to clinical laboratories, clinicians, and patients that can advance basic, translational, and disease-focused research and molecular diagnostics/companion diagnostics.

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Christian Brothers University, Memphis, TN	B.S.	1987-1991	Chemistry
Vanderbilt University, Nashville, TN	Ph.D.	1991-1995	Biochemistry
University of Oregon, Eugene, OR	PostDoc	1995-1999	Biophysics/Enzymology

Asuragen®

CPRIT Product Development Grant CP120017:
A Retrospective

Gary J. Latham, PhD
Senior Vice President R&D

Presented to CPRIT
February 21, 2018

Asuragen is a molecular diagnostics product company focused in genetics and oncology

Personalized medicine now requires precision molecular diagnostic kitted products

Ushering in New Era of Personalized Medicine

Asuragen products address this opportunity

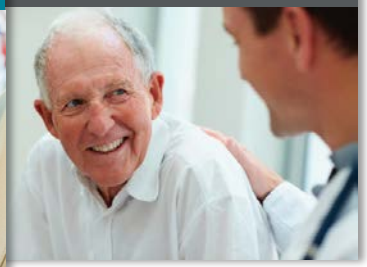
GENOMIC MEDICINE

Reproductive Health

Inherited Disease

Oncology

Diseases of Aging



Deployable Kits for Complex Molecular Testing

Addressing challenging unmet needs in precision medicine head on

Invent **proprietary chemistries**
to make testing practical

Build **standardized cGMP**
reagents and controls

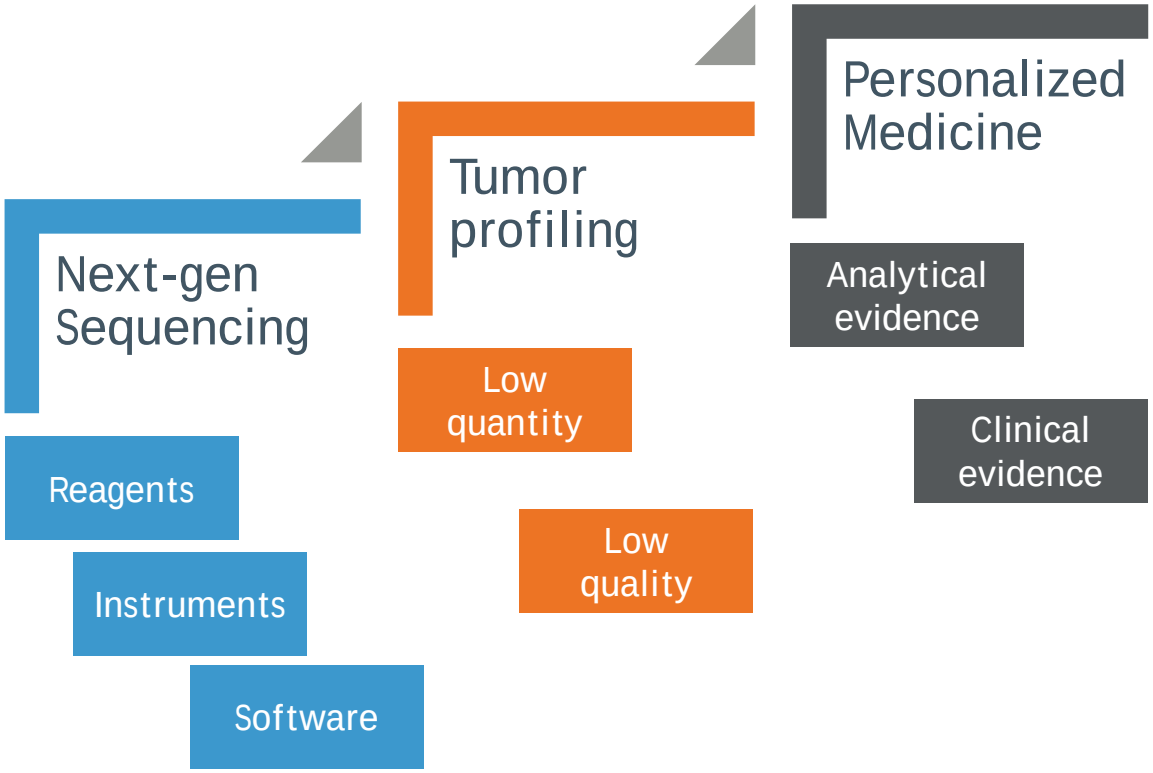
Run on **available platforms**

Expand menu with
same workflows

Provide
automated interpretation
software

Product Development Award CP120017

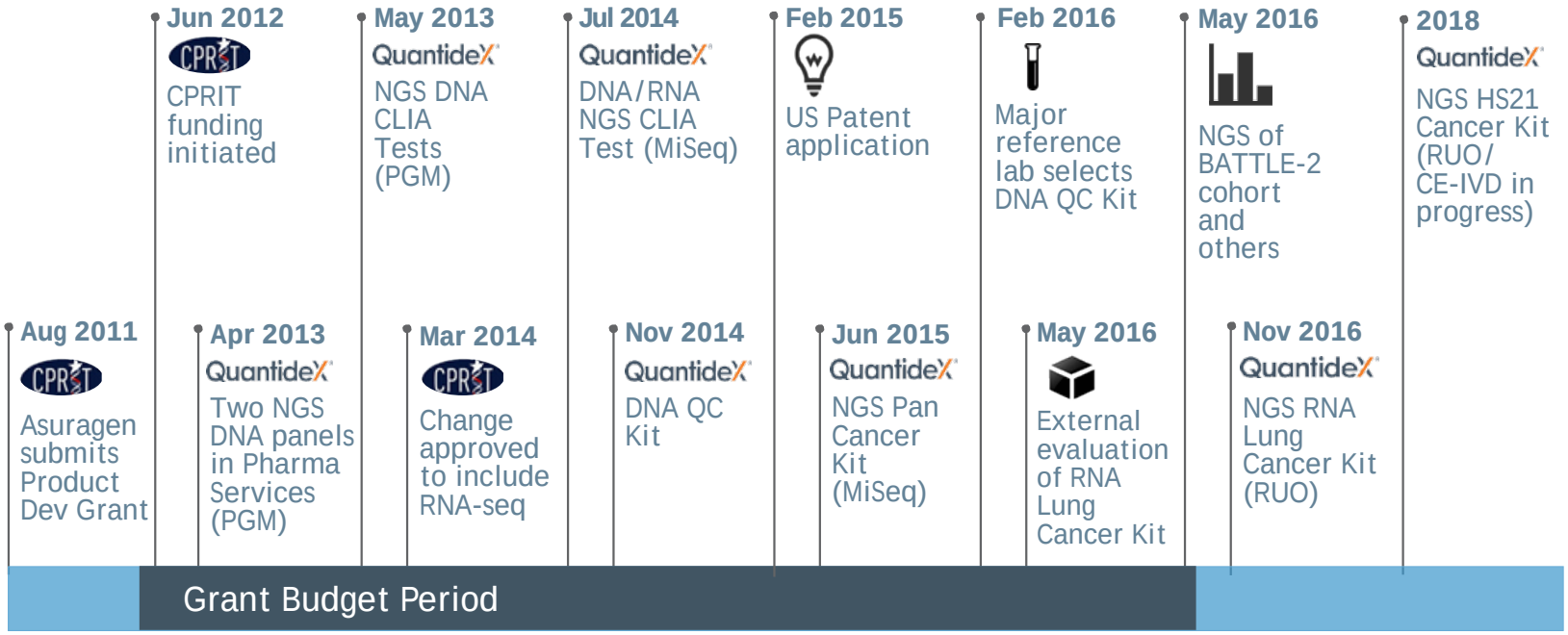
June 2012 - May 2016



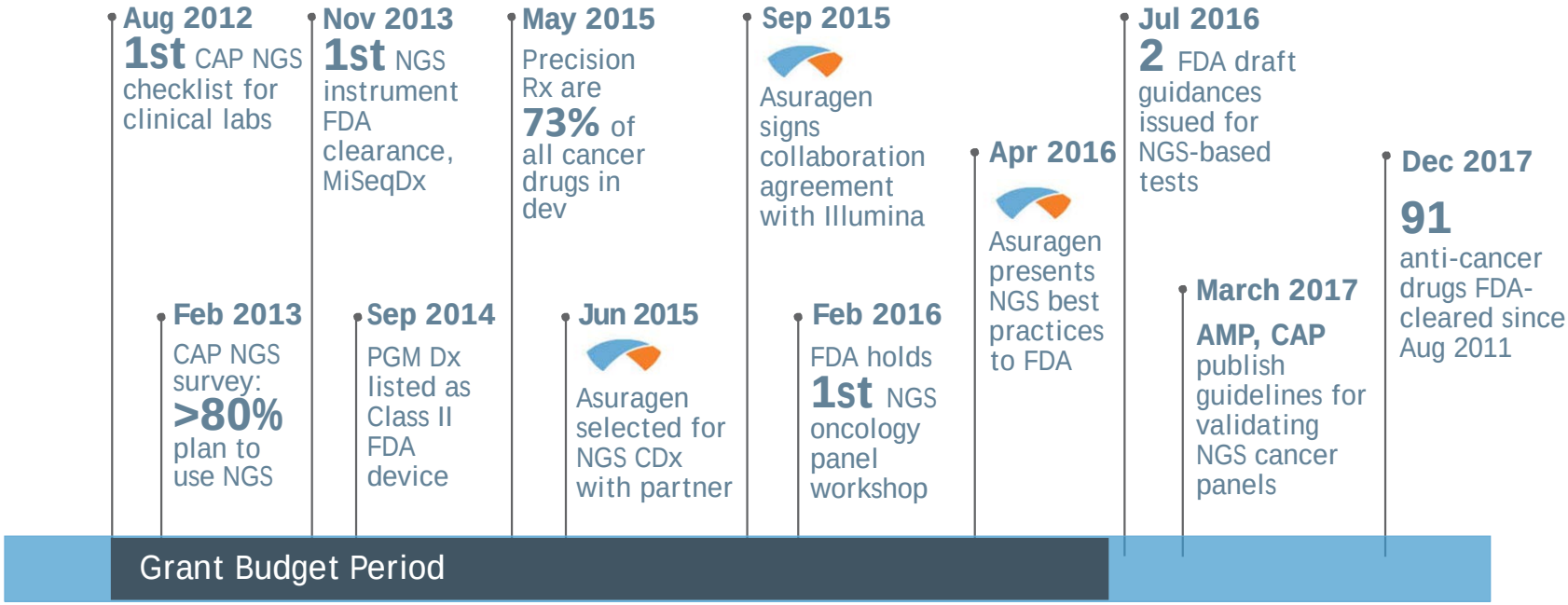
Asuragen®

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
Making Cancer History®

CPRIT-supported Advances in NGS Tumor Profiling

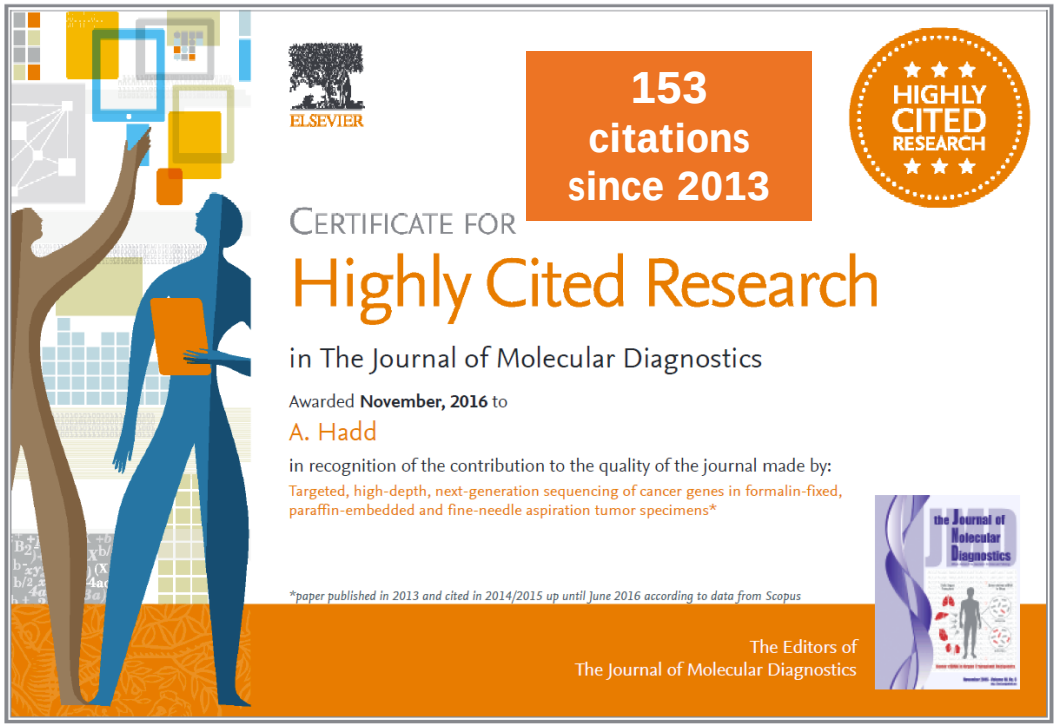


Asuragen Progress Paced with NGS Precision Medicine



High-impact Science = High-impact Publications

Asuragen sequencing study among the most cited articles since 2013



400 citations for all NGS publications from CPRIT funding period

https://www.journals.elsevier.com/the-journal-of-molecular-diagnostics/most-cited-articles

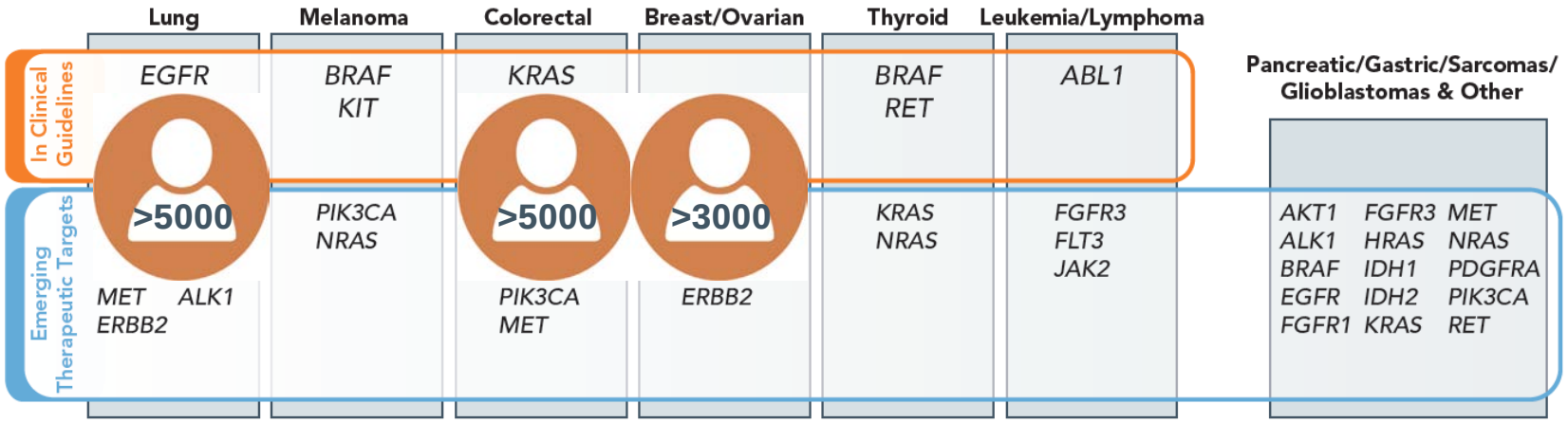
QuantideX® NGS HS21 Kit

A complete system of reagents and bioinformatics software

- NCCN guidelines & targets for emerging therapies*
- >1,600 known COSMIC variants reported in 21 genes
- Representing 80% of known variants in target genes
- Annotated reporting of SNVs, SNPs & Indels

NCCN National Comprehensive Cancer Network®

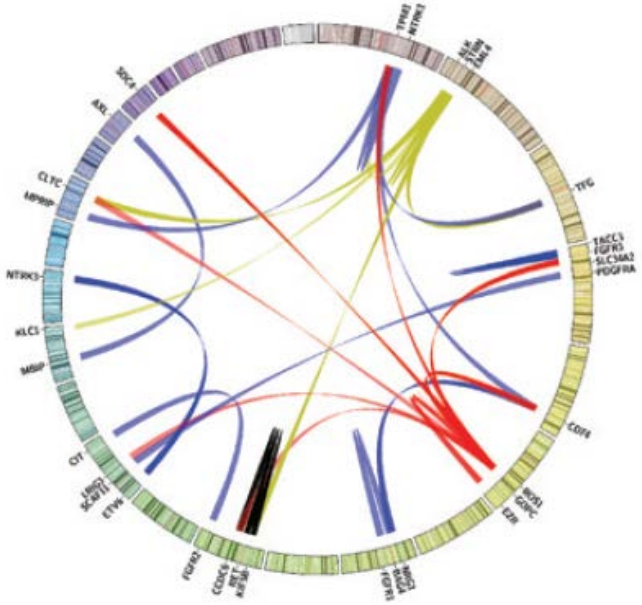
ClinicalTrials.gov
A service of the U.S. National Institutes of Health



For Research Use Only. Not for use in diagnostic procedures.

QuantideX® NGS RNA Lung Cancer Kit

A complete system of reagents and bioinformatics software



3'/5' Imbalance
ALK
ROS1
RET
NTRK1
PDGFRA

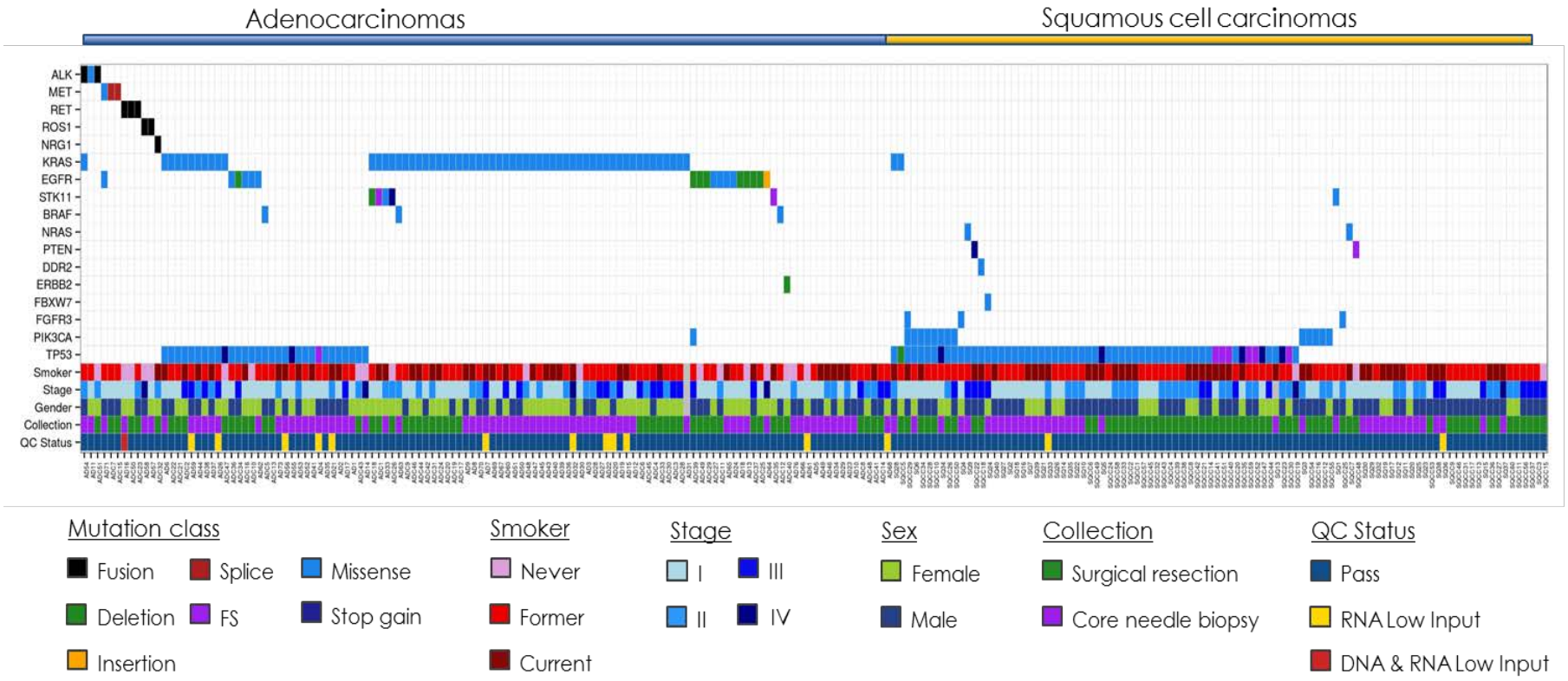
Exon Skipping Event
MET e13:e14
MET e14:e15
MET e13:e15

3' Fusion Genes	# of Fusions
ALK	53
ROS1	22
RET	12
FGFR3	7
NTRK3	3
NTRK1	4
NRG1	2
FGFR1	1
FGFR2	1
MBIP	1
PDGFRA	1

**Content sourced from: NCCN Guidelines, customer needs, COSMIC, Clinicaltrials.gov, publications & other databases.*

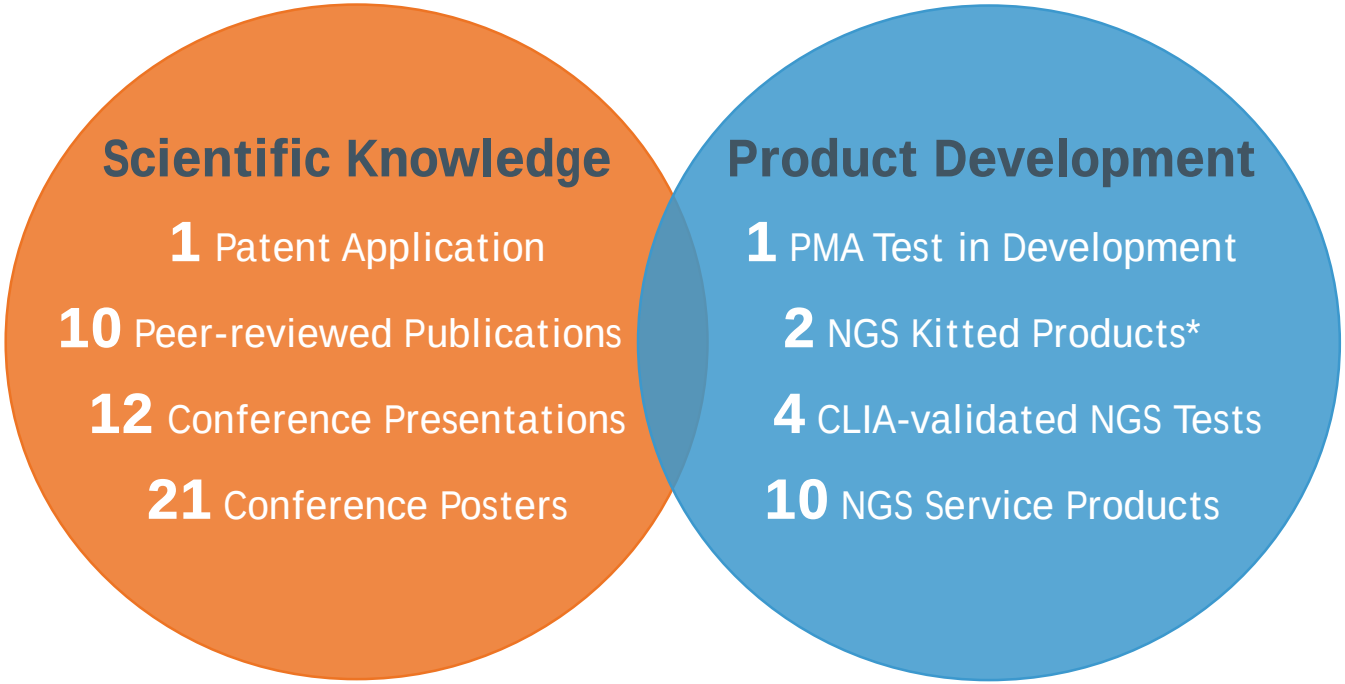
QuantideX® DNA and RNA NGS Panels can Combine to Generate Multi-omic Results for Actionable Targets

Manuscript in preparation



Collaboration with MD Anderson Cancer Center

Asuragen's CPRIT Project by the Numbers

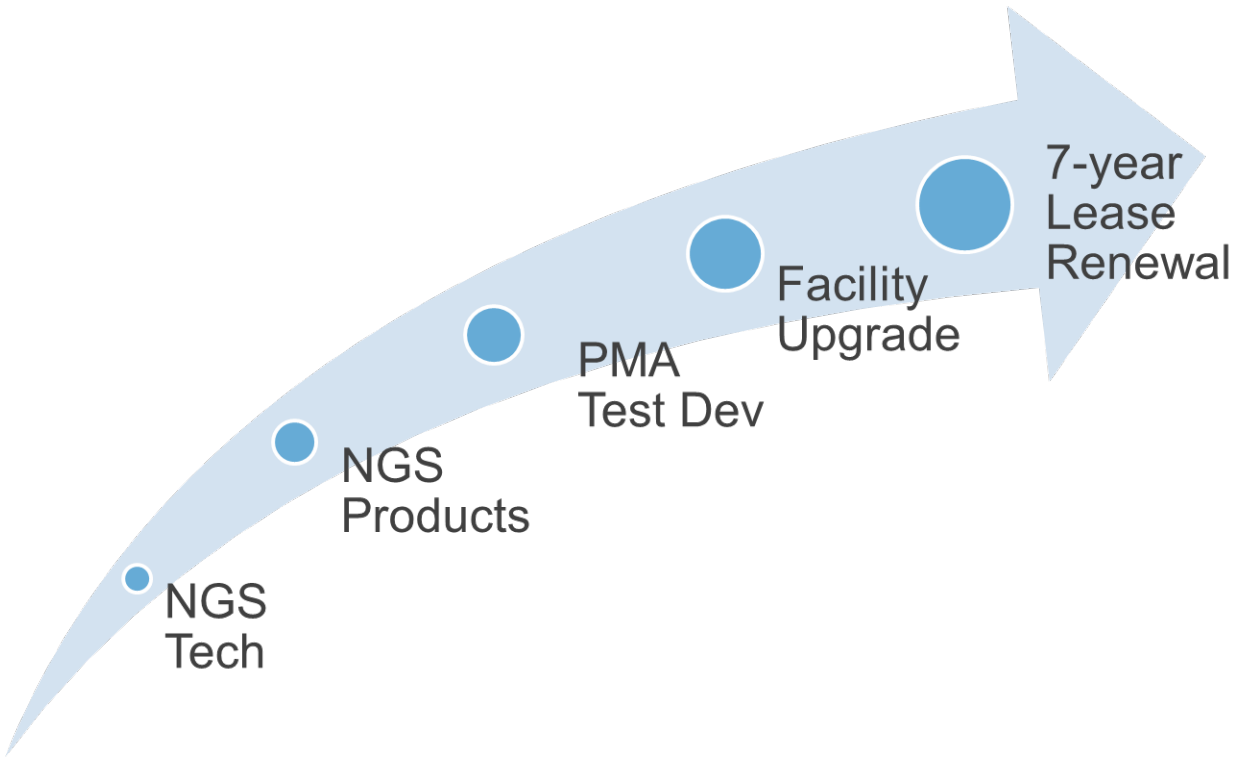


Royalties Paid to CPRIT from **2012-Present**

95% Milestone Achievement

*For Research Use Only. Not for use in diagnostic procedures.

CPRIT Investment Directly Led to Products and Continued Economic Development



Thank you

- Asuragen team
- MD Anderson collaborators
- CPRIT and staff

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CHIEF EXECUTIVE OFFICER REPORT, AGENDA ITEM 6
DATE:	FEBRUARY 14, 2018

As of this writing the Chief Executive Officer's Report for the February 21, 2018, Oversight Committee (OC) meeting will consist of the following items:

- Personnel update, including introduction of new staff
- FY 2018 Grant Award Funds Available (attached)
- CEO Report Pursuant to Health & Safety Code § 102.260(c) (see attached: Progress and continued merit of each research program funded by CPRIT)

Other topics may be added as warranted.

In addition, for your reference a copy of the December 2017 CPRIT Activities Update previously provided to you is included at the end of this tab. These reports are done in months in which the OC does not meet. Since we had the Special Meeting in January only one report has been done since the November 2017 meeting. The next report should be provided around March 31, 2018.

*****

CPRIT has awarded **1,191** grants totaling **$1.887 billion**

- 190 prevention awards totaling $195.4 million
- 1001 academic research and product development research awards totaling $1.691 billion

Of the $1.691 billion in academic research and product development awards,

- 29.7% of the funding ($501.8 million) supports clinical research projects
- 25.9% of the funding ($437.6 million) supports translational research projects
- 26.2% of funding ($444.1 million) supports recruitment awards
- 14.7% of the funding ($248.0 million) supports discovery stage research projects
- 3.5% of funding ($59.9 million) supports training programs

CPRIT has 14 open Requests for Applications (RFAs)

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

FY 2018 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

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

	Prevention Grants	Academic Research Grants	PD Research Grants			
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 28,022,956	$ 189,202,317	$ 63,067,439			$ 280,292,712
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	$ 28,022,956	$ 187,100,122	$ 62,366,707			$ 277,489,785
Announced Grant Awards						
Prevention Dissemination Award	$ 294,804		$ -			
AR Recruitment Awards (3)		$ 10,000,000				
AR Core Facility Supplement (RP170691)		$ 943,570	$ -			
Announced Grant Award Subtotal	$ 294,804	$ 10,943,570	$ -	$ -		$ 11,238,374
Grant Award Adjustments						
Declined Recruit Award (MDACC-Skok) 11/2017 Slate	$ -	$ (6,000,000)	$ -			$ (6,000,000)
Revised Grant Award Subtotal	$ 294,804	$ 4,943,570	$ -			$ 5,238,374
Available Funds as of Jan. 26, 2018	$ 27,728,152	$ 182,156,552	$ 62,366,707			$ 272,251,411
Pending Grants-PIC Recommendations						
Prevention Dissemination Award	$ 299,571					
Prevention Awards	$ 12,806,002					
AR Recruitment Awards (5)		$ 14,000,000				
Individual Investigator Research Awards		$ 46,195,197				
Pending Award Subtotal	$ 13,105,573	$ 60,195,197	$ -			$ 73,300,770
Total Grant Funding Committed	$ 13,400,377	$ 65,138,767	$ -			$ 78,539,144
1% Grant Funding Buffer	$ -	$ 2,102,195	$ 700,732			$ 2,802,927
Potential Available Funds as of Feb. 21, 2018	$ 14,622,579	$ 121,961,355	$ 62,366,707			$ 198,950,641

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

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CHIEF EXECUTIVE OFFICER REPORT
DATE:	DECEMBER 21, 2017

Topics in this memo include preparation for the special January Oversight Committee meeting, the resignation of Dr. David Cummings from the Oversight Committee, recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, and updates from Compliance, Programs, and Operations.

Upcoming Oversight Committee Meetings

The OC will meet January 17, 2018, at 10:00 a.m. in the CPRIT staff offices: Suite 6-127 of the Travis Building, 1701 North Congress Avenue, Austin, Texas 78701. CPRIT will post the final agenda for the meeting by January 9, 2018. The tentative agenda includes discussion and possible action on FY 2019 and future program priorities, funding estimates for 2020-2023, and the legislative appropriations request for the 2020-21 fiscal biennium. To maximize the use of everyone's time at the January 17 meeting these topics will be discussed in detail in three special program Oversight Committee subcommittee teleconferences scheduled as follows:

- Prevention—January 8, 2018, at 4:00 p.m.
- Academic Research—January 10, 2018, at 10:00 a.m.
- Product Development Research—January 11, 2018, at 10:00 a.m.

Call-in information and subcommittee materials will be provided to you a week in advance of each subcommittee.

David A. Cummings, MD, Resigns from the Oversight Committee

Unfortunately, Dr. Cummings had to resign from the Oversight Committee because his wife works for Angelo State University, a CPRIT Prevention grantee. State law prohibits someone from serving on the Oversight Committee who either works for or has a spouse employed by a CPRIT grantee. As a result, there are two vacant positions on the Oversight Committee.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- The Entertainment Industry Foundation's Stand Up To Cancer program announced a $7.0 million award to support The University of Texas M.D. Anderson Cancer Center (MD Anderson) led "Dream Team" whose goal is to stop pancreatic cancer before symptoms occur. The initiative focuses on developing the technologies needed to find cancer or pre-cancerous activity at its earlier possible juncture and the treatments to stop its progression. The multi-institution team is led by CPRIT grantee Anirban Maitra, MBBS, professor of pathology and scientific director of the Sheikh Ahmed Pancreatic Cancer Research Center at MD Anderson.

- CPRIT grantee Dr. Anil Sood of MD Anderson was selected by the National Cancer Institute to receive its prestigious Outstanding Investigator Award to continue his work to develop RNA interference (RNAi) therapeutics for ovarian cancer. Dr. Sood's research is important because RNAi-based drugs can directly target and turn off cancer-associated genes; however, important safety issues need to be addressed before RNAi-based drugs are ready for clinical use. Dr. Sood's research is heralded as having identified a promising strategy to deliver RNAi-drugs safely.

Notable CPRIT Supported Research and Prevention Accomplishments

- CPRIT sponsored research at MD Anderson finds that adherence to surgical treatment guidelines has improved significantly among older Texas patients with colon cancer since 2001, while adherence to chemotherapy guidelines following colon cancer surgery has remained largely unchanged with many older patients receiving less than recommended treatment. The study, published in the journal *Cancer*, analyzed Texas Cancer Registry and Medicare data from patients with colon cancer diagnosed in Texas between 2001 and 2011. The study is important because adherence to treatment guidelines is proven to increase colon cancer cures.

- A CPRIT supported research collaboration between Bruce Weisman, Ph.D., a Rice University chemist, and Robert Bast, M.D., an ovarian cancer specialist at MD Anderson, is developing a highly sensitive nanotube-based probe to locate ovarian cancer in a rodent model. The research, reported in the journal *ACS Applied Materials and Interfaces*, is important because more sensitive diagnostic tools for the early detection of ovarian cancer are needed. This collaboration also demonstrates the benefit of engineers and cancer researchers working together.

- CPRIT supported research at Baylor College of Medicine (BCOM) has opened the possibility of new treatment strategies for medulloblastoma, the most common type of brain tumor in children. A subset of medulloblastomas was found to be dependent on a growth promoting factor called Atoh1 that can be inhibited by a drug in a mouse model. Importantly, the drug did not target normal brain cells. The findings reported in the journal *eLife* are important because more than 300 new cases of medulloblastoma are diagnosed in the United States

every year and current treatments offer limited success and may leave patients with severe side effects.

- Medicenna Therapeutics is developing a novel immune-oncology therapy applicable to multiple cancers. Their "empowered cytokine" therapy targets the interleukin-4 (IL-4) receptor where it disrupts both cancer cells and the tumor microenvironment. The company announced Phase I and Phase 2 clinical trial results of its lead compound, MDNA55, in recurrent glioblastoma. Glioblastoma is the most common and deadliest brain cancer.

  Medicenna's multicenter study showed an overall response rate of 56%, with a complete response rate of 20% and a median survival of 210 days. These key metrics are better than any previously published studies and exceed expectations. In addition to promising efficacy data, the clinical trial demonstrated a good safety profile.

- Aeglea Biotherapeutics, Inc. is developing a novel arginine depletion therapy. Tumors with impaired ability to make arginine have enhanced sensitivity to extracellular arginine depletion, making them easier to target and kill. The company is developing AEB1102 to treat cancers which have demonstrated a metabolic dependency on arginine.

  Aeglea is currently conducting Phase 1 trials in cancer patients with advanced solid tumors and acute myeloid leukemia to evaluate the therapy's safety and tolerability. Data from these trials have demonstrated that AEB1102 reduces blood arginine levels, providing initial human proof of mechanism of action.

  Aeglea recently published new preclinical research showing AEB 1102 exerts additive anti-tumor and synergistic survival benefits when combined with immunomodulators of the PD-1 pathway. In addition, the company announced a clinical collaboration agreement with Merck to evaluate the combination of AEB1102 with Merck's immune-oncology drug KEYTRUDA for the treatment of patients with small cell lung cancer.

- Pelican Therapeutics, Inc. develops drugs designed to activate a patient's immune system against cancer. Pelican has utilized the CPRIT award to support the preclinical development, manufacturing and clinical development of a 70-patient Phase 1 clinical trial for PTX-35, the company's lead asset. PTX-35, in combination with checkpoint inhibitors and other immunotherapy agents, may improve clinical outcomes for patients diagnosed with a broad range of cancer types.

- DNAtrix, Inc. is developing DNX-2401, a novel oncolytic virus immunotherapy. DNX-2401, a potent oncolytic adenovirus, induces tumor-specific cell killing and initiates an antitumor immune response to cancer cells while leaving normal cells intact. Clinical studies of a single dose of DNX-2401 in adults with recurrent glioblastoma have demonstrated prolonged survival while maintaining a favorable safety profile compared to approved therapies.

  DNAtrix has an ongoing clinical study in glioblastoma patients. In early December, the company announced that it had enrolled its first pediatric patient in a new study. This Phase 1 study will assess the same compound in pediatric patients with diffuse intrinsic pontine

glioma (DIPG). DIPG is a highly aggressive, infiltrative tumor of the brainstem that typically affects children aged 4-11 years. There is no effective treatment, and due to the anatomical location of the tumor, surgical resection is often not possible.

Separately, DNAtrix recently published new preclinical research showing a backup compound, Delta-24-RGDOX, triggers an antitumor immune response and tumor-specific immune memory leading to prolonged survival in difficult-to-treat models of cancer.

- Immatics developed XPRESIDENT technology, a novel method of identifying peptide targets on tumor cells. XPRESIDENT can identify four-fold more targets than conventional methods. Identifying a relevant target is a critical to developing targeted immunotherapies. The company used this technology to identify multiple new relevant receptors and novel immunotherapies to target them. Clinical studies are ongoing to assess these immunotherapy agents.

  Immatics announced Roche exercised its option under its existing agreement to exclusively license a proprietary immunotherapy target for further development and commercialization in oncology. This target was identified and validated using Immatics' XPRESIDENT platform. Successful development and subsequent commercialization of cancer immunotherapies could trigger payment of additional development and sales milestones as well as royalty payments on worldwide net sales. Licensing a compound to a big pharma company for further development is a key milestone and validation of success for small biotech firms.

Personnel

CPRIT has 35 authorized full-time equivalent (FTE) positions, of which 34 (33 employees plus 1 contracted) are filled as of December 31, 2017.

- Claudia Leal, who has worked at CPRIT as a contract employee, accepted the permanent position of Executive Assistant effective January 1.

- Sandra Reyes was promoted from her position as Executive Assistant to the new Operations Specialist position effective January 1.

- We are in the process of filling the vacant Grant Accountant and Executive Assistant positions.

CPRIT Outreach

- During November and December, CPRIT Product Development staff attended nine networking events to build program awareness and meet with prospective applicants. Increased awareness and understanding of CPRIT's Product Development program and award mechanism enhances both the quantity and quality of applications.

- Several staff members attended the Texas Healthcare & Bioscience Institute fall meeting on November 2, 2017. Among numerous presentations of interest was a legislative panel

concerning CPRIT's future. Panelists included Senator Charles Schwertner and Representatives Four Price, Donna Howard and Sarah Davis. Several of the panelists spoke highly of CPRIT.

- Kristen Doyle, Heidi McConnell, Dr. Jim Willson, Michael Lang, Chris Cutrone, and I met on November 6, 2017, with representatives from the Texas Cancer Partnership to discuss CPRIT's and the Partnership's tentative plans for the 86th Texas Legislature that convenes in January 2019.

- Prevention program staff conducted a webinar for 50 attendees on the new RFA, Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations (EPS), on November 30, 2017.

- A series of cancer policy forums hosted by the American Cancer Society Cancer Action Network (ACS CAN) were held in Austin, Houston, and Arlington. ASC CAN invited CPRIT staff to present at each meeting regarding CPRIT's work. Presentations were made by Dr. Willson (Austin, November 29), Kristen Doyle (Arlington, December 4) and me (Houston, December 7). Presiding Officer Will Montgomery and Dr. Bill Rice attended the event in Austin. Mr. Montgomery also attended the Arlington event. The forums included presentations by legislators, CPRIT grantees, cancer survivors or their families, and a video from Dr. Ray Perryman on CPRIT's economic benefit to Texas. Legislators included State Senator Kirk Watson and Representatives Jason Villalba, Chris Turner, John Zerwas, and Sarah Davis. Former state representative Jim Keffer also spoke at the forum. Approximately 30-40 people attended each event.

- On December 8, 2017, Kristen Doyle and I met with newly assigned Governor's Office policy staff to provide an update on CPRIT activities.

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 December 20, 2017, 23 required reports from 10 entities have not been filed by the set due date; 21 (91%) are Academic Research grants and two (9%) are Product Development Research grants. CPRIT's grant accountants and grant compliance specialists continue to review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required report(s). In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

FSR Reviews

CPRIT's Grant Compliance Specialists performed 213 second-level reviews of grantee Financial Status Reports (FSRs) for the entire month of November through December 20, 2017. Thirty-six FSRs (17%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The 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 one grantee to remediate audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there are no grantees with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

Desk Reviews

Grant Compliance Specialists performed 26 desk-based financial monitoring/reviews for the month of November through December 20, 2017, to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Grant Compliance Specialists are working with nine grantees to remediate desk review findings.

On-Site Reviews

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

Annual Compliance Attestation (Self-Certification)

CPRIT requires grantees to submit an annual self-certification by December 31 demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and

procedures, the grant contract, and Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Grant Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. Compliance staff is working with 19 grantees who have not yet submitted the required attestation.

Training and Support

A new Authorized Signing Official (ASO) training webinar is being scheduled with the University of North Texas Health Science Center at Fort Worth in early January. This training will cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, new ASOs are required to complete a compliance training within 60 days of the change.

Academic Research Program Update

Advisory Committee Meetings

The University Advisory Committee and the Advisory Committee for Childhood Cancers met on November 13, 2017, and November 14, 2017, respectively. The agendas included developing content for required annual reports and presentations to the Oversight Committee at its February meeting. Mr. Montgomery and Drs. Rice and Patel attended and actively participated in the University Advisory Committee meeting. Dr. Patel also attended the Advisory Committee for Childhood Cancers meeting.

FY 2018 Cycle 1 (18.1) RFAs Update

Table 1 displays the number of applications submitted for cycle 18.1 by RFA mechanism. Notable is a 25% increase in applications submitted to this cycle as compared to the FY 2017 cycle. These applications have been peer reviewed and we expect recommendations from the Scientific Review Council (SRC) soon. Dr. Willson will present the award recommendations to the Program Integration Committee and the Oversight Committee in February 2018.

Table 1: FY 2018.1 Individual Investigator Research Application Submissions by Mechanism

#IIRAs Submitted	#IIRACCA Submitted	#IIRACB Submitted	#IIRACT Submitted	#IIRAP Submitted	Total # Submissions
356	39	43	54	40	532

IIRA: Individual Investigator Research Awards
IIRACCA: Individual Investigator Research Awards for Cancer in Children and Adolescents
IIRACB: Individual Investigator Research Awards for Computational Biology
IIRACT: Individual Investigator Research Awards for Clinical Translation
IIRAP: Individual Investigator Research Awards for Prevention and Early Detection

Recruitment Summary Data

Table 2 displays the number of recruitment applications submitted for cycles 18.3, 18.4 and 18.5, which were reviewed by the SRC on December 14, 2017. SRC-recommended grant applications will be presented to the Program Integration Committee and the Oversight Committee for approval at the February 21, 2018, Oversight Committee meeting.

Table 2: Summary of Recruitment Application Submissions Cycles 18.3, 18.4 & 18.5

Cycles 18.1-18.2	# Applications Submitted
Recruitment Established Investigators	3
Recruitment Rising Stars	2
Recruitment of First-Time Tenure Track Faculty Members	4
Total	**9**

FY 2018 Cycle 2 Request for Academic Research Applications

Following approval by the Oversight Committee in August, CPRIT released three Requests for Applications (RFAs) on August 25, 2017. A description of the three RFAs is provided below. CPRIT will receive proposals through January 31, 2018. Applications will be reviewed in May 2018 and the SRC-recommended applications will be presented to the Program Integration Committee and the Oversight Committee for approval in August 2018.

- **Core Facility Support Awards (CFSA) (RFA R-18.2 CFSA)**
  Supports the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. CPRIT is particularly interested in supporting core facilities that provide enabling services to cancer investigators from multiple Texas institutions. Applications responding to this RFA that address one of the program priorities for academic research adopted by CPRIT's Oversight Committee are particularly encouraged.
  Award: Up to $3,000,000 (total costs) for the first 2 years and up to $1,000,000 (total costs) for each subsequent year; Maximum duration: 5 years

- **High-Impact/High Risk Research Awards (HIHR) (RFA R-18.2 HIHR)**
  Provides short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Applications responding to this RFA that address one of the program priorities for academic research adopted by CPRIT's Oversight Committee are particularly encouraged.
  Award: Up to $200,000 (total costs); Maximum duration: 2 years.

- **Multi-Investigator Research Awards (MIRA) (RFA R-18.2 MIRA)**
  This Multi-Investigator Research Award (MIRA) mechanism is intended to support highly integrated programs of collaborative and cross-disciplinary research among multiple Texas investigators. Applications responding to this RFA that address one of the

program priorities for academic research adopted by CPRIT's Oversight Committee are particularly encouraged.
Award: Up to $6,000,000 (total costs); Maximum duration: 4 years.

FY 2019 Cycle 1 Request for Academic Research Applications

CPRIT will announce and post five RFAs on January 8, 2018. These RFAs were initially presented to the Oversight Committee for approval in August. CPRIT will accept applications from March 7,2018, through June 6, 2018. Applications will be reviewed in October 2018 and the applications recommended by the SRC will be presented to the Program Integration Committee and the Oversight Committee for approval in February 2019. The five RFAs are:

- **Individual Investigator Research Awards (IIRA) (RFA R-19.1 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-19.1-IIRACCA)**
  Supports applications for innovative research projects addressing questions to 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-19.1-IIRACB)**
  Supports applications for innovative mathematical or computational research projects addressing questions to advance 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-19.1-IIRAP)**
  Supports applications for innovative research projects addressing questions to 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-19.1 – IIRACT)**
  Supports applications for innovative clinical research to 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.

Product Development Research Program Update

FY 2018 Cycle 1 Product Development Research Applications

Eighteen applications were submitted and accepted in August 2017. The first round of peer review selected four companies to present their proposals at the Product Development Peer Review panel meeting on October 25 in Houston. The panel selected two companies requesting $39.7 million for additional due diligence.

The Product Development Review Council (PDRC) will meet to review the due diligence reports in mid-January and make final recommendations for grant awards. Companies recommended by the PDRC and Program Integration Committee will be presented for Oversight Committee consideration in February.

FY 2018 Cycle 2 Product Development Research Applications

Request for Applications (RFAs) for the two Product Development Award mechanisms (Texas Company and Relocation Company) were approved by the Oversight Committee in November 2017 and posted December 15. Applications will be accepted through February 7. Award recommendations will be presented to the Oversight Committee in August for review and approval.

Prevention Program Update

FY 2018 Cycle 1 (18.1) Prevention Applications

CPRIT released three RFAs in June 2017 for the first review cycle of FY 2018. Peer review panels met December 11 – 14 to evaluate the 34 17.2 prevention applications requesting $46,348,666 (see table below). The Prevention Review Council (PRC) will meet in mid-January

to make award recommendations to the Program Integration Committee and the Oversight Committee. Dr. Garcia will present the recommendations to the Oversight Committee in February.

Mechanism	Number Received	Total $ Requested
Evidence-based Cancer Prevention Services	28	$38,438,664
Tobacco Control and Lung Cancer Screening	6	$ 7,910,002
TOTAL	**34**	**$46,348,666**

One application for the Dissemination of CPRIT-Funded Cancer Control Interventions mechanism was received this quarter and will be reviewed by the PRC on January 18, 2018.

FY 2018 Cycle 2 (18.2) Prevention RFAs

CPRIT released three RFAs for the second cycle of FY 2018 on November 20. Applications are due February 21, 2018, with peer review panels meeting in May 2018. The Oversight Committee will consider the recommendations at the August 2018 meeting. RFAs released in November include:

- **Evidence-Based Cancer Prevention Services (EBP)**
  Seeks projects to deliver evidence-based cancer prevention and control clinical services. Priority will be given to projects that address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects. Award: Maximum of $1,500,000; Maximum duration of 36 months.

- **Tobacco Control and Lung Cancer Screening (TCL)**
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. Seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth. Award: Maximum of $1,500,000; Maximum duration of 36 months.

- **Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations (EPS)**
  Seeks to support the coordination and expansion of evidence based services to prevent cancer in underserved populations that do not have adequate access to cancer prevention interventions and health care thereby bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence based models shown to work in similar communities to prevent and control these cancers.

Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. Expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Award: Maximum of $3,000,000; Maximum duration of 36 months.

- **Dissemination of CPRIT-Funded Cancer Control Interventions (DI)**
  Seeks projects to facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. Proposed projects should be able to develop one or more "products" based on the results of the CPRIT-funded intervention and should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding. This mechanism is continuously open, and applications are reviewed quarterly by the PRC.
  Award: Maximum of $300,000; Maximum duration of 24 months.

Communications Update

Cancer Awareness Month Activities

Media outreach is planned to generate earned media for National Cervical Health Awareness Month (January) and National Cancer Prevention Month (February). We will work with CPRIT's institutional partners in Houston (BCOM, MD Anderson, UTMB-Galveston, TAMUHSC, The Rose) to focus on media in that market. Short videos for social media will also be created and distributed on CPRIT social media outlets, including a feature on the Moncrief Cancer Institute in February.

The City of Houston has confirmed that it will present a proclamation in May 2018 to recognize National Cancer Research Month. Communications is working with our Houston institutions and the city on proclamation language and event logistics.

Innovations in Cancer Prevention and Research V Conference

A two-minute conference recap video that was shown at the November 18 Oversight Committee meeting was sent out via social media and email announcing that the conference website was updated with photos and speaker presentations. Our institutional partners also shared the video on social media. In addition, CPRIT conducted on-camera interviews with 10 speakers and grantees over the course of the conference for future videos and media relations efforts in 2018.

A final report on the conference will be produced when attendee evaluations are tallied and revenue and expense are finalized.

Operations and Finance Update

Required Reports

CPRIT finance and purchasing staff submitted several reports and documents required by state reporting guidelines.

- Michelle Huddleston and Heidi McConnell completed the FY 2017 Annual Financial Report and submitted it to the Comptroller's Office on November 15.

- Dan Limas and Heidi McConnell completed CPRIT's 2018 Operating Budget and submitted it to the Legislative Budget Board and Governor's Office on November 30.

- Don Brandy and Heidi McConnell completed the Historically Underutilized Business (HUB) Self-Assessment Report for the 2016-17 Biennium and the HUB Plan for Fiscal Years 2018 and 2019 and submitted the consolidated document to the Legislative Budget Board and Comptroller's Office on November 30.

- Don Brandy and Heidi McConnell submitted the agency's Procurement Plan and Contract Management Handbook updated for new state requirements and internal process changes effective for FY 2018 to the Comptroller's Office on December 1.

Audits

- McConnell & Jones LLP, the financial audit firm that CPRIT contracts with to perform its statutorily-required independent financial audit, completed CPRIT's FY 2017 Financial Statements audit report on December 1 and presented the final report with no findings to the Audit Subcommittee at a special subcommittee meeting on December 4. The completion of this audit required data, documents, and input not only from finance but also from other staff across the agency including operations, legal, and compliance. In addition to the finance audit, the auditor tested overall agency compliance with internal processes and procedures, the agency's administrative rules, and certain state laws. The audit report was submitted to the Comptroller's Office as well as the State Auditor's Office on December 15. Oversight Committee members will receive copies of the FY 2017 Financial Statement audit report, FY 2017 Annual Financial Report and FY 2018 Operating Budget by mail.

- The State Auditor's Office (SAO) issued a draft *Audit Report on Performance Measures at the Cancer Prevention and Research Institute* which resulted in two recommendations to improve CPRIT's performance measure reporting processes on November 28. The SAO audit team held an audit exit meeting with Kristen Doyle, Heidi McConnell, Vince Burgess, Mike Lang, Rosemary French, Ramona Magid, Lisa Nelson, and me on December 6. On December 12, CPRIT provided management responses to address the findings by implementing additional processes and procedures to verify performance measure data. The SAO released the report publicly on December 27.

