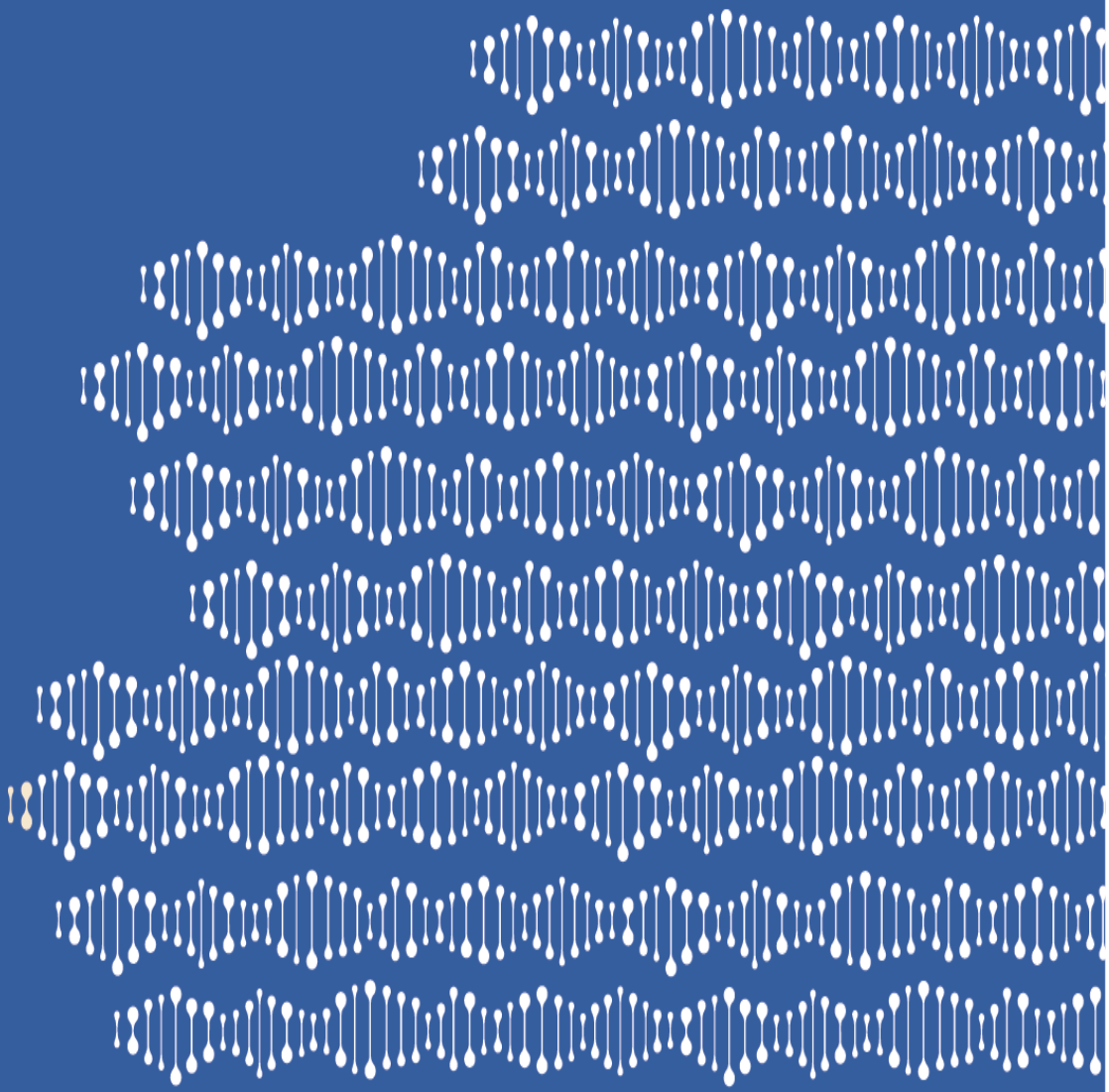
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

August 17, 2022



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

August 17, 2022
9:00 a.m.

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

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. Also as authorized by Texas Government Code § 551.127, one or more Oversight Committee members may participate remotely in the meeting by videoconference. The Oversight Committee member presiding over the meeting will be physically present at the above-listed location, which will be open to the public. Anyone wishing to offer public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the May 18, 2022, meeting — Tab 1
4. Public Comment
5. Grantee Presentation – Robert Alan Hromas, M.D., Dean, Long School of Medicine, The University of Texas Health Sciences Center San Antonio — Tab 2
6. Chief Executive Officer Report — Tab 3
7. Chief Compliance Officer Report and Compliance Certification of Grant Award Process — Tab 4
8. Chief Scientific Officer Report — Tab 5
   - Grant Award Recommendations
9. Chief Prevention Officer Report — Tab 6
   - Grant Award Recommendations
10. Chief Product Development Officer Report — Tab 7
    - Grant Award Recommendations
11. Internal Auditor Report — Tab 8
    - FY 2023 Internal Audit Plan
12. Scientific Research and Prevention Program Committee Appointments — Tab 9
13. Advisory Committees — Tab 10
    - Clinical Trial Advisory Committee Annual Report
    - Schedule for FY 2023 Advisory Committee Annual Report Presentations
14. FY 2023 Honoraria Policy — Tab 11
15. Health & Safety Code Section 102.1062 Waivers — Tab 12

16. Amendments to 25 T.A.C. Chapters 703 — Tab 13
    - Proposed Amendments to Chapter 703 and Authorization to Publish in *Texas Register*
17. Chief Operating Officer Report — Tab 14
18. Contract Approvals — Tab 15
    - CPRIT 2023 Innovations VI Conference Venue
    - Economic Assessment of the Cost of Cancer in Texas (contract renewal)
    - Internal Audit Services (contract renewal)
19. Intellectual Property Project Update — Tab 16
20. Communications Program Update — Tab 17
21. Subcommittee Business
22. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
23. Consultation with General Counsel
24. Future Meeting Dates and Agenda Items — Tab 18
    - FY 2023 Meeting Dates
25. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Summary Overview of the August 17, 2022, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the August 17, 2022, Oversight Committee meeting.

Grantee Presentation
Robert Alan Hromas, M.D., Dean, Long School of Medicine, The University of Texas Health Sciences Center San Antonio, will provide an update on his CPRIT grant project.

CEO Report
Wayne Roberts will present the CEO's report and address issues including a personnel update, grant funds available for FY 2022 and other topics.

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

Chief Scientific Officer Report and Grant Award Recommendations
Dr. Michelle Le Beau will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) three award recommendations for Recruitment of First-Time, Tenure-Track Faculty Members, and Recruitment of Established Investigator, totaling $10,000,000.

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

Chief Prevention Officer Report and Grant Award Recommendations
Ramona Magid will update the Oversight Committee on the on the agency's prevention activities and present the PIC's nine award recommendations totaling $14,443,836. The recommended awards include Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations and Evidence-Based Cancer Prevention Services.

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 and Grant Award Recommendation
Dr. Ken Smith will provide an update on the Product Development Program. He will also present the PIC's nine award recommendations for Texas Company, Relocation Company and Seed Company Product Development Research Awards totaling $64,868,655.

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

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and the FY 2023 audit plan.

Appointments to the Scientific Research and Prevention Programs Committee
Mr. Roberts has provisionally appointed 27 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. CPRIT has provided biographical sketches for the appointees for the Oversight Committee's consideration.

Advisory Committee Annual Report
The Clinical Trial Advisory Committee will provide its FY 2022 annual report. Mr. Roberts will also provide a proposed schedule of presentations for the advisory committees' FY 2023 reports to the Oversight Committee.

FY 2023 Honoraria Policy
Mr. Roberts will present CPRIT's FY 2023 honoraria policy for peer reviewers. The FY 2023 policy includes proposed changes to the product development program honoraria.

Health & Safety Code § 102.1062 Waivers
Mr. Roberts will present three conflict of interest waivers pursuant to Texas Health and Safety Code 102.1062. The FY 2023 waivers are for Don Brandy, Dr. John Hellerstedt, and the Review Council Members. The Oversight Committee approved similar waivers for these three for FY 2022.

Amendment to 25 TAC Chapter 703
Cameron Eckel will present proposed amendments to the agency's Chapter 703 administrative rules for approval to post in the *Texas Register* for public comment. CPRIT will bring the proposed amendments back to the Oversight Committee for final approval in November.

Chief Operating Officer Report and Contract Approvals
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the third quarter of FY 2022. She will also present recommendations for contract approvals for the following services: an economic assessment of the cost of cancer in Texas, internal audit, and the CPRIT 2023 Innovations VI conference venue.

Intellectual Property Project Update
Tracey Davies will provide an update on CPRIT's project to implement a streamlined and standardized reporting process to better track and understand the amount and nature of CPRIT-funded IP.

Communications Program Update
Mark Loeffler will update the Oversight Committee on CPRIT's communication efforts, including coverage of the agency and grantees in earned media, digital media and social media.

FY 2023 Meeting Dates
Mr. Roberts will present the proposed dates for the FY 2023 Oversight Committee quarterly meetings and the regular subcommittee meetings for Oversight Committee approval.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Minutes
May 18, 2022

NOTE: Unless the information is confidential, the reports, presentations, and grant award information referenced in the minutes are available at http://ocmeetings.cprit.texas.gov in the "Oversight Committee Board Packet" section for the corresponding meeting date.

Call to Order – Agenda Item 1

With a quorum present, Vice Presiding Officer Dr. David Cummings called the meeting to order at 9:00 a.m. and asked Oversight Committee Secretary Cindy Barberio Payne to take attendance of the members.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present
David Cummings, M.D.
Donald (Dee) Margo
Ambrosio Hernandez, M.D.
Will Montgomery
Cindy Barberio Payne
Bill Rice, M.D.
Craig Rosenfeld, M.D.

MOTION:
On a motion by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to excuse Presiding Officer Dr. Mahendra Patel's absence.

Adoption of Minutes from the February 16, 2022, Meeting – Agenda Item 3 – Tab 1

MOTION:
On a motion by Dr. Rosenfeld and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the minutes of the February 16, 2022, Oversight Committee meeting as presented.

Public Comment – Agenda Item 4

Vice Presiding Officer Dr. Cummings noted for the record that no member of the public requested to provide comments.

Chief Executive Officer Report – Agenda Item 5, Tab 2

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

Vice Presiding Officer Dr. Cummings recognized Chief Executive Officer Wayne Roberts to present his report.

Mr. Roberts advised Oversight Committee members of the amount of FY 2022 funds available. He introduced newly hired CPRIT staff, including Dr. Abria Magee who began work as the program manager for product development. Mr. Roberts went on to inform members that they will receive a CPRIT-specific email address. He gave a brief preview on an update for the product development project that CPRIT staff have been working on to increase outreach.

Mr. Roberts and Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies reported on their trip to Israel as part of the Texas-Israel Alliance. Dr. Rosenfeld inquired about CPRIT working with the BIRD Foundation to fund research projects.

Chief Compliance Officer Report and Compliance Certification for the Proposed Grant Awards – Agenda Item 6, Tab 3

Vice Presiding Officer Cummings recognized Chief Compliance Officer Vince Burgess to present the Compliance Report and Compliance Certification of Grant Award Process. Mr. Burgess presented the Compliance Report for the past quarter's activities.

There were no questions from the Oversight Committee members.

Mr. Burgess presented the Compliance Certification for the proposed academic research grant awards, confirming that the proposed awards and review process complied with all applicable state and agency requirements.

Chief Scientific Officer Report and Grant Award Recommendations – Agenda Item 7, Tab 4

Vice Presiding Officer Dr. Cummings recognized Dr. Le Beau to present the academic research program award recommendations.

Dr. Le Beau directed Oversight Committee members to page 4 of the agenda packet and provided an overview of the proposed FY 2023 Recruitment RFAs.

Dr. Le Beau then directed Oversight Committee members to page 4 of the Proposed Grant Awards Book that listed the Scientific Review Council (SRC) and Program Integration Committee (PIC) recommendations for the FY2022 Recruitment Cycles 22.7, 22.8 and 22.9, which included 19 applications totaling $57,998,029.

Dr. Le Beau reported that because the SRC recommendations exceeded the funds budgeted to fund Academic Research Program awards for the third quarter of 2022, the PIC deferred action on two recruits. The two deferred applications, totaling $10,000,000, include one Recruitment of Established Investigator award recommended by the SCR for The University of Texas M.D. Anderson Cancer Center and one Recruitment of Rising Star award recommended by the SRC to The University of Texas Southwestern Medical Center.

FY 2022 Cycle 7 – 9 Recommended Awards

Rank	App. ID	Mechanism	Candidate	Organization	Budget	Overall Scores
1	RR220084	RFTFM	Linde Miles	The University of Texas Southwestern Medical Center	$2,000,000	**1.0**
2	RR220087	RRS	Hans Renata	Rice University	$4,000,000	**1.0**
3	RR220068	RFTFM	Elizabeth Wasmuth	The University of Texas Health Science Center at San Antonio	$2,000,000	**1.0**
4	RR220069	RFTFM	William Hudson	Baylor College of Medicine	$2,000,000	**1.0**
5	RR220075	RFTFM	Nicholas Riley	The University of Texas at Austin	$2,000,000	**1.0**
6	RR220033	REI	Pavan Reddy	Baylor College of Medicine	$6,000,000	**1.0**
7	RR220062	RFTFM	Aria Vaishnavi	The University of Texas M. D. Anderson Cancer Center	$2,000,000	**1.0**
8	RR220065	RFTFM	Mingjie Dai	Rice University	$2,000,000	**1.4**
9	RR220072	RRS	Christine Lovly	The University of Texas M. D. Anderson Cancer Center	$4,000,000	**1.4**
10	RR220063	RRS	Ku-Lung Hsu	The University of Texas at Austin	$4,000,000	**1.7**
11	RR220051	REI	Michael Taylor	Baylor College of Medicine	$6,000,000	**1.8**
12	RR220081	RFTFM	Jonathan Clinger	Baylor University	$1,998,029	**2.0**
13	RR220086	RFTFM	Jason Schenkel	The University of Texas M. D. Anderson Cancer Center	$2,000,000	**2.0**
14	RR220088	RRS	Abdel Kareem Azab	The University of Texas Southwestern Medical Center	$2,000,000	**2.0**
17*	RR220055	RFTFM	Samantha Yruegas	Rice University	$2,000,000	**2.0**
18	RR220066	RFTFM	Deepshika Ramanan	The University of Texas M. D. Anderson Cancer Center	$2,000,000	**2.2**
19	RR220035	RFTFM	Qian Zhu	Baylor College of Medicine	$2,000,000	**2.5**

***The PIC deferred action on the two applications ranked 15 and 16 by the SRC. The Oversight Committee did not consider the two deferred applications.
REI = Recruitment of Established Investigator
RRS = Recruitment of Rising Stars
RFTFM = Recruitment of First-Time, Tenure Track Faculty Members

Conflict of Interest Notification

Vice Presiding Officer Dr. Cummings noted for the record that no Oversight Committee member had reported a conflict with any award recommendations presented today.

Approval Process – Academic Research Awards

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Mr. Montgomery, the Oversight Committee members voted unanimously to approve the PIC's recommendations for the 17 academic research recruitment awards.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee members voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

Approval Process – FY 2023 RFAS

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee members voted to approve the proposed FY2023 RFAs presented by Dr. Le Beau.

Chief Prevention Officer Report – Agenda Item 8, Tab 5

Vice Presiding Officer Cummings recognized Chief Prevention Officer Ramona Magid to present the prevention program update. She highlighted the release of two new requests for applications.

Oversight Committee members and Ms. Magid also discussed the impact of the pandemic on cancer screenings.

Chief Product Development Officer Report – Agenda Item 9, Tab 6

Vice Presiding Officer Dr. Cummings recognized Interim Chief Product Development Officer Dr. Ken Smith to present the Product Development Research update.

Dr. Smith reported on the status of the applications under review in the current 22.2 cycle. He noted that the total amount of funding requested by applications in due diligence exceed the $72 million dollar allotment for FY 2022 Product Development Research awards.

Dr. Smith presented the five proposed FY2023 Product Development Requests for Applications (RFAs): Texas Therapeutic Company Award (TTCA), Texas Device Company Award (TDeCA), Texas Diagnostic Company Award (TDiCA), Texas Emerging Frontier Company Award (TEFCA), and Texas Seed Company Award (SEED).

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee members voted to approve the proposed FY 2023 RFA's presented by Dr. Smith.

Internal Auditor Report – Agenda Item 10, Tab 7

Vice Presiding Officer Dr. Cummings recognized Dan Graves, representing CPRIT's internal auditor Weaver & Tidwell, to give the Internal Auditor's Report. Mr. Graves updated the committee members on the FY 2022 Internal Audit Plan schedule. He directed the members to page 7-3 of the meeting book with the list of audits and audit advisory engagements, explaining that Weaver would review and re-evaluate the audit follow-ups on information technology general controls, communications, governance, and information security as well as the disaster recovery and business continuity follow-up advisory audit to focus on information technology issues, some of which overlap, around the same time in May-June.

There were no questions for Mr. Graves.

Scientific Research and Prevention Program Committee Appointments – Agenda Item 11, Tab 8

Vice Presiding Officer Dr. Cummings recognized Mr. Roberts to present his two appointments to the Scientific Research and Prevention Program Committee.

> **MOTION:**
> On a motion by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve Dr. Jaffee and Dr. Wang's appointment to the Scientific Research and Prevention Program Committee.

Advisory Committees – Item 12, Tab 9

Vice Presiding Officer Dr. Cummings recognized Mr. Roberts to present the Presiding Officer's new appointments to the Prevention Advisory Committee and the Product Development Advisory Committee.

Mr. Roberts presented proposed appointees to the Prevention Advisory Committee: Dorothy Gibbons and Dr. Rakhshanda Rahman; and proposed appointees to the Product Development Advisory Committee: Dr. Gabby Everett, Victoria Ford, Heather Hansen, Dan Hargrove, and Dr. Tom Luby.

> **MOTION:**
> On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee members voted unanimously to approve the Presiding Officer's appointments to the Prevention Advisory Committee and the Product Development Advisory Committee.

<u>Product Development Advisory Committee presentation</u>

Vice Presiding Officer Cummings recognized Dr. Smith to introduce Andrew Strong and Dr. Michele Park, co-chairs of the Product Development Advisory Committee.

Mr. Strong and Dr. Park presented the PDAC's report. They discussed the capital market conditions and global biotech declines, explaining that CPRIT is of great value of early-stage

biotech companies given the current state of the market. Despite the market challenges, biotech employment is on the rise, private capital markets are tight but holding and venture/private debt placements are still brisk. The PDAC recommends that CPRIT increases the number of product development awards made annually, implement new RFAs and improve the efficiency of current review process.

In response to an Oversight Committee member's question, Dr. Smith and Ms. Doyle explained that the proposed changes for the FY 2023 product development program review process will address several of the PDAC's recommendations.

Members thanked Mr. Strong and Dr. Park for the presentation.

Geographic Diversity Advisory Committee presentation

Vice Presiding Officer Dr. Cummings called on Dr. Le Beau to introduce Dr. Sarah Williams-Blangero, Chair of the Geographic Diversity Advisory Committee (GDAC) to provide the GDAC Annual Report. Dr. Williams-Blangero presented the GDAC annual report.

In response to a question by an Oversight Committee member inquiring about the due date for the Texas Regional Excellence in Cancer (TREC) Letter of Intent, Dr. Williams-Blangero noted that the TREC letter of intent was due April 25.

Members thanked Dr. Williams-Blangero for the presentation.

Amendments to 25 T.A.C. Chapters 703 – Item 13, Tab 10

Vice Presiding Officer Dr. Cummings recognized Assistant General Counsel Cameron Eckel to present the proposed rule amendments. Ms. Eckel reviewed the proposed final order approving a rule amendment initially presented at the February Oversight Committee meeting. CPRIT published the proposed amendment in the March 4th edition of the *Texas Register*; CPRIT did not receive any public comments.

> **MOTION:**
> On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the final order adopting rule changes to the Texas Administrative Code Chapter 703.

Chief Operating Officer Report – Agenda Item 14, Tab 11

Vice Presiding Officer Dr. David Cummings recognized Chief Operating Officer Heidi McConnell to present her report. Ms. McConnell updated members on CPRIT's revenue sharing payments, bond issuance, and work on the agency's strategic plan for FY 2023-2027, which CPRIT will submit to the Governor's Office on June 1. Ms. McConnell also provided an update on the CPRIT Conference, noting that CPRIT received several proposals for the conference venue.

In response to a question from an Oversight Committee member about the proposed location of the conference, Ms. McConnell reported that Fort Worth and Galveston submitted proposals.

Legislative Appropriations Request for 2024 – 2025 Biennium – Agenda Item 15, Tab 12

Ms. McConnell reviewed the Legislative Appropriations Request (LAR) for the 2024-25 Biennium. She informed the committee that CPRIT expects the instructions on compiling the LAR to come in June and that the LAR will be due in August.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the proposed LAR for 2024-2025.

Contract Approvals – Agenda Item 16, Tab 13

Ms. McConnell reviewed the proposed contract approvals for an increase in budget of the FY 2022 outside counsel contract with Baker Botts to $125,000 and the FY 2023 grant management support services contract renewal for one year with an amount not to exceed $9,984,746.

In response to a question by an Oversight Committee member inquiring if CPRIT usually expends the full amount of the GDIT contract, Ms. McConnell explained that the contract amount is the maximum amount and that CPRIT does not typically expend the full amount.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the proposed increase to the FY 2022 outside counsel contract budget in the amount recommended by staff and to approve renewing the contract with GDIT for grant management support services.

Fiscal Year 2023 Bond Issuance Resolution – Agenda Item 17, Tab 14

Ms. McConnell reviewed the proposed resolution authorizing the Texas Public Finance Authority (TPFA) to issue debt on behalf of CPRIT for FY 2023.

In response to a question by an Oversight Committee member inquiring about current bond rates, Ms. McConnell responded that rates are starting to increase. The rate was approximately 2.19% in 2021. She has not received a recent report from TPFA.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the resolution requesting financing for $300 million in bond proceeds by the TPFA in FY 2023.

Communication Report – Agenda Item 18, Tab 15

Vice Presiding Officer Dr. Cummings recognized Communications Director Mark Loeffler to present his report. Mr. Loeffler updated the committee members on communications activities.

There were no questions for Mr. Loeffler.

Subcommittee Business – Agenda Item 19
Compliance Investigation Pursuant to Health & Safety Code § 102.2631 – Agenda Item 20
Consultation with General Counsel – Agenda Item 21

Vice Presiding Officer Dr. Cummings announced that the Oversight Committee would not take up standing agenda items 19, 20 and 21.

Future Meeting Dates and Agenda Items – Agenda Item 22

Vice Presiding Officer Dr. Cummings reminded the Oversight Committee members that they would convene for their next regular meeting on August 17. He advised members that the Oversight Committee may convene a special meeting with the chairs of the Advisory Committee and the Review Committee Councils to discuss program priorities. CPRIT staff would provide more information.

Adjournment – Agenda Item 23

> **MOTION:**
> There being no further business, the Oversight Committee unanimously voted to approve Vice Presiding Officer Dr. Cumming's motion to adjourn, which Dr. Rosenfeld seconded.

Meeting adjourned at 11:57p.m.

_____ _____

Signature Date

Robert Hromas, MD, FACP

Dr. Hromas is the **Dean at the Long School of Medicine** and the Vice President for Medical Affairs at the University of Texas Health Science Center in San Antonio. The Long School of Medicine has over 1500 faculty, 900 medical students, and 865 residents and fellows, and cares for 2.4 million patients annually. Prior to that, he was Chair of the Department of Medicine at University of Florida Health, where he is also Vice President of the University of Florida Physicians Clinical Practice Association, and a member of the UF Health Hospital Executive Board. He has personally trained 29 graduate students or fellows, most of which have entered academic careers, and 21 junior faculty, almost all of which have obtained tenure, with three obtaining Hematology-Oncology Division Chief and two of which obtaining Departmental chair positions. He has served on editorial boards of Blood and of Stem Cells. He has won numerous teaching and patient care awards, including the Indiana University Humanism in Medical Education Award, the Indiana University Board of Trustees Outstanding Teacher Award, and the New Mexico People Living Through Cancer Caring Award. He has chaired Scientific Affairs for the American Society of Hematology and served as their congressional and media representative. He has published over 190 research papers with an H-index of 56. He has been continuously funded by the National Institutes of Health for over three decades and has chaired multiple NIH and American Cancer Society study sections and policy panels. He has multiple patents and has co-founded two biotechnology companies that translated new compounds into clinical trials, Abfero (exited at purchase) and Dialectic Therapeutics. His laboratory has isolated and characterized multiple novel cytokines and several DNA mutations leading to leukemia. He has identified several key components of DNA repair pathways. He created a drug development consortium at the University of Florida that translated University science to the clinic. He is the author of the Harper-Collins leadership book, Einstein's Boss- 10 Rules for Leading Genius. He was elected to the Liaison Committee on Medical Education, the accrediting body for US and Canadian medical schools. He is the founding Chair of the Board for the UT Health San Antonio Regional Physician Network ACO and the founding Chair of the Board for the new UT Health Multispecialty Research Hospital. For these and other accomplishments he has been elected to the American Society of Clinical Investigation, Association of Professors of Medicine, the American Clinical and Climatologic Association, and the Association of American Physicians.

Jill Biden at the Mays Cancer Center

CPRIT Oversight Committee Report

Robert Hromas, MD, FACP

Dean, Long School of Medicine

Vice President, UT Health Center San Antonio

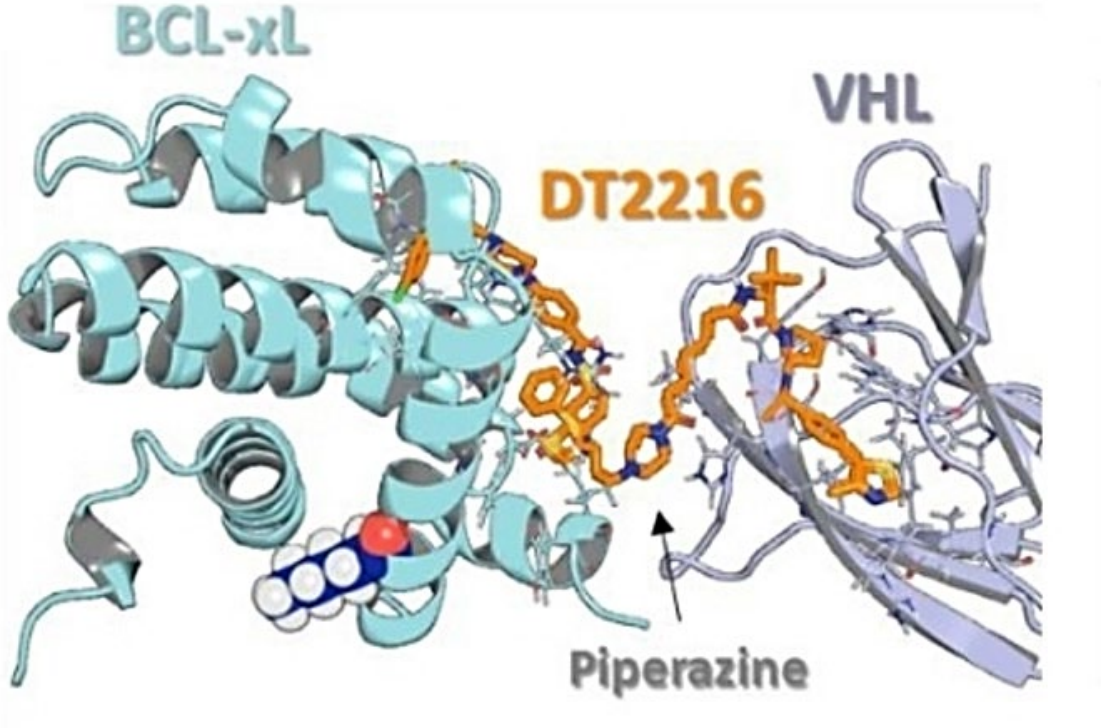
CPRIT Awardee- Academic Research, Seed Company, Texas Company

Mays Cancer Center

Disclosures

- Co-founder and holds equity in Dialectic Therapeutics, which has the license for DT2216

BCL-XL mediates half of cancer resistance to treatment and is one of the major undrugged targets in oncology. Development of inhibitors has been limited by on-target platelet toxicity.