- On December 4 the Weaver internal audit team started its field work on its Post-Award Grant Management/Contracting audit in CPRIT's offices. An exit meeting with CPRIT staff was held December 20 with the final audit report including management responses expected in January.

Upcoming Subcommittee Meetings

In addition to the three meetings leading up to the special January Oversight Committee, listed below are the regularly scheduled subcommittees in advance of the February 2018 OC meeting.

Board Governance	February 8 at 10:00 a.m.
Audit	February 12 at 10:00 a.m.
Prevention	February 13 at 10:00 a.m.
Academic Research	February 14 at 10:00 a.m.
Product Development	February 15 at 10:00 a.m.
Nominations	February 16 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 **1,191** grants totaling **$1.887 billion**

- 190 prevention awards totaling $195.4 million
- 1001 academic research and product development research awards totaling $1.691 billion

Of the $1.691 billion in academic research and product development awards,

- 29.7% of the funding ($501.8 million) supports clinical research projects
- 25.9% of the funding ($437.6 million) supports translational research projects
- 26.2% of funding ($444.1 million) supports recruitment awards
- 14.7% of the funding ($248.0 million) supports discovery stage research projects
- 3.5% of funding ($59.9 million) supports training programs.

CPRIT has 12 open Requests for Applications (RFAs)

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

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2018

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	0		4										4	
New Grant Contracts Signed	9	19	7	11	6								52	
New Grant Contracts In Negotiation			12										12	
Grant Reimbursements Processed (#)	191	172	138	120	126								747	
Grant Reimbursements Processed ($)	$ 14,402,580	$ 24,849,514	$ 12,652,218	$ 16,464,363	$ 12,888,800								$ 81,257,475	
Revenue Sharing Payments Received	$ 1,500	$ 35,140	$ 7,557	$ -	$ 21,969								$ 66,166	$ 3,300,382
Total Value of Grants Contracted ($)	$ 11,469,175	$ 30,088,458	$9,750,000	$ 16,294,571	$ 10,138,500								$ 77,740,704	
Grants Awarded (#)/ Applications Rec'd (#)														
Debt Issued ($)/Funding Awarded ($)	73%	73%	72%	72%	72%									
Grantee Compliance Trainings/Monitoring Visits	0	1	0	0	1								2	
Awards with Delinquent Reimbursement Submission (FSR)			1											
Awards with Delinquent Matching Funds Verification			8											
Awards with Delinquent Progress Report Submission			7											
IA Agency Operational Recommendations Implemented	0	0	0	0	0								0	
IA Agency Operational Recommendations In Progress	12	12	12	12	12									
Open RFAs	6	7	7	12	12									
Prevention Applications Received	38	4	0	1	0								43	759
Product Development Applications Received	0	0	0	0	0								0	402
Academic Research Applications Received	2	2	5	1	208								218	6,231
Help Desk Calls/Emails	161	192	121	132	285								891	
MISSION														
ACADEMIC RESEARCH PROGRAM														
Number of Research Grants Announced (Annual)	0		3										3	
Recruited Scientists Announced														202
Recruited Scientists Accepted														150
Recruited Scientists Contracted	`													139
Published Articles on CPRIT-Funded Projects (#)														
Jobs Created & Maintained (#)														
Trainees in CPRIT-Funded Training Programs (#)														
Clinical Trials (#)														71
Number of Patents Resulting from Research														

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2018

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Patent Applications														
Number of Investigational New Drugs														
PRODUCT DEVELOPMENT RESEARCH PROGRAM														
Number of Product Development Grant Announced (Annual)			0										0	
Life Science Companies Recruited (in TX)														9
Published Articles on CPRIT-Funded Projects														
Number of Jobs Created & Maintained														515
Clinical Trials (#)														15
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PREVENTION PROGRAM														
Number of Prevention Grants Announced (Annual)			1										1	
People Served by CPRIT-Funded Prevention and Control Activities			483,648										483,648	
People Served through CPRIT-Funded Education and Training			201,481										201,481	
People Served through CPRIT-Funded Clinical Services			282,167										282,167	
TRANSPARENCY														
Total Website Hits (Sessions)	5,959	5,881	5,928	5,613	7,209								30,590	
Total Unique Visitors to Website (Users)	4,359	4,234	4,305	4,417	4,773								22,088	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER**
Subject:	**FY 2017 REPORT ON PROGRAM MERIT AND PROGRESS PURSUANT TO TEXAS HEALTH & SAFETY CODE § 102.260(C)**
Date:	**FEBRUARY 21, 2018**

Summary

Fiscal year 2017 was another year of progress for CPRIT and its three programs: Academic Research, Prevention, and Product Development Research. Key metrics indicate that CPRIT is affecting Texas' national standing in both cancer research and the biomedical industry. Through fiscal year 2017 (FY 2017), CPRIT has awarded $1.886 billion, nearly 67% of the funds it estimates to be available for awards in its constitutional authorization. Texas Health and Safety Code § 102.260(c) requires the Chief Executive Officer to report at least annually to the Oversight Committee on the progress and continued merit of each research program. CPRIT's Academic Research Program, Prevention Program and Product Development Research Program showed progress and merit in FY 2017.

This report provides an overview illustrating the progress made in advancing CPRIT's mission to create and expedite innovation in cancer research and cancer prevention. Aligning program activities with the program priorities adopted by the Oversight Committee is a good gauge of progress and merit. This report highlights each program's implementation of the FY 2017 program priorities. CPRIT's FY 2017 *Annual Report* and quarterly *Achievements Report* provide more information on CPRIT awards.

With regard to progress made by individual grant projects within each of CPRIT's three programs, Texas Administrative Code § 703.21 requires all CPRIT grantees to submit progress reports at least annually. Outside experts evaluate these progress reports to ensure that the grantee has made sufficient progress and should continue work under the grant. To the extent that an expert reviewer determines that a grant project is not making sufficient progress, CPRIT may take a number of actions, including contract termination.

Academic Research Program

CPRIT's Academic Research Program supports innovative and meritorious projects that are discovering new information about cancer that can lead to prevention, early detection, and cures; translating new and existing discoveries into practical advances in cancer diagnosis and treatment; and increasing the prominence and stature of Texas in the fight against cancer.

In FY 2017, CPRIT's Academic Research Program awarded 118 grants totaling $210.39 million. The Oversight Committee approved awards across Academic Research as follows: Core Facilities Support Awards (11 applications awarded), Early Translational Research (7 applications awarded), High-Impact/High-Risk (19 applications awarded), Individual Investigator Research Awards (26 applications awarded), Individual Investigator Research Awards for Cancer in Children and Adolescents (7 applications awarded), Individual Investigator Research Awards for Computational biology (3 applications awarded), Individual Investigator Research Awards for Prevention and Early Detection (5 applications awarded), and Research Training Awards (5 applications awarded).

Academic Research Program Priorities

The Oversight Committee adopted the following FY 2017 program priorities for the Academic Research Program:

- Recruitment of outstanding cancer researchers to Texas;
- Investment in core facilities;
- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Computational biology and analytic methods;
- Childhood cancers; and
- Population disparities and cancers of importance in Texas.

The following table illustrates how many Academic Research grants awarded in FY2017 address the program priorities.

FY 2017 DATA BY ACADEMIC RESEARCH PROGRAM PRIORITIES*		
Priorities Addressed	Number of Grants	Award Amount
Recruitment of outstanding cancer researchers to Texas	35	$99,100,000
Investment in core facilities	11	$46,560,000
A broad range of innovative, investigator-initiated academic research projects	41	$38,770,000
Prevention and early detection	14	$21,260,046
Computational biology and analytic methods	14	$39,983,177
Childhood cancers	22	$46,478,271
Population disparities and cancers of importance in Texas (lung, liver, cervix cancers)	21	$40,896,125

**Some grants address more than one priority*

Thirty-five recruits accepted positions at Texas institutions in FY 2017, for a total of $99.1 million in recruitment grant awards for the year. CPRIT continues to build a critical mass of cancer researchers in Texas by supporting recruitment of cancer scientists and clinicians as cancer research scholars to academic institutions in Texas. This program has been highly successful in enhancing Texas' cancer research efforts and increasing the external visibility of the state in this field, which ultimately benefits the life sciences infrastructure in Texas.

Prevention Program

CPRIT's Prevention Program supports effective, evidence-based prevention programs to underserved populations in the state. The Prevention Program grants help Texans reduce the risk of cancer, identify cancers earlier, and assist people in finding cancer treatment. These efforts ease the burden of cancer in Texas. Texas has seen a decrease in death rates from cancer by 7% between 2009 and 2014, which translates to nearly 6,800 averted deaths.

The Oversight Committee approved 17 grants during FY 2017 totaling $26 million. By the end of FY 2017, CPRIT has supported $195.1 million in 189 Prevention Program grants. Ninety

Prevention Program projects were active during the fiscal year. Of the 90 projects actively providing programs and services to Texans, 79% focused on clinical service delivery, 9% on professional education and training and 12% focused on public education and outreach.

In addition to the impact on the health of Texans, Prevention Program grants improve the healthcare system and foster collaborations. Health system improvements include reducing wait times for diagnostic testing and the number of people lost to follow-up, implementing patient reminder systems, enhancing electronic medical records, and training community health care workers to educate and navigate people through the system. These grants stimulate greater collaboration among academic institutions, community organizations, and clinics.

Prevention Program Priorities

The Oversight Committee adopted the following FY 2017 Prevention Program priorities:

- Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence;
- Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; and
- Underserved populations.

CPRIT released 10 Prevention Program RFAs in FY 2017 including one on Colorectal Cancer Prevention Coalitions and another on Cancer Prevention and Navigation to Clinical Services. The table below reflects how active projects in FY 2017 address Prevention Program priorities.

FY 2017 FUNDING BY PREVENTION PROGRAM PRIORITIES*		
Priorities Addressed	Number of Grants	Award Amount
Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.	11	$14,229,009
Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence.	10	$15,068,341
Prioritize underserved populations.	17	$26,043,833

** Some grants address more than one priority.*

Product Development Research Program

CPRIT's Product Development Research Program funds innovative and scientifically meritorious product development projects with the potential of translating research discoveries into commercial products that can benefit cancer patients. During FY 2017, the Oversight Committee approved three Product Development Research awards totaling $41.1 million.

CPRIT has made 32 Product Development Research awards totaling $329.6 million through FY 2017. Fourteen CPRIT-funded company projects conducted clinical trials in FY 2017, reaching cancer patients in Texas with innovative, early stage treatments. The Product Development Research program benefits not only cancer patients, but like CPRIT's recruitment grants, the Product Development Research awards are a vital component in building the life sciences infrastructure and community in Texas. Twenty-one companies with CPRIT-funded projects have connections with Texas institutions.

Additionally, through August 31, 2017, CPRIT companies raised $1.37 billion in follow-on funding from other investors, indicating private sector confidence in the high quality, merit-based peer review and due diligence review process. These follow-on investments and activities testify to the quality of the CPRIT-funded projects and CPRIT's review process.

Product Development Research Program Priorities

The Oversight Committee adopted the following FY 2017 Product Development Research Program Priorities:

- Supporting development of novel projects that offer therapeutic or diagnostics 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 sciences expertise, especially experienced C-level staff to new life science companies in Texas; and
- Providing appropriate return on Texas taxpayer investment.

The following below depicts the program priorities fulfilled by the three Product Development Research grants awarded in FY 2017.

FY 2017 FUNDING BY CPRIT PRODUCT DEVELOPMENT RESEARCH PROGRAM PRIORITIES*		
Priorities Addressed	# Grants	Award Amount
Funding novel projects that offer therapeutic or diagnostics not currently available, i.e., disruptive technologies	3	$41,144,783
Funding projects addressing large or challenging unmet medical needs	3	$41,144,783
Investing in early stage projects when private capital is least available	1	$8,998,067
Stimulating commercialization of technologies developed at Texas institutions	3	$41,144,783
Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life sciences expertise, especially experienced C-level staff to new life science companies in Texas	1	$8,998,067
Providing appropriate return on Texas taxpayer investment	3	$41,144,783

** Some grants address more than one priority.*

Diversity Initiatives

Cancer is an equal opportunity disease; it does not discriminate. However, those that fall within a certain demographic, geographic area, or genetic profile may have unequal cancer experiences and likelihood of survival. CPRIT has made addressing cancer disparities a high priority, funding prevention projects targeting the historically underserved and emphasizing cancer research efforts affecting minority populations. While building a cancer-fighting ecosystem in Texas, CPRIT is aware that reaching diverse populations includes building a workforce within this ecosystem that reflects diversity. I highlight the following four examples demonstrating CPRIT's commitment to addressing cancer disparities.

MHP Salud Colonia Outreach Program

The Rio Grande Valley (RGV) located along the U.S.-Mexico border is home to high rates of colorectal and breast cancer and the highest rates of cervical cancer incidence and mortality in the state. MHP Salud, a national nonprofit organization that implements and runs Community

Health Worker, or Promotor(a) programs, uses CPRIT funds to implement a Colonia Outreach Program for education on cancer screening in the RGV colonias. The organization, in partnership with Nuestra Clinica Del Valle (NCDV), has developed an effective system to ensure eligible patients receive culturally and linguistically appropriate education on colorectal, breast, and cervical cancer screening. NCDV refers patients to a MHP Salud Promotor(a) who provides health insurance navigation to patients prior to their screening.

NCDV integrates the Promotor(a) into its process; as a result, the collaboration is successfully improving screening rates and making lasting changes for the RGV community. Since starting the program in May 2015, nearly 3,400 individuals in the RGV colonias and surrounding areas of Hidalgo and Starr county have received one-on-one, Promotor(a)-facilitated outreach and education related to cancer screening at NCDV's eleven clinics. The CPRIT-funded program has successfully identified cancers in the target community:

- 506 breast cancer screenings completed with 29 positive results identified;
- 246 cervical cancer screenings completed with 3 positive results identified; and
- 455 colorectal cancer screenings completed with 5 positive results identified.

This project provides one of Texas' most vulnerable and underserved communities access to education, screening services, and care, including appropriate insurance enrollment when cancer is diagnosed.

The Asian American Health Coalition - HOPE Clinic

Houston's foreign-born Asian population is fast-growing, increasing 48% between 2000 and 2010. More than 4,000 refugees settled in Harris County between 2011 and 2012. The growing ethnic Asian populations in Houston face significant cancer disparities. The incidence and mortality rate of liver cancer in the local Asian population is 69% and 36% higher, respectively, compared to Harris County overall. Breast cancer is the leading cancer diagnosis among Asian American women; however, as an ethnic group, Asian American women are the least likely to receive a mammogram. Similarly, although colorectal cancer is among the three most commonly diagnosed cancers for Asian Americans, this group has the lowest colorectal cancer screening rates of all ethnic groups. Cervical cancer also affects Asian populations disproportionately. The American Cancer Society reports that the Vietnamese have the highest incidence and mortality rates of cervical cancer. Lung cancer is the leading cause of cancer deaths for Asian American women and second leading cause for Asian American men.

Asian immigrants and refugees can be hard to reach because of differences in language, habits, customs, and values. Barriers to accessing prevention and quality health services include

linguistic isolation, insufficient health information, and a shortage of ethnically sensitive and culturally competent health facilities. With a staff that speaks more than 22 languages, CPRIT grantee HOPE Clinic is uniquely suited to serve Asian immigrants living primarily in Southwest Houston as well as refugees that may come from elsewhere in the city. HOPE Clinic provides primary and preventive care for approximately half of Houston's Asian refugees.

HOPE Clinic provides linguistically and culturally competent prevention and related education services to address breast, cervical, and liver cancer. As recently as 2013, 73% of HOPE Clinic patients were best served in a language other than English. Among other evidence-based strategies, HOPE Clinic uses the Chronic Care Model from the National Health Disparities Collaboratives to develop a comprehensive, cost effective and high-quality cancer control program. Projects for Asians and refugees incorporate tailored strategies for reaching out to distinct ethnic groups with special expertise. HOPE Clinic providers offer clinical evidence-based services such as clinical breast exams, mammography, diagnostic mammograms, Pap tests, colposcopies, Hepatitis B screenings, and vaccines to prevent Hepatitis B and the Human Papilloma Virus (HPV). Translators, patient educators, care coordinators, and outreach staff provided by HOPE Clinic complement education and outreach strategies tailored to the multicultural target population.

Focusing on Cancers of Significance in Texas

All CPRIT academic research RFAs include information regarding the Oversight Committee's program priorities. These priorities have driven interest in research focused on population disparities and three cancers of high importance in Texas – lung cancer, liver (hepatocellular) cancer, and cervical cancer. CPRIT has awarded 59 research grants in the past two years (17% of the CPRIT academic research awards made between fiscal years 2015 and 2017) targeting these cancers of significance and addressing the population disparities.

Liver cancer is becoming the fastest-rising cause of cancer-related deaths in the country, and Texas has the highest death rate from liver cancer of any state. Many Texans, including a disproportionate number of Hispanics and African Americans, have Hepatitis C, Hepatitis B, or alcoholic liver disease, which are known risk factors for liver cancer.

Collaborating investigators at the four Texas NCI-designated cancer centers – Baylor College of Medicine, The University of Texas MD Anderson Cancer Center, The University of Texas Southwestern Medical Center, and The University of Texas Health Science Center at San Antonio – created the Texas Hepatocellular Carcinoma Consortium (THCCC). These institutions house the expertise to study the eradication of liver cancer in Texas and throughout the world.

With CPRIT funding, the investigators are developing an ecosystem of collaborative research institutions and forming the epicenter for liver cancer research.

Cancer Research Recruitment and Training Diversity Initiatives

CPRIT's Academic Research Program works with academic centers located in geographic regions with a limited number of federal and CPRIT cancer research awards. Recent CPRIT Scholar recruitment awards to Texas Tech University Health Sciences Center at El Paso, Texas Tech University Health Sciences Center, and The University of Texas Health Science Center at Tyler are early indicators of the growing cancer research programs in these areas.

CPRIT's Research Training Awards to nine Texas institutions of higher learning facilitate the training of the next generation of outstanding cancer researchers. CPRIT encourages individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds to participate in CPRIT's training programs. In addition to predoctoral and postdoctoral research training, potential opportunities include undergraduate summer research internship programs, particularly those directed at recruiting underrepresented minorities. Twenty percent of the trainees supported by CPRIT Research Training Awards are from racial and or ethnic backgrounds currently underrepresented in academic research. This provides a diverse pool of highly trained scientists available to address the state's and the nation's basic, population-based, clinical, and translational cancer research needs.

Conclusion

CPRIT's three programs show merit and progress and should continue operations. The work conducted under the purview of CPRIT's programs is part of an iterative cycle with observations emerging from the laboratory making their way to the public and back again to the laboratory. Essential players in this cycle are basic scientists, physician scientists, clinical researchers, product development entrepreneurs, public health professionals, health care providers, patients, community organizations, early stage companies, and research institutions across Texas.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	FEBRUARY 12, 2018

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

Training and Support

A new Authorized Signing Official (ASO) training webinar was conducted with the University of North Texas Health Science Center at Fort Worth on January 24, 2018. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, new ASOs are required to complete a compliance training within 60 days of the change.

A grantee training webinar is scheduled for March 7, 2018. The training will cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This will be the first training offered this year in support of the annual compliance training requirement which states that the Authorized Signing Official (ASO) and at least one other employee from each grantee organization must attend an annual compliance training by November 1 of each year.

Financial Status Report (FSR) Reviews

CPRIT's Grant Compliance Specialists performed 167 second-level reviews of grantee FSRs for the month of January and a total of 269 reviews for the quarter. Of the 167 FSRs, 26 (15%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The 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 one grantee to remediate audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there are no grantees with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

Desk Reviews

Grant Compliance Specialists performed 25 desk-based financial monitoring/reviews during the month of January to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Grant Compliance Specialists are working with nine grantees to remediate desk review findings.

On-Site Reviews

Grant Compliance Specialists have scheduled two on-site reviews for February and March. On-site reviews typically include an examination of the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance.

Annual Compliance Attestation (Self-Certification)

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

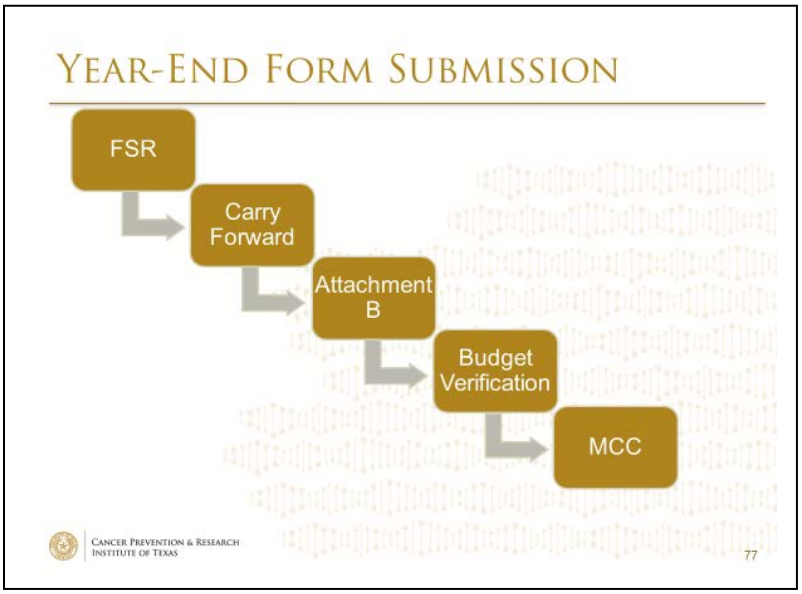
Submission Status of Required Grant Recipient Reports

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 January 31, 2018, 38 required reports from 11 entities had not been filed by the set due date; 33 (87%) are Academic Research grants and five (13%) are Product Development Research grants. Of the 38 delinquent reports, 32 (84%) are Matching Compliance Certification forms, five (13%) are Progress Reports, and one (3%) is a Financial Status Report.

CPRIT's grant accountants and grant compliance specialists continue to review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required report(s). In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports. The increase in delinquent reports for this period, specifically the Matching Compliance Certification form, is attributable to a recent programming change to CPRIT's grants management system (CGMS). This change now requires grantees to submit forms in a specific order and only after the previous form as been approved.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	JAMES WILLSON, MD., CHIEF SCIENTIFIC OFFICER
SUBJECT:	ACADEMIC RESEARCH PROGRAM UPDATE
DATE:	FEBRUARY 21, 2018

FY 2018 Cycle 2 Academic Research Applications

CPRIT released three RFAs for the second cycle of FY 2018 (18.2) in August 2017. Two hundred and three applications were received by the deadline. Peer review panels will meet May 18-25 in Dallas/Fort Worth to conduct their review. The Oversight Committee will consider the PIC's recommendation at the August 2018 meeting.

Mechanism	Number Received
Core Facilities Support Awards	27
High-Impact/High Risk Research Awards	153
Multi-Investigator Research Awards	23
Total	**203**

*FY 2019 Cycle 1 Academic Research RFAs

CPRIT posted the RFAs for the first cycle of FY 2019 (19.1) on December 1, 2017. Applications are due in June 2018, peer review in October 2018, and consideration by the Oversight Committee in February 2019. The RFAs include:

- **Individual Investigator Research Awards (19.1)**
  Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
  Award: Up to $300,000 per year; maximum duration: 3 years.

- **IIRA Childhood and Adolescent Cancers (19.1)**
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality

from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
Award: Up to $300,000 per year; maximum duration: 4 years.

- **IIRA Computational Biology (19.1)**
  Supports applications for innovative mathematical or computational research projects addressing questions that will advance our knowledge in any aspect of cancer. Areas of interest include data analysis of cellular pathways, microarrays, cellular imaging, cancer imaging or genomic, proteomic, and metabolomics databases; descriptive mathematical models of cancer, as well as mechanistic models of cellular processes and interactions and use of artificial intelligence approaches to build new tools for mining cancer research and treatment databases.
  Award: Up to $300,000 per year; maximum duration: 3 years.

- **IIRA Clinical Translation (19.1)**
  Supports applications which propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.
  Award: Up to $400,000 per year. Maximum duration: 3 years. Applicants that plan on conducting a clinical trial as part of the project may request up to $600,000 per year in total costs and a maximum duration of 4 years.

- **IIRA Prevention and Early Detection (19.1)** **New area of emphasis**
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer and research. Research may be laboratory, clinical, or population-based, and may include behavioral/intervention, dissemination or health services/outcomes research and strategies for implementation research to reduce cancer incidence or promote early detection. Research projects that propose to conduct implementation research designed to accelerate the adoption and deployment of sustainable, evidence-based cancer prevention and screening interventions at multiple levels and in different clinical and community settings are encouraged.
  Award: Up to of $300,000 per year for laboratory and clinical research; Up to $500,000 per year for population-based research. Exceptions permitted if extremely well justified; maximum duration: 3 years.

*RFAs approved by the CPRIT Oversight Committee, August 16, 2017

Individual Investigator Research Awards for Prevention and Early Detection (IIRAP) RFA Webinar

The Academic Research and Prevention Programs are jointly hosting a webinar on February 15, 2018 to communicate interest in receiving applications on implementation research designed to accelerate the adoption and deployment of evidence-based cancer prevention and screen interventions. Dr. Ross Brownson, a leading expert in implementation research and applied epidemiology will briefly describe implementation research and discuss examples of possible research opportunities; in particular, opportunities to build on the work of CPRIT Prevention Program grantees. Drs. Garcia, Willson and Brownson will be available to answer questions.

FY 2019 Cycle 2 Academic Research RFAs (Proposed)

The FY 2019 RFA release schedule was discussed by the Oversight Committee Research subcommittee on February 14, 2018 and is attached for the Oversight Committee's consideration.

Proposed Academic Research RFA Mechanisms FY2019:

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

- **Recruitment of Rising Stars (FY19)**
  Recruits outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.
  Award: Up to $4 million over a period of five years.

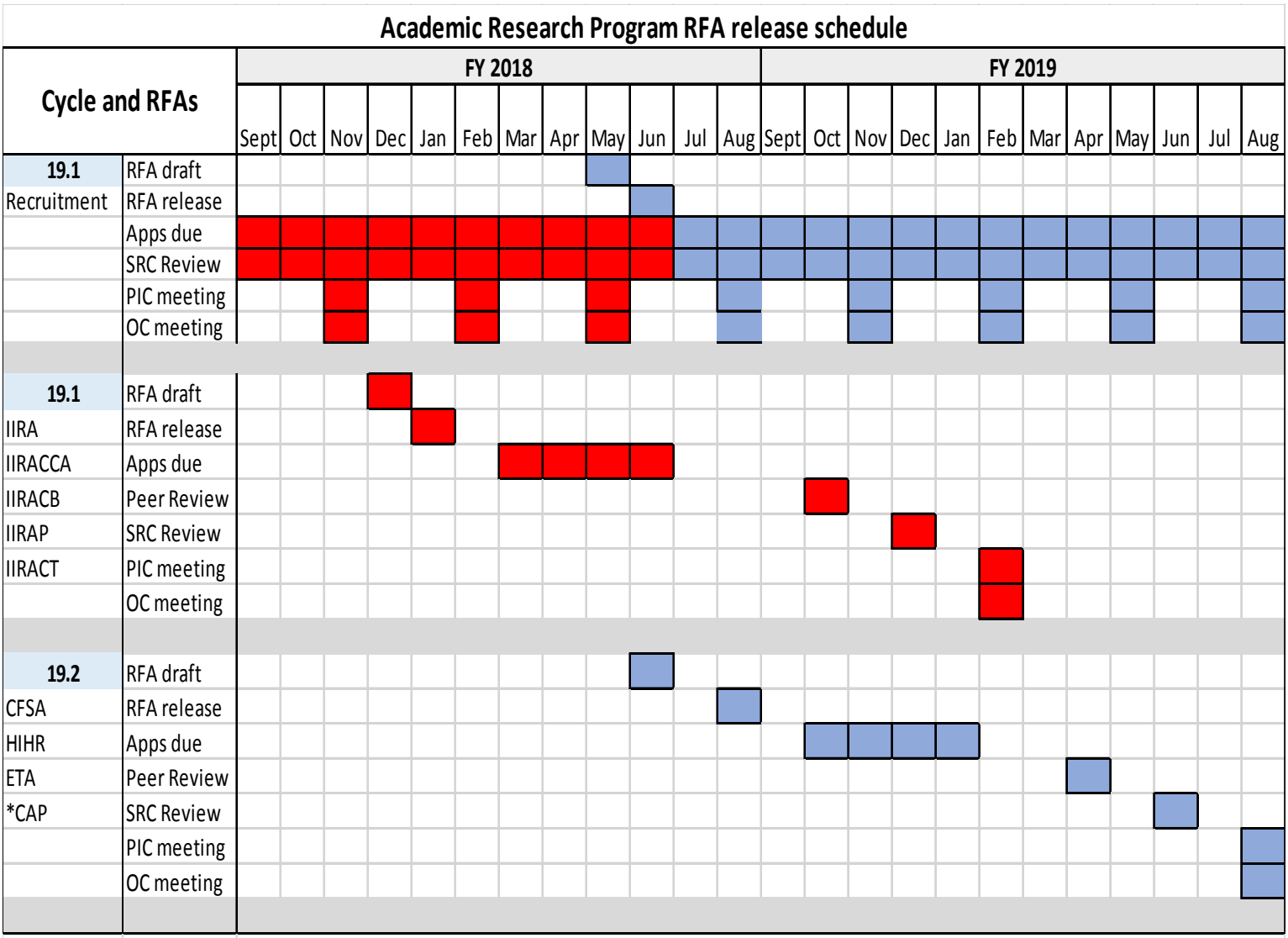
- **Recruitment of First-Time Tenure Track Faculty Members (FY19)**
  Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research.
  Award: Up to $2 million over a period of five years.

- **Core Facilities Support Awards (CFSA) (RFA R-19.2 CFSA)**
  Solicits applications from institutions to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer.
  Award: Up to $3M (total costs) for the first 2 years and up to $1M (total costs) for each subsequent year; Maximum duration: 5 years.

- **High Impact/High Risk Research Awards (HIHR) (RFA R-19.2 HIHR)**
  Provides short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.
  Award: Up to $200,000 (total costs); Maximum duration: 2 years.

- **Early Translation Awards (ETA) (RFA-R-19.2 ETA)**
  Supports projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario and preclinical toxicology and formulation to de-risk the development of lead compounds or devices. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. Presentation of a time line with stage gates for development is required. A public or private company is not eligible.
  Award: $1 to 2 million in total costs over a period of 1-2 years.

Academic Research Program RFA Release Schedule



Note:	
RED	In Process
Blue	Proposed

IIRA- Individual Investigator Research Awards, **IIRACCA-** IIRA Childhood and Adolescent Cancers
IIRACB- IIRA Computational Biology, **IIRAP-** IIRA Prevention and Early Detection, **IIRACT-** IIRA Clinical Translation
CFSA- Core Facilities Support Awards, **HIHR-** High Impact/High Risk Awards, **ETA**- Early Translation Awards
***CAP** - Collaborative Action Program to reduce liver cancer mortality in Texas (Note: RFA in development will be considered in May 2018.)

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: FEBRUARY 12, 2018

FY 2018 Cycle 1 Prevention Applications

CPRIT released four RFAs for the first review cycle of FY 2018 (18.1) in June 2017. Peer review panels met December 11 - 14 in Dallas to evaluate the thirty-four (34) prevention applications requesting $46,348,666. The Prevention Review Council (PRC) met January 18. The Oversight Committee will consider the Program Integration Committee's recommendations on February 21.

FY 2018 Cycle 2 Prevention RFAs

CPRIT released three RFAs for the second cycle of FY 2018 on June 8. Applications are due February 21 with peer review panels meeting May 22 - 25. The Oversight Committee will consider the recommendations at the August 2018 meeting. Dissemination mechanism applications are reviewed and recommended quarterly. RFAs released include:

- Evidence-Based Cancer Prevention Services (EBP)
- Tobacco Control and Lung Cancer Screening (TCL)
- Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations (EPS) – released for the first time
- Dissemination of CPRIT-Funded Cancer Control Interventions (DI)

FY 2019 Cycle 1 Prevention RFAs

The FY2019 RFA release schedule was discussed by the Oversight Committee Prevention subcommittee on February 13 and is attached for the Oversight Committee's consideration.

Other activities

Prevention program staff continue to work with Dr. Jennifer Knight on drafting the 2017 Texas Cancer Plan.

Ramona Magid, Senior Program Manager for Prevention, attended the quarterly Cancer Alliance of Texas meeting on February 8. She is the CPRIT representative on the executive committee of the alliance.

PREVENTION RFA Descriptions

Evidence-Based Cancer Prevention Services

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

Tobacco Control and Lung Cancer Screening

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

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

This award mechanism seeks to support the coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Award: Maximum of $3M; Maximum duration of 36 months.

Dissemination of CPRIT-Funded Cancer Control Interventions

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

Prevention Program RFA Release Schedule Timeline – FY 2019

		FY 2019 $28,022,956 available funds																							
		2017				2018												2019							
		Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
19.1	RFA draft																								
	RFA release																								
EPS	Apps due																								
EBP	Peer Review																								
TCL	PRC meeting																								
DI	PIC meeting																								
	OC meeting																								
19.2*	RFA draft																								
	RFA release																								
EPS	Apps due																								
EBP	Peer Review																								
TCL	PRC meeting																								
DI	PIC meeting																								
	OC meeting																								

EBP: Evidence Based Prevention Services

TCL: Tobacco Control and Lung Cancer Screening

DI: Dissemination of CPRIT Funded Interventions

EPS: Expansion to Rural and Medically Underserved Areas (includes Colorectal Cancer Coalitions)

Dependent on funds available after Feb 2019

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

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

SUBJECT: 2017 CONFERENCE EVALUATION REPORT

DATE: FEBRUARY 12, 2018

The fifth CPRIT Innovations in Cancer Prevention and Research conference was held November 11-12, 2017 at the Renaissance Hotel in Austin, Texas. A report on attendance, registrant survey results and budget for the conference follows.

Registration and attendance

Eight hundred thirty-six (836) people registered for the conference, 35 of whom were CPRIT staff. Of the 730 that answered the question about which track they were interested in attending, 382 indicated they were interested in attending the Academic Research track, 173 the Product Development Research track and 175 the Prevention track.

Survey results

A conference survey was available onsite and online. One hundred eighteen (118) responses were received for a response rate of 15%. While response rate is low, the information still gives an indication of satisfaction with the conference. The key points and themes are summarized here and the detailed survey results including comments are attached.

When asked which track they attended (some selected more than one track), 74 (63.8%) indicated the Academic Research track, 15 (12.9%) the Product Development Research track, and 50 (43.1%) the Prevention track.

Satisfaction with the conference content and speakers

Overall, the feedback regarding the content and speakers was positive. When asked for feedback about the plenary sessions, on average, 87% considered them to be excellent or above average. The presentation by Dr. Lowy on HPV received the highest rating.

The individual tracks were also rated. On Monday there was a combined Academic Research and Prevention track with 2 presentations. The sessions were considered excellent or above average by 85% of attendees. Some of the respondents indicated they felt the content was too scientific for them and they would have liked to see more targeted prevention content on the first day. The Academic Research track (3 sessions) was rated excellent to above average by 83%, the Prevention track (3 sessions) by 87% and Product Development Research track (4 sessions) by 79% of attendees. Some of the comments about Product Development Research were that a list and schedule of companies presenting would have been helpful.

Plenary sessions ranked as the most important aspect of the conference, followed by poster sessions and networking. A suggestion for the poster session was to label the poster boards as group A or B and to group the posters by topic.

We also asked for suggestions on future topics and speakers and received many ideas to consider in planning the next conference.

Conference format and location
When asked about their preferred conference format, 86% preferred CPRIT hold a 2019 Innovations Conference with a similar format and 11% preferred several smaller events around the state. In terms of location for future conferences, 37% preferred Houston, 32% Austin, 17% Dallas and 8% San Antonio.

Logistics
Themes emerging from the feedback on conference logistics indicated they would have liked more time for audience Q&A and networking. Other comments suggested the meeting space for the plenary sessions was crowded and uncomfortable and that we should seek a larger venue.

Compared to 2015, this year's attendees were satisfied with the food quantity and quality. This year, our challenge with the hotel involved the quality of their AV support. We were able to negotiate a price reduction due to the AV problems.

Communications activities

During the conference, the communications team conducted media relations efforts resulting in 12 stories in Austin and across the state, including one in Spanish language format from Univision Austin. The stories were carried in the markets of Abilene, Amarillo, Brownsville, El Paso, Lubbock, Midland-Odessa, San Angelo, Texarkana, Waco and Wichita Falls.

In addition, the team conducted on-camera interviews with 10 speakers and grantees over the course of the conference for future videos and media relations efforts in 2018. The communications team developed real-time video content for all CPRIT's social media channels including Facebook, Twitter and YouTube. Over 4,700 impressions during the conference period were made on Twitter.

Budget
Revenue from registration was projected to be $ 233,100 and current revenue collected is $251,295. Conference proceeds are still being allocated for non-credit card transactions, so this amount will increase marginally. Budgeted expenses were $376,424 and projected actual expenses are $328,209. The major expense variances (savings) from budget were in audiovisual costs and budget for unexcepted expenses that was not needed. Expenses will be offset by $20,481 in revenue from the previous conference. In summary, the net expense over revenue is estimated to be around $56,000.

Summary and Recommendations

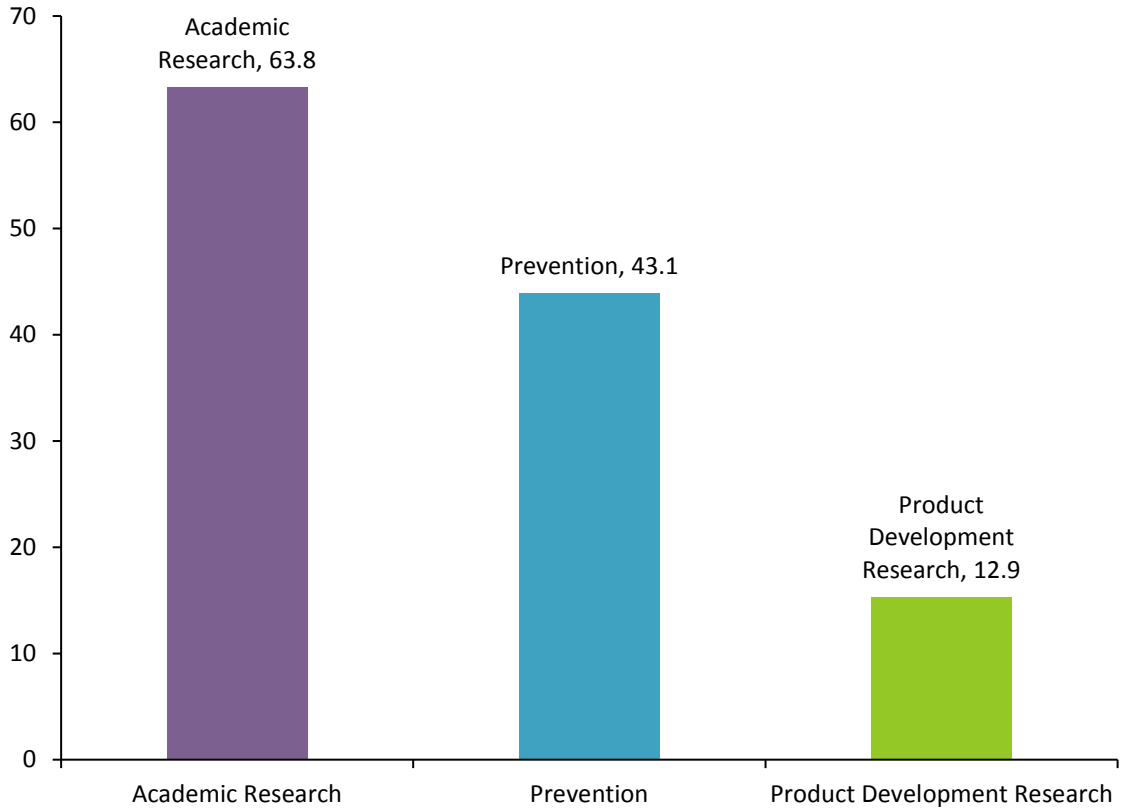
By all accounts, the 2017 conference was a success. Attendees and speakers were favorably impressed with the quality of the conference.

Considerations for the next conference include:

- In addition to having plenary speakers, consider different formats or ways to organize the sessions
-Increase formal networking opportunities
-Provide an electronic, searchable version of the abstracts in advance of the meeting
-Label the poster boards with Group A or B and group by topic

2017 CPRIT
Innovations Conference Survey Results

Which breakout track did you mostly attend?



Value	Percent	Count
Academic Research	63.8%	74
Prevention	43.1%	50
Product Development Research	12.9%	15

Rate and give us your feedback about the plenary sessions you attended both positive and negative.

	Excellent	Above Average	Average	Below Average	Poor	N/A	Responses
Precision Medicine in Cancer Prevention, Screening and Treatment: The HPV Paradigm (Dr. Douglas Lowy)	60	26	5	2	0	18	114
Evolving Developments in Immunotherapy: A Look at the Future (Moderator: Dr. Patrick Hwu)	50	31	9	2	0	22	114
When Precision Medicine Is Not So Precise (Dr. Neil Spector)	55	22	11	4	1	23	116
Diet, Obesity, Lifestyle and Cancer: Risk and Survival (Dr. Graham Colditz and Dr. Charles Fuchs)	51	37	8	4	0	15	115

Rate and give us your feedback about the plenary sessions you attended both positive and negative. - comments

- All of these talks were educational and inspirational!
- Can we have a copy of presenters' ppt slides?
- Dr. Fuchs was outstanding but not Dr. Colditz (nothing new)
- Dr. Charles Fuchs' talk, although not in my field, was my favorite talk of the conference. Great speaker, engaging, interesting data.
- I was particularly impressed by the strong case for the important effects of diet & lifestyle on cancer risk. Being that these also have a strong impact on the risks for other top health problems (cardiovascular disease, diabetes), I think that more attention should be given to promoting effective implementation of these preventive measures in our state and beyond.
- I would like to see a Registered Dietitian presenting the Diet, Obesity and Cancer-related topics.
- It would be perfect if more recent advances could be covered.
- Lovely
- My favorite session, very informative!
- Neil Spector's presentation was incredible.
- Please remind all speakers that "correlation does not imply causation" :)
- Some new content on diagnostics would have been nice.
- Specifically, Drs. Wargo, Heslof, and Walker were excellent.
- Spector was interesting and entertaining but completely off-topic and not relevant to a cancer conference
- The speakers did a good job of communicating to a diverse audience.
- These were all fantastic sessions. The speakers were knowledgeable and provocative and provided much food for thought.
- Would have preferred Dr. Spector\'s talk to be more focused on his recent research with less focus on his experience as a heart transplant patient. We got the point in 20 minutes, but it went on for 50 minutes. Dr. Colditz was good for a historical perspective, but not a good speaker. Would have been better served to hear more from Dr. Fuchs, including recent research. For all sessions, needed to be more scientifically oriented for this audience, and less oriented to lay people. The meeting organizers need to decide what the purpose of the plenary sessions is, then choose the speakers accordingly.
- Would recommend concurrent sessions because the biology related presentation was not of relevance to my research.
- Did not attend all sessions. only the first one was really appealing to my research interests.
- Honestly, all of the sessions were outstanding, really.
- This information provided me with current evidence to formulate life style changes and create opportunities for the younger generation to get a head start on avoiding cancer if possible.

Rate and give us your feedback about the Academic Research/ Prevention sessions you attended.

	Excellent	Above Average	Average	Below Average	Poor	N/A	Responses
Epigenome: Environmental Interactions - Impact on Cancer Risk and Targets for Prevention	36	29	10	2	1	25	103
Liquid Biopsies-State of Science for Early Detection, Diagnosis	26	34	8	2	0	29	99

Rate and give us your feedback about the Academic Research sessions you attended.

	Excellent	Above Average	Average	Below Average	Poor	N/A	Responses
Progress on Childhood Cancer Research	19	25	6	0	0	44	94
Update on CPRIT-Funded Core Facility Research	21	18	5	1	0	50	95
CPRIT Research RFA Funding Mechanisms	21	13	9	3	0	49	95

Rate and give us your feedback about the Prevention sessions you attended.

	Excellent	Above Average	Average	Below Average	Poor	N/A	Responses
Dissemination and Implementation Science for Cancer Control: Realizing the Potential of Discoveries	25	21	6	1	0	43	96
Approaches to Community Needs Assessment and Stakeholder Engagement	29	18	11	6	1	43	99
Dissemination and Implementation – Strategies and Examples	29	22	4	2	0	46	94

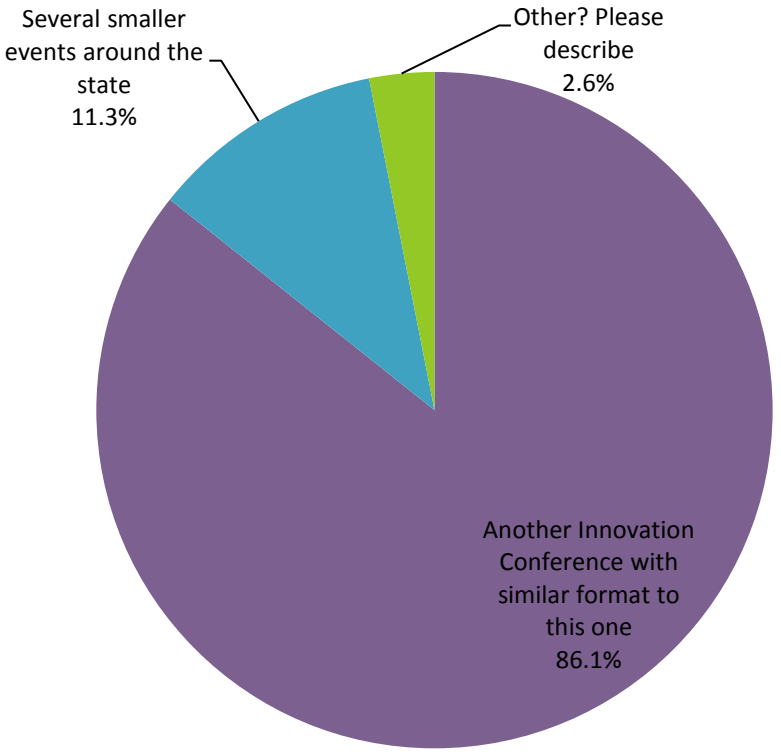
Rate and give us your feedback about the Product Development sessions you attended.

	Excellent	Above Average	Average	Below Average	Poor	N/A	Responses
Product Development Research Company Showcase	11	14	7	0	1	54	87
Clinical Trial Design	13	11	6	0	0	58	88
High Cancer Drug Prices: Causes, Patient Impact, and Potential Solutions	12	8	1	1	1	63	86
Start Up Trials and Tribulations	7	8	3	1	2	64	85

Rank in order of importance (with 1 being most important to you and 6 being least important to you) the following aspects of the CPRIT conference:

Overall Rank	Item	Score	Total Respondents
1	Plenary Speakers	430	111
2	Poster Sessions	418	106
3	Networking	401	114
4	Panel Discussions	357	105
5	Hearing from CPRIT leadership	365	104
6	Hearing progress reports from CPRIT grantees	322	103

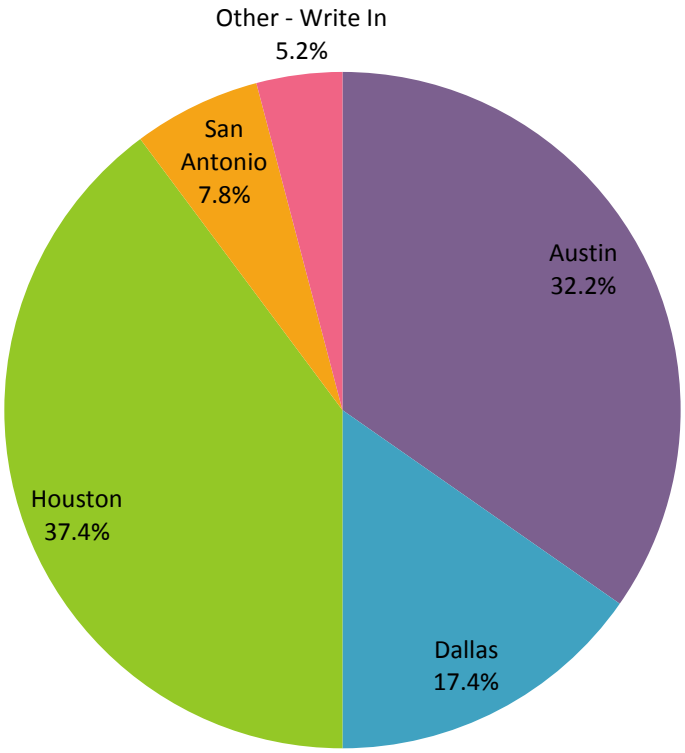
For 2019, would you prefer for CPRIT to hold (Select One):



Value	Percent	Count
Another Innovation Conference with similar format to this one	86.1%	99
Several smaller events around the state	11.3%	13
Other? Please describe	2.6%	3
	Totals	98

- An annual meeting focused on updates from grantees; CPRIT and State leadership speakers. If academic speakers, have them focus on their research and pitch to the largely scientific audience.
- Add cancer type-specific smaller meetings with more focused presentations and discussions
- Opportunity for CPRIT grantees to present best work orally

Where would you like future CPRIT conferences held?



Value	Percent	Count
Austin	32.2%	37
Dallas	17.4%	20
Houston	37.4%	43
San Antonio	7.8%	9
Other - Write In: Downtown Austin, not the Arboretum, El Paso, Open to any, including Waco or Temple, West Texas, Hawaii	5.2%	6
	Totals	115

Please list topics/sessions you would like to see covered at future CPRIT conferences.

- Imaging and drug delivery of cancer
- Cancer care delivery (health system work)
- Primary prevention Policy interventions; Obesity prevention
- I think short talks (~10 min each) should be chosen from the abstracts for one or more sessions.
- Top level scientists and researchers Success stories from CPRIT grantees
- More prevention opportunities being held at the same time as the research/science focused sessions. Day 2 was amazing because I could go to the prevention sessions instead of the research focused sessions. Day 1 was so science heavy that I couldn't get as much out of the presentations because they were so high level (rightfully so).
- The basic science sessions were very good, but perhaps we need a little more focus on patient care.
- More prevention oriented speakers (specifically on HPV vaccine), also cancer prevention intervention development and implementation, specifically.
- Preclinical models and immunotherapy combination
- Molecular mechanisms and targets of cancer metastasis
- More prevention focus at the population level
- Drug discovery in cancer treatment
- Novel drug targets for cancers
- New approaches to cancer therapies. This one focused too much on immuno-oncology. There are many novel approaches that were not really discussed, like protein therapies, new drugs, anti-cancer peptides. Additionally, it would be nice to have 1 or 2 keynotes that discuss what Core facilities are supported by CPRIT, as they can aid in many if not most projects.
- I'd like to see more on diagnostics.
- Big data / analytics.
- Cancers related to the Central Nervous System.
- Computational biology, big data
- Trials and tribulations in clinical trials More on clinical development Regulatory pathways
- Efforts, progress, opportunities, barriers, and threats regarding implementation of preventive measures. Engaging stakeholders, influencers, and decision-makers beyond health providers: legislative, commercial/business, educational institutions, community organizations, social media, etc. Particularly key influencers for prevention not typically associated with healthcare: restaurant and grocery industries' power over healthy food options and supply; entertainment industry's (TV, movies, other video media) power to promote healthy eating habits, conversations about health, screening, disease prevention, etc. Social media's role in promoting awareness of healthy habits and other preventive decisions & actions. Significant advances and disruptive innovations in therapy and diagnostics.
- Up-to-date advances in cancer research Translational and clinical trials: initiation and implementation. The Prevention track was sorely missing sessions that could be attended on Monday. The last conference I attended was in 2012 and there were presentation panels from grantees instead of all posters. I learned the most from posters and would have liked to have spoken to other poster program personnel that were scheduled at the same time as mine. The next day the posters were either taken down or no personnel to provide additional information.
- More on radiation oncology
- I would love to hear about more prevention topics, specifically on ROI and how that was done.
- Additional focus on clinical and translational science.
- Pediatric cancer
- Preclinical models and immunotherapy combination
- Survivorship

- The role of behavioral health and the changing landscape of cancer research
- Updates on prevention for various cancer sites. New screening techniques advances in cancer treatment
- For future CPRIT conferences, it would be nice to see more prevention presentations on implementation, patient navigations, and addressing barriers.
- New approaches to cancer therapies. This one focused too much on immuno-oncology. There are many novel approaches that were not really discussed, like protein therapies, new drugs, anti-cancer peptides. Additionally, it would be nice to have 1 or 2 keynotes that discuss what core facilities are supported by CPRIT, as they can aid in many if not most projects.
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- The basic science sessions were very good, but perhaps we need a little more focus on patient care.
- More focus on liver cancer and prevention, telehealth and implications for cancer prevention and treatment for underserved populations, primary care practice redesign to improve cancer prevention.
- More prevention opportunities being held at the same time as the research/science focused sessions. Day 2 was amazing because i could go to the prevention sessions instead of the research focused sessions. Day 1 was so science heavy that i couldn't get as much out of the presentations because they were so high level (rightfully so).
- Up-to-date advances in cancer research translational and clinical trials: initiation and implementation
- Prevention -topic related workshops to discuss challenges and share solutions, implementing programs, lessons learned but in interactive format - training on topics e.g. Evaluation or d and i or material development, etc. -- review of successful programs ready for implementation
- Venue: Houston - it is where the bulk of the CPRIT grant money goes and where the research is conducted. For topics: see above - focus on what it takes to get a CPRIT grant and progress reports by grantees. Posters, although nice, could be optional. No one had the time to see them all.
- More prevention oriented speakers (specifically on HPV vaccine), also cancer prevention intervention development and implementation, specifically.
- Efforts, progress, opportunities, barriers, and threats regarding implementation of preventive measures. Engaging stakeholders, influencers, and decision-makers beyond health providers: legislative, commercial/business, educational institutions, community organizations, social media, etc. Particularly key influencers for prevention not typically associated with healthcare: restaurant and grocery industries' power over healthy food options and supply; entertainment industry's (tv, movies, other video media) power to promote healthy eating habits, conversations about health, screening, disease prevention, etc. Social media's role in promoting awareness of healthy habits and other preventive decisions & actions. Significant advances and disruptive innovations in therapy and diagnostics.

Who would you like to see as a keynote speaker at the next CPRIT conference?

- Dr. James Allison
- Many speakers in the prevention track mentioned articles by Russ Glasgow and his RE-AIM approach. Steven Woolf was also mentioned several times.
- Giulio F. Draetta, MD, PhD
- Peter Davies
- Speakers from other NCI-designated comprehensive cancer centers than in Texas
- Someone from NCI that can speak to their research priorities.

- A benefactor of a CPRIT grant, i.e. someone who receives services. Bring the human side of the grant world into light. While research may be exciting, ultimately, hearing how someone has benefitted from it is what drives most people in this field to continue the work.
- Dr. David Grosshans, Dr. Radhe Mohan
- Dr. Richard Wender
- Norman E. "Ned" Sharpless, MD
- Jerry Shay
- Walter Willette Steven Clinton, MD PHD, Robert Chapkin, Robert Waterland
- Atul Gawande
- Anyone from Forks Over Knives studies.
- Basic scientist but also someone doing T3-T4 (really community based research).
- Maria Fernandez, PhD
- Encourage speakers from TX to be keynote.

Other Comments/Suggestions:

- Product development needed breaks and be better organized. There was no list of the presentations and order. Tables in the back were useless.
- As noted above, the networking opportunities are the biggest plus for this meeting, so perhaps lengthen the breaks between sessions by 5 minutes or so
    - I strongly encourage you to continue the sit-down lunch provided: in years past we wasted a lot of time standing in line for a buffet, but this year the networking opportunities were enhanced by the way lunch was provided
    - Would like a lot more "brainstorming time with some of the great speakers this year; by the time they were finished with their lectures or mini-lectures, there was little time for Q&A, and a large ballroom setting might not be conducive to give-and-take with audience members. Perhaps we could have a panel of great speakers (e.g., Drs. Hwu, Wargo, Heslof, Walker in a smaller venue where audience members could really bore down on specific issues...
    - For poster sessions, since all posters were up from the beginning (which was a great idea!), I would suggest adding a "Session A" or "Session B" label to each poster number on the board. It was sometimes unclear if the presenter had decided to not stand by his/her poster or if it was in a different session. It would be nice to have that visually indicated so that we can note which posters to come back for on the next session. Often, interest is piqued as we are walking by, not just via the abstracts printed in the conference book. (Something simple like "157A" to indicate poster 157, Session A.
    - Please try to balance out Research and Prevention speakers. Most prevention sessions were on the second day. For those of us who had to leave earlier, this didn't leave much time to learn about topics relevant to us. Quite honestly, I didn't really attend any sessions other than the opening speaker on the first day for this reason.
    - Overall, this was a great conference and good
- I would have loved a soup instead of salad for lunches. I liked the product development showcase, and this should be continued.
- A bigger space should be considered for next year, or a better layout of the seating. It was very crowded and uncomfortable.
- CPRIT is building a wonderful CV of new recruits to the state of Texas, other external funding brought in, publications, discoveries, community impacts, etc. But, I think one important outcome of CPRIT is being largely ignored. A wealth of digital data (primarily genome, proteome, etc) is being produced under CPRIT, and represents a massive opportunity for retrospective studies. We desperately need a platform to make these data shareable and public to other researchers. (Similar to NIH's Cancer Genome Atlas or Genome Data Commons).
- Publish agenda more in advance to determine whether to allocate resources to attend both days.

- Excellent conference! Well run and outstanding speakers.
- Mike Lang does an excellent job of officiating; good experience, personality, strikes the right tone. However, the Product Development section needs an overhaul to get me to attend again:
    - List the companies that will be presenting, by time, so that the audience knows 'who' is speaking 'when.
    - Focus on progress of these companies: how did they achieve their award, what did they do wrong, what did they do right that tipped them over the top, impart the progress that has been made, step by step, since their award was made. These are only 3-year funding opportunities, so should not be difficult to focus their talks accordingly. Lastly, put it all in perspective of value inflection; where were they when they started, where are they now, what partnerships, funding have they been able to make, how is their exit strategy progressing, changing based on initial thoughts, etc. In other words, pitch the presentation to help future potential grantees achieve their goals and the state to realize the value their investment has made. I did not see any of this in these presentations.
- Great conference. Everything flowed really well. You had a great schedule of people and allowed them to speak with enough time to explain their progress and their efforts. I appreciated hearing about their studies. I think I would like to see more prevention programs to note their challenges and progress as well. Also, I would love to see more diet and exercise information shared from research perspectives.
- Poster session needs a major re-vamp. Suggestions:
    - Arrange posters by topic, and clearly delineate at the session and in abstract book
    - Display posters from session 1 and 2 in separate areas, do not mix together, you basically had to go through the whole area each day, it was too much.
    - Have searchable abstracts,
- Integration of Research and Product Development is critical. E.g. product development area adjacent to poster sessions. Early career professionals most need exposure to the product development track since the vast majority of them will need to find jobs outside academia. The distant location of the product development track and lack of any information on that track in the book resulted in a missed an opportunity to give them that exposure.
- Conference room is not good. It is very hard to view the presentation from back or from middle. Additional monitors in the room (one in the middle section of the conference room) would certainly help.
- If feasible, I think 1-2 sessions of small niche groups (~50 people) with panel discussions would be fantastic. The second day was an overwhelming amount of talks and would have been broken up well by a panel discussion type lecture.
- The complimentary breakfast was much appreciated, as was free Wi-Fi I room (came with my Marriot rewards membership). It was irksome to be changed for parking, when the CPRIT handout stated it would be free!
- Lunch was nice however food at poster reception could have more of a cancer prevention focus (no cured meats, more veggies). More breakfast on day 1. Limited prevention focus until day 2, so I felt there was less for me.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	COMMUNICATIONS UPDATE
DATE:	FEBRUARY 21, 2018

The following is an overview of the agency's communication activities through February 21, 2017.

Earned Media

CPRIT was the subject of coverage in the local Austin media market as a result of the American Cancer Society Can Action Network's (ACS CAN) forum about CPRIT at the UT Dell Medical School on November 29, 2017. CPRIT Chief Scientific Officer Jim Willson was interviewed as well as CPRIT grantees Jonathan Sessler and Thomas Yankeelove of The University of Texas at Austin. Cam Scott of ACS CAN hosted the forum and was interviewed, and Senator Kirk Watson was quoted when he spoke at the forum.

Grant Awards Announcement: Following the Oversight Committee's approval of grant awards at its November 29 meeting, CPRIT distributed a press release to local, regional and national outlets announcing 4 grants through its Scholars program.

Coverage: (November 15, 2017 – February 12, 2018)

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

Coverage Highlights: (see clipped articles following report)

- November 29, 2017, *KXAN, NBC Austin*, Could Taxpayer-funded Cancer Research End in Texas?
- November 29, 2017, *Spectrum News Austin,* Time Could be Running Out For Texas' Cancer Research Initiative
- November 29, 2017, *KTBC, FOX Austin*, UT Cancer Research Leaders Request Legislators Take a Look at Additional Funding
- January 10, 2018, *Anahuac Progress*, The Rose receives $1.3 million to expand women's breast healthcare in 38 Texas counties

- January 11, 2018, *ScienMag Science Magazine*, Researchers Demonstrate RAS Dimers Are Essential For Cancer
- January 18, 2018, *The ASCO Post*, Presurgical Targeted Therapy Delays Relapse of High-Risk Stage III Melanoma
- January 25, 2018, *BioSpace*, What You Need to Know About Immune-Onc Therapeutics
- January 25, 2018, *Texas Monthly*, Here Come the MedTech Makers
- February 6, 2018, *Houston Business Journal*, Here are the Houston Stocks that were Walloped during the Market's Drop

Cancer Awareness Months

Cancer Prevention Awareness Month-February

- Communications is working with Baylor College of Medicine, The University of Texas Medical Branch and Hope Clinic on earned media in Houston for Cancer Prevention Awareness Month. As of date, Univision has agreed to work with us and we are reaching out to other Houston stations.
- Short videos of grantee interviews for social media will also be created and distributed for Cancer Prevention Awareness month.

National Cancer Research Month-May

- Ann Tanabe, CEO of BioHouston was interviewed as part of a video for National Cancer Research Month which will be pitched to media in Houston and used for social media.
- Houston Mayor Pro Tem Ellen Cohen will present a proclamation recognizing National Cancer Research Month before the City Council in early May. CPRIT partner institutions plan to have researchers and leadership representatives attend. Mayor Sylvester Turner will also be present. We are working with the institutions on a media strategy for the event.
- The Texas Medical Center's TMC Pulse Magazine has agreed to publish a story featuring CPRIT and cancer research in its May edition.

Other Activities

- Plans are being made to interview patients who have benefited from the work of CPRIT researchers. These include patients treated at The University of Texas Southwestern Medical Center, Baylor College of Medicine and The University of Texas MD Anderson Cancer Center.
- An interview with Jinming Gao and Baran Sumer of The University of Texas Southwestern Medical Center/OncoNano is planned for National Oral, Head, and Neck Cancer Awareness Week (April 8–15).
- Chris Cutrone is supporting media relations efforts ahead of a press conference to announce Shrikanth Gadad's CPRIT recruitment grant to Texas Tech Health Sciences Center at El Paso in conjunction with the Texas Tech University System Regents' meeting in El Paso March 1-2.

- Communications staff met Univision’s leadership staff in Houston on February 1. Topics included how Univision can work with CPRIT and its grantees to inform the community of available cancer prevention resources.

Social media:

Facebook (last 28 days):

- Reach: 861
- Engagement: 178
- Most popular post: ICYMI: CPRIT grantee Salarius Pharmaceuticals is mentioned in the "Here Come the Med-Tech Makers" section of this Texas Monthly article: https://www.texasmonthly.com/articles/the-most-innovative-people-in-texas.

Twitter

- 6,400 impressions over entire month
- Top tweet: Watch @bcmhouston Dr. Anderson discuss cervical cancer screenings and CPRIT's support: https://cprit.us/2rIeiMU. #cervicalcancerawarenessmon

TIME COULD BE RUNNING OUT FOR TEXAS' CANCER RESEARCH INITIATIVE

By Max Gorden | November 29, 2017 @8:05 PM

STATEWIDE — With the clock running on funding, health care leaders are urging the state to keep paying for cancer research.

Industry experts met Wednesday to discuss the future of the Cancer Prevention and Research Institute of Texas, or CPRIT.

The agency was approved by voters ten years ago, and has since pumped about $2 billion into finding cures.

But some lawmakers are calling for CPRIT to become self-sufficient, a move institute leaders say doesn't fit with its mission of high-risk discovery research.

"This is not an area where self-sufficiency or support from major pharmacutical industry is really going to be realized," said CPRIT Chief Scientific Officer Dr. Jim Willson

CPRIT has about a billion more left to award. However, CPRIT leaders say so far they've already spurred nearly $8 billion in business activity here in Texas because of their grants.

And while some lawmakers are calling for it to be self-sufficient, the program has maintained the support of other lawmakers like Sen. Kirk Watson, D-Austin, who attended Wedneday's forum.

"People need to know what the value of CPRIT has been," Watson said.

For cancer researcher Tom Yankeelov, who models cancers at UT, getting rid of the institute would be a huge blow to Texas.

"I think it's difficult to overstate the significance of CPRIT," Yankeelov said.

http://spectrumlocalnews.com/tx/austin/news/2017/11/30/time-could-be-running-out-for-texas--cancer-research-initiative-

kxan IN-DEPTH. INVESTIGATIVE.

Could taxpayer-funded cancer research end in Texas?

By Kate Weldaw
Published: November 29, 2017, 5:58 am | Updated: November 29, 2017, 10:27 am

Related Coverage

CPRIT enters 10th year of working with cancer research

Affidavit: CPRIT probe didn't target Gov. Rick Perry

AUSTIN (KXAN) — A big debate on how state tax money is spent to fund cancer research heads to UT Dell Medical School Wednesday, after accusations that millions of dollars was mismanaged. Sen. Kirk Watson and officials from CPRIT and UT researchers will talk about whether funding should continue for the Cancer Prevention Research Institute of Texas.

In 2007, voters approved $3 billion in funding for CPRIT. The first grants were handed out in 2009 with funding coming to an end in 2022. Dr. Jonathan Sessler, a professor of chemistry and biochemistry and the University of Texas says the funding has put Texas on the map as the leading state researching a cure for cancer.

"It's made us the center, the best in the world," Sessler said. "The best of the best want to come here and are coming here — those of us who are here are not being lured away. It has made cancer the prime research focus."

It has also created more than 11,000 jobs, and UT brought 12 top researchers in who have received a combined $74 million in funding from CPRIT. New vaccines, drugs and a device called a cancer pen that can detect skin cancer have been developed.

But, CPRIT made headlines in 2012 when more than $50 million dollars in grants were mismanaged. That led to Sen. Charles Schwertner (R) Georgetown sponsoring a bill during the 2015 legislation session calling on CPRIT to become self-sufficient with its funding in the future. While it didn't pass, it was a signal lawmakers might not want to renew it.

Some point to new leadership at CPRIT since the 2012 mismanagement that now holds the funding accountable.

"It uses a peer-reviewed process that is second to none. It uses peer reviewers from out of state to make sure there isn't any unfair bias within the state of Texas," says Cam Scott, senior director of Texas Government Relations with the American Cancer Society.

Another question from lawmakers is whether enough tangible treatments have been created from the funding. Dr. Sessler, a three-time cancer survivor, says developing new cancer drugs takes time.

"It takes $1 billion to $2 billion to develop a cancer drug and it takes a decade or a decade and a half to develop," Sessler said. "The goal of CPRIT should not be a pharmaceutical company."

The American Cancer Society polled 800 Texas voters to determine whether there was support for continued funding of CPRIT and found 74 percent of respondents supported it.

Lawmakers will likely decide next session whether to provide additional funding. Leaders will meet at the UT Dell Medical School Wednesday from 2 to 4 p.m. to discuss the matter. The public is invited to attend.

http://kxan.com/2017/11/29/could-taxpayer-funded-cancer-research-end-in-texas/

UT cancer research leaders request legislators take a look at additional funding

Tax-payer cancer research funding is dwindling.

The Cancer Prevention Research Institute of Texas is predicting by 2023 they will have used all tax-payer funds that is why they are looking towards legislators to acquire additional funding.

Wednesday cancer research leaders and legislators discussed the future of research funding at UT Dell Medical School. UT Chemistry professor Dr. Jonathan Sessler shared his battle with cancer when he was a teenager.

"I was treated by radiation but then relapsed and few years later I went through a whole cycle of really nasty chemo therapy," Dr, Sessler said. "The nausea drugs were not very good in those days and I basically spent a year in bed vomiting."

It was then he said a good physician from Stanford told him, "You're a chemist. Find new cancer drugs." So he did. In 2016 he was named UT's 2016 Inventor of the Year.

His research has led to more than 75 U.S patents, a discovery of a new class of molecules and helped start up the biotech company Pharmacylics. "We are going to be the Houston Astros of Cancer a long time of frustration followed by wonderful success," said Sessler.

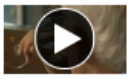
Sessler is among many UT researchers receiving funding by CPRIT.

The debate on whether or not tax-payers should fund cancer research comes a few years after CPRIT had more than 50 million dollars in grants mismanaged. An error Cam Scott Senior Director of Government Relations for the American Cancer Society said the agency has been working to ensure doesn't happen again.

"We are going to have a decision to make about whether to continue in investing in this work that has put Texas in the forefront of cancer research or let promising scientific research sit on the shelves and collect dust," Scott said. "CIPRIT is now the model of accountability a model of transparency and really other state agencies could model off the work that CIPRIT does to make sure it's doing everything just right."

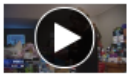
The American Cancer Society will host a policy forum series at several other institutions across the state to help start the conversation on cancer research funding.

Related Headlines


Alcohol linked to cancer


Daily Greens gives back for Breast Cancer...


Breast Cancer Awareness: A Story of Survival


Sadie's Sleigh helping bring Christmas to kids


Weight gain may increase cancer risk

http://www.fox7austin.com/news/local-news/ut-cancer-research-leaders-request-legislators-take-a-look-at-additional-funding

THE PROGRESS Anahuac

The Rose receives $1.3 million to expand women's breast healthcare in 38 Texas counties

When Maria found a lump in her breast, her first concern was her family and how would they manage without her. She was uninsured and did not have the resources for an exam. A friend referred her to The Rose, where she received a complete diagnostic workup. All of her medical services, including a diagnostic mammogram, ultrasound,

biopsy and physician examination, were made possible by a Cancer Prevention Research Institute of Texas (CPRIT) grant, services that she could not afford but services that were too critical to delay.

Once diagnosed, other programs at The Rose moved her into treatment. At 42 years old with stage 2 ductal carcinoma, her prognosis is excellent.

Maria was one of 4,109 women, from 34 Texas counties, who The Rose served from Sept. 2015 to Aug. 2017 through a previous CPRIT grant funding The Rose's Empower Her® Sponsorship Program .

The Rose receives $1.3 million to expand women's breast healthcare in 38 Texas counties

The Rose's Grants and Compliance Manager, Trina Hans,

at 2017 Innovations in Cancer Prevention and Research Conference

"Breast cancer doesn't discriminate, whether a woman is 42 or 82, insured or uninsured, she deserves access to annual screening which in turn means early detection and longer survival," said Dorothy Gibbons , CEO and Co-Founder of The Rose. "Unfortunately, 68 percent of uninsured women do not receive regular breast health screenings, which results in late stage cancer and a higher mortality rate."

Recently, The Rose was awarded an additional $1.3 million by CPRIT to extend breast cancer screening services from 34 to 38 Texas counties. The grant also enables The Rose to serve 2,767 underserved women who would otherwise delay or skip their breast cancer screening because of barriers such as distance and finances.

"Women in rural Texas counties have greater access-to-care barriers and are more likely to have breast cancer diagnosed at a late stage, which in some cases is fatal. Since 2010, CPRIT grants have made it possible to serve women in outlying counties through our Mobile Mammography Program. Over these past seven years, hundreds of lives have been saved," Gibbons said.

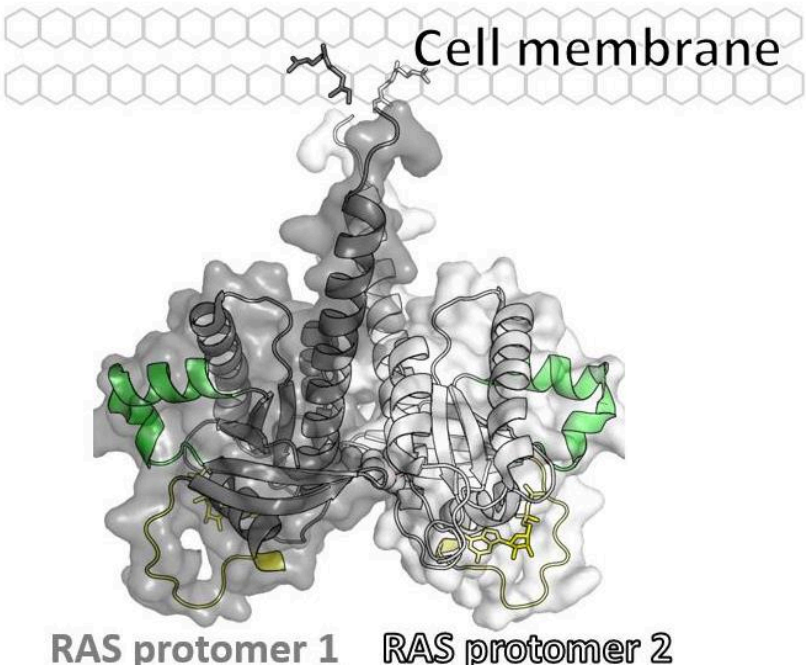
The Rose recently added a Mobile Mammography Health Coach to its mobile fleet to meet the increased demand for screening services and provide state-of-the-art 3D mammography imaging. The Coach is equipped with a separate medical examination suite where collaborating partners provide other vital health screenings. The 40 ft. self-contained Coach is ideal for businesses, school districts, civic centers, community clinics and physician offices. It offers

convenience and quality breast health services. For more information, or to donate or volunteer, please visit www.therose.org . To schedule interviews, please contact Mageida Sopon at 832-310-5124 or mageida@medley-inc.com .

http://www.thevindicator.com/anahuac_progress/news/article_3332d290-f57b-11e7-9247-4b093d9f14b0.html

SCIENMAG
Science Magazine

Researchers Demonstrate RAS Dimers Are Essential For Cancer



Credit: UT Southwestern

DALLAS – Jan. 11, 2018 – Mutated RAS genes are some of the most common genetic drivers of cancer, especially in aggressive cancers like pancreatic and lung cancer, but no medicines that target RAS are available despite decades of effort.

Researchers at UT Southwestern's Simmons Cancer Center have shown that RAS molecules act in pairs, known as dimers, to cause cancer, findings that could help guide them to a treatment.

"RAS mutations are one of the most common causes of cancer and there are no options for attacking them. The dimerization activity of RAS gives us a solid lead for moving forward," said Dr. Kenneth Westover, Assistant Professor of Radiation Oncology and Biochemistry with the Harold C. Simmons Comprehensive Cancer Center at UT Southwestern Medical Center, which is recognizing its 75th anniversary this year.

The question of RAS dimerization has been hotly debated, he said, but researchers previously haven't been able to prove what RAS dimers look like, limiting the ability to design experiments that assess their importance in normal physiology and cancer. The UT Southwestern team led by Dr. Westover used X-ray crystallography data to predict what a RAS dimer might look like, then tested the model in cells using a method called fluorescence resonance energy transfer (FRET) to show when RAS forms dimers and when it does not.

The study, published in the journal *Cell*, provides a foundation for further studies that delve into RAS biology and could potentially pave the way to develop new cancer drugs that target RAS dimerization.

"The primary function of RAS is to transmit signals that tell a cell to grow and divide, a pathway commonly hijacked in cancer. What became clear in our studies is that RAS needs to dimerize to efficiently pass signals in cells. Moreover, RAS dimerization appears to be a crucial event for mutated forms of RAS to cause cancer," said Dr. Westover, part of the Simmons Lung Cancer Team.

Members of the Westover research lab teamed up with researchers from the Dana Farber Cancer Institute to show that RAS dimers are essential in a number of cancer cell systems and animal models of cancer.

This work was supported by The US Department of Defense, V Foundation for Cancer Research, and the Cancer Prevention and Research Institute of Texas.

The Harold C. Simmons Comprehensive Cancer Center is the only NCI-designated Comprehensive Cancer Center in North Texas and one of just 47 NCI-designated Comprehensive Cancer Centers in the nation. Simmons Cancer Center includes 13 major cancer care programs. In addition, the Center's education and training programs support and develop the next generation of cancer researchers and clinicians. Simmons Cancer Center is among only 30 U.S. cancer research centers to be designated by the NCI as a National Clinical Trials Network Lead Academic Participating Site.

The ASCO Post

Presurgical Targeted Therapy Delays Relapse of High-Risk Stage III Melanoma

Key Points

- All seven patients treated with standard of care surgery had their disease progress, with median time to progression at 2.9 months.
- Of 14 patients randomized to the neoadjuvant combination, 4 progressed, with median time to progression of 19.7 months.
- Of the seven patients who achieved a pathologic complete response after presurgical therapy, none experienced distant disease relapse.

A pair of targeted therapies given before and after surgery for melanoma produced at least a sixfold increase in time to progression compared to standard-of-care surgery for patients with stage III disease, Amaria et al reported in *The Lancet Oncology*. Patients who had no sign of disease at surgery after combination treatment did not progress to metastasis.

Early results of the study comparing surgery to pre- and post-surgical treatment with the BRAF inhibitor dabrafenib (Tafinlar) and the MEK inhibitor (Mekinist) trametinib were so strikingly positive that MD Anderson's data safety monitoring board ordered the randomized, prospective phase II trial halted and changed to a single-arm using the combination.

"These results are encouraging for patients with surgically resectable stage III melanoma, who face a high rate of relapse and progression to metastatic disease," said lead author **Rodabe Amaria, MD**, Assistant Professor of Melanoma Medical Oncology at MD Anderson. "Our proof-of-concept study strongly supports further assessment of neoadjuvant therapy for this high-risk population, which has a 5-year survival rate of less than 50%."

The targeted combination is approved by the U.S. Food and Drug Administration for stage IV metastatic melanoma that features a *BRAF* V600 mutation. Dr. Amaria, senior author **Jennifer Wargo, MD**, Associate Professor of Surgical Oncology and Genomic Medicine, and colleagues hypothesized that the combination could help patients with stage III *BRAF*-mutant disease.

Trial Findings

The trial was designed to enroll 84 patients randomized to either upfront surgery or to 8 weeks of the targeted combination followed by surgery and another 44 weeks of combination treatment. An interim data analysis occurred after 21 patients were treated.

At a median follow-up time of 18.6 months:

- All seven patients treated with standard of care surgery had their disease progress, with median time to progression at 2.9 months.
- Of 14 randomized to the neoadjuvant combination, 4 progressed, with median time to progression of 19.7 months.
- Of the 7 patients who achieved a pathologic complete response after presurgical therapy, none experienced distant disease relapse.
- Median overall survival had not been reached in either arm.

Importance of Pathologic Complete Response

Reaching pathologic complete response appears to be a powerful indicator of treatment success, Dr. Amaria said. Twelve patients in the neoadjuvant group proceeded to surgery, with seven achieving pathologic complete response. Only one relapsed, with a small tumor in the same area as the original tumor. Three patients who reached a partial pathologic response relapsed, with all developing brain metastases, a common risk in *BRAF*-positive disease.

"As we accumulate more data, we can further explore the importance of pathologic complete response," Dr. Wargo said. "If we can prove that pathologic complete response is important in achieving superior outcomes, then the next step is to ask 'what can you do to get to [pathologic complete response]?'"

Biopsies and blood samples taken in the trial allowed the team to begin to address those issues.

- Patients that did not reach pathologic complete response had tumors with high levels of phosphorylated ERK, a growth-promoting protein in the MEK pathway, before combination treatment began.
- Research has shown evidence of an immune response in successful treatment with BRAF inhibitors, even though these drugs are not explicitly immunotherapies. The team found penetration of tumors by CD8-positive T cells in pathologic complete response patients, but evidence of T-cell exhaustion in tumors of patients who did not reach pathologic complete response. Two checkpoint proteins that stifle immune response, TIM3 and LAG3, were found in abundance on T cells in those patients.
- Whole-exome sequencing revealed no significant difference in mutational load or copy-number alterations at baseline between responders and nonresponders. However, those who did not reach pathologic complete response often had known genetic aberrations that cause resistance to the combination.

These differences provide pathways for larger, additional studies and point to possible combination therapy approaches. Since the original trial was halted, 11 patients have enrolled in the neoadjuvant study.

Toxicities from the combination were primarily grade 1 and 2 side effects expected with dabrafenib and trametinib, most commonly chills, headache, and fever. There were eight grade 3 events, no grade 4 events, and no deaths related to treatment. Two patients in the surgical arm and one in the neoadjuvant arm died from disease progression.

Those in the standard-of-care surgery arm were offered a variety of adjuvant therapies, including interferon-alpha, the checkpoint blockade drug ipilimumab (Yervoy), biochemotherapy, or observation. Existing adjuvant therapies at the time the trial was enrolling had extremely low response rates as well as harsh side effects, Dr. Amaria said. Only one patient chose to have postsurgical therapy in that arm.

Novartis Pharmaceuticals provided drugs and funded the clinical aspects of the study, but played no role in study design, execution, data collection, analysis, or interpretation. Correlative studies of tumors and blood samples were funded by the Cancer Prevention and Research Institute of Texas, MD Anderson's Melanoma Moon Shot, and the Dr. Miriam and Sheldon G. Adelson Medical Research Foundation.

http://www.ascopost.com/News/58460

What You Need to Know About Immune-Onc Therapeutics

Published: Jan 25, 2018 | By Mark Terry

Immune-Onc Therapeutics launched in September 2016 and is headquartered in Palo Alto, Calif., where it focuses on developing therapeutic antibodies for immuno-oncology treatments.

The company has inked licensing deals with **Albert Einstein College of Medicine**, **Memorial Sloan Kettering Cancer Center**, **The University of Texas Health Science Center at Houston** and **The University of Texas Southwestern Medical Center.** In addition, in June 2017, it was selected to participate in the **StartX Med Accelerator Summer 2017 Program.** StartX is a **Stanford University**-affiliated nonprofit organization.

Charlene Liao, Immune-Onc Therapeutics's chief executive officer, president and co-founder, told **BioSpace,** "As the name suggests, it is a company focused on advancing first-in-class immuno-oncology therapeutics to improve the lives of patients with cancer. Our scientific framework emphasizes targeting immune-suppressive cells to mobilize the host's systemic immunity. We believe we hold the keys to some of the crucial immune-suppressive cell types in the tumor microenvironment."

Company Leadership

Charlene Liao – Chief Executive Officer, President and Co-Founder. Prior to founding Immune-Onc, Liao was Project Team Leader, Portfolio Management and Operations with **Genentech**. Prior to joining Genentech, she was Director of Business Development for **Rigel**.

Guo-Liang Yu – Co-Founder. Guo-Liang Yu is the founding president of the **Chinese Biopharmaceutical Association**.

Company Financing

The company launched with a $7 million Series A financing. Major investors included **Fame Mount Limited** and **CLI Ventures.** "Immuno-oncology drugs are transforming cancer care worldwide," Liao said in a statement. "We are grateful for the support of our Series A investors who share our vision to pursue novel therapeutic antibodies targeting the immune system and tumor microenvironment. Our immune-oncology programs leverage the latest scientific insights to advance new treatment options for cancer patients."

Liao told BioSpace that the company is actively discussing a Series B financing with leading venture capital firms.

Pipeline

In a June statement, **Andrew Lee,** the co-founder of StartX Med said, "Immune-Onc is developing a strong portfolio of innovative immuno-oncology drugs with first-in-class potential. With the wealth of industry expertise in drug discovery and development coupled with relentless focus on execution, they will be achieving exciting new milestones while working with StartX."

Liao said, "Since the inception of our company, we have built an impressive pipeline of innovative immuno-oncology drugs with first-in-class potential. Our lead program is in IND-enabling stage, with anticipated IND in the first half of 2019. It is a novel therapeutic antibody for the treatment of acute myeloid leukemia (AML), with the possibility to expand to solid tumors."

Market Competition

For several years, now immuno-oncology has been the hot area in oncology treatment. According to the **Pharmaceutical Research and Manufacturers of America** there were more than 240 immuno-oncology treatments in development. One of the big developments of 2017 was when **Gilead** shortly after acquiring **Kite Pharma** had its CAR-T immuno-oncology product, Yescarta, approved by the **U.S. Food and Drug Administration.** Not long after, **Novartis'** Kymriah, another CAR-T product, was approved by the FDA. There are numerous companies, big and small, working in this area.

"We believe we have a lead position in developing novel therapeutics against a family of targets that are expressed in myeloid cells, among others," Liao told BioSpace. "Therefore, our competitors could be companies with active programs targeting myeloid derived immune suppressive cells (MDSC)."

Dollars and Deals

In March 2017, Immune-Onc signed an exclusive worldwide license deal with Albert Einstein College of Medicine and Memorial Sloan Kettering Cancer Center. Under the terms of the agreement, Immune-Onc acquired the exclusive global rights to develop and commercialize novel biotherapeutics for cancer immunotherapy and other diseases. In addition, Immune-Onc and the Albert Einstein College of Medicine launched a multi-year research collaboration to identify and develop a new generation of biotherapeutics that modulate the immune system.

In a statement, Liao said, "Einstein is recognized globally as a premier medical institution focused on discovery and translation of innovative biomedical research to clinical applications. MSK is the world's oldest and largest private cancer center and is renowned for having successfully produced nine U.S. FDA approved drugs. Immune-Onc is very pleased to license innovative biotherapeutic candidates from Einstein and MSK. We are honored to partner with world-class investigators at Einstein to provide new treatment options for cancer patients in the near future."

In April 2017, the company signed a license and collaboration agreement with The University of Texas Health Science Center at Houston and The University of Texas Southwestern Medical Center. Under that deal, Immune-Onc acquired the exclusive global rights to develop and commercialize novel biotherapeutics with applications in cancer and other diseases. It also has a multi-year research collaboration with UTHealth and UTSW to develop biotherapeutics. It will leverage the Cancer Prevention & Research Institute of Texas Therapeutic Monoclonal Antibody Lead Optimization and Development Core Facility at UTHealth to advance lead antibodies from academic labs.

What to Look For

The company hopes to move into the clinic in 2019. Liao noted, "Acute myeloid leukemia is the most common type of acute leukemia in adults. Our lead program in AML offers a fast-to-market development path to address this significant unmet medical need. Immune-Onc has assembled a strong team of drug development experts from leading biopharmaceutical companies. With the wealth of industry expertise in drug discovery and development coupled with relentless focus on execution, we will be achieving exciting new milestones."

See **Top Life Science Startups 2018**
See **Top Life Science Startups 2017**
See **Top Life Science Startups 2016**
See **Top Life Science Startups 2015**

https://www.biospace.com/article/exclusive-what-you-need-to-know-about-immune-onc-therapeutics/

TexasMonthly

15 Innovators Reshaping Texas

Here Come the Med-Tech Makers

Procyrion is far from the only ambitious start-up to emerge from the effort to build a thriving med-tech and biotech scene in Texas. In Houston, **IntuiTap** is developing an imaging gadget that aims to take the guesswork (and some of the pain) out of spinal taps. In Austin, **TeVido BioDevices,** which was co-founded by a UT–El Paso professor, hopes to help breast cancer survivors by creating new nipples using 3-D bioprinters.

Illustration by Tim Tomkinson

One of the most promising signs for the industry is that start-ups are relocating here to grow their companies. **Salarius Pharmaceuticals,** which is developing epigenetic drugs to tackle rare childhood cancers, was lured to Houston in 2016 from Utah by an $18.7 million grant from the Cancer Prevention and Research Institute of Texas and a residency at the Texas Medical Center.

HOUSTON BUSINESS JOURNAL

Feb 6, 2018,

Here are the Houston stocks that were walloped during the market's drop (update)

Update: This story and its slides have been updated to reflect stock prices ending on Feb. 5.

U.S. and global stock markets are suffering, according to the Financial Times and The New York Times. Many Houston companies aren't faring so well, either.

Out of the 132 public companies with headquarters in the Houston area, a market cap of $100 million and a minimum share value of $1, all but seven experienced a drop in stock price between Jan. 28 and Feb. 5, according to data collected by American City Business Journals, Houston Business Journal's parent company.

Bellicum Pharmaceuticals Inc. (Nasdaq: BLCM) experienced the largest drop — plummeting 35 percent. On Jan. 29, its shares were at $8.68 each, and they closed Feb. 5 at $5.51. The pharmaceutical company is down 39 percent year-to-date.

One factor affecting this decrease was the U.S. Food and Drug Administration's announcement that placed a clinical hold on U.S. studies of Bellicum's lead development asset, BPX-501, according to financial news publishers The Motley Fool and Market Exclusive.

Bellicum published a release Jan. 30 about the hold on the drug, which received $17 million from the Cancer Prevention and Research Institute of Texas in 2016 for further development.

However, 2017 wasn't good to the biotech company, either. Bellicum's stock price fell 38 percent — from $13.62 to $8.41 per share — between Jan. 1, 2017, and Dec. 31, 2017.

Conn's Inc. (Nasdaq: CONN), meanwhile, was among the top-performing stocks in 2017 in Houston, yet it, too, is experiencing a large drop in its shares, from $35.45 on Jan. 29 to $30 on Feb. 5, or a 15 percent decrease.

But not all of Houston's public companies are suffering. In fact, Erin Energy Corp. (NYSE: ERN) saw a 14 percent jump in its stock price between this and last Monday. And Ion Geophysical Corp. (NYSE: IO), which was the No. 1 performing company in Houston for stock-price growth last year, saw 5 percent growth between Jan. 29 and Feb. 5.

Here's how Houston's five largest public companies, based on 2016 revenue, are handling the drops between Jan. 29 and Feb. 5:

1. Phillips 66 (NYSE: PSX) saw a 9 percent drop, from $104.25 per share to $95.21 each.
2. Sysco Corp. (NYSE: SYY) saw a 9 percent drop, from $63.39 to $57.48.
3. LyondellBasell (NYSE: LYB) saw a 10 percent drop, from $120.91 to $108.77.
4. Schlumberger Ltd. (NYSE: SLB) saw a 7 percent drop, from $76.38 to $71.35.
5. ConocoPhillips (NYSE: COP) saw a 6 percent drop, from $59.66 to $55.84.

https://www.bizjournals.com/houston/news/2018/02/06/here-are-the-houston-stocks-that-were-walloped.html

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT:	FEBRUARY 21, 2018, PRODUCT DEVELOPMENT REPORT
DATE:	FEBRUARY 14, 2018

FY 2018 Product Development Award Cycles

FY 18.1 Product Development Award Cycle

Eighteen applications were accepted for the FY 18.1 PD award cycle. The peer review panels selected four companies to present at the in-person peer review meeting. Two companies advanced for due diligence evaluations. The Product Development Review Council reviewed the diligence reports prepared regarding the two firms and did not recommend either for funding.

FY 18.2 Product Development Award Cycle

CPRIT released its second cycle of applications for FY 2018 in December 2017. Twenty applications were submitted by the February 7 deadline. The applications will undergo peer review in March and April, with final consideration of the award recommendations expected in August 2018.

Future Award Cycles

FY 19 Product Development Award Cycle

Following the discussion at the January 17, 2018, Oversight Committee meeting, Product Development plans to maintain its existing schedule and release two RFA award cycles annually through 2021. CPRIT will develop the RFAs for award cycle 19.1 by May, with a planned release in June.

New Seed Award Mechanism

With the Oversight Committee's approval, the Product Development Research Program plans to release a new Seed Award RFA starting with award cycle FY 19.1. This award mechanism is intended to catalyze company formation. It will support lead compound development, target validation, initial efficacy and toxicology testing, and business opportunity validation. CPRIT will provide a maximum of $3 million in award funding over a three-year timeline to early stage companies based in Texas or those willing to relocate to Texas. Standard Product Development award requirements will apply (e.g. peer review, Texas location criteria, matching requirements, royalty return, etc.). The Oversight Committee's Product Development Subcommittee recommends approval of this award mechanism.

CPRIT Product Development Outreach

CPRIT Product Development staff continue to conduct outreach activities to spread awareness about funding opportunities, review criteria, and eligibility. During 2018 CPRIT Product Development staff participated in the following outreach activities:

- Attended the Medical Device Summit in Austin on February 1, 2018
- Presented at the JLabs "Meet With…" series in Houston and conducted one-on-one meetings with potential applicants on February 7, 2018.
- Presented to a group of entrepreneurs at the Fannin Innovation Studio in Houston on February 7, 2018.

I will give an invited presentation at the Pulse Healthcare Innovation Breakfast Series in Dallas on February 22 and attend the Medical Device Strategy conference in Austin later this month. I expect outreach to increase in the coming months to build awareness of the New Seed Award, pending Oversight Committee approval.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CPRIT Oversight Committee Product Development Report

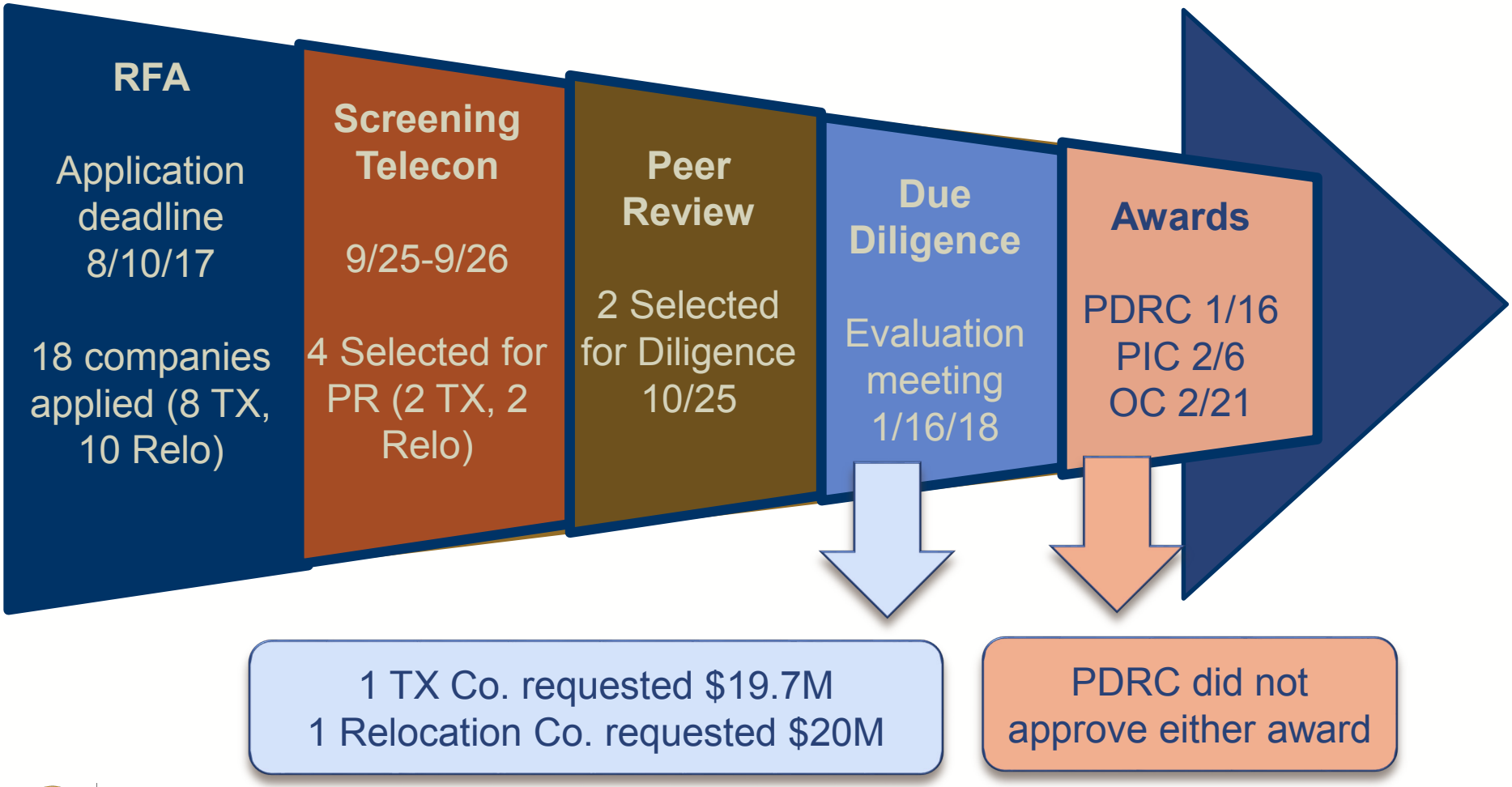
February 21, 2018

Presented By:
Michael Lang
Chief Product Development Officer

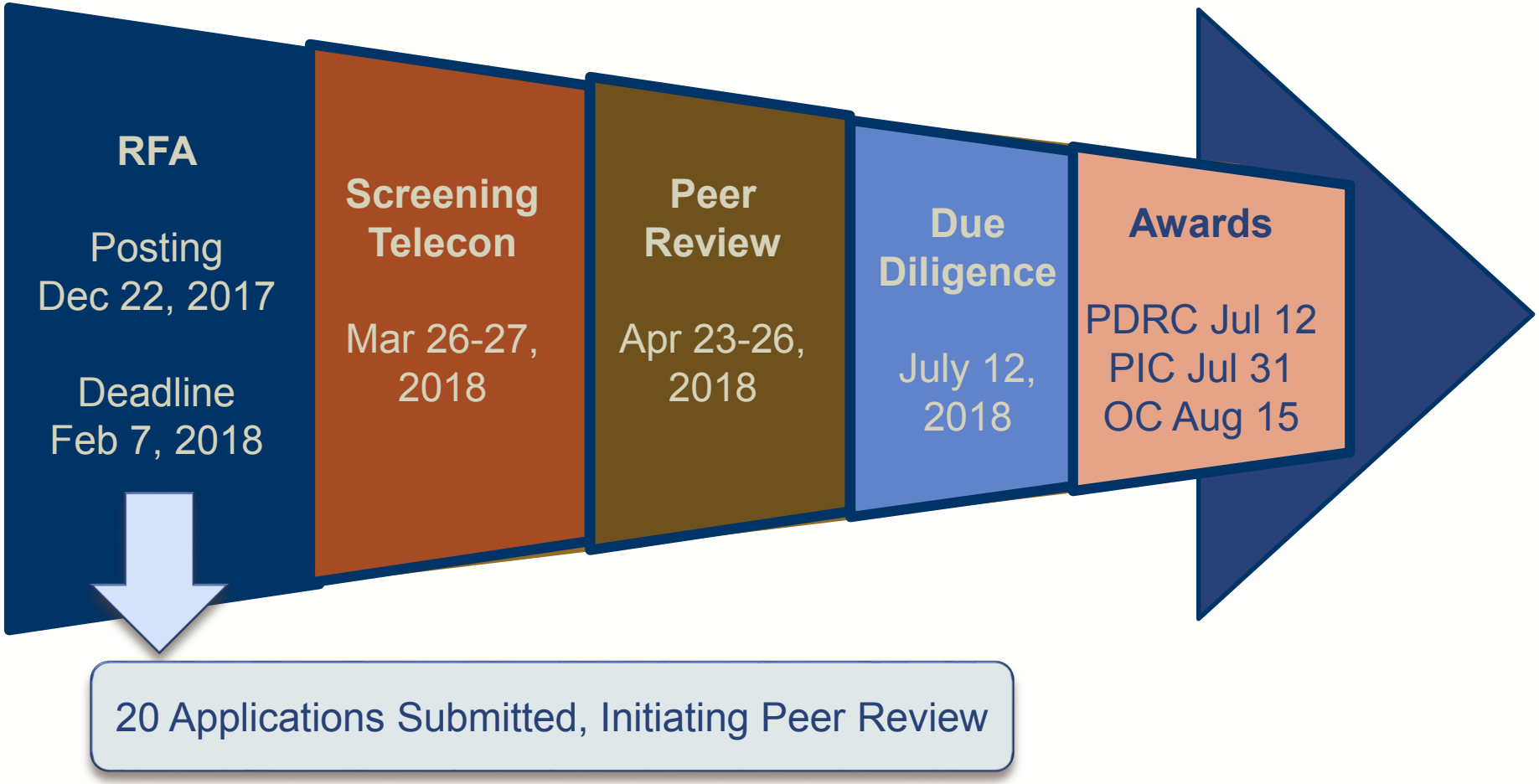
Product Development Agenda

- **Open PD Award Cycles Update – FY 18.1 & 18.2**
- Planned PD Award Cycles FY 19.1
  - Texas Company Award RFA
  - Relocation Company Award RFA
  - New Seed Award supporting company formation
- New Seed Award Overview

PD Award Cycle Update – 18.1



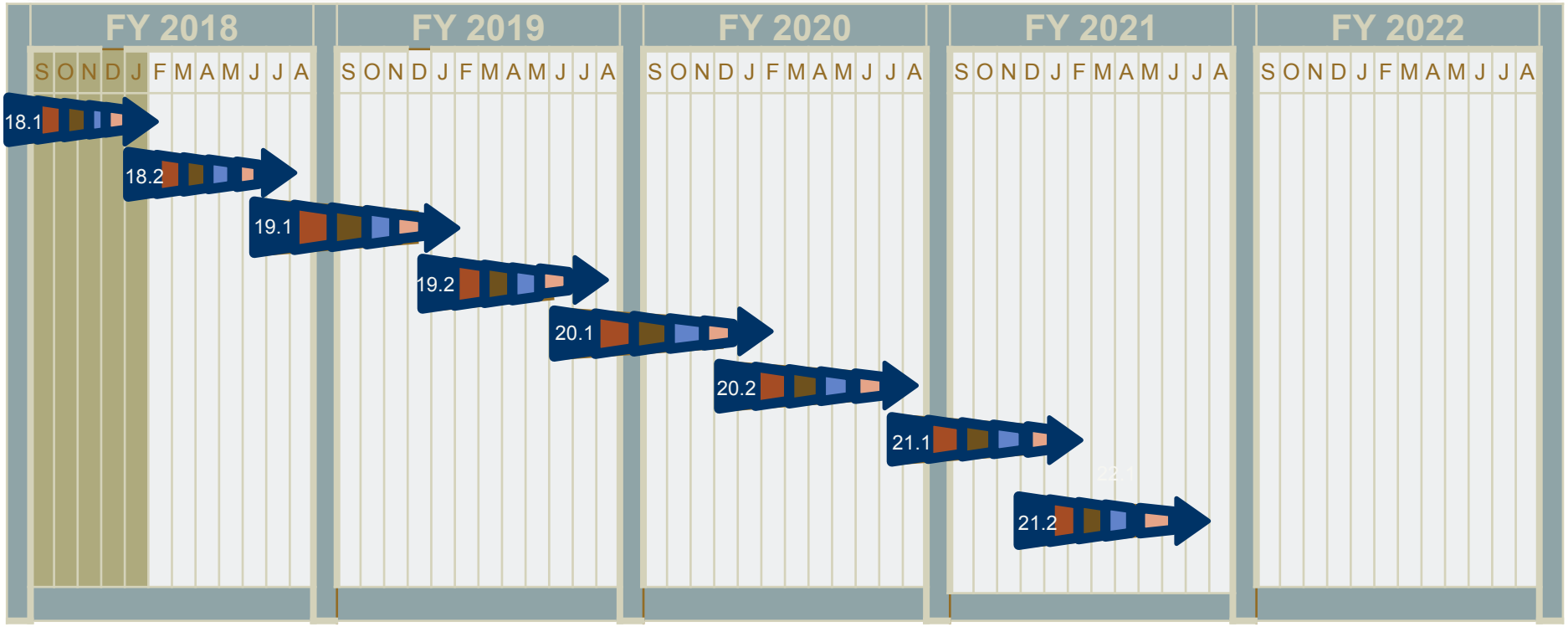
Schedule for RFA Cycle 18.2



Product Development Agenda

- Open PD Award Cycles Update – FY 18.1 & 18.2
- **Planned PD Award Cycles FY 2019 - 2021**
  - **Texas Company Award RFA**
  - **Relocation Company Award RFA**
  - **New Seed Award supporting company formation**
- **New Seed Award Overview**

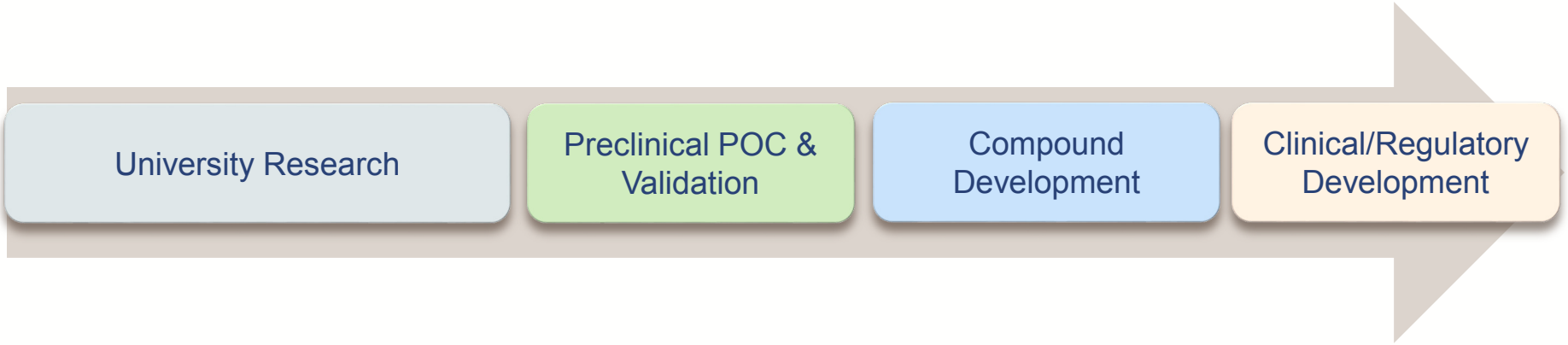
RFA Budget & Timeline, 2018-2022



FY 2019 – 2021 will included 3 RFAs per cycle

- ❑Texas Company Award RFA – Same as Current
- ❑Relocation Co. Award RFA – Same as Current
- ❑Seed Award RFA – New Mechanism

Drug Development Process



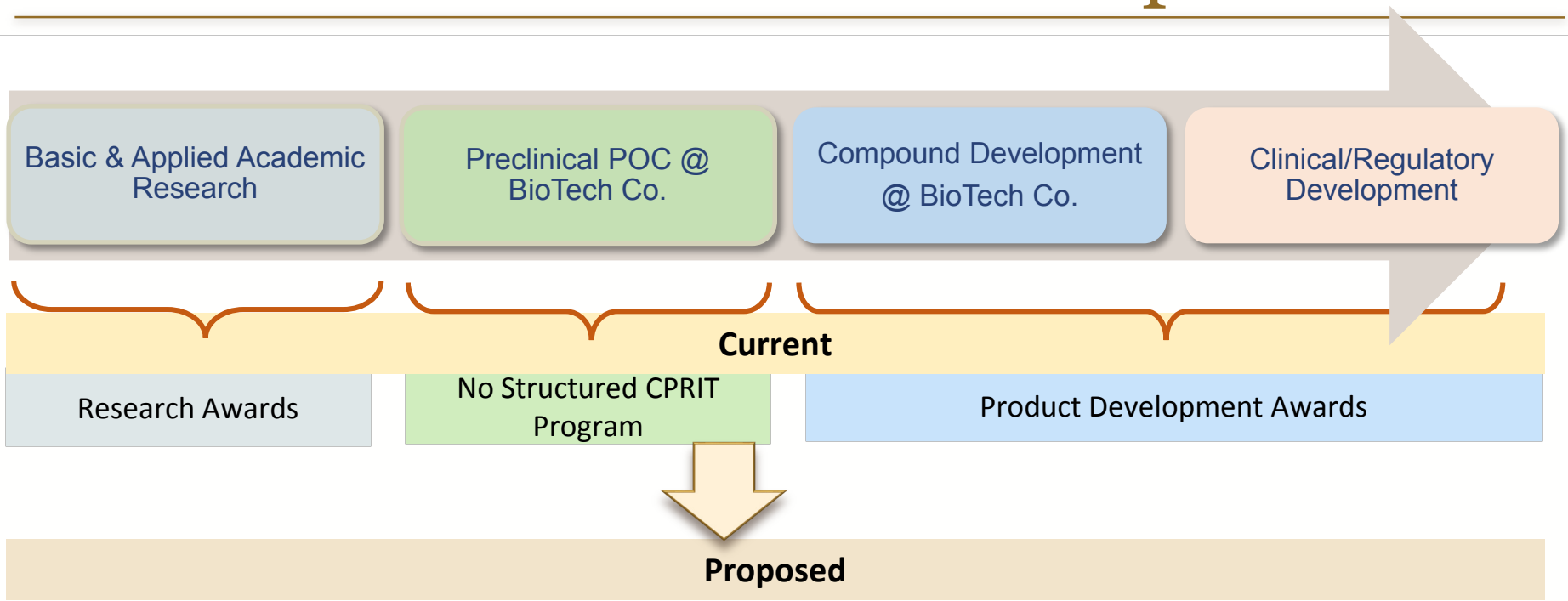
Stage	Basic Research	Applied Research	Newco Spinout	Compound Development	Clinical Development and Regulatory
Objective	Understand Disease Biology	Do Something New (Target ID)	Find lead target, develop POC, validate technology	Demonstrate Safety and Efficacy, Preclinical and Clinical Development	Confirm Safety, Efficacy & Regulatory Approval
Who	Academic PIs	Academic PIs	PIs & Entrepreneurs	BioTech Startups	Phase 1 & 2 – BioTechs Phase 3 & Regulatory, Big Pharma
Funding	Government Grants i.e. NIH	Most Government; Some Company & Philanthropy	Seed Funding (SBIR, Angels, etc.)	VCs	VCs and Big Pharma

78% of CPRIT R&D Funds to Academic Research

No Structured CPRIT Program

22% of CPRIT R&D Funds to Product Development

ETRA & Seed Award Proposal



Enhanced ETRA Program – Technology Validation

- **Institutions provide development support to PIs**
- **PI and development experts collaborate to insure commercial viability**

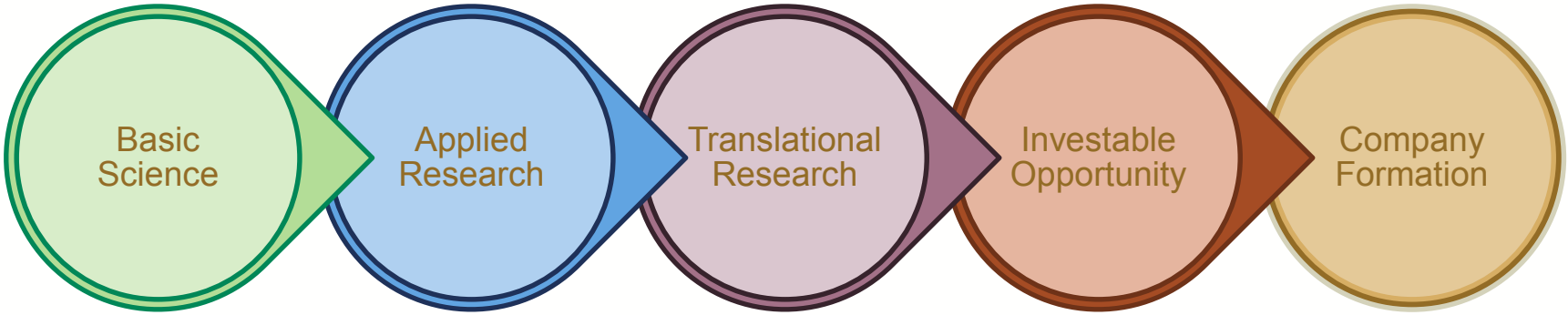
Deliverable is validated compound and opportunity

Seed Award Program - Company Formation & Early Dev.