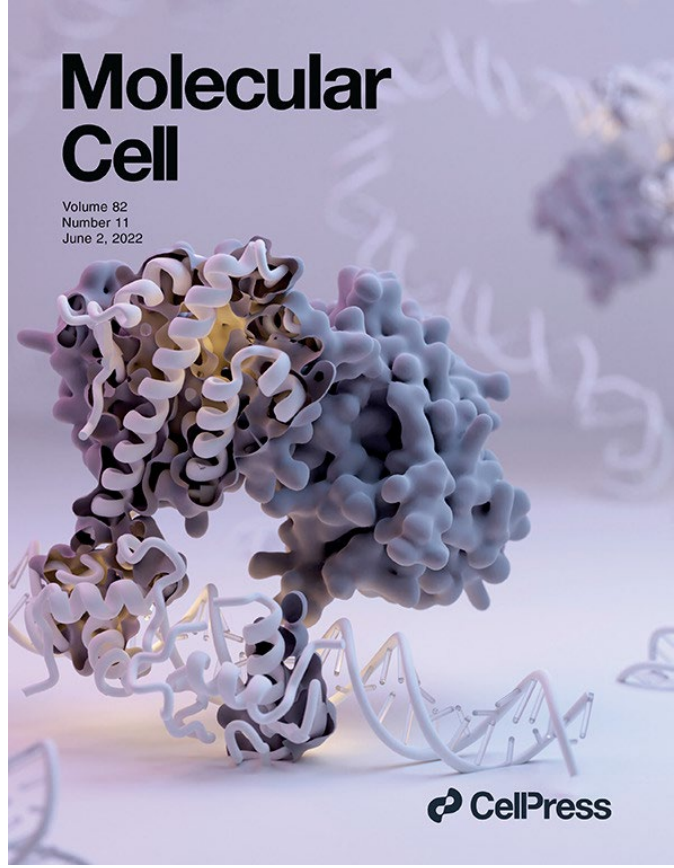
DT2216 overcomes the platelet toxicity that limits anti-BCL-XL drugs

UT COI management plan supervised by the UTHSCSA President in place

UT Health San Antonio CPRIT Recruitment Awards

- 8 First-Time Tenure Track ($2M each)
  - Siyuan Zheng (2017)
  - Peng Zhao (2020)
  - Xiaoli Sun (2020)
  - Elizabeth Wasmuth (2022)
- 1 Rising Star ($4M)
  - Shaun Olsen (2019)- Cryo-EM Core Director
- 4 Established Investigator ($6M each)
  - Patrick Sung (2017)- Greehey Inst Director
  - Alex Mazin (2020)
  - David Gius (2020)- Rad Onc Vice Chair
  - Reuben Harris (2021)- Biochem Chair


Wasmuth



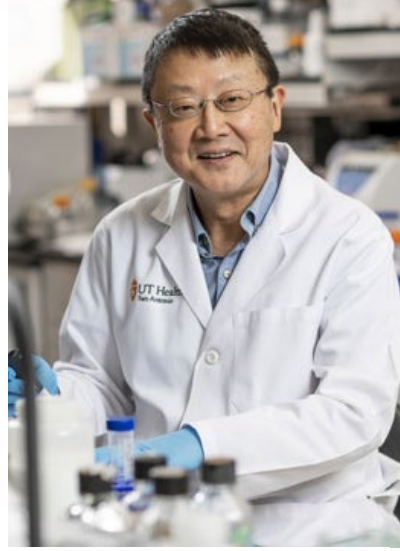
First Androgen Receptor-ERG oncoprotein structure bound to DNA resolved, which defined the AR-ERG dimer interface to target for prostate cancer by our CPRIT-funded Center for Innovative Drug Discovery

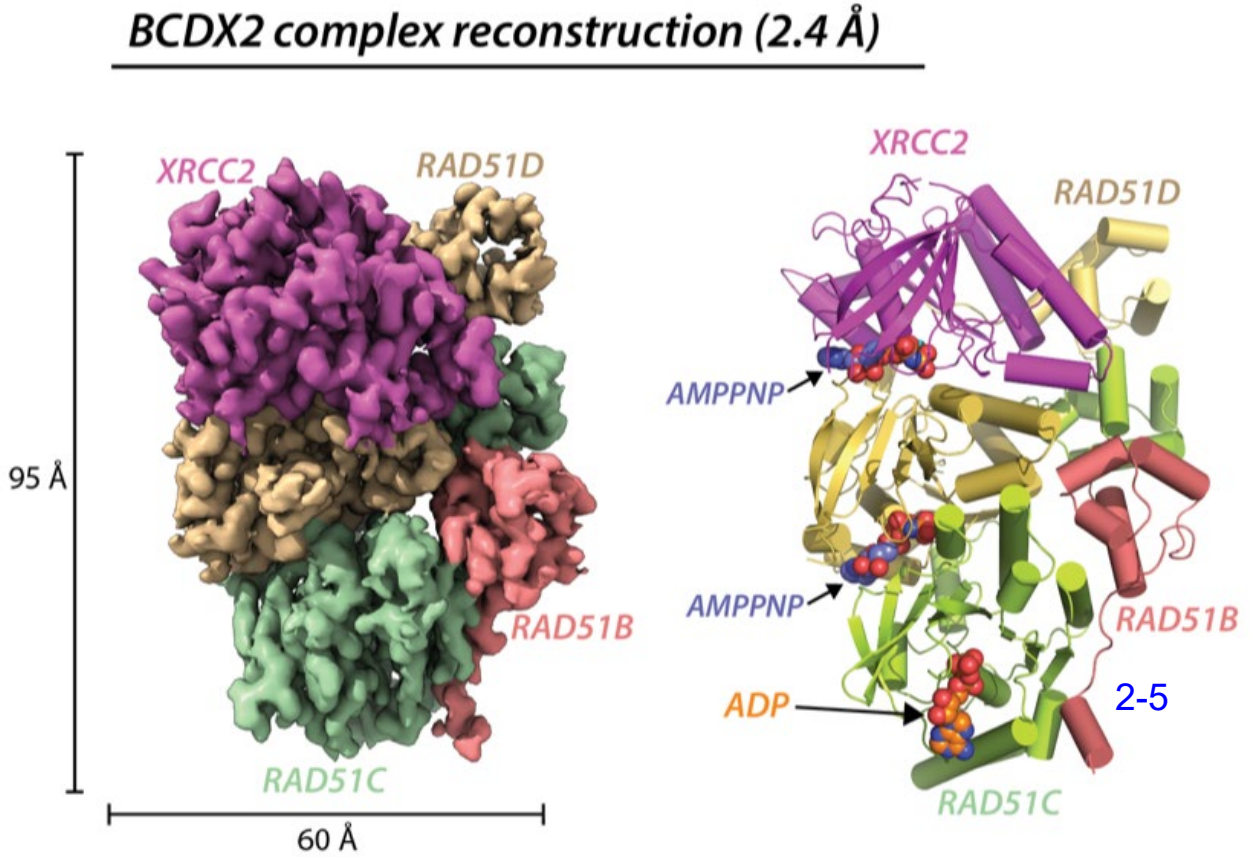
Olsen/Sung collaboration

Return on Investment for Recruitment Awards

- 27 added external grants
  - 18 transferred
  - 9 new
  - 90% NIH (2 PO1s)
  - 5% DoD
  - 5% Foundation
- $34.5 M total cost new grants in TX
- Increased mentorship of trainees and faculty resulting in additional funding
- Creating the environment that attracts talented scientists in a virtuous circle

BCDX2 required for BRCA1/2-mutant breast/ovarian cancer, and is a novel target for drug development



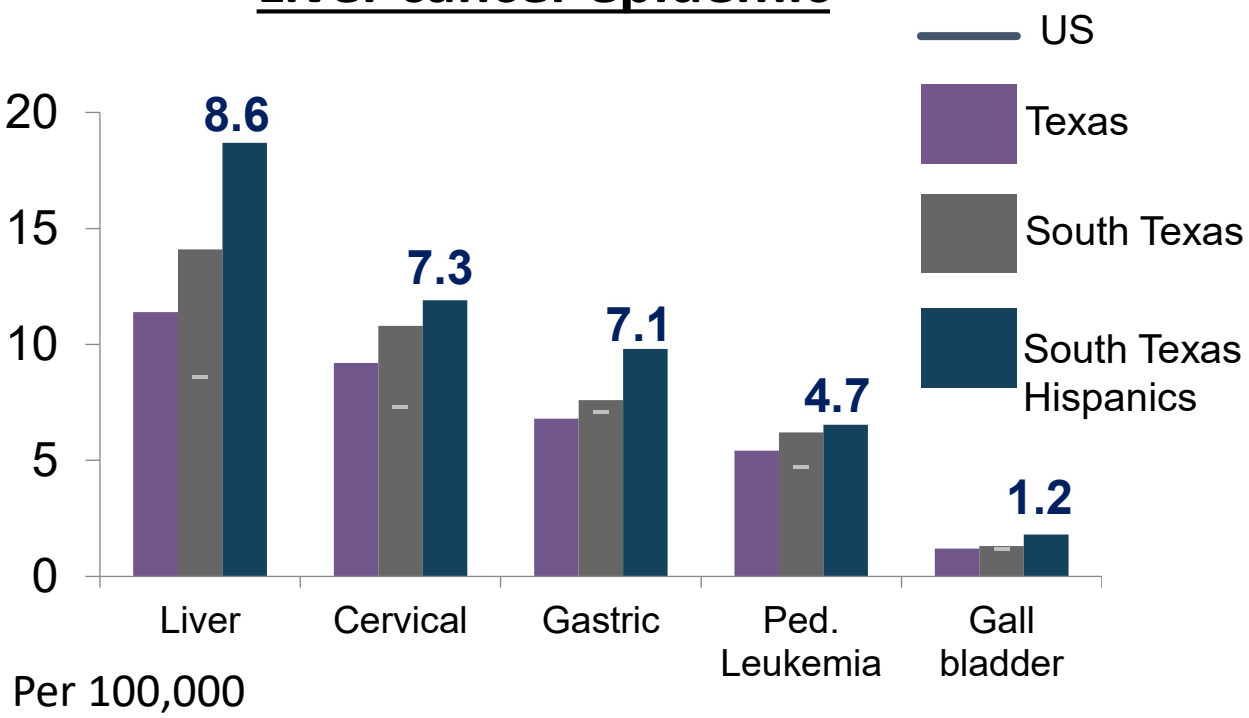


UT Health San Antonio Academic Research and Prevention Awards

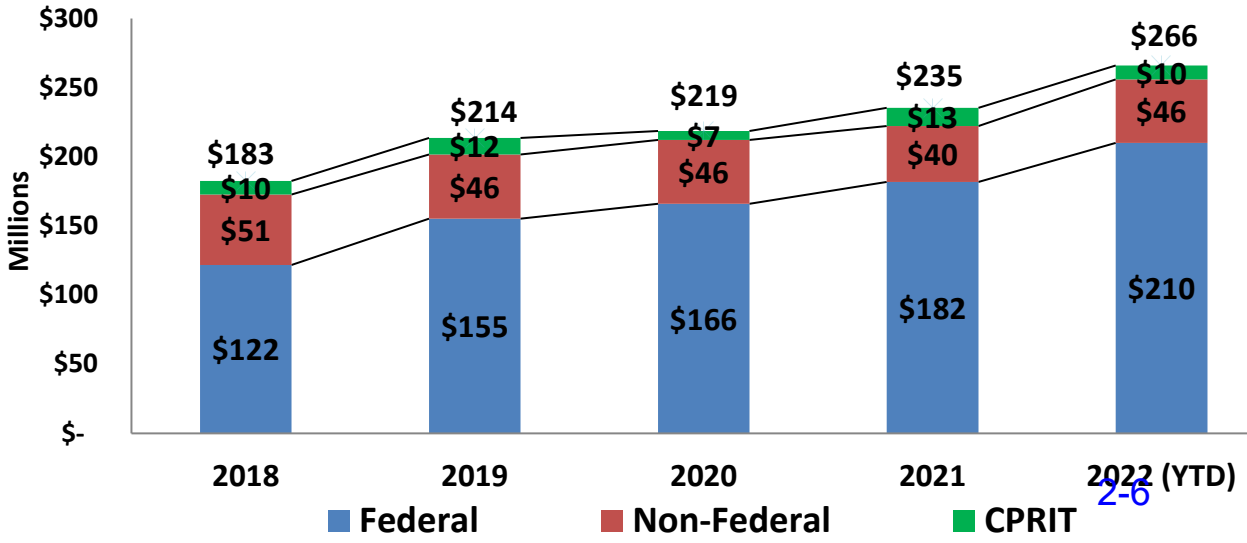
- 65 total Academic Research grants given to 39 Investigators
  - $69 M total costs
- 16 Prevention Awards to 9 Investigators
  - $16 M total costs

CPRIT floats all boats!

Liver cancer epidemic



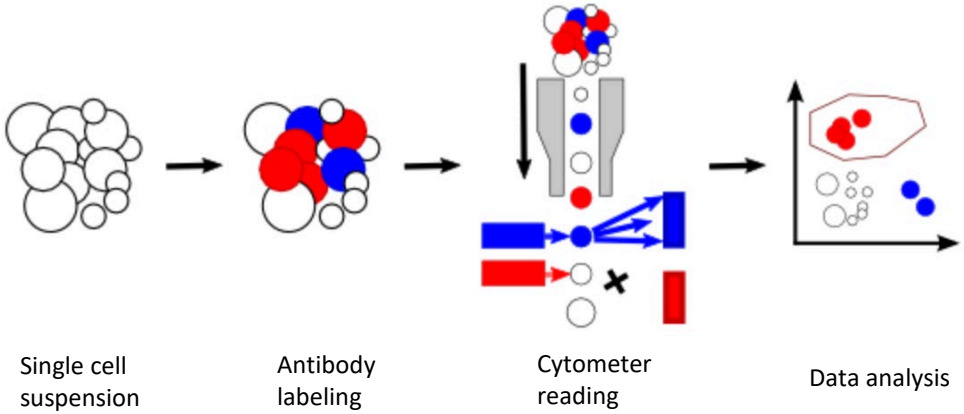
UTHSCSA Total Sponsored Research



CPRIT-funded

Flow Cytometry Shared Resource

Scientific Director: Michael Berton, Ph.D.
Grants/Contracts supported: 113
Total Extramural Funds: $85 M



Instruments:

- BD FACSAria Fusion Cell Sorter
- BC Cytoflex SRT Benchtop Sorter
- Cytek Aurora Full-Spectrum Analyzer
- BD Symphony A5 SE Analyzer (Sept 2022)
- BD LSRII Analyzer
- BD FACSCelesta Analyzer

Services:

- ✓ Training courses on operating the analyzers and cell sorters. Training courses on data analysis.
- ✓ Assisted usage on all the analyzers and cell sorters.
- ✓ Consultation on experimental design and panel design for high-parameter cell phenotyping.
- ✓ Data analysis and figure preparation for grants and publications.

2-7

Funding: CPRIT Core Support Award RP210126, NIH 1S10OD030432-01A1

UT Health San Antonio

CPRIT-funded

Center For Innovative Drug Discovery

Co-Directors: Daohong Zhou, MD & Stanton McHardy, PhD

Collaborating Cores at UTHSA

GCCRI Target Identification Core (TIC) – Zhou
- CRISPR screening
- Gene editing
- Proximity-based assay
- Activity-based protein profiling

Structural Biology Core – Olsen
- X-ray crystallography
- Cryo-EM
- NMR
- Protein Production

CIDD Cores Supported by CPRIT

High Throughput Screening Core (HTS) – Zhou
- Chemical libraries (>170K)
- Plate-based HTS
- Imaging-based HTS
- MST, SPR/GCI HTS

UTHSA

UTSA Medicinal Chemistry Core (MCC) – McHardy
- Compound Design
- Analogues synthesis
- SAR
- PROTAC

UTSA

Computer-Aided Drug Discovery Core (CADD) – Yuan
- Virtual screening
- *De novo* design
- AI-based drug discovery

UTHSA

Collaborating Core at UTSA

Preclinical Pharmacology Core – Clanton
- ADME
- DMPK
- DDI
- Schrodinger platform

CIDD Drug Discovery Pipeline

Target Validation
- RAD54
- ECT2
- APOBECs

Hit/Lead Discovery
- SAMHD1 PROTAC
- FOXM1 PROTAC
- PELP1 PROTAC
- ATR PROTAC
- EYA4 SMI
- ALKBH5 SMI
- EEPD1 SMI

Lead Optimization
- Menin PROTAC
- SMARC2 PROTAC
- Tamoxifen-ShigaToxin
- RAD52 SMI

Pre-clinical development
- **BCL-XL/BCL-2 PROTAC**
- ERβ Agonist
- PKCε SMI
- YAP1 PROTAC

Clinical trials
- **BCL-XL PROTAC**
- Rhenium nanolipids
- eRapa
- CT-179
- CCL2

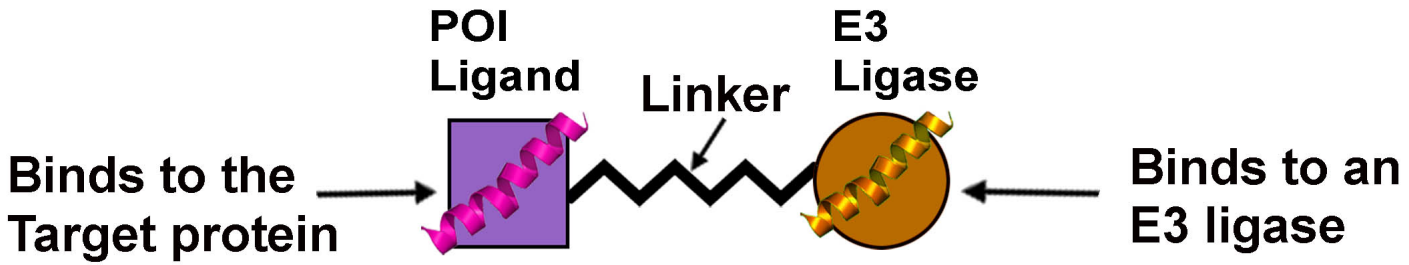
Drugs

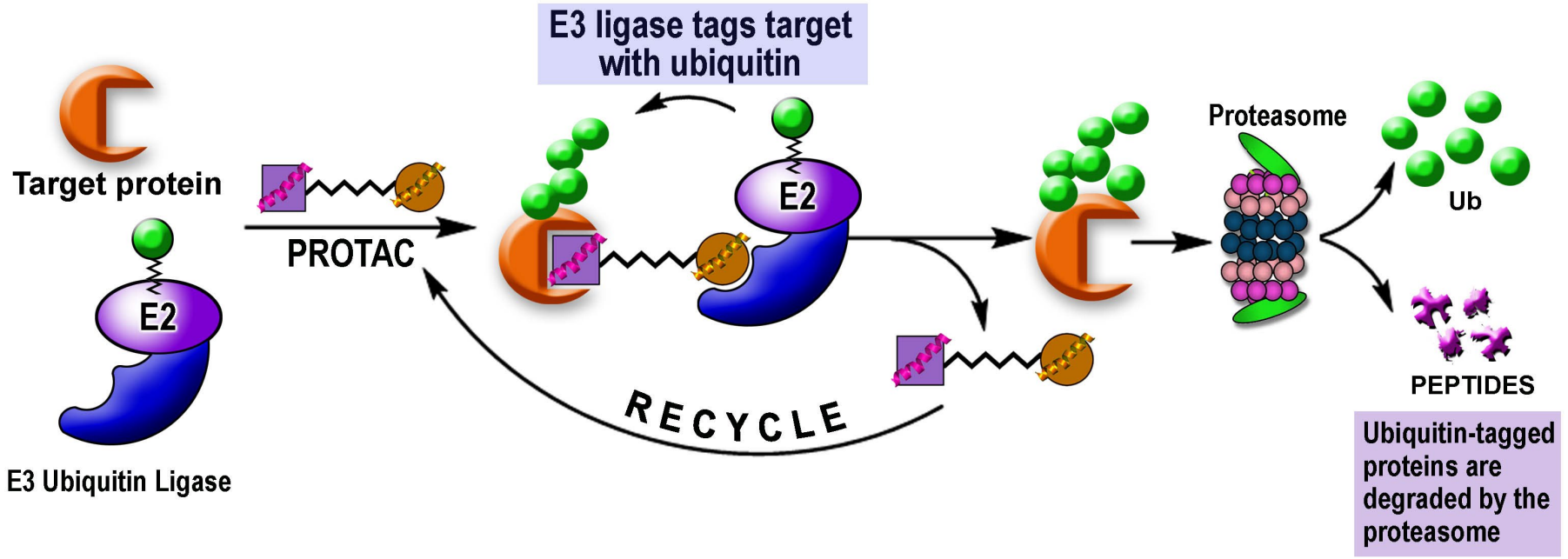
2-8

5 new cancer drugs from our science in clinical trials!

Protein Targeting Chimera (PROTAC) is a new technology that targets proteins for destruction

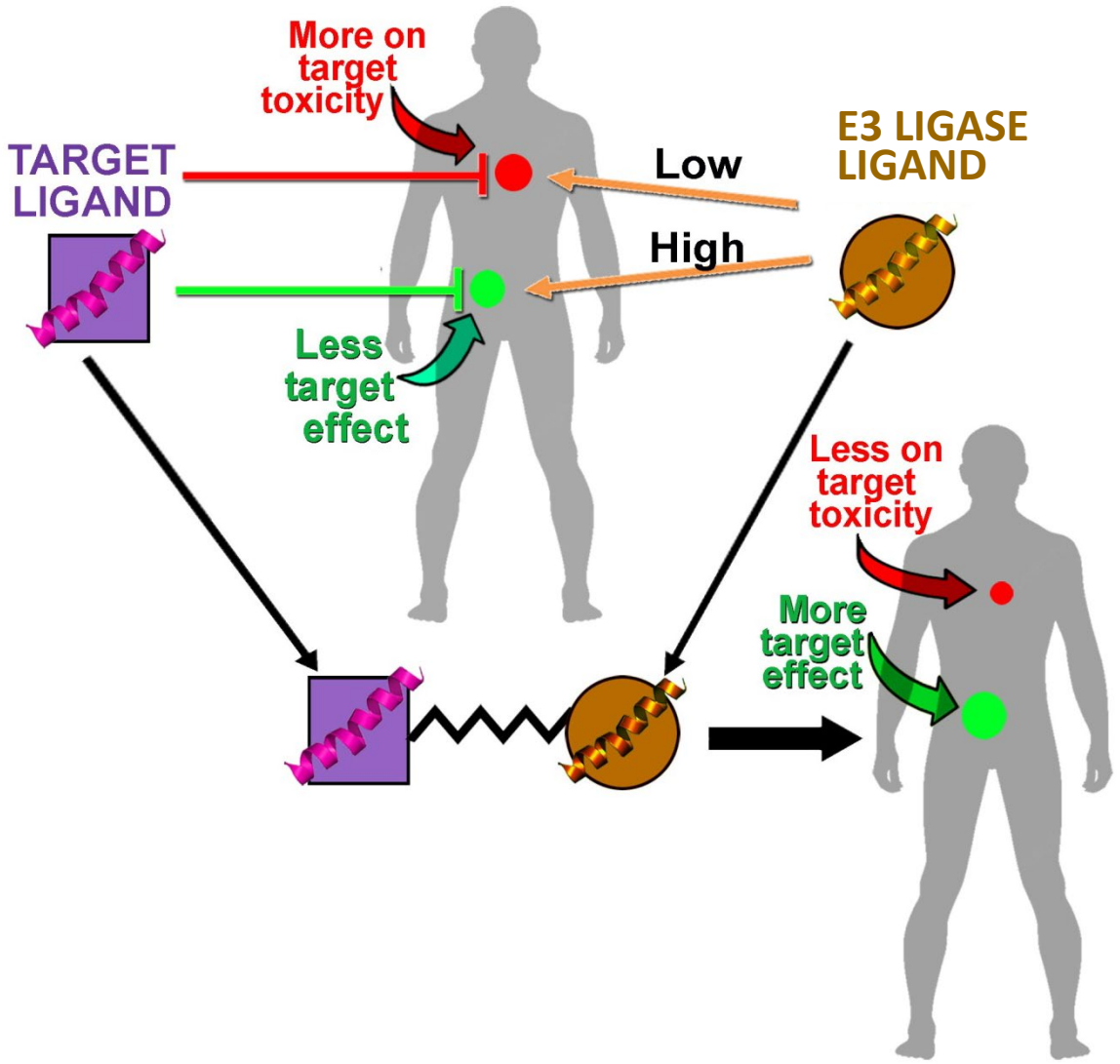
CIDD focuses on this technology



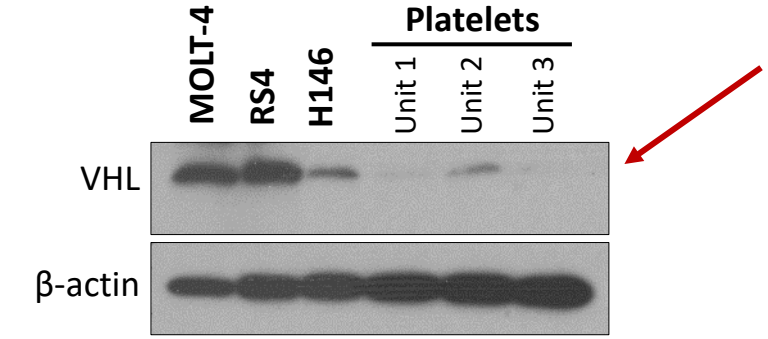


Advantages: Decreased resistance, prolonged action due to recycling of PROTAC

Can a BCL-XL inhibitor be converted to a BCL-XL PROTAC to reduce its platelet toxicity?



Yes, by using an E3 ligase that is not expressed in platelets but is expressed in the cancer!

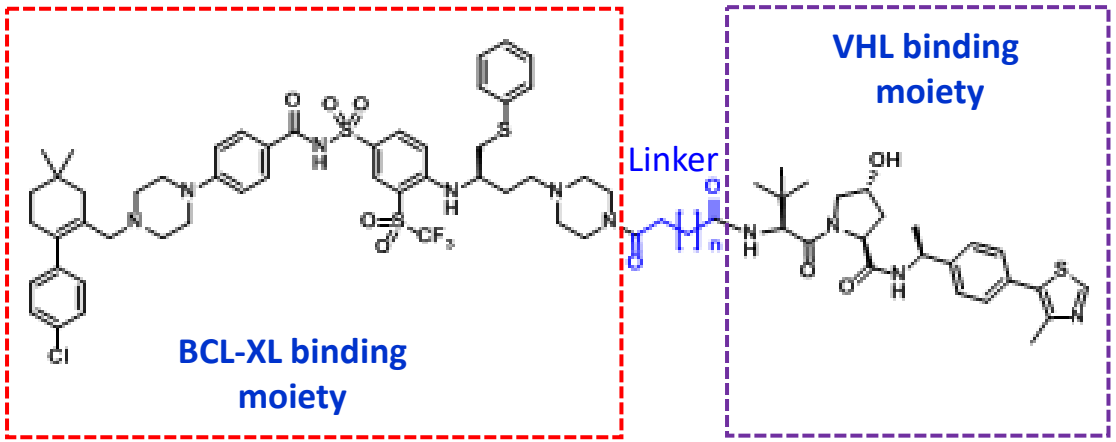


VHL is poorly expressed in platelets

UT Health San Antonio Long School of Medicine

Rationally designed BCL-XL PROTAC DT2216

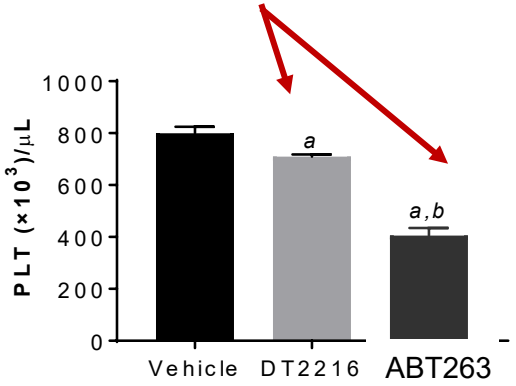
- DT2216 was selected as Dialectic Therapeutics' optimized lead compound because of its:
  - High potency and specificity
  - High chemical stability (for ambient storage and transportation)
  - Little microsomal and hepatocyte metabolism
  - Long half-life of effective concentrations easily achievable in vivo
  - Lack of interaction with or activation of CYP45, avoiding drug-drug interactions, permitting combination with other chemotherapeutic agents
  - Did not induce thrombocytopenia in animals

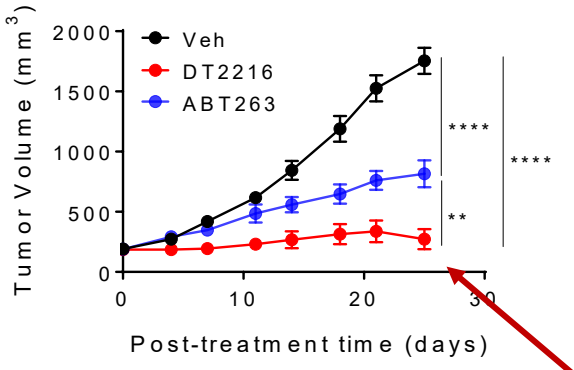


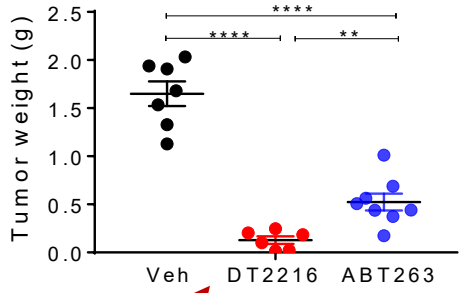
Kahn et al. Nat Med. 2019 Dec;25(12):1938-1947

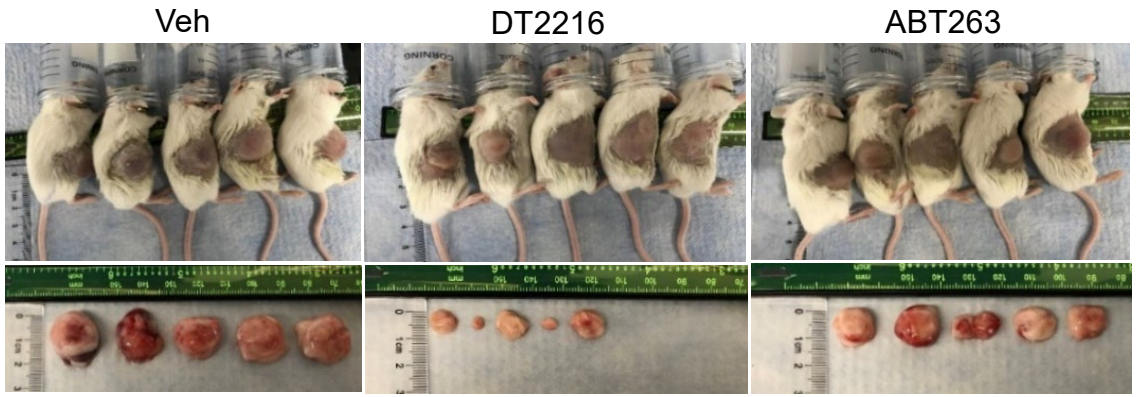
DT2216 is a more potent against MOLT4 T-ALL than ABT263 *in vivo*

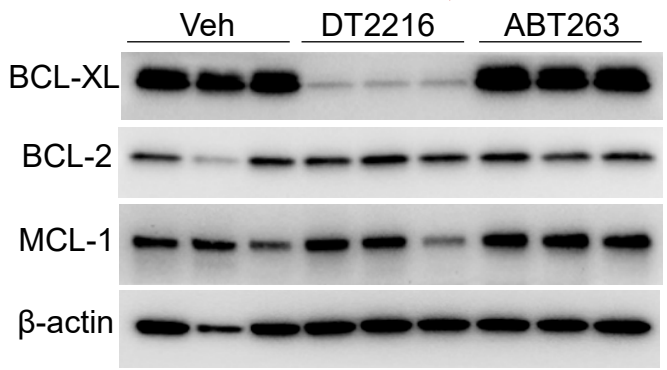
ABT263 (Navitoclax) failed clinical development because of on-target dose-dependent thrombocytopenia