- **Seed awards support company formation & early development**
- **Technical & commercial de-risking sufficient for private investment**

Deliverable is investible compound and opportunity

Seed Awards Program Details



Seed Award RFA Proposal

- Fund product development, preclinical research and early clinical research necessary to demonstrate initial clinical safety and efficacy
- Targets early-stage oncology startups based in Texas
- Startup companies receive seed award with review panel & OC approval

Process - Similar to Current Programs

1. Standard RFA & deliverables
2. Vetted by CPRIT peer review panel w OC approval
3. Standardized selection criteria, deal docs, and CPRIT return structure with limited diligence
4. Matching funds required
5. Quarterly updates & adjustments, tranche funding

Awards Limits = $3MM for 3 year project

Seed Award Deliverables – Investable Company

1. **Lead Compound**
   - Lead compound selection
   - Target validation
   - Administration and dosing regime understood
   - Validate efficacy, safety, toxicology, metabolism
2. **Business Opportunity**
   - Target Product Profile
   - Development plan & commercial strategy (w/ potential pitfalls and alternatives), IP, etc.
   - Define competitive safety and efficacy thresholds
   - Designated CEO actively fundraising

Objective: Investable Opportunity With CEO Actively Fundraising

Discussion Items

- Approval Request – Three RFAs for FY 2019
  - Texas Company Award RFA – Same as Current
  - Relocation Co. Award RFA – Same as Current
  - Seed Award RFA – New Mechanism

Appendix

Rich Pipeline of Texas Cancer Projects

Research Investment
- NCI
- Philanthropy
- CPRIT

Cancer Research Projects at TX Institutions

Start up Cancer Companies

CPRIT R&D Investment (Since 2010)

MD Anderson
- 244 Awards, $341 MM

UTSW HSC (since 2013)
- 267 Awards, $326 MM

Baylor (since 2013)
- 173 Awards, $225 MM

MD Anderson (annually)
- 130 invention disclosures
- 12 new drugs applications

UTSW HSC (since 2013)
- 169 Active Projects
- 69 New Compounds
- 71 Patents

Baylor (since 2013)
- 26 Cancer Projects
- 58 Patent Applications

MD Anderson
- Averages 4 newco's annually

UTSW HSC (since 2011)
- 15 Startups, 11 Active

Baylor (since 2010)
- 7 Cancer startups
- 6 licenses

CPRIT Has Seeded Numerous New Technologies in TX
Translational and Seed Funding Accelerates Their Commercialization

CPRIT-Funded Companies from Texas Research Institutions

UT System

• UT Austin	Aeglea
• UT San Antonino HSC	NanoTx
• UT Southwestern HSC	OncoNano, Peloton
• MD Anderson	DNATrix

Other Texas Research Institutions

• Texas Tech Med School	CerRx
• Baylor College of Medicine	Cell Medica, Viracyte
• Texas A&M	Fujifilm Diosynth

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Catalyzing Commercialization of Texas Research

October 11, 2017

Presented to: CPRIT's University Advisory Committee

By: Dr. Jim Willson
Michael Lang

Translational Research & University Spinouts

Background

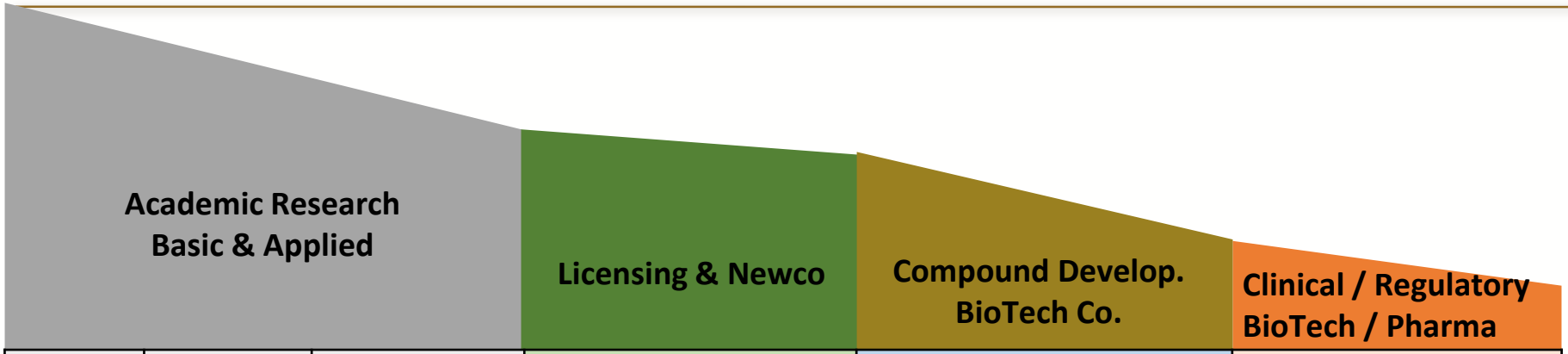
- Background - Nearly $100 MM research investment per spinout
- Objective - Increase commercialization of TX cancer research
- Benefits - more therapies, TX economic development, enhance TX research institutions.

Support

- Continuity of support to support commercially viable research and launch startup firms
- Modified Early Translational Research Awards program supporting investible opportunities with development expertise and translational development funding
- Support New Company formation

Success Metrics = New Companies formed & capital raised

Drug Development Process



	Academic Research Basic & Applied		Licensing & Newco	Compound Develop. BioTech Co.	Clinical / Regulatory BioTech / Pharma
Stage	Basic Research	Applied Research	Newco Spinout	Compound Development	Clinical Development and Regulatory
Objective	Understand Disease Biology	Do Something New (Target ID)	Form Newco to Develop Drug	Find, Optimize, Validate Lead Compounds, Demo Safety and Efficacy	Confirm Safety, Efficacy & Regulatory Approval
Who	Academic PIs	Academic PIs	PIs Tech Transfer Offices & Entrepreneurs	BioTech Startups	Phase 1 & 2 – BioTechs Phase 3 & Regulatory, Big Pharma
Funding	Government Grants i.e. NIH	Most Government; Some Company & Philanthropy	Seed Funding (SBIR, Angels, etc.)	VCs	VCs and Big Pharma

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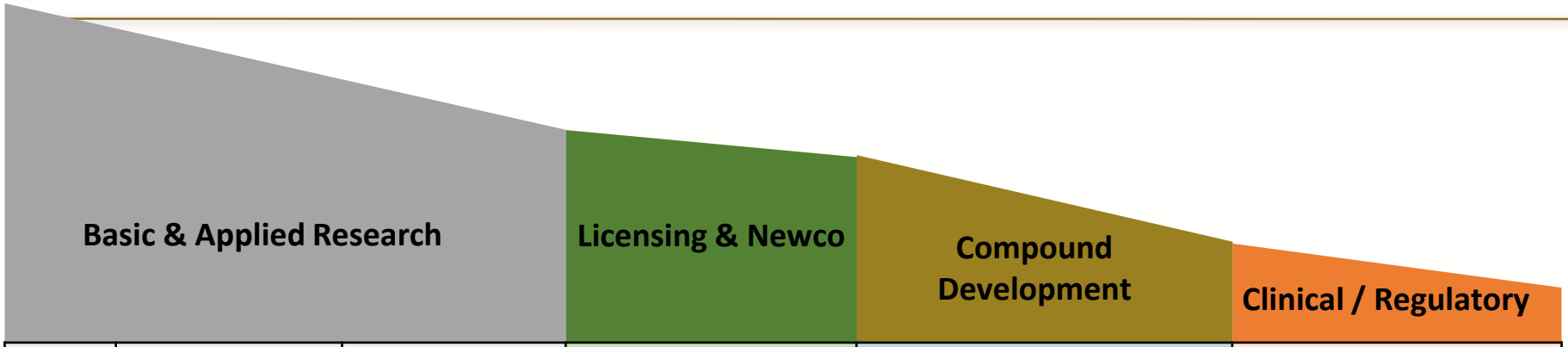
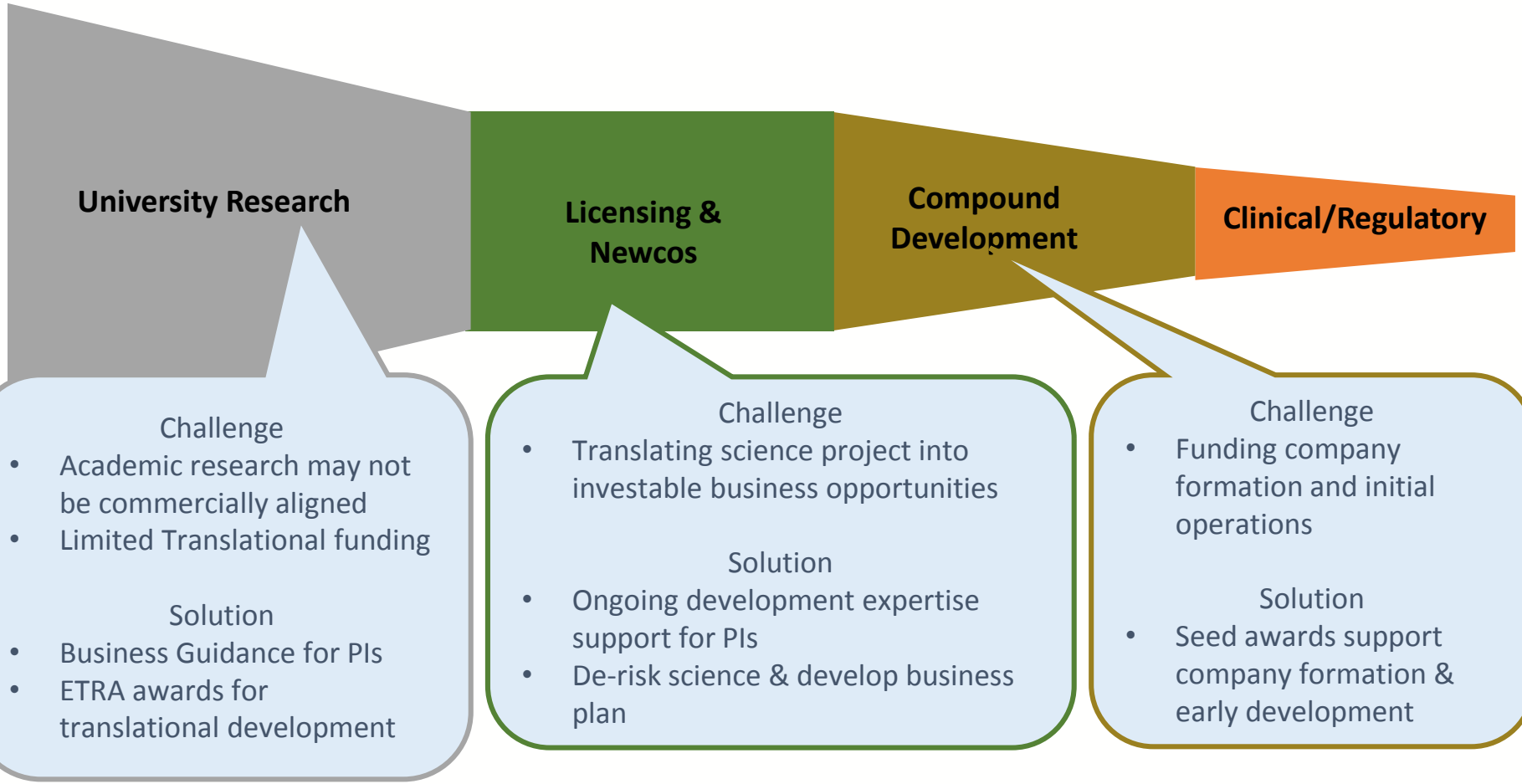
22% of CPRIT R&D Funds to Product Development

Drug Development - Key Issues



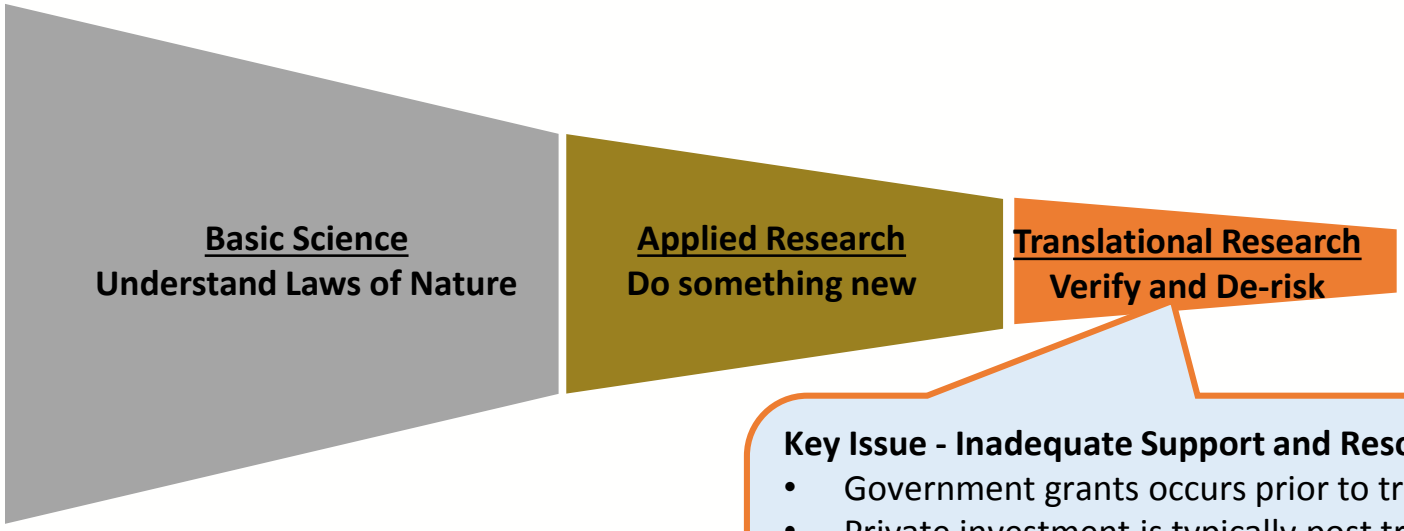
	Basic Research	Applied Research	Newco Spinout	Compound Development	Clinical Development and Regulatory
Issues	• Research may not be linked to clinical needs • Hard to fund research outside of traditional interests	• Research may not be linked to clinical needs • Limited verification • Universities lack translational research expertise	• Limited funds available • Challenging process • Mistakes made by inexperienced founders can doom startups	• Limited funds available for compound development • High attrition rate • Expensive FDA-mandated process • Specialized outsourced services required	• Limited funds available for early clinical studies • Expensive FDA-mandated process • Government policies affect regulators and payers

Enhancing CPRIT's Impact



Institutions and CPRIT Collaborate to Bridge "Valley of Death" Funding Gap
Continuum of Support Translates Science Projects Into Startup Companies

Limited Translational Research Support



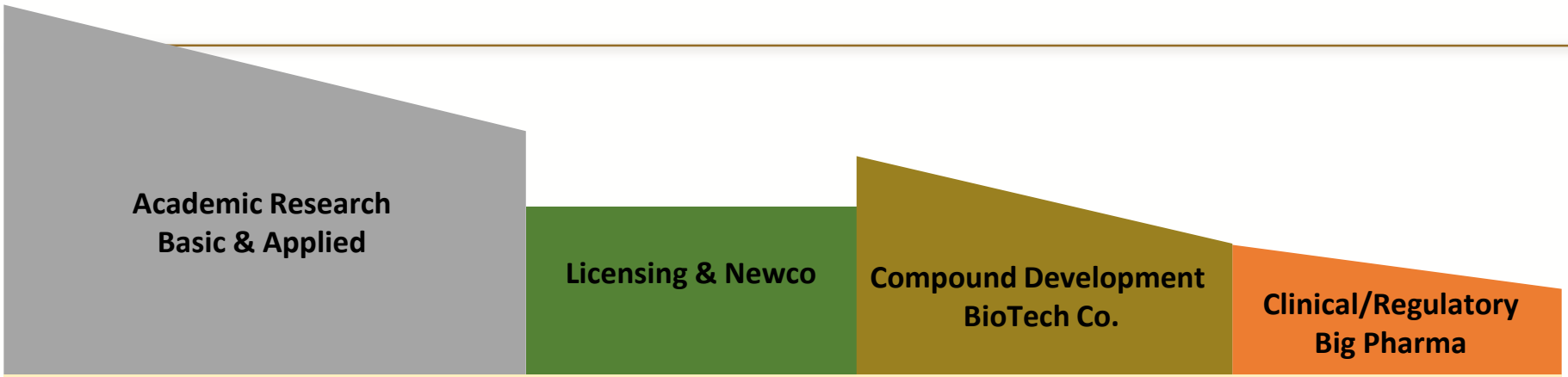
Key Issue - Inadequate Support and Resources

- Government grants occurs prior to translational research
- Private investment is typically post translational research
- Business and development expertise may not be available
- Universities lack translational research expertise (Formulation , Toxicology, GLP, Clinical Trials, Pharmacokinetics, etc.)

Catalyzing Commercialization of CPRIT Funded Research

- CPRIT provides project funding (ETRAs and Seed Awards)
- Institutions provide development expertise
- PIs and development experts collaborate to validate science and business opportunity
- Objective is investible business opportunity + designated CEO actively fundraising

Summary



Current

Research Awards

No Structured CPRIT Program

Product Development Awards

Proposed

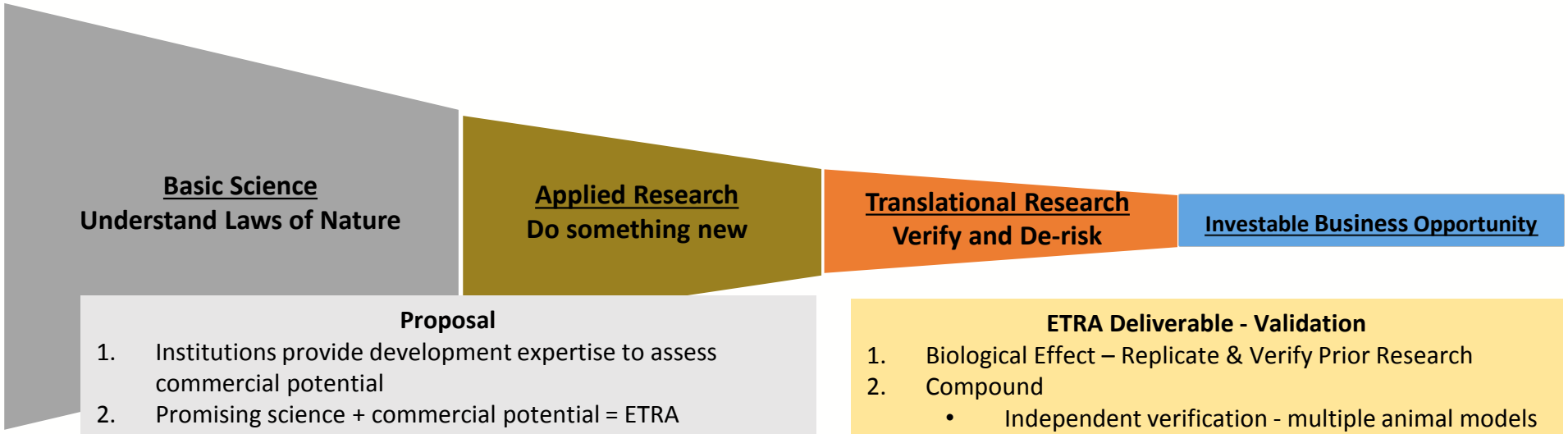
Enhanced ETRA Program to Support Validation

- Institutions provide development support to PIs
- PI and development experts collaborate to insure commercial viability
- Deliverable is validated compound and opportunity

Seed Award Program to Support Company Formation

- Seed awards support company formation & early development
- Technical & commercial de-risking sufficient for private investment
- Deliverable is investible compound and opportunity

Modified ETRA Program Details



Proposal

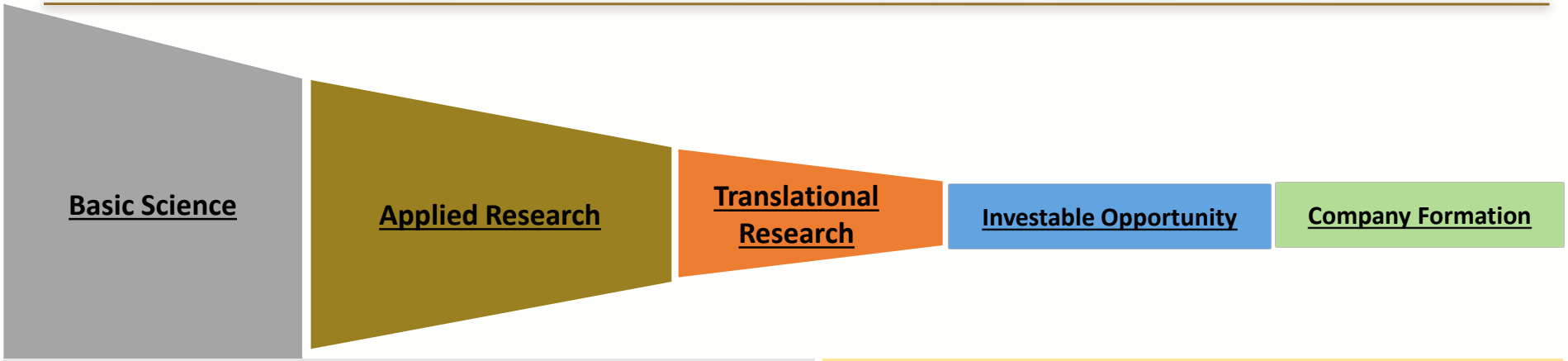
1. Institutions provide development expertise to assess commercial potential
2. Promising science + commercial potential = ETRA candidates
3. PI + development expert apply for ETRA (standard RFA and deliverables)
4. ETRA applicants jointly vetted by combo academic research and product development research panels
5. ETRA Awards Target = $3MM for 3 year project

ETRA Deliverable - Validation

1. Biological Effect – Replicate & Verify Prior Research
2. Compound
   - Independent verification - multiple animal models
   - Preliminary safety & toxicology
   - Manufacturability
3. Business Opportunity – Comprehensive Business Plan
   - Clinical utility, target market, financial plan
   - Clinical & regulatory pathway, development plan
   - IP strategy

Objective: Validated Opportunity + Designated CEO

Seed Awards Program Details



Seed Award RFA Proposal

- Funds NewCos from research conducted in Texas
- Startup companies receive seed award w review panel & OC approval
- Awards Target = $3MM for 3 year project

Process - Similar to Current Programs

1. Standard RFA & deliverables
2. Vetted by CPRIT peer review panel w OC approval
3. Standardized selection criteria, deal docs, and CPRIT return structure with limited diligence
4. Matching funds required
5. Quarterly updates & adjustments, tranche funding

Seed Award Deliverables – Investable Company

1. Lead Compound
   - Lead compound selection
   - Target validation
   - Administration and dosing regime understood
   - Validate efficacy, safety, toxicology, metabolism
2. Business Opportunity
   - Target Product Profile
   - Development plan & commercial strategy (w/ potential pitfalls and alternatives), IP, etc.
   - Define competitive safety and efficacy thresholds
   - Designated CEO actively fundraising

Objective: Investable Opportunity With CEO Actively Fundraising

Continuity of Development Activities

	R&D Awards		ETRA	Seed Award		PD Award	
Target Validation	Exploratory Screening	Screening/ Hit to Lead	Lead Development	Candidate Selection	Preclinical Evaluation	Phase 1 Clinical Evaluation	Phase 2 Clinical Evaluation
Evaluate and define the role of therapeutic target in disease initiation and/or progression	Conduct a technology overview	Run screen(s)	Establish laboratory objectives for clinical efficacy	Evaluate synthesis and proposed clinical formulation	Manufacture GMP-grade bulk drug/active pharmaceutical ingredient (API)	API production process development	API production process scale up
Is the target associated with disease pathology?	Develop a screening strategy	Assess mechanism of action for link to disease	Resolve IP issues	Evaluate biopharmaceutical properties (absorption in rodents and non-rodents, clearance, and bioavailability)	Conduct IND-directed toxicology studies including toxicokinetics	Conduct FIM clinical studies to assess safety and preliminary efficacy (if applicable)	Conduct Phase 2 proof of principle clinical studies
	Identify potential biomarkers (efficacy/surrogate)	Determine desirable potency	Evaluate activity in validated disease models	Initial preclinical toxicology, PK and PD assessments	Determine preclinical MTD, DLTs, and starting dose	Dose ranging studies	Evaluate safety
Identify causal/driver variant(s)/patient populations with genetic backgrounds susceptible to intervention.	Develop a strategy for “clinical readiness”	Determine evidence of structure–activity relationship	Evaluate structure–activity relationship	Assess potency against clinical efficacy	Validate PK/PD assay(s) and specimen handling SOPs	Evaluate safety	Evaluate Tolerability
	Prepare medical needs assessment	Evaluate functional activity in vitro	Evaluate physicochemistry	Evaluate biodistribution	Develop and validate product characterization and release assays	Evaluate tolerability and side effects	Evaluate PK
	Prepare project operational plan	Determine selectivity for target	Differentiate leads from competitors and current therapies	Evaluate clinical readiness of PK/PD assay(s) and specimen handling SOPs	Characterize clinical product	Evaluate PK	Preliminary efficacy
		Evaluate physicochemistry (Rule-of-Five compliance)/in silico modeling	Evaluate preliminary safety issues (Non GLP gross tox evaluation)	Assess amenability to imaging	Prepare CMC package and toxicology summary report	Preliminary efficacy evaluation(if applicable)	Update clinical strategy and plan Phase 3 studies
		Evaluate PK and PD using best available tools	Develop PD and toxicology biomarker assays(s)	Evaluate safety issues (most sensitive species) in range-finding toxicology studies	Prepare and review clinical protocol at each participating site	Update clinical strategy and plan Phase 2/3 studies	Prepare and file Phase 3 IND studies
		Assess amenability to synthesis	Assess achievability of human PK/PD profile	Prepare clinical development plan	Prepare and file IND	Prepare and file Phase 2 IND studies	
		Evaluate stability	Assess feasibility of scale-up and bulk synthesis				

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:	FEBRUARY 16, 2018

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 February 16, 2018, and recommends that the Oversight Committee vote to approve the appointments.

Discussion

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

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

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

Recommendations for Scientific Research and Prevention Programs Committees

Recommendations for Academic Research Peer Review Panels

- Heather Christofk, Ph.D.
- Jose Conejo-Garcia, M.D., Ph.D.
- Patrick Grohar, M.D., Ph.D.
- Ting Wang, Ph.D.

Recommendations for Prevention Peer Review Panels

- Kathleen L. Irwin, M.D., MPH, FACPM, FIDSA

Recommendations for Product Development Research Peer Review Panels

- John C. McKew, Ph.D.
- George L. Trainor, Ph.D.

Recommendations for Academic Research Peer Review Panels

- Heather Christofk, Ph.D.
- Jose Conejo-Garcia, M.D., Ph.D.
- Patrick Grohar, M.D., Ph.D.
- Ting Wang, Ph.D.

BIOGRAPHICAL SKETCH

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

NAME: Heather Christofk

eRA COMMONS USER NAME (credential, e.g., agency login): HCHRISTOFK2

POSITION TITLE: Associate 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 California, Los Angeles	B.S.	12/2001	Molecular, Cell, and Developmental Biology
Harvard University	Ph.D.	11/2007	Cell and Developmental Biology
University of California, San Francisco	Postdoc	06/2008	Cancer Biology

A. Personal Statement

I have spent the past 15 years working on the regulation and role of cancer metabolism in tumor growth. As a graduate student, I identified a key protein in cancer metabolism – the M2 splice isoform of pyruvate kinase – and the mechanism by which it contributes to cancer cell proliferation by promoting anabolic glucose metabolism downstream of growth factor-induced receptor tyrosine kinase signaling pathways. As a postdoctoral researcher, I continued to study the interconnection of growth factor signaling pathways and metabolism. The overarching goal of my laboratory at UCLA is to understand how metabolic transitions are regulated in differentiation, virus infection, and malignant transformation. By elucidating regulatory mechanisms for metabolic transitions in normal and disease states, I hope to identify and develop novel treatment strategies for cancer patients.

B. Positions and Honors

Positions and Employment

2001-2002 Staff Research Associate, Laboratory of Dr. Hong Wu, University of California, Los Angeles
2002-2007 Graduate Student, Laboratory of Dr. Lewis Cantley, Harvard Medical School, Boston, MA
2007-2008 Postdoctoral Scholar, Laboratory of Dr. Frank McCormick, University of California, San Francisco
2008-2016 Assistant Professor, Department of Molecular and Medical Pharmacology, David Geffen School of Medicine, University of California, Los Angeles
2013-present Co-Director, UCLA Metabolomics Center
2016-present Joint appointment in the Department of Biological Chemistry, David Geffen School of Medicine, University of California, Los Angeles
2016-present Associate Professor, Departments of Biological Chemistry and Molecular and Medical Pharmacology, David Geffen School of Medicine, University of California, Los Angeles
2017 Co-Director, Signal Transduction and Therapeutics Program, UCLA Jonsson Comprehensive Cancer Center
2018 Director of Basic and Translational Research, UCLA Jonsson Comprehensive Cancer Center

Honors

2010	Damon Runyon Cancer Research Foundation-Rachleff Innovation Award
2010	Searle Scholar Award
2011	NIH Director's New Innovator Award
2012	Concern Foundation Research Award
2016	American Cancer Society Research Scholar Award
2016	Rose Hills Foundation Research Scholar Award
2017	AAAS Wachtel Cancer Research Award Honorable Mention
2017	Ablon Scholar Award
2018	Lead Organizer for the Keystone Symposium on Tumor Metabolism

Service

2013 – 2016	Ad Hoc Reviewer for Italian Association for Cancer Research
2015	Ad Hoc Reviewer for Swiss National Science Foundation
2015	Ad Hoc Reviewer for the Natural Sciences and Engineering Research Council of Canada
2016 – present	Editorial Board Member of *PLOS Biology*
2016	Ad Hoc Reviewer for NCI Special Emphasis Panel ZCA1 SRB-L
2017	Ad Hoc Reviewer for NCI Tumor Cell Biology Study Section
2017 – present	Editorial Board of *Oncogene*
2017 – present	Editorial Board Member of *iScience*
2018	AACR Annual Meeting Program Committee

C. Contributions to Science

1. Identification of the M2 splice isoform of pyruvate kinase (PKM2) as a key modulator of cancer metabolism and tumor growth downstream of tyrosine kinase signaling pathways. As a graduate student, I discovered that a single splice isoform switch in pyruvate kinase, which occurs in all cancers studied to date, is necessary for the Warburg effect and confers a selective growth advantage for tumor cells. I also discovered a direct link between growth factor signaling pathways and metabolic flux control through inhibition of PKM2 activity. From these findings, I proposed that the Warburg effect in cancer cells supports cell growth by allowing for the use of glucose metabolites for anabolic purposes such as fatty acid and nucleotide biosynthesis. These findings helped reignite interest in the field of cancer metabolism since they (a) supported a role for altered metabolism in promoting growth of tumors, (b) suggested that growth factor signaling pathways may converge in upregulating anabolic metabolism, and (c) identified PKM2 activation as an attractive cancer treatment strategy.

a. **Christofk HR**, Vander Heiden MG, Harris MH, Ramanathan A, Gerszten RE, Wei R, Fleming MD, Schreiber SL, and Cantley LC (2008). The M2 splice isoform of pyruvate kinase is important for cancer metabolism and tumour growth. *Nature* 452, 230-233. PMID: 18337823.

b. **Christofk HR**, Vander Heiden MG, Wu N, Asara JM, and Cantley LC (2008). Pyruvate kinase M2 is a phosphotyrosine-binding protein. *Nature* 452, 181-186. PMID: 18337815.

c. International Patent Application No: PCT/US2008/009828. Title: Activators of Pyruvate Kinase M2 and Methods of Treating Disease. Authors: Lewis C. Cantley, Ph.D., Matthew G. Vander Heiden, M.D., Ph.D., **Heather R. Christofk, Ph.D**.

d. Anastasiou D, Yu Y, Israelsen WJ, Jiang JK, Boxer MB, Hong BS, Tempel W, Dimov S, Shen M, Jha A, Yang H, Mattaini KR, Metallo CM, Fiske BP, Courtney KD, Malstrom S, Khan TM, Kung C, Skoumbourdis AP, Veith H, Southall N, Walsh MJ, Brimacombe KR, Leister W, Lunt SY, Johnson ZR, Yen KE, Kunii K, Davidson SM, **Christofk HR**, Austin CP, Inglese J, Harris MH, Asara JM, Stephanopoulos G, Salituro FG, Jin S, Dang L, Auld DS, Park HW, Cantley LC, Thomas CJ, Vander Heiden MG (2012). Pyruvate kinase activators promote tetramer formation and suppress tumorigenesis. *Nature Chemical Biology* 2012 8(10): 839-47. PMID: 22922757. PMCID: PMC3711671.

2. Deciphering mechanisms of virus-induced metabolic reprogramming. My laboratory has found that adenovirus E4ORF1 activates MYC-induced transcription of specific metabolic genes to enhance anabolic glucose metabolism, glutamine catabolism, and promote optimal virus replication. This work, together with other recent studies in cancer cells and activated T cells, suggests that MYC is critical hub for promoting anabolic metabolism across multiple pathophysiological conditions. We have proposed that viruses can be useful tools for studying mechanisms and key nodes of metabolic reprogramming in cancer, and for elucidating promising cancer metabolism drug targets. Our work also suggests that drugs targeting cancer metabolism may be useful as anti-virals given the overlap between metabolic reprogramming in tumor cells and virus-infected cells.

a. Thai M, Graham NA, Braas D, Nehil M, Komisopoulou E, Kurdistani SK, McCormick F, Graeber TG, and **Christofk HR** (2014). Adenovirus E4ORF1-induced MYC activation promotes host cell anabolic glucose metabolism and virus replication. *Cell Metabolism* 19, 694-701. PMCID: PMC4294542.

b. Thai M*, Thaker S*, Feng J, Du Y, Hu H, Wu TT, Graeber TG, Braas D, **Christofk HR** (2015). MYC-induced reprogramming of glutamine catabolism supports optimal virus replication. * equal contribution. *Nature Communications* 6:8873. PMCID: PMC4660206.

3. Identification of growth-promoting nutrients and nutrient transporter activities in cancer. Although much of the cancer metabolism field is focusing on metabolic enzymes and the role the play in cancer growth, less attention has been paid to the nutrients and nutrient transporters that promote cancer anabolic metabolism. My laboratory has identified asparagine as an important and limiting nutrient for cancer cell proliferation through use by amino acid antiporters as an exchange factor. Proliferating cells export asparagine in order to import amino acids from the extracellular environment, such as arginine and serine, through amino acid antiporters to maintain mTORC1 activation and anabolic metabolism. These findings underlie the mechanistic basis for L-asparaginase efficacy in patients with acute lymphoblastic leukemia and suggest rational combination strategies with L-asparaginase in other cancers. Additionally, we have characterized a new growth-promoting function of the cancer drug target monocarboxylate transporter 1, independent of its canonical role in mediating lactate transport, which has important implications for use of inhibitors towards this transporter in the clinic.

a. Hong CS, Graham NA, Braas D, Gu W, Espindola Camacho C, Mah V, Maresh EL, Alavi M, Bagryanova L, Krotee PA, Gardner BK, Saramipoor Behbahan I, Horvath S, Chia D, Mellinghoff IK, Hurvitz SA, Dubinett SM, Critchlow SE, Kurdistani SK, Goodglick L, Graeber TG, **Christofk HR** (2016). MCT1 modulates cancer cell pyruvate export and growth of tumors that co-express MCT1 and MCT4. *Cell Reports* 14:1590-601. PMCID: PMC4816454.

b. Krall AK, Xu S, Graeber TG, Braas D, **Christofk HR** (2016). Asparagine promotes cancer cell proliferation through use as an amino acid exchange factor. *Nature Communications* 7:11457. PMCID: PMC4855534.

4. Identification of nucleoside salvage activity in liposarcomas. Most aggressive cancers exhibit glycolytic metabolism and can be non-invasively imaged in patients using positron emission tomography (PET) with 18F-fluorodeoxyglucose (FDG). However, some aggressive cancers, including a subset of liposarcomas, are FDG-PET negative in the clinic. My lab used LC-MS/MS-based metabolomic footprinting analysis to characterize the alternative carbon sources used by patient-derived liposarcoma (LPS) cell lines. Through our metabolomics approach, we found that LPS cells consume nucleosides from cell culture media. We confirmed elevated nucleoside salvage activity in a subset of liposarcomas, and found that they are identifiable using noninvasive PET imaging with the cytidine analog FAC and sensitive to gemcitabine. Thus, we suggested a new treatment paradigm for liposarcoma patients using FAC-PET in the clinic to delineate gemcitabine responders from nonresponders. Our metabolomics-based approach to analyze the nutrients consumed by patient-derived cancer cell lines can be generalizable to studying other cancer types.

a. Braas D, Ahler E, Tam B, Nathanson D, Riedinger M, Benz MR, Smith KB, Eilber FC, Witte ON, Tap WD, Wu H, **Christofk HR** (2012). Metabolomics strategy reveals subpopulation of

liposarcomas sensitive to gemcitabine treatment. *Cancer Discovery* 2(12):1109-17. PMCID: PMC3531869.

b. Smith KB, Tran LM, Tam BM, Shurell EM, Li Y, Braas D, Tap WD, **Christofk HR**, Dry SM, Eilber FC, Wu H (2013). Novel dedifferentiated liposarcoma xenograft models reveal PTEN down-regulation as a malignant signature and response to PI3K pathway inhibition. *Am J Pathol.* 182(4):1400-11. PMCID: PMC3620414.

5. Defining the role of glycolytic metabolism in stem cells. Human embryonic stem cells (hESCs) exhibit increased glycolytic metabolism and reduced respiration relative to differentiated counterparts. We have examined the functional role of glycolytic metabolism in stem cell biology, specifically in hESC self-renewal and differentiation capacity. In pluripotent stem cells, we have found that naïve hESCs are even more glycolytic than primed hESCs, further suggesting a link between glycolysis and the pluripotent state. However, surprisingly, we have found that hESC metabolism greatly varies depending on whether the cells are cultured on a layer of stromal feeder cells versus in feeder-free conditions – culture systems that are used interchangeably in the stem cell field. We found that stromal cells secrete factors that reprogram hESC metabolism, in part through modulation of MYC activity. These findings have important implications for regenerative medicine since they suggest that metabolic manipulation of hESCs may improve maintenance of the pluripotent state or differentiation efficiency, and they suggest that stromal cells reprogram the metabolic state of hESCs in ways that may impact cell fate decisions. We have also characterized the metabolism of hair follicle stem cells, and found that modulation of pyruvate metabolism through inhibition of lactate dehydrogenase or the mitochondrial pyruvate carrier blocks or enhances hair follicle stem cell differentiation and the hair cycle, respectively.

a. Gu W, Gaeta X, Sahakyan A, Chan A, Hong CS, Kim R, Braas D, Plath K, Lowry WE*, **Christofk HR***. Glycolytic metabolism plays a functional role in regulating human pluripotent stem cell state. * co-corresponding. ***Cell Stem Cell***, 19:1-15 (2016).

b. Flores A, Schell J, Krall AS, Jelinek D, Miranda M, Grigorian M, Braas D, White AC, Zhou JL, Graham NA, Graeber T, Seth P, Evseenko D, Coller HA, Rutter J, **Christofk HR***, Lowry WE*. Lactate dehydrogenase activity drives hair follicle stem cell activation. *co-corresponding. ***Nature Cell Biology***, 19: 1017-26 (2017).

c. Schell JC, Wisidagama DR, Bensard C, Zhao H, Wei P, Tanner J, Flores A, Mohlman J, Sorensen LK, Earl CS, Olson KA, Miao R, Waller TC, Delker D, Kanth P, Jiang L, DeBerardinis RJ, Bronner MP, Li DY, Cox JE, **Christofk HR**, Lowry WE, Thummel CS, Rutter J. Control of intestinal stem cell function and proliferation by mitochondrial pyruvate metabolism. ***Nature Cell Biology***, 19: 1027-36 (2017).

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/heather.christofk.1/bibliography/47782286/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

RO1 CA215185-01A1 (Christofk) 12/1/17 – 11/30/22
NIH/NCI
Nutrient Regulation of Cancer Cell Growth
The goals of this study are to determine whether respiration contributes to cancer cell proliferation through aspartate-dependent asparagine synthesis, to assess co-treatment strategies with asparaginase to exploit cancer cell dependence on asparagine for growth, and to examine lactate regulation of mTORC1 and ATF4 activities.

R01 AR070245-01A1 (Christofk and Lowry) 12/1/17 – 11/30/22
NIH/NIAMS
Metabolic Control of Hair Follicle Stem Cell Homeostasis and Tumorigenesis
The goals of this study are to determine the role of metabolism in hair follicle stem cell homeostasis and squamous cell carcinoma tumor formation in mice.

RSG-16-111-01-MPC (Christofk) 7/1/16 – 6/30/20
American Cancer Society
Use of Viruses to Study Cancer Metabolism
The goal of this project is to use adenovirus infection as a model system to identify key metabolic events important for anabolic metabolism and tumor growth.
Role: PI

JCCC-BSCRC Ablon Scholars Award (Christofk) 7/1/17 – 6/30/18
This award funds my research program to investigate regulation of metabolic transitions in cells, with a specific emphasis on cancer cells.

Completed Research Support (within last 3 years)

DP2 OD008454-01 (Christofk) 9/30/11 - 6/30/16
NIH
Regulation of the Warburg Effect in Cancer
The major goals of this project are to define the molecular events responsible for aerobic glycolysis in breast cancer and their contribution to tumor growth and maintenance.
Role: PI

U54 CA151819 (Heath) 9/30/11 – 8/31/15
NCI
Nanosystems Biology Cancer Center 2
The goals of this project are to use in vitro and in vivo molecular imaging technologies to study metabolic switches during malignant transformation and to identify alternative carbon sources than glucose necessary for proliferation of non-glycolytic cancers.
Role: Project PI

Rose Hills Foundation-BSCRC Innovation Award (Christofk) 7/1/16 – 6/30/17
Nutrient Regulation of Cancer Cell Growth
The goals of this project are to assess rational combination treatment strategies with L-Asparaginase for cancer treatment and to examine lactate as a negative feedback signal for anabolic metabolism and cancer cell growth.

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: **Conejo-Garcia, Jose R**

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

POSITION TITLE: **Chair and Senior Member**

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 Zaragoza, Zaragoza, Spain	M.D.	12/90	Medicine
University Hospital of Guadalajara, Spain	Residency	12/96	Clinical Chemistry
University of Alcala, Alcala de Henares, Spain	Ph.D.	02/98	Molecular Oncology
University of Bern, Bern, Switzerland	Postdoc	06/98-05/99	Pancreatic cancer
University of Pennsylvania, Philadelphia, PA	Postdoc	05/01-08/05	Tumor Immunology

A. Personal Statement

I am the Chair of the Department of Immunology at Moffitt Cancer Center. The goal of my research program is to identify and target mechanisms governing the balance between immunosuppression and protective immunity in the tumor microenvironment, with an emphasis on the role of cancer-driven pathological myelopoiesis. This application will build on novel insights obtained by my colleague and long-term collaborator Dr. Tworoger to gain insight into the immunobiology of ovarian cancer in a big cohort of patients. By combining translational understanding and clinical specimens with mechanistic studies in mouse models, my research program has contributed in various roles to elucidate most of the mechanisms driving protective immunity against ovarian cancer that have been unveiled in recent years, as demonstrated by >100 recent articles that total >9,000 citations in Scopus. My independent studies on regulatory myeloid cells, the role of the microbiome and epigenetic control of the anti-tumor immune response have been funded in the past by federal grants that currently support a combination of productive basic and translational researchers in my laboratory, all of them focused on the immunobiology of cancer. I hope that my distinctive expertise on understanding and targeting the immunobiology of cancer and proven record of productivity will clearly show that my laboratory is superbly positioned to support the accomplishment of the proposed Aims.

Most representative primary publications from the lab in the last 4 years:

1. Stephen TL, Rutkowski MR, Allegrezza MJ, Perales-Puchalt A, Tesone AJ, Svoronos N, Nguyen J, Borowsky ME, Tchou J, and *Conejo-Garcia JR* (2014). Transforming Growth Factor-beta-Mediated Suppression of Antitumor T Cells Requires FoxP1 Transcription Factor Expression. **Immunity**; 41: 427-39. PMC4174366.
2. Rutkowski MR, Stephen TL, Svoronos N, Allegrezza MJ, Perales-Puchalt A, Tesone AJ, Escovar-Fadul X, Nguyen JM, Cadungog MG, Zhang R, Salatino M, Rabinovich GA, Tchou J, *Conejo-Garcia JR* (2015). Microbially driven TLR-dependent signalling governs distal malignant progression through tumor-promoting inflammation. **Cancer Cell**; 27: 27-40. PMC4293269.
3. Svoronos N, Perales-Puchalt A, Allegrezza MJ, Rutkowski MR, Payne KK, Tesone AJ, Nguyen JM, Curiel TJ, Cadungog MG, Singhal S, Eruslanov EB, Tchou J, Zhang R, *Conejo-Garcia JR* (2017). Tumor cell-independent estrogen signaling drives malignant progression through MDSC mobilization. **Cancer Discovery**. 7: 72-85. PMC5222699.
4. Stephen TL, Payne KK, Chaurio RA, Allegrezza MJ, Zhu H, Perez-Sanz J, Perales-Puchalt A, Nguyen JM, Vara-Ailor AE, Eruslanov EB, Borowsky ME, Zhang R, Laufer TM, *Conejo-Garcia JR* (2017). SATB1 expression governs epigenetic repression of PD-1 in tumor-reactive T cells. **Immunity**; 46: 51-64. PMC5336605.

B. Positions and Honors

Employment / Experience

2016-present Chair and Senior member, Department of immunology, Moffitt Cancer Center, Tampa, FL
2015-2016 Professor, TME & Metastasis Program, The Wistar Institute, Philadelphia, PA
2013-2016 Director of Graduate Studies, The Wistar Institute Cancer Center, Philadelphia, PA
2011-2020 Wistar Associate Professor of Pathology&Laboratory Medicine, University of Pennsylvania
2012-2016 Program Leader, The Wistar Institute Cancer Center, Philadelphia, PA
2010-2015 Associate Professor, TME & Metastasis Program, The Wistar Institute, Philadelphia, PA
2005-2010 Assistant Professor, Dartmouth Medical School, Lebanon, NH
2001-2005 Postdoc/Research Associate, University of Pennsylvania, Philadelphia, PA
2000-2001 Project Leader, IPF Pharmaceuticals GmbH, Hannover, Germany
1993-1996 Residency, University Hospital of Guadalajara, Spain

Honors / Awards

2017-present External Advisory Board (UT Health San Antonio and the UT San Antonio Cancer Center)
2017-2019 AACR Cancer Immunology (CIMM) Steering Committee
2016-2021 Mentor of the Ovarian Cancer Academy (Department of Defense)
2016-present European Academy of tumor Immunology (elected member)
2015-2018 Program Committee Member (American Association of Immunologists)
2011-2015 Transplantation, Tolerance and Tumor Immunology NIH Study Section, chartered member
2015 Tumor Immunobiology Section (2016 AACR Program Committee).
2011-present Board Editor, *Journal of Leukocyte Biology*
2012-present Editorial Advisory Board, *MicroRNA Diagnostics and Therapeutics*
2012 Chair, Major Symposium on Tumor Immunity, A.A. of Immunologists Centennial Celebration
2010-present Abstract Programming Chair (Tumor Immunology), American Association of Immunologists
2009-2013 Minority Affairs Committee Member (American Association of Immunologists)
2006 & 2009 Liz-Tilberis Award for Excellence in Ovarian Cancer Research.
1997-1998 Post-residency Fellowship, Fondo de Investigación Sanitaria, Spain (FIS 97/5315).
1998 International Fellowship, University of Bern, F. Investigación Sanitaria, Spain (BEFI 98/9524).

C. Contributions to Science

1. In my early publications at the University of Pennsylvania, I was fortunate to contribute to most of the seminal discoveries that have established the framework for our current understanding of the immunobiology of ovarian cancer. I co-1st-authored the pioneering manuscript that identified human ovarian carcinoma as an immunogenic disease, at a time when the prevailing view in the field was that only melanoma or virus-associated tumors were truly immunogenic. This finding, subsequently corroborated by other groups, was followed by the identification of immunosuppressive networks orchestrated by both myeloid cells (tolerogenic DCs, termed by us Vascular Leukocytes or VLCs) and regulatory T lymphocytes. These results have been central for the advancement of the field of tumor immunology in general, beyond the specifics of the immunobiology of ovarian cancer, as documented by **>3,500 citations** in Scopus for just the 3 papers referenced below:
   a. Zhang L*, *Conejo-Garcia JR******, Katsaros D, Gimotty P, Massobrio M, Regnani G, Makrigiannakis A, Schlienger K, Liebman MN, Rubin SC, Coukos G. Intratumoral T cells, recurrence and survival in epithelial ovarian cancer. ***N Engl J Med***; 348:201-211, 2003. (*******Equal contribution*) [*Editorial* comment].
   b. *Conejo-Garcia JR*, Benencia F, Courreges MC, Kang E, Mohamed-Hadley A, Buckanovich RJ, Holtz DO, Jenkins A, Na H, Zhang L, Wagner DS, Katsaros D, Caroll R, Coukos G. Tumor-infiltrating dendritic cell precursors recruited by a β-defensin contribute to vasculogenesis under the influence of Vegf-A. ***Nat Med****;* 10:950-958, 2004.
   c. Curiel TJ, Coukos G, Zou L, Alvarez X, Cheng P, Mottram P, Evdemon-Hogan M, *Conejo-Garcia JR*, Zhang L, Burow M, Zhu Y, Wei S, Kryczek I, Daniel B, Gordon A, Myers L, Lackner A, Disis ML, Knutson KL, Chen L, Zou W. Specific recruitment of regulatory T cells in ovarian carcinoma fosters immune privilege and predicts reduced survival. ***Nat Med****;* 10:942-949, 2004.
2. Subsequent independent studies in my laboratory have progressively elucidated the mechanisms whereby pathological myelopoiesis promotes a phenotypic switch in Dendritic Cells (DCs) during ovarian cancer progression, which determines the transition from immunological control of malignant

progression to exponential tumor growth. Our work also unveiled a major mechanism of deregulated myelopiesis in cancer-bearing hosts driven by estrogenic signal, which promotes the mobilization and enhanced suppressive activity of both lineages of MDSCs. This has open new avenues for combining anti-estrogens and checkpoint inhibitors at Moffitt. In a seminal study performed in collaboration with Laurie Glimcher, we also identified ER stress as a major driver of tumor-associated DC-mediated immunosuppression in ovarian cancer. By understanding the orchestration of these pathways, we have also validated approaches to reverse this tumor-promoting activity and transform tumor-associated APCs from immunosuppressive/pro-angiogenic drivers of malignant progression into an immunostimulatory cell type. These advances are illustrated in these representative publications:

a. Cubillos-Ruiz J, Engle X, Scarlett U, Martinez D, Barber A, Elgueta R, Wang L, Nesbeth Y, Durant Y, Gewirtz AT, Sentman CL, Kedl R, *Conejo-Garcia JR*. Polyethylenimine-based siRNA nanocomplexes reprogram tumor-associated dendritic cells via TLR5 to elicit therapeutic antitumor immunity. **J Clin Invest**; 119:2231-2244, 2009. PMC2719935.
b. Scarlett UK, Rutkowski MR, Rauwerdink AM, Fields J, Escovar-Fadul X, Baird J, Cubillos-Ruiz JR, Jacobs AC, Gonzalez J, Weaver J, Fiering S, *Conejo-Garcia JR*. Ovarian cancer progression is controlled by phenotypic changes in dendritic cells. **J Exp Med**; 209:495-506, 2012. PMC3302234. [*Covered as Leading Edge by Cell, Faculty of 1000, Nature Reviews in Cancer Highlights* and *FIGO news cover*].
c. Cubillos-Ruiz JR, Silberman PC, Rutkowski MR, Chopra S, Perales-Puchalt A, Song M, Zhang S, Bettigole S, Gupta D, Holcomb K, Hedrick-Ellenson LH, Caputo T, Lee AH, *Conejo-Garcia JR*, Glimcher LH (2015). ER Stress Sensor XBP1 Controls Anti-tumor Immunity by Disrupting Dendritic Cell Lipid Homeostasis. **Cell**: 1527–1538. PMC4580135. [Merad M.& Salmon H; *News and Views* in *Nature* 523, 294–295: "Cancer: A dendritic-cell brake on antitumour immunity"] [Research Highlights in *Nature Reviews Immunol*. 15: "Stressed DCs can't handle T cells"] [Highlighted in *Cancer Discovery* 5: "The ER Stress Factor XBP1 Inhibits Antitumor Immune Responses"] [Garris C & Pittet MJ. "ER Stress in Dendritic Cells Promotes Cancer". Preview comment on JR Cubillos-Ruiz et al., *Cell*. 161: 1527–1538].
d. Svoronos N, Perales-Puchalt A, Allegrezza MJ, Rutkowski MR, Payne KK, Tesone AJ, Nguyen JM, Curiel TJ, Cadungog MG, Singhal S, Eruslanov EB, Tchou J, Zhang R, *Conejo-Garcia JR* (2017). Tumor cell-independent estrogen signaling drives malignant progression through MDSC mobilization. **Cancer Discovery**. 7: 72-85. PMC5222699. [**Editor's Choice**: Ferrarelli LK; "Tamoxifen as an immunotherapy" *Sci. Signal.*10, 2017] [Featured article. Welte T., Zhang, XHF & Rosen JM; Comment in *Cancer Discovery* 7, 17: "Repurposing Antiestrogens for Tumor Immunotherapy"].

3. In complementary studies aimed to understand how tumors suppress protective immunity, we have also characterized novel intrinsic and extrinsic mechanisms driving T cell unresponsiveness in the tumor microenvironment, and in particular in solid ovarian tumors. A particularly significant contribution is the identification of the transcription factor Foxp1, commonly up-regulated in tumor-infiltrating lymphocytes in multiple cancers, as a repressor of T cell effector activity through a transcriptional program that involves cooperation with TGF-β-dependent networks. Other major advance was the identification for the first time of how genetic variation influences tumor-promoting inflammation (and, subsequently, malignant progression) through interactions with commensal bacteria. This seminal work, highlighted as "free featured article" in *Cancer Cell*, identified for the first time how systemic changes that affect multiple leukocyte subsets (including myeloid progenitors and γδ T cells) are critically determined by the crosstalk between the microbiota and $TLR5^+$ hematopoietic cells at distal locations, while tumors remain sterile. Representative publications of these contributions are as follows:
   a. Nesbeth Y, Scarlett U, Cubillos-Ruiz J, Martinez D, Engle X, Turk MJ, *Conejo-Garcia JR*. Elimination of ovarian cancer dendritic cells boosts endogenous anti-tumor immunity elicited by adoptively transferred lymphocytes. **Cancer Res**; 69:6331-6338, 2009. [*Cancer Research Highlights and side bar cover*]. PMC2755640.
   b. Nesbeth Y, Martinez D, Toraya S, Scarlett U, Cubillos-Ruiz J, Rutkowski M, *Conejo-Garcia J*. $CD4^+$ T cells elicit host immune responses to MHC-II- ovarian cancer through CD40-mediated licensing of dendritic cells and CCL5 secretion. **J Immunol**; 184:5654-5662, 2010. PMC2874073.
   c. Stephen TL, Rutkowski MR, Allegrezza MJ, Perales-Puchalt A, Tesone AJ, Svoronos N, Nguyen J, Borowsky ME, Tchou J, and *Conejo-Garcia JR*. Transforming Growth Factor-beta-Mediated Suppression of Antitumor T Cells Requires FoxP1 Transcription Factor Expression. **Immunity**; 41: 427-39, 2014. PMC4174366. [Highlighted in: Zitvogel L. & Kroemer G. Targeting Foxp1 for reinstating anticancer immunosurveillance. *Preview comment* on TL Stephen et al., *Immunity*. 41: 345-7].

d. Rutkowski MR, Stephen TL, Svoronos N, Allegrezza MJ, Perales-Puchalt A, Tesone AJ, Escovar-Fadul X, Nguyen JM, Cadungog MG, Zhang R, Salatino M, Rabinovich GA, Tchou J, *Conejo-Garcia JR*. Microbially driven TLR-dependent signaling governs distal malignant progression through tumor-promoting inflammation. **Cancer Cell**; 27: 27-40, 2015. PMC4293269 [***Free Featured Article**; Cancer Cell 27 (1)*] [Highlighted in *Nature Reviews Cancer* 15: 69; Immune responses to commensal bacteria] [Highlighted in *Cancer Discovery*. 5: OF4; Uncovering Microbes' Role in Tumor Progression] [Highlighted in *The Scientist* 29: "Manipulative Microbiomes"] [Pfirschke C, Garris C & Pittet MJ. Common TLR5 Mutations Control Cancer Progression. *Preview comment* on Rutkowski et al., *Cancer Cell*. 27: 27-40]

4. In recent years, my research program has evolved to understand the epigenetic mechanisms driving the immune-environment of solid tumors. These studies have primarily focused on the crosstalk between different cells types but underscore the importance of the genomic organizer Satb1 in the pro-inflammatory, paradoxically immunosuppressive activity of Dendritic Cells infiltrating solid ovarian tumors. Satb1 is particularly relevant because it alters the 3D structure of transcriptionally poised heterochromatin, thus bringing together distanced genomic regions and defining their accessibility to transcription factors. In addition, Satb1 serves as a docking platform for many epigenetic modifiers, both writers and erasers. Our recent studies have demonstrated, for instance, that Satb1 is a crucial repressor of PD-1 up-regulation in anti-tumor T cells, but this immunostimulatory activity is abrogated by TGF-β-induced down-regulation of Satb1 in the TME. Understanding how the 3D structure of the genome influences immune phenotypes in health and cancer will be a future major interest for the lab. Representative contributions in seminal epigenetic studies are as follows:
   a. Bitler BG, Garipov A, Amatangelo M, Kossenkov A, Schultz DC, Shih IM, *Conejo-Garcia JR*, Speicher DW, Zhang R (2015). Targeting EZH2 methyltransferase activity in ARID1A mutated cells as a synthetic lethal therapeutic strategy. **Nature Med.**; 21: 231-238, 2015. PMC4352133.
   b. Tesone AJ, Rutkowski MR, Brencicova E, Svoronos N, Perales-Puchalt A, Stephen TL, Allegrezza MJ, Payne KK, Nguyen JM, Wickramasinghe J, Tchou J, Borowsky ME, Rabinovich GA, Kossenkov AV, *Conejo-Garcia JR* (2016). Satb1 Overexpression Drives Tumor-Promoting Activities in Cancer-Associated Dendritic Cells. **Cell Reports**.14: 1774–1786. PMC4767618 [Highlighted in *Cancer Discovery* 6:OF1; "How Ovarian Cancer Evades Immune Scrutiny"(News in Brief)]
   c. Stephen TL, Payne KK, Chaurio RA, Allegrezza MJ, Zhu H, Perez-Sanz J, Perales-Puchalt A, Nguyen JM, Vara-Ailor AE, Eruslanov EB, Borowsky ME, Zhang R, Laufer TM, *Conejo-Garcia JR* (2017). SATB1 expression governs epigenetic repression of PD-1 in tumor-reactive T cells. **Immunity**; 46:51-64. PMC5336605. [*Most read: Last 30 days* list in *Immunity* (1/29/2017-3/6/2017)] [Highlighted in: Nixon BG. & Li MO; Satb1: Restraining PD1 and T Cell Exhaustion. *Preview comment* on TL Stephen et al., *Immunity*. 46: 3-5].

5. More recently, we have combined our expertise in the immunobiology of gynecologic malignancies with the knowledge of multiple experts to optimize and test in preclinical systems a variety of immunotherapeutic approaches for the treatment of gynecologic malignancies that include the use of nanomaterials; combinatorial interventions; antibody-based treatments; vaccines; and, as aforementioned, the adoptive transfer of tumor-reactive T cells, including novel chimeric receptors. Translational work will be the second pillar of my research program in upcoming years, through the ongoing support of pharmaceutical companies. Some (non-redundant) representative publications of these contributions published in the last 2 years are as follows:
   a. Allegrezza MJ, Rutkowski MR, Stephen TL, Svoronos N, Perales-Puchalt A, Nguyen JM, Singhal S, Eruslanov EB, Tchou J, Conejo-Garcia JR (2016). Trametinib drives T cell-dependent control of k-Ras-mutated tumors by inhibiting pathological myelopoiesis. **Cancer Res**. 76: 6253-6265. PMC5094194.
   b. Allegrezza MJ, Rutkowski MR, Stephen TL, Svoronos N, Tesone AJ, Perales-Puchalt A, Nguyen JM, Sarmin F, Sheen MR, Jeng EK, Tchou J, Wong HC, Fiering S, Conejo-Garcia JR (2016). IL-15 agonists overcome the immunosuppressive effects of MEK inhibitors. **Cancer Res**. 76: 2561-72. PMC4873368.
   c. Perales-Puchalt A, Svoronos N, Rutkowski MR, Allegrezza MJ, Tesone AJ, Payne KK, Wickramasinghe J, Nguyen JM, O'Brien SW, Cadungog M, Connolly DC, Tchou J, Curiel TJ, *Conejo-Garcia JR* (2016). Follicle-stimulating hormone receptor is expressed by most ovarian cancer subtypes and is a safe and effective immunotherapeutic target. **Clin. Cancer Res**. 23:441-53. PMC5241180.

Complete List of Published Work in MyBibliography, including **73 manuscripts published since 2008**:
https://www.ncbi.nlm.nih.gov/sites/myncbi/jose.conejo-garcia.1/bibliography/41147020/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

1. Title: Initiation and evolution of the ovarian cancer microenvironment
   Principal Investigator: **Jose R Conejo-Garcia**
   Granting Agency: NCI
   Type: R01 (2CA157664)
   Period: 07/01/2016 – 06/30/2021
   Goals: The goal of this project is to define the mechanisms of accumulation of myeloid leukocytes during malignant progression, as well as their role in the oncogenic transformation of ovarian epithelial cells.

2. Title: Effects of common polymorphisms in immune sensors in tumor immunosurveillance
   Principal Investigator: **Jose R Conejo-Garcia**.
   Granting Agency: NCI
   Type: Type: R01 (CA178687)
   Period: 09/01/2013 – 06/30/2018
   Goals: The major goals of this project are to elucidate very common polymorphisms in pattern recognition receptors influence systemic immunosurveillance and the orchestration of different anti-tumor immune microenvironments.

Subawards

1. Title: Ovarian Cancer Academy
   Principal Investigator: Juan R. Cubillos-Ruiz (Early Career Investigator).
   Granting Agency: Department of Defense
   Role: Mentor of Dr. Juan Cubillos-Ruiz (10% salary support).
   Period: 06/01/2016–03/31/2021

2. Title: Developing a Human in Mouse Cancer Model with a Completely Humanized Stroma.
   Principal Investigator: Ronald J. Buckanovich.
   Role: Subaward (5% effort).
   Granting Agency: NCI (R01 CA211913)
   Type: R01 ($58,500/year, direct costs)
   Period: 07/01/2017 - 06/30/2020

Pending Research Support

1. Title: Regulatory Dendritic Cells in cancer.
   Principal Investigator: **Jose R Conejo-Garcia** (15% effort).
   Granting Agency: NCI (2R01CA124515; RO1 competitive renewal; **percentile 6**)
   Type: Type: R01 ($225,000/year, direct costs)
   Period: 4/1/2018– 5/31/2023

BIOGRAPHICAL SKETCH

NAME: Grohar, Patrick J.

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

POSITION TITLE: Associate Professor, Van Andel Research Institute, Center for Cancer & Cell Biology

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Villanova University, Villanova PA	B.S.	05/1995	Chemistry
Wayne State University, Detroit, MI	Ph.D.	05/2001	Chemistry
Wayne State University, Detroit, MI	M.D.	05/2003	Medicine
Johns Hopkins University, Baltimore, MD		06/2006	Residency, Pediatrics
Johns Hopkins University/National Cancer Institute Baltimore & Bethesda, MD		06/2009	Fellowship, Pediatric Hematology-Oncology

A. Personal Statement

My professional goal is to aspire to the ideals of the physician-scientist, providing compassionate patient care while developing innovative new approaches to treat pediatric cancer. In part because of an encounter with a particular patient, my laboratory is focused on improving outcomes for patients with sarcomas by developing small molecule inhibitors of the oncogenic transcription factors believed to be responsible for malignant transformation and progression. I have developed a high-throughput screen targeting EWS-FLI1 in Ewing sarcoma and identified mithramycin, a drug that translated to the clinic in a phase I/II trial. In addition, we characterized trabectedin as an inhibitor of EWS-FLI1. Ongoing efforts are focused on further developing both compounds by studying structurally related analogs as well as developing and translating novel molecularly targeted combination therapies. In addition, we have developed an imaging based biomarker to facilitate the clinical translation of our EWS-FLI1 directed therapies to the clinic. We are working to develop novel and innovative clinical trial designs to use this tracer to maximize the suppression of target and minimize off target toxicity. In the process, we hope to improve the translation of EWS-FLI1 directed therapies and learn about the therapeutic targeting of EWS-FLI1 in patients. Finally, more recently we have conducted a number of studies with the goal of understanding the most effective way to target oncogenic transcription factors for pediatric malignancies. These studies involve both the mechanistic investigation of molecular pharmacology of transcription drug targeting and investigation of our approaches in other pediatric malignancies.

B. Positions and Honors

Positions and Employment

2003-2006 Pediatric Residency, Johns Hopkins Hospital Baltimore, MD: Research Track
2006-2009 Pediatric Oncology Fellowship, Johns Hopkins Hospital & The National Cancer Institute
2008-2009 Chief Fellow, Johns Hopkins Hospital & The National Cancer Institute
2010-2011 Instructor, Pediatric Oncology Branch, National Cancer Institute, National Institutes of Health
2011-2012 Assistant Clinical Investigator, Pediatric Oncology Branch, National Cancer Institute, National Institutes of Health
2012-2015 Assistant Professor (tenure track), Pediatrics, Cancer Biology and Pharmacology, Vanderbilt University School of Medicine
2015- Member, Division of Hematology/Oncology, Helen De Vos Children's Hospital
2015- Associate Professor of Pediatrics, Michigan State University Department of Pediatrics
2015- Associate Professor, Center for Cancer and Cell Biology, Van Andel Institute
2015- Children's Oncology Group Bone Tumor Steering Committee Member
2015- Vice Chair: Children's Oncology Group, Ewing Sarcoma Biology Committee
2015- Scientific Review Board, Alex's Lemonade Stand Foundation

2016- Developmental Therapeutic Committee Member: Sarcoma Alliance for Research Through Collaboration (SARC)
2016, 2017 Grant Reviewer, National Science Foundation of Switzerland
2016- Medical Director, Sean Karl Foundation
2017 Ad hoc reviewer: Cancer Molecular Pathobiology Study Section, National Cancer Institute, National Institutes of Health

Certification

2009 Board Certified in Pediatrics
2011 Board Certified in Pediatric Oncology

Honors:

1995 Villanova University Varsity Lacrosse Student-Athlete Award
1997 Phi Lambda Upsilon National Chemistry Honor Society
2003 Graduation with Distinction in Biomedical Research, Wayne State University-SOM
2008-2010 Pediatric Oncology Branch Research Competition: 1st Place
2008 Chief Fellow
2010 Finalist: American Association for Cancer Research (AACR) Scholar in Training Award
2010 Career Development Award, Sarcoma Alliance for Research through Collaboration (SARC)
2011 Fellows Award for Research Excellence (FARE), National Institutes of Health (awarded 2010)
2012 Turner-Hazinski Award Vanderbilt University
2012 St. Baldrick's Scholar Award
2012 Hyundai Hope on Wheels, Hope Scholar
2013 Junior Faculty Development Program, Vanderbilt University
2017 St. Baldrick's Scholar Award

C. Contribution to Science

1. Structure and function of post-transcriptional modifications of ribosomal RNA

In graduate school, I employed a chemical biology approach to understand the function of the modified nucleoside pseudouridine in the bacterial ribosome.

Grohar, P. J.; Chow, C. S. A practical synthesis of the modified RNA nucleoside pseudouridine. Tetrahedron Lett. **1999**, 40, 2049-2052. doi: 10.1016/S0040-4039(99)00162-8.

Meroueh, M.; **Grohar, P. J.**; Qiu, J.; SantaLucia, J.; Scaringe, S. A.; Chow, C. S. Unique structural and stabilizing roles for the individual pseudouridine residues in the 1920 region of Escherichia coli 23S rRNA. Nucleic Acids Res. **2000** May 15;28(10), 2075-2083. PMCID: PMC105375

2. Molecular targeting of tyrosine kinases for human cancer

I have worked extensively on the therapeutic targeting of kinases particularly early in my career. I synthesized novel SRC inhibitors, explored kinase targeting in leukemia and in rhabdomyosarcoma. We characterized a feedback activation of AKT with mTOR inhibition that has been cited 480 times. inhibition of mTOR that activates AKT via the IGF1R receptor. This article has been cited over 600 times.

Schroeder, M. C.; Hamby, J. M.; Connolly, C. J. C.; **Grohar, P. J.**; Winters, R. T.; Barvian, M. R.; et al.; Showalter H. D. Soluble 2-substituted amino[2,3-d]pyrimidin-7-yl ureas. Structure-Activity Relationships (SAR) against selected tyrosine kinases and exploration of in vitro and in vivo anticancer activity. J Med Chem **2001** Jun 7;44(12), 1915-1926. PMID: 11384237 [PubMed - indexed for MEDLINE]

Ge, Y., Jensen, T. L., Stout, M. L., Flatley, R. M., **Grohar, P. J.,** Ravindranath, Y., Matherly, L. H., Taub, J. W. The role of cytidine deaminase and GATA1 mutations in the increased cytosine arabinoside sensitivity of Down Syndrome myeloblasts and leukemia cell lines. Cancer Research **2004** Jan 15;64(2), 728-735. PMID: 14744791 [PubMed - indexed for MEDLINE]

Wan, X., Harkavy B., Shen, N., **Grohar, P**., Helman, L.J. Rapamycin induces feedback activation of Akt signaling through an IGF-1R-dependent mechanism. Oncogene **2007** Mar 22;26(13), 1932-1940. (603 citations) PMID: 17001314 [PubMed - indexed for MEDLINE]

Yeung, C., Ngo, V. N., **Grohar, P. J.**, Arnaldez, Fl, Asante, A., Wan, X., Khan, J., Hewitt, S.M., Khanna, C., Staudt, L. M., Helman, L. J. Loss-of-function screen in rhabdomyosarcoma identifies CRKL-YES as a critical signal for tumor growth. Oncogene. 2013 Nov 21;32(47):5429-38. PMCID: PMC3898328

3. Identification of mithramycin as an inhibitor of EWS-FLI1
We screened more than 50,000 compounds to identify mithramycin as an inhibitor of EWS-FLI1 and translated this compound to the clinic. More recently, we have reported second-generation mithramycin analogs with improved targeting of the EWS-FLI1 transcription factor. This work has provided the basis for a number of ongoing studies to develop this compound for this indication.

Grohar, P. J., Woldemichael, G., Griffin, L. B., Yeung, C., Chen, Q., Pommier, Y., Khanna, C., Khan, J., McMahon, J., Helman, L.J. Identification of an inhibitor of the EWS-FLI1 transcription factor by high-throughput screening. J Natl Cancer Inst **2011** Jun 22;103(12): 962-978. (112 citations) PMCID: PMC3119649

Osgood, C. L., Maloney, K. N., Kidd, C. G., Kitchen-Goosen, S. M., Segars, L. E., Gebregiorgis, M., Woldemichael, G. M., He, M., Sankar, S., Lessnick, S. L., Kang, M.,Smith, M. A., Turner, L., Madaj, Z. B., Winn, M. E., Nuñez, L. E., Gonzalez-Sabin, J., Helman, L. J., Morís, F., **Grohar, P. J.** "Identification of mithramycin analogs with improved targeting of the EWS-FLI1 transcription factor" **2016** Clin Cancer Res Mar 15

Grohar, P. J., Glod J., Peer C.J., Sissung, T.M., Arnaldez, F.I., Long, L., Figg, W. D., Whitcomb, P., Helman, L. J., Widemann, B. C. *Cancer Chemother Pharmacol* **2017** Jul 22

4. Development of trabectedin as an EWS-FLI1 inhibitor
Trabectedin (Ecteinascidin 743; ET-743; Yondelis) is a natural product that we have characterized as an EWS-FLI1 inhibitor. We subsequently proposed a novel synergistic targeted combination therapy with irinotecan that focuses the drug associated DNA damage on Ewing sarcoma cells based on this suppression of EWS-FLI1 activity; a combination showing activity in the clinic. Ongoing efforts, funded by an R01 included characterizing the mechanism of suppression, and developing second and third generation analogs.

Grohar, P. J., Griffin, L. B., Yeung, C., Chen, Q., Pommier, Y., Khanna, C., Khan, J., Helman, L.J. Ecteinascidin 743 (ET-743) interferes with the activity of EWS-FLI1 in Ewing's sarcoma cells. Neoplasia **2011** Feb;13(2): 145-153. (77 citations) PMCID: PMC3033593

Grohar, P.J., Segars, L. E., Yeung, C., Mendoza, A., Helman, L. J. Dual targeting of EWS-FLI1 activity and the associated DNA damage response with Trabectedin and SN38 synergistically inhibits Ewing sarcoma cell growth Clin Cancer Res **2014** Mar 1;20(5):1190-203. (37 citations) PMID: 24277455

Tancredi, R., Zambelli, A, DaPrada, G.A., Fregoni, V., Pavesi, L., Riccardi, A., Burdach, S., **Grohar, P.J.,** D'Incalci, M., Targeting the EWS-FLI1 transcription factor in Ewing sarcoma. Cancer Chemother Pharmacol **2015** Jun;75(6):1317-20.

Herzog, J., von Klot-Heydenfeldt, F., Jabar, S., Ranft, A., Rossig, C., Dirksen, U., Van den Brande, J., D'Incalci, M., von Leuttichau, I., **Grohar, P. J.,** Berdel, W. E., Burdach, S., Trabectedin followed by irinotecan can stabilize disease in advanced translocation-positive sarcomas. Sarcoma **2016** 2016:7461783.

Harlow, M. L., Maloney, K., Roland, J., Navarro, M., Easton, M. K., Kitchen-Goosen, S. M., Boguslawski, E., Madaj, Z. B., Johnson, B. K., Bowman, M. J., D'Incalci, M., Winn, M. E., Turner, L., Hostetter, G., Galmarini, C. M., Aviles, P., **Grohar, P.J.** Lurbinectedin inactivates the Ewing sarcoma oncoprotein EWS-FLI1 by redistributing it within the nucleus. Cancer Res **2016** 76(22): 6657-6668

5. Clinical translation of targeted therapy for Ewing sarcoma
The final component of our bench to bedside approach is to aid in the clinical translation of new therapies for sarcomas. For a rare disease, this involves national and international collaborations. Aside from the two clinical studies listed above, I have recently chaired two sessions focused on translation therapeutics at international conferences CTOS and ANSET-ENCCA in Berlin and Paris. In addition, I am a member of the bone tumor steering committee and vice-chair of the Ewing sarcoma biology committee for our national

network of children's hospitals, the Children's Oncology Group. Most recently, my leadership in this area was recognized with an invited talk and associated review paper at the annual meeting for the American Society of Clinical Oncology (ASCO). Our laboratory work in this arena is focused on two main areas, identification of therapeutic vulnerabilities for the transcription factor drug targets and developing companion assays for clinical trials to allow us to ask therapeutic questions in patients. We have performed a genome wide siRNA screen to characterize splicing as a therapeutic vulnerability in Ewing sarcoma. In addition, we have characterized a compound being developed for other indications, called Englerin A, that impairs the ability of EWS-FLI1 to bind chromatin. Finally, we have recently reported a PET tracer and correlative quantitative immunofluorescent assay that will allow us to measure EWS-FLI1 suppression in patients.

Kovar H, Amatruda J, Brunet E, Burdach S, Cidre-Aranaz F, de Alava E, Dirksen U, van der Ent W, **Grohar P**, et al. The second European interdisciplinary Ewing sarcoma research summit - A joint effort to deconstructing the multiple layers of a complex disease. Oncotarget **2016** Feb 23; 7(8): 8613-24

Caropreso, V., Darvishi, E., Turbyville, T. J., Ratnayake, R., **Grohar, P. J.**, McMahon, J. B., Woldemichael, G. Englerin A inhibits EWS-FLI1 DNA binding in ewing sarcoma cells. **2016** J Biol Chem; May 6; 291 (19):10058-66

Grohar, P.J.*, Kim, S.*, Rangel Rivera G.O., Sen, N., Haddock, S., Harlow, M. L., Maloney, K. N., Zhu, J. et al. Functional genomic screening reveals splicing of the nascent *EWS-FLI1* fusion transcript as a vulnerability in Ewing sarcoma. Cell Rep **2016** Jan 26; 14(3): 598-610

Osgood, C. L., Tantawy, M. N., Maloney, N., Madaj, Z. B., Peck, A., Boguslawski, E., Jess, J., Buck, J., Winn, M.E., Manning, H.C., **Grohar, P.J**. 18F-FLT Positron Emission Tomography (PET) is a pharmacodynamic marker for EWS-FLI1 activity and Ewing sarcoma. Sci Rep **2016** Sep 27; 6: 33926

Grohar, P. J., Janeway, K. A., Mase, L.D., Schiffman, J.D. Advances in the Treatment of Pediatric Bone Sarcomas. Am Soc Clin Oncol Educ Book. **2017**

Complete List of Published Work in MyBibliography
https://www.ncbi.nlm.nih.gov/sites/myncbi/1Zo68UgyGzmQ5/bibliography/48282123/public/?sort=date&direction=ascending

D. Research Support

Current Research Support

National Cancer Institute, PI: Grohar 09/07/15-08/31/20
National Institutes of Health
1R01-CA188314
Development of Trabectedin Analogs that Target the EWS-FLI1 Transcription Factor.
The goal of this study is to develop the small molecule trabectedin as an EWS-FLI1 inhibitor. The work involves characterizing the mechanism of suppression, developing second generation analogs and novel combination therapies.

St. Baldrick's Research Grant Award PI: Grohar 07/01/17–06/30/18
Small molecule targeting of EWS-FLI1 Binding to Chromatin
The goal of this study is to develop and innovative technology called long read sequencing to map the binding of EWS-FLI1 to the genome. The work involves developing this technology to validate a gene signature of EWS-FLI1. We will use this signature to evaluate the top hits from a previously completed 56,000 compound high throughput small molecule screening campaign to identify compounds that reverse the EWS-FLI1 gene signature.

Alex's Lemonade Innovation Award PI: Grohar 10/01/17–9/30/19
Development of the second generation mithramycin analog, EC8042 as an EWS-FLI1 inhibitor
The goal of this proposal is to perform IND enabling studies of the mithramycin analog EC8042 to increase the interest in developing this compound for the clinic. We employ innovative sequencing technologies to map the consequence of EC8042 treatment on chromatin structure and RNAPII dynamics. In addition, we will optimize

the dose, route and schedule of administration of the drug and determine the effect of drug treatment on the three dimensional structure of the tumor using PET imaging technologies.

Hyundai Hope on Wheels Hope Grant PI: Gedminas Role: Mentor 07/01/17–06/30/19
Development of trabectedin as a targeted therapy for EWSR1-WT1 and Desmoplastic Small Round Cell Tumor (DSRCT). This study is to support the scientific development of a clinical fellow in the laboratory, Jenna Gedminas, MD. The work involves a mechanistic exploration of the small molecule called trabectedin as a targeted therapy for DSRCT.

Van Andel Institute Faculty Innovation Award PI: Grohar 10/01/16-10/01/17
Development of genome wide siRNA screening functional genomic capabilities
The goal of this award was to establish genome wide siRNA screening in my laboratory. We obtained a genome wide library as well as the capabilities to do these screens in our laboratory. We have established production collaborations with other investigators to initiate functional genomic screens.

Completed Research Support
Alex's Lemonade Stand Reach Award PI: Grohar 01/01/14–12/31/16
Development of a Pharmacodynamic Marker of EWS-FLI1 Activity to Aid in the Clinical Translation of Targeted Therapies for Ewing Sarcoma
The goal of this proposal is to develop pharmacodynamic measurements of EWS-FLI1 activity for in vivo applications.

Turner Hazinski Award PI: Grohar 07/01/12–06/30/14
Small Molecule Drug Discovery for the Treatment of Pediatric Sarcomas

Hyundai Hope on Wheels Hope Grant PI: Grohar 09/01/12–11/30/14
Identification of Novel EWS-FLI1 Targeted Mithramycin Analogs with Improved Potency and Target Specificity

Sarcoma Alliance for Research through Collaboration (SARC) PI: Grohar 07/01/2010-11/01/2013
Career Development Award, Years of funding: 2010-2013
Role: Principal Investigator
Development of Targeted Therapies for Ewing Sarcoma

St. Baldrick's Research Grant Award PI: Grohar 07/01/12–06/30/13
Development of Trabectedin as an EWS-FLI1 Directed Therapy for Ewing Sarcoma

BIOGRAPHICAL SKETCH

NAME: Wang, Ting

eRA COMMONS USER NAME (agency login): TINGWANG

POSITION TITLE: Associate Professor

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
Peking University (China), Beijing	BS	07/1997	Biochemistry and Molecular Biology
Washington University	MS	05/2002	Computer Sciences
Washington University	PHD	05/2006	Computational Biology
Xinyang Military Academy, Xinyang	Other training	05/1993	Military training
University of California, Santa Cruz	Postdoctoral Fellow	09/2009	Computational Biology

A. PERSONAL STATEMENT

I started my lab with a strong commitment to the development of computational and systems methods for understanding genetic and epigenetic regulatory networks. I focus on developing both experimental and computational strategies to investigate DNA methylation and transposable elements in human health and diseases. I have been a co-investigator on NIH U01 Roadmap Epigenome grant to create reference epigenome maps of normal human tissues. Current work in my lab is funded by an R01 from NIH to develop tools for integrative epigenomic data analysis and visualization, two R01s from NIH to investigate transposable elements' role in gene regulation, one U01 from NIH to investigate 3D genome structure, one U24 from NIH to establish a data coordination center for environmental epigenomics, one U01 from NIH to participate the ENCODE Consortium, and by a research scholar grant from American Cancer Society to study DNA methylation of enhancers in cancer development. Most of the computational infrastructure my lab developed, including next generation genomic data visualization platform and DNA methylation technology can be directly applied to Dr. McDonald's project. I am excited to apply and extend my expertise in genomics and epigenomics to an important area of cancer research.

I am committed to training graduate students, medical students, postdocs and junior faculties in cutting-edge science, especially those from under-represented backgrounds. I am the director for the Computational and Systems Biology graduate program. I serve on the admission committee of DBBS. I serve as mentors on four NIH T32 training grants. I am the course master of Bio5488, a graduate-level course that introduces modern genomics. I also give lectures in several other graduate-level courses, including Medical Genetics, Computational Molecular Biology, Research Exploration in Genomics, and Introduction to Bioinformatics. I have graduated 7 PhD students (including one from under-represented background), and currently mentor 8 pre-doctoral trainees and 3 postdoc fellows. Of the 7 graduated PhDs, four are now scientists at Biotech Companies including Novartis and Monsanto, 3 are conducting postdoc research in top labs in Europe or US. Two postdoc fellows I trained obtained faculty positions at prestigious research institutes in the US (St. Jude Hospital and Washington University). I have mentored 8 junior faculties and clinical fellows at both Washington University and other Institutes. I have served on 62 thesis committees and many qualifying exam committees.

Peer-reviewed Publications (Selected from a total of 72)

1. Brocks D, Schmidt CR, Daskalakis M, Jang HS, Shah NM, Li D, Li J, Zhang B, Hou Y, Laudato S, Lipka DB, Schott J, Bierhoff H, Assenov Y, Helf M, Ressnerova A, Islam MS, Lindroth AM, Haas S, Essers M, Imbusch CD, Brors B, Oehme I, Witt O, Lübbert M, Mallm JP, Rippe K, Will R, Weichenhan D, Stoecklin G, Gerhäuser C, Oakes CC, Wang T, Plass C (2017) DNMT and HDAC inhibitors globally induce cryptic TSSs encoded in long terminal repeats. Nat Genet. 49, 1052–1060 (2017). doi: 10.1038/ng.3889. PMID: 28604729
2. Lowdon RL, Jang HS, and Wang T. (2016) Evolution of epigenetic regulation in vertebrate genomes. Trends Genet. 2016 May;32(5):269-83. PMID: 27080453
3. Xie M, Hong C, Zhang B, Lowdon RF, Xing X, Li D, Zhou X, Lee HJ, Maire CL, Ligon KL, Gascard P, Sigaroudinia M, Tlsty TD, Kadlecek T, Weiss A, O'Geen H, Farnham PJ, Madden PA, Mungall AJ, Tam

A, Kamoh B, Cho S, Moore R, Hirst M, Marra MA, Costello JF, Wang T. DNA hypomethylation within specific transposable element families associates with tissue-specific enhancer landscape. Nat Genet. 2013 Jul;45(7):836-41. PubMed PMID: 23708189; PubMed Central PMCID: PMC3695047.
4. Sundaram V, Cheng Y, Ma Z, Li D, Xing X, Edge P, Snyder MP, Wang T. Widespread contribution of transposable elements to the innovation of gene regulatory networks. Genome Res. 2014 Dec;24(12):1963-76. PubMed PMID: 25319995; PubMed Central PMCID: PMC4248313.
5. Zhou X, Li D, Zhang B, Lowdon RF, Rockweiler NB, Sears RL, Madden PA, Smirnov I, Costello JF, Wang T. Epigenomic annotation of genetic variants using the Roadmap Epigenome Browser. Nat Biotechnol. 2015 Feb 18;PubMed PMID: 25690851. PMCID: PMC4467764
6. Kundaje A, Meuleman W, Ernst J, Bilenky M, Yen A, Heravi-Moussavi A, Kheradpour P, Zhang Z, Wang J, Ziller MJ, Amin V, Whitaker JW, Schultz MD, Ward LD, Sarkar A, Quon G, Sandstrom RS, Eaton ML, Wu YC, Pfenning AR, Wang X, Claussnitzer M, Liu Y, Coarfa C, Harris RA, Shoresh N, Epstein CB, Gjoneska E, Leung D, Xie W, Hawkins RD, Lister R, Hong C, Gascard P, Mungall AJ, Moore R, Chuah E, Tam A, Canfield TK, Hansen RS, Kaul R, Sabo PJ, Bansal MS, Carles A, Dixon JR, Farh KH, Feizi S, Karlic R, Kim AR, Kulkarni A, Li D, Lowdon R, Elliott G, Mercer TR, Neph SJ, Onuchic V, Polak P, Rajagopal N, Ray P, Sallari RC, Siebenthall KT, Sinnott-Armstrong NA, Stevens M, Thurman RE, Wu J, Zhang B, Zhou X, Beaudet AE, Boyer LA, De Jager PL, Farnham PJ, Fisher SJ, Haussler D, Jones SJ, Li W, Marra MA, McManus MT, Sunyaev S, Thomson JA, Tlsty TD, Tsai LH, Wang W, Waterland RA, Zhang MQ, Chadwick LH, Bernstein BE, Costello JF, Ecker JR, Hirst M, Meissner A, Milosavljevic A, Ren B, Stamatoyannopoulos JA, Wang T, Kellis M. Integrative analysis of 111 reference human epigenomes. Nature. 2015 Feb 19;518(7539):317-30. PubMed PMID: 25693563. PMCID: PMC4530010

B. POSITIONS AND HONORS

Positions and Employment

1998 - 2001	Medical research technician, Washington University in St. Louis
2006 - 2009	PostDoc, UNIVERSITY OF CALIFORNIA SANTA CRUZ
2009 - 2015	Assistant Professor, WASHINGTON UNIVERSITY
2015 -	Associate Professor, WASHINGTON UNIVERSITY

Other Experience and Professional Memberships

Honors

1997	Bachelor of Science with Honors, Magna Cum Laude, Peking University, Beijing, China
2004	Kauffman Fellowship in Life Science Entrepreneurship, Kauffman Foundation
2005	GlaxcoSmithKline Bioinformatics Prize, ISMB
2006	Helen Hay Whitney Fellowship, Helen Hay Whitney Foundation
2011	Special recognition for excellence in mentoring, Twelfth Annual Faculty Mentor Awards, Washington University
2011	Tomorrow's PI, Genome Technology, nominated by Francis Collins
2011	Basil O'Connor Scholar, March of Dimes Foundation

C. Contribution to Science

1. TRANSPOSABLE ELEMENTS AND GENE REGULATION: I have made major contribution to the understanding of transposable elements' role in the evolution of gene regulatory networks. During my time as a postdoc fellow in Dr. David Haussler's lab, I discovered that more than 30% of binding sites of the tumor suppressor protein p53 in the human genome was evolutionarily introduced by a type of transposable element called endogenous retrovirus (ERV). This work provided the first genome-wide evidence that supports a hypothesis proposed by Barbara McLintock and refined by Eric Davidson and Roy Britten, that transposable elements can shape gene regulatory networks in a genome-wide, systematic fashion. Since starting my own laboratory, I continued investigating how transposable elements impact genetic and epigenetic regulation. In 2013 my lab reported in a Nature Genetics paper that specific families of transposable elements are hypomethylated in specific tissue or cell types, and they encode tissue or

cell-type specific enhancers. In 2014 my lab reported in Genome Research a survey of 26 pairs of transcription factors in both human and mouse and found that 2~40% of binding sites of these transcription factors are contributed by transposable elements, majority of which are species-specific. These work robustly established a large contribution of transposable elements to gene regulation, and have been considered major milestones in the field.

a. Wang T, Zeng J, Lowe CB, Sellers RG, Salama SR, Yang M, Burgess SM, Brachmann RK, Haussler D. Species-specific endogenous retroviruses shape the transcriptional network of the human tumor suppressor protein p53. Proc Natl Acad Sci U S A. 2007 Nov 20;104(47):18613-8. PubMed PMID: 18003932; PubMed Central PMCID: PMC2141825.

b. Xie M, Hong C, Zhang B, Lowdon RF, Xing X, Li D, Zhou X, Lee HJ, Maire CL, Ligon KL, Gascard P, Sigaroudinia M, Tlsty TD, Kadlecek T, Weiss A, O'Geen H, Farnham PJ, Madden PA, Mungall AJ, Tam A, Kamoh B, Cho S, Moore R, Hirst M, Marra MA, Costello JF, Wang T. DNA hypomethylation within specific transposable element families associates with tissue-specific enhancer landscape. Nat Genet. 2013 Jul;45(7):836-41. PubMed PMID: 23708189; PubMed Central PMCID: PMC3695047.

c. Sundaram V, Cheng Y, Ma Z, Li D, Xing X, Edge P, Snyder MP, Wang T. Widespread contribution of transposable elements to the innovation of gene regulatory networks. Genome Res. 2014 Dec;24(12):1963-76. PubMed PMID: 25319995; PubMed Central PMCID: PMC4248313.

d. Sundaram V, Choudhary MNK, Pehrsson E, Xing X, Fiore C, Pandey M, Maricque B, Udawatta M, Ngo D, Chen Y, Paguntalan A, Ray T, Hughes A, Cohen BA, Wang T. (2017) Functional cis regulatory modules encoded by mouse specific endogenous retrovirus. Nature Communications. 10.1038/NCOMMS14550. PubMed PMID: 28348391; PubMed Central PMCID: PMC5379053

2. REGULATORY FUNCTION OF DNA METHYLATION: I have made significant contribution to the development of genomics tools to measure DNA methylation and the understanding of regulatory function of DNA methylation. In 2009 and between my postdoc training and starting my own lab, I spent several months in Dr. Joseph Costello's lab at UCSF to develop two sequencing-based, genome-wide DNA methylation assays (MeDIP-seq and MRE-seq). This was the beginning of our productive collaboration that so far has generated over a dozen high profile publications and several funded projects, including the Reference Epigenome Mapping Center of the NIH's Roadmap Epigenomics project. In 2013, my lab was among the first to publish that the majority of DNA methylation differences between healthy human cells are in enhancer elements, but not in promoter regions as previously believed. In 2014, my lab was among the first to demonstrate that by using DNA methylation and other epigenomic profiling we can robustly construct gene regulatory networks, much more so that using gene expression profiles. In the same year we also showed that in cancer, DNA methylation abnormality is much more profound in enhancer regions than promoter regions. In 2015, my lab was the first to map out DNA methylation profiles during the first 24 hours of zebrafish embryogenesis, and to construct corresponding gene regulatory networks based on developmental enhancers discovered by our approach. Our work over the past 5 years has generated highly efficient and cost effective DNA methylomics techniques, and robustly established that enhancers are a major target of DNA methylation during development, cellular differentiation, and disease genesis.

a. Maunakea AK, Nagarajan RP, Bilenky M, Ballinger TJ, D'Souza C, Fouse SD, Johnson BE, Hong C, Nielsen C, Zhao Y, Turecki G, Delaney A, Varhol R, Thiessen N, Shchors K, Heine VM, Rowitch DH, Xing X, Fiore C, Schillebeeckx M, Jones SJ, Haussler D, Marra MA, Hirst M, Wang T, Costello JF. Conserved role of intragenic DNA methylation in regulating alternative promoters. Nature. 2010 Jul 8;466(7303):253-7. PubMed PMID: 20613842; PubMed Central PMCID: PMC3998662.

b. Zhang B, Xing X, Li J, Lowdon RF, Zhou Y, Lin N, Zhang B, Sundaram V, Chiappinelli KB, Hagemann IS, Mutch DG, Goodfellow PJ, Wang T. Comparative DNA methylome analysis of endometrial carcinoma reveals complex and distinct deregulation of cancer promoters and enhancers. BMC Genomics. 2014 Oct 6;15:868. PubMed PMID: 25286960; PubMed Central PMCID: PMC4198682.

c. Kundaje A, Meuleman W, Ernst J, Bilenky M, Yen A, Heravi-Moussavi A, Kheradpour P, Zhang Z, Wang J, Ziller MJ, Amin V, Whitaker JW, Schultz MD, Ward LD, Sarkar A, Quon G, Sandstrom RS, Eaton ML, Wu YC, Pfenning AR, Wang X, Claussnitzer M, Liu Y, Coarfa C, Harris RA, Shoresh N, Epstein CB, Gjoneska E, Leung D, Xie W, Hawkins RD, Lister R, Hong C, Gascard P, Mungall AJ, Moore R, Chuah E, Tam A, Canfield TK, Hansen RS, Kaul R, Sabo PJ, Bansal MS, Carles A, Dixon JR, Farh KH, Feizi S, Karlic R, Kim AR, Kulkarni A, Li D, Lowdon R, Elliott G, Mercer TR, Neph SJ, Onuchic V, Polak P, Rajagopal N, Ray P, Sallari RC, Siebenthall KT, Sinnott-Armstrong NA, Stevens M, Thurman RE, Wu J, Zhang B, Zhou X, Beaudet AE, Boyer LA, De Jager PL, Farnham PJ, Fisher

SJ, Haussler D, Jones SJ, Li W, Marra MA, McManus MT, Sunyaev S, Thomson JA, Tlsty TD, Tsai LH, Wang W, Waterland RA, Zhang MQ, Chadwick LH, Bernstein BE, Costello JF, Ecker JR, Hirst M, Meissner A, Milosavljevic A, Ren B, Stamatoyannopoulos JA, Wang T, Kellis M. Integrative analysis of 111 reference human epigenomes. Nature. 2015 Feb 19;518(7539):317-30. PubMed PMID: 25693563. PMCID: PMC4530010

d. Lee HJ, Lowdon RF, Maricque B, Zhang B, Stevens M, Li D, Johnson SL, Wang T. Developmental enhancers revealed by extensive DNA methylome maps of zebrafish early embryos. Nat Commun. 2015 Feb 20;6:6315. PubMed PMID: 25697895; PubMed Central PMCID: PMC4339225.