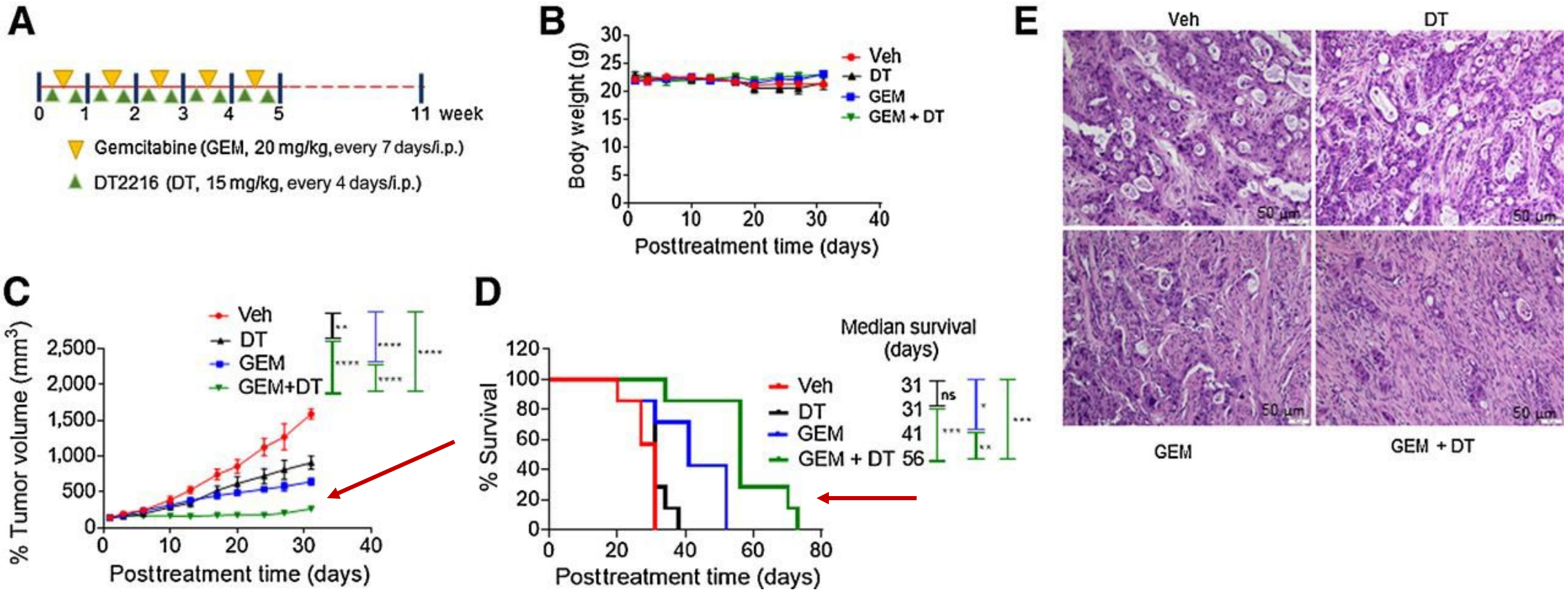




2-12

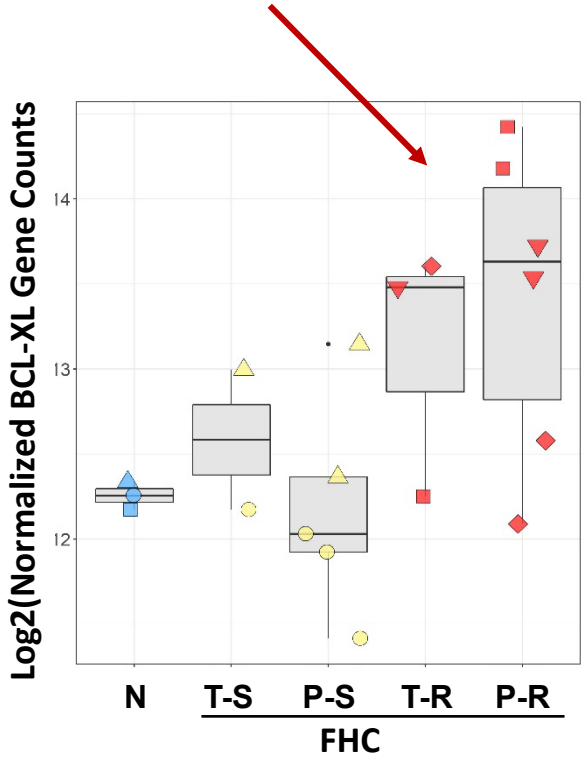
Khan S. et al. Nature Medicine, 2019

DT2216 can sensitize pancreatic cancer to gemcitabine

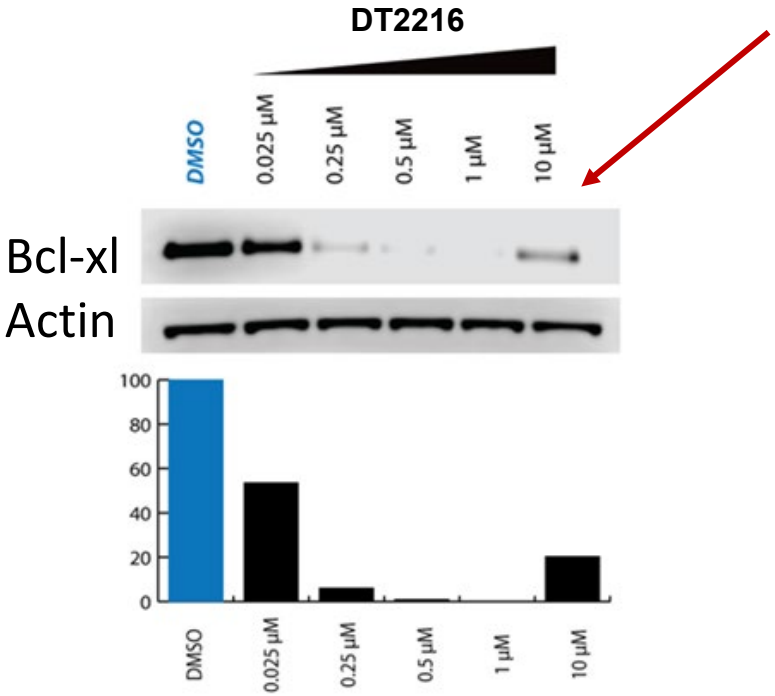


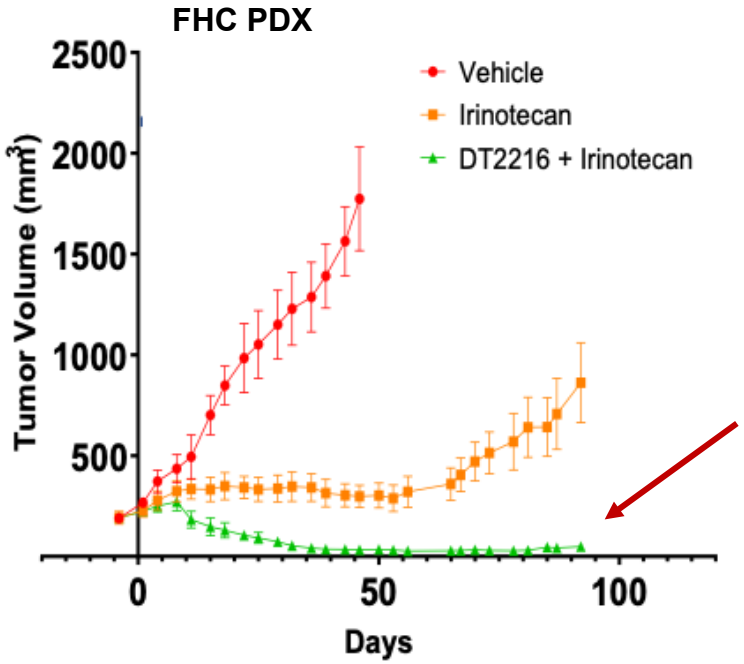
Thummuri D. et al. Mol Cancer Ther, 2022

DT2216 sensitizes fibrolamellar hepatocellular carcinoma (FHC) to irinotecan



N=normal; T-S=sensitive FHC tumors; P-S= sensitive FHC PDXs; T-R=resistant FHC tumors; P-R=resistant FHC PDXs





IP DT2216 15mg/kg, 2x/w x 3 wks

IP Irinotecan 5mg/kg, qd x5/wk x 2 wks

2-14

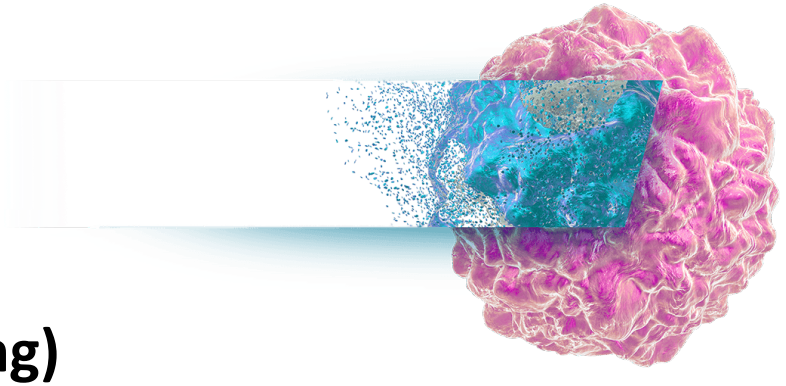
Lalazar G et al. Cancer Discov, 2021

Shebl B et al. JCI Insight, in press

Dialectic Seed Company Award Aims

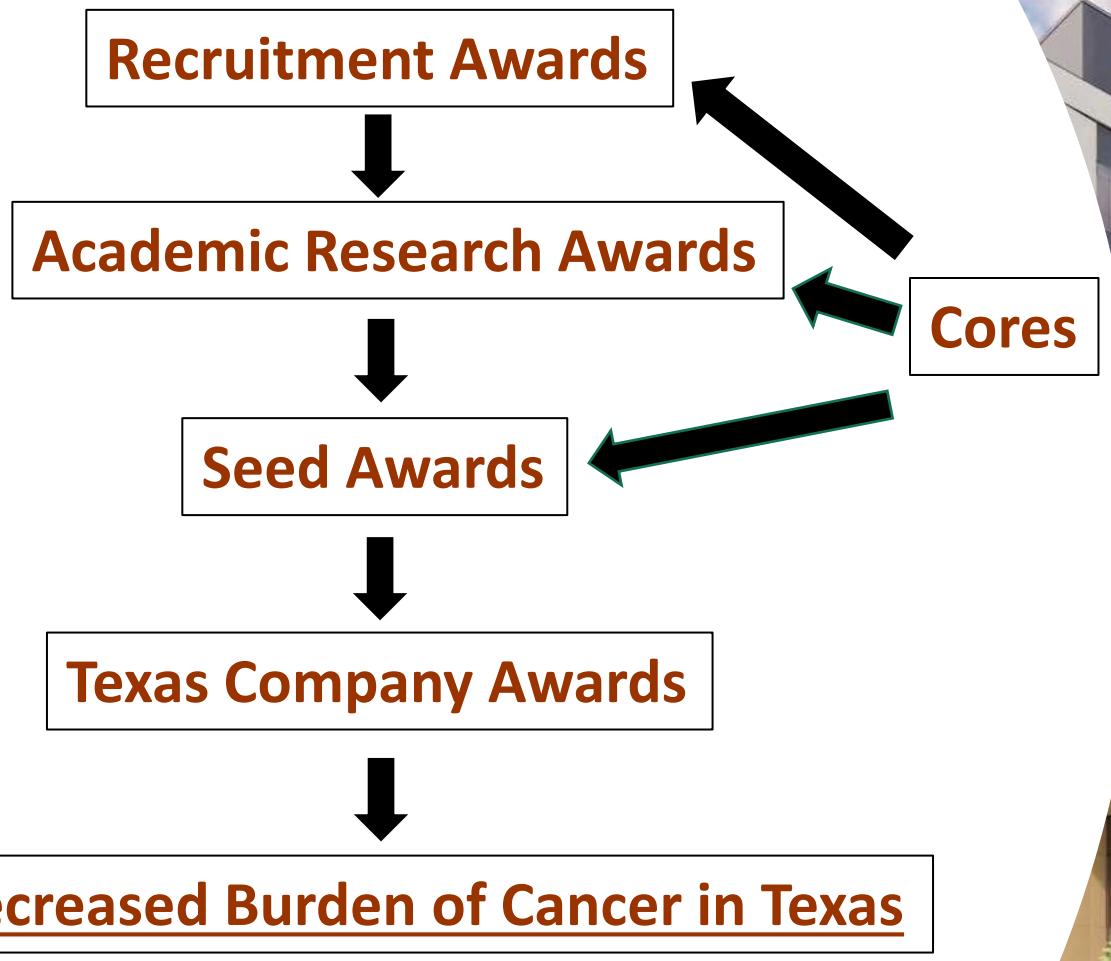
- **Good Manufacturing Practice synthesis of DT2216 to scale and IV Formulation**
  - *DT2216 not orally bioavailable and hydrophobic, formulated as a lipid nanoparticle for IV*
  - *Synthetic pathway optimized, 1 kG synthesized under GMP conditions*
- **Systematic PK/PD, Metabolism and Excretion studies**
  - *Half life after IV dose ~6-12 hrs, depending on species, longer in humans*
  - *Distributes to all tissues but CNS*
  - *Three liver metabolites excreted in urine, none toxic*
- **Dose finding and Good Laboratory Practice Toxicity Studies in two mammalian models**
  - *GLP rat and dog toxicity studies indicated that thrombocytopenia at hug doses was the only toxicity*
- **FDA IND submission**
  - *#IND151351 filed 1-19-21, approved 2-18-21*

Dialectic Therapeutics Texas Company Award Aims



- **Complete Phase 1 safety and dose finding trial (on-going)**
  - *Three sites: Mays Cancer Center, Northwestern and Mary Crawley*
  - *Currently on fourth dose level, 6 patients accrued, one patient had grade 3 DLT*
  - *PK demonstrates that current dose level can achieve 50-fold higher concentrations than are needed for tumor efficacy based on murine studies*
  - *PD demonstrates that we can degrade target in blood leukocytes*
  - *Should have recommended Phase 2 dose by November, 2022*
  - *FDA granted Fast Track 1-22-22, Orphan Drug designation 3-14-22*
- **Complete Phase 2 efficacy trial in T-cell lymphoma (future)**
  - *Accrue 132 pts, Primary End Point is Overall Response Rate (MSK lead)*
  - *Use BH3 profiling to predict patient responses*
  - *Perform simultaneous Phase 2 trials in Myelofibrosis (Dana-Farber lead) and pediatric fibrolamellar carcinoma (MSK lead)*

CPRIT awards build on each other



CPRIT Recruitment/Academic awards leads to new products

144 bed UTHSCSA Multispecialty Research Hospital under construction- Focusing on Cancer Clinical Trials

Can CPRIT be improved?

- **Should smaller recruitment grants be given in order to give more?**
  - *Recruits say they would have come for less funding*
  - *Permit roll over of funds because it can be hard to spend funds in one year (COVID, moving the lab, hiring is slow, equipment and supplies often back-ordered)*
- **Should there be a new category for the Valley of Death? To get to a Seed Award?**
  - *Medicinal chemistry is often limiting*
  - *Non-GLP PK/PD/Toxicity is not expensive and increases value*
  - *Help with spinning out companies (legal, taxes, business plans, HR) since TX VC small*
- **Should CPRIT hold a VC day in Austin for new drugs/diagnostics for all its grant holders?**
  - *Generate a wider audience than any one individual or institution*
- **Should the match for the new product awards be less than half or be a one time total?**
  - *The match means that the best drugs/diagnostics do not always get funded, but rather the ones with the best connections*
  - *Requiring the match in the bank in the later years decreases the pace of productivity*

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 6: CHIEF EXECUTIVE OFFICER REPORT
DATE:	AUGUST 8, 2022

The Chief Executive Officer Report presented at the August 17 Oversight Committee meeting will include the following items. In addition, attached behind this memo are copies of the June and July 2022 CPRIT Activity Updates for your reference.

FY 2022 Grant Awards Funds Available and CPRIT Dashboard (Attachments 1 and 2)

Today's awards include the final ones from FY 2022 appropriations. If the Oversight Committee approves the 21 awards at the recommended level of $89.3 million, we will close FY 2022 awards with a $3.5 million balance.

Also included is CPRIT's dashboard of metrics the agency tracks on a regular basis.

Personnel

CPRIT currently has 39 of our 44 full-time equivalent (FTE) positions filled.

We recently hired two new grant accountants. Tina Molander, who has worked as a contract employee, accepted the permanent position July 1 and Adela Saenz joined the team July 15.

Sharanya Vadiyala accepted the position of Program Statistician on July 25.

Somadina "Soma" Emenike will join CPRIT on August 24 as Information Security Officer. Mr. Emenike comes to us by way of Texas Tech University Health Sciences Center at Lubbock.

Special Oversight Committee Meetings

There will be a special Oversight Committee via videoconference at 9:00 a.m. on September 14, 2022.

I also expect that CPRIT will hold a special Oversight Committee meeting in late January 2023 to consider Texas Regional Excellence in Cancer (TREC) awards. Like the special meeting in September, we will likely hold the January 2023 meeting via a video conference.

Additional items will be discussed as warranted.

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

*****

CPRIT has awarded **1,776** grants totaling **$3.041 billion**

- 265 prevention awards totaling $313.5 million
- 1,511 academic research and product development research awards totaling $2.727 billion

Of the $2.727 billion in academic research and product development research awards,

- 29.2% of the funding ($795.2 million) supports clinical research projects
- 24.0% of the funding ($655.6 million) supports translational research projects
- 30.5% of funding ($831.6 million) supports recruitment awards
- 13.0% of the funding ($354.3 million) supports discovery stage research projects
- 3.3% of funding ($90.4 million) supports training programs.

CPRIT has 6 open Requests for Applications (RFAs)

- 2 Academic Research Recruitment
- 1 Academic Research
- 3 Prevention

FY 2022 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 27,659,031	$ 251,353,693		$ 20,987,276	$ 300,000,000
Appropriations Transfer to DSHS		$ (3,118,032)		$ 3,118,032	
Adjusted Appropriations	$ 27,659,031	$ 248,235,661		$ 24,105,308	$ 300,000,000
Total Available for All Grants			$ 275,894,692		
1% of Total Available Grant Funding			$ 2,758,947		
Adjusted Grant Award Funding	27,659,031	$ 245,476,714			$ 273,135,745

	Prevention Grants	Academic Research Grants	PD Research Grants			
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 27,659,031	$ 173,764,963	$ 74,470,698			$ 275,894,692
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	$ 27,659,031	$ 171,833,700	$ 73,643,014			$ 273,135,745
Announced Grant Awards						
Recruitment Awards (12)	$ -	$ 38,000,000	$ -			
Prevention Awards (7)	$ 13,189,929	$ -	$ -			
Product Development Research Awards (2)	$ -	$ -	$ 5,998,261			
ACR Individual Investigator Research Awards (42)	$ -	$ 42,812,071	$ -			
ACR IIRA-Focused Awards (17)	$ -	$ 26,769,097	$ -			
Recruitment Awards (6)	$ -	$ 23,999,382	$ -			
Recruitment Awards (17)	$ -	$ 47,998,029				
Announced Grant Award Subtotal	$ 13,189,929	$ 179,578,579	$ 5,998,261	$ -		$ 198,766,769
Grant Award Adjustments						
12/13/21 Declined Recruit (MDA-Delgoffe) 11/2021 Slate	$ -	$ (4,000,000)	$ -			$ (4,000,000)
2/17/22 Declined Recruit (UTD-Dai) 11/2021 Slate		$ (4,000,000)				$ (4,000,000)
3/14/22 Declined IIRA (BCM-Fuqua) 2/2022 Slate		$ (900,000)				$ (900,000)
3/21/22 Reduction to RP220492 for Overlap (UTSW-Morrison)		$ (524,418)				$ (524,418)
5/18/22 Declined Recruit (UT-Austin-Riley) 5/2022 Slate		$ (2,000,000)				$ (2,000,000)
5/25/22 Declined Recruit (MDA-Ramanan) 5/2022 Slate		$ (2,000,000)				$ (2,000,000)
5/31/22 Declined Recruit (UTSW-Miles) 5/2022 Slate		$ (2,000,000)				$ (2,000,000)
7/06/22 Reduction to RP220101 (MDA-Kadara)		$ (213,982)				$ (213,982)
7/12/22 Reduction to RP220480 (BCM-Wang)		$ (38,813)				$ (38,813)
Revised Grant Award Subtotal	$ 13,189,929	$ 163,901,366	$ 5,998,261			$ 183,089,556
Uncommitted Grant Funds as of July 13, 2022	$ 14,469,102	$ 7,932,334	$ 67,644,753			$ 90,046,189
Pending Grants-PIC Recommendations						
Prevention Awards (9)	$ 14,443,836	$ -	$ -			
Recruitment Awards (3)	$ -	$ 10,000,000	$ -			
PDR Awards (9)	$ -	$ -	$ 64,868,655			
Pending Award Subtotal	$ 14,443,836	$ 10,000,000	$ 64,868,655			$ 89,312,491
Total Pending Grant & Grant Funds Committed	$ 27,633,765	$ 173,901,366	$ 70,866,916			$ 272,402,047
Uncommitted Grant Funds	$ 25,266	$ (2,067,666)	$ 2,776,098			$ 733,698
Rebudget of Remaining PDR Funds to ACR		$ 2,067,666	$ (2,067,666)			
Revised Pending Grant & Grant Funds Committed	$ 27,633,765	$ 175,969,032	$ 70,866,916			$ 274,469,713
Total Uncommitted Funds as of August 18, 2022	$ 25,266	$ (0)	$ 708,432			$ 733,698
1% Grant Funding Buffer	$ -	$ 1,931,263	$ 827,684			$ 2,758,947
Total Uncommitted Funds	$ 25,266	$ 1,931,263	$ 1,536,116			$ 3,492,645

Operating Budget Detail		
Indirect Administration	$	4,928,381
Grant Review & Award Operations	$	16,058,895
Subtotal, CPRIT Operating Costs	$	20,987,276
Cancer Registry Operating Cost Transfer	$	3,118,032
Total, Operating Costs		24,105,308

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2022

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			12			76			17				105	
New Grant Contracts Signed	22	26	16	10	6	2	24	42	4	3	1		156	
New Grant Contracts In Negotiation			9			12			10				31	
Grant Reimbursements Processed (#)	126	162	156	129	133	189	176	145	182	170	95		1663	
Grant Reimbursements Processed ($)	$ 21,921,638	$ 28,164,298	$ 11,711,647	$ 17,758,038	$ 18,810,529	$ 22,750,016	$ 22,615,358	$ 13,764,043	$ 12,038,375	$ 21,573,811	$ 10,989,010		$ 202,096,762	
Revenue Sharing Payments Received	$ 2,341,908	$ 22,365	$ 6,579	$ 2,442	$ 25,645	$ 3,582	$ 114,600	$ 5,712	$ 161,825	$ 27,550	$ 11,246		$ 2,723,453	$ 7,663,071
Grants Awarded (#)/ Applications Rec'd (#)	18%	18%	18%	18%	18%	19%	19%	19%	19%	18%	18%			
Grantee Compliance Trainings	2	3	2	1	0	3	4	1	3	3	0		22	
Grantee Compliance Monitoring Visits	0	0	1	3	1	3	3	2	2	2	4		21	
Awards with Delinquent Reimbursement Submission (FSR)			0			1			2					
Awards with Delinquent Matching Funds Verification			2			6			4					
Awards with Delinquent Progress Report Submission			2			0			2					
MISSION														
Open RFAs	3	7	11	13	13	6	8	8	6	11	3			
Prevention Applications Received	16	0	0	0	0	16	0	0	0	0	0		32	935
Product Development Applications Received	0	0	0	0	34	0	0	0	0	0	0		34	644
Academic Research Applications Received	5	3	4	4	124	12	10	12	0	329	0		503	8,668
Help Desk Calls/Emails	113	116	77	94	159	138	95	137	163	124	119		1,335	
Number of Research Grants Announced (Annual)	0		12			65			17				94	
Recruited Scientists Contracted														263
Number of Product Development Grants Announced (Annual)			0			2			0				2	
Life Science Companies Recruited (in TX)													0	12
Number of Product Development Jobs Created & Maintained														738
Number of Prevention Grants Announced (Annual)			0			7			0				7	
Total Number of Education, Navigation and Training Services			147,482			149,504			153,879				450,865	
Total Number of Clinical Services			56,122			46,422			50,720				153,264	
Published Articles on CPRIT-Funded Projects (#)														
Clinical Studies (#)														202
Number of Patent Applications														
Number of Patents Resulting from Research														
TRANSPARENCY														
Total Website Hits (Sessions)	9,694	8,961	9,110	7,619	9,559	12,521	10,114	8,138	11,406	9,291	8,411			
Total Unique Visitors to Website (Users)	7,737	7,065	7,184	6,004	7,192	9,215	8,014	6,285	8,490	7,047	6,658			

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR MAY AND JUNE
DATE:	JULY 1, 2022

Topics in this memo address CPRIT activities in May and June, including recent milestones in our fight against cancer, a staffing summary, outreach efforts, and updates from Compliance, Programs, and Operations.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Earlier this spring, the Royal Society of Chemistry announced the election of Jeremiah Gassensmith, PhD, associate professor of chemistry and biochemistry at The University of Texas at Dallas, as a Royal Society of Chemistry Fellow. The Society, whose origins date back to 1841, is the world's oldest society of chemists, and recognizes leaders in the chemical sciences who have made exceptional contributions to the field and are committed to promoting the global value of chemistry. Dr. Gassensmith's work focuses on the intersection of organic and solid-state chemistry with emphasis on applications such as the development of new types of contrast agents for use in magnetic resonance imaging and precise methods to deliver therapeutic drugs. CPRIT awarded Dr. Gassensmith a $200,000 grant for his work studying radiation-induced release of chemotherapeutic agents in vivo (RP170752).

- Nanotechnology is increasingly important to developing new treatments for cancer, as well as for early detection, diagnosis, and cancer management using imaging. In April, the National Institutes of Health awarded a 5-year, $2.6 million T32 training grant to CPRIT Scholar Gang Bao, PhD., and CPRIT grantee Konstantin Sokolov, PhD. The grant supports training for future oncology professionals at Rice University and The University of Texas MD Anderson Cancer Center to translate nano-enabled cancer applications to the clinic.

  The grant is part of the NIH's Ruth L. Kirschstein program, which enables institutions to recruit trainees from groups historically underrepresented in health-related research. Both Rice and MD Anderson offer strong resources and institutional support, and mentors have a wide range of expertise in early cancer detection, molecular diagnosis, treatment and cancer management. Dr. Sokolov outlined the importance of the grant, explaining, "Nanotechnology offers new possibilities for cancer diagnosis and treatment that differ greatly from traditional methods, and it's important that we be ready to deploy them. That

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

takes training, and we feel there's no better way to do that than to draw upon the range of talent and experience at MD Anderson and Rice."

Rice University recruited Dr. Bao, the Foyt Family Professor of Bioengineering, to Texas in 2014 from the Georgia Institute of Technology and Emory University with $6 million Established Investigator recruitment award (RR140081). Since coming to Texas, Dr. Bao has received three more CPRIT grants (RP170721, RP210116, RP220518). Dr. Sokolov, a professor of imaging physics at The University of Texas MD Anderson Cancer Center received two CPRIT grants totaling (RP170314, RP200223).

- Advancements in cancer research and care have occurred at an impressive pace in the last decade. The premiere journal, *Nature Medicine*, dedicated its April 19 "Focus" issue to the question of how to harness and build on these advances. The microbiome is one such advance, and a plethora of microbiome-targeting therapies are now under investigation for cancer therapy, particularly in combination with immunotherapy. CPRIT grantee, Jennifer Wargo, MD (RP200574), a professor in the department of genomic medicine at The University of Texas MD Anderson Cancer Center, and colleagues outline the current state of microbiome research to prevent and treat cancer. They predict that microbial targeting could become a pillar of personalized cancer care in the future (Park EM et al., *Nature Medicine* 28:690-703, 2022).

- Foresight Diagnostics announced the appointment of CPRIT Scholar Christopher Flowers, MD, to its Scientific Advisory Board on April 27. Foresight Diagnostics is a privately held diagnostics company developing novel liquid biopsy testing platforms to detect minimal residual disease. Dr. Flowers is an internationally renowned oncologist specializing in treating B cell lymphoma and rare subtypes of lymphoma. He is also an expert in identifying and overcoming socioeconomic and cultural factors leading to cancer disparities in African Americans. Dr. Flowers currently serves as Chair and Professor of the Department of Lymphoma-Myeloma and co-Director of the Center's B Cell Lymphoma Moon Shot Program at The University of Texas MD Anderson Cancer Center. MD Anderson recruited Dr. Flowers from Emory University to Texas in 2019 with a $6 million CPRIT Established Investigator recruitment award (RR190079).

- OncoNano Medicine, Inc. announced June 1 that Kartik Krishnan, MD, PhD, will serve as the company's Chief Medical Officer. Dr. Krishnan will be responsible for formulating and leading all clinical development efforts and operations at OncoNano. Additionally, Dr. Krishnan will develop and implement the strategic clinical plans for OncoNano, including the creation of a medical affairs team, as the company further advances its clinical oncology development programs.

  Southlake-based OncoNano Medicine is developing a new class of products that utilize principles of molecular cooperativity in their design to exploit pH as a biomarker to diagnose and treat cancer with high specificity. OncoNano designs its interventions and product candidates to help patients across the continuum of cancer care. These include solid tumor therapeutics, agents for real-time image-guided surgery and a platform of immuno-oncology

therapeutics that activate and guide the body's immune system to target cancer. OncoNano's lead development candidate, pegsitacianine, is a novel fluorescent nanoprobe that is currently under study in Phase 2 clinical trials as a real-time surgical imaging agent for use in multiple cancer surgeries.

OncoNano received three CPRIT Product Development Research awards to develop ONM-100 to detect breast, head and neck, and skin cancers, including a $6 million award (DP140072) in 2014 and a $10 million award (DP200081) in 2020. The company also received a $15.4 million CPRIT Product Development Research award (DP190066) in 2019 to develop a novel T-cell activating cancer vaccine for solid tumors.

- *Houston Style Magazine*, *pulse!* (HBCU Library Alliance news source), and the *HBCU Advocate* featured Texas Southern University's Breast Cancer Screening and Prevention Center project (PP210049), directed by Dr. Veronica Ajewole, on June 2, June 7 and June 9, respectively.

- Immatics and Bristol Myers Squibb announced June 2 an expansion of their strategic alliance to pursue the development of multiple allogeneic off-the-shelf TCR-T and/or CAR-T programs. This cellular immunotherapy involves using T cells from donors' circulating blood. In the collaboration, Bristol Myers Squibb and Immatics will develop two programs owned by Bristol Myers Squibb, with both companies having the option to develop up to four additional programs each. The programs will utilize Immatics' proprietary gamma delta T cell-derived, allogeneic Adoptive Cell Therapy (ACT) platform, called ACTallo, and a suite of next-generation technologies developed by Bristol Myers Squibb.

  On June 7, Immatics announced a strategic research collaboration with Editas Medicine, a leading genome editing company, to combine gamma-delta T cell adoptive cell therapies and gene editing to develop cancer treatments.

  Immatics, based in Tuebingen, Germany and Houston, received a $19.6 million CPRIT Product Development Research award in 2015 (DP150029).

- Invectys, Inc., The University of Texas MD Anderson Cancer Center and the Cell Therapy Manufacturing Center (CTMC) - a joint venture between MD Anderson and National Resilience, Inc. – announced a strategic collaboration June 16 to jointly develop a reliable, compliant, and scalable process for human leukocyte antigen (HLA)-G targeted chimeric antigen receptor (CAR) T cell therapy for solid tumors. The alliance will combine the technology of Invectys with the cell therapy development and manufacturing capabilities of CTMC and MD Anderson's clinical trial knowledge. Invectys' technology acts on and removes HLA-G-expressing tumor cells, thereby lowering these immunosuppressive effects to reactivate the immune system of the patient.

  The Houston-based Invectys received a $14.2 million CPRIT Product Development Research grant in 2020 to fund the company's HLA-G CAR T program (DP200034).

Notable CPRIT-Supported Research Accomplishments

- Scientists recognize that the Schlafen 11 gene (SLFN11) encodes a DNA/RNA helicase that unwinds DNA for replication. SLFN11 guards cells against damage by blocking replication at stressed replication points, leading to cell death in the presence of damage, and sensitizing cancer cells to DNA-damaging agents. For these reasons, SLFN11 has emerged as a promising predictive biomarker of response to therapy for several drug classes including platinum and PARP inhibitors.

  Carl Gay, MD, PhD, a CPRIT Early Clinical Investigator and assistant professor at The University of Texas MD Anderson Cancer Center, led a study evaluating the detection of SLFN11 in circulating tumor cells (CTCs) as an alternative to tissue sampling. Using a novel assay that the team developed, 83% (53/64) of blood samples from 42 patients with small cell lung cancer (SCLC) had detectable CTCs, and 55% (29/53) had SLFN11-positive CTCs. Patients actively receiving platinum treatment showed the lowest number of CTCs and a significantly lower percentage of SLFN11-positive CTCs. Analysis from patients with longitudinal samples suggested that a decrease in CTC number and in SLFN11 expression correlated with clinical response.

  SCLC is an aggressive malignancy with no established predictive biomarkers to guide treatment selection. Thus, the ability to detect SLFN11 in CTCs from SCLC patients using a non-invasive blood test adds a valuable tool for longitudinal monitoring of response to therapy. CPRIT grant RP210159 supported this work, which the *British Journal of Cancer* published April 19 (Br J Cancer (2022), https://doi.org/10.1038/s41416-022-01811-9).