3. BIG-BIODATA INTEGRATION AND VISUALIZATION: I have strong interest and expertise in big-biodata integration and visualization. I have been considered one of the most innovative scientists in developing visualization techniques in Genome Browsers. When I trained as a postdoc with David Haussler, I invented the UCSC Cancer Genomics Browser and published a corresponding author paper in Nature Methods. Since starting my own lab, I have been the driving force behind the effort to make the data from Roadmap Epigenomics project and ENCODE project readily accessible by the broad research community. I invented the WashU Epigenome Browser, which currently hosts over 30,000 genome-wide datasets. The innovations we brought to the Browser have resulted in several milestone publications in Nature Methods and Nature Biotechnology. For example, our Browser allows investigators to use epigenetic data to automatically annotate genetic variants, including those associated with complex diseases and traits. I have also played a leadership role in dissemination of genomic resources and tools, including running workshops at large meetings (i.e., ASHG, Keystone, etc). My leadership position in this field can be demonstrated in the recent Joint Meeting of NIEHS Core Centers and Training Directors, where I was the Keynote speaker. My lab continues to conduct innovative research in bio data integration and visualization.
   a. Zhou X, Maricque B, Xie M, Li D, Sundaram V, Martin EA, Koebbe BC, Nielsen C, Hirst M, Farnham P, Kuhn RM, Zhu J, Smirnov I, Kent WJ, Haussler D, Madden PA, Costello JF, Wang T. The Human Epigenome Browser at Washington University. Nat Methods. 2011 Nov 29;8(12):989-90. PubMed PMID: 22127213; PubMed Central PMCID: PMC3552640.
   b. Zhou X, Lowdon RF, Li D, Lawson HA, Madden PA, Costello JF, Wang T. Exploring long-range genome interactions using the WashU Epigenome Browser. Nat Methods. 2013 May;10(5):375-6. PubMed PMID: 23629413; PubMed Central PMCID: PMC3820286.
   c. Zhou X, Li D, Lowdon RF, Costello JF, Wang T. methylC Track: visual integration of single-base resolution DNA methylation data on the WashU EpiGenome Browser. Bioinformatics. 2014 Aug 1;30(15):2206-7. PubMed PMID: 24728854; PubMed Central PMCID: PMC4103599.
   d. Zhou X, Li D, Zhang B, Lowdon RF, Rockweiler NB, Sears RL, Madden PA, Smirnov I, Costello JF, Wang T. Epigenomic annotation of genetic variants using the Roadmap Epigenome Browser. Nat Biotechnol. 2015 Feb 18;PubMed PMID: 25690851. PMCID: PMC4467764
4. ALGORITHM DEVELOPMENT IN COMPUTATIONAL BIOLOGY: I was trained a computational biologist as a graduate student by Dr. Gary Stormo. I developed the first motif finding algorithm that combines phylogenetic information with gene regulation. Over the years of training and research, I have acquired significant expertise in algorithm, computer science, machine learning, and statistics, and have continued developing advanced computational methods for genomic research. My recent contributions are focused on methods in analyzing DNA methylation data. For example, my lab was the first to apply a conditional random fields-based framework (methylCRF) to integrate DNA methylation data. By combining MeDIP-seq and MRE-seq data, the methylCRF method can accurately assess genome-wide DNA methylation level at single CpG resolution. The quality of our assessment is at least as good as a most high-profile competitive method, whole-genome bisulfite sequencing (WGBS), but the cost of our method is merely 3~4% of that of WGBS.
   a. Wang T, Stormo GD. Combining phylogenetic data with co-regulated genes to identify regulatory motifs. Bioinformatics. 2003 Dec 12;19(18):2369-80. PubMed PMID: 14668220.
   b. Wang T, Stormo GD. Identifying the conserved network of cis-regulatory sites of a eukaryotic genome. Proc Natl Acad Sci U S A. 2005 Nov 29;102(48):17400-5. PubMed PMID: 16301543; PubMed Central PMCID: PMC1297658.
   c. Zhang B, Zhou Y, Lin N, Lowdon RF, Hong C, Nagarajan RP, Cheng JB, Li D, Stevens M, Lee HJ, Xing X, Zhou J, Sundaram V, Elliott G, Gu J, Shi T, Gascard P, Sigaroudinia M, Tlsty TD, Kadlecek T, Weiss A, O'Geen H, Farnham PJ, Maire CL, Ligon KL, Madden PA, Tam A, Moore R, Hirst M, Marra

MA, Zhang B, Costello JF, Wang T. Functional DNA methylation differences between tissues, cell types, and across individuals discovered using the M&M algorithm. Genome Res. 2013 Sep;23(9):1522-40. PubMed PMID: 23804400; PubMed Central PMCID: PMC3759728.

d. Stevens M, Cheng JB, Li D, Xie M, Hong C, Maire CL, Ligon KL, Hirst M, Marra MA, Costello JF, Wang T. Estimating absolute methylation levels at single-CpG resolution from methylation enrichment and restriction enzyme sequencing methods. Genome Res. 2013 Sep;23(9):1541-53. PubMed PMID: 23804401; PubMed Central PMCID: PMC3759729.

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/myncbi/ting.wang.1/bibliography/44420340/public/?sort=date&direction=ascending

D. RESEARCH SUPPORT

Ongoing Research Support

2014/07/01-2018/06/30 RSG-14-049-01-DMC, American Cancer Society
Wang, Ting (PI)
Epigenetic control of transposable element derived enhancers in cancer
This project investigates impact of transposable elements on cancer gene regulatory networks.

2013/07/16-2017/06/30 R01 HG007354-01, National Human Genome Research Institute (NHGRI)
Wang, Ting (PI)
ADVANCED EPI/GENOME BROWSER WITH ENHANCED VISUALIZATION AND ANALYSIS TOOLS
This project develops advanced bioinformatics tools for genomics and epigenomcis studies.

2014/09/01-2017/06/30 R01 HG007175-01A1, National Human Genome Research Institute (NHGRI)
Wang, Ting (PI)
DECODING THE IMPACT OF TRANSPOSABLE ELEMENTS ON GENE REGULATION
This project develops computational and experimental tools to investigate transposable elements.

2015/09/16-2020/08/31 U01 CA200060-01, National Cancer Institute (NCI)
Wang, Ting (PI)
The WashU 4DN Network Data Coordination and Integration Center
This project establishes a Data Visualization Center for the 4D Nucleome Network.

2016/05/01-2021/04/30 U24 ES026699-01, National Institute of Environmental Health Sciences (NIEHS)
Wang, Ting (PI)
The WashU TaRGET Environmental Epigenomics Data Coordination Center
This project establishes a Data Coordination Center for the TaRGET Consortium.

2017/02/01-2017/01/31 U01 HG009391-01, National Human Genome Research Institute (NHGRI)
Wang, Ting (PI)
Connecting transposable elements and regulatory innovation using ENCODE data
This project uses ENCODE data to investigate regulatory roles of transposable elements.

Recommendations for Prevention Peer Review Panels

- Kathleen L. Irwin, M.D., MPH, FACPM, FIDSA

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: Irwin, Kathleen Lovell

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

POSITION TITLE: Leader, Evidence Review Team (former name Guideline Development Team), Office of Director, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention

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
Brown University, Providence, RI	B.S (with honors)	06/1978	Biology
Boston University School of Medicine, Boston, MA	M.D.	06/1983	Medicine
University of Washington, Seattle, WA (NCI Epidemiology Training Fellowship and Research Awards)	M.P.H	12/1989	Epidemiology
Epidemic Intelligence Service	NA	06/1986	Applied epidemiology
Preventive Medicine Residency, Centers for Disease Control (CDC), Atlanta, GA	Board Certification		Preventive Medicine and Public Health

A. Personal Statement

I am a senior medical officer at the U.S. Centers for Disease Control and Prevention with more than three decades of skills and experience in

- prevention and management of reproductive tract cancer and infectious diseases
- development and evaluation of health programs and policies
- public health and health services research in domestic and international settings
- development of evidence-based public health and clinical guidelines

B. Positions since 1998 (See CV for earlier positions.)

2016-	Leader, Evidence Review Team (former name Guideline Development Team), Office of Director, Division of Healthcare Quality Promotion, CDC, Atlanta, GA
2011-2016	Leader, Guideline Development Team, Office of Director, Division of HIV/AIDS Prevention, CDC, Atlanta, GA
2011	Consultant, Division of Cancer Prevention and Control, CDC, Atlanta, GA
2007-2011	Senior Scientist and Consultant, World Health Organization, Initiative for Vaccine Research (Geneva, Switzerland), and International Agency for Research on Cancer (Lyon, France)
2006	Public Health Consultant, Geneva, Switzerland
1998-2005	Chief, Health Services Research and Program Evaluation Branch, Division of STD Prevention, CDC, Atlanta, GA

C. Selected Contributions to Research, Policy, and Programs (See CV for details and all publications.)

My work has improved understanding of the etiology, prevention, and detection of cervical cancer and sexually transmitted infections and identified screening and prevention strategies and standards for these conditions that have been subsequently put into practice in U.S. and other countries. For example, I

- developed the scientific basis and recommendations for WHO's HPV vaccination guidance that resulted in vaccine introduction in several countries and funding commitment by the GAVI Vaccine Alliance
- demonstrated gaps in knowledge, diagnosis, and management of HIV, HPV, and other STD that resulted in new prevention and program operations guidelines, clinician training programs, patient education materials, and screening programs in hospitals, clinics, jails, and community sites
- designed and implemented Africa's first HIV testing and counseling program in 1980s (DR Congo)
- demonstrated performance of rapid HIV tests that resulted in CDC's recommendations on rapid testing
- identified HIV strains circulating in high prevalence cities that informed HIV vaccine development
- demonstrated that HIV increases risk of pelvic inflammatory disease that resulted in changes in CDC's AIDS surveillance case definition and treatment recommendations
- developed CDC's evidence-based Chlamydia screening recommendations that resulted in coverage of screening tests by insurers and Department of Defense and new health system performance measures

I have conducted a diverse range of public health and clinical research and program assessments, many of which involved multicenter or international collaborations. I developed several evidence-based health guidelines for the U.S. or other countries that were based on systematic reviews of international literature and advice of expert panels. Examples of my publications in two areas are summarized here.

Reproductive Tract Cancers

Primary research and service delivery assessments

- **Irwin KL**, Rosero-Bixby L, Oberle MW, et al. Oral contraceptives and cervical cancer risk in Costa Rica: Detection bias or causal association? JAMA 1988; 259:59-64.
- Oberle MW, Rosero-Bixby L, **Irwin KL**, et al. Cervical cancer risk and use of depot-medroxyprogesterone acetate in Costa Rica. Int J Epidemiol 1988; 17:718-23.
- **Irwin KL**, Oberle MW, Rosero-Bixby L. Screening practices for cervical and breast cancer in Costa Rica. Bull Pan Am Health Org 1991; 25:16-26.
- **Irwin KL**, Montano D, Kasprzyk D, et al. Cervical cancer screening, abnormal cytology management, and counseling practices in the United States. Obstet Gynecol 2006; 108:397-409.
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Evidence-based guidelines and supporting evidence

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Primary research and service delivery assessments

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Evidence-based guidelines and supporting evidence

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- DiNenno EA, Prejean J, **Irwin K**, et al. Recommendations for HIV Screening of Gay, Bisexual, and Other Men Who Have Sex with Men – United States, 2017. MMWR 2017; 66:830-832.

D. Additional Information (see CV for details):

Subject matter expertise

- Prevention of and screening for human papillomavirus, HIV, chlamydia, and other infections
- Vaccine development and implementation
- Reproductive tract cancer prevention and control
- Health of women and adolescents
- Advanced French language skills

Research, program evaluation, and policy development methodology

- Proficient in health services research and program evaluation methods, including
    - protocol development, implementation tools, and IRB and OMB research and survey standards
    - observational and experimental designs, multivariate analyses, provider and community surveys
    - analysis of administrative and claims data
    - cost-effectiveness and resource allocation analyses, disease burden estimation
    - focus groups, key informant interviews, and content analysis of health policies
- Evidence-based guideline development, including systematic literature reviews and Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology

Experience as Principal Investigator

1992-1997 Multicenter study of the influence of HIV infection on pelvic inflammatory disease
1999-2002 Multicenter evaluation of adherence to CDC guidelines for treating Chlamydia and genital warts
1999-2003 Multicenter feasibility study of STD control as an HIV preventive strategy in the U.S.
2001-2005 National survey of clinician knowledge, attitudes, and practices about HPV and related conditions
2001-2005 Multicenter evaluation of delivery of STD and Hepatitis services to HIV-infected patients in U.S.
2006-2008 HPV vaccine recommendations in national immunization programs
2015-2017 National household survey of Ebola knowledge, attitudes, and practices in Guinea during an epidemic

Expert Committee Membership and Consultations

- Served on 14 intramural expert committees at CDC, including 9 that developed federal health guidance on HIV, STD, microbicides, contraceptives, and public health research practices
- Advised 14 federal or non-federal organizations, including World Health Organization, UK Medical Research Council, NIH, HRSA, and Indian Health Service that developed guidance on HPV vaccines, contraceptives, Chlamydia screening, and STD program evaluation

Leadership, management, and supervision

- Secured competitive, agency-wide CDC awards, e.g., $2.5 million for microbicide research; $2 million to evaluate adherence to CDC's STD Treatment Guidelines in private sector and services in HIV care clinics
- Secured supplement to $7 million grant to WHO for human papillomavirus research and policy development based on successful execution of technical, policy, and communication components
- Served as project officer for > 20 cooperative agreements, contracts, grants, and inter-agency agreements with universities, research organizations, and health departments
- Led several multicenter projects involving OMB and IRB review or extramural data sharing agreements
- Served on >20 CDC panels that evaluated applications for cooperative agreements and contracts
- Built new partnerships with U.S. and international health organizations for conducting research and program assessments and for developing public health and clinical recommendations
- Built consensus about complex scientific and health issues as chair and member of expert panels
- Recruited, trained, and supervised > 40 clinicians, health scientists, behavioral scientists, evaluation specialists, program managers, economists, and interns
- Developed standards for public health research and evaluation for CDC and state health departments
- Outbreak response (e.g., lead technical officer for Guinea in CDC's Emergency Operations Center)

Training, teaching, and capacity building

- Delivered > 200 scientific training programs, workshops and lectures to clinicians and other health professionals in U.S. Europe, Asia, Africa, and Latin America
- As adjunct professor, trained and supervised health professions students at Emory University

Selected Licenses and Memberships

1985- Unrestricted medical license, State of Georgia
1990- Fellow, American College of Preventive Medicine
2002- Fellow, Infectious Diseases Society of America
2003- Member, AcademyHealth (Health Services Research Professional Society)
2016- Member, Guidelines International Network

Selected Honors and Awards from CDC, US Public Health Service, and other organizations

1987 Langmuir Prize for best paper written by an Epidemic Intelligence Service Officer, CDC
2005 Best Research Paper, American Academy of Family Practice
2005 Award for Collaborative Success of Workgroup on Human Papillomavirus Infection, CDC
2015 Director's Recognition Award for leading cross-agency federal workgroup that developed national guideline on HIV Prevention with Adults and Adolescents with HIV, CDC
2017 Peavy Award for Excellence in Human Capital Management for expanding community workforce capacity through program guidance on HIV testing in nonclinical settings, CDC
1987-2002 3 USPHS Commendation Medals, 1 Achievement Medal, and 4 Unit Commendations for domestic and international research on cancer and HIV, federal guideline development, and service delivery initiatives to prevent infectious diseases and promote women's health

Recommendations for Product Development Research Peer Review panels

- John C. McKew, Ph.D.
- George L. Trainor, Ph.D.

John C. McKew, Ph.D.

Boyds, Maryland 20841
USA **Web: http://www.linkedin.com/in/johncmckew**

TRANSLATIONAL RESEARCH HIGHLIGHTS

- Key strategic contributor on leadership team for aTyr Pharma; participated in multiple investor presentations, S1 writing, roadshow presentations, and all activities surrounding both a mezzanine and IPO funding round resulting in ~ $180 MM raise.
- Successfully developed the Therapeutics for Rare and Neglected Diseases Program at the NIH from concept to fully functional intramural research program that delivered multiple clinical candidates in its first three years
- Productive 24 year career in biotech, academia and the pharmaceutical industry leading and managing drug discovery teams from hit-to–lead through clinical development
- Singular ability to recruit, motivate and retain top scientific talent across multiple scientific disciplines; excels at performance management, goal setting and mentoring
- Actively manage a $30-40 Million/year budget; internal scientific team management as well as outsourcing
- Led team that performed due diligence on >250 scientific opportunities and selected final portfolio
- Succesfully filed or collaborated on 16 INDs and 10 clinical studies in last 5 years

EXPERIENCE

Chief Scientific Officer Lumos Pharma **3/2016 – Present**

- Key role in creating development strategy, regulatory strategy and agency interactions needed to advance LUM-001 from preclinical stage through clinical development
- Lead scientific team to develop and source assets orphan disease arena using a virtual pharma approach

Vice President of Research, aTyr Pharma **10/2014 – 3/2106**

- Led research group focused on developing novel pipeline of physiocrines for a variety of rare disease indications using multiple novel strategies for hit identification

- Interface closely with the clinical group to support the ongoing clinical development of aTyr's lead molecule Resolaris currently in a phase 1b/2 trial in FSHD and LGMD2B
- Led aTyr's non-clinical safety program and early manufacturing strategy for an engineered protein therapeutic that advanced to IND candidate status
- Contributed to 2 INDs and multiple FDA interactions

Acting Scientific Director; Division of Preclinical Development, NCATS 2010 – 10/2014

- Recruited, led, and retained an intramural, multi-disciplinary team of scientists devoted to advancing therapeutics through novel collaborative research teams
- Developed the Therapeutics for Rare and Neglected Diseases (TRND) program from concept to fully functioning team continuing to deliver novel therapeutic options for underserved patient populations (TRND)
- Rebranded and reinvigorated the NIH-RAID program into the BrIDGs program which successfully created IND enabling packages for multiple programs with modalities as diverse as gene therapy, peptides, and small molecules (BrIDGs)
- Created and refined novel mechanisms to solicit and evaluate collaborative research projects to ensure a rich pipeline of projects and unique methods to attract outside investment to finalize the clinical development of graduates of the programs
- Successful management of a 35 project rare disease research portfolio resulted to date in four collaborators/assets being acquired based on data TRND generated to derisk the projects: AesRx to Baxter ($14 MM upfront, $850 MM upon approval) Afraxis to Genentech ($187 MM upon approval), Bikam to Shire ($2 MM upfront, $90 MM upon approval), ManNac to Altimira (terms not disclosed) and HP-β-CD licensed to Vtesse (subsequently sold to Sucampo for $200 MM upfront).
- Thought leader in the scientific and regulatory strategy that advanced AES-103, ManNac, and HP-β-CD through pre-clinical development and into early clinical development within the TRND program
- Actively managed a ~$90 million/year department research budget; effectively used intramural research and contract resources to ensure the biggest impact on projects from a limited budget; full understanding of the use of government contracts, prime sub-contractors, collaborative research agreements, FAR, and Bayh Dole Act relating to intellectual property
- Successfully created novel collaborations to advance translational research with not-for-profits, multiple NIH institutes, FDA, biotech and pharma
- Sought after expert on rare disease therapeutic development and repurposing; multiple invited lectures, high impact opinion pieces and quotes in trade publications

Wyeth Research (Genetics Institute before acquisition); Cambridge, Massachusetts 1993 - 2010

Associate Director Exploratory Chemistry **2005 - 2010**

- Progressed a portfolio of >20 concurrent early stage projects with a group of up to 15 researchers
- Responsible for the hit-to-lead portfolio for the Cardiovascular, Musculoskeletal, and Metabolic Disease therapeutic areas; progressed this portfolio through hit finding approach, hit to lead triage, validation of hits, and optimization of hits using small focused arrays
- Developed successful project leaders through mentoring and development opportunities
- Delivered adequate chemical equity for each project using multiple hit generation strategies including virtual screening, fragment based screening (SPR and NMR) in addition to functional HTS data.
- Minimized hit to lead times by incorporating computational tools to manage data, predict properties and metabolism in conjunction with analog planning into each team

Principal Scientist **2003 - 2005**

- Led a project team of 20 chemists at 3 sites that delivered Giripladib, Efipladib and Ecopladib; first in class anti-inflammatory $cPLA_2\alpha$ clinical compounds with a broad range of indications
- Addressed physicochemical properties of $cPLA_2\alpha$ inhibitors by scaffold hopping existing pharmacophore. Chemotypes potent in whole blood assays with $logd_{7.4}$ <4.5 were discovered.
- Broadened clinical potential of $cPLA_2\alpha$ inhibitors by participating in the design of crucial in vivo POC experiments for asthma, stroke, atherosclerosis, MS and thrombosis indications.
- Developed a back up in less than 6 months to replace a front runner lost to compound related toxicity

Early Employment History

Senior Research Scientist II **1998 - 2003**

Senior Research Scientist I **1995 - 1998**

Research Scientist II **1993 - 1995**

Principle Investigator Responsibility

PI on 7 different CRADAs and PI on a Grant from University of Pennsylvania's Center for Orphan Disease Research and Therapy ($150,000/yr for 2 years)

EXTERNAL VISIBILITITY

Presentations, Publications, and Patents

- >60 invited lectures, >50 publications, >45 poster presentations 10 granted US patents, quoted in New Scientist, SciBx, Medicus, Think Magazine, Chemistry and Biology, Clinical and Translational Science, Genetic Engineering and Biotechnology News, Start Up Blog, Drug Discovery News, Chemical and Engineering News, New York Times and Pro Publica.
- link to pdf of publications

Adjunct Associate Professor Boston University School of Medicine

- Developed an innovative Graduate level course as Course Director and Lecturer in GMS PM 881

Chair-Elect, Chair and Immediate past Chair of the Northeastern Section of the American Chemical Society (2009-2011)

- http://www.nesacs.org

Scientific Advisory Board Member National Disease Research Interchange

- **http://ndriresource.org**

Symposium Organizer for National and Regional Scientific Meetings

- Contributed to planning multiple national and regional meetings, ACS, MARM, DIA Rare Disease Conferences, Advances in Chemical Science, NIH/FDA Symposium on Natural History Studies

Editorial Contributions

- Guest Co-Editor for an issue of Current Topics in Medicinal Chemistry with a theme of novel public private partnerships to develop therapeutics (**2014**, *14(3)*,)

EDUCATION

Post-Doctoral Studies, Firmenich; Geneva, Switzerland	Mentor: Christian Chapuis	1993
Post-Doctoral Studies, University of Geneva; Switzerland;	Mentor: Wolfgang Oppolzer	1992
Ph.D., University of California, Davis; Davis, California;	Mentor: Mark Kurth	1991
B.S., Chemistry & Biochemistry, SUNY Stony Brook, New York;	Mentor: Glenn Prestwich	1986

HONORS AND AWARDS

Graduate of the NIH Executive Leadership Program 2014 (Brookings Institution), OOPD Heroes of Rare Diseases Research awarded to TRND 2013 by the FDA, NIH Directors award 2015, NIH Directors award 2013, NIH Directors Award 2012, Chemluminary award presented to NESACS from ACS during my leadership tenure 2011, Wyeth Team of the Year Award, 2001; Wyeth Peer Award of Excellence, 2003; Wyeth Publication of the Year Awards, 2006; 2007; 2008; Wyeth Eagles Program Graduate 2006-2008.

PUBLICATIONS AND **PATENTS**

PUBLICATIONS

1. Ory; D. S., Ottinger; E. A.,Yanjanin Farhat; N., King; K. A., Jiang; X., Weissfeld; L., Berry-Kravis; E., Davidson; C. D., Bianconi; S., Keener; L. A., Rao; R., Soldatos; A., Sidhu; R., Walters. K. A., Xu; X., Thurm; A., Solomon; B., Pavan; W. J., Machielse; B. N., Kao, M., Silber; S.A., McKew; J.C., Brewer;

C. C., Vite; C. H., Walkley, S. U. DVM, Austin; C. P., Porter; F. D. **Intrathecal 2-hydroxypropyl-β-cyclodextrin decreases neurological disease progression in Niemann-Pick Disease, type C1: an ad-hoc analysis of a non-randomized, open-label, phase 1/2 trial** *In Press Lancet*

2. Patel, P.R.; Sun, W., Kim, M.; Huang, X.; Sanderson, P.E.; Tanaka, T.; McKew, J.C.; Simeonov, A.; Williamson, K.C.; Zheng, W.; Huang, W. **In vitro evaluation of imidazo[4,5-*c*]quinolin-2-ones as gametocytocidal antimalarial agents** *Submitted to Bioorg. Med. Chem. Let.*
3. Natasha T., Malik, N., Shah, S., Zhao, J., Class, B., Aguisanda, F., Southall, N., Xia, M., McKew, J.C., Rao, M, and Wei Zheng.; **High-throughput Phenotypic Screening of Human Astrocytes to Identify Compounds that Protect Against Oxidative Stress** *Stem Cells Translational Medicine,* **2015**, 5(5), 613-627
4. Balasegaram M, Kolb P, McKew J, Menon J, Olliaro P, Sablinski T, et al. (2017) An open source pharma roadmap. PLoS Med 14(4): e1002276. https://doi.org/10.1371/journal.pmed.1002276
5. Shi, Y.; Xu, X.; Fang, M.; Zhang, M.; Li, Y.; Gillespie, B.; Yorke, S.; Yang, N.; McKew, J. C.; Gahl, W. A. Huizing, M.; Carrillo-Carrasco, N.; Wang A. Q.; **Quantitative Hydrophilic Interaction Chromatography–Mass Spectrometry Analysis of N-acetylneuraminic Acid and N-Acetylmannosamine in Human Plasma** J. Chromatogr. B 1000, 2015, 105-111.
6. Wang, M.; Long, Y.; Huang, X.; Southall, N.; McKew, J.C.; Zheng, W. **Identification of Glycolate Oxidase Inhibitors as Lead Compounds for Drug Development to Treat Primary Hyperoxaluria Type 1 Disease** *Scientific Reports,* **2016,***6*, 34060
7. Jennifer Kouznetsova, J.; Sun, W.; Martínez-Romero, C.; Tawa, G.; Shinn, P.; Chen, C, Z.; Schimmer, A.; Sanderson, P.; McKew, J.C.; Zheng, W.; García-Sastre, A. **Identification of 23 compounds that block Ebola virus like particle entry from a repurposing screen of 600 approved drugs** *Emerg. Microbes Infect.***2014**, *3(12)*, e84
8. Fagnan, D.E.; Yang, N.; McKew, J.C.; Lo, A. **Financing Translational Medicine: A Portfolio Analysis of the NCATS Rare Diseases Portfolio** *Science Translational Medicine* **2015**, 7(276), 1-7
9. Eishingdrelo, H.; Sun, W.; Li, H.; Wang, L.; Eishingdrelo, A.; Dai, S.; McKew, J.C.; Zheng, W.; **ERK and β-Arrestin Interaction:A Converging Point of Signaling Pathways for Multiple Types of Cell Surface Receptors** *J Biomol Screen* 2015, 20(3):341-9
10. Ong, C.C.; Gierke, S.; Pitt, C.; Cheng, C.K.; Zhou, W.; Strickland, L.; Schmidt, M.; Duron, S.D.; Campbell, D.; Zheng, W.; Dehdashti, S.; Shen, M.; Yang, N.; McKew, J.C.; Chernoff, J.; Forrest, W.; Haverty, P.M.; Chin, S.-F.; Rakha, E.A.; Green, A.R.; Ellis, I.O.; Caldas, I.O.; O'Brien, T.; Friedman, L.S.; Koeppen, H.; Rudolph, J.; Hoeflich, K.P. **Small molecule inhibition of group I PAKs in breast cancer induces apoptosis and potentiates the activity of microtubule stabilizing agents** submitted to *Breast Cancer Research* 2015, **17**:59 doi:10.1186/s13058-015-0564-5
11. Stephenson, D.; Perry, D.; Bens, C.; Bain, L.J.; Berry, D.; Krams, M.; Sperling, R.; Dilts, D.; Luthman, J.; Hanna, D.; McKew, J.; Temple, R.; Fox, A., F.; Fields, O.; Salloway, S.; Katz, R.;

Charting a path toward combination therapy for Alzheimer's disease *Expert Review of Neurotherapeutics,* **2014,** 12-25.

12. De Dios, J.K.; Shrader, J.; Joe, G.; McClean, J.C.; Williams, K.; Evers, R.; Ciccone, C.; Draper, D.; Latham, L.; Mankodi, A.; Huizing, M.; McKew, J.C.; Bluemke, D.; Gahl, W.A.; Carrillo-Carrasco, N. **Atypical presentation of GNE myopathy with asymmetric hand weakness** Neuromuscular Disorders, **2014**, 24, 1063–1067
13. Celeste, F.; Vilboux,T.; Ciccone, C.; Karl de Dios, J.; Malicdan, M.C.; Leoyklang, P.; McKew, J.C.; Gahl, W.A.; Carrillo-Carrasco, N.; Huizing, M. **Mutation Update for *GNE* Gene Variants Associated with GNE Myopathy** *Human Mutation,* **2014**, DOI: 10.1002/humu.22583
14. Yu, D.; Swaroop. S.; Wang, M.; Baxa, U.; Yang, Y.; Yan, Y.; Coksaygan, T.; DeTollad, L.; Austin, C.P.; McKew, J.C.; Gong, D.W.; Zheng, W. **Niemann-Pick disease type C: induced pluripotent stem cells for neural disease modeling and drug efficacy testing**, *J. Biomolecular Screening,* **2014**, 1-10.
15. Shen, J.; Grewal, G.; McKew, J. C. **New Financial and Research Models for Pediatric Orphan Drug Development: Focus on the NCATS TRND Program** *Pharmaceutical Medicine,* **2014,** 28(1), 1-6.
16. Sun, W.; Tanaka, T.; Magle, C.T.; Huang, W.; Southall, N.; Huang, R.; Dehdashti, S.J.; McKew, J. C.; Williamson, K.C.; Zheng, W. **Chemical Signatures and New Drug Targets for Gametocytocidal Drug Development** *Scientific Reports* 4 : 3743 | DOI: 10.1038/srep03743
17. Thomas, C.J.; McKew, J.C. **Playing Well with Others! Initiating and Sustaining Successful Collaborations between Industry, Academia and Government** *Current Topics in Medicinal Chemistry*, **2014**, *14(3)*, 291-293
18. Ottinger, E.A.; Kao, M. L.;Carrillo-Carrasco, N.; Yanjanin, N.; Shankar, R.K.; Janssen, M.; Brewster, M.; Scott, I.; Xu, X.; Cradock, J.; Terse, P.; Dehdashti, S.J.; Marugan, J.; Zheng, W.; Portilla, L.; Hubbs, A.; Pavan, W. J.; Heiss, J.; Vite, C. H.; Walkley, S. U.; Ory D. S.,Silber, S.A.; Porter, F.D.; Austin, C.P.; McKew, J.C. **Collaborative Development of 2-Hydroxypropyl-β-Cyclodextrin for the Treatment of Niemann-Pick Type C1 Disease** *Current Topics in Medicinal Chemistry*, **2014**, *14(3)*, 330-339
19. Xu, M.; Liu, K.; Swaroop, M.; Sun, W.; Dehdashti, S. J.; McKew, J. C.; Zheng, W. (2013). **A Phenotypic Compound Screening Assay for Lysosomal Storage Diseases.** *J Biomol Screen*. August 27, 2013. DOI: 10.1177/1087057113501197
20. Sun, W.; Park, Y. D.; Sugui, J.A.; Fothergill, A.; Southall, N.; Shinn, P.; McKew, J. C.; Kwon-Chung, K. J.; Zheng, W.; Williamson, P. R. (2013). **Rapid Identification of Antifungal Compounds against Exserohilum Rostratum Using High Throughput Drug Repurposing Screens** August 21, 2013. *PLoS One*. 8, e70506

21. Rabjohns, J. L. A.; Park, Y. – D.; Dehdashti, S. J.; Zheng, W.; Williamson, P. R. **A High Throughput Screening Assay for Fungicidal Compounds against Cryptococcus Neoformans** *J Biomol Screen.* July 29, 2013, doi: 10.1177/1087057113496847
22. Dehdashti, S. J.; Abbott, J.; Nguyen, D. –T.; McKew, J. C.; Williamson, P. R.; Zheng, W. **High Throughput Screening Assay for Viability of Cryptococcus Neoformans under Nutrient Starvation Condition** *Analytical and Bioanalytical chemistry.* 2013 Aug; 405(21):6823-9. PMID:23812880
23. Dehdashti, J.S.; Zheng, W.; Gever, R. J.; Wilhelm, R.; Nguyen, D. T.; Sittampalam, G.; McKew, J. C.; Austin, C. P.; Prusiner, B.S.; **A High-throughput Screening Assay for Determining Cellular Levels of Total Tau Protein** *Curr Alzheimer Res.* **2013** Sep;10(7):679-87
24. Zheng, W.; Thorne, N.; McKew, J. C. **Phenotypic screens as a renewed approach for drug discovery** *Drug Discovery Today.* **2013**, 18(21-22), 1067‑1073
25. Jones, R. A.; Zheng, W.; McKew, J. C.; Chen, C. Z. **An Alternative Direct Compound Dispensing Method Using the HP D300 Digital Dispenser** *Journal of Laboratory Automation,* **2013**, 18(5). 367-374.
26. McKew, J. C.; Pilon, A. M.; **NIH TRND program: successes in preclinical therapeutic development** *TIPS* **2013**, *34(2)*, 87-89.
27. Tanaka, T.K.; Dehdashti, J. D.; Nguyen, D. T.; McKew, J.C.; Zheng, W.; Williamson, K. C. **A Quantitative High Throughput Screening Assay for Identifying Gametocytocydal Compounds** *Mol. Biochem. Parasit.* **2013**, *188,* 20-25.
28. Swaroop, M.; Thorne, N.; Rao, M.S.; Austin, C.P.; McKew, J.C.; Zheng, W. **Evaluation of Cholesterol Reduction Activity of Methyl-β-cyclodextrin Using Differentiated Human Neurons and Astrocytes** *J Biomol Screen*. **2012**, *17*, 1243-51.
29. Xu, M.; Liu, K.; Swaroop, M.; Porter, F.D.; Sidhu, R.; Firnkes, S.; Ory, D.S.; Marugan, J.J.; Xiao, J.; Southall, N.; Pavan, W.J.; Davidson, C.; Walkley, S.U.; Remaley, A.T.; Baxa, U.; Sun, W.; McKew, J.C.; Austin CP, Zheng W. **δ-Tocopherol Reduces Lipid Accumulation in Niemann-Pick Type C1 and Wolman Cholesterol Storage Disorders** *J Biol Chem*. **2012**, *287(47),* 39349-39360
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9. Seehra, Jasbir S.; Kaila, Neelu; McKew, John C.; Lovering, Frank E.; Bemis, Jean E.; Xiang, Yibin; Chen, Lihren **Inhibitors of Phospholipase Enzymes** U.S. Patent 6,630,496 B1, Oct. 7, 2003.
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GEORGE L. TRAINOR, Ph.D.

Wilmington, DE 19803

SUMMARY

- Proven drug discovery leader with over 35 development candidates advanced into development across multiple therapeutic areas, including oncology, virology, and neuroscience.
- Experienced in all aspects of oncology drug discovery including therapeutic area strategy, target selection, lead identification, lead optimization, and drug candidate qualification.
- Respected team leader, adept at developing and managing teams of 100+ scientists.
- Extensive expertise in conceptualizing, establishing, and managing research alliances with both internal and external partners.
- Broad capabilities in the in-licensing and out-licensing of assets including due diligence and opportunity analysis.
- Experience in partnering and licensing in the Asian sector (Japan, China, India).
- Expertise in discovery portfolio analysis and sustainability.
- Deep understanding of the development and implementation of transformational research technologies (2011 ACS Heroes of Chemistry Award for fluorescence-tagged terminator DNA sequencing).
- Outstanding communicator in all forums (50 invited symposium and university lectures).
- Demonstrated productivity with over 85 peer-reviewed publications and 20 issued US patents.

EXPERIENCE

BIOMOTIV – The Harrington Project for Discovery and Development 2012-Present
Venture Partner

- Scientific Leadership in medicinal chemistry and in all aspects of drug discovery through to clinical candidate selection.
- Due diligence and portfolio management in a bio-accelerator environment.

HARRINGTON DISCOVERY INSTITUTE -- The Harrington Project for Discovery and Development 2013-Present
Member of the Innovation Support Center

- Provide drug discovery and medicinal chemistry consultation to Harrington Scholars in the US and UK.

TRAINOR CONSULTING, LLC 2011-Present
Partner, Executive Pharmaceutical Consultant

- Consulting services on all aspects of pharmaceutical discovery.
- Experience with large pharma, biotech, and non-profits on a “one off”, periodic, or continuous basis.
- Special expertise in conducting due diligence behind firewalls on programs, lead series, and drug candidates.
- Experience as an expert witness.
- On site consultation provided internationally.

PELOTON THERAPEUTICS (Dallas, TX) 2016-Present
Scientific Advisory Board Member

ASET THERAPEUTICS (Stonybrook, NY) 2016-Present
Scientific Advisory Board Member

ENTERPRISE THERAPEUTICS (UK) 2015-2017
Scientific Advisory Board Member

KLOGENE THERAPEUTICS INC. (Cambridge, MA) 2015-Present
Scientific Advisory Board Member

BRISTOL-MYERS SQUIBB CO. 2002-2010
***Vice President, Oncology and Early Discovery Chemistry**, 2008-2010*
***Executive Director, Oncology and Early Discovery Chemistry**, 2002-2008*

- Leadership of a team of 100+ scientists.
- Responsible for all oncology chemistry, hits-to-leads chemistry across all BMS therapeutic areas, chemical synthesis, and radiochemistry.
- Advanced candidates targeted at Her1/2, VEGFR2, met, AR, IGF-1R, etc.
- Initiated and/or supervised alliances with Ambit, Nerviano, Exelixis, et al.
- Led portfolio sustainability and research project team optimization initiatives.
- Active Member of the Drug Discovery and Early Development Senior Leadership Team.

DUPONT-MERCK / DUPONT PHARMACEUTICAL CO. 1991-2002
***Executive Director, Chemistry**, 1998-2002*
***Senior Director, Chemistry**, 1994-1998*
***Associate Director, Cancer Research**, 1993*
***Associate Director, Nucleic Acid Technology**, 1991-1992*

- Candidates advanced: antitumor agents, HIV (NNRTIs, PIs), and CNS targets (CRF, etc.)
- Preclinical development studies leading to US marketing approval for the NNRTI efavirenz (Sustiva^{TM}).
- Seminal studies on antisense oligonucleotide sequence selection and *in vivo* pharmacology.

DUPONT CENTRAL RESEARCH AND DEVELOPMENT 1981-1991
***Associate Director**, 1991*
***Research Leader**, 1987-1990*
***Member of the Research Staff**, 1981-1986*

- Co-inventor of the Genesis 2000TM DNA Sequencing system.
- Lead inventor on the US patent covering the use of fluorescence-tagged, chain-terminating nucleotides for automated DNA sequencing.

EDUCATION

COLUMBIA UNIVERSITY, Department of Chemistry 1979-1981
NIH Postdoctoral Fellow
- Advisor: Prof. Ronald Breslow

HARVARD UNIVERSITY, Department of Chemistry 1979
Ph.D. and M.A. in Organic Chemistry
- Thesis Advisor: Prof. Yoshito Kishi

STEVENS INSTITUTE OF TECHNOLOGY 1974
B. S. Chemistry
- Research Advisor: Prof. Ajay Bose

PROFESSIONAL ACTIVITIES

- Pacifichem, Inc.: Board of Directors, Chair (2014-2016) 2014-Present
- Study Sections: DOE, NIH, OTA for Genomic Studies 1988-1990
- Conference Chair: GRC (Bioorg Chem), ACS MARM 1991-2000
- Pacifichem Organizing Committee 1996-2005
- Section Editor – Annual Reports in Medicinal Chemistry 1996-2002
- Member: ACS, AACR

AWARDS

- 2011 American Chemical Society Heroes of Chemistry Award for "Dye Terminator DNA Sequencing".

George L. Trainor

Publications

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14. M. A. Jensen, R. J. Zagursky, G. L. Trainor, A. J. Cocuzza, A. Lee, and E. Y Chen, Sequence, **1** (4) 233-239 (1991). *"Improvements in the Chain-Termination Method of DNA Sequencing through the Use of 7-Deaza-2'-deoxyadenosine"*

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B. Daptgupta, C. D. Dzierba, T. M. Sielecki, A. Galka, T. L. Johnson, A. G. Takvorian, M. Rafalski, P. Kasireddy-Polam, S. Vig, A. G. Arvanitis, G. Zhang, T. F. Molski, R. C. Zaczek, A. P. Combs, P. J. Gilligan, G. L. Trainor, J. J. Bronson, J. E. Macor, *"Synthesis and SAR of 8-aza-quinoxalin-2(1H)-one as corticotrophin-releasing factor-1 receptro antagonists"* [238th Nat. Mtg. of the Amer. Chem. Soc., Washington D. C., Aug. 16-20, 2009]

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Proceedings and Chapters

M. A. Kashdan and G. L. Trainor, "DNA Sequencing Technology" in *Biotechnology and the Human Genome, Innovations and Impact*, Ed. A. D. Woodhead and B. J. Barnhart, Plenum Press, New York (1988). [Science Writer's Workshop on Biotechnology and the Human Genome, Brookhaven National Laboratory, New York, September 14 - 16, 1987]

R. J. Dam, J. M. Prober, and G. L. Trainor, "The Science, Rationale, and Implications of Automated DNA Sequencers" in *World Biotech Report 1988*, Online Publications, London (1988). [Proceedings of Biotech 88, London, UK, May 1988]

G. L. Trainor, J. M. Prober, and R. J. Dam, "Fluorescence Detection in Nucleic Acid Analysis" in *Banbury Report 32: DNA Technology and Forensic Science*, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York (1989). [Banbury Conference on DNA Technology and Forensic Science, Banbury Center of Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, November 28 - December 1, 1988]

G. L. Trainor, Guest Editor, Bioorg. Med. Chem. Lett. **4** (8), 1994. Symposia-in-Print Number 10, "*Modified Oligonucleotides"*.

G. L. Trainor, Editor, Perspect. Drug Disc. Des. **4**, 1996. *"Antisense Therapeutics"*.

D. D. Christ and G. L. Trainor, Biotechnol.: Pharmaceut. Aspects **1**, 327-336 (2004). "Free Drug! The critical importance of plasma protein binding in new drug discovery".

G. L. Trainor, *Expert Opin. Drug Discov*. **2**(1) 51-64 (2007). "The Importance of Plasma Protein Binding in Drug Discovery".

G. L. Trainor, *Ann. Rep. Med. Chem*., **42**, 489-502 (2007). "Plasma Protein Binding and the Free Drug Principle: Recent Applications and Developments"

Presentations

Invited Lectures

Science Writer's Workshop on Biotechnology and the Human Genome: Innovations and Impacts, Brookhaven Laboratory, Upton NY, "Advances in DNA Sequencing", September 1987.

The Oak Ridge Conference on Advanced Analytical Concepts for the Clinical Laboratory, Savannah GA, "A Fluorescence-Based Nucleic Acid Analysis System", April 1988.

Workshop on International Cooperation for the Human Genome Project, Valencia, Spain, October 1988.

ATB '88 Advance Technology for the Clinical Laboratory and Biotechnology, Milan, Italy, "A Fluorescence-Based Nucleic Acid Analysis System", November 1988.

Banbury Center Conference on DNA Technology and Forensic Science, Cold Spring Harbor NY, "Fluorescence Detection in Nucleic Acid Analysis", December 1988.

American Chemical Society, Delaware Section Meeting, Wilmington DE, "A Fluorescence-Based System for Nucleic Acid Sequencing", January 1989.

20th NSF Workshop on Organic Synthesis and Natural Products Chemistry, Holderness NH, July 1989.

American Chemical Society National Meeting, *Organic Chemistry in Industry Symposium*, Miami Beach FL, "Chemical Reagents for Molecular Biology", September 1989.

Natural Products Gordon Research Conference, New Hampton NH, "Chemical Reagents for Molecular Biology", July 1990.

Advances in Interpretative Biochemistry, Toronto General Hospital, "Methodologies for Genetic Analysis", September 1990.

Nagoya Conference: Frontier of Organic Synthesis--Rational Creation of Biologically Active Molecules, Nagoya, Japan, "Chemical Reagents for Molecular Biology", December 1990.

Middle Atlantic Regional American Chemical Society Meeting, Newark DE, "Novel Oligonucleotide Analogues with a Sulfur-Based Linkage", May 1991.

Symposium in Honor of Ronald Breslow, Columbia University, NY, "Chemical Reagents for Molecular Biology", August 1991.

Delaware Valley Enzymology Club, King of Prussia, PA, "Progress and Prospects in Nucleic Acid-Based Therapeutics", November 1991.

Banbury Center Conference on Oligonucleotide Manipulation of Gene Expression: Its Therapeutic Potential, Cold Spring Harbor, NY, "Oligonucleotide Analogues with Sulfamate and Sulfamide Internucleotide Linkages", October 1992.

Western Biotech Conference, San Diego, CA, “An Antisense Therapeutic Approach to Multidrug Resistance: Sequence Selection”, Ocotber 1995.

Symposium in Honor of Yoshito Kishi, Harvard University, Cambridge, MA, "Cyclic Urea Based HIV Protease Inhibitors: A Perspective", April 1997.

Middle Atlantic Regional American Chemical Society Meeting, Pleasantville NY, "Cyclic Urea Based HIV Protease Inhibitors: A Perspective", May 1998.

221st American Chemical Society National Meeting, San Diego, CA, "Search for next generation HIV protease inhibitors: the discovery of DPC 681 and DPC 684", April 2001.

Medicinal Chemistry Gordon Research Conference, New London, NH, "Plasma Protein Binding and Drug Action", August 2004.

Drew Residential School on Medicinal Chemistry, Madison, NJ, "Plasma Protein Binding", June 2005.

Drew Residential School on Medicinal Chemistry, Madison, NJ, "Plasma Protein Binding", June 2006.

Lab Automation 2007, Palm Springs, CA, "The Impact of Automation on Drug Discovery Today and Tomorrow", January 2007.

Drew Residential School on Medicinal Chemistry, Madison, NJ, "Plasma Protein Binding", June 2007.

Annual Meeting of the American Association for Cancer Research, San Diego, CA, "Cancer Target Validation: A Cautionary Tale", April 2008.

Drew Residential School on Medicinal Chemistry, Madison, NJ, "Plasma Protein Binding", June 2008.

Applied Pharmaceutical Analysis, Boston, MA, "Plasma Protein Binding and Drug Action", September 2008.

ACS ProSpectives: Topics and Tactics in Current Drug Design, Cambridge, MA, "Protein Binding in Drug Discovery", October 2008.

Drew Residential School on Medicinal Chemistry, Madison, NJ, "Plasma Protein Binding", June 2009.

Drew Residential School on Medicinal Chemistry, Madison, NJ, "Plasma Protein Binding", June 2010.

240st American Chemical Society National Meeting, Washington D. C., "Managing Plasma Protein Binding", August 2010.

Drew Residential School on Medicinal Chemistry, Madison, NJ, "Plasma Protein Binding", June 2011.

Contributed Lectures and Posters

American Chemical Society National Meeting, Philadelphia PA, "Preparation, Structure, and Reactivity of a Glucopyranosyliron Compound", August 1984.

Nucleic Acids Gordon Research Conference, New Hampton NH, "A Fluorescence-Based Nucleic Acid Analysis System", June 1987.

Molecular Genetics Gordon Research Conference, Newport RI, "A Fluorescence-Based Nucleic Acid Analysis System" (poster), August 1987.

Genome Mapping and Sequencing, Cold Spring Harbor NY, "An Automated System for Fluorescence-Based Nucleic Acid Analysis", April 1988.

American Chemical Society National Meeting, Toronto, Canada, "The Design and Synthesis of Fluorescence-Tagged Dideoxynucleotides for Automated DNA Sequencing", June 1988.

1989 UCLA Symposium on Biotechnology and Genetic Disease, Steamboat Springs CO, "3'- and 5'-Fluorescence-Labeling of DNA for Sequencing and Mapping" (poster), March 1989.

Nucleic Acid Applications, San Diego CA, "Chemical Reagents for Molecular Biology" (poster), October 1989.

IUB Conference on Nucleic Acid Therapeutics, Clearwater Beach, Florida, "Novel Oligonucleotide Analogues with a Sulfur-Based Linkage" (poster), January 1991.

86th Annual Meeting of the American Association for Cancer Research, Toronto, Canada, "DMP 315: a novel, non-symmetrical bis-imide with outstanding antitumor activity against human solid tumor xenografts" (poster), March 1995.

American Chemical Society National Meeting, San Diego, CA, "The Discovery of DPC 681 and DPC 684: Inhibitors of HIV Protease with Superior Resistance Profiles" (poster), September 2002.

University Lectures

University of Minnesota, Department of Chemistry, Minneapolis MN, "A Fluorescence-Based System for Nucleic Acid Analysis", October 1987.

California Institute of Technology, Department of Chemistry, Pasadena CA, "Automated DNA Sequencing with Fluorescence-Tagged Dideoxynucleotides", December 1987.

Villanova University, Department of Chemistry, Villanova PA, "A Fluorescence-Based System for Nucleic Acid Analysis", September 1988.

Columbia University, Department of Chemistry, New York NY, "Fluorescence-Based Nucleic Acid Analysis", November 1988.

University of Rochester, Department of Biophysics, Rochester NY, "Fluorescence-Based Nucleic Acid Analysis", March 1989.

University of California, San Diego, Department of Chemistry, La Jolla CA, "Chemical Reagents for Molecular Biology", April 1990.

Cornell University, Department of Chemistry, Ithaca, NY, "Novel Oligonucleotide Analogues with a Sulfur-Based Linkage", February 1991.

Purdue University, West Lafayette, Indiana, Department of Medicinal Chemistry and Pharmacognosy, "Novel Oligonucleotide Analogues with a Sulfur-Based Linkage", March 1991.

Rockefeller University, New York, NY, "Novel Oligonucleotide Analogues with a Sulfur-Based Linkage", March 1991.

Manhattan College, Bronx, NY, Sigma XI Chapter, "A System for Fluorescence-Based DNA Sequencing", December 1991.

State University of New York at Stony Brook, Stony Brook, NY, "Nucleic Acid-Based Therapeutics: Progress and Prospects", December 1991.

Scripps Institute, La Jolla, CA, "Cancer Chemotherapy: New Drugs and New Approaches", December 1993.

Indiana University, Bloomington, IN, "An Antisense Therapeutic Approach to Multidrug Resistance", April 1995.

Manhattan College, Bronx, NY, "Cyclic Urea-Based HIV Protease Inhibitors: A Perspective", March 1997.

Scripps Institute, La Jolla, CA, "Cyclic Urea-Based HIV Protease Inhibitors: A Perspective", January 1998.

Lehigh University, Teleconference: Lead Optimization Course, "Cyclic Urea-Based HIV Protease Inhibitors: A Perspective on Optimization of Drug Candidates", May 1999.

University of Utah, Department of Medicinal Chemistry, Salt Lake City, Utah, "The Search for Next Generation HIV Protease Inhibitors", May 2002.

National Institutes of Health, Scientific Review Section, Bethesda, MD, "Plasma Protein Binding and Drug Action", May 2002.

Columbia University, Department of Chemistry, New York NY, "Chemical Principles of Drug Action *in vivo*", April 2006.

Lehigh University, Teleconference: Pharmacology Course, "Binding to Plasma Proteins", Oct. 2008.

Univ. Cal., Irvine, Irvine, CA, “Plasma Protein Binding and Drug Action”, Mar 2010.

Pennsylvania Biotechnology Center, Doylestown, PA, “Chemical Principles of Drug Action *in vivo”*, May 2012.

Drexel University, Dept. of Medicinal Chemistry, Philadelphia, PA, “Chemical Principles of Drug Action *in vivo”*, January 2013.

Patents

US Patent 5,047,519, Frank W. Hobbs, Jr., Anthony J. Cocuzza, and George L. Trainor, *"Alkynylamino Nucleotides"*, issued 9/10/91. [Inventorship corrected to add GLT, 10/17/95]

US Patent 5,151,507, Frank W. Hobbs, Jr. and George L. Trainor, *"Alkynylamino Nucleotides"*, issued 9/29/92.

US Patent 5,242,796, James M. Prober, Rudy J. Dam, Charles W. Robertson, Frank W. Hobbs, Jr. and George L. Trainor, *"Method, System, and Reagents for DNA Sequencing"*, issued 9/7/93.

US Patent 5,276,143, Subramaniam Sabesan and George L. Trainor, *"Dideoxyfructonucleosides and Deoxyfructonucleotides"*, issued 1/4/94.

US Patent 5,306,618, James M. Prober, Rudy J. Dam, Charles W. Robertson, Frank W. Hobbs, Jr. and George L. Trainor, *"Method, System, and Reagents for DNA Sequencing"*, issued 4/26/94.

US Patent 5,332,666, James M. Prober, Rudy J. Dam, Charles W. Robertson, Frank W. Hobbs, Jr. and George L. Trainor, *"Method, System, and Reagents for DNA Sequencing"*, issued 7/26/94.

US Patent 5,470,967, Edward M. Huie and George L. Trainor, *"Oligonucleotide Analogues with Sulfamate Linkages"*, issued 11/28/95.

US Patent 5,558,991 George L. Trainor, *"DNA Sequencing Method Using Ayclonucleoside Triphosphates"*, issued 9/24/96.

US Patent 5,608,063 Frank W. Hobbs, Jr. and George L. Trainor, *"Method, System, and Reagents for DNA Sequencing"*, issued 3/4/97.

US Patent 5,625,081 George L. Trainor, *"Fluorescent Dye Intermediates"*, issued 4/29/97.

US Patent 6,391,919 Robert F. Kaltenbach and George L. Trainor, *"Bis-amino Acid Sulfonamides Containing Substituted Benzylamines as Inhibitors of HIV Protease"*, issued 5/21/02.

US Patent 6,528,681 Robert F. Kaltenbach and George L. Trainor, *"Halogenated Triphenylethylene Derivatives as Selective Estrogen Receptor Modulators"*, issued 3/4/03.

US Patent 6,617,310 Robert F. Kaltenbach and George L. Trainor, *"Phosphate Esters of Bis-amino Acid Sulfonamides Containing Substituted Benzylamines"*, issued 9/9/03.

US Patent 6,927,224 Robert F. Kaltenbach, Simon P. Robinson, and George L. Trainor, *"Selective Estrogen Receptor Modulators"*, issued 8/9/05.

US Patent 7,045,540 Robert F. Kaltenbach, Simon P. Robinson, and George L. Trainor, *"Selective Estrogen Receptor Modulators"*, issued 5/16/06.

US Patent 7,323,587 Robert F. Kaltenbach, Simon P. Robinson, and George L. Trainor, *"Selective Estrogen Receptor Modulators"*, issued 1/29/08.

US Patent 7,323,587 Robert F. Kaltenbach, Simon P. Robinson, and George L. Trainor, *"Selective Estrogen Receptor Modulators"*, issued 1/29/08.

US Patent 7,442,700 H. Mastalerz, D. M. Vyas, G. L. Trainor, and A. V. Gavai, *"Pyrrolotriazine Compounds Useful as Kinase Inhibitors and Methods of Treating Kinase-Associated Conditions Therewith"*, issued 10/28/08.

US Patent 8,633,200 Annapurna Pendri, Guo Li, Samuel Gerritz, David R. Langley, George L. Trainor, and Nicholas A. Meanwell, *"Inhibitors of Human Immunodeficiency Virus Replication"*, issued 1/21/14.

2017 CPRIT University Advisory Committee Annual Report
Submitted for the CPRIT Oversight Committee
February 21,2018

University Advisory Committee
Membership Roster

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Vice Chair, 2016-2018
Dean, Graduate School Biomed Sciences
Professor, Epigenetics & Mol. Carcin.
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Duncan Cancer Center
Baylor College of Medicine

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Immediate Past Chair, 2016-2018
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University of Houston System
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University of Houston

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University of Texas Medical Branch at Galveston

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Chair and Professor, Department of Biomedical Sciences
VP for Research
Associate Dean, Graduate School of Biomedical Sciences
Texas Tech University Health Sciences Center El Paso

Yousif Shamoo, Ph.D.
Vice Provost for Research
Rice University

University of Houston
To be appointed

University of North Texas Health Science Center at Fort Worth
To be appointed

2017 UAC Meetings, Reports and Teleconferences.
January 2017—preparation and submission of the 2016 Annual Report by UAC
March 21, 2017 meeting
May 16, 2017 teleconference meeting
July 25, 2017—CPRIT Leadership Visit to Houston to meet with University Tech Transfer University staff
November 14, 2017-UAC meeting at CPRIT Conference in Austin

The CPRIT University Advisory Committee worked closely with Dr. Willson and the CPRIT Office to continue building upon the accomplishments of our cancer researchers to serve the citizens of Texas.

As shown above, the CPRIT UAC met as a full committee, either by conference call or in person on three occasions, including at the Annual CPRIT Innovations Conference in November 2017. In addition, the CPRIT Leadership visited Houston on July 25th to meet with Technology Transfer personnel at Universities to discuss approaches to catalyze interventions and technologies effective in prevention and treatment of cancer. Overall, the major topics discussed by the UAC included i) alignment of available funds and priorities for RFA's, ii) Y18 mechanisms of funding and deadlines, iii) the impact of the biennial Texas Legislative session on CPRIT and, in turn, iv) the best means of summarizing and underscoring the impact that CPRIT has had in Texas. These discussion topics and UAC recommendations are summarized as follows.

UAC Perspectives: CPRIT Initiatives

CANCER RESEARCH IN THE STATE OF TEXAS: Four major areas of emphasis

1. WHERE IT HAS EMERGED THANKS TO CPRIT

Core facilities funding (CFSA): a major institutional investment; made possible through CPRIT funding (14 of 30 research orgs). There are now collaborations through core facilities across Texas Institutions.

Important mechanisms for optimizing reach and inclusiveness: High Impact/High Risk award - (25 of 30 research orgs) and Individual Investigator awards (20/30).

2. WHERE IT HAS THRIVED & REACHED HIGHER PLANES

Building Comprehensive Cancer Centers and gaining significant extramural NCI-funding: Return on investment (ROI)

- UT MD Anderson Cancer Center was the only NCI-designated Comprehensive Cancer Center in TX prior to CPRIT.
- Now, Baylor College of Medicine and UT-Southwestern have each gained NCI-designation as Comprehensive Cancer Centers.

Recruitment awards – Established Investigators and First-Time Faculty, as well as Individual

Investigator, awards are major factors.

ROI: Leveraging investment to gain extramural funding, patents, publications and developing therapies.

3. WHERE CPRIT IS PAVING THE WAY OF THE FUTURE

Recruitment awards – First-Time Tenure-Track Faculty, as well as Individual Investigator, awards are major factors.

Research training grant awards – Investment in the Next Generation of cancer researchers: PhD, MPH, MD/PhD, postdoctoral fellows, summer interns

Investment in infrastructure – Core facility awards

4. WHERE CPRIT IS LINKED TO THERAPIES AND PREVENTION

Early Translational Research Awards (ETRA) – to cross the Valley of Death in development of new therapies – better understanding of this mechanism is needed

IIRA: Clinical Translation – better metrics on successes needed

Research and development needed in the areas of health disparities, prevention and screening – these are critical

UAC Recommendations of 2017

- Improve effectiveness of Early Translational Research Awards (ETRA) – to cross the Valley of Death in development of new therapies
    - Gathering of CPRIT's Jim Willson and Mike Lang with various Tech Transfer offices, Office of Research and innovators in Houston to increase understanding of what is needed in a new RFA

- Improve Multi-Investigator Research Award (MIRA) outcomes
    - Evidence of true synergy between projects required
    - Limit number of investigators and projects – must be exceptional with a track record of existing interactions amongst the project leaders
    - New RFA released

UAC Recommendations for the Future

- Improve information and communication on ROI to the public
    - What metrics are most useful?
        - Gain in extramural funds thanks to initial CPRIT funding
        - Creating jobs and increasing talent pool in Texas
        - Establishing new clinical trials and therapeutic development

        - Attracting entrepreneurial investment and link to developing therapeutics and treatments

- How can CPRIT gather effective information and disseminate it?
    - Link individual, specific recruits to their personal stories of successes – new strategies to attack cancers, how this attracted investment in Texas
    - Use more than CPRIT progress reports to gather information
        - Require all CPRIT funded investigators to link NIH Commons ID and ORCID to public and CPRIT
        - Site-visit major CPRIT funded institutions and discuss their ROI calculations and successes

- Improve the CPRIT website
    - Updated information is sorely needed
    - Shorten the "Read more" stories and make more readily accessible
    - Make the website attractive and friendly

- Ask institutions for layperson-ready stories of CPRIT-funded successes
    - What clinical therapies and trials are readily attributable to CPRIT investment?
        - How have these attracted donors and/or entrepreneurial investment?
        - Make these publicly available

- Highlight how CPRIT investment has impacted our state's underserved population and what measures will be taken to increase this impact

2017 UAC Annual Report

CPRIT University Advisory Committee Annual Report

Presented to the CPRIT Oversight Committee February 21, 2018

Chair: Michelle Barton, PhD – UT MD Anderson Cancer Center

Immediate-past chair: Mary Ann Ottinger, PhD – University of Houston

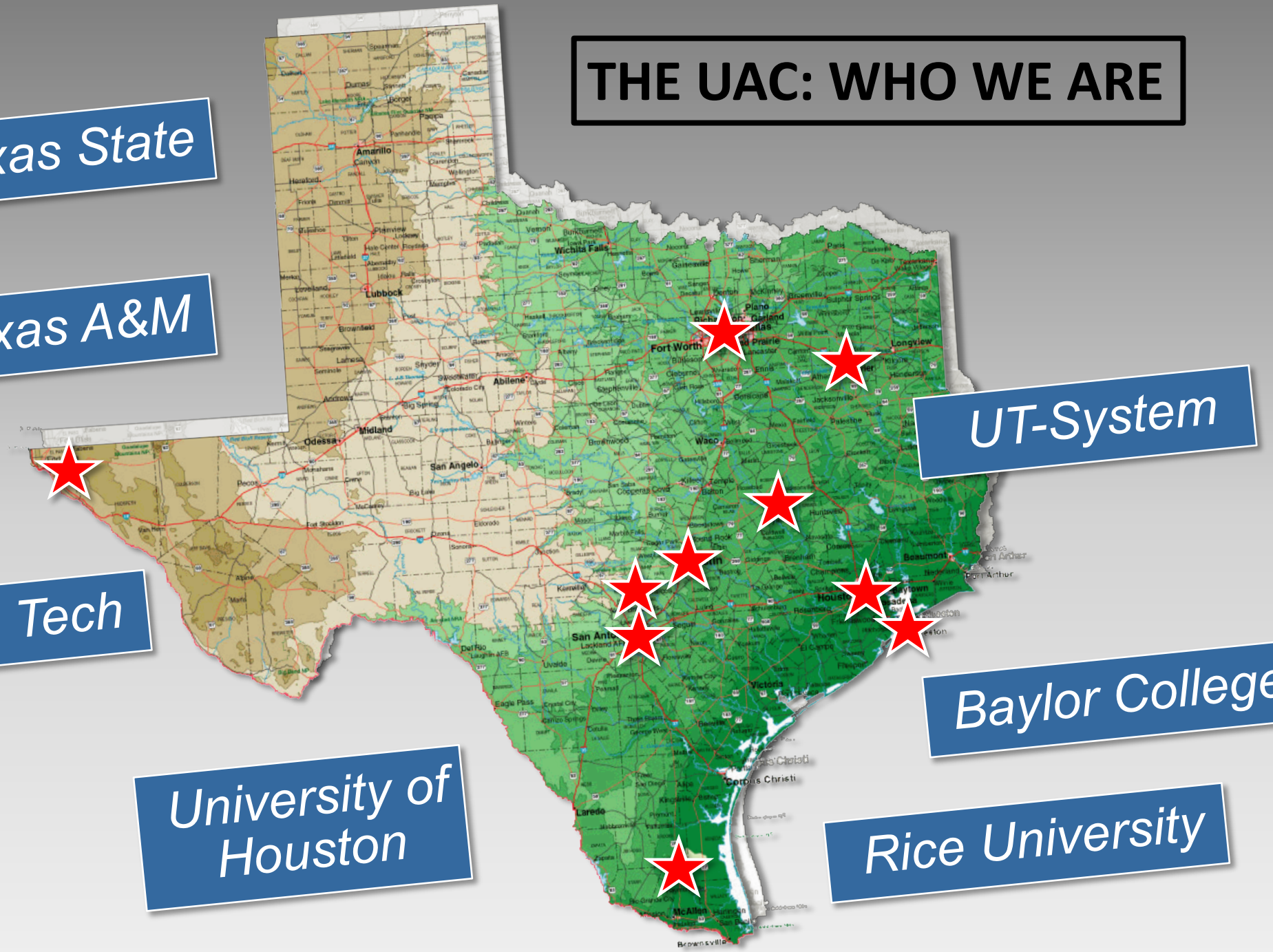
Vice-chair: C. Kent Osborne, MD – Baylor College of Medicine

Background

- The mission of the University Advisory Committee (UAC)

  "Advises the UOC on the role of higher education in cancer research. The nine members of the UAC include representatives of all Texas public university systems and private research universities."

THE UAC: WHO WE ARE



Background

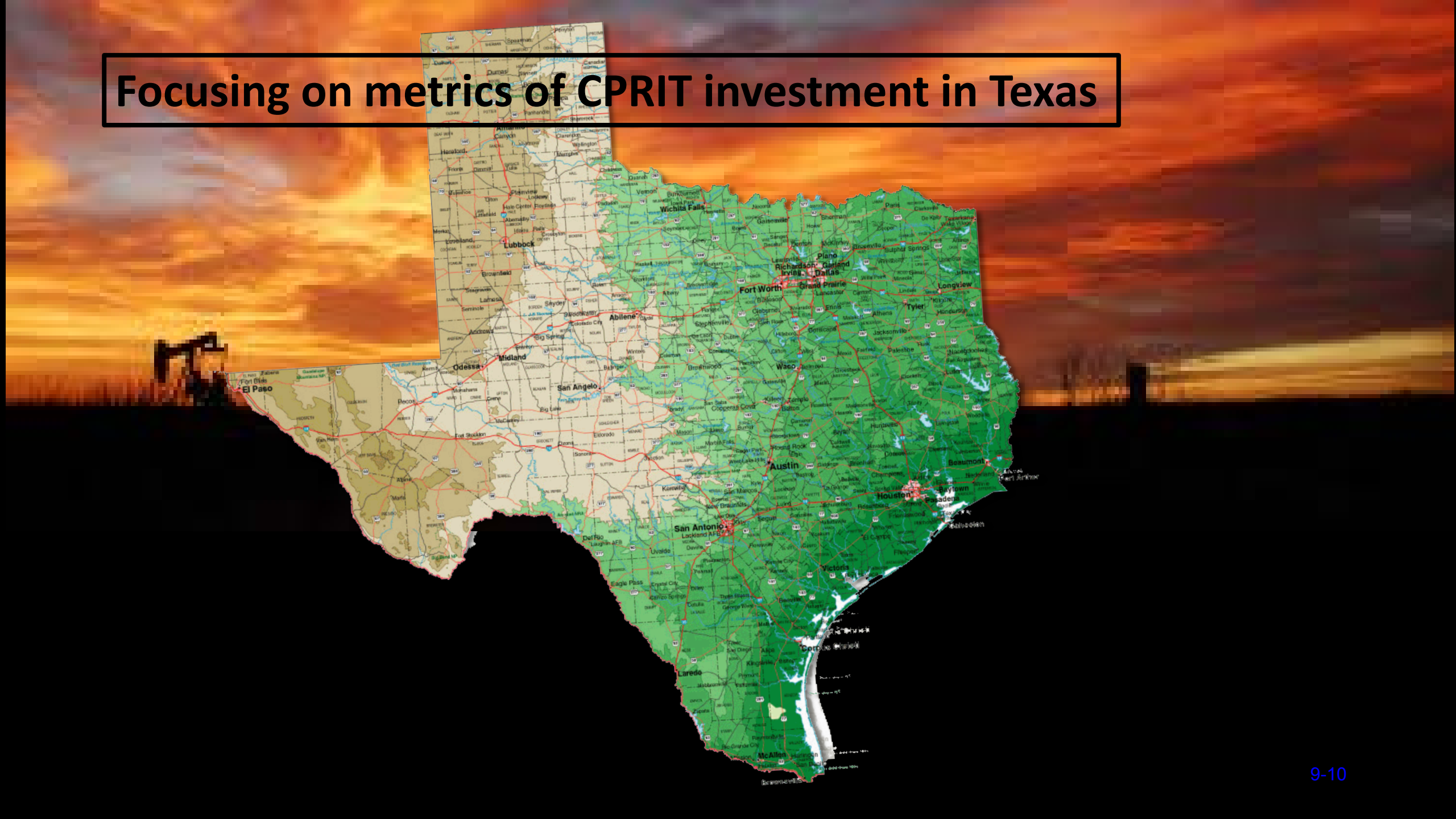
- The focus of the University Advisory Committee (UAC)

  How has CPRIT impacted cancer research across Texas?

  What are the most effective mechanisms of CPRIT funding?

  Where should priorities lie for future and sustained impact?

Focusing on metrics of CPRIT investment in Texas



UAC Perspectives: CPRIT Impact

CANCER RESEARCH IN THE STATE OF TEXAS

1. WHERE IT HAS EMERGED THANKS TO CPRIT

2. WHERE IT HAS THRIVED & REACHED HIGHER PLANES

3. WHERE CPRIT IS PAVING THE WAY OF THE FUTURE

4. WHERE CPRIT IS LINKED TO THERAPIES AND PREVENTION

UAC Perspectives: CPRIT Initiatives

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UAC Perspectives: CPRIT Initiatives

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2. WHERE IT HAS THRIVED & REACHED HIGHER PLANES

- Recruitment awards – Established Investigators and First-Time Faculty, as well as Individual Investigator, awards are major factors.

- ROI: Leveraging investment to gain extramural funding, patents, publications and developing therapies.

2. WHERE IT HAS THRIVED & REACHED HIGHER PLANES

Centers of Excellence catalyzed by CPRIT (examples):

Four Established Investigators recruited through CPRIT provide ”missing expertise” to increase cancer research at Rice University, where previously limited, and greater interactions across the Texas Medical Center.

Immuno-oncology program at MD Anderson catalyzed by recruitment of Jim Allison, leading to the Parker Institute initiative, the Biden Moonshot lead program, and Stand Up to Cancer programs with emergence of new national leaders, such as Jennifer Wargo. Biotech company Immatics moved to Houston to develop immunotherapies with two current clinical trials at MD Anderson featuring CPRIT-funded investigators.

2. WHERE IT HAS THRIVED & REACHED HIGHER PLANES

CPRIT support of the Baylor Proteomics Core Facility and faculty recruitments led to Baylor's designation as one of the initial NIH Proteogenomic Translational Research Centers. The Center is led by CPRIT Scholar, Matthew Ellis, M.D., and will focus on breast cancer biomarkers in the context of clinical trials.

The development of a Kidney Cancer SPORE at UTSW represents national recognition of an NCI-funded ($11 Million) center of research excellence targeting early detection and treatment of adult and pediatric kidney cancer. CPRIT support established the foundation for each one of the four projects headed by Jim Brugarolas, M.D., Ph.D., James Amatruda, M.D., Ph.D., Ralph DeBerardinis, M.D., Ph.D., and Joshua Mendell, M.D., Ph.D.

UAC Perspectives: CPRIT Initiatives

CANCER RESEARCH IN THE STATE OF TEXAS

3. WHERE CPRIT IS PAVING THE WAY OF THE FUTURE

- Recruitment awards – First-Time Tenure-Track Faculty, as well as Individual Investigator, awards are major factors.

- Research training grant awards – Investment in the Next Generation of cancer researchers: PhD, MPH, MD/PhD, postdoctoral fellows, summer interns

- Investment in infrastructure – Core facility awards

CPRIT Impact by Mechanism

Mechanism	# Cumulative Awards	Cumulative Award Funds	Follow-on Funds	Patent Applications	#Publications Published
Recruitment	151	$444,090,000	$257,822,782	66	1300
Core Facility Support Awards	41	$154,970,000	$160,314,232	10	275
High Impact/High Risk	123	$24,530,000	$29,647,058	27	199
Individual Investigator Research Awards	394	$381,750,000	$274,301,151	90	1770
Early Translational Research Awards	36	$48,860,000	$6,764,280	7	39
Multiple Investigator Research Awards	201	$247,710,000	$153,933,249	37	1363
Research Training Awards	23	$59,880,000	$17,998,816	8	799
Totals	**969**	**$1,361,7900**	**$900,781,568**	**245**	**5745**

Data through August 31, 2017

UAC Perspectives: CPRIT Initiatives

4. WHERE CPRIT IS LINKED TO THERAPIES AND PREVENTION

Early Translational Research Awards (ETRA) – to cross the Valley of Death in development of new therapies – better understanding of this mechanism is needed

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UAC Recommendations for the Future

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    - Use more than CPRIT progress reports to gather information
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  - Improve the CPRIT website
    - Updated information is sorely needed
    - Shorten the “Read more” stories and make more readily accessible
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    - Make these publicly available
  - Highlight how CPRIT investment has impacted our state’s underserved population and what measures will be taken to increase this impact

Academic Research Program Priorities 2018

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research
- ➡ Prevention and early detection
- Computational biology and analytic methods
- Childhood cancers
- ➡ Population disparities and cancers of importance in Texas

Academic Research Program Priorities 2019

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions
- Computational biology and analytic methods
- Childhood cancers
- Population disparities and cancers of importance in Texas: Hepatocellular cancer and obesity-linked cancers

February 2018 Oversight Committee
Internal Audit Status Report
As of February 12, 2017

Weaver and Tidwell, LLP (Weaver) is the outsourced internal auditor of the Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Alyssa Martin, Partner and Daniel Graves, Partner.

2018 Internal Audit Plan and Schedule

The table below reflects the activity to date Weaver has completed for the 2018 Internal Audit Plan.

NEW INTERNAL AUDITS		
Internal Audit	**Description**	**Timing**
Post Award Grant Contracting and Monitoring	Fieldwork for the Post Award Grant Contracting and Monitoring audit was completed on December 20, 2017. We issued the report on February 1, 2018. The audit resulted in an overall assessment of "Strong" with one finding. Moderate Risk Findings: 1. Separated Employee User Access in the outsourced partner's grant monitoring portal Follow-up procedures on the remediation of the findings will be included in the proposed audit plan for fiscal year 2019.	Complete
Communications	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Communications practices. Communication methods to be evaluated may include Website Content Compliance, Newsletter/Listserv, Grantee Communications, Achievement Report, Media Relations, and Publicly Available Information	March 2018
State Reporting	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's State Reporting practices. Activities to be evaluated will include Annual Reporting, Texas Cancer Plan, other Statutory State Reporting, and relevant Research and Analytical supportive data. Activities will also include responding to Public Information Act Requests	May 2018
Information Technology Services	The planned Internal Audit Over Information Technology Services is proposed to be deferred.	Deferred

FOLLOW-UP PROCEDURES		
Follow-Up	**Description**	**Timing**
Training Follow-Up • 2 Moderate Findings	Fieldwork for these follow-up procedures was completed on January 19, 2018. The report was issued February 2, 2018. Both findings from the prior year's audit were remediated	Complete
Internal Agency Compliance Follow-Up • 1 Low Finding	Fieldwork for these follow-up procedures was completed on January 19, 2018. The report was issued February 2, 2018. The one finding from the prior year's audit was remediated	Complete
IT Security Follow-up	Fieldwork for initial follow-up procedures was completed on February 2, 2018. Additional follow-up procedures are scheduled to be performed in June 2018.	June 2018
Pre-Award Grant Management Follow-up • 1 High Finding • 2 Moderate Findings	Internal Audit will perform follow-up procedures on the 3 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	March 2018
Procurement and P-Cards Follow-up • 7 Moderate Findings • 2 Low Findings	Internal Audit will perform follow-up procedures on the 9 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	April 2018

We have prepared a summary schedule of audits, their status and a summary of the findings by risk rating. The schedule maps out the internal audit and follow-up procedures performed, by year, the report date, report rating, and the findings by risk rating. The summary schedule is attached.

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

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of February 12, 2018

					Open Findings				Closed Findings				Total Findings			
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**
Fiscal Year 2015																
Grant Management	2015	Complete	July 27, 2015	Satisfactory	-	8	1	9	-	-	-	-	-	8	1	9
Expenditures Internal Audit	2015	Complete	August 24, 2015	Strong	-	-	2	2	-	-	-	-	-	-	2	2
2014 Governance and IT Follow-Up	2015	Complete	August 14, 2015	Satisfactory	-	-	-	9	-	-	-	7	-	1	1	2
2014 Grantee Monitoring Follow-Up	2015	Complete	July 31, 2015	Satisfactory	-	-	-	14	-	-	-	11	1	-	2	3
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	-	-	-	-
2015 Information Technology Follow-Up	2016	Complete	N/A	N/A	-	1	1	2	-	1	1	2	-	-	-	-
Fiscal Year 2016 Subtotal					**-**	**13**	**6**	**19**	**-**	**9**	**2**	**11**	**-**	**4**	**4**	**8**
Fiscal Year 2017																
Training Program Internal Audit	2017	Complete	March 10, 2017	Strong	-	2	-	2	-	-	-	-	-	2	-	2
Internal Agency Compliance	2017	Complete	April 17, 2017	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Pre-Award Grant Management	2017	Complete	May 30, 2017	Satisfactory	1	2	-	3	-	-	-	-	1	2	-	3
Procurement and P-Card Internal Audit	2017	Complete	August 4, 2017	Satisfactory	-	7	2	9	-	-	-	-	-	7	2	9
2016 Information Security Follow-Up	2017	Complete	May 30, 2017									-	-	-	-	-
2016 Commodity and Service Contracts Follow-Up	2017	Complete	July 13, 2017	Strong	-	3	2	5	-	3	2	5	-	-	-	-
2016 Revenue Follow-Up	2017	Complete	July 8, 2017	Strong	-	-	2	2	-	-	2	2	-	-	-	-
2016 Cash Management Follow-Up	2017	Complete	July 13, 2017	Strong	-	1	-	1	-	1	-	1	-	-	-	-
Fiscal Year 2017 Subtotal					**1**	**16**	**6**	**23**	**-**	**4**	**4**	**8**	**1**	**12**	**2**	**15**
Fiscal Year 2018																
Post Award Grant Monitoring Internal Audit Grant Contracting Internal Audit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Communication Internal Audit	2018	March 2018	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-
State Reporting Internal Audit	2018	May 2018	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-
Information Technology Services Internal Audit	2018	May 2018	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-
2016 Information Security Follow-Up	2018	Fieldwork Complete	TBD	TBD	Fieldwork is complete. Exit meeting was held on February 9, 2018.											
2017 Training Program Follow-Up	2018	Complete	February 2, 2018	Strong	-	2	-	2	-	2	-	2	-	-	-	-
2017 Internal Agency Compliance Follow-Up	2018	Complete	February 2, 2018	Strong	-	1	-	1	-	1	-	1	-	-	-	-
2017 Pre-Award Grant Management Follow-Up	2018	March 2018	TBD	TBD	1	2	-	3	-	-	-	-	1	2	-	3
2017 Procurement and P-Card Follow-Up	2018	April 2018	TBD	TBD	-	7	2	9	-	-	-	-	-	7	2	9
Fiscal Year 2018 Subtotal					**1**	**13**	**2**	**16**	**-**	**3**	**-**	**3**	**1**	**10**	**2**	**13**

FISCAL YEAR 2018 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**	
Post Award Grant Monitoring Internal Audit Grant Contracting Internal Audit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	-	1	-	1	**FY 2019**
Communication Internal Audit	2018	March 2018	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-	**TBD**
State Reporting Internal Audit	2018	May 2018	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-	**TBD**
Information Technology Services Internal Audit	2018	May 2018	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-	**TBD**
Information Security Internal Audit	2016	Fieldwork Complete	TBD									-					**June 2018**
Training Program Internal Audit	2017	Complete	February 2, 2018	Strong	-	2	-	2	-	2	-	2	-	-	-	-	**NA**
Internal Agency Compliance	2017	Complete	February 2, 2018	Strong	-	1	-	1	-	1	-	1	-	-	-	-	**NA**
Pre-Award Grang Management	2017	March 2018	TBD	TBD	1	2	-	3	-	-	-	-	1	2	-	3	**March 2018**
Procurement and P-Cards	2017	April 2018	TBD	TBD	-	7	2	9	-	-	-	-	-	7	2	9	**April 2018**
Total Findings For Internal Audit Follow-Up					**1**	**13**	**2**	**16**	**-**	**3**	**-**	**3**	**1**	**10**	**2**	**13**	

Cancer Research and Prevention Institute of Texas
2018 Internal Audit Plan*
For the Year Ending August 31, 2018

Audit Area	Risk Rating	Summary Procedures	Audit Focus	Timing
2018 Planned New Internal Audits				
Post Award Grant Monitoring	High	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Grant Contracting and Post-Award Grant Monitoring practices. Activities to be evaluated will include Fund Availability, Certifications, Contract Terms, Grant Contract Execution, Grantee Monitoring, Sub-Recipient Monitoring, Grantee Reporting, and Scientific Review.	Internal Audit	Complete
Grant Contracting	Moderate			
Communications	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Communications practices. Activities to be evaluated will include Website Content Compliance, Newsletter/Listserv, Grantee Communications, Achievement Report, Media Relations, and Publicly Available Information.	Internal Audit	March 12 - 23, 2018
State Reporting	High	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's State Reporting practices. Activities to be evaluated will include Annual Reporting, Research/Analytical Supporting, Texas Caner Plan, State Reporting, Public Information Act Requests, and Ad Hoc Reporting.	Internal Audit	May 14 - 25, 2018
2018 Planned Internal Audit Follow-up				
Training	Moderate	Internal Audit will perform follow-up procedures on the 2 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	Complete
Internal Agency Compliance	Moderate	Internal Audit will perform follow-up procedures on the 1 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	Complete
Information Security	High	Internal Audit will perform follow-up procedures on the 7 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	January 15 - 19, 2018 June 4 - 8, 2018
Pre-Award Grant Management	High	Internal Audit will perform follow-up procedures on the 3 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	March 19 - 23, 2018
Procurement and P-Cards	High	Internal Audit will perform follow-up procedures on the 9 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	April 9 - 13, 2018
2018 Planned Annual Requirements				
Project Management	NA	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management	Ongoing
Update Risk Assessment	NA	Perform required annual update of risk assessment	Policy Compliance	Ongoing
Annual and Quarterly Board Reports	NA	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Committee of internal audit activities.	Policy Compliance	Ongoing

***The 2018 Internal Audit Plan was revised as of February 2018. The planned Internal Audit Over Information Services for fiscal year 2018 is proposed to be deferred.**

Cancer Prevention & Research Institute of Texas

IA # 01-18 Internal Audit Report over Post-Award Grant Contracting and Monitoring
Report Date: December 20, 2017
Issued: February 1, 2018

weaver
Assurance • Tax • Advisory

CONTENTS

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 December 4, 2017, through December 20, 2017 relating to the Post-Award Grant Contracting and Monitoring processes.

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

A. Confirm the design of internal controls over Post-Award Grant Contracting and Monitoring processes ensure that consistent processes are implemented and designed effectively to manage the grant application and evaluation process.
B. Ensure that controls over selected critical processes within Post-Award Grant Contracting and Monitoring processes are operating effectively and that required grant application documentations is obtained and reviewed.
C. Ensure that access to view, process or modify data in the key IT applications is restricted to appropriate personnel.

To accomplish these objectives, we conducted interviews with CPRIT personnel responsible for Post-Award Grant Contracting and Monitoring. We also reviewed documentation and performed specific testing procedures to assess controls. Procedures were performed at CPRIT's office and completed on December 20, 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
February 1, 2018

Cancer Prevention and Research Institute of Texas

IA# 01-18 Internal Audit Report over Post-Award
Grant Contracting and Monitoring
Report Date: December 20, 2017
Issued: February 1, 2018

Background

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

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

Since June 1, 2016, CPRIT Post-Award Grant Contracting and Monitoring activities included:

- 167 contracts executed
- 177 contracts closed
- 755 active grants
- 16 advance payments
- 247 contract extensions
- 348 desk reviews and 39 on-site reviews
- 3,287 grant disbursements totaling approximately $349 million

The Grant Contracting process begins with the creation and execution of a grant contract. A standard grant contract template is maintained in the CPRIT Grants Management System (GCMS) and modified for each grant contract. All contracts and contract amendments are approved and executed by the CEO through an electronic sign-off in CGMS. Executed contracts are binding unless and until modified by a contract revision signed by the recipient and CPRIT's CEO, or the contract is terminated.

Upon execution of a grant contract, the grantee must submit quarterly Financial Status Reports (FSRs) to request reimbursement for grant funds within 90 days of the fiscal quarter. All FSRs receive a thorough review by CPRIT personnel, including a review by the Grant Accountant and a secondary review by the Grant Specialist to ensure that expenses charged are allowable per the grant contract. After approval of the FSR in CGMS, the Operations Manager or Operations Specialist approves the payment voucher in the state's Centralized Accounting and Payroll/Personnel System (CAPPS) upon completion of the grant pedigree verifying that all required reports have been completed. Then the Chief Operating Officer electronically approves the payment in CAPPS.

In addition to FSRs, grantees are required to submit annual reports including the Annual Inventory Report, HUB Form, Revenue Sharing Form, Grant Progress Reports, and single audits, which are reviewed and approved in CGMS by appropriate CPRIT staff to ensure compliance with contract terms.

Cancer Prevention and Research Institute of Texas

IA# 01-18 Internal Audit Report over Post-Award
Grant Contracting and Monitoring
Report Date: December 20, 2017
Issued: February 1, 2018

On an annual basis, CPRIT compliance staff complete a risk assessment update to identify high-risk rated grantees, for which an on-site or desk review will be performed. Desk reviews include a review of grantee's policies and procedures regarding grant management, while on-site reviews include a more thorough review of a grantee's procedures, procurement practices, inventory management, accounting system, and segregation of duties. For all desk and on-site reviews, a Grant Monitoring Report is completed and submitted to the grantee. The report which identifies any deficiencies found in the review. Grantees are required to provide corrective action responses (if applicable) within 30 days of the report date, and the compliance staff follows-up with grantees who do not provide corrective action responses in a timely manner.

Grantees may receive no-cost grant extensions, provided that the grantee has submitted all required reports to CPRIT. The average extension is six months. All extensions are reviewed and approved by program staff and the Operations Manager prior to approval by the Chief Executive Officer.

The final step of the Grant Contracting and Post-Award Grant Monitoring processes is the grant close-out. Grantees must submit a final FSR and a Final Grant Progress Report in order to receive the last grant payment. Final Progress Reports are reviewed similarly to the review of the Annual Progress Reports to assess the success and progress over the grant's life. Final FSRs are the FSR for the last quarter of the grant, however, the indirect cost for the life of the grant is verified to ensure that indirect costs amount to no more than 5% of the total grant expenditures. Payment of the last FSR follows the same process described above.

Upon receipt of all required reports and approval of the Final Grant Progress Report and last FSR, CGMS automatically closes out the grant.

Audit Objective and Scope

The audit focused on CPRIT's post-award grant contracting and monitoring processes to execute contracts and monitor compliance with contract terms. Key functions and sub-processes within the Post-Award Grant Contracting and Monitoring processes that were reviewed include:

- Contract Execution
- Contract Compliance
- Financial Reporting
- Grantee Reporting
- Compliance Monitoring
- Contract Extension
- Contract and Funding Closeout

The audit scope did not include the following Pre-Award Grants Management processes:

- RFA Review Process
- Conflict of Interest Disclosure
- Scientific Research and Prevention Program Review (including travel coordination)
- Grant Application Approval
- Grant Award Approval

Cancer Prevention and Research Institute of Texas

IA# 01-18 Internal Audit Report over Post-Award
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Report Date: December 20, 2017
Issued: February 1, 2018

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

Contract Execution

- Award commitments/contracts are appropriately authorized by the Oversight Committee
- Use of standard contract templates are appropriate and approved
- Deviations to standard and required contract terms are appropriate and approved
- Contracts clearly define compliance requirements and include State requirements
- Required grantee certifications are reviewed and approved prior to contract execution
- Contract amendments and revisions are appropriately reviewed and approved

Contract Compliance

- State grant laws and regulations are met
- Contracts are in compliance with CPRIT Administrative Rules
- Arrangements allowing self-dealing or kickback payments are not in place
- Conflicts of interest by the grantee have been identified and reported
- Contract records are adequately documented and maintained

Financial Reporting

- FSR reimbursement requests are reviewed and approved
- Grant costs charged to grants are monitored
- Grant payments are approved prior to disbursement
- Periodic financial monitoring procedures regarding budgets, expenditure coding, and fixed assets are performed
- Use of matching funds is reviewed and validated for completeness and accuracy
- Financial reports and audits are reviewed and potential irregularities and exceptions are investigated

Grantee Progress Reporting

- Grantee progress reports are monitored for completeness, accuracy and timeliness
- Programmatic/scientific assessments of progress report results are conducted
- Reports are reviewed for compliance with contract terms
- Cost analysis of grant program progress results is performed

Compliance Monitoring

- Grantee risk assessment is maintained and utilized to determine appropriate grantee monitoring procedures
- Grantees receive onboarding and periodic compliance and management training
- Grant costs charged are monitored
- Use of matching funds is reviewed and validated for completeness and accuracy
- Grantee policies and procedures are reviewed
- Grantee accounting systems are reviewed for sufficiency
- Grantee segregation of duties is assessed
- Grantee procurement practices are reviewed to ensure appropriate use of grant funds
- Grantees have appropriate controls and monitoring of inventory purchased with grant funds
- Agreements with subcontractors include all CPRIT contractual requirements and administrative regulations
- Grantees have procedures in place to monitor subcontractors for compliance
- Corrective action follow-up is performed with grantees with deficiencies

Contract Extension

- Grantee financial and programmatic performance is evaluated prior to extension approval
- Extensions are reviewed and approved

Contract and Funding Closeout

- Grant expenditures are verified prior to closeout
- All open requests for reimbursement are validated and reconciled
- Grant and grantee documents are archived and retained
- Final grantee progress report evaluations and verifications are performed
- Final reimbursement payments are approved

Our procedures included interviewing key personnel to confirm our understanding of the current processes in place, examining existing documentation, evaluating the internal controls over the process, and testing the effectiveness of the controls in place. We evaluated the existing policies, procedures and processes in their current state. Our coverage period was from June 1, 2016, through November 30, 2017.

Executive Summary

Through our interviews, observations, evaluation of internal control design, and testing of controls, we identified one finding. A reported finding includes the item that has been identified and is considered to be a non-compliance issue with documented CPRIT policies and procedures, with rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover significant risks to CPRIT. This issue could have significant financial or operational implications.

Cancer Prevention and Research Institute of Texas

IA# 01-18 Internal Audit Report over Post-Award
Grant Contracting and Monitoring
Report Date: December 20, 2017
Issued: February 1, 2018

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: Confirm the design of internal controls over Post-Award Grant Contracting and Monitoring processes ensure that consistent processes are implemented and designed effectively to manage the grant application and evaluation process.	We identified 31 controls to be in place in the process, and determined that all relevant risks were covered.	**STRONG**
Objective B: Ensure that controls over selected critical processes within Post-Award Grant Contracting and Monitoring processes are operating effectively and that required grant application documentations is obtained and reviewed.	Controls in place were operated effectively and as designed. We verified that control activities were consistently followed and covered relevant risks within the process.	**STRONG**
Objective C: Ensure that access to view, process or modify data in the key IT applications is restricted to appropriate personnel.	Access to CGMS and the CohnReznick Portal was generally appropriate. We identified the following opportunity for improvement: • Ensure that access to the CohnReznick portal is removed upon employee separation from CPRIT.	**STRONG**

One other opportunity for improvement was identified through our interviews, evaluation of internal control design and transactional testing. This observation included the item that is not considered to be a non-compliance issue with documented CPRIT policies and procedures. It is considered a process improvement observation and the intent for the recommendation is to strengthen current CPRIT processes and controls. The observation was provided to management separately.

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IA# 01-18 Internal Audit Report over Post-Award
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Conclusion

Based on our evaluation, the Post-Award Grant Contracting and Monitoring processes have procedures and controls in place to conduct effective management of the significant processes within CPRIT. However, we identified an opportunity to improve system-related controls that affect the processes and effectiveness of the Post-Award Grant Contracting and Monitoring processes.

As part of the employee separations process, CPRIT should ensure that user access to all key IT systems is evaluated and deactivated upon the user's separation from CPRIT. The timely removal of user access from key IT systems ensures the effectiveness of controls within the Post-Award Grant Contracting and Monitoring processes.

Follow-up procedures will be conducted as part of the 2019 Internal Audit Plan to validate the effectiveness of the steps taken to address the finding identified.

Detailed Procedures Performed, Findings, Recommendations and Management Response

Detailed Procedures Performed, Findings, Recommendations and Management Response

Our procedures included interviewing key agency personnel to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the process. We evaluated the existing policies, procedures and processes in their current state.

Objective A: Design of Internal Controls

Confirm the design of internal controls over Post-Award Grant Contracting and Monitoring processes ensure that consistent processes are implemented and designed effectively to manage the grant application and evaluation process.

Procedures Performed: We conducted interviews with key personnel throughout CPRIT and examined existing documentation to confirm our understanding of the internal controls for the Post-Award Grant Contracting and Monitoring processes. We confirmed the design of controls within the following critical sub processes:

- Contract Execution
- Contract Compliance
- Financial Reporting
- Grantee Reporting
- Compliance Monitoring
- Contract Extension
- Contract and Funding Closeout

We evaluated whether the design of the confirmed internal controls sufficiently mitigates the critical risks associated with the Post-Award Grant Contracting and Monitoring processes. We identified unacceptable risk exposures due to control design inadequacy or opportunities to strengthen the effectiveness of the existing control design.

Results: We identified 31 controls in place over the significant activities within the Post-Award Grant Contracting and Monitoring processes. No findings were identified.

Process Area	Expected Controls	Control Coverage
Contract Execution	7	5
Contract Compliance	5	5
Financial Reporting	7	8
Grantee Reporting	4	3
Compliance Monitoring	12	8
Contract Extensions	2	3
Contract Closeout	4	4
Grant Funding Closeout	3	4
Total	**44**	**40**

Duplicate Control: The total number of controls identified is 31. However, based on their design, controls address risks in multiple processes. We have mapped the 31 identified controls to the processes in which they mitigate the risks within the processes.

Objective B: Effectiveness of Controls

Ensure that controls over selected critical processes within Post-Award Grant Contracting and Monitoring processes are operating effectively and that required grant application documentations is obtained and reviewed.

1. **Procedures Performed:** We selected a sample of 35 from the population of 167 contracts that were executed and effective between June 1, 2016, and November 30, 2017, and verified the following:

    - Award commitments/contracts were appropriately authorized by the CEO
    - Grantee certifications were reviewed and approved prior to contract execution
    - Contracts were in compliance with state laws and CPRIT Administrative Rules

    Results: No findings identified.

2. **Procedures Performed:** We selected a sample of 40 from the population of 755 grants active between June 1, 2016, and November 30, 2017, and verified the following:

    - Contract amendments were approved by the CEO and signed by the Applicant's Authorized Signing Official
    - All executed contract documents, including attachments, amendments, and the approved proposal and application were maintained in CGMS
    - CPRIT reviewed Grant Progress Reports to determine whether sufficient progress was made consistent with the scope of work and timeline set forth in the Grant Contract.

    Results: No findings identified.

3. **Procedures Performed:** We selected a sample of 40 from the population of 3,287 grant disbursement between June 1, 2016, and November 30, 2017, and verified the following:

    - Contracts were executed prior to funding grant awards
    - Financial Status Reports (FSRs) and corresponding reimbursement requests were reviewed and approved by CPRIT personnel
    - FSR Check Lists were completed for each FSR Review and a secondary review was performed by a Grant Specialist
    - Use of matching funds was reviewed and validated for completeness and accuracy
    - The total amount per the Financial Status Report (FSR) agreed to the total disbursed per the Voucher

    Results: No findings identified.

4. **Procedures Performed:** We selected a sample of 4 from the population of 16 advance payments between June 1, 2016, and November 30, 2017, and verified the following:

    - Advance payments for grant award funds were approved by the Oversight Committee
    - Expenditures and supporting documentation were reviewed by Grant Accountants and reconciled to outstanding advance amounts before any additional funds were disbursed

    Results: No findings identified.

5. **Procedures Performed:** We reviewed the grantee risk assessments for FY 2017 and FY 2018, and verified the following:

    - The grantee risk assessment was consistently maintained and updated.

    Results: No findings identified.

6. **Procedures Performed:** We selected a sample of 40 from the population of 348 desk reviews and 5 from the population of 39 on-site reviews performed between June 1, 2016, and November 30, 2017, and verified the following:

    - CPRIT obtained and reviewed financial statement audit reports from grantees that had grant expenditures in excess of $750,000
    - Grantee monitoring procedures (desk and on-site reviews) were executed based on the grantee risk assessment guidelines
    - Grantee monitoring procedures include reviews of grantee:
        - Financial statements and single audits (if applicable)
        - Policies and Procedures
        - Inventory Management
        - Accounting System Sufficiency
        - Segregation of duties
        - Subcontractor requirements and monitoring
    - Corrective action follow-up was performed for grantees and sub-recipients with deficiencies

    Results: No findings identified.

7. **Procedures Performed:** We selected a sample of 3 from the population of 6 quarterly Oversight Committee meetings between June 1, 2016, and November 30, 2017, and verified the following:

    - The report provided to the Oversight Committee regarding grantees that fail to comply with reporting requirements was accurate and complete

    Results: No findings identified.

8. **Procedures Performed:** We selected a sample of 40 from the population of 247 contract extensions between June 1, 2016, and November 30, 2017, and verified the following:

    - Contract extensions included a formal justification, were evaluated against grantee programmatic performance, and were approved by the Program Manager and CEO

    Results: No findings identified.

9. **Procedures Performed:** We selected a sample of 20 from the population of 177 close-out or early terminations between June 1, 2016, and November 30, 2017, and verified the following:

    - All open requests for reimbursement were validated and reconciled
    - Grantee documents were appropriately archived
    - Close-out final progress reports were complete
    - All final progress reports were verified prior to close-out
    - Grant funds were reconciled by funding source prior to close-out
    - Close-out final payments were approved appropriately

    Results: No findings identified.

Objective C: System Access

Ensure that access to view, process or modify data in the key IT applications is restricted to appropriate personnel.

1. **Procedures Performed:** We obtained the user access permissions for the CPRIT Grants Management System (CGMS) from CSRA. We evaluated the CGMS user permissions to verify that access to CGMS was restricted to active, appropriate personnel.

   Results: No findings identified.

2. **Procedures Performed:** We obtained the user access permissions for the CohnReznick portal from CohnReznick. We evaluated the CohnReznick portal user permissions to verify that access to the CohnReznick portal was restricted to active, appropriate personnel.

   Results: We identified a former CPRIT employee who continued to have access to the CohnReznick portal after they separated employment from the agency.

   Finding 1 – MODERATE – Separated Employee User Access
   We identified a former CPRIT employee who had access to the CohnReznick portal after they separated employment the agency on September 30, 2017. The CPRIT employee's access was removed on December 19, 2017.

   Recommendation: CPRIT should implement procedures, as part of the employee separations process, to validate that all user accounts have been deactivated, including accounts where third-party vendors administer the user access. The process should include the receipt of positive confirmation from CPRIT IT and third-party vendors that all user IDs have been deactivated, or access has been otherwise removed.

   CPRIT Management Response: CPRIT management agrees that verification of user access to IT systems managed internally and by third-party vendors should be deactivated in a timely manner. CPRIT's Information Technology Governance Committee will ensure that access to the CohnReznick portal and any new third-party system access is addressed in the employee separation process and documentation.

   Responsible Party: Operations Manager, Information Technology Officer, Chief Operating Officer

   Implementation Date: August 31, 2018

Appendix

Cancer Prevention and Research Institute of Texas

IA# 01-18 Internal Audit Report over Post-Award
Grant Contracting and Monitoring
Report Date: December 20, 2017
Issued: February 1, 2018

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

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IA# 01-18 Internal Audit Report over Post-Award
Grant Contracting and Monitoring
Report Date: December 20, 2017
Issued: February 1, 2018

Risk Ratings

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

Cancer Prevention & Research Institute of Texas

IA # 02 -18 Internal Audit Follow-Up Procedures
Report over Internal Agency Compliance
Report Date: January 19, 2018
Issued: February 2, 2018

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

This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period January 8, 2018, through January 19, 2018 relating to the finding from the 2017 Internal Audit Report over Internal Agency Compliance, dated February 24, 2017.

The objective of these follow-up procedures was to validate that adequate corrective action has been taken in order to remediate the issue identified in the 2017 Internal Audit Report over Internal Agency Compliance.

To accomplish this objective, we conducted interviews with key personnel responsible for Internal Agency Compliance. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the Cancer Prevention and Research Institute of Texas office and were completed on January 19, 2018.

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

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
February 2, 2018

Cancer Prevention and Research Institute of Texas

IA # 02 -18 Internal Audit Follow-Up Procedures Report over
Internal Agency Compliance
Report Date: January 19, 2018
Issued: February 2, 2018

Background

In 2017, internal audit procedures over CPRIT's internal agency compliance process were completed and reported to the Oversight Committee. The internal audit report over CPRIT's internal agency compliance procedures and activities identified one area for improvement related to a missing annual Conflict of Interest Form for the PIC Member from the Texas Department of State Health Services.

The 2018 Internal Audit Plan included performing procedures to validate that CPRIT management has taken steps to address the internal audit finding.

Follow-Up Procedures Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the finding included in the 2017 Internal Audit Report over Internal Agency Compliance, and to validate that appropriate corrective action had been taken. The 2017 report identified the following finding:

- The PIC Member from DSHS did not submit the required annual Conflict of Interest Form

Our follow-up procedures included the following:

- Review of the updated checklist for submission of annual conflict of interest statements.
- Examination of the submission of annual Conflict of Interest Forms for fiscal year 2018.

Executive Summary

The finding from the 2017 internal agency compliance internal audit included non-compliance issues with CPRIT policies and procedures, rules and regulations required by law, or where these is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have financial or operational implications.

In the 2017 internal audit, we identified one finding, which was risk rated as **Moderate**.

Through our interviews, review of documentation, observations, and testing, we determined that the 2017 Internal Agency Compliance finding was remediated.

Risk Rating	Finding	Remediated	Partially Remediated	Open
High	-	-	-	-
Moderate	1	1	-	-
Low	-	-	-	-
Total	**1**	**1**	**-**	**-**

Cancer Prevention and Research Institute of Texas

IA # 02 -18 Internal Audit Follow-Up Procedures Report over
Internal Agency Compliance
Report Date: January 19, 2018
Issued: February 2, 2018

A summary of our results, by audit objective, is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings.*

FOLLOW-UP ASSESSMENT	STRONG

SCOPE AREA	RESULT	RATING
Objective: Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2017 Internal Audit Report over Internal Agency Compliance.	We identified that procedures implemented by management adequately addressed and remediated the prior open finding.	STRONG

Conclusion

Based on our evaluation, CPRIT management has made satisfactory effort to remediate the finding from the 2017 internal audit report. We recommend continued diligence in maintaining internal controls over internal agency compliance processes.

Detailed Procedures Performed, Findings, Recommendations and Management Response

Cancer Prevention and Research Institute of Texas

IA # 02 -18 Internal Audit Follow-Up Procedures Report over
Internal Agency Compliance
Report Date: January 19, 2018
Issued: February 2, 2018

Detailed Procedures Performed, Findings, Recommendations and Management Response

Our procedures included interviewing key personnel, examining existing documentation or communication, and performing test procedures to validate corrective actions taken. In addition, we evaluated the existing policies, procedures and processes.

Objective: Validate Remediation

Validate that adequate corrective action has been taken in order to remediate the issue identified in the 2017 Internal Audit Report over Internal Agency Compliance.

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 on an annual basis.

We identified that the PIC member representing 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.

Procedures Performed: We verified that the review checklist for submission of annual conflict of interest statements by Oversight Committee members, PIC members, and CPRIT employees was updated to include the PIC member from DSHS as well as all active Oversight Committee members, PIC members, and CPRIT employees.

We reviewed the submission of annual Conflict of Interest Forms for all Oversight Committee members and PIC members for FY 2018. In addition, we selected a sample of 6 out of 36 employees required to submit FY 2018 Conflict of Interest Forms and verified that the forms were completed timely.

Results: Finding remediated.

Appendix

Cancer Prevention and Research Institute of Texas

IA # 02 -18 Internal Audit Follow-Up Procedures Report over
Internal Agency Compliance
Report Date: January 19, 2018
Issued: February 2, 2018

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

Cancer Prevention and Research Institute of Texas

IA # 02 -18 Internal Audit Follow-Up Procedures Report over
Internal Agency Compliance
Report Date: January 19, 2018
Issued: February 2, 2018

Risk Ratings

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

Cancer Prevention & Research Institute of Texas

IA # 03 -18 Internal Audit Follow-Up Procedures
Report over Training Program
Report Date: January 19, 2018
Issued: February 2, 2018

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The Oversight Committee
Cancer Prevention and Research Institute of Texas
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This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period January 8, 2018, through January 19, 2018 relating to the findings from the 2017 Internal Audit Report over Training Program, dated February 6, 2017.

The objective of these follow-up procedures was to validate that adequate corrective action has been taken in order to remediate the issues identified in the 2017 Internal Audit Report over Training Program.

To accomplish this objective, we conducted interviews with key personnel responsible for the Training Program. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the Cancer Prevention and Research Institute of Texas office and were completed on January 19, 2018.

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

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
February 2, 2018

Cancer Prevention and Research Institute of Texas

IA# 03 -18 Internal Audit Follow-Up Procedures Report over Training Program
Report Date: January 19, 2018
Issued: February 2, 2018

Background

In 2017, internal audit procedures over CPRIT's training program process were completed and reported to the Oversight Committee. The internal audit report over CPRIT's training program procedures and activities identified two areas for improvement related to the timely completion of required Oversight Committee member trainings and the timely completion of employee civil rights trainings.

The 2018 Internal Audit Plan included performing procedures to validate that CPRIT management has taken steps to address the internal audit findings.

Follow-Up Procedures Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the findings included in the 2017 Internal Audit Report over Training Program, and to validate that appropriate corrective action had been taken. The 2017 report identified the following findings:

- CPRIT did not have policies and procedures in place to ensure that required trainings from Oversight Committee members were completed within a 90-day timeframe. Additionally, there was one Oversight Committee member that did not complete the required Public Information Act Training within the 90-day timeframe.
- Three employees did not complete the required update of their Civil Rights Training within the required timeframe.

Our follow-up procedures included the following:

- Interview of key personnel with responsibility for required trainings to identify corrective actions taken to address prior findings
- Review of policies, procedures, and other related documentation
- Ensure that policies and procedures were appropriately implmeneted to address prior findings

Executive Summary

The findings from the 2017 training program internal audit included non-compliance issues with CPRIT policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have financial or operational implications.