- Iterion Therapeutics, Inc., a venture-backed, clinical-stage biotechnology company developing novel cancer therapeutics, presented findings involving its research into tegavivint at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, held the first week of June in Chicago. The findings included initial results from a Phase 1 study of tegavivint in patients with desmoid sarcomas.

  Tegavivint is a potent and selective first-in-class small molecule inhibitor of Transducin Beta-like Protein One (TBL1), a novel downstream co-factor in the Wnt/beta-catenin signaling pathway. Increased expression beta-catenin and TBL1 are associated with metastasis and poor prognosis in a broad range of tumor types. Tegavivint's targeting of TBL1 prevents TBL1/beta-catenin complex formation, specifically inhibiting beta-catenin's oncogenic transcriptional activity without disrupting key cell membrane functions that scientists have linked to toxicity common to other drugs in this pathway.

  Iterion CEO Rahul Aras, PhD, explained the impact of these early findings, "The data presented at ASCO complements research presented earlier this year at AACR, which cumulatively demonstrate the safety, tolerability and clinical activity of tegavivint in the treatment of desmoid tumors. We are particularly excited to present these results at ASCO, the world's preeminent oncology conference, because the data also serve to highlight the potential of our ongoing tegavivint programs in AML, non-small cell lung cancer, and

pediatric solid tumors. These cancer indications, like desmoid tumors, are associated with nuclear beta-catenin overexpression, which has historically been considered undruggable. We believe tegavivint's unique mechanism of action provides an opportunity to selectively disrupt the interaction of beta-catenin and TBL1, which in turn, allows for the specific degradation of nuclear beta-catenin without impacting key cell membrane functions that have been linked to previously reported toxicity."

Houston-based Iterion received two CPRIT Product Development Research Award grants totaling $18.9 million to fund this work (CP130058 and DP220019).

- Researchers at the Dan L. Duncan Comprehensive Cancer Center at Baylor College of Medicine identified a combination therapy that holds promise for treating triple negative breast cancer (TNBC), an aggressive subtype of breast cancer that occurs more frequently in African American women with an overall poorer prognosis than other subtypes of breast cancer.

  In preclinical studies using a mouse model for TNBC, Dr. Jeffrey Rosen and collaborators found that a combination of drugs tackling the tumor on two fronts resulted in durable tumor regression. In previous studies, the investigators found that the chemotherapy drug cyclophosphamide eliminated tumor cells; however, the tumors eventually recurred infiltrated by immune cells, called macrophages. The investigators hypothesized that the macrophages supported the growth of the tumor cells and explored the possibility that eliminating both the tumor cells (using cyclophosphamide) and macrophage cells (using a small molecule inhibitor) would lead to tumor regression. Not only did the animals have a durable response, but they also had immune cells that were capable of eradicating new tumor growth. Importantly, the investigators identified a similar ‘macrophage signature’ in human TNBCs and are planning to conduct an early-phase clinical trial to assess the value of this treatment approach in patients.

  Several CPRIT grants supported this work, published in the June 15 volume of *Cancer Research* (82:2281-2297, 2022), including a training grant (RP160283) and four core facilities grants (RP 170668 Data Science and Informatics Core for Cancer Research), RP180672 Cytometry and Cell Sorting Core, RP150578 Combinatorial Drug Discovery Program, and RP170719 Integrated Microscopy Core).

Personnel

CPRIT has filled 39 of our 44 full-time equivalent positions.

CPRIT has two open job postings: Information Resources Manager (closing June 30) and Program Manager for Research and Prevention (closing July 11).

CPRIT Outreach

Texas-Israel Trade Delegation

As reported at the May 18 Oversight Committee meeting, Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies and I participated in a trade delegation to Israel sponsored by the Texas-Israel Alliance from April 29 through May 7. Our participation promoted CPRIT's Product Development Research Program to early-stage Israel cancer life science companies and major Israeli health-related academic institutions needing to establish a foothold in America.

Based on the number of follow-on meetings we have held since returning, it was a successful trip that established good relationships and potential partnerships. Some of the companies and organizations we have met with include Lavaa (May 25), Early (May 25), AION Labs (June 6), Rabin Medical Center (June 6), Dr. Amichay Meirovitz, Chief of Oncology, Soroka Medical Center (June 11), and Curesponse (June 20). We are planning a second follow-up meeting with the Rabin Medical Center that will include Dr. Le Beau.

Additionally, we are working to identify and coordinate with other entities and sources of investment funds in Texas that are investing in Israeli companies. For example, The Cancer Focus Fund recently invested in KAHR, an aMoon Ventures portfolio company.

Looking ahead, the Texas-Israel Alliance will host a healthcare innovation summit on November 14 on the Rice University campus in Houston. Tentative topics include the Advanced Research Projects Agency for Health (ARPA-H) and computational biology. Attendees will include the Israeli Consular General for the Southwest United States and AION Labs, with whom we have had continuing discussions about ways we can work together to promote companies in Texas, and perhaps co-invest in those companies. We hope that several additional companies and academic health centers from our May trade delegation will attend as well.

2022 BIO International Conference

Interim Chief Product Development Officer and Due Diligence Dr. Ken Smith and Ms. Davies represented CPRIT at the 2022 BIO International Convention in San Diego June 13 – 16. The BIO International Conference is the largest global event for the biotechnology industry, attracting over 15,000 biotechnology and pharma leaders for one week of intensive networking to discover new opportunities and promising partnerships. Attendees are innovators across the wide spectrum of life science, including drug discovery, biomanufacturing, genomics, nanotechnology, and cell therapy.

CPRIT joined with Texas Healthcare & Bioscience Institute (THBI) and the Office of the Governor's Office of Economic Development and Tourism to host the BioTexas Booth. The BioTexas delegation members epitomize the innovation happening in the Texas Life Science industry, with representatives from economic development corporations, life science companies, universities, research institutes, and other related partners in all parts of the state.

In addition to other networking opportunities, Dr. Smith and Ms. Davies held individual one-on-one meetings with more than 30 companies and entities interested in learning more about CPRIT product development program opportunities. Product Development Program Manager Dr. Abria Magee is following up with more information and scheduling additional meetings. CPRIT staff is also virtually introducing companies and research entities interested in partnering with Texas academic institutions or innovation centers.

Advanced Research Projects Agency for Health (ARPA-H)

Also reported previously, Ms. Davies, Deputy Executive Officer and General Counsel Kristen Doyle and I are members of a steering committee to coordinate state efforts to bring President Biden's proposed ARPA-H to Texas. This effort started in July 2021. In May, Congress appropriated $1 billion for ARPA-H and approved authorizing legislation June 22. We assisted in coordinating significant supporters in the Texas congressional delegation to demonstrate wide bipartisan support to bring this federal agency to Texas.

In late May Lyda Hill Holdings retained a Washington, D.C. based lobby firm, Akin Gump Strauss Hauer & Feld LLP, and the public relations firm of Highwater Strategies with Fort Worth and Washington offices, to strengthen and support the Texas effort to land ARPA-H in Texas. This additional professional assistance and presence in Washington D.C. significantly improves the odds that Texas' efforts will succeed. Additional support from other sources may also be forthcoming.

I traveled to Washington D.C. with former CPRIT Oversight Committee member Tom Luce June 27 – June 29 and others to meet with staff of the Texas legislative delegation to thank them for their support and discuss other strategies to increase the likelihood that Texas will be home to this groundbreaking initiative that will strengthen the state's growing life science bona fides.

We also met with Marvin Figueroa, Director of Intergovernmental and External Affairs of the US Department of Health and Human Services. Mr. Figueroa is a key senior staff member to Secretary Xavier Becerra. As with the congressional staff discussions, this visit also provided a significant opportunity to introduce CPRIT to individuals who had no familiarity with our agency. Mr. Figueroa was particularly interested in CPRIT especially after I mentioned that we are the second leading funder of cancer research and prevention in the world. He tentatively committed to visiting Texas to become better acquainted with our significant life science and health infrastructure assets.

Discussions and activities related to this initiative occur continuously. We will keep you advised as developments warrant.

Other Staff Outreach

Staff outreach activities during May and June include:

- CPRIT Chief Scientific Officer Dr. Michelle Le Beau serves as a member of the national Board of Directors for the American Cancer Society, and participated in a virtual quarterly Board meeting May 18 - 19, focusing on the Society's integrated strategic and financial plan for its mission of advocacy, discovery science, and patient support.

- On May 19 Dr. Smith, Dr. Magee, Ms. Davies, Ms. Doyle and I met with representatives of Insightec, an early-stage company interested in applying for a product development program award.

- Chief Operating Officer Heidi McConnell, Ms. Doyle and I briefed staff of the Senate Committee on Health and Human Services about CPRIT's award-making process and operations on May 23.

- Dr. Smith, Ms. Doyle, Ms. Davies, and Dr. Magee met with CPRIT Product Development Grantee, Hummingbird Biosciences on June 1. Hummingbird Biosciences presented data on their latest project.

- On June 1 Ms. Davies and I briefed the director of the Governor's Division of Economic Development and her staff on our Texas-Israel Alliance trade mission to Israel and discussed sharing material promoting the state in other outreach efforts to entice cancer-related companies to Texas.

- Ms. Davies, Ms. Doyle and Dr. Magee met with Parthenon Therapeutics on June 2 about product development program opportunities.

- On June 3, Dr. Smith, Dr. Magee and Ms. Doyle met with CPRIT product development grantee Invectys, Inc. The company discussed their latest project results and opportunities for future funding.

- Ms. Davies and I briefed the chief executive officer/president of the Texas Economic Development Corporation on June 8 regarding our Texas-Israel Alliance trade mission to Israel and discussed CPRIT's inclusion in similar delegations. The Governor may begin prioritizing life science company recruitment to Texas next year and interest in CPRIT's participation on future delegations should be high.

- On June 9 Dr. Peter Pisters, President of The University of Texas MD Anderson Cancer Center, hosted Dr. Le Beau for a tour of the facilities. Dr. Le Beau also participated in discussions regarding MD Anderson's cancer programs, strategic plan, community engagement and outreach, and cancer prevention programs.

- Ms. McConnell, Ms. Doyle and I briefed our new budget and policy liaison in the Governor's Office about CPRIT's award-making process and operations on June 9.

- On June 13, Ms. Doyle, Ms. McConnell and I updated new Senate Committee on Finance Chair Senator Joan Huffman about CPRIT's statewide activities as well as programs specifically benefitting her district.

- Dr. Magee visited the Texas Medical Center Innovation (TMC[i]) on June 13. She met with CPRIT Product Development grantees, Anovac, Inc. and Salarius Pharmaceuticals.

- As a member of the NCI Board of Scientific Advisors, Dr. Le Beau participated in a June 14-15 joint virtual meeting of the NCI's National Cancer Advisory Board and Board of Scientific Advisors to review new and renewal RFA concepts for NCI's research portfolio.

- Dr. Le Beau, Ms. McConnell, Ms. Doyle, Senior Program Manager for Academic Research Dr. Patty Moore and I met on June 15 with former state representative Patrick Rose and representatives of the Happy Lungs Project to discuss possible mutual interests and potential future application for CPRIT project funding. Mr. Rose was one of the original authors of CPRIT's enabling legislation and constitutional amendment in 2007.

- On June 20 I met with the governmental affairs staff of Baylor College of Medicine to discuss shared priorities for the 2023 legislative session.

- Ms. Davies, Ms. Doyle and I met with Dale Craymer, President of the Texas Taxpayers and Research Association and Tatianna Yale of the Texas Medical Center to discuss property tax issues encountered by a prospective drug manufacturing company wanting to operate in Houston. Specifically, unlike most states, pursuant to a constitutional provision, Texas includes inventory in the base calculations for business property taxes. This provision places Texas at a competitive disadvantage when competing with most other states in recruiting manufacturing and capital-intensive companies. The discussion focused on how other entities have addressed this issue as well as the likelihood of getting the constitutional provision modified.

- Ms. Doyle and I met on June 30 with Israeli Consulate General to the Southwest Livia Link-Raviv and the Director of the Texas-Israel Alliance Toba Hellerstein about additional ways to promote CPRIT to Israeli life science companies and research institutes and to initiate discussions for innovative collaborations.

Initial discussions with Lyda Hill Interests and the Texas Economic Development Corporation have started on CPRIT product development outreach efforts in Boston, Los Angeles, and perhaps London.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT has $1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of June 23, twelve entities had not filed four Academic Research reports, six Prevention reports, and eight Product Development reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 335 second-level reviews of grantee Financial Status Reports (FSRs) in May and June. Thirty-two FSRs (10%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of the grantees' independent audit reports and the resolution of issues named in these reports. A grantee who spends $750,000 or more in state awards in the grantee's fiscal year must undertake a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee sends the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, all grantees have submitted the required 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 requests more time by the due date and I approve the request.

Desk Reviews

Compliance specialists performed 12 enhanced desk-based financial monitoring reviews in May and June. Enhanced desk reviews verify that grantees spend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with two grantees to remediate enhanced desk review findings.

Onsite Reviews

CPRIT completed four virtual onsite reviews in May and June. Onsite reviews examine the grantees' financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with five grantees to remediate onsite review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Texas Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. As of June 23, one grantee has not submitted their annual Compliance Attestation. As a result, CPRIT will not disperse additional grant funds until CPRIT approves the submitted attestations. Also, as part of the annual attestation process, CPRIT requires Product Development grantees to submit documentation demonstrating compliance with the Texas Location Criteria. Compliance specialists are working with one grantee to submit the required documentation.

Training and Support

CPRIT staff conducted one new Authorized Signing Official (ASO) training with Asylia Therapeutics. 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, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

CPRIT staff conducted one new Grantee training webinar in May and June for the Texas Health Institute. 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, CPRIT requires new grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

CPRIT staff conducted a series of Annual Compliance Training webinars over June 7-9 for 134 grantee staff. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the second training series offered this year for the annual compliance training requirement, which requires the Authorized Signing Official and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

Match Expenditures Review

CPRIT requires academic research and product development research grantees to show that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as "CPRIT's matching funds requirement," requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT's statute allows an institution of higher education to use its federal indirect cost rate as a credit toward the required 50% match.

Product development grantees and those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed one annual match expenditure review in May and June. The total amount of match expenses reviewed by compliance staff for FY 2022 is $6,041,856.39.

Academic Research Program Update

In my June 22 memo, I explained that CPRIT has committed its allocated budget for the FY 2022 Academic Research Program grant cycle due to an unprecedented number of awards approved in February and May. We attribute the unprecedented increase this year largely to the expansion of activities at academic and research institutions after two years of pandemic-related exigencies and, to a lesser degree, to the expansion of targeted RFAs offered by CPRIT.

CPRIT stopped accepting FY 2022 recruitment applications in May and will defer recommending the second cycle of FY 2022 Academic Research Program awards until September. Moving some FY 2022 awards into the next fiscal year reduces funds available for new awards in 2023. To address this, CPRIT plans to limit recruitment and research grant awards and not to release RFAs for some grant mechanisms in FY 2023. CPRIT hopes to resume funding all Academic Research Program grant award mechanisms at historical levels in FY 2024.

FY 2022 and FY 2023 Recruitment Applications

As noted, CPRIT stopped accepting FY 2022 recruitment applications. CPRIT released the FY 2023 recruitment RFAs June 14, with review of applications beginning in September. CPRIT limits the FY 2023 recruitment awards to Established Investigator and First Time-Tenure Track faculty grants and imposes institutional limits on the number of recruitment applications submitted. With both measures in place, CPRIT expects to award fewer FY 2023 recruitment grants.

Academic Research FY 2022 Review Cycle 2 (22.2)

CPRIT released four RFAs for review cycle 22.2 on August 30, 2021. The application portal opened October 13, 2021. CPRIT received 120 applications by the January 12 deadline. Peer review panels met April 26 through May 5. However, because the potential amount of the cycle 22.2 award recommendations would likely far exceed the amount available for academic research awards in FY 2022, the Scientific Review Council (SRC) will defer recommending cycle 22.2 awards until September. Dr. Le Beau will present the SRC's recommendations to the Oversight Committee at its special meeting September 14.

Cycle 22.2 Mechanism	Received	Funds Requested
Core Facility Support Awards	23	$87,087,114
Clinical Trial Network Award	2	$6,000,000
Early Clinical Investigator Award	6	$8,726,495
High Impact/High Risk Research Awards	89	$22,122,480
TOTAL	**120**	**$123,936,089**

Academic Research FY 2023 Review Cycle 1 (23.1)

CPRIT released several RFAs for the first cycle of FY 2023 (23.1) in January and began accepting applications for targeted and untargeted Individual Investigator Research Awards in March through June 8. Dr. Le Beau will present the cycle 23.1 grant recommendations to the PIC and the Oversight Committee in February 2023. We expect to award fewer targeted and untargeted individual investigator awards in the 23.1 cycle due to limited funds available for new grants for the remainder of FY 2023 cycle and the carryover of cycle 22.2 grants into FY 2023.

CPRIT opened the portal May 16 to receive Texas Regional Excellence in Cancer Awards (TREC) applications through September 8. Dr. Le Beau will present the TREC award recommendations to the PIC and Oversight Committee at a proposed special Oversight Committee meeting in January 2023.

Cycle 23.1 RFA Mechanism	Applications	Requested Funding
Individual Investigator Research Awards	235	$241,561,941
Individual Investigator Research Awards for Cancer in Children and Adolescents	30	$42,048,859
Individual Investigator Research Awards for Clinical Translation	19	$35,897,103
Individual Investigator Research Awards for Computational Systems Biology of Cancer	23	$26,041,589
Individual Investigator Research Awards for Prevention and Early Detection	22	$36,681,588
Total	**329**	**$382,231,080**

CPRIT does not plan to offer a second cycle of grant awards in FY 2023. CPRIT will closely monitor the situation and discuss other potential options with CPRIT stakeholders and the

Oversight Committee as they develop. CPRIT remains committed to all award mechanisms and hopes to resume all at historical levels beginning in FY 2024.

Product Development Research Program Update

Product Development Research FY 2022 Cycle 2 (22.2)

CPRIT released three product development RFAs in October 2021 for the second review cycle of FY 2022. CPRIT opened the application portal on December 1, 2021, and received 34 proposals by the January 26 deadline. Peer review panels met March 21 – 22 and selected 15 companies to present proposed projects live via Zoom April 11 - 14. Following company presentations, the review panels selected 11 companies to move into due diligence review by the Product Development Review Council (PDRC). The Product Development Review Council (PDRC) will meet in July to review the due diligence reports and make final award recommendations for FY 2022 awards.

Interim Chief Product Development and Due Diligence Officer Dr. Ken Smith will present the PDRC's grant recommendations for cycle 22.2 to the PIC and the Oversight Committee in August. Because the number of potential awards may exceed the amount of funding available for product development grants in FY 2022, the PDRC may defer making some award recommendations until September. If that is the case, Dr. Smith will present the delayed award recommendations at the special Oversight Committee September 14 for approval.

Cycle 22.2 Mechanism	Applications Received	Funds Requested	Presenting	Funds Requested	Due Diligence	Funds Requested
Texas Company	10	$118,319,140	7	$86,183,386	5	$70,273,519
Relocation Company	8	$86,095,315	1	$14,268,200	1	$14,268,200
Seed Company	16	$41,832,547	7	$19,486,736	5	$13,486,736
TOTAL	**34**	**$246,247,002**	**15**	**$119,938,222**	**11**	**$98,028,455**

Product Development FY 2023 Review Cycle

At its May 18 meeting, the Oversight Committee approved five* FY 2023 requests for applications (RFAs) for the Product Development Research program. The FY 2023 RFAs included changes to the product development application and review process for the FY 2023 review cycle. The most notable change is the use of a preliminary application and review process to provide applicants with a faster indication of whether the company's proposed cancer research and development project demonstrates sufficient scientific merit and a compelling premise to warrant submitting a full application.

The Texas Comptroller's Office is currently reviewing the proposed Product Development RFAs. We will release the RFAs after the Comptroller's review. We have received no questions or feedback from the reviewers. It is likely that we will receive some response in July. Until we

can post the RFAs, we are providing summaries of the four FY 2023 RFAs and answer some FAQs regarding the changes to the FY 2023 review process on the product development landing page.

We plan to open the portal to receive preliminary applications in August. The first deadline for full applications will be November 1, 2022, with award recommendations scheduled for February 2023.

* After internal discussion and with the PDRC, we elected to offer a "FY 2023 Texas Devices and Diagnostics Company" RFA instead of separate RFAs for device companies and diagnostic companies.

Prevention Program Update

Prevention FY 2022 Review Cycle 2 (22.2)

The Prevention Program released three RFAs on October 19, 2021. CPRIT opened the application portal November 15, 2021, to receive proposals through the February 9 deadline for the second cycle of FY 2022 awards. Peer review panels met by teleconference April 25 - 26. The PRC met June 3 to finalize recommendations. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in August.

Cycle 22.2 Mechanism	Applications	Funds Requested
Evidence-based Cancer Prevention Services	9	$ 8,978,733
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	4	$9,479,601
Tobacco Control and Lung Cancer Screening	3	$2,999,861
TOTAL	**16**	**$21,458,195**

Prevention FY 2023 Review Cycle 1 (23.1)

CPRIT released three RFAs (listed below) on June 2 for the first cycle of FY 2023. Applicants must submit proposals by August 31. CPRIT has scheduled peer review for December 2022. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in February 2023.

- Dissemination of CPRIT-Funded Cancer Control Interventions RFA

  This award mechanism funds 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 able 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: $450,000
Maximum duration: 36 months

- Primary Prevention of Cancer RFA

  This award mechanism funds multilevel interventions to reduce cancer risk, disease burden, and cancer disparities. CPRIT wants to increase the implementation of evidence-based strategies to ensure that all Texans benefit from the cancer prevention knowledge that we currently have. Modifiable risk behaviors include tobacco use, obesity, physical inactivity, unhealthy eating, alcohol use, sun exposure, HPV vaccination, Hepatitis B vaccination, and environmental/occupational cancer exposures. Applications should also assess and address social determinants that contribute to cancer burden and disparities (e.g., cultural factors, unmet needs, access barriers) and structure interventions to address the unique circumstances of the population the project will served.

  Award maximum: $1million for new projects and $2.5 million for expansion projects
  Maximum duration: 60 months

- Cancer Screening and Early Detection RFA

  This award mechanism funds the delivery of evidence-based clinical services to screen for cancer and pre-cancer in underserved populations who do not have adequate access to cancer early detection 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, have nationally recommended screening methods, and use evidence-based methods to screen for these cancers.

  Award maximum: $1 million for new projects and $2.5 million for expansion projects
  Maximum duration: 60 months

Advisory Committee Meetings

- The Geographic Diversity Advisory Committee met May 6 and June 3.
- The Prevention Advisory Committee met May 19
- The University Advisory Committee met June 13.
- The Clinical Trials Advisory Committee met June 24.
- The Advisory Committee on Childhood Cancer met June 27.

Operations, Audit and Finance Update

CPRIT's internal auditor (Weaver) is conducting field work on the vendor contract compliance audit and is initiating the follow-up procedures related to the outstanding findings on IT issues.

Earlier this year, CPRIT issued a 2023 conference venue request for proposals (RFP), which was open to all regions in Texas. CPRIT staff, including Heidi McConnell, Ramona Magid, and Mark Loeffler, and CPRIT's conference planner Deb Swift of Swift Solutions completed evaluations of the submitted proposals. At the August Oversight Committee meeting, staff will present its recommendation to use the Moody Gardens Hotel, Spa and Convention Center on Galveston Island for the CPRIT's Innovations Conference venue on October 1-3, 2023. We plan to use Sunday, October 1, to set up all the meeting rooms, grantee poster display area, and audiovisual equipment, with the conference opening to attendees on October 2.

CPRIT submitted its Strategic Plan for Fiscal Years 2023 to 2027 to the Governor, Legislative Budget Board (LBB), and other required legislative offices on May 31. The finance staff is working with LBB to finalize the agency's budget base reconciliation for the 2022-23 biennium. The Governor's Office and LBB have not yet issued instructions for agencies to complete their Legislative Appropriations Requests for the 2024-25 biennium.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the August 17 Oversight Committee meeting. We will send instructions for signing onto the Zoom platform along with the subcommittee agenda and meeting materials one week prior to the meeting.

Board Governance	August 4 at 10:00 a.m.
Audit	August 8 at 10:00 a.m.
Prevention	August 9 at 10:00 a.m.
Academic Research	August 10 at 10:00 a.m.
Product Development	August 11 at 10:00 a.m.

******

CPRIT has awarded **1,776** grants totaling **$3.041 billion**

- 265 prevention awards totaling $313.5 million
- 1,511 academic research and product development research awards totaling $2.727 billion

Of the $2.727 billion in academic research and product development research awards,

- 29.6% of the funding ($795.2 million) supports clinical research projects
- 24.0% of the funding ($655.6 million) supports translational research projects
- 30.5% of funding ($831.6 million) supports recruitment awards
- 13.0% of the funding ($354.3 million) supports discovery stage research projects
- 3.3% of funding ($90.4 million) supports training programs.

CPRIT has 6 open Requests for Applications (RFAs)

- 2 Research Recruitment
- 1 Academic Research
- 3 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR JULY 2022
DATE:	AUGUST 1, 2022

Topics in this memo address preparation for the upcoming August 17 Oversight Committee meeting and CPRIT activities in July, including recent milestones in our fight against cancer, a staffing summary, outreach efforts, and updates from Compliance, Programs, and Operations.

Planning for the August 17 Oversight Committee Meeting

The Oversight Committee will meet in person on Wednesday, August 17, in the Texas Capitol Extension. We will have a full agenda with grant award recommendations as well as an annual report from the Clinical Trials advisory committees. Please notify me as soon as possible if you are unable to attend the August 17 meeting or have schedule constraints that require you to arrive at the meeting after 9:00 a.m. or leave prior to 12:30 p.m.

You will receive an email from CPRIT by August 5 with a link and password to access the Program Integration Committee's award recommendations via the grant award portal. The portal has a summary of the award slates, as well as supporting documentation for each proposed award, including the application, CEO affidavit, summary statement, and grant pedigree. Please allow time to complete the individual conflict of interest checks and review the supporting material.

Attached is a draft meeting agenda. CPRIT will post the final agenda for the Oversight Committee meeting by August 9. Oversight Committee members will receive an electronic copy of the agenda packet by August 10. Hard copies of the agenda and proposed award packet will be available at the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- The Voelcker Fund announced June 14 that Masahiro Morita, PhD, Assistant Professor in the Department of Molecular Medicine at The University of Texas Health Science Center at San Antonio, received its prestigious Young Investigator Award for his work investigating the link between obesity and increased risk of developing hepatocellular carcinoma. The $450,000 three-year award will support research into his hypothesis that overnutrition leads

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

to dysregulation of protein synthesis, excessive energy production by mitochondria, cellular stress and, ultimately, chronic inflammation. Dr. Morita's long-term goals are to translate novel findings from this project to develop new therapeutic strategies for obesity-associated liver cancer. He received a $1 million CPRIT grant in February to study organelle communication during transition from fatty liver to hepatocellular carcinoma (RP220267).

- On June 27, the Lung Cancer Research Foundation announced the appointment of CPRIT Scholar Kathryn O'Donnell, PhD, Associate Professor in the Department of Molecular Biology, The University of Texas Southwestern Medical Center, to its Scientific Advisory Board. Dr. O'Donnell's work focuses on understanding the mechanisms that contribute to lung cancer initiation, progression, and metastasis, and applying these insights toward the development of new therapies for lung cancer. The Lung Cancer Research Foundation is a leading non-profit organization focused on funding innovative research to improve outcomes for people with lung cancer. UT Southwestern recruited Dr. O'Donnell from Johns Hopkins University in 2010 with a $2 million First-Time, Tenure-Track recruitment award (RR1101). Since coming to Texas, Dr. O'Donnell has received more than $3 million in additional CPRIT research awards (RP150676, RP190610, RP200327).

- The University of Texas at Austin Dell Medical School's June 28 online newsletter featured CPRIT-funded prevention projects directed by Dr. Michael Pignone and Dr. Elizabeth Kvale. Dr. Pignone leads the colorectal and lung cancer screening and alcohol use programs (PP200066, PP170082 and PP200036) and Dr. Kvale directs the breast cancer screening project (PP200034).

- On July 5 Aravive Biologics, Inc., a late clinical-stage oncology company developing targeted therapeutics to treat metastatic diseases, announced the appointment of Dr. Robert Gellar as Chief Medical Officer. Dr. Geller is a medical oncologist with 30 years of drug development experience. Dr. Geller has authored over 200 publications and abstracts and has served as reviewer for numerous medical journals. The Houston-based company received a $20 million Product Development Research Award (DP150127) in 2015 to develop targeted therapies against acute myeloid lymphoma and certain solid tumor indications including ovarian, pancreatic, and breast cancer.

- KPRC TV (Houston) interviewed CPRIT Scholar Natalia V. Kirienko, PhD, Associate Professor of Biosciences at Rice University, on July 12 about her groundbreaking discovery of potential new drugs that target the mitochondria, the energy-producing powerhouse of cells. In collaboration with Marina Konopleva, MD, a renowned physician scientist and leukemia specialist at The University of Texas MD Anderson Cancer Center, the investigators demonstrated that these compounds were highly toxic to acute myeloid leukemia cells as a sole treatment and worked synergistically to increase the efficacy of existing chemotherapy drugs like doxorubicin.

  The work, published June 7 in the journal *Leukemia*, reports how leukemia cells hijack the normal cellular processes to ramp-up energy and metabolite production to fuel their rapid growth and, thus, mitochondria-weakening drugs might impair leukemia cells, making them

more susceptible to chemotherapy. Rice recruited Dr. Kirienko to Houston from Massachusetts General Hospital and Harvard Medical School in 2015 with a $2 million First-Time, Tenure-Track recruitment award (RR150044).

- *U.S. News & World Report* "Best Hospitals for Cancer" edition ranked four Texas cancer centers among the top 35 cancer centers in the 2022-2023 rankings released July 26. The University of Texas MD Anderson Cancer Center retained its distinction as the No. 1 adult cancer hospital in the country. The University of Texas Southwestern Medical Center (25), Houston Methodist Hospital (29), and the Dan Duncan Comprehensive Cancer Center at Baylor St Luke's Medical Center (35) all ranked among the top 35 cancer centers. The rankings reflect patient outcomes measurements, patient satisfaction, the availability of advanced technologies, nursing quality, specialty-specific certifications, services for patients and their families and expert opinions of specialists in the field.

Notable CPRIT-Supported Research Accomplishments

- Genome editing using the Nobel Prize winning CRISPR/Cas9 technology holds great promise for more effective treatment of cancer and other diseases due to its ability to inactivate, or repair, rogue cancer-causing genes. However, as they grow, many solid tumors surround themselves with a thick (fibrous), hard-to-penetrate wall of cellular proteins, and getting drugs past that stiff barricade is difficult. One approach to delivering drugs is based on the use of nanoparticles, ultrafine materials between 1-100 nanometers in diameter. Despite its promise, nanotechnology faces challenges, including gaining entry to the target tissues.

  CPRIT Scholar Daniel Siegwart, PhD, Associate Professor of Biochemistry at The University of Texas Southwestern Medical Center and the Simmons Comprehensive Cancer Center is a recognized expert for overcoming major hurdles using nanoparticles, having previously shown how to direct nanoparticles to specific tissues in the body.