In the 2017 internal audit, we identified two finding, which were risk rated as **Moderate**.

Cancer Prevention and Research Institute of Texas

IA# 03 -18 Internal Audit Follow-Up Procedures Report over Training Program
Report Date: January 19, 2018
Issued: February 2, 2018

Through our interviews, review of documentation, observations, and testing, we determined that both of the 2017 training program findings were remediated.

Risk Rating	Finding	Remediated	Partially Remediated	Open
High	-	-	-	-
Moderate	2	2	-	-
Low	-	-	-	-
Total	**2**	**2**	**-**	**-**

We also determined that management has taken appropriate corrective action for the observations that were identified and communicated through the 2017 Internal Audit Over Training Program.

A summary of our results, by audit objective, is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings.*

FOLLOW-UP ASSESSMENT	STRONG

SCOPE AREA	RESULT	RATING
Objective: Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2017 Internal Audit Report over Training Program.	We identified that procedures implemented by management adequately addressed and remediated the prior open findings.	STRONG

Conclusion

Based on our evaluation, CPRIT management has made satisfactory effort to remediate the findings from the 2017 internal audit report. We recommend continued diligence in maintaining internal controls over training program processes.

Detailed Procedures Performed, Findings, Recommendations and Management Response

Cancer Prevention and Research Institute of Texas

IA# 03 -18 Internal Audit Follow-Up Procedures Report over Training Program
Report Date: January 19, 2018
Issued: February 2, 2018

Detailed Procedures Performed, Findings, Recommendations and Management Response

Our procedures included interviewing key personnel, examining existing documentation or communication, and performing test procedures to validate corrective actions taken. In addition, we evaluated the existing policies, procedures and processes.

Objective: Validate Remediation

Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2017 Internal Audit Report Over Training Program.

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.

> **Procedures Performed:** We verified that the policies and procedures related to the completion and documentation of Oversight Committee required trainings, including the Public Information Act, Open Meetings Act, and contract oversight trainings were updated to include the specific timeframe for completion of all required trainings.
>
> We verified that Mahendra Patel and David Cummings completed all required trainings timely.
>
> **Results:** Finding remediated.

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 review period, three did not maintain current Civil Rights Training as required by state law. The three employees' training updates were 3-14 months delinquent. All three have since separated employment from CPRIT.

> **Procedures Performed:** We reviewed the EEO Civil Rights Training Log and verified that the tracking spreadsheet for monitoring of employee civil rights training dates was updated.
>
> We reviewed all civil rights trainings completed between December 1, 2016, through November 30, 2017 and verified that the trainings were completed timely.
>
> **Results:** Finding remediated.

Appendix

Cancer Prevention and Research Institute of Texas

IA # 03 -18 Internal Audit Follow-Up Procedures Report over Training Program
Report Date: January 19, 2018
Issued: February 2, 2018

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

Cancer Prevention and Research Institute of Texas

IA # 03 -18 Internal Audit Follow-Up Procedures Report over Training Program
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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:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 14: FISCAL YEAR 2020-2023 BUDGET SCENARIOS
DATE:	FEBRUARY 14, 2018

Summary

The Oversight Committee identified one scenario at the January 17, 2018, special meeting as the preferred funding projection for the remainder of CPRIT's statutory authority. I discussed this funding scenario with an initial group of legislators familiar with CPRIT, representatives of CPRIT grantees, and cancer advocates. I also discussed the possibility of an estimated $190 million general revenue exceptional item request in fiscal years 2020-21 to maintain current operating levels. I recommend Oversight Committee approval of the preferred funding scenario and the exceptional item request.

Discussion

The Oversight Committee held a special meeting on January 17, 2018, to address two issues—setting program priorities for fiscal year 2019 and CPRIT's fiscal biennium 2020-2021 appropriations request. After discussion of several broad options for awarding the amount remaining between fiscal years 2020 and 2022, the Oversight Committee identified a preferred option. (I have attached summaries of the three main funding options.) The Oversight Committee's preferred option, Scenario 4, allocates equal amounts of funding available for awards in fiscal years 2020 and 2021 and none in 2022, the last year in which CPRIT is authorized to make awards prior to its sunset review in 2023.

The Oversight Committee also indicated interest in making an exceptional item request to offset the declining bond funds available and to sustain current grant award operations through the 2020-21 fiscal biennium. The exceptional item would total about $190 million in general revenue. The Oversight Committee instructed me to discuss these two items with interested parties from the prevention, university, and life science industry communities as well as legislators familiar with CPRIT.

The representatives from the prevention, university, and life science industry communities recognized the benefit in maximizing funds available for the three CPRIT grant programs afforded by Scenario 4. They endorsed this approach, especially in conjunction with the exceptional item request to provide full funding in the 2020-21 fiscal biennium. They report that

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this approach begins the discussion about losing momentum in Texas cancer research and prevention activities if CPRIT ends August 31, 2023.

The legislators and legislative staff also recognized the logic behind Scenario 4. They agree that the exceptional item request will trigger a legislative policy discussion of continuing CPRIT beyond 2023. Due to state fiscal constraints and other funding priorities, they cautioned against expecting the legislature to approve the exceptional item request. However, they all agreed that "you can't get what you don't ask for" and understood that the request allows advocates the opportunity to discuss CPRIT's importance to the state's cancer research, prevention, and life science industry environment.

Based on the information available at this writing, I recommend that the Oversight Committee adopt Scenario 4 for planning purposes and use in drafting the agency's request for legislative appropriations for the fiscal biennium beginning September 1, 2019. I also recommend that the agency request general revenue funding in an amount to continue current operational levels in the 2020-21fiscal biennium, estimated to be $190 million.

Other items yet to be determined related to the agency's appropriations request will be discussed at the May 16, 2018, Oversight Committee meeting.

		Appropriations				Grant Funding									
		G	H		I	J	K	L	M	N	O	P	Q	R	S
	Appropriation Year	Total Budget	Appropriations for Agency Operations and Transfer to DSHS	Agency Operations as Percent of Total Budget	Appropriations Available for Grant Awards	Prevention Grants Announced/ Projected	Percent PREV Awards of Available Award Funding	Academic Research Grants Awarded/ Projected	Percent AR Awards of Available Award Funding	Product Development Research Grants Awarded/ Projected	Percent PDR Awards of Available Award Funding	Total Grant Awards Awarded/ Projected	Total Research Award Funding Only	Percent AR Awards of Available Research Awards	Percent PDR Awards of Available Research Awards
SCENARIO 3: FUND AR RECRUITMENT, PREVENTION DISSEMINATION, AND PD AWARDS IN 2022	2020	$ 192,000,000	$ 20,000,000	9%	$ 172,000,000	$ 17,200,000	10.0%	$ 108,360,000	63.0%	$ 46,440,000	27.0%	$ 172,000,000	$ 154,800,000	70.0%	30.0%
	2021	$ 163,998,229	$ 20,000,000	10%	$ 143,998,229	$ 14,399,823	10.0%	$ 90,718,884	63.0%	$ 38,879,522	27.0%	$ 143,998,229	$ 129,598,406	70.0%	30.0%
	2022*	$ 67,828,279	$ 14,150,000	16%	$ 53,678,279	$ 5,367,828	10.0%	$ 33,817,316	63.0%	$ 14,493,135	27.0%	$ 53,678,279	$ 48,310,451	70.0%	30.0%
	2023**	$ 13,000,000	$ 13,000,000	100%	$ -	$ -		$ -		$ -		$ -	$ -		
		$ 436,826,508				**$ 288,142,586**		**$ 1,929,121,478**		**$ 593,925,646**		**$ 2,811,189,710**	**$ 2,523,047,124**		

* Assumptions: 1) SRC only meets by phone to review recruitment applications during first six months of year then disband as in first scenario; 2) PDRC and one product development review panel have meeting to review product development applications during first half of year along with legal and business management due diligence contracts in place; 3) PRC only meets by phone to review prevention dissemination applications during the first 6 months of year

** Assumptions: Only fund agency operations for necessary post-award grant management, compliance monitoring program, and other required agency functions.

SCENARIO 4: ALLOCATE EQUAL AMOUNTS OF AWARD FUNDING IN 2020-2021	2020	$ 205,413,254	$ 20,000,000	8%	$ 185,413,254	$ 18,541,325	10.0%	$ 116,810,350	63.0%	$ 50,061,579	27.0%	$ 185,413,254	$ 166,871,929	70.0%	30.0%
	2021	$ 205,413,254	$ 20,000,000	8%	$ 185,413,254	$ 18,541,325	10.0%	$ 116,810,350	63.0%	$ 50,061,579	27.0%	$ 185,413,254	$ 166,871,929	70.0%	30.0%
	2022*	$ 13,000,000	$ 13,000,000	100%	$ -	$ -		$ -		$ -		$ -	$ -		
	2023*	$ 13,000,000	$ 13,000,000	100%	$ -	$ -		$ -		$ -		$ -	$ -		
		$ 436,826,508				**$ 288,257,586**		**$ 1,929,845,978**		**$ 594,236,146**		**$ 2,812,339,710**	**$ 2,524,082,124**		

*Assumptions: Only fund agency operations for necessary post-award grant management, compliance monitoring program, and other required agency functions.

SCENARIO 5: ALLOCATE EQUAL AMOUNTS OF GRANT FUNDING IN 2020-2022	2020	$ 141,275,503	$ 20,000,000	12%	$ 121,275,503	$ 12,127,550	10.0%	$ 76,403,567	63.0%	$ 32,744,386	27.0%	$ 121,275,503	$ 109,147,953	70.0%	30.0%
	2021	$ 141,275,503	$ 20,000,000	12%	$ 121,275,503	$ 12,127,550	10.0%	$ 76,403,567	63.0%	$ 32,744,386	27.0%	$ 121,275,503	$ 109,147,953	70.0%	30.0%
	2022	$ 141,275,502	$ 20,000,000	12%	$ 121,275,502	$ 12,127,550	10.0%	$ 76,403,566	63.0%	$ 32,744,386	27.0%	$ 121,275,502	$ 109,147,952	70.0%	30.0%
	2023*	$ 13,000,000	$ 13,000,000	100%	$ -	$ -		$ -		$ -		$ -	$ -		
		$ 436,826,508				**$ 287,557,586**		**$ 1,925,435,978**		**$ 592,346,146**		**$ 2,805,339,710**	**$ 2,517,782,124**		

*Assumptions: Only fund agency operations for necessary post-award grant management, compliance monitoring program, and other required agency functions.

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:	**FEBRUARY 12, 2018**

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule changes to §§ 701.37 and 703.26 as originally considered at the November 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.

The Oversight Committee approved publication of proposed rule amendments §§ 701.37 and 703.26 at the November meeting. CPRIT published the proposed rules in the *Texas Register* and made the rules available on the agency's website. No comments were received.

The Board Governance Subcommittee met on February 8th to review the 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 orders to the Secretary of State. The rule changes become effective 20 days after the date CPRIT files the orders with the Secretary of State.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 701. Policies and Procedures

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the new rule §701.37. The new rule sets travel policy requirements for grant recipients. CPRIT published the proposed new rule in the December 15, 2017, issue of the *Texas Register* (42 TexReg 7090).

Reasoned Justification

The proposed new rule § 701.37 requires grant recipients to follow the requirements of the State of Texas travel policy administered by the Texas Comptroller of Public Accounts in order for travel expenses to be reimbursed with CPRIT grant award funds. The new rule also describes the appropriate documentation that must be submitted to support travel expense reimbursement requests and provides guidance regarding special requirements for international travel expenses to be reimbursed with CPRIT grant funds.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding § 701.37.

The rule change is adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that Kristen Pauling Doyle, General Counsel, reviewed the adoption of the rules and found it to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on February 23, 2018.

Rule § 701.37 Grant Recipient Travel Policy

(a) Travel costs for Grant Recipients are allowable based on the State of Texas travel policy, administered by the Texas Comptroller of Public Accounts, provided that costs are deemed by the Institute to be reasonable and necessary. The Institute will not reimburse a Grant Recipient for travel expenses in an amount that exceeds the standards in the State of Texas travel policy.

(b) Grant Recipients must provide adequate supporting documentation when requesting reimbursement for travel expenses on a Financial Status Report pursuant to §703.24.

(1) A separate travel expense report should be submitted for each trip taken.

(2) Meal costs may be charged on an actual cost basis or on a per diem, provided that one method is used uniformly on an entire trip.

(3) Lodging expenses must be supported with either a receipt or, if a receipt is unavailable, the canceled check or credit card slip used to pay the lodging expense, the credit card billing on which the lodging charges appear, or a copy of the check, slip or billing.

(4) Mileage must be supported with a detailed record of actual point-to-point mileage with odometer readings or copies of mapping website mileage. Mileage should not be rounded to the nearest decimal point.

(5) Transportation expenses must be supported with a receipt or itinerary. If neither is available then a Grant recipient should provide the canceled check or credit card slip used to pay for the transportation, the credit card billing on which the transportation charges appear, or a copy of the receipt, check, slip or billing.

(6) Rental of motor vehicles must be supported by a receipt and/or rental contract.

(7) Incidental expenses must be supported by an itemization of the expenses incurred.

(c) International travel must either be part of the Grant Recipient's approved budget in the Grant Contract, or the Grant Recipient must receive prior approval from CPRIT for the international travel if the international travel is added to the budget subsequently.

(1) International travel costs may be reimbursed according to the United States Department of State rates, if the costs are deemed by CPRIT to be reasonable and necessary.

(2) Grant Recipients should submit requests for reimbursement in United States dollar amounts. If the original cost is in a foreign currency, the Grant Recipient must convert the cost to a dollar amount and provide documentation of the exchange rate used for the conversion.

(d) Nothing herein prohibits a Grant Recipient from having more restrictive internal travel policy requirements.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendment to § 703.26. The proposed change expands the list of unallowable costs to include payments by a grant recipient to a subcontractor that employs a relative of the grant recipient's key personnel working on the same project. CPRIT published the proposed amendment in the December 15, 2017, issue of the *Texas Register* (42 TexReg 7091).

Reasoned Justification

The proposed change to § 703.26(e) prohibits payment by a grant recipient to a subcontractor if the subcontractor employs an individual who is a relative, as defined by Texas Administrative Code § 701.3(57), of key personnel employed by the grant recipient and working on the same grant project. The expense is unallowable if the grant recipient uses grant funds to pay the subcontractor for any portion of the relative's salary or if the relative is responsible for submitting on behalf of the subcontractor expenses for payment by the grant recipient. The grant recipient may request that the Institute's Chief Executive Officer allow an exception to pay a subcontractor that employs a relative. If the Chief Executive Officer grants an exception, he must notify the Oversight Committee in writing. If a grant recipient has stricter internal policies concerning this issue than set forth in the proposed amendment, the rule will not supersede those internal policies. The purpose of this proposed rule change is to reduce potential conflicts of interest between a grant recipient and a subcontractor.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendment to § 703.26.

The rule change is adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that Kristen Pauling Doyle, General Counsel, reviewed the adoption of the rules and found it to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on February 23, 2018.

RULE § 703.26 Allowable Costs

(a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.

(1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.

(2) A cost is allocable if the cost:

(A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;

(B) Is assigned the Grant Award in accordance with the relative benefit received;

(C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;

(D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and

(E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.

(3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with §703.24.

(b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, Texas Health and Safety Code, the Institute's administrative rules, and the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from the Uniform Grant Management Standards on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.

(d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.

(e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:

(1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(2) Contributions to a contingency reserve or any similar provision for unforeseen events.

(3) Contributions and donations made to any individual or organization.

(4) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(5) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(7) An honorary gift or a gratuitous payment.

(8) Interest and other financial costs related to borrowing and the cost of financing.

(9) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(10) Liability insurance coverage.

(11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(12) Professional association fees or dues for the Grant Recipient or an individual.

(13) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(14) Fees for visa services.

(15) Payments to a subcontractor if the subcontractor working on a Grant Award project employs an individual who is a Relative of the Principal Investigator, Program Director, Company Representative, Authorized Signing Official, or any person designated as Key Personnel for the same Grant Award project (collectively referred to as “affected Relative”), and:

(A) the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative’s salary; or

(B) the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.

(C) For exceptional circumstances, the Institute’s Chief Executive Office may grant an exception to allow payment of Grant Award funds if the Grant Recipient notifies the Institute prior to finalizing the subcontract. The Chief Executive Officer must notify the

Oversight Committee in writing of the decision to allow reimbursement for the otherwise unallowable expense.

(D) Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.

(f) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To: **OVERSIGHT COMMITTEE MEMBERS**

From: **KRISTEN PAULING DOYLE, GENERAL COUNSEL**
CAMERON L. ECKEL, STAFF ATTORNEY

Subject: **CHAPTER 703 PROPOSED RULE CHANGES**

Date: **FEBRUARY 12, 2018**

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee approve the proposed administrative rule changes for publication in the *Texas Register* for public comment. The proposed changes affect Texas Administrative Code Chapter 703.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes. State law requires agencies to use a rulemaking process, which includes an opportunity for the public to comment on proposed rules and rule changes before the agency adopts the final policy.

The Board Governance subcommittee met on February 8th to discuss the proposed rule changes with legal staff. The proposed amendments to §§ 703.13 and 703.21 change the due date of the single audit determination form to 60 days after a grant recipient's fiscal year end, rather than the anniversary of the grant contract effective date. This change addresses an administrative issue that inadvertently caused some grant recipients' single audit determination forms to be due before the end of their fiscal year. The subcommittee voted to recommend approval and publication of the proposed rule changes to the Oversight Committee.

Next Steps

CPRIT will publish the proposed rule changes in the *Texas Register*. The publication date begins the 30-day period soliciting public comment. CPRIT will post the proposed rule on CPRIT's website and announce the opportunity for public comment via the CPRIT electronic list serve. CPRIT legal staff will summarize all public comments for the Oversight Committee's consideration when approving the final rule changes in May.

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 §§ 703.13(b) and 703.21(b)(2)(B). The proposed amendments change the due date of the single audit determination form, which Grant Recipients are required to submit to the Institute annually.

Background and Justification

The proposed amendment to § 703.13(b) changes the due date of the single audit determination form to 60 days after the close of the Grant Recipient's fiscal year. CPRIT requires every grant recipient to submit the single audit determination form reporting whether the grant recipient has expended $750,000 or more in state award funds. The amount of grant funds expended determines if the Grant Recipient must submit an audit. Changing the due date removes confusion regarding when single audit determination forms should be submitted and provides for a more streamlined submission process. The proposed change to § 703.21(b)(2)(B) ensures that the due date of the single audit determination form is consistently referenced within Chapter 703.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule change is in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule change is in effect the public benefit anticipated due to enforcing the rule will be the clarification of the single audit determination form due date.

Small Business and Micro-Business Impact Analysis

Ms. Doyle has determined that the rule change will not affect small businesses or micro businesses.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the section will be in effect:

(1) the proposed rule changes will not create or eliminate a government program;

(2) implementation of the proposed rule changes will not affect the number of employee positions;

(3) implementation of the proposed rule changes will not require an increase or decrease in future legislative appropriations;

(4) the proposed rule changes will not affect fees paid to the agency;

(5) the proposed rule changes will not create new rules;

(6) the proposed rule changes will expand existing rules;

(7) the proposed rule changes will not change the number of individuals subject to the rules; and

(8) The rule changes are unlikely to have a significant impact on the state's economy. Although these changes are likely to have neutral impact on the state's economy, the Institute lacks sufficient data to predict the impact with certainty.

Submit written comments on the proposed rule changes to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than April 9, 2018. The Institute asks parties filing comments to indicate whether they support the rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.texas.gov. Comments may be submitted by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes the rule changes under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter. Kristen Pauling Doyle, the Institute's General Counsel, has reviewed the proposed amendments, and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article, or code affected by these rules.

§ 703.13 Audits and Investigations

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(1) A Grant Recipient shall maintain its records pertaining to the specific Grant Contract for a period of three years following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(2) The Grant Recipient may maintain its records in either electronic or paper format.

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. [~~within 60 days of the anniversary date of the Grant Contract effective date~~]. The Grant Recipient shall report whether the Grant Recipient has expended $750,000 or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended $750,000 or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e).

(1) The audited time period is the Grant Recipient's fiscal year.

(2) The audit must be submitted to the Institute within 30 days of receipt by the Grant Recipient but no later than 270 days following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than the 270th day following the close of the Grant Recipient's fiscal year.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

(e) For purposes of this rule, an agreed upon procedures engagement is one in which an independent certified public accountant is hired by the Grant Recipient to issue a report of findings based on specific procedures to be performed on a subject matter.

(1) The option to perform an agreed upon procedures engagement is intended for a non-profit or for-profit Grant Recipient that is not subject to Generally Accepted Government Audit Standards (also known as the Yellow Book) published by the U.S. Government Accountability Office.

(2) The agreed upon procedures engagement will be conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants.

(3) The certified public accountant is to perform procedures prescribed by the Institute and to report his or her findings attesting to whether the Grant Recipient records is in agreement with stated criteria.

(4) The agreed upon procedures apply to all current year expenditures for Grant Awards received by the Grant Recipient. Nothing herein prohibits the use of a statistical sample consistent with the American Institute of Certified Public Accountants' guidance regarding government auditing standards and 2 CFR Part 200, Subpart F, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

(5) At a minimum, the agreed upon procedures report should address:

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

(E) Grant Award expenditures (payroll and non-payroll related transactions);

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

(6) The certified public accountant should consider the specific Grant Mechanism and update or modify the procedures accordingly to meet the requirements of each Grant Award and the Grant Contract reviewed.

§ 703.21 Monitoring Grant Award Performance and Expenditures

(a) The Institute, under the direction of the Chief Compliance Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and exercise proper stewardship over Grant Award funds.

Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.

(b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:

(1) Financial Status Reports Review - The Institute shall review Grant Award expenditures reported by Grant Recipients on the quarterly Financial Status Reports and supporting documents to determine whether expenses charged to the Grant Award are:

(A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(2) Timely submission of Grant Award Reports - The Institute shall monitor the submission of all required reports and implement a process to ensure that Grant Award funds are not disbursed to a Grant Recipient with one or more delinquent reports.

(3) Grant Progress Reports - The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the scope of work and timeline set forth in the Grant Contract.

(A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

(B) Unless specifically stated otherwise herein, the annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:

(i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;

(ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;

(iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;

(iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;

(v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;

(vi) A Historically Underutilized Businesses report;

(vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;

(viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;

(ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;

(x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report, which shall be submitted pursuant to the timeline in §703.11. In order to receive disbursement of grant funds, the most recently due verification of the amount of Matching Funds must be approved by CPRIT;

(xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and

(xii) A single audit determination form, which shall be submitted pursuant to the timeline in § 703.13.

(C) Notwithstanding subparagraph (B) of this paragraph, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding reports. The approval shall be in writing and maintained in the Institute's electronic Grants Management System. The Chief Program Officer's approval may cover more than one report and more than one fiscal quarter.

(D) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

(E) The Grant Progress Report will be evaluated pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff. In order to receive disbursement of grant funds, the final progress report must be approved by CPRIT.

(F) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts).

(G) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.

(H) In order to receive disbursement of grant funds, the most recently due progress report must be approved by CPRIT.

(I) If a Grant Recipient fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Award funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is approved.

(J) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific tranches of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a tranche of funding shall be known as "Tranche Grant Progress Report."

(i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.

(ii) Grant Funds for the next tranche of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.

(4) Desk Reviews - The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

(5) Site Visits and Inspection Reviews - The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.

(6) Audit Reports - The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).

(A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.

(B) The written plan shall be retained by the Institute as part of the Grant Contract record.

(c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.

(d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.

(1) To the extent that the methods described in subsection (b) of this section are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.

(2) Records will be maintained in the electronic Grant Management System as described in §703.4 of this chapter (relating to Grants Management System).

(e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.

(f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.

(g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER**
Subject:	**CHIEF OPERATING OFFICER REPORT**
Date:	**JANUARY 9, 2018**

CPRIT Financial Overview for FY 2018, Quarter 1

FY 2018, Quarter 1 Operating Budget

CPRIT's 2018 budget for operating costs in the Indirect Administration and Grant Review and Award Operations line items is $1,009,583 higher than appropriations because the agency carried forward $731,882 in general obligation bond proceeds from FY 2017 to FY 2018 for IT software, hardware, and support services acquisitions and for seven service contracts that the agency extended with no additional cost. This amount also includes $276,075 in conference fee revenue for CPRIT's 2017 conference held in November 2017. The agency expended or obligated approximately $1.5 million, or 46%, in Indirect Administration and approximately $3.9 million, or 73%, in Grant Review and Award Operations, which is about 92% of the overall administrative budget for the fiscal year.

During the first quarter, the agency received $44,197 in revenue sharing payments.

FY 2018, Quarter 1 Performance Measure Report

CPRIT reported on its two key quarterly performance measures to the Legislative Budget Board. The agency exceeded performance on the prevention measure of number of people served. However, it did not meet performance on the product development measure for company relocations to Texas because no company grant recipients relocated to Texas during the quarter.

Debt Issuance History

In September 2017, the Texas Public Finance Authority issued $68.2 million in general obligation bonds on CPRIT's behalf. This was the total amount of funding that CPRIT required for operating expenses and grant award obligations for the year.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of November 30, 2017

Indirect Administration (B.1.1.)

		2018 Appropriated	2018 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,617,425	$ 1,586,372		$ 300,050	1,286,322	19%	$ 300,050	$ 1,286,322
1002	Other Personnel Costs	52,785	38,785		4,303	34,482	11%	4,303	34,482
2001	Professional Fees and Services	826,175	940,382		818,221	122,161	87%	818,221	122,161
2003	Consumable Supplies	27,584	27,584		3,728	23,856	14%	3,728	23,856
2004	Utilities	58,577	58,577		33,321	25,256	57%	33,321	25,256
2005	Travel	45,000	45,000		17,176	27,824	38%	17,176	27,824
2006	Rent-Building	-	18,408		9,622	8,786	0%	9,622	8,786
2007	Rent-Machine and Other	32,172	32,172		5,089	27,083	16%	5,089	27,083
2009	Other Operating Expenses	370,934	420,730		270,183	150,548	64%	270,183	150,548
	Subtotal - Indirect Administration (B.1.1.)	**$ 3,030,652**	**$ 3,168,010**	**1.06%**	**$ 1,461,692**	**$ 1,706,319**	**46%**	**$ 1,461,692**	**$ 1,706,319**

Grant Review and Award Operations (A.1.3.)

		2018 Appropriated	2018 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 2,991,208	2,949,626		$ 794,066	$ 2,155,560	27%	$ 794,066	$ 2,155,560
1002	Other Personnel Costs	3,856	3,856		20,610	(16,754)	0%	20,610	(16,754)
2001	Professional Fees and Services	10,443,893	11,138,507		9,639,917	1,498,590	87%	9,639,917	1,498,590
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	1,628	1,628		303	1,325	19%	303	1,325
2005	Travel	87,500	87,500		7,640	79,860	9%	7,640	79,860
2009	Other Operating Expenses	218,997	162,114		14,865	147,249	9%	14,865	147,249
	Conference		276,074		194,341	81,734	70%	194,341	81,734
	Subtotal - Grant Operations (A.1.3.)	**$ 13,747,082**	**$ 14,619,306**	**4.90%**	**$ 10,671,742**	**$ 3,947,564**	**73%**	**$ 10,671,742**	**$ 3,947,564**

Grants

		2018 Appropriated	2018 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,037,956	$ 28,037,956		$ -	$ 28,037,956	0%	$ -	$ 28,037,956
4000	Grants - Research (A.1.1.)	255,239,310	$ 252,269,756		-	$ 252,269,756	0%	-	252,269,756
	Subtotal - Grants	**$ 283,277,266**	**$ 280,307,712**	**94.03%**	**$ -**	**$ 280,307,712**	**0%**	**$ -**	**$ 280,307,712**
	Grand Totals	**$ 300,055,000**	**$ 298,095,028**	**100.00%**	**$ 12,133,434**	**$ 285,961,594**	**4%**	**$ 12,133,434**	**$ 285,961,594**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of November 30, 2017

	11/01/2017-11/30/2017	AY 18 Year to Date as of 11/30/2017
Beginning Balance : 11/01/2017		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 11/30/2017		**$ 600,506.00**

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds ($303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of November 30, 2017

	11/01/2017-11/30/2017	AY 18 Year to Date as of 11/30/2017
Beginning Balance : 11/01/2017		**$ -**
Increases:		
(1) License Plate Revenue Received	$ 786.47	$ 2,482.29
Total Increases	**$ 786.47**	**$ 2,482.29**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	-	-
Total Reductions	**$ -**	**$ -**
Ending Balance, 11/30/2017		**$ 2,482.29**

Note:

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of November 30, 2017

		11/01/2017-11/30/2017	AY 18 Year to Date as of 11/30/2017
Beginning Balance : 11/01/2017			**$ 146,495.68**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ 5,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ 46,467.96	$ 212,542.96
(4)	Conference Registration Fees-Credit Card	$ 1,184.37	$ 5,452.71
Total Increases		**$ 47,652.33**	**$ 222,995.67**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ (1,226.50)	$ (5,452.71)
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ (1,226.50)**	**$ (5,452.71)**
Ending Balance, 11/30/2017			**$ 364,038.64**

Begin balance is $68,000.00 for application fees and $78,560.19
($583.57 CC fees + $57,495.62 + 20,416.49 registration + $64.51 interest) for conference fees

Cancer Prevention and Research Institute of Texas

Interest & Sinking Fund Account - 5168

As of November 30, 2017

		11/01/2017-11/30/2017	AY 18 Year to Date as of 11/30/2017
Beginning Balance : 11/01/2017			**$ 38,695.04**
Increases:			
(1)	Revenue Sharing / Royalties	$ 7,616.03	$ 44,329.52
			\
Total Increases		**$ 7,616.03**	**$ 83,024.56**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance, 11/30/2017			**$ 83,024.56**

Note: Beginning Balance $38,695.04

Cancer Prevention and Research Institute of Texas
FY 2018, 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	500,000	282,167				282,167	56.43%
Number of Entities Relocating to TX for Cancer Research Related Projects	2	0				0	0.00%
Annual Age-adjusted Cancer Mortality Rate	156.8	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT-Funded Research Projects	900	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	1,325	N/A	N/A	N/A	N/A		0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT grantees deliver these education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter.
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.

	Issuance Amounts		Cash Balance Sept 2016	Total Available Cash Balance After Issuance (estimated)
FY 11 Prevention	$ -		$ -	$ -
FY 11 Research	$ -		$ -	$ -
FY 11 Subtotal		**$ -**		
FY 12 Prevention	$ -		$ -	$ -
FY 12 Research	$ 7,770,008		$ -	$ 7,770,008
FY 12 Subtotal		**$ 7,770,008**		
FY 13 Prevention	$ -		$ -	$ -
FY 13 Research	$ 3,952,830		$ -	$ 3,952,830
FY 13 Subtotal		**$ 3,952,830**		
FY 14 Prevention	$ 2,721,020		$ -	$ 2,721,020
FY 14 Research	$ 9,205,146		$ -	$ 9,205,146
FY 14 Subtotal		**$ 11,926,166**	$ -	
FY 15 Prevention	$ 2,906,673		$ -	$ 2,906,673
FY 15 Research	$ 12,472,474		$ -	$ 12,472,474
FY 15 Subtotal		**$ 15,379,147**		
FY 16 Prevention	$ 3,533,914		$ -	$ 3,533,914
FY 16 Research	$ 5,532,719		$ -	$ 5,532,719
FY 16 Subtotal		**$ 9,066,633**		**$ 9,066,633**
FY 17 Indirect Administration	$ 1,515,326		$ -	$ 1,515,326
FY17 Grant Review and Award Ops	$ 6,905,113		$ -	$ 6,905,113
FY 17 Transfer to DSHS	$ 1,484,777		$ -	$ 1,484,777
FY 17 Prevention	$ -		$ -	$ -
FY 17 Research	$ -		$ -	$ -
FY 17 Subtotal		**$ 9,905,216**		**$ 67,066,633**
Total	**$ 58,000,000**	**$ 58,000,000**		

Total Prevention	$ 9,161,607
Total Research	$ 38,933,177
Total Administration	$ 8,420,439
Required Transfer	$ 1,484,777
TOTAL	$ 58,000,000

		Issuance Amounts		Cash Balance Sept 2016	Total Available Cash Balance After Issuance (estimated)
FY 11 Prevention		$ -		$ -	$ -
FY 11 Research		$ -		$ -	$ -
	FY 11 Subtotal		**$ -**		
FY 12 Prevention		$ -		$ -	$ -
FY 12 Research		$ 7,770,008		$ -	$ 7,770,008
	FY 12 Subtotal		**$ 7,770,008**		
FY 13 Prevention		$ -		$ -	$ -
FY 13 Research		$ 3,952,830		$ -	$ 3,952,830
	FY 13 Subtotal		**$ 3,952,830**		
FY 14 Prevention		$ 2,721,020		$ -	$ 2,721,020
FY 14 Research		$ 9,205,146		$ -	$ 9,205,146
	FY 14 Subtotal		**$ 11,926,166**	$ -	
FY 15 Prevention		$ 2,906,672		$ -	$ 2,906,672
FY 15 Research		$ 12,472,475		$ -	$ 12,472,475
	FY 15 Subtotal		**$ 15,379,147**		
FY 16 Prevention		$ 3,533,914		$ -	$ 3,533,914
FY 16 Research		$ 5,532,719		$ -	$ 5,532,719
	FY 16 Subtotal		**$ 9,066,633**		**$ 9,066,633**
FY 17 Indirect Administration		$ 1,515,326		$ -	$ 1,515,326
FY17 Grant Review and Award Ops		$ 6,905,113		$ -	$ 6,905,113
FY 17 Transfer to DSHS		$ 1,484,777		$ -	$ 1,484,777
FY 17 Prevention		$ -		$ -	$ -
FY 17 Research		$ -		$ -	$ -
	FY 17 Subtotal		**$ 9,905,216**		**$ 67,066,633**
Total		**$ 58,000,000**	**$ 48,933,367**		

Total Prevention	$ 5,627,692
Total Research	$ 33,400,459
Total Administration	$ 8,420,439
Required Transfer	$ 1,484,777
TOTAL	$ 48,933,367

	Issuance Amounts		Cash Balance March 2016	Total Available Cash Balance After Issuance (estimated)
FY 11 Prevention	$ -		$ -	$ -
FY 11 Research	$ 9,794,848		$ 3,142,506	$ 12,937,354
FY 11 Subtotal		**$ 9,794,848**		
FY 12 Prevention	$ -		$ 6,695,630	$ 6,695,630
FY 12 Research	$ 13,712,651		$ 25,064,488	$ 38,777,139
FY 12 Subtotal		**$ 13,712,651**		
FY 13 Prevention	$ -		$ 8,564,338	$ 8,564,338
FY 13 Research	$ 3,772,344		$ 12,497,997	$ 16,270,341
FY 13 Subtotal		**$ 3,772,344**		
FY 14 Prevention	$ 2,721,020		$ 1,419,008	$ 4,140,028
FY 14 Research	$ 33,697,192		$ (19,348,710)	$ 14,348,482
FY 14 Subtotal		**$ 36,418,212**		
FY 15 Prevention	$ 2,906,673		$ 9,756,202	$ 12,662,875
FY 15 Research	$ 13,093,226		$ 600,620	$ 13,693,846
FY 15 Subtotal		**$ 15,999,899**		
FY 16 Indirect Administration	$ 1,511,890		$ -	$ 1,511,890
FY16 Grant Review and Award Ops	$ 8,230,615		$ -	$ 8,230,615
FY 16 Transfer to DSHS	$ 1,484,777		$ -	$ 1,484,777
FY 16 Prevention	$ 1,174,764		$ -	$ 1,174,764
FY 16 Research	$ -		$ -	$ -
FY 16 Subtotal		**$ 12,402,046**		**$ 140,492,079**
Total	**$ 92,100,000**	**$ 92,100,000**		

Total Prevention	$ 6,802,457
Total Research	$ 74,070,261
Total Administration	$ 9,742,505
Required Transfer	$ 1,484,777
TOTAL	$ 92,100,000

		Partial GO Issuance Held to December	Original December GO Issuance	Total Q2 Disbursement Based on GO Issuance	Est. Available Balance
FY 11 Prevention		0	$ -	$ -	$ -
FY 11 Research		0	$ 9,794,848	$ 9,794,848	$ 19,589,696
	FY 11 Subtotal	**$ -**	**$ 9,794,848**	**$ 9,794,848**	
FY 12 Prevention		$ 2,946,847	$ -	$ 2,946,847	$ 2,946,847
FY 12 Research		$ 13,653,153	$ 15,712,651	$ 29,365,804	$ 31,425,302
	FY 12 Subtotal	**$ 16,600,000**	**$ 15,712,651**	**$ 32,312,651**	
FY 13 Prevention			$ -	$ -	$ 1,697,080
FY 13 Research			$ 5,456,683	$ 5,456,683	$ 11,583,046
	FY 13 Subtotal	**$ -**	**$ 5,456,683**	**$ 5,456,683**	
FY 14 Prevention			$ 2,721,019	$ 2,721,019	$ 5,442,038
FY 14 Research			$ 9,405,635	$ 9,405,635	$ 23,470,418
	FY 14 Subtotal	**$ -**	**$ 12,126,654**	**$ 12,126,654**	
FY 15 Prevention			$ 2,906,673	$ 2,906,673	$ 6,532,494
FY 15 Research			$ 7,202,491	$ 7,202,491	$ 13,399,207
	FY 15 Subtotal	**$ -**	**$ 10,109,164**	**$ 10,109,164**	
FY 16 Indirect Administration		$ -	$ -	$ -	$ 1,491,243
FY16 Grant Review and Award Ops		$ -	$ -	$ -	$ 6,137,852
FY 16 Transfer to DSHS		$ -	$ -	$ -	$ 1,484,777
FY 16 Prevention		$ -	$ -	$ -	$ -
FY 16 Research		$ -	$ -	$ -	$ -
	FY 16 Subtotal	**$ -**	**$ -**	$ -	$ 125,200,000
Total		**$ 16,600,000**	**$ 53,200,000**	**$ 69,800,000**	

Total Prevention	$	8,574,539
Total Research	$	61,225,461
Total Administration	$	-
Required Transfer	$	-
TOTAL	$	69,800,000

September 2015 Issuance Request Detail (Split Original Projection based on Available Liquidity up to $300 million)

	Issuance Amounts		September CP Issuance	December GO Issuance	Est. Available Balance
FY 11 Prevention	$ -		$ -		$ -
FY 11 Research	$ 9,794,848		$ 9,794,848		$ 9,794,848
FY 11 Subtotal		**$ 9,794,848**	**$ 9,794,848**	**$ -**	
FY 12 Prevention	$ 2,946,847		$ -	$ 2,946,847	$ 2,946,847
FY 12 Research	$ 15,712,651		$ 2,059,498	$ 13,653,153	$ 15,712,651
FY 12 Subtotal		**$ 18,659,498**	**$ 2,059,498**	**$ 16,600,000**	
FY 13 Prevention	$ 1,697,080		$ 1,697,080		$ 1,697,080
FY 13 Research	$ 6,126,363		$ 6,126,363		$ 6,126,363
FY 13 Subtotal		**$ 7,823,443**	**$ 7,823,443**	**$ -**	
FY 14 Prevention	$ 2,721,019		$ 2,721,019		$ 2,721,019
FY 14 Research	$ 14,064,783		$ 14,064,783		$ 14,064,783
FY 14 Subtotal		**$ 16,785,802**	**$ 16,785,802**	**$ -**	
FY 15 Prevention	$ 3,625,821		$ 3,625,821		$ 3,625,821
FY 15 Research	$ 6,196,716		$ 6,196,716		$ 6,196,716
FY 15 Subtotal		**$ 9,822,537**	**$ 9,822,537**	**$ -**	
FY 16 Indirect Administration	$ 1,491,243		$ 1,491,243		$ 1,491,243
FY16 Grant Review and Award Ops	$ 6,137,852		$ 6,137,852		$ 6,137,852
FY 16 Transfer to DSHS	$ 1,484,777		$ 1,484,777		$ 1,484,777
FY 16 Prevention	$ -		$ -		$ -
FY 16 Research	$ -		$ -		$ -
FY 16 Subtotal		**$ 9,113,872**	**$ 9,113,872**	**$ -**	$ 72,000,000
Total	**$ 72,000,000**	**$ 72,000,000**	**$ 55,400,000**	**$ 16,600,000**	

Total Prevention	$ 10,990,767		$ 8,043,920	$ 2,946,847
Total Research	$ 51,895,361		$ 38,242,208	$ 13,653,153
Total Administration	$ 7,629,095		$ 7,629,095	$ -
Required Transfer	$ 1,484,777		$ 1,484,777	$ -
TOTAL	$ 72,000,000		$ 55,400,000	$ 16,600,000

June 2015 Issuance Request Detail

		Issuance Amounts		Cash Balance March 2015	Est. Available Balance
FY 11 Prevention		$ -		$ -	$ -
FY 11 Research		$ 9,794,848		$ -	$ 9,794,848
	FY 11 Subtotal		**$ 9,794,848**		
FY12 Prevention		$ 2,946,847		$ -	$ 2,946,847
FY 12 Research		$ 15,712,651		$ -	$ 15,712,651
	FY 12 Subtotal		**$ 18,659,498**		
FY 13 Prevention		$ 1,697,082		$ -	$ 1,697,082
FY 13 Research		$ 6,322,150		$ -	$ 6,322,150
	FY 13 Subtotal		**$ 8,019,232**		
FY 14 Prevention		$ 2,721,020		$ -	$ 2,721,020
FY 14 Research		$ 27,733,686		$ -	$ 27,733,686
	FY 14 Subtotal		**$ 30,454,706**		
FY 15 Indirect Administration		$ -		$ -	$ -
FY15 Grant Review and Award Ops		$ 39,627		$ -	$ 39,627
FY 15 Transfer to DSHS		$ -		$ -	$ -
FY 15 Prevention		$ 1,875,000		$ -	$ 1,875,000
FY 15 Research		$ 6,157,089		$ -	$ 6,157,089
	FY 15 Subtotal		**$ 8,071,716**		
Total		**$ 75,000,000**	**$ 75,000,000**		

Total Prevention	$ 9,239,949
Total Research	$ 65,720,424
Total Administration	$ 39,627
Required Transfer	$ -
TOTAL	$ 75,000,000

April 2015 Issuance Request Detail

	Issuance Amounts		Cash Balance March 2015	Est. Available Balance
FY 11 Prevention	$ -		$ -	$ -
FY 11 Research	$ 21,169,169		$ -	$ 21,169,169
FY 11 Subtotal		**$ 21,169,169**		
FY12 Prevention	$ 5,893,694		$ -	$ 5,893,694
FY 12 Research	$ 31,052,500		$ -	$ 31,052,500
FY 12 Subtotal		**$ 36,946,194**		
FY 13 Prevention	$ 3,394,167		$ -	$ 3,394,167
FY 13 Research	$ 12,502,568		$ -	$ 12,502,568
FY 13 Subtotal		**$ 15,896,735**		
FY 14 Prevention	$ 5,442,039		$ -	$ 5,442,039
FY 14 Research	$ 18,796,233		$ -	$ 18,796,233
FY 14 Subtotal		**$ 24,238,272**		
FY 15 Indirect Administration	$ 1,860,426		$ -	$ 1,860,426
FY15 Grant Review and Award Ops	$ 8,007,231		$ -	$ 8,007,231
FY 15 Transfer to DSHS	$ 1,484,777		$ -	$ 1,484,777
FY 15 Prevention	$ 1,875,000		$ -	$ 1,875,000
FY 15 Research	$ 522,196		$ -	$ 522,196
FY 15 Subtotal		**$ 13,749,630**		
Total	**$ 98,250,370**	**$ 112,000,000**		

Total Prevention	$ 16,604,900
Total Research	$ 84,042,666
Total Administration	$ 9,867,657
Required Transfer	$ 1,484,777
TOTAL	$ 112,000,000

October 2014 Issuance Request Detail

	Issuance Amounts		Cash Balance Sept 2014	Est. Available Balance
FY 11 Prevention	$ 584,647		$ 4,107,398	$ 4,692,045
FY 11 Research	$ 11,374,322		$ (3,579,669)	$ 7,794,653
FY 11 Subtotal		**$ 11,958,969**		
FY12 Prevention	$ 2,946,847		$ 3,276,662	$ 6,223,509
FY 12 Research	$ 18,461,528		$ 1,507,227	$ 19,968,755
FY 12 Subtotal		**$ 21,408,375**		
FY 13 Prevention	$ 1,697,082		$ 1,697,082	$ 3,394,164
FY 13 Research	$ 6,100,505		$ 5,966,538	$ 12,067,043
FY 13 Subtotal		**$ 7,797,587**		
FY 14 Prevention	$ 2,721,020		$ 897,953	$ 3,618,973
FY 14 Research	$ 4,619,128		$ -	$ 4,619,128
FY 14 Subtotal		**$ 7,340,148**		
FY 15 Indirect Administration	$ 1,504,985		$ -	$ 1,504,985
FY15 Grant Review and Award Ops	$ 6,105,159		$ -	$ 6,105,159
FY 15 Transfer to DSHS	$ 1,484,777		$ -	$ 1,484,777
FY 15 Prevention	$ -		$ -	$ -
FY 15 Research	$ -		$ -	$ -
FY 15 Subtotal		**$ 9,094,921**		
Total	**$ 48,505,079**	**$ 57,600,000**		

Total Prevention	$ 7,949,596
Total Research	$ 40,555,483
Total Administration	$ 7,610,144
Required Transfer	$ 1,484,777
TOTAL	$ 56,115,223

October 2014 Issuance Request Detail					
	Issuance Amounts		Cash Balance May 2014	Est. Available Balance	
FY 11 Prevention	$ 1,339,619		$ 4,107,398	$ 5,447,017	
FY 11 Research	$ 11,374,322		$ (3,579,669)	$ 7,794,653	
FY 11 Subtotal		**$ 12,713,941**			
FY12 Prevention	$ 2,946,847		$ 3,276,662	$ 6,223,509	
FY 12 Research	$ 18,924,311		$ 1,507,227	$ 20,431,538	
FY 12 Subtotal		**$ 21,871,158**			
FY 13 Prevention	$ 1,697,082		$ 1,697,082	$ 3,394,164	
FY 13 Research	$ 6,068,404		$ 5,966,538	$ 12,034,942	
FY 13 Subtotal		**$ 7,765,486**			
FY 14 Indirect Administration	$ 825,075		$ 1,785,549	$ 2,610,624	
FY14 Grant Review and Award Ops	$ 2,019,129		$ 7,251,229	$ 9,270,358	
FY 14 Prevention	$ 898,185		$ 897,953	$ 1,796,138	
FY 14 Research	$ 14,207,026		$ -	$ 14,207,026	
FY 14 Subtotal		**$ 17,949,415**			
Total	**$ 60,300,000**	**$ 60,300,000**			

Total Prevention	$ 6,881,733
Total Research	$ 50,574,063
Total Administration	$ 825,075
TOTAL	$ 58,280,871

March 2014 Issuance Request Detail

		Issuance Amounts		Cash Balance (Jan. 2014)	Est. Available Balance
FY 11 Prevention		$ 1,385,418		$ 4,107,398	$ 5,492,816
FY 11 Research		$ 11,375,827		$ (3,579,669)	$ 7,796,158
	FY 11 Subtotal		**$ 12,761,245**		
FY12 Prevention		$ 2,946,847		$ 3,276,662	$ 6,223,509
FY 12 Research		$ 13,828,775		$ 1,507,227	$ 15,336,002
	FY 12 Subtotal		**$ 16,775,622**		
FY 13 Prevention		$ 1,697,082		$ 1,697,082	$ 3,394,164
FY 13 Research		$ 6,119,634		$ 5,966,538	$ 12,086,172
	FY 13 Subtotal		**$ 7,816,716**		
FY 14 Administration		$ 8,748,464		$ 4,223,744	$ 12,972,208
FY 14 Prevention		$ 897,953		$ -	$ 897,953
FY 14 Research		$ -		$ -	$ -
	FY 14 Subtotal		**$ 9,646,417**		
Total		**$ 47,000,000**	**$ 47,000,000**		

Total Prevention	$ 6,927,300
Total Research	$ 31,324,236
Total Administration	$ 8,748,464
TOTAL	$ 47,000,000

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN DOYLE, DEPUTY EXECUTIVE OFFICER AND GENERAL COUNSEL

SUBJECT: SPECIAL ISSUES SUBCOMMITTEE CHARTER AND CHANGES TO THE BOARD GOVERNANCE SUBCOMMITTEE CHARTER

DATE: FEBRUARY 14, 2018

At the January Oversight Committee meeting, members discussed the need for a new Oversight Committee subcommittee to address special issues as they arise, including legislative matters. The proposed Special Issues Subcommittee charter summarizes the new subcommittee's assigned duties.

The Board Governance Subcommittee is currently responsible for reviewing legislation affecting CPRIT. If the Oversight Committee approves establishing the Special Issues Subcommittee and its proposed charter, the Board Governance Subcommittee charter should be revised to avoid overlapping duties.

The Board Governance Subcommittee is responsible for reviewing and recommending proposed changes to Oversight Committee organizational documents. The subcommittee reviewed the proposed Special Issues Subcommittee charter and the changes to the Board Governance Subcommittee charter and recommends the Oversight Committee approve these documents.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

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

BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas ("CPRIT" or "Institute") established a Special Issues Subcommittee (the "Subcommittee") on February 21, 2018. This Charter, adopted by the Oversight Committee of the Cancer Prevention and Research Institute of Texas ("Oversight Committee") on February 21, 2018, supersedes any other documents relating to the Special Issues Subcommittee.

PURPOSE

The primary purpose of the Subcommittee is to advise the Oversight Committee on special issues, including planning for CPRIT's sunset review and associated legislative issues.

COMPOSITION

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

MEETINGS AND QUORUM

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

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

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

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

DUTIES AND RESPONSIBILITIES

The Subcommittee has the following duties and responsibilities:

- Assist the Oversight Committee and CPRIT staff regarding legislative matters, including providing timely feedback on potential and pending legislation;
- Advise the Chief Executive Officer and CPRIT staff, as requested, on potential governmental affairs issues;
- Provide recommendations to the Oversight Committee on proposed legislative filings, including CPRIT's Legislative Appropriations Request and State Strategic Plan; and
- Address any other special topics as the Oversight Committee Presiding Officer may assign to the Subcommittee.

OTHER DUTIES

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

In addition to its duties and responsibilities, the Oversight Committee Chair may delegate to the Subcommittee and the Subcommittee shall perform such additional special functions, duties, or responsibilities related thereto.

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

BACKGROUND

The Oversight Committee of the Cancer Prevention and Research Institute of Texas ("CPRIT" or "Institute") established a Board Governance and Ethics Subcommittee (the "Subcommittee") on September 5, 2012. This Charter, adopted by the Oversight Committee on November 22, 2013, supersedes any other documents relating to the Board Governance and Ethics Subcommittee.

PURPOSE

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

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

COMPOSITION

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

Board Governance Subcommittee. The Oversight Committee may replace any member of the Subcommittee by a majority vote of the Oversight Committee.

MEETINGS AND QUORUM

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

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

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

DUTIES AND RESPONSIBILITIES

The Subcommittee has the following duties and responsibilities:

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

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

OTHER DUTIES

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

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

Oversight Committee Meetings and Standing Subcommittees Meetings 2019

November 2018

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
10/28	10/29	10/30 PIC Meeting CPRIT Staff Only	10/31 Portal Opens	1 Board Governance	2	3
4	5 Audit	6 Prevention	7 Academic Research	8 Product Development	9 Nominations	10
11	12	13	14	15	16	17
18	19	20	**21 Oversight Committee Meeting**	22 *-Holiday-*	23 *-Holiday-*	24

February 2019

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
3	4	5 PIC Meeting CPRIT Staff Only	6 Portal Opens	7 Board Governance	8	9
10	11 Audit	12 Prevention	13 Academic Research	14 Product Development	15 Nominations	16
17	18 *-Holiday-*	19	**20 Oversight Committee Meeting**	21	22	23

May 2019

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
4/28	4/29	4/30 PIC Meeting CPRIT Staff Only	1 Portal Opens	2 Board Governance	3	4
5	6 Audit	7 Prevention	8 Academic Research	9 Product Development	10 Nominations	11
12	13	14	**15 Oversight Committee Meeting**	16	17	18

August 2019

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
4	5	6 PIC Meeting CPRIT Staff Only	7 Portal Opens	8 Board Governance	9	10
11	12 Audit	13 Prevention	14 Academic Research	15 Product Development	16 Nominations	17
18	19	20	**21 Oversight Committee Meeting**	22	23	24

Note: Unless the subcommittee members agree to a different time, all subcommittee meetings will begin at 10:00 a.m. with the exception of 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.