  As reported May 12 in *Nature Nanotechnology*, Dr. Siegwart led a research team seeking to tackle another challenge – delivering the nanoparticles to tumors surrounded by a protective barrier wall (Nat Nanotechnol 2022 May 12. doi: 10.1038/s41565-022-01122-3). Using an ingenious approach, the researchers designed lipid nanoparticles – small spheres of fatty molecules that can carry the necessary molecular payload required for gene editing, namely a nucleic acid sequence to target the gene of interest, and the enzyme needed to cleave the DNA at its target.

  They began with nanoparticles optimized to travel to the liver and incorporated a small piece of RNA (called short interfering RNA) designed to shut-off a protein – focal adhesion kinase, or FAK– involved in mediating the adhesion of cells to each other and to their surroundings. By reducing the levels of FAK, the investigators not only weakened the structure of the extracellular matrix, making it easier for the nanoparticles to enter the tumor tissue, but they also created the route for immune cells to infiltrate the tumor. Embedded within the engineered nanoparticles was the encapsulated CRISPR/Cas9 molecular machinery to edit

the PD-L1 gene. Many cancer cells use PD-L1 to regulate, or "put the brakes on," the immune system's ability to attack tumors. Disrupting the PD-L1 gene can lift the brakes and enable a patient's immune system to eradicate cancer cells.

The research team tested the new nanoparticles with four mouse models of ovarian and liver cancer, demonstrating that by weakening the stiff matrix around the tumors, more nanoparticles reached the cells, effectively disabling the PD-L1 gene, activating the immune system, and leading to significantly smaller tumors. While researchers must do more work to show the safety and efficacy of the nanoparticles in a variety of tumors, this technology holds promise, particularly in conjunction with existing cancer therapies that harness the immune system to fight cancer.

UT Southwestern recruited Dr. Siegwart to Dallas from the Massachusetts Institute of Technology in 2012 with a $2 million First-Time, Tenure-Track recruitment award (R1212). Dr. Siegwart also received a $900,000 CPRIT grant (RP19025)1 to support this work.

- Physicians and scientists have long held the belief that all invasive breast cancers following ductal carcinoma in situ (DCIS) arise from the original DCIS precursor lesion. Researchers from The University of Texas MD Anderson Cancer Center, led by CPRIT Scholar and Chair of Genomic Medicine, Andy Futreal, PhD and CPRIT grantee Nicholas Navin, PhD, Professor of Genetics, and Bioinformatics and Computational Biology, directed the US team of the global Cancer Grand Challenges PRECISION study that interrogated whether subsequent invasive breast cancers are, in fact, connected to the original DCIS. Answering this question is important because distinguishing between low-risk and high-risk DCIS helps clinicians avoid overtreatment.

  The scientific community considers this question a global challenge because relatively few women with DCIS later develop invasive cancer. Assembling the required expertise and pooling paired biospecimens from the initial DCIS and subsequent invasive cancer developing in the same breast required worldwide effort.

  Using the technologies provided by the CPRIT-supported Integrated Single Cell Genomics Core Facility led by Dr. Navin, the researchers performed genomic sequencing on all samples, including single-cell sequencing on a subset of samples, to compare the mutations and genomic alterations between DCIS and invasive breast cancers. The results revealed that 75% of paired samples were indeed related, meaning they shared the same genetic profile, and the invasive cancer developed from the DCIS lesion. Surprisingly, 18% of the paired samples were unrelated, indicating that the two cancers developed independently. Researchers were unable to clarify the relationship between the DCIS and the invasive cancers in 7% of the results.

  The findings provide a deeper understanding of the biology of DCIS and may explain why researchers have been unable to identify biomarkers that could accurately predict the risk of DCIS recurrence as invasive cancer. This new information provides a starting point to identify better predictive tests to determine which DCIS lesions are most likely to progress to

invasive cancer, changing the way clinicians treat patients in the future. The June 9 edition of *Nature Genetics* reported the study results 54:850-860, 2022. MD Anderson recruited Dr. Futreal to Houston from the Wellcome Trust Sanger Institute in 2011 with a $7 million Established Investigators recruitment award (R1205). MD Anderson established the Integrated Single Cell Genomics Core in 2018 with an $4.9 million award from CPRIT (RP180684).

- A simple, non-invasive blood test may soon predict the risk of developing liver cancer. Texas has the highest age-adjusted incidence of liver cancer in the US with a disproportionately high risk in Hispanics. Historically, hepatitis B and alcoholic liver disease were associated with a high risk of developing hepatocellular carcinoma (HCC) but, today, non-alcoholic fatty liver disease (NAFLD) represents the major risk factor. Now, scientists at The University of Texas Southwestern Medical Center have developed a blood test to predict which NAFLD patients are most likely to develop liver cancer.

  An estimated one-quarter of adults in the US have NAFLD; with the increasing incidence of obesity and diabetes, scientists expect the incidence of NAFLD to grow. NAFLD is an excess of fat in liver cells that can cause chronic inflammation and liver damage – creating a permissive environment for the development of liver cancer. For NAFLD patients considered to be most at risk for liver cancer, doctors recommend a demanding screening program involving imaging the liver by ultrasound every six months. However, pinpointing which patients fall into this group is challenging, and typically involves multiple liver biopsies.

  Led by CPRIT Scholar Yujin Hoshida, MD, PhD, Associate Professor of Internal Medicine, Division of Digestive and Liver Diseases, the research team examined previously stored blood samples from NAFLD patients and identified a set of 133 genes expressed at higher or lower levels in the livers of patients who went on to develop liver cancer over a 15-year follow-up period. The team was able to sort patients into high-risk vs. low-risk groups with a high degree of accuracy, identifying which patients clinicians do not need to follow closely.

  In accordance with known risk factors for liver cancer, most of these genes and proteins predictive of HCC risk were immune and inflammatory molecules. To develop a clinical assay, the investigators converted the gene panel into a test of levels of four secreted proteins measured in blood samples for easier risk assessment and validated this test in an independent cohort of patients with NAFLD or cirrhosis. In addition to providing a much-needed risk-prediction assay, this simple blood test will be valuable in evaluating medical interventions, such as chemoprevention approaches, to reduce liver cancer risk.

  The June 22 volume of *Science Translational Medicine* 14:650, 2022 reported this work. UT Southwestern recruited Dr. Hoshida to Texas from the Icahn School of Medicine at Mount Sinai in 2018 with a $4 million Rising Star recruitment award (RR180016). Another CPRIT Scholar, Dr. Zhenyu Zhong, also recruited to UT Southwestern in 2018 from UC San Diego (RR180014) contributed to the study, as did CPRIT grantee Dr. Shuang Liang (RP200197).

- Pediatric patients with diffuse intrinsic pontine glioma (DIPG) have a poor prognosis with a median survival of less than one year. Scientists have evaluated oncolytic viral therapy in patients with pediatric gliomas elsewhere in the brain but lack data regarding oncolytic viral therapy in patients with DIPG.

  The June 30 edition of the *New England Journal of Medicine* published study results from the phase 1 dose-escalation clinical trial of DNAtrix, Inc.'s oncolytic adenovirus (DNX-2401) in a small cohort of 12 pediatric patients (age 3 – 18) with DIPG. The patients received a single virus infusion through a catheter placed in the cerebellar peduncle, followed by radiotherapy. DNX-2401 appeared safe and feasible, and over a median follow-up of 17.8 months, results showed that nine patients experienced a reduction in tumor size, three patients had a partial response and eight patients had stable disease. Two patients remained alive at last follow-up, with one patient free of tumor progression at 38 months.

  The Houston and California-based company received a $10.8 million Company Commercialization grant (CP130013) in 2014 to develop modified cold viruses to treat aggressive brain cancers. DNAtrix's lead program, DNX-2401 (formerly Delta-24-RGD), is an oncolytic immunotherapy engineered specifically to infect, replicate in, and directly kill cancer cells, as well as elicit a broad anti-tumor immune response. Scientists are currently evaluating DNX-2401 as a potential treatment for highly aggressive brain tumors, including glioblastoma in adults and DIPG in children. The FDA has granted DNX-2401 Fast Track and Orphan designation for recurrent glioblastoma and Fast Track & Rare Pediatric Disease designations for DIPG.

Personnel

CPRIT has filled 39 of our 44 full-time equivalent positions.

CPRIT hired two grant accountants and a program statistician. Dr. Ken Smith accepted the position of Chief Product Development Officer. He previously served as Interim Chief Product Development Officer.

CPRIT has three positions in progress: Information Resources Manager, Information Security Officer, and Program Manager for Research and Prevention.

CPRIT expects to post two positions in August: Digital Communications Specialist and Product Development Program assistant.

CPRIT Outreach

The 2022 CPRIT/Carson Leslie Foundation Researchers' RoundUp

CPRIT, the Carson Leslie Foundation, and Lyda Hill Philanthropies hosted the second annual "Researchers' RoundUp" conference July 24 – 26 at Pegasus Park in Dallas. The three-day event assembled childhood and adolescent/young adult cancer researchers from across Texas to discuss current research activities and trends in the fight against the deadliest disease faced by children in the US. The first Researchers' RoundUp convened January 2020, but COVID-19 protocols prevented the in-person conference from resuming until this summer.

A highlight of the three-day event was the ceremony honoring Senator Jane Nelson with the Carson Leslie Foundation's "Helping Kids Fight Cancer" award. The award recognizes her unparalleled commitment to children with cancer and their families throughout Texas. Senator Nelson authored the legislation that created CPRIT in 2007 and reauthorized it in 2019. She served as chair of two powerful Senate committees responsible for overseeing and funding Texas' fight against cancer. With Senator Nelson's support, 12% of CPRIT's research portfolio funds childhood cancer research project, three times the amount of NCI funding (on a comparative basis.)

Both Chief Scientific Officer Dr. Michelle Le Beau and I spoke at the conference. Several CPRIT representatives also attended, including Oversight Committee Presiding Officer Dr. Mahendra Patel, Deputy Executive Officer and General Counsel Kristen Doyle, Director of Academic Research Dr. Patty Moore, and Program Manager for Product Development Dr. Abria Magee.

The Researchers' RoundUp serves as a model for smaller, impactful meetings of CPRIT-funded researchers from across the state that address not only their ongoing work but also allow for future collaborations. Dr. Le Beau and Dr. Moore worked closely with the Advisory Committee on Childhood Cancer to develop the agenda. Annette Leslie, co-founder of the Carson Leslie Foundation, was instrumental in securing the space and handling all logistics, from meals to entertainment, to ensure a seamless, productive event.

Texas-Israel Trade Delegation

As reported at the May 18 Oversight Committee meeting, Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies and I participated in a trade delegation trip to Israel sponsored by the Texas-Israel Alliance in late April/early May. Our participation promoted CPRIT's Product Development Research Program to early-stage Israel cancer life science companies and major Israeli health-related academic institutions interested in establishing a US presence.

Following our trip, CPRIT has introduced several companies to the various life science centers in the state and we have been working with multiple NCI-designated cancer centers to facilitate various academic and research collaborations. Additionally, Ms. Doyle and I met with the Israeli

Consul General Secretary on June 30 to discuss further the potential relationships and synergies between Texas' companies and research centers. We anticipate this relationship continuing to grow and strengthen over time.

The Texas-Israel Alliance will host a healthcare innovation summit on November 14 on the Rice University campus in Houston. Tentative topics include the Advanced Research Projects Agency for Health (ARPA-H) and computational biology. Attendees will include the Israeli Consular General for the Southwest United States and AION Labs, with whom we have had continuing discussions about ways we can work together to promote companies in Texas, and perhaps co-invest in those companies. We hope that several additional companies and academic health centers we met on our trade delegation trip will attend as well.

Advanced Research Projects Agency for Health (ARPA-H)

Ms. Davies, Ms. Doyle and I are members of a steering committee to coordinate state efforts to bring President Biden's proposed ARPA-H to Texas. This effort started in July 2021. In May, Congress appropriated $1 billion for ARPA-H and approved authorizing legislation June 22. We communicate extensively with the Texas congressional delegation about the benefit to the state's life science ecosystem to locate the new federal agency in Texas.

Other states or cities with documented interest in hosting ARPA-H are Georgia, Illinois (Chicago), Philadelphia, Michigan, Massachusetts, North Carolina, Ohio (Cleveland), Maryland and Missouri. I expect New York and California will enter the competition as well.

The Texas congressional delegation has sent two letters to U.S. Health and Human Services Secretary Xavier Becerra supporting the ARPA-H initiative, one from Democrats and one from Republicans. All Democrats signed and half of the Republicans signed.

The Washington lobby team retained by Lyda Hill Interests arranged meetings on July 13 with seven of the Republicans who either did not sign the letter or voted against the House ARPA-H legislation. I attended the meetings, highlighting how Texas' unprecedented support for CPRIT speaks to the state's leadership on innovative health approaches. The reaction to our visit was positive—it appears that several now support the effort and the remaining may follow. The group is arranging visits with other members of the Texas delegation in district offices during the August recess.

Of the seven representatives with which we met, only Rep. Jodey Arrington was familiar with CPRIT. The meetings provided an opportunity to raise CPRIT awareness and every legislator took notice, particularly after I explained that CPRIT is the second largest public funder of cancer research and prevention in the world, behind only the National Cancer Institute.

Discussions and activities related to this initiative occur continuously. We will keep you advised as developments warrant.

Other Staff Outreach

Staff outreach activities during July include:

- OncLive OnAir featured Dr. Le Beau in a podcast entitled "Leukemia Pioneers Chronicle Career Experiences and Milestones" released online June 27. The panel included Dr. Judith Karp and Dr. Azra Raza. They discussed challenges and opportunities faced in their early careers as women in the leukemia field, the ways they overcame these challenges, and the unique pitfalls and successes they have experienced.

- Dr. Moore attended the Governor's Commission on Women and State Agency Council quarterly meeting on July 1. She introduced the speaker from Texas State University who provided an overview of the University's SCALEUP program, designed to help local businesses thrive by taking an evidence-based approach in understanding the unique challenges that minority businesses face when growing.

- On July 7 CPRIT Chief Operating Officer Heidi McConnell and I briefed new Legislative Budget Board analysts assigned to CPRIT on our processes, history, financing, and staffing requirements.

- In July, Dr. Magee met with executives and staff for several companies interested in CPRIT and opportunities in Texas. These include Artidis (July 8 and July 20), GeneFirst Limited (July 12), LIfT Biosciences (July 18), and Diakonos Therapeutics (July 19).

- On July 12, the CPRIT Product Development Program Manager, Dr. Magee met with the Dr. Tom Luby, Director of the Texas Medical Center Innovation Center (TMCi) and a CPRIT product development advisory committee member.

- Dr. Le Beau participated as a panelist of women leaders and trainees in the "Leadership in Oncology and Biomedicine" panel discussion on July 20. The panel was a component of the 2022 SHE (Summer Healthcare Experience) in Oncology Program created by the Livestrong Cancer Institute at The University of Texas at Austin. The program launched in 2019 and expanded in 2021 with support from the American Cancer Society to include four additional cancer centers across the country. This is a two-week program for female high school students in Central Texas and four other states providing an educational deep dive into research, clinical care, and community support, as well as to developing leadership skills and an open and ongoing discussion of the challenges unique to women in the fields of oncology and academic medicine.

- Dr. Magee visited TMCi on July 20, meeting with Dr. Luby, TMC Innovation Associate Director Dr. Emily Riser, and TMC Innovation Program Manager Ahmed AlRawi. While at the TMCi campus, Dr. Magee also met with CEO of BIOHouston Ann Tanabe and two Entrepreneurs in Residence - Dr. Sarah Hein and Enrique Gomez - with the CPRIT-funded Accelerator for Cancer Therapeutics (ACT).

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT has $1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of July 22, twelve entities had not filed 18 Academic Research reports, one Prevention reports, and nine Product Development reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 77 second-level reviews of grantee Financial Status Reports (FSRs) in July. Four FSRs (5%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Match Expenditures Review

CPRIT requires academic research and product development research grantees to show that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as "CPRIT's matching funds requirement," requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT's statute allows an institution of higher education to use its federal indirect cost rate as a credit toward the required 50% match.

Product development grantees and those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed two annual match expenditure review for two grantees in July. The total amount of match expenses reviewed by compliance staff for FY 2022 is $9,813,316.68.

Desk Reviews

Compliance specialists performed 13 enhanced desk-based financial monitoring reviews in July. Enhanced desk reviews verify that grantees spend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past

fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with one grantee to remediate enhanced desk review findings.

Onsite Reviews

CPRIT completed four virtual onsite reviews in July. Onsite reviews examine the grantees' financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with five grantees to remediate onsite review findings.

Intellectual Property Reporting Project Update

As CPRIT matures into its second decade, we are exploring opportunities for CPRIT to become an additional resource for entities seeking to commercialize CPRIT-funded discoveries. Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies is leading a project to better organize and use the intellectual property (IP) information that CPRIT's award contract requires grantees to report to CPRIT.

CPRIT has accumulated a tremendous amount information about IP generated with CPRIT funding through more than a decade of grantee self-reporting. CPRIT receives IP information via the grantee's annual progress report and by notifications from the grantee institution's technology transfer office regarding IP disclosures, patent prosecution events, and IP licensing activity.

Grantee reporting allows CPRIT to track overall numbers of patents, licenses, and related activity. However, the detail of the information varies by institution. In some instances, this variability makes it difficult to correlate the IP information with the related grant and complicates our ability to analyze the data on a macro level.

For the past several months, Ms. Davies has evaluated the reporting history of 14 grantee institutions and worked with the institutions' tech transfer office staff to develop better, more succinct reporting. Based on her analysis, Ms. Davies created a list of 12 standard items that grantees should report to CPRIT on a regular basis. The 14 grantee institutions are working with CPRIT to implement the updated IP reporting format and to ensure that past IP reporting is comprehensive.

Streamlining and standardizing grantee IP reporting will minimize underreporting and provides CPRIT better insight into the IP volume and quality of CPRIT-funded research activity. It is likely that CPRIT will house the standardized IP material in an external database that will allow search capabilities for non-confidential information regarding the generation of IP and the commercialization of IP resulting from CPRIT-funded grant activity

Ms. Davies will provide a brief update on the project at the August 17 Oversight Committee meeting and answer any questions.

Academic Research Program Update

In my June 22 memo, I explained that CPRIT has committed almost the entirety of its allocated budget for the FY 2022 Academic Research Program grant cycle due to an unprecedented number of awards approved in February and May. We attribute the unprecedented increase this year largely to the expansion of activities at academic and research institutions after two years of pandemic-related exigencies and, to a lesser degree, to the expansion of targeted RFAs offered by CPRIT.

CPRIT stopped accepting FY 2022 recruitment applications in May. As of this writing, except for two recruitment award recommendations, the Academic Research program will defer recommending the second cycle of FY 2022 Academic Research Program awards until September. Moving some FY 2022 awards into the next fiscal year reduces funds available for new awards in 2023. To address this, CPRIT plans to limit recruitment and research grant awards and not to release RFAs for some grant mechanisms in FY 2023. CPRIT hopes to resume funding all Academic Research grant award mechanisms at historical levels in FY 2024.

FY 2022 and FY 2023 Recruitment Applications

As noted, CPRIT stopped accepting FY 2022 recruitment applications. CPRIT released the FY 2023 recruitment RFAs June 14, with review of applications beginning in September. CPRIT limits the FY 2023 recruitment awards to Established Investigator and First Time-Tenure Track faculty grants and imposes institutional limits on the number of recruitment applications submitted. As a result, CPRIT expects to award fewer FY 2023 recruitment grants.

Academic Research FY 2022 Review Cycle 2 (22.2)

CPRIT released four RFAs for review cycle 22.2 on August 30, 2021. The application portal opened October 13, 2021. CPRIT received 120 applications by the January 12 deadline. Peer review panels met April 26 through May 5. However, because the potential amount of the cycle 22.2 award recommendations would likely far exceed the amount available for academic research awards in FY 2022, the Scientific Review Council (SRC) will defer recommending cycle 22.2 awards until September. Dr. Le Beau will present the SRC's recommendations to the Oversight Committee at its special meeting September 14.

Cycle 22.2 Mechanism	Received	Funds Requested
Core Facility Support Awards	23	$87,087,114
Clinical Trial Network Award	2	$6,000,000
Early Clinical Investigator Award	6	$8,726,495
High Impact/High Risk Research Awards	89	$22,122,480
TOTAL	**120**	**$123,936,089**

Academic Research FY 2023 Review Cycle 1 (23.1)

CPRIT released several RFAs for the first cycle of FY 2023 (23.1) in January and began accepting applications for targeted and untargeted Individual Investigator Research Awards in March through June 8. Dr. Le Beau will present the cycle 23.1 grant recommendations to the PIC and the Oversight Committee in February 2023. We expect to award fewer targeted and untargeted individual investigator awards in the 23.1 cycle due to limited funds available for new grants for the remainder of FY 2023 cycle and the carryover of cycle 22.2 grants into FY 2023.

CPRIT opened the portal May 16 to receive Texas Regional Excellence in Cancer Awards (TREC) applications through September 8. Dr. Le Beau will present the TREC award recommendations to the PIC and Oversight Committee at a proposed special Oversight Committee meeting in January 2023.

Cycle 23.1 RFA Mechanism	Applications	Requested Funding
Individual Investigator Research Awards	235	$241,561,941
Individual Investigator Research Awards for Cancer in Children and Adolescents	30	$42,048,859
Individual Investigator Research Awards for Clinical Translation	19	$35,897,103
Individual Investigator Research Awards for Computational Systems Biology of Cancer	23	$26,041,589
Individual Investigator Research Awards for Prevention and Early Detection	22	$36,681,588
Total	**329**	**$382,231,080**

CPRIT does not plan to offer a second cycle of grant awards in FY 2023. We will closely monitor the situation and discuss other potential options with CPRIT stakeholders and the Oversight Committee as they develop. CPRIT remains committed to all award mechanisms and hopes to resume all at historical levels beginning in FY 2024.

Product Development Research Program Update

Product Development Research FY 2022 Cycle 2 (22.2)

CPRIT released three product development RFAs in October 2021 for the second review cycle of FY 2022. CPRIT opened the application portal on December 1, 2021, and received 34 proposals by the January 26 deadline. Peer review panels met March 21 – 22 and selected 15 companies to present proposed projects live via Zoom April 11 - 14. Following company presentations, the review panels selected 11 companies to move into due diligence review by the Product Development Review Council (PDRC). The Product Development Review Council (PDRC) met July 13, 14 and 19 to review the due diligence reports and make final award recommendations for FY 2022 awards. Chief Product Development Officer Dr. Ken Smith will present the PDRC's grant recommendations for cycle 22.2 to the PIC and the Oversight Committee in August.

Because the number of potential awards may exceed the amount of funding available for product development grants in FY 2022, the PDRC deferred a final decision on one application until next fiscal year. If the PDRC decides to recommend the deferred application for an award in September, Dr. Smith will present the recommendation at the special Oversight Committee September 14 for approval.

Cycle 22.2 RFA	Apps Received	Funds Requested	Invited to Present	Funds Requested	Due Diligence	Funds Requested	PDRC	Funds Requested
Texas Company	10	$118,319,140	7	$86,183,386	5	$70,273,519	3	$37,113,604
Relocation Company	8	$86,095,315	1	$14,268,200	1	$14,268,200	1	$14,268,315
Seed Company	16	$41,832,547	7	$19,486,736	5	$13,486,736	5	$13,486,736
TOTAL	**34**	**$246,247,002**	**15**	**$119,938,222**	**11**	**$98,028,455**	**9**	**$64,868,655**

Product Development FY 2023 Review Cycle

At its May 18 meeting, the Oversight Committee approved five* FY 2023 requests for applications (RFAs) for the Product Development Research program. The FY 2023 RFAs included changes to the product development application and review process for the FY 2023 review cycle. The most notable change is the use of a preliminary application and review process to provide applicants with a faster indication of whether the company's proposed cancer research and development project demonstrates sufficient scientific merit and a compelling premise to warrant submitting a full application.

The Texas Comptroller's Office reviewed the proposed Product Development RFAs and provided feedback. The recommended changes are not substantive. We plan to release the RFAs and open the portal to receive preliminary applications in mid to late August. The first deadline for full applications will be November 1, 2022, with award recommendations scheduled for February 2023.

* After internal discussion and with the PDRC, we elected to offer a "FY 2023 Texas Devices and Diagnostics Company" RFA instead of separate RFAs for device companies and diagnostic companies.

Recruiting Expert Reviewers for the FY 2023 Review Cycle

Due to our increased outreach efforts and the community's interest in CPRIT's streamlined review process, we expect to receive more high-quality applications in FY 2023 than we have in previous years. To prepare for this increased volume, Dr. Smith and Dr. Magee have been working with our stakeholders (the Product Development Advisory Committee, current grantees, Oversight Committee members, GDIT, etc.) for the past several months to identify potential new product development review panel members.

CPRIT is especially interested in recruiting new reviewers with backgrounds in devices, diagnostics, and emerging technologies. We have received a positive response; Dr. Smith and Dr. Magee are in the process of interviewing more than 20 candidates. We appreciate the

Oversight Committee's response to our request – several potential reviewers came from your referrals. I expect to appoint some of these new reviewers for the Oversight Committee's consideration as early as the August meeting.

Prevention Program Update

Prevention FY 2022 Review Cycle 2 (22.2)

The Prevention Program released three RFAs on October 19, 2021. CPRIT opened the application portal November 15, 2021, to receive proposals through the February 9 deadline for the second cycle of FY 2022 awards. Peer review panels met by teleconference on April 25. The PRC met June 3 to finalize recommendations. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in August.

Cycle 22.2 Mechanism	Applications	Funds Requested
Evidence-based Cancer Prevention Services	9	$8,978,733
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	4	$9,479,601
Tobacco Control and Lung Cancer Screening	3	$2,999,861
TOTAL	**16**	**$21,458,195**

Prevention FY 2023 Review Cycle 1 (23.1)

CPRIT released three RFAs (listed below) on June 2 for the first cycle of FY 2023. Applicants must submit proposals by August 31. CPRIT has scheduled peer review for December 2022. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in February 2023.

- Dissemination of CPRIT-Funded Cancer Control Interventions RFA

  This award mechanism funds 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 able 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: $450,000
  Maximum duration: 36 months

- Primary Prevention of Cancer RFA

  This award mechanism funds multilevel interventions to reduce cancer risk, disease burden, and cancer disparities. CPRIT wants to increase the implementation of evidence-based strategies to ensure that all Texans benefit from the cancer prevention knowledge that we currently have. Modifiable risk behaviors include tobacco use, obesity, physical inactivity, unhealthy eating, alcohol use, sun exposure, HPV vaccination, Hepatitis B vaccination, and environmental/occupational cancer exposures. Applications should also assess and address social determinants that contribute to cancer burden and disparities (e.g., cultural factors, unmet needs, access barriers) and structure interventions to address the unique circumstances of the population the project will served.

  Award maximum: $1million for new projects and $2.5 million for expansion projects
  Maximum duration: 60 months

- Cancer Screening and Early Detection RFA

  This award mechanism funds the delivery of evidence-based clinical services to screen for cancer and pre-cancer in underserved populations who do not have adequate access to cancer early detection 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, have nationally recommended screening methods, and use evidence-based methods to screen for these cancers.

  Award maximum: $1 million for new projects and $2.5 million for expansion projects
  Maximum duration: 60 months

Advisory Committee Meetings

- The Geographic Diversity Advisory Committee will meet August 5.

Operations, Audit and Finance Update

CPRIT's internal auditor (Weaver) is conducting field work on the vendor contract compliance audit and is initiating the follow-up procedures related to the outstanding findings on IT issues.

The Governor's Office and Legislative Budget Board (LBB) released instructions for the 2024-25 Legislative Appropriations Request (LAR) on July 5, 2022. CPRIT staff is compiling the required elements of the request according to the proposed agency budget for the 2024-25 biennium approved by the Oversight Committee on May 18, 2022. CPRIT must submit the LAR to the Governor's Office and LBB by August 12.

Earlier this year, CPRIT issued a 2023 conference venue request for proposals (RFP), which was open to all regions in Texas. CPRIT staff, including Heidi McConnell, Ramona Magid, and Mark Loeffler, and CPRIT's conference planner Deb Swift of Swift Solutions completed evaluations of the submitted proposals. At the August Oversight Committee meeting, staff will present its recommendation to use the Moody Gardens Hotel, Spa and Convention Center on Galveston Island for the CPRIT's Innovations Conference venue on October 1-3, 2023. We plan to use Sunday, October 1, to set up all the meeting rooms, grantee poster display area, and audiovisual equipment, with the conference opening to attendees on October 2.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the August 17 Oversight Committee meeting. We will send instructions for signing onto the Zoom platform along with the subcommittee agenda and meeting materials one week prior to the meeting.

Board Governance	August 4 at 10:00 a.m.
Audit	August 8 at 10:00 a.m.
Prevention	August 9 at 10:00 a.m.
Academic Research	August 10 at 10:00 a.m.
Product Development	August 11 at 10:00 a.m.

******

CPRIT has awarded **1,776** grants totaling **$3.041 billion**

- 265 prevention awards totaling $313.5 million
- 1,511 academic research and product development research awards totaling $2.727 billion

Of the $2.727 billion in academic research and product development research awards,

- 29.6% of the funding ($795.2 million) supports clinical research projects
- 24.0% of the funding ($655.6 million) supports translational research projects
- 30.5% of funding ($831.6 million) supports recruitment awards
- 13.0% of the funding ($354.3 million) supports discovery stage research projects
- 3.3% of funding ($90.4 million) supports training programs.

CPRIT has 6 open Requests for Applications (RFAs)

- 2 Research Recruitment
- 1 Academic Research
- 3 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	AUGUST 8, 2022

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

Submission Status of Required Grant Recipient Reports

CPRIT has $1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of July 25, 12 entities had not filed 12 Academic Research reports, two Prevention reports, and nine Product Development reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who spend $750,000 or more in state awards in the grantee's fiscal year must undertake a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee sends the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, all grantees have submitted the required audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective

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

action plan unless the grantee requested more time by the due date of the required audit and CPRIT's CEO approves the request. Compliance specialists are working with two grantees to complete the required corrective actions.

Financial Status Report Reviews

CPRIT's compliance specialists performed 463 second-level reviews of grantee Financial Status Reports (FSRs) in May, June, and July. Forty-two FSRs (9%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Compliance specialists performed 25 enhanced desk-based financial monitoring reviews in May, June, and July. Enhanced desk reviews verify that grantees spend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with one grantee to remediate enhanced desk review findings.

Onsite Reviews

Compliance specialists completed eight virtual onsite reviews in May, June, and July. Onsite reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with four grantees to remediate onsite review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual attestation form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. All grantees have submitted their annual Compliance Attestation. Pursuant to Texas Administrative Code §701.19, CPRIT requires Product Development grantees to demonstrate that they will relocate to Texas as a condition of the grant award. As part of the annual attestation process, Product Development grantees are required to submit documentation demonstrating compliance with the Texas Location Criteria. Compliance specialists are working with one grantee to submit the required documentation.

Match Expenditures Review

CPRIT requires academic research and product development research grantees to show that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as "CPRIT's matching funds requirement," requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT's statute allows an institution of higher education to use its federal indirect cost rate as a credit toward the required 50% match.

Product development grantees plus those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff reviews grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed three annual match expenditure reviews for three grantees in May, June, and July. The total amount of match expenses reviewed by compliance staff for FY 2022 is $9,813,316.68.

Training and Support

CPRIT staff conducted one new grantee training webinar in May for the Texas Health Institute. 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, CPRIT requires new grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

CPRIT staff conducted one new Authorized Signing Official (ASO) training webinar for Asylia Therapeutics. 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, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

CPRIT staff conducted a series of annual compliance training webinars on June 7-9 for 98 grantee staff. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the second training series offered this year for the annual compliance training requirement which requires the Authorized Signing Official and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

Grantee Risk Assessment and FY23 Monitoring Plan

Compliance staff is finalizing the FY23 Grantee Risk Assessment. Risk Assessments are performed on a quarterly and annual basis. The Risk Assessment Model considers several factors in determining grantee risk including:

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

Risk Assessments assign a priority ranking (1, 2, or 3) to grant recipients, which is used to determine monitoring and training needs for the coming fiscal year. Compliance monitoring reviews are designed to evaluate grantee compliance with grant requirements included in the Texas Administrative Code, Texas Health and Safety Code, CPRIT Policies and Procedures, Texas Grant Management Standards, and terms of the grant contract.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MICHELLE LE BEAU, PH.D., CHIEF SCIENTIFIC OFFICER
SUBJECT:	ACADEMIC RESEARCH PROGRAM UPDATE
DATE:	AUGUST 17, 2022

FY2022 Cycle 2 (22.2) RFA Submission data and review status

CPRIT released four RFAs for the second cycle of FY 2022 on August 30, 2021. The application portal opened October 13, 2021. CPRIT received 120 applications requesting $123,936,089 by the January 12, 2022, deadline. Peer review panels met in May. Dr. Le Beau will present the Scientific Review Council's recommendations to the PIC and the Oversight Committee in September 2022. Table 1 displays the submission data and requested funding.

Table 1: FY2022 Cycle 2 (22.2) Submission Data and Requested Funding

RFA Mechanism	# Applications Submitted	Requested Funding
Core Facility Support Awards	23	$87,087,114
Clinical Trials Network Award	2	$6,000,000
Early Clinical Investigator Award	6	$8,726,495
High Impact/High Risk Research Awards	89	$22,122,480
TOTAL	120	$123,936,089

FY2023 Cycle 1 RFA's

CPRIT released six RFAs for the first cycle of FY2023 as displayed in Table 2. Dr. Le Beau will present the PIC recommendations to the Oversight Committee in January 2023 (Texas Regional Excellence in Cancer Awards (TREC) and February 2023 for the Individual Investigator Research Awards (targeted and untargeted).

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

Table 2: **FY2023 Cycle 1 (23.1) Submission Data and Requested Funding**

RFA Mechanism	# Applications Submitted	Requested Funding
Individual Investigator Research Awards (IIRA)	235	$241,561,941
Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)	30	$42,048,859
Individual Investigator Research Awards for Clinical Translation (IIRACT)	19	$35,897,103
Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)	23	$26,041,589
Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)	22	$36,681,588
Total	**329**	**$382,231,080**

The National Cancer Institute (NCI) and the Academic Research Program: Collaboration.

Drs. Le Beau and Moore met with leadership of the NCI CONNECT study who are interested in Texas joining the study cohort. The CONNECT study is designed to address priorities in cancer prevention research, which include emerging exposures, novel biomarkers, genomics; current-edge methodology and diverse and special populations.

Recruiting experts to Academic Research FY23.1 Peer Review Panels

Drs. Le Beau and Moore have diligently worked with the Scientific Review Council (SRC), CPRIT Advisory Committee members and GDIT to identify and recruit the scientific expertise to meet the scientific rigor of the FY23.1 RFA applications. Mr. Roberts will provide an overview of the 9 recruited experts.

Researchers RoundUP

The CPRIT & Carson Leslie Foundation Researcher's RoundUP, led by Drs. Gorlick and Parsons (Chairs of CPRITs Advisory Committee on Childhood Cancers) brought 75 pediatric and adolescent cancer researchers to Dallas for an interactive two-day strategic planning conference. The goal of the meeting was to bring together pediatric cancer research experts across the state of Texas as well as CPRIT leadership to identify state-wide priorities to advance cancer research and care for Texas children with cancer.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: AUGUST 10, 2022

FY 2022 Review Cycle 2 (22.2)

The Prevention Program released three RFAs on October 19, 2021. CPRIT opened the application portal November 15 to receive proposals through the February 9, 2022, deadline. Sixteen applications requesting $21,458,195 were submitted. The peer review panel met by teleconference on April 25. Programmatic review by the Prevention Review Council (PRC) was conducted June 3, 2022. The Program Integration Committee (PIC) met August 3 to consider the PRC's recommendations. Ms. Magid presents the PIC's award recommendations to the Oversight Committee on August 18.

FY 2022.2 (22.2) Application Data by Mechanism

Mechanism	Received	Funds Requested
Evidence-based Cancer Prevention Services	9	$8,978,733
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	4	$9,479,601
Tobacco Control and Lung Cancer Screening	3	$2,999,861
TOTAL	**16**	**$21,458,195**

FY 2023 Cycle 1 (23.1) Prevention RFAs

CPRIT released three (3) RFAs on May 6 for the first cycle of FY 2023. Applications are due on August 31 and peer review is scheduled for December 2022. Ms. Magid will present the PRC's award recommendations to the PIC and the Oversight Committee in February 2023.

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

FY 2023 Prevention RFAs

Dissemination of CPRIT- funded Cancer Prevention and Control Interventions

This RFA solicits applications that will describe and package strategies or approaches to introduce, modify, and implement previously funded CPRIT evidence-based cancer prevention and control interventions for dissemination to other settings and populations in the state. To be eligible, the applicant should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed projects should also identify and assist others in overcoming barriers to implementation.

Award: Maximum of $450,000; maximum duration of 36 months

Primary Prevention of Cancer – *NEW*

This award mechanism focuses on increasing implementation of evidence-based strategies to ensure that all Texans benefit from the cancer prevention knowledge that we currently have. CPRIT seeks to fund multilevel interventions to reduce cancer risk, disease burden, and cancer disparities. Modifiable risk behaviors include tobacco use, obesity, physical inactivity, unhealthy eating, alcohol use, sun exposure, HPV vaccination, Hepatitis B vaccination, and environmental/ occupational cancer exposures. Applications should also assess and address social determinants that contribute to cancer burden and disparities (e.g., cultural factors, unmet needs, access barriers). Interventions and communications should be structured to address the unique circumstances of the population to be served.

Award: Maximum of $1M for new projects and $2.5M for expansion projects; maximum duration of 60 months

Screening and Early Detection– *NEW*

Summary:
This award mechanism seeks to support the delivery of evidence-based clinical services to screen for cancer and pre-cancer in underserved populations who do not have adequate access to cancer early detection 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, have nationally recommended screening methods, and use evidence-based methods to screen for these cancers.

Award: Maximum of $1M for new projects and $2.5M for expansion projects; maximum duration of 60 months

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS
From: KEN SMITH, PHD, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject: PRODUCT DEVELOPMENT RESEARCH PROGRAM UPDATE
Date: AUGUST 10, 2022

Product Development Research FY 2022 Cycle 2 (22.2)

CPRIT released three product development RFAs in October 2021 for the second review cycle of FY 2022. CPRIT opened the application portal on December 1, 2021, and received 34 proposals by the January 26 deadline. Peer review panels met March 21 – 22 and selected 15 companies to present proposed projects live via Zoom April 11 - 14. Following company presentations, the review panels selected 11 companies to move into due diligence review by the Product Development Review Council (PDRC). The Product Development Review Council (PDRC) met July 13, 14 and 19 to review the due diligence reports and make final award recommendations for FY 2022 awards.

Because the number of recommended awards exceeded the amount of funding available for product development grants in FY 2022, the PDRC deferred a final decision on one application until next fiscal year. If the PDRC decides to recommend the deferred application for an award, Dr. Smith will present the recommendation at an Oversight Committee meeting in FY 2023.

Cycle 22.2 RFA	Apps Received	Funds Requested	Invited to Present	Funds Requested	Due Diligence	Funds Requested	PDRC	Funds Requested
Texas Company	10	$118,319,140	7	$86,183,386	5	$70,273,519	3	$37,113,604
Relocation Company	8	$86,095,315	1	$14,268,200	1	$14,268,200	1	$14,268,315
Seed Company	16	$41,832,547	7	$19,486,736	5	$13,486,736	5	$13,486,736
TOTAL	**34**	**$246,247,002**	**15**	**$119,938,222**	**11**	**$98,028,455**	**9**	**$64,868,655**

Product Development FY 2023 Review Cycle

At its May 18 meeting, the Oversight Committee approved five* FY 2023 requests for applications (RFAs) for the Product Development Research program. The FY 2023 RFAs included changes to the product development application and review process for the FY 2023 review cycle. The most notable change is the use of a preliminary application and review process to provide applicants with a faster indication of whether the company's proposed cancer research and development project demonstrates sufficient scientific merit and a compelling premise to warrant submitting a full application.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | www.cprit.state.tx.us

The Texas Comptroller's Office reviewed the proposed Product Development RFAs and provided feedback. The recommended changes are not substantive. We plan to release the RFAs and open the portal to receive preliminary applications in mid to late August. The first deadline for full applications will be November 1, 2022, with award recommendations scheduled for February 2023.

* After internal discussion and with the PDRC, we elected to offer a "FY 2023 Texas Devices and Diagnostics Company" RFA instead of separate RFAs for device companies and diagnostic companies.

Recruiting Expert Reviewers for the FY 2023 Review Cycle

Due to our increased outreach efforts and the community's interest in CPRIT's streamlined review process, we expect to receive more high-quality applications in FY 2023 than we have in previous years. To prepare for this increased volume, Dr. Magee and I have been working with our stakeholders (the Product Development Advisory Committee, current grantees, Oversight Committee members, GDIT, etc.) for the past several months to identify potential new product development review panel members.

CPRIT is especially interested in recruiting new reviewers with backgrounds in devices, diagnostics, and emerging technologies. We have received a positive response; Dr. Magee and I have interviewed more than 20 candidates. We appreciate the Oversight Committee's response to our request – several potential reviewers came from your referrals. CPRIT CEO Wayne Roberts has provisionally appointed many of these new reviewers for the Oversight Committee's consideration at the upcoming meeting.

In addition to recruiting new reviewers, CPRIT will add three new PRDC members in FY 2023 to assist in the preliminary application review and other PDRC assignments. The preliminary application process is a new component in the FY 2023 product development review process. CPRIT will accept preliminary applications at any time and provide feedback to the applicant within 3 – 5 weeks regarding whether the applicant is a fit for the CPRIT program. PDRC members will be responsible for reviewing all preliminary applications. We expect the number of preliminary applications to be substantial. Adding the three new PDRC members will help manage this significant responsibility. The Oversight Committee previously approved the appointments of the three PDRC members to serve as peer reviewers, so no Oversight Committee action is necessary.

August 2022 Oversight Committee
Internal Audit Status Report
As of August 1, 2022

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 Daniel Graves, Partner.

2022 Internal Audit Plan and Schedule

Based on the approved 2022 Internal Audit Plan by the Oversight Committee, we have completed the internal audits and follow-up procedures for the 2022 Internal Audit Plan.

2022 INTERNAL AUDITS		
Internal Audit	**Description**	**Status**
IT General Computer Controls Remediation Assistance	The advisory audit was planned to provide CPRIT assistance in designing control procedures and templates to implement in order to remediate the findings identified in the FY 2021 IT General Computer Controls Internal Audit. We have assisted CPRIT in updating all 25 separate policies and consolidating them into one global IT policy. The 25 revised policies have been reviewed with the IT Governance Committee, and the final global IT policy is in their review. We provided templates for CPRIT IT to use in documentation of their performance of controls and procedures. A template for a Statement of IT Integrity has also been provided to CPRIT IT to facilitate their self-assessment and reporting of compliance with IT policies and procedures to CPRIT management every six months.	Complete
Vendor Contract Compliance	Internal Audit will evaluate the risk of significant vendor contracts in place at CPRIT. Based on the risk evaluation, vendor contracts will be evaluated for compliance with key provisions, terms and conditions of the contract, as well as on the performance with the delivery of goods and/or services in alignment with the contract.	In Progress
Records Management – Grantee Compliance Records Advisory Audit	Internal Audit will provide audit advisory services to evaluate the grantee compliance record migration from a third-party designed system to the integrated CPRIT system. Consulting services will include the validation of the system configuration, verification of the completeness of the data migration and testing the accuracy of data classification and mapping.	Cancelled

Procurement	Internal Audit will validate CPRIT's compliance with the requirements for procurements specified in the State of Texas Procurement and Contract Management Guide.	August 2022

2022 INTERNAL AUDIT FOLLOW-UPS		
Information Technology General Computer Controls and Information Security Follow-Up	Internal Audit will perform possible follow-up procedures on the findings from the 2021 internal audit to ensure corrective action has been taken.	Cancelled
Communications Follow-Up • 1 High Finding • 2 Moderate Findings	Internal Audit will perform possible follow-up procedures on the findings from the 2021 internal audit to ensure corrective action has been taken.	In Progress
Governance Follow-up • 1 Moderate Finding	Internal Audit will perform possible follow-up procedures on the findings from the 2021 internal audit to ensure corrective action has been taken.	In Progress
Disaster Recovery and Business Continuity Planning Advisory Follow-up • 5 recommendations	Internal Audit will perform possible follow-up procedures on the remaining open recommendations from the 2021 audit advisory work.	In Progress

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.

We also updated the FY 2022 Internal Audit Risk Assessment and prepared a proposed Internal Audit Plan for FY 2023 for the review and approval of the Oversight Committee. Once approved, the audit plan will be included in the 2023 Annual Internal Audit Report that is due to the State Auditor's Office, LBB, and Governor's Office in November.

Daniel Graves

Daniel Graves, CPA, Internal Auditor
Partner
Weaver and Tidwell L.L.P.

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of August 1, 2022

					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 2017																
2016 Information Security Follow-Up	2017	Complete	May 30, 2017													
Fiscal Year 2017 Subtotal					**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Fiscal Year 2018																
Communications Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	4	-	5
2016 Information Security Follow-Up	2018	Complete	July 17, 2018													
Fiscal Year 2018 Subtotal					**1**	**4**	**-**	**5**	**-**	**-**	**-**	**-**	**1**	**4**	**-**	**5**
Fiscal Year 2019																
2016 Information Security Follow-Up	2019	Cancelled	N/A													
2018 Communications Follow-Up	2019	Complete	August 30, 2019	Satisfactory	1	4	-	5	-	2	-	2	1	2	-	3
Fiscal Year 2019 Subtotal					**1**	**4**	**-**	**5**	**-**	**2**	**-**	**2**	**1**	**2**	**-**	**3**
Fiscal Year 2020																
Governance	2020	Complete	October 30, 2020	Strong	-	1	-	1	-	-	-	-	-	1	-	1
2016 Information Security Follow-Up	2020	Complete	N/A													
2018 Communications Follow-Up	2020	Complete	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3
Fiscal Year 2020 Subtotal					**1**	**5**	**-**	**6**	**-**	**2**	**-**	**2**	**1**	**3**	**-**	**4**
Fiscal Year 2021																
Sunset Self-Assessment Advisory	2021	Cancelled	N/A	N/A	-	-	-	-	-	-	-	-	-	-	-	-
Information Technology General Computer Controls	2021	Complete	September 24, 2022													
Grantee Compliance Records Management	2021	Rescheduled	FY 2022	N/A	-	-	-	-	-	-	-	-	-	-	-	-
2016 Information Security Follow-Up	2021	Rescheduled	FY 2022													
2018 Communications Follow-Up	2021	Rescheduled	FY 2022	N/A	1	4	-	5	-	2	-	2	1	2	-	3
2020 Governance Follow-up	2021	Rescheduled	FY 2022	Strong	-	1	-	1	-	-	-	-	-	1	-	1
2020 Disaster Recovery and Business Continuity Follow-up	2021	Complete	September 28, 2021	N/A	-	-	-	-	-	-	-	-	-	-	-	-
Fiscal Year 2021 Subtotal					**1**	**5**	**-**	**6**	**-**	**2**	**-**	**2**	**1**	**3**	**-**	**4**

Open Items Summary

					Findings				Closed Findings				Total Open Findings				
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**Timing of Follow-Up Procedures by IA**
Information Technology General Computer Controls	2021	September 2021	September 24, 2022														**FY 2022**
2020 Governance	2020	July 2020	October 30, 2020	Strong	-	1	-	1	-	-	-	-	-	1	-	1	**FY 2022**
2016 Information Security Follow-Up	2020	August 2020	N/A														**FY 2022**
2018 Communications Follow-Up	2020	November 2020	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3	**FY 2022**
Total Findings For Internal Audit Follow-Up					**1**	**5**	**-**	**6**	**-**	**2**	**-**	**2**	**1**	**3**	**-**	**4**	

NOTE: The 2020 Disaster Recovery and Business Continuity findings are recommendations for improvement of the DR/BCP documentation. Therefore, they do not have a risk rating associated with them.

Cancer Research and Prevention Institute of Texas

Proposed Internal Audit Plan

Fiscal Year 2023

Draft - For Discussion Purposes Only

Audit Area	Risk Rating	Summary Procedures	Audit Focus	Timing
2023 Planned New Internal Audits				
Contract Risk Assessment	High	Internal Audit will provide audit advisory services to evaluate and assist CPRIT Management in the development of a contracts risk assessment as part of CPRITS Quality Assessment Plan. The Audit Advisory Consulting services will include an evaluation of the risks associated with agency's contracts and the process to quantify the probability and impact of those risks to CPRIT. The evaluation will also include an evaluation of the procedures in place to comply with the Texas Procurement and Contract Management Guide v2.1.	Internal Audit Advisory	October-November 2022
Post - Award Grant Compliance Program Assessment	High	Internal Audit will provide audit advisory services to evaluate the compliance processes in place for post-award grantee compliance monitoring. The evaluation of the Compliance group's procedures will include the process the Compliance group uses to update the grantee risk assessment, perform desk reviews, and execute on-site reviews. The audit advisory consulting services will also include recommendations for improvement and mitigation of risks related to the CPRIT grant portfolio.	Internal Audit Advisory	February - March 2023
IT General Controls	High	Internal Audit will evaluate the risks and internal controls in place related to CPRIT's Information Technology practices. Activities to be evaluated will include Network Operations, Help Desk Support, Change Management, Website Maintenance, Back-Up and Recovery.. The audit will also include follow-up of Information Security findings from prior audits.	Internal Audit	April-May 2023
2023 Planned Internal Audit Follow-up				
Contract Compliance	High	Internal Audit will perform possible follow-up procedures on the findings from the 2022 internal audit to ensure corrective action has been taken.	Follow-up	February 2023
Special Projects		Special projects as directed and designated by CPRIT management.	Follow-up	TBD
2023 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 of internal audit activities to the Audit Sub-Committee and Oversight Committee.	Policy Compliance	Ongoing

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	APPOINTMENT TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	AUGUST 8, 2022

Summary and Recommendation

The Chief Executive Officer has appointed 27 experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. At their August 4 meeting, the Board Governance subcommittee reviewed the appointees and recommends approval by the Oversight Committee.

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 a significant 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 Board Governance 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 Board Governance Subcommittee reviewed the appointees at its August 4 meeting and recommends their approval by the Oversight Committee.

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

Scientific Research and Prevention Programs Committee (SRPP) Appointments
August 2022

	Appointee	CPRIT Program
1.	Dario Altieri, MD	Academic Research
2.	Luis Carvajal-Carmona, PhD	Academic Research
3.	Gloria Coronado, PhD	Academic Research
4.	Danica Galonić Fujimori, PhD	Academic Research
5.	Maryellen Giger, PhD	Academic Research
6.	Charles Kahn, MD, MS	Academic Research
7.	Matthias Karajannis, MD	Academic Research
8.	Mara Sherman, PhD	Academic Research
9.	Weiping Zou, MD, PhD	Academic Research
10.	Amy Cipau, MBA	Product Development Research
11.	Bibhash Mukhopadhyay, PhD	Product Development Research
12.	Brian T. Cunningham, PhD	Product Development Research
13.	David Aaron Russler-Germain, MD, PhD	Product Development Research
14.	Francesco Ferraro, MD, PhD	Product Development Research
15.	Jennifer A. Foltz, PhD	Product Development Research
16.	Kathleen Swan, JD	Product Development Research
17.	Mary Wheeler, PhD, MBA	Product Development Research
18.	Melissa M. Berrien-Elliott, PhD	Product Development Research
19.	Michael Rossbach, Prof. Dr. rer. nat.	Product Development Research
20.	Phyllis Whiteley, PhD	Product Development Research
21.	Robert Sons, PhD	Product Development Research
22.	Romy Seth	Product Development Research
23.	Samuel Straface, PhD	Product Development Research
24.	Tian Yu, PhD	Product Development Research
25.	Vel Murugan, PhD, MBA	Product Development Research
26.	Vikas Goyal, MBA	Product Development Research
27.	Yuan Zhi, PhD	Product Development Research

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

Academic Research nominations for Peer Reviewers

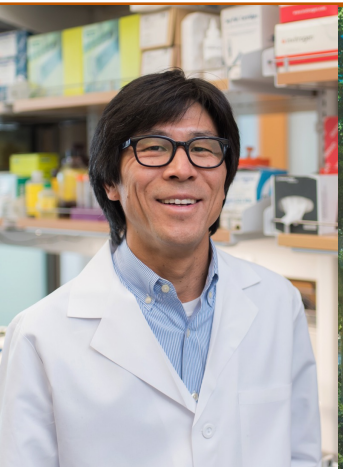
Nominees	Panel Assignment	Expertise
Dario Altieri, MD President and Chief Executive Officer Cancer Center Director The Wistar Institute Philadelphia, PA	Basic Cancer Research -2	Metabolism, cellular stress and survival, mechanism of tumor resistance, regulation of tumor bioenergetics.
Luis Carvajal-Carmona, PhD Director for Basic Science, Endowed Chair in Basic Science, Department of Biochemistry and Molecular Medicine, UC Davis School of Medicine, Davis, CA	Cancer Prevention Research	Cancer genetic susceptibility, genetic variation associated with disease, development of molecularly guided therapies, genetics, and epidemiology of cancer in Latinos.
Gloria Coronado, PhD Distinguished Investigator, Mitch Greenlick Endowed Scientist for Health Disparities, Center for Health Research Kaiser Permanente Northwest Portland, OR	Cancer Prevention Research	Cancer, health disparities, health services and economics, implementation research.
Danica Galonić Fujimori, PhD Professor and Vice-Chair Departments of Cellular and Molecular Pharmacology & Pharmaceutical Chemistry, University of California San Francisco, San Francisco, CA	Basic Cancer Research -2	Nucleic acid synthesis, bioconjugation self-assembly, Tissue Engineering, cell-cell interactions
Maryellen Giger, PhD A.N. Pritzker Distinguished Service Professor of Radiology Department of Radiology The University of Chicago Chicago, IL	Imaging Technology and Informatics	Computer-aided diagnosis, machine learning, breast cancer, deep learning, radiomics
Charles Kahn, MD, MS Professor and Vice Chair of Radiology Department of Radiology University of Pennsylvania Philadelphia, PA	Imaging Technology and Informatics	Radiology, Artificial Intelligence/Machine Learning, health information technology, health care innovation
Matthias Karajannis, MD Chief, Pediatric Neuro-Oncology Service	Basic Cancer Research -1	Pediatric Hematology, Oncology, Neuro-oncology, Brain Tumors,

Memorial Sloan-Kettering Cancer Center New York, NY		Brain Cancer, Brain and Spinal Cord Tumors, Childhood Cancers, Schwannoma, NF2
Mara Sherman, PhD Associate Professor Department of Cell, Developmental & Cancer Biology, Oregon Health &Science University ,Portland, OR	Cancer Biology	Pancreatic cancer, tumor microenvironment, cancer metabolism, epigenetics
Weiping Zou, MD, PhD Professor of Pathology, Immunology, Biology, and Surgery Director, Center of Excellence for Cancer Immunology, and Immunotherapy Department of Surgery University of Michigan School of Medicine, Ann Arbor, MI	Basic Cancer Research -1	Tumor Immunity, Immune Suppression, Immune Vaccination, Breast Cancer, Colon Cancer, Melanoma, Ovarian Cancer, Non-small Cell Lung Cancer

S. Gail Eckhardt, MD, FASCO

S. Gail Eckhardt is a tenured Professor, inaugural Director of the Livestrong Cancer Institutes, Chair of the Department of Oncology, and Associate Dean of Cancer Programs at the University of Texas at Austin's Dell Medical School. Dr. Eckhardt has served on numerous committees and study sections, including the ASCO Molecular Oncology Task Force, the ASCO Board of Directors, the FDA Oncology Drugs Advisory Committee, and the National Cancer Institute (NCI) Cancer Centers Study Section. She is a member of the NCI Investigational Drug Steering Committee and serves on 11 external advisory boards of NCI-designated cancer centers. She was a lead mentor in ASCO's Leadership Development Program, is currently a member of the Board of Directors of the Association of American Cancer Institutes (AACI) and Chair of the Cancer Prevention and Research Institute of Texas' Clinical Trials Advisory Committee. Dr. Eckhardt recently was awarded the 2022 Hologic, Inc Endowed Women Who Conquer Cancer Mentorship Award.

Dr. Eckhardt is the Principal Investigator on grants involving early clinical trials and colorectal cancer research, has conducted numerous early phase clinical trials and has published over 200 manuscripts. Her area of interest is in the preclinical and early clinical development of combinations of molecularly targeted compounds, with a disease focus on colorectal cancer. Dr. Eckhardt earned her undergraduate degree in chemistry from Stephen F. Austin State University and her medical degree from the University of Texas Medical Branch in Galveston. She conducted her internship and residency in Internal Medicine at the University of Virginia Medical School, followed by a post-doctoral research fellowship in Experimental and Molecular Medicine at Scripps Research Institute in La Jolla, California, and a fellowship in Medical Oncology at the University of California San Diego.



CPRIT Clinical Trials Advisory Committee: Fiscal Year 2022 Annual Report

CPRIT Oversight Committee Meeting
August 17, 2022

S. Gail Eckhardt MD
Chair

CTAC Membership

- **C. Kent Osborne, MD**, Dan L Duncan Comprehensive Cancer Center, BCM
- **Ruben Mesa, MD**, Mays Cancer Center, UTHSCSA
- **Carlos Arteaga, MD**, Harold Simmons Comprehensive Cancer Center, UTSWMC
- **S. Gail Eckhardt, MD**, Livestrong Cancer Institute, DMC, UT Austin
- **David S. Hong, MD**, UTMDACC
- **C. Patrick Reynolds, MD, PhD,** Cancer Center, TTUHSC
- **Ronan Kelly, MD,** Baylor Scott and White, Sammons Cancer Center

Planned CTAC Membership Revisions

- Plan to add a member from both the Prevention Advisory Council as well as the Advisory Committee on Childhood Cancers---this should streamline shared priorities across groups
- Add an industry member with expertise in engaging diverse communities as well as regulatory knowledge of telehealth/consenting and local labs in early clinical trials
- Replace vacancy of a member from Product Development Advisory Committee
- Consider:
  - Adding a member that is leader of either/both Diversity/Equity/Inclusion (DEI) or Community Outreach and Engagement (COE) at NCI center in Texas

CTAC Meetings

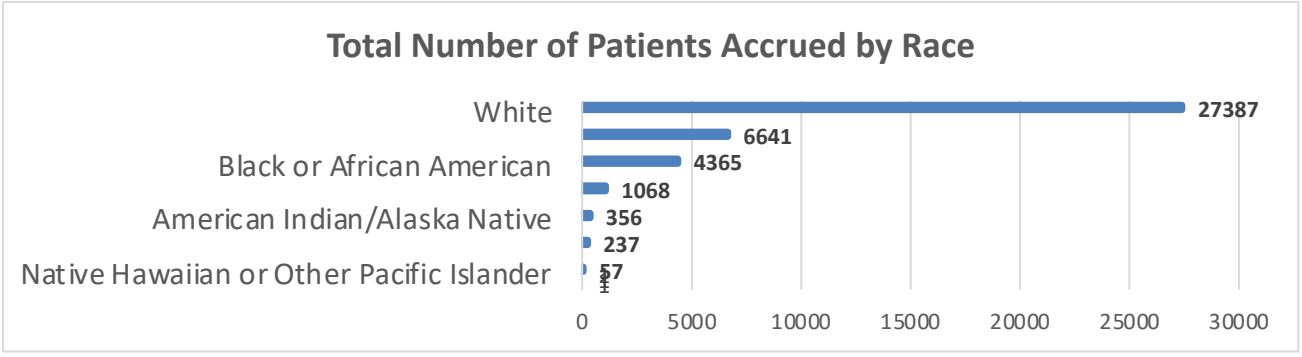
1. **March 25, 2022:**

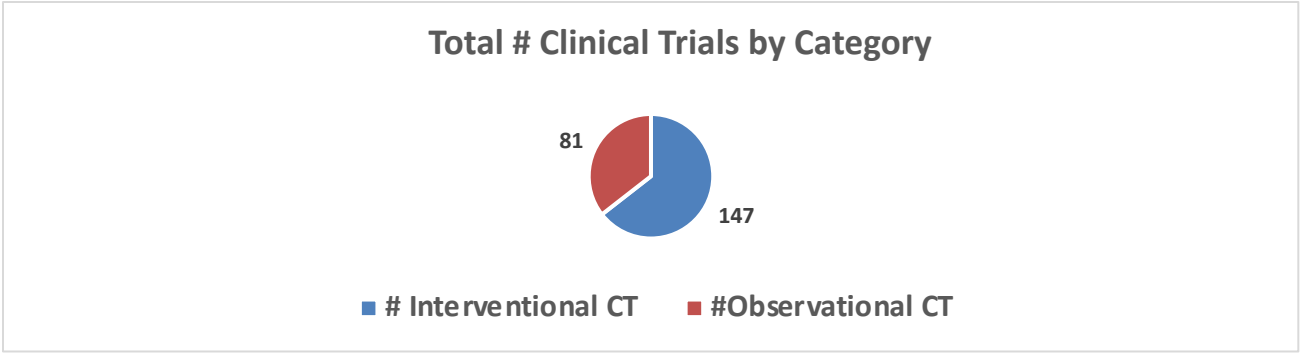
- Reviewed the committee roster and discussed recommendations of new members/institutions
- Agreed on quarterly CTAC meetings
- Discussed metrics needed for new initiatives: Early Clinical Investigator Award (ECIA) and Clinical Trials Network Award (CTNA)

2. **June 24, 2022:**

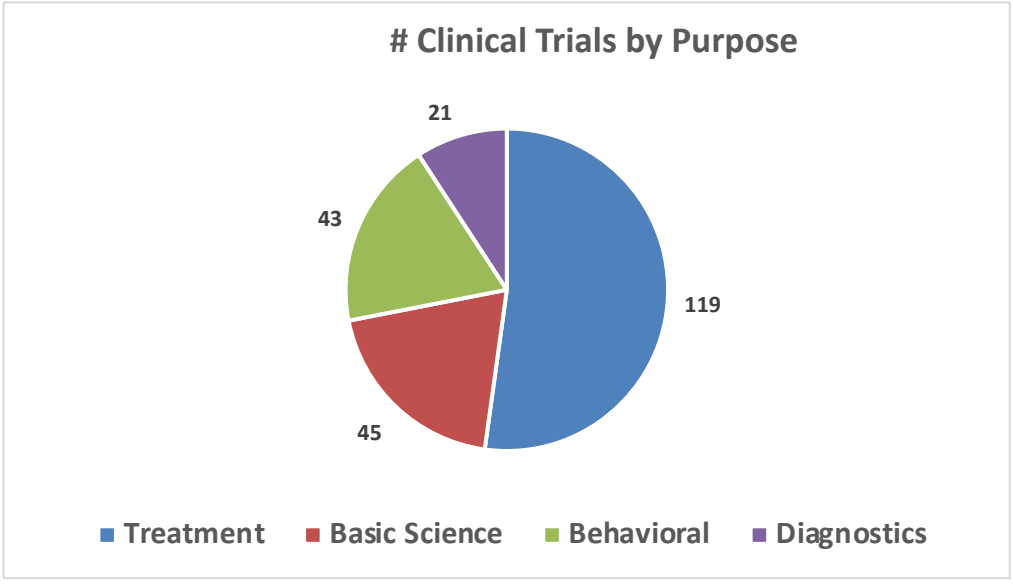
- Reviewed submission data on the RFAs
- Discussed issues related to the RFAs
- Discussed the Annual Report

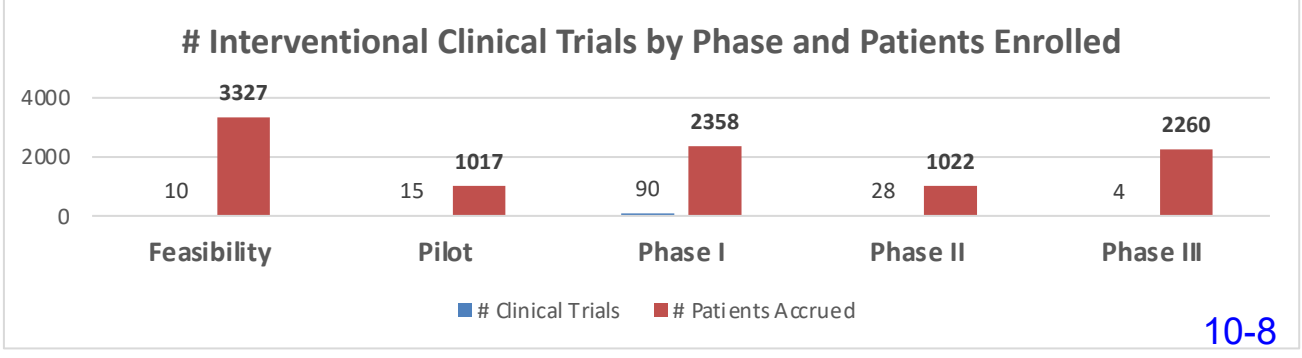
Academic Research Programs: 186 clinical trials; **39,277** patients enrolled; **7654** publications





Cumulative Clinical Research Data





Update on recent RFAs

Early Clinical Investigator Award (ECIA)

Rationale:

- The clinician scientist is becoming a dying breed due to aggressive productivity metrics; less protected time for protocol development and patient accrual
- At the same time, drug development is booming around precision medicine and immunotherapy

Funding mechanism:

- Early investigator (less than three years from fellowship)
- 50% protected time
- 300K x 5 years; clinical trial required

FY20 RFA released in August 2019 (8S/**4F**)
FY21 RFA released in August 2020 (11S/**5F**)
FY22 RFA released in August 2021 (9S/TBDF)

Early Clinical Investigator Award Metrics

Applicants (total): 25

- 16 M: 9 F
- 6 institutions

Awardees (2020-2021): 9

- 9 M: 0 F **Race:** 3 Asian, 4 White, 1 >1 race, Unknown 1
- 5 institutions

Types of studies: Treatment: Phase I Allogeneic CD30.CAR-EBVSTs in Patients With Relapsed or Refractory CD30-Positive Lymphomas; Diagnostic: Positron Emission Tomography for the diagnosis of immune checkpoint inhibitor-related myocarditis

Accrual: 17 patients

Impact: 5 publications

Opportunities:

- Need to ensure gender balance and diversification
- There still may be a bias towards physician scientists (faculty with lab effort) which was not intent of RFA
- May need to adjust protected time and/or amount of award
- Bottom line is that *retention/promotion of these clinicians* is primary metric with impact on patients

Clinical Trial Network Award (CTNA)

Rationale:

- With the plethora of agents in development, qualified investigators *and sites* are needed
- Need more access to trials in rural and underserved areas in Texas
- Equal access to early-phase clinical trials is an *equity issue*

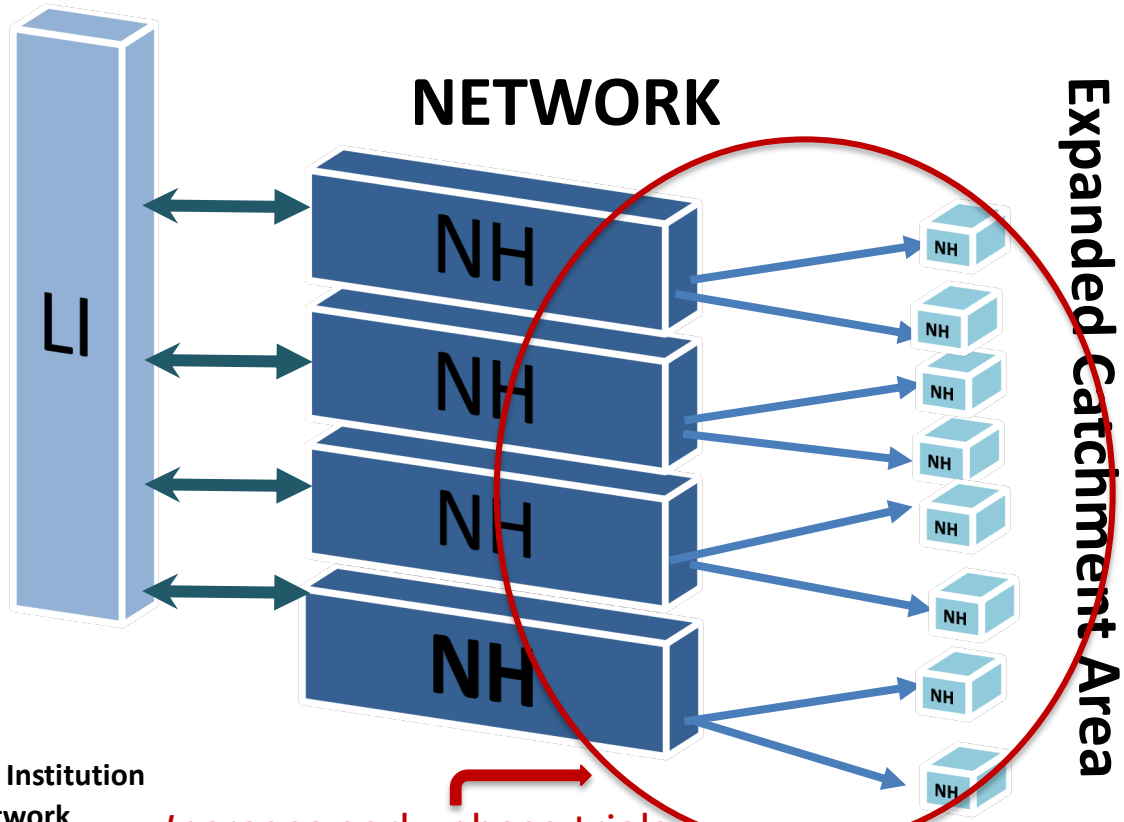
Funding mechanism:

- Up to $600,000 annually for Stage 1 and up to $900,000, annually for Stage 2
- Lead institution (LI) to engage network hospitals (NH)

FY21.2: Applications: (5S/**1F**)
FY22.2: Applications:(2S/Pending Review)

Clinical Trials Network Model

Lead Institution Mentoring Plan



10-12

Clinical Trial Network Award Metrics

Applicants (total): 5

Awardees (total): 1; MDACC LI, Phase I: LBJ Harris County NH; UTMB NH; Phase II: Outside Houston, underserved populations

Types of studies:

Accrual:

Impact:

Too early to assess

Opportunities:

- Concerns over representation/distribution of lead institutions (LIs)
- Agreements between lead institutions and network hospitals can take time
- Rural West Texas under-represented
- Local competition among hospitals systems and practices

Future Plans:

- Perhaps we need to reimagine/reinvigorate this plan…..

Current Environmental Context:

- The NCI, other cancer organizations, the FDA, industry, and academic/community cancer centers are aligned on continuing to *diversify enrollment* to clinical trials
- Access to *early clinical trials by all patients* is considered an *equity issue*; traditionally these trials are comprised of white patients with socioeconomic advantages
- During COVID, in order to continue to provide life-saving treatment for cancer patients, modifications were made to *enable remote participation and monitoring* of patients on trials
- The FDA published a *draft guidance* April 2022 “Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Subgroups in Clinical Trials”

How can we reimagine a Texas CTN?

Discovery Work

After the March meeting we initially set out to learn more about experiences with state-wide clinical trials network and about the current regulatory environment on telehealth (TH), remote participation:

1. **Patrick Leohrer, MD and HOG** (Hoosier Oncology Group):

- HOG was set up as partnership between IU and community sites for trials
- Incentive for community was ability to Co-Chair trials and present at ASCO
- Plan was investigator-initiated not just industry studies
- Trials taken on were "simple" (phase II/III)
- Community issues: $$, time required to create infrastructure, lack of incentives for MDs, inability to take on complex trials like Phase I
- Next focus *BIG 10 Cancer Research Consortium*---academic cancer centers; hope to add prevention and screening studies

Discovery Work

2. FDA Rick Pazdur, Paul Kluetz: Question to FDA was whether there were *inherent regulatory roadblocks* to using TH, local labs, remote consenting and monitoring for early-phase trials

- Answer was *no*.
- FDA is "*interested in advancing trial efficiencies, reducing patient burden, increasing accrual of a diverse population*…"
- Referred me to several publications on decentralized clinical trials (DCT) post-COVID, and retention of best practices
- In terms of early-phase trials, nothing in regulations mandating on site treatment and assessment if TH approach deemed safe for patients.

What we learned: 1) *Conventional* academic-community partnerships have largely been *ineffective* in providing access to early-phase trials to underserved and rural patients, 2)There really are *no hard regulatory barriers to* using DCT principles in diversifying access to clinical trials

Next Steps: Next-Gen Texas CTN

- We are going to *expand CTAC membership* as stated on earlier slide; this should ensure that we have the right expertise and stakeholders
- A call is being set up with Dr. Pat LoRusso (Yale/expertise in early clinical trials and underserved populations) about her recently launched *"hybrid decentralization model"*
- Dr. Ruma Bhagat: Principal Science Leader, *Global Health Equity and Population Sciences* at Genentech is going to join next CTAC meeting; hoping she will join as industry member
- With reinvigorated membership and expertise, we intend reexamine the ways that CPRIT can better engage underserved and rural communities in Texas and consider steps toward a:

Next-Gen Texas CTN

Conclusions

- COVID impacted all clinical research programs
- CPRIT CTAC launched *2 new RFAs* that are still primarily in the evaluation phase, too early to assess impact
- For the *Early Clinical Investigator Award*, we need to ensure the RFA targets clinical investigators and improve diversity of applicants and awardees
- For the *Clinical Trials Network*, we are embarking on a plan to:
  - Leverage lessons learned and tools utilized during COVID that enabled *decentralized clinical research* (DCT)
  - Expand CTAC membership expertise in this area
  - Continue the discovery process
  - Consider stepwise revision of CTNA to ***Next-Gen Texas CTN***
- CPRIT is poised to have great impact on clinical research programs in Texas; must stay relevant and responsive to the global clinical research environment to serve *all* Texas cancer patients

Thank you!

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE

FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

SUBJECT: FY 2023 HONORARIA POLICY

DATE: AUGUST 10, 2022

Summary and Recommendation

CPRIT's enabling legislation requires the Chief Executive Officer, with Oversight Committee approval, to adopt a policy for honoraria paid for peer review services. While the proposed FY 2023 honoraria for Prevention Program and Academic Research Program reviewers remain the same as the approved amounts for FY 2022, the proposed FY 2023 policy includes changes for the Product Development Program honoraria to accommodate approved alterations to the FY 2023 review process. These proposed changes include a preliminary review process and greater flexibility for use of ad hoc expert reviewers. I recommend that the Oversight Committee approve the FY 2023 honoraria policy.

Background

CPRIT's Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") review grant applications and recommend grant awards for meritorious projects addressing cancer prevention and research (including product development) in Texas. State law authorizes CPRIT to pay honoraria to individuals appointed to CPRIT's Scientific Research and Prevention Programs committees (Health and Safety Code § 102.151(d)). The ability to pay honoraria is essential to retaining individuals with the expertise and experience to carry out the complex review process required by CPRIT's statute and administrative rules.

In its January 2013 report, the State Auditor's Office recommended CPRIT implement a process supporting the honorarium it pays, to justify any changes, and to ensure that the honoraria are reasonable and competitive for the value CPRIT receives. The State Auditor also advised CPRIT to adopt documentation and process requirements for honoraria payments. CPRIT's statute incorporates the State Auditor's guidance at Texas Health and Safety Code § 102.151(e).

CPRIT's program staff relied upon historical information and anticipated workload projections to perform a detailed analysis of the activities, hours, and units for peer reviewer workload. The FY 2023 policy incorporates the roles and responsibilities assigned to Review Council chairs, Peer Review committee chairs, and peer review committee members and justifies the FY 2023 honorarium amount paid for each role. When honoraria rates are not standard across CPRIT's three programs, the policy justifies the reasons for paying different amounts.

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

Changes to the FY 2023 Product Development Program Honoraria

The Oversight Committee approved changes to the FY 2023 Product Development Program's review process at its May 18 meeting. These changes increase the efficiency of the review without sacrificing the integrity of the unbiased, conflict-free, expert-driven process. To accommodate the flexibility and greater use of ad hoc reviewers in the revamped FY 2023 review cycle, CPRIT proposes the following modifications to the Product Development Program honoraria policy for FY 2023.

- Establishing honoraria for the preliminary application review process

  The proposed FY 2023 Product Development Program honoraria policy reflects our expectation that at least eight PDRC members will review all preliminary applications and will commit 60 – 100 hours reviewing and scoring the applications in FY 2023.

  Filing of a required preliminary application by the companies seeking CPRIT grants is the most significant change proposed for the FY 2023 review process. Applicants must submit a preliminary application to a portal that receives applications at any time to be eligible for an invitation to submit a full application. The preliminary application is comprised of a 2-page executive summary, a 16-slide deck providing an overview of the scientific basis for the proposed project, and a 1-page explanation of the project's aims and requested budget.

  CPRIT expects to receive at least 50 preliminary applications in FY 2023. This is due to several factors, including CPRIT's increased outreach to potential applicants, the streamlined preliminary application and review, and the ability to file a preliminary application at any time.

  Product Development Review Council (PDRC) members will review all preliminary applications and decide which applicants will receive invitations to submit full applications. In addition to the PDRC members' expertise, their experience reviewing product development applications recommended for awards over the past decade provides consistency in this new process. The PDRC reviewers are familiar with the scientific merit required for successful CPRIT product development applications. Their expert review of the preliminary applications will be crucial to the quality of projects in the CPRIT product development pipeline.

- Setting honoraria by number of applications reviewed vs. review cycle

  The proposed FY 2023 Product Development Program honoraria policy is based on the number of applications reviewed by the expert rather than a flat fee for participation in the entire review cycle.

  Under the proposed policy the expert/advocate reviewer will receive $1,650 for each product development application reviewed, representing 15 – 25 hours of work and panel meeting(s).

If the application moves to due diligence, the reviewer will receive an additional $800 in recognition of the further work and meetings (8 – 12.5 hours) involved with due diligence review. The individual that leads the review panel receives an additional honorarium of $650 for the 6 – 10 hours work necessary to manage the review process, coordinate documentation, and represent the panel's recommendation to the PDRC and CPRIT.

This proposed change provides more flexibility for CPRIT to use ad hoc reviewers whose expertise aligns with the application's underlying science, product, and development/ regulatory stage. Pre-2023, the Product Development Program relied upon two review panels populated by 20-24 experts that met two times per year to evaluate all product development applications submitted by a set deadline. For scheduling purposes, the process required CPRIT to create the panels in advance of receiving applications, which decreased CPRIT's ability to add reviewers with specific expertise based upon the applications received. In addition, some potential expert reviewers were unable to participate due to the time commitment (at least three full business days of meetings per cycle, plus more time for reviewing and scoring applications.)

CPRIT is actively recruiting individuals experienced in oncology product development with expertise in areas such as devices, diagnostics, production of radionuclides, manufacture of cell-based therapies, processes to improve the quality of samples used for cancer research or clinical care, and emerging technologies including AI and bioinformatics. A manageable time commitment for the reviewers is a significant incentive for potential candidates and is crucial to CPRIT's ability to expand its bench of expert reviewers.

- Reflecting additional PDRC work in the base honoraria

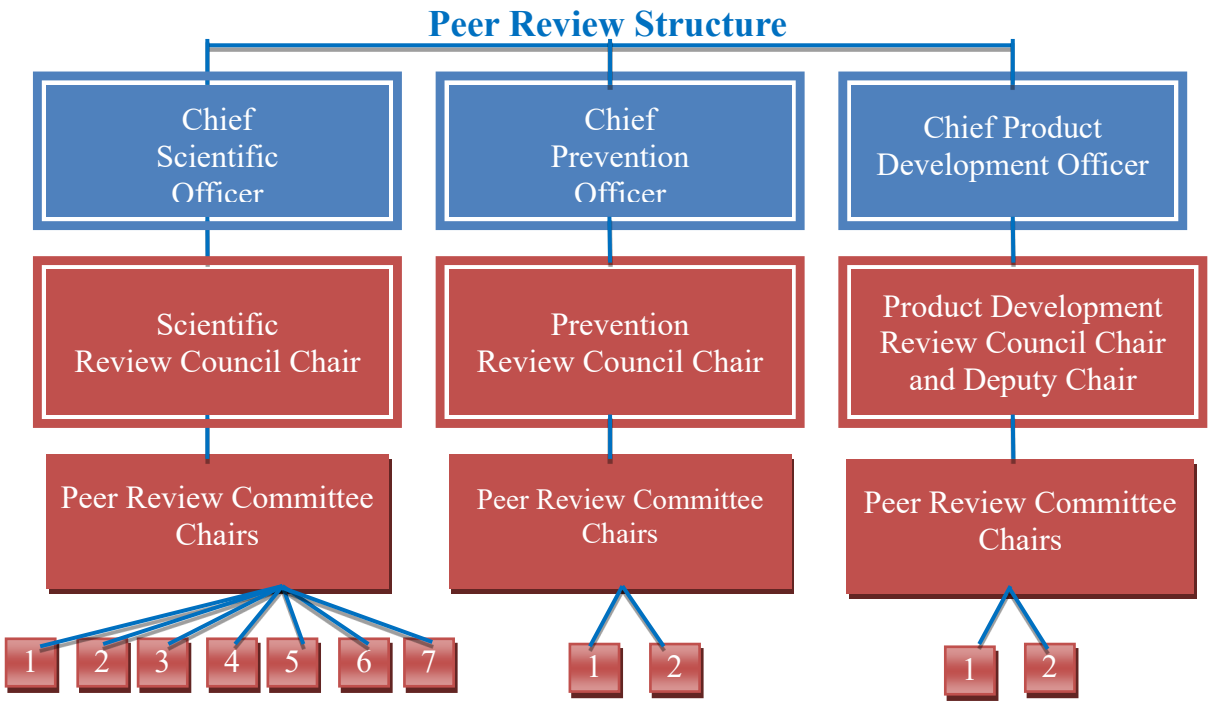
The proposed FY 2023 Product Development Program honoraria policy specifies "base" honoraria for PDRC members that recognizes the additional work performed by the PDRC, including advising CPRIT on proposed requests for applications, the review process, and the product development portfolio. The PDRC also reviews the reported progress of each active company project at least annually and advises CPRIT during semi-monthly conferences.

Prior to FY 2023, the PDRC honoraria policy included the activities reflected in the proposed base honoraria as well as full participation in the two annual review cycles. Separating the application review honoraria from the base honoraria in FY 2023 also provides the PDRC members the flexibility to participate in full application review as their schedule permits.

The FY 2023 base honoraria policy includes an optional $10,000 honorarium for serving as a board observer on behalf of CPRIT, representing 35 – 57.5 hours of work annually. The board observer position provides CPRIT real-time insight into management issues and company progress. CPRIT used a PDRC member to serve as a board observer and function as CPRIT's representative with OncoNano Medicine in FY 2022. Based on CPRIT's experience piloting the use of board observers, it is likely that CPRIT will expand the use of a board observer position to other company grantees in FY 2023, when appropriate.

CPRIT PEER REVIEW FY 2023 HONORARIA POLICY[1]

Peer review of prevention and research applications is the evaluation process conducted by qualified experts for feasibility, significance, and potential for impact. Like many funding agencies, CPRIT has implemented a tiered peer review process designed to identify the best projects based on excellence, program-specific objectives, and organizational priorities.[2] Maximizing the success of CPRIT's academic research, product development, and prevention programs is dependent upon the quality of the peer reviewers CPRIT recruits. Therefore, the peer reviewers must be exceptionally qualified, highly respected, well-established members of the cancer research, product development, and prevention communities.



CPRIT relies upon a pool of more than 200 expert peer reviewers to evaluate, score and rank grant applications based upon significance and merit. As reflected above, the general peer review structure is the same for CPRIT's three grant programs. CPRIT assigns reviewers to peer review committees based upon their expertise and background. The evaluations conducted by the peer review committees inform the list of grant applications recommended for CPRIT grant awards.[3]

CPRIT's expert peer reviewers live and work outside Texas, which is an uncommon requirement among grant-making organizations. CPRIT implemented this peer reviewer qualification to

[1] Adopted pursuant to TEX. HEALTH & SAFETY CODE Section 102.151(e).
[2] The National Academies of Sciences recommends a tiered approach to peer review.
[3] For more information about the grant review process undertaken by the peer review committees, please see CPRIT's administrative rules, 25 T.A.C. Part 11, Sections 703.6 and 703.7.

11-4

ensure an impartial review, minimize conflicts of interest, and provide the opportunity to select the best projects without regard for self-interest.

Honoraria

In recognition of the work undertaken by CPRIT peer reviewers, state law authorizes CPRIT to pay honoraria to its peer reviewers.[4] CPRIT's ability to pay honoraria is essential to retaining individuals with the expertise and experience to carry out the complex review process required by statute and CPRIT's administrative rules.

CPRIT recruits world-renowned experts who live and work outside of the state to be peer reviewers. CPRIT's residency policy is important to maintaining a review process that minimizes the potential for political and other outside influences, but it means that the CPRIT review process, by design, lacks non-monetary incentives common to other grant review processes that may otherwise justify the time commitment required of CPRIT peer reviewers in addition to their full-time jobs.

Specifically, CPRIT reviewers are not eligible to compete for CPRIT grants. This is different from other cancer grant-making organizations such as National Institutes of Health (NIH), Centers for Disease Control and Prevention, Department of Defense, American Cancer Society, and Susan G. Komen for the Cure. For example, NIH reviewers may review grant applications as well as compete for NIH grants. Familiarity with the NIH review process gained by serving as an NIH peer reviewer provides the individual a significant non-monetary benefit since that understanding better positions the reviewer to compete for and secure NIH grant funds as an applicant. This benefit is not available to CPRIT's reviewers.

A second nonmonetary benefit from serving on a review panel is that such service is an indication of external recognition in one's field, which is essential for academic and industry promotions. Using individuals already well established in their careers means that this is not an incentive for CPRIT peer reviewers to participate.

The Chairs of CPRIT review committees are all highly distinguished in their respective fields and bring enormous stature to the peer review process. Unlike chairs of other review processes, CPRIT's chairs are responsible for recruiting peer reviewers for their panel. In addition, they serve as strategic advisors for CPRIT's grant programs. These responsibilities are unique to CPRIT review committee chairs and require more effort and expertise than simply chairing a committee. Having committee chairs of this caliber distinguishes CPRIT's peer review process from all others.

Honoraria Payment Process and Documentation

Review Council and Committee Chairs receive quarterly honoraria payments directly from CPRIT. The honoraria payment process for Review Council chairs and Committee chairs is as follows:

[4] TEX. HEALTH & SAFETY CODE Section 102.151(d)

11-5

1. At the end of the fiscal quarter, the Review Council chairs and Committee chairs submit to CPRIT a written confirmation of the work performed and an estimate of hours* spent related to CPRIT's peer review activities for the quarter.

2. The CPRIT Program Officer reviews the confirmations and approves payment of quarterly honoraria to the Review Council chair and Committee chairs.

3. CPRIT's financial staff authorizes payment of the honoraria and retains the documentation supporting the honoraria payment.

4. The Chief Compliance Officer and Internal Auditor may also review the confirmations submitted.

* NOTE: CPRIT pays honorarium for the annual service of the Review Council chair or Committee chair. The payment does not use an hourly wage structure; the estimated number of hours devoted to CPRIT activities by a Review Council or Committee chair may vary by quarter depending upon the timing of review cycle activities. CPRIT uses the hourly estimate at the end of the year to set honoraria payment structures for the next fiscal year.

CPRIT's third party grant administrator pays peer reviewers for each review cycle in which they participate. To document the work performed by a peer review committee member for the review cycle, CPRIT's third party grant administrator confirms that the reviewer attended the peer review meeting and submitted written comments and scores for the grants assigned to the reviewer for evaluation.

CPRIT also reimburses travel expenses and pays the Texas state per diem when peer reviewers, Review Council chairs, and Committee chairs travel to attend peer review meetings. CPRIT relies upon standard travel documentation for travel reimbursements.

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

Peer Review Responsibilities

All CPRIT programs plan standard multi-cycle grant review activities to fully award all available grant funds allocated for FY 2023. At the time that CPRIT was pricing its FY 2023 third-party grant management contract, uncertainty remained regarding whether the COVID-19 pandemic would continue to restrict or otherwise affect in-person meetings and associated travel. To avoid cancellation fees, CPRIT will continue to convene peer review meetings via videoconference for

FY 2023. CPRIT first used videoconference meetings for all peer review activities held after March 2020 and the process has worked well.

Review Council Chairs

The Council Chair works directly with the CPRIT Program Officer to coordinate the peer review activities for each CPRIT program. The CPRIT model for peer review is unique. Other grant-making programs typically use committee chairs only to preside at committee meetings; however, CPRIT engages preeminent experts in their field for the Council Chair and Committee Chair positions to advise CPRIT on program aspects, including the short-term and long-term direction of the program, the review process itself, and the award portfolio composition. The chair's does this work in addition to the administrative tasks associated with chairing Review Council meetings. Many of the Council Chair responsibilities are similar across the three CPRIT programs, including:

- advising on the selection of committee chairs
- recruiting specialized peer reviewers and assisting with peer reviewer selection
- reviewing all abstracts of projects discussed at Prevention, Scientific, and Product Development Review Council meetings
- chairing Review Council meetings
- chairing a peer review panel meeting if a chair has an unexpected conflict[5]
- finalizing grant award recommendations submitted to the Chief Executive Officer
- providing ongoing advice to CPRIT staff on programs, review processes, and future funding opportunities

Estimated Annual Time Commitment: CPRIT expects Council Chairs to commit approximately 300 hours to CPRIT-related activities in FY 2023. This equates to 14.4% of a standard 2080-hour work year. **Table 1** provides a detailed analysis of the activities, hours, and units used to project the Council Chair workload. The information in Table 1 reflects 2018 – 2022 review cycle information and the projected workload for FY 2023.

NOTE: Due to changes in the Product Development Program review process beginning FY 2023, CPRIT is instituting a bifurcated honoraria policy for the Product Development Review Council (PDRC) Chair and Deputy Chair:

- As reflected on Table 1, the PDRC Chair and Deputy Chair[6] will receive a base honoraria that reflects their work advising CPRIT on the review process and RFAs, monitoring the preliminary application review implementation, advising CPRIT on review panel assignments as well as activities coordinating the review of annual progress reports and milestone funding decisions and providing expert advice and assistance related to CPRIT's product development portfolio and substantive grant contract amendment requests.

[5] The Product Development Committee Chair regularly chairs review committee meetings.
[6] In FY 2016, CPRIT created the PDRC Deputy Chair position. This position is equivalent to the PDRC Chair position except that the Deputy Chair will not prepare slate recommendation for the Chief Executive Officer. CPRIT will continue to use a Deputy Chair position for FY 2023.

- In addition to the base honoraria, if the PDRC Chair or Deputy Chair participate in the review of preliminary applications and/or the review of full applications, they will receive honoraria for participation in those review activities as set forth on Table 4.

Hourly Rate Proxy: CPRIT pays honorarium for the annual service of the Review Council chair and is not based on an hourly wage structure. However, for comparison, the honoraria paid to Review Council chairs equate to a $250/hour rate. This is in line with hourly rates paid for skilled professional services in other industries and less than the $500/hour rate paid for medical experts in malpractice cases.[7] The hourly rate used by CPRIT is also likely to be less than rates used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is greater than the $72,000 - $83,400 honoraria paid to CPRIT Review Council Chairs.

Review Committee Chairs

A Committee Chair leads each peer review committee. The CPRIT model for peer review is unique. Other grant-making programs typically use committee chairs only to preside at committee meetings; CPRIT engages preeminent experts in their field for the Committee Chair positions to advise CPRIT on program aspects, including the short-term and long-term direction of the program, the review process itself, and the award portfolio composition. The Committee Chair does this work in addition to the administrative tasks associated with chairing peer review committee meetings. Committee Chairs are also members of the Review Council for the program. Duties of the committee chair include:

- recruiting reviewers for their review panels
- assigning applications to their panel members
- becoming familiar with the abstracts and applications assigned to their panel
- determining order of review for applications for panel discussion
- chairing panel discussions; capturing key discussion points
- reviewing full applications to participate in programmatic review meetings
- evaluating CPRIT Scholar recruitment grants (Scientific Review Committee chairs)
- assessing due diligence and intellectual property reports for product development applications (Product Development Review Committee chairs)
- ranking grant applications and developing a list of recommended grant awards and supporting information for consideration by the CPRIT Program Integration Committee
- reviewing annual progress reports and milestone funding decisions (Product Development Program)
- participating in meetings with CPRIT staff to provide advice on future program directions, processes, evaluation criteria, and other related issues

[7] Data from *National Medical Consultants, P.C.*, a physician owned and operated company representing a panel of over 2700 medical experts who are distinguished specialists in all areas of medicine.

Estimated Annual Time Commitment: The amount of time spent on committee chair activities varies depending on the program. CPRIT expects Review Committee chairs to commit between 190 and 250 hours to CPRIT-related activities in FY 2023. **Table 2** provides a detailed analysis of the activities, hours, and units used to project the committee chair workload. The information in Table 2 reflects 2009 – 2022 review cycle information and the projected workload for FY 2023. For the purposes of the honoraria policy, CPRIT refers to Product Development Review Council members as "committee chairs" and they perform all activities listed in Table 2.

NOTE: Due to changes in the Product Development Program review process beginning FY 2023, CPRIT is instituting a bifurcated honoraria policy for the PDRC Committee Chairs:

- As reflected on Table 2, the PDRC Committee Chairs will receive a base honorarium that reflects their work advising CPRIT on the review process and RFAs, as well as activities coordinating the review of annual progress reports and milestone funding decisions and providing expert advice and assistance related to CPRIT's product development portfolio and substantive grant contract amendment requests.

- In addition to the base honoraria, the PDRC Committee Chairs participating in the review of preliminary applications and/or the review of full applications will receive honoraria for their participation in those review activities as set forth on Table 4.

Hourly Rate Proxy: CPRIT pays honorarium for the annual service of the Review Committee chair and is not based on an hourly wage structure. However, for comparison, the honoraria paid to Committee chairs equates to a $200/hour fee. This is in line with hourly rates paid for skilled professional services in other industries and less than the $500/hour rate paid for medical experts in malpractice cases.[8] The hourly rate used by CPRIT is also likely to be less than rates used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is more than the $37,000 - $50,000 honoraria paid to CPRIT Review Committee Chairs.

Review Committee Members

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

Estimated Time Commitment per Review Cycle: Peer reviewer activity varies by program and number of applications assigned. CPRIT expects academic research peer reviewers to commit

[8] Data from *National Medical Consultants, P.C.*, a physician owned and operated company representing a panel of over 2700 medical experts who are distinguished specialists in all areas of medicine.

approximately 85 hours per review cycle. Prevention peer reviewers will commit 55-70 hours per cycle. **Table 3** provides a detailed analysis of the activities, hours, and units used to project the peer review workload. The information in Table 3 reflects 2009–2022 review cycle information and the projected workload for FY 2023.

For product development peer reviewers, CPRIT is instituting a change for FY 2023 that pays honoraria on an application vs. review cycle basis. This change provides CPRIT more flexibility to use ad hoc reviewers whose expertise aligns with the application's underlying science, product, and development/ regulatory stage. Pre-2023, the Product Development Program relied upon two review panels populated by 20-24 experts that met two times per year to evaluate all product development applications submitted by a set deadline. For scheduling purposes, the process required CPRIT to create the panels in advance of receiving applications, which decreased CPRIT's ability to add reviewers with specific expertise based upon the applications received. In addition, some potential expert reviewers were unable to participate due to the significant time commitment (at least four full business days of meetings per cycle and 80 – 100 hours for reviewing and scoring applications.) A manageable time commitment for the reviewers is a significant incentive for potential review candidates and is crucial to CPRIT's ability to expand its bench of expert reviewers.

Hourly Rate Proxy: CPRIT pays honorarium to Academic Research and Prevention peer reviewers for a given review cycle, which is not based on an hourly wage structure. However, for comparison, honoraria paid to Academic Research and Prevention peer reviewers equates to a rate of $50/hour. Honoraria paid to Product Development peer reviewers is $65/hour. These reviewers must have both academic research and product development backgrounds and are more difficult to recruit. While the hourly rates are significantly less than those paid to professionals of this caliber, the rate is appropriate given the workload and responsibilities compared to Review Council and Committee chairs.

Comparison to other Grant Making Organizations

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

- International Cancer Research Partners (ICRP) surveyed 31 of its partner organizations and 21 responded. The report found that organizations paid different honoraria depending on the role of the reviewer. Chairs often received more than committee members did, and teleconference or online reviewers typically received less

compensation than those members who participated in-person. The report did not compute an average based on the supplied data.[9]

- CPRIT's third party grant administrator reports that two other clients pay reviewers $1,250 and $2,000 per review meeting.

- NCI's website reports that NCI pays $200 per day of review in addition to travel expenses.

[9] The report did not include a range, but the survey sponsors indicated the range for compensation for panel members was $150-$3,000 per day.

Table 1. Council Chair Activities (See Table 5 for an explanation of the correlation between units and hours.)

Table 1 - Review Council Chair Activities, Hours, Units						
Academic Research Program		**Prevention Program**		**Product Development Program – Base***		
Units	Activity	Units	Activity	Units Chair	Units Deputy	Activity
5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	20	20	Review grantee progress reports, advise staff on grantee activities, overall program direction; semi-monthly conference calls w/ staff
3.5	Help select and recruit Committee Chairs	2	Help select and recruit Committee Chairs	3	3	Select and recruit review council members and expert reviewers
6	Advise on peer review, CPRIT 2.0, FY 2023 Program Priorities, and other processes as needed	2	Advise on peer review and other processes as needed	5	5	Advise on peer review process and RFAs, participate in grant application/review webinars and other programmatic processes as needed
5	Review draft RFAs, propose new ones, etc	4	Review draft RFAs, propose new ones, etc	4.5	4.5	Advise/monitor preliminary review.
3	Communicate with Committee Chairs prior to peer review & programmatic mtg	1	Communicate with Committee Chairs prior to peer review & programmatic mtg	4.5	4.5	Assign full applications to panels, monitor full application review process
2	Prepare for Programmatic meetings; review materials	4	Prepare for Programmatic meetings; review materials	2	2	Advise/monitor due diligence review
2	Lead programmatic review	4	Lead programmatic review	3	2	Lead /participate in slate discussion
2	Prepare slate recommendations for CEO and Oversight Committee Chair	1	Prepare slate recommendations for CEO and Oversight Committee Chair			
24	Review recruitment applications, become familiar with applications for discussion	15	Review abstracts, attend portions of panel meetings, back up for panel Chair			
6	Lead monthly discussion on recruitment awards	4	Collaborate on articles for publication			
4	Analyze data for Research program	4	Analyze data for Prevention program			
		3	Participate in quarterly teleconference			
		6	Review dissemination applications			
		5	Review Annual and Final progress reports			
62.5		60		42	41	
$ 1,200	Unit cost	$1,200	Unit cost		$1,200	Unit cost
$ 250	Hourly rate	$250	Hourly rate		$250	Hourly rate
$75,000	Annual honoraria	**$72,000**	Annual honoraria		**$50,400**	Annual base honoraria Chair
					$49,200	Annual base honoraria Deputy Chair

*The PDRC Chair and Vice Chair may receive honoraria in addition to the base honoraria if they participate in reviewing preliminary or full applications. See Table 4.

Table 2. Committee Chair* Activities (See Table 5 for an explanation of the correlation between units and hours.)

Table 2 - Committee Chair Activities, Hours, Units					
Academic Research Review		**Prevention Review**		**Product Development Review – Base***	
Units	Activity	Units	Activity	Units	Activity
2	Select/recruit committee members	2	Select/recruit committee members	2	Select/recruit committee members
3	Review draft RFAs and provide input (as needed)	2	Review draft RFAs and provide input (as needed)	18	Review grantee progress reports; advise staff on grantee activities; participate in semi-monthly conference calls with staff.
10	Read abstracts; assign grants to reviewers	12	Read abstracts assigned to their committee; review panel assignments	3	Advise on review process, RFAs; participate in grant application/review webinars and other programmatic processes as needed
1	Assist with follow up of delinquent reviewers	1	Assist with follow up of delinquent reviewers	2	Participate in award slate meetings.
4	Chair the assigned committee review process via conference call or in person meeting	6	Chair the assigned committee review process via conference call or in person meeting		
1	Prepare for Programmatic meetings; review materials	2	Prepare for Programmatic meetings; review materials		
1	Participate in Chair's programmatic review meetings	6	Participate in Chair's programmatic review & debriefing meetings		
6	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs, CPRIT 2.0 and FY 2023 Program Priorities	2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs		
		3	Prepare and participate in quarterly Review Council teleconferences		
24	Review recruitment applications	4	Review dissemination applications		
5	Participate in monthly review of recruitment applications	2	Participate in review of dissemination applications		
57		42		25	
$875	Unit cost	$875	Unit cost	$875	Unit cost
$200	Hourly	$200	Hourly	$200	Hourly
$50,000	**$50,000** Annual honoraria	$36,750	**$37,000** Annual honoraria	$21,875	**$22,000** Annual honoraria

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

* For the Product Development Program, the members of the Product Development Review Council (PDRC) fulfill the "Committee Chair" activities.

** The PDRC may receive honoraria in addition to the base honoraria if they participate in reviewing preliminary or full applications. See Table 4.

Table 3. Peer Reviewer Activities per Cycle (See Table 5 for an explanation of the correlation between units and hours.)

Prevention Review: ~20 reviewers		Academic Research Review: ~ 130 reviewers	
Units	**Activity**	**Units**	**Activity**
1	Declaration of expertise and conflicts	1	Declaration of expertise and conflicts
8	Preparation of full critiques	10	Preparation of critiques*
1	Premeeting preparation of video conferencing capabilities	1	Premeeting preparation of video conferencing capabilities
4	Participation at meeting	3	Participation at meeting
1	Post-meeting discussion**	1	Post-meeting discussion**
1	Post-meeting survey to provide CPRIT feedback on CPRIT 2.0	1	Post-meeting survey to provide CPRIT feedback on CPRIT 2.0
16	$250 Unit cost $50 avg. hourly rate $4,000 per cycle	17	$250 Unit cost $50 avg. hourly rate $4,250 per cycle

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

NOTE: CPRIT pays peer reviewers only for activities in which they participate. For example, participation at a research peer review meeting is 3 units (11-15 hours) and CPRIT values each unit at $250; thus, the amount paid to an academic research peer reviewer for attendance at a peer review meeting is $750. If the reviewer was unable to attend the meeting, then CPRIT subtracts $750 from the honorarium paid to the reviewer. In the event a Review Council chair, Committee chair, or peer reviewer is not able to complete a full review cycle due to unforeseen circumstances, the CPRIT Program Officer may approve, in his or her discretion, a partial payment of the honorarium.

Table 4. Product Development Peer Reviewer Activities per Application (See Table 5 for the correlation between units and hours.)

Preliminary Application Review (PDRC members only) ~ 8 – 12 members	
Units	**Activity**
2	Declaration of conflicts
14	Review, score and critique preliminary applications
4	Participation in preliminary application panel teleconference
20	**Total Units for Preliminary Application Review**
$875	**Unit Cost**
$17,500	**Total**
Full Application Review (per application) ~ 60 reviewers	
Units	**Activity**
.5	Declaration of conflicts and expertise
3.5	Review full application, score and prepare critique
1	Participate in company presentation meeting and peer review panel discussion
2.5*	Participate in due diligence review and meetings, funding recommendation
2**	Lead panel member who manages panel discussion, coordinates critiques and scoring
5 – 9.5	**Total Review Units per Full Application**
$325	**Unit cost**
$1,625 – $3,075	**Total per Full Application**
* Only those applications scoring sufficiently well will proceed to due diligence review; reviewer will only receive this additional honorarium if the application undergoes due diligence review.	
** Each review panel will have one lead member; only the reviewer designated as the lead member receives this additional honorarium.	

Table 5. Hours and Units Calculation

PARTICIPATION (HOURS)	UNITS		Council Chairs (and Vice Chair)	Committee Chairs	Peer reviewers
1-5	1		Unit Cost		
6-10	2		$1200	$875	$250-$325
11-15	3		Average Hourly Rate		
16-20	4		$250	$200	$50-$65
21-25	5		Honoraria		
26-30	6		$65,400 - $83,400 annually	$36,750 - $50,000 annually	$4,250 - $6,500 per cycle
31-35	7				
36-40	8				
41-45	9				
46-50	10				
51-55	11				
56-60	12				
61-65	13				
66-70	14				
71-75	15				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER—REVIEW COUNCILS FY 2023
DATE:	AUGUST 1, 2022

Waiver Request and Recommendation

I request that the Oversight Committee approve a fiscal year 2023 conflict of interest waiver for review council members pursuant to Health & Safety Code § 102.1062 "Exceptional Circumstances Requiring Participation." Unlike other conflict of interest waivers that the Oversight Committee has approved previously, CPRIT does not grant this waiver for a specific conflict of interest or person. Instead, CPRIT intends to invoke this waiver as necessary to address the unusual scenario when a review council member has a conflict with a grant application that is part of the larger group of proposals that the review panel or review council must act upon (usually to recommend for awards). The waiver is necessary for a review council member to participate in the overall discussion and vote on the slate of award recommendations. This waiver is the same waiver the Oversight Committee approved for FY 2022.

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

Background

Health & Safety Code § 102.1062 directs the Oversight Committee to adopt administrative rules governing the waiver of the conflict of interest requirements of the statute in exceptional circumstances. CPRIT's administrative rule § 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year. The rules require that a majority of the Oversight Committee members must vote to approve the waiver. CPRIT must report any approved waiver to the lieutenant governor, speaker of the house of representatives, the governor, and the standing committees of each house of the legislature with primary jurisdiction over CPRIT matters.

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

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

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

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

Exceptional Circumstances Requiring the Review Council Member's Participation

To approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. In this case, exceptional circumstances exist due to the necessity of the review council member's participation in the process to develop the overall award recommendation slates and the Oversight Committee should grant the proposed waiver. The limitations mitigate the potential for bias.

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

Proposed Waiver and Limitations

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

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

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

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

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- CPRIT limits this waiver to review council members operating under the circumstances specified in this request.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER – DR. JOHN HELLERSTEDT, FY2023
DATE:	AUGUST 1, 2022

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2023 for Program Integration Committee (PIC) member Department of State Health Services (DSHS) Commissioner Dr. John Hellerstedt, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Commissioner Hellerstedt to participate in CPRIT's review process as a PIC member if DSHS applies for a CPRIT grant. Together with the waiver's proposed limitations, adequate protections are in place to mitigate factors other than merit and the established grant criteria affecting the award of grant funds. The waiver is the same as previously approved for the past several years.

Background

Governor Abbott appointed Dr. Hellerstedt as DSHS Commissioner on January 1, 2016. The DSHS Commissioner is a statutorily designated member of the PIC. As a PIC member, Commissioner Hellerstedt must exercise discretion related to whether to recommend applications proposed for grant awards to the Oversight Committee for final approval.

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

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

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

Exceptional Circumstances Requiring Commissioner Hellerstedt's Participation

To approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. The statute compels Commissioner Hellerstedt's participation in the review process. The Oversight Committee should grant the proposed waiver so that CPRIT may fulfill legislative intent that the DSHS Commissioner serve as a PIC member. If DSHS applies for a CPRIT grant, the proposed limitations will substantially mitigate any potential for bias.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Section 102.106(c)(3), I recommend that if DSHS applies for a CPRIT grant in FY 2023, the Oversight Committee permit Commissioner Hellerstedt to continue to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. Attend and participate fully in the PIC meetings except that Commissioner Hellerstedt shall not participate in the PIC's discussion or vote on grant award recommendations to DSHS;

2. Have access to grant application information developed during the grant review process, except for information related to DSHS applicants, if any; and

3. Provide information to the Oversight Committee or CPRIT personnel about the grant review process and applications recommended by the PIC for grant awards, including answering questions raised by the Oversight Committee or CPRIT personnel. If Commissioner Hellerstedt provides information on his own initiative in a review cycle in which DSHS is a grant applicant, the information provided by Commissioner Hellerstedt should be general information related to the overall grant application process and not advocate specifically for grant applications submitted by DSHS.

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

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- CPRIT limits this waiver to the conflict of interest specified in this request. To the extent that Commissioner Hellerstedt has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(3), then Commissioner Hellerstedt will follow the required notification and recusal process.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE CHAIR MAHENDRA PATEL
FROM:	WAYBE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER—BRANDY FY 2023
DATE:	AUGUST 1, 2022

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2023 for Mr. Donald Brandy, CPRIT's Purchaser and HUB Coordinator, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The Oversight Committee approved the same waiver for Mr. Brandy since FY 2015.

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

Background

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

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

CPRIT employees may engage in outside employment so long as the employment does not detract from the employee's ability to fulfill his or her responsibilities to CPRIT. Employees

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

must receive written approval from the CEO to engage in outside employment and I notify the Audit Subcommittee regarding any approvals. I also annually report to the Oversight Committee all approved outside employment. I notified the Audit Subcommittee regarding my approval for Mr. Brandy's outside employment and the subcommittee first discussed it at the December18, 2014, subcommittee meeting.

Exceptional Circumstances Requiring Mr. Brandy's Participation

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

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

However, as part of his official duties there may be circumstances requiring Mr. Brandy to procure goods or services on CPRIT's behalf from a university that has also employed him as a tennis referee. This is unlikely to occur; to date, CPRIT has had only two service contracts (both now closed) with an academic institution, Texas Tech University and The University of Texas at Austin LBJ School of Public Affairs. As CPRIT's lead contact for agency purchases, Mr. Brandy should be able to perform his official duties as fully as possible. Any involvement with university athletic department personnel resulting from his outside employment is unlikely to be the same individuals at the university responsible for contracting with CPRIT.

Proposed Waiver and Limitations

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

1. Provide the Chief Operating Officer a list of universities that have used his services as referee during the past twelve months;
2. Notify the Chief Operating Officer prior to taking any action on a contract or other procurement document that would result in payment of CPRIT funds to a university on the list referenced above; and

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

3. The Chief Operating Officer, in conjunction with the CEO, Chief Compliance Officer and General Counsel, can review the circumstances and determine whether to recuse Mr. Brandy from involvement in the procurement.

Important Information Regarding this Waiver and the Waiver Process

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

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER & GENERAL COUNSEL CAMERON L. ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	CHAPTER 703 - PROPOSED RULE CHANGES
DATE:	AUGUST 8, 2022

Summary and Recommendation

The Board Governance Subcommittee convened August 4 to discuss the suggested rule changes to Texas Administrative Code Chapter 703. Publication of the anticipated rule changes in the *Texas Register* is the first step in the agency rulemaking process. CPRIT Staff will bring back the proposed rule amendments and any public comments to the Oversight Committee in November for final approval.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes as well as managing other requirements of Texas Health and Safety Code Chapter 102. State law requires agencies to use a rulemaking process, which includes an opportunity for the public to comment on the rule changes before the agency adopts the final policy.

The Board Governance Subcommittee met on August 4 to discuss the proposed rule changes to Texas Administrative Code (TAC) Chapter 703. The subcommittee voted to recommend that the Oversight Committee approve publication of the suggested changes in the *Texas Register*.

The proposed amendments impact five different sections in Chapter 703. First, the amendment to TAC § 703.11 adds grantee expenses to relocate to Texas to the list of eligible funds that count towards a grantee's matching funds requirement. Next, the amendment to TAC § 703.24 changes the deadline from 21 days to five (5) business days for a grantee to provide corrections to Financial Status Report (FSR) supporting documentation. If a grantee does not provide the requested corrections within five business days then CPRIT may disapprove the FSR. Lastly, the proposed amendments to §§ 703.10, 703.15, and 703.26 replace references to Uniform Grant Management Standards with Texas Grant Management Standards.

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

Next Steps

Once approved by the Oversight Committee, CPRIT will publish the proposed rule changes in the *Texas Register*. The publication date begins the 30-day period for soliciting comment from interested members of the public. CPRIT will also post the proposed rule changes on our website and announce the opportunity for public comment via CPRIT's electronic list serve. CPRIT legal staff will summarize any comments received from the public for the Oversight Committee's consideration when approving the final rule changes in November.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") proposes amending 25 Tex. Admin. Code §§ 703.11 (relating to the eligibility of certain grant recipient expenses to quality as matching grant funds) and 703.24 (relating to submission of corrections to grant recipient documentation supporting Financial Status Reports.) The Institute further proposes amendments to 25 Tex. Admin. Code §§ 703.10, 703.15, and 703.26 to references to Uniform Grant Management Standards with Texas Grant Management Standards.

Background and Justification

The proposed amendment to § 703.11(c) adds a new paragraph (7) allowing a grant recipient to count expenditures the grant recipient incurs for relocating its operations and personnel to Texas toward the grant recipient's matching funds obligation. Texas Health and Safety Code § 102.255(c) requires a research grant recipient to dedicate an amount of matching funds equal to one-half of the amount of the research grant awarded. Section § 703.11 provides examples of eligible grant recipient expenditures to fulfill the matching funds requirement. Grant recipients who relocate to Texas to carry out the goals and objectives of their CPRIT grant may be eligible to count those relocation expenses as matching funds.

The proposed amendment to § 703.24(a)(5) requires a grant recipient to provide information necessary to correct a deficiency in the supporting documentation of a Financial Status Report (FSR) within five (5) business days of a request from the Institute. If the grant recipient fails to provide the requested information, the Institute may disapprove the FSR. Currently, CPRIT permits a grant recipient 21 days to respond to a request regarding FSR supporting documentation. Changing the response time to 5 business days will expedite review of FSR supporting documentation.

The proposed amendments to §§ 703.10(c)(11), 703.15(b)(3), and 703.26(b) update outdated references to Uniform Grant Management Standards (UGMS) in the Institute's administrative rules with the new Texas Grant Management Standards (TxGMS) references. The Comptroller of Public Accounts published TxGMS to replace UGMS effective 2022. The Institute refers grant recipients to TxGMS, when there are not Institute-specific guidelines within CPRIT's statute and/or administrative rules.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and General Counsel for CPRIT, has determined that for the first five-year period the rule change is in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule change is in effect the public benefit anticipated due to enforcing the rule will be clarifying grantee reporting obligations and consequences.

Small Business, Micro-Business, and Rural Communities Impact Analysis

Ms. Doyle has determined that the rule change will not affect small businesses, micro businesses, or rural communities.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the proposed rule change will be in effect:

(1) the proposed rule change will not create or eliminate a government program;

(2) implementation of the proposed rule change will not affect the number of employee positions;

(3) implementation of the proposed rule change will not require an increase or decrease in future legislative appropriations;

(4) the proposed rule change will not affect fees paid to the agency;

(5) the proposed rule change will not create new rule;

(6) the proposed rule change will not expand existing rule;

(7) the proposed rule change will not change the number of individuals subject to the rule; and

(8) The rule change is unlikely to have an impact on the state's economy. Although the change is likely to have neutral impact on the state's economy, the Institute lacks enough data to predict the impact with certainty.

Submit written comments on the proposed rule change to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than October 3, 2022. The Institute asks parties filing comments to indicate whether they support the rule revision proposed by the Institute and, if the party requests a change, to provide specific text for the proposed change. Parties may submit comments electronically to kdoyle@cprit.texas.gov or by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes the rule change under the authority of the Texas Health and Safety Code Annotated, §102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle has reviewed the proposed amendment 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.

<rule>

§703.10. Awarding Grants by Contract.

The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds and enter into a written contract with the Grant Recipient.

(b) The Oversight Committee may delegate Grant Contract negotiation duties to the Chief Executive Officer and the General Counsel for the Institute. The Chief Executive Officer may enter into a written contract with the Grant Recipient on behalf of the Oversight Committee.

(c) The Grant Contract shall include the following provisions:

(1) If any portion of the Grant Contract has been approved by the Oversight Committee to be used to build a capital improvement, the Grant Contract shall specify that:

(A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale;

(2) Terms relating to Intellectual Property Rights and the sharing with the Institute of revenues generated by the sale, license, or other conveyance of such Project Results consistent with the standards established by this chapter;

(3) Terms relating to publication of materials created with Grant Award funds or related to the Cancer Research or Cancer Prevention project that is the subject of the Grant Award, including an acknowledgement of Institute funding and copyright ownership, if applicable:

(A) Acknowledgment of Institute funding must include the grant number of every Institute-funded grant contributing to the work memorialized in the publication; and

(B) Subparagraph (A) of this paragraph is effective beginning September 1, 2021;

(4) Repayment terms, including interest rates, to be enforced if the Grant Recipient has not used Grant Award funds for the purposes for which the Grant Award was intended;

(5) A statement that the Institute does not assume responsibility for the conduct of the Cancer Research or Cancer Prevention project, and that the conduct of the project and activities of all investigators are under the scope and direction of the Grant Recipient;

(6) A statement that the Cancer Research or Cancer Prevention project is conducted with full consideration for the ethical and medical implications of the project and that the project will comply with all federal and state laws regarding the conduct of the Cancer Research or Prevention project;

(7) Terms related to the Standards established by the Oversight Committee in Chapter 701 of this title (relating to Policies and Procedures) to ensure that Grant Recipients, to the extent reasonably possible, demonstrate good faith effort to purchase goods and services for the Grant Award project from suppliers in this state and from historically underutilized businesses as defined by Chapter 2161, Texas Government Code, and any other state law;

(8) An agreement by the Grant Recipient to submit to regular inspection reviews of the Grant Award project by Institute staff during normal business hours and upon reasonable notice to ensure compliance with the terms of the Grant Contract and continued merit of the project;

(9) An agreement by the Grant Recipient to submit Grant Progress Reports to the Institute on a schedule specified by the Grant Contract that includes information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Institute funding;

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

(11) An agreement that the Grant Recipient will abide by the Texas [~~Uniform~~] Grant Management Standards (TxGMS) [~~(UGMS)~~] published [~~adopted~~] by the Comptroller of Public Accounts Statewide Procurement Division [~~Governor's Office~~], if applicable, unless one or more standards conflicts with a provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules. Such interpretation of the Institute rules and TxGMS [~~UGMS~~] shall be made by the Institute;

(12) An agreement that the Grant Recipient is under a continuing obligation to notify the Institute of any adverse conditions that materially impact milestones and objectives included in the Grant Contract;

(13) An agreement that the design, conduct, and reporting of the Cancer Research or Prevention project will not be biased by conflicting financial interest of the Grant Recipient or any individuals associated with the Grant Award. This duty is fulfilled by certifying that an appropriate written, enforced Conflict of Interest policy governs the Grant Recipient;

(14) An agreement regarding the amount, schedule, and requirements for payment of Grant Award funds, if such advance payments are approved by the Oversight Committee in accordance with this chapter. Notwithstanding the foregoing, the Institute may require that up to ten percent of the final tranche of funds approved for the Grant Award must be expended on a reimbursement basis. Such reimbursement payment shall not be made until close out documents described in this section and required by the Grant Contract have been submitted and approved by the Institute;

(15) An agreement to provide quarterly Financial Status Reports and supporting documentation for expenses submitted for reimbursement or, if appropriate, to demonstrate how advanced funds were expended;

(16) A statement certifying that, as of June 14, 2013, the Grant Recipient has not made and will not make a contribution, during the term of the Grant Contract, to the Institute or to any foundation established specifically to support the Institute;

(17) A statement specifying the agreed effective date of the Grant Contract and the period in which the Grant Award funds must be spent. If the effective date specified in the Grant Contract is different from the date the Grant Contract is signed by both parties, then the effective date shall control;

(18) A statement providing for reimbursement with Grant Award funds of expenses made prior to the effective date of the Grant Contract at the discretion of the Institute. Pre-contract reimbursement shall be made only in the event that:

(A) The expenses are allowable pursuant to the terms of the Grant Contract;

(B) The request is made in writing by the Grant Recipient and approved by the Chief Executive Officer; and

(C) The expenses to be reimbursed were incurred on or after the date the Grant Award recommendation was approved by the Oversight Committee;

(19) Requirements for closing out the Grant Contract at the termination date, including the submission of a Financial Status Report, a final Grant Progress Report, an equipment inventory, a HUB and Texas Business report, a revenue sharing form, a single audit determination report form and a list of contractual terms that extend beyond the termination date;

(20) A certification of dedicated Matching Funds equal to one-half of the amount of the Research Grant Award that includes the name of the Research Grant Award to which the matching funds are to be dedicated, as specified in Section §703.11 of this chapter (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants);

(21) The project deliverables as described by the Grant Application and stated in the Scope of Work for the Grant Contract reflecting modifications, if any, approved during the Peer Review process or during Grant Contract negotiation;

(22) An agreement that the Grant Recipient shall notify the Institute and seek approval for a change in effort for any of the Senior Members or Key Personnel of the research or prevention team listed on the Grant Application, including any proposed temporary leave of absence of a Principal Investigator, Program Director, or Company Representative;

(23) An agreement that the Grant Recipient is legally responsible for the integrity of the fiscal and programmatic management of the organization; and

(24) An agreement that the Grant Recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The Grant Recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the Institute if the infraction is related to a Grant Award.

(d) The Grant Recipient's failure to comply with the terms and conditions of the Grant Contract may result in termination of the Grant Contract, pursuant to the process prescribed in the Grant Contract, and trigger repayment of the Grant Award funds.

§703.11. Requirement to Demonstrate Available Funds for Cancer Research Grants.

(a) Prior to the disbursement of Grant Award funds, the Grant Recipient of a Cancer Research Grant Award shall demonstrate that the Grant Recipient has an amount of Encumbered Funds equal to at least one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award.

(1) The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract.

(2) A Grant Recipient of a multiyear Grant Award may certify Matching Funds on a year-by-year basis for the amount of Award Funds to be distributed for the Project Year based upon the Approved Budget.

(3) A Grant Recipient receiving multiple Grant Awards may provide certification at the institutional level.

(4) Nothing herein restricts the Institute from requiring the Grant Recipient to demonstrate an amount of Encumbered Funds greater than one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award. To the extent that a greater Matching Funds amount will be required, the Institute shall include the requirement in the Request for Applications and in the Grant Contract.

(b) For purposes of the certification required by subsection (a) of this section, a Grant Recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the five percent (5%) Indirect Cost limit imposed by §102.203(c), Texas Health and Safety Code, subject to the following requirements:

(1) The Grant Recipient shall file certification with the Institute documenting the federal indirect cost rate authorized for research grants awarded to the Grant Recipient;

(2) To the extent that the Grant Recipient's Matching Funds credit does not equal or exceed one-half of the Grant Award funds to be distributed for the Project Year, then the Grant Recipient's Matching Funds certification shall demonstrate that a combination of the dollar amount equivalent credit and the funds to be dedicated to the Grant Award project as described in subsection (c) of this section is available and sufficient to meet or exceed the Matching Fund requirement;

(3) Calculation of the portion of federal indirect cost rate credit associated with subcontracted work performed for the Grant Recipient shall be in accordance with the Grant Recipient's established internal policy; and

(4) If the Grant Recipient's federal indirect cost rate changes six months or less following the anniversary of the Effective Date of the Grant Contract, then the Grant Recipient may use the new federal indirect cost rate for the purpose of calculating the Grant Recipient's Matching Funds credit for the entirety of the Project Year.

(c) For purposes of the certification required by subsection (a) of this section, Encumbered Funds must be spent directly on the Grant Project or spent on closely related work that supports, extends, or facilitates the Grant Project and may include:

(1) Federal funds, including, but not limited to, American Recovery and Reinvestment Act of 2009 funds, and the fair market value of drug development support provided to the recipient by the National Cancer Institute or other similar programs;

(2) State of Texas funds;

(3) funds of other states;

(4) Non-governmental funds, including private funds, foundation grants, gifts and donations;

(5) Unrecovered Indirect Costs not to exceed ten percent (10%) of the Grant Award amount, subject to the following conditions:

(A) These costs are not otherwise charged against the Grant Award as the five percent (5%) indirect funds amount allowed under §703.12(c) of this chapter (relating to Limitation on Use of Funds);

(B) The Grant Recipient must have a documented federal indirect cost rate or an indirect cost rate certified by an independent accounting firm; and

(C) The Grant Recipient is not a public or private institution of higher education as defined by §61.003 of the Texas Education Code.

(6) Funds contributed by a subcontractor or subawardee and spent on the Grant Project, so long as the subcontractor's or subawardee's portion of otherwise allowable Matching Funds for a Project Year may not exceed the percentage of the total Grant Funds paid to the subcontractor or subawardee for the same Project Year.

(7) Costs incurred by the Grant Recipient to relocate the Grant Recipient's operations and/or personnel to Texas.

(d) For purposes of the certification required by subsection (a) of this section, the following items do not qualify as Encumbered Funds:

(1) In-kind costs;

(2) Volunteer services furnished to the Grant Recipient;

(3) Noncash contributions;

(4) Income earned by the Grant Recipient that is not available at the time of Grant Award;

(5) Pre-existing real estate of the Grant Recipient including building, facilities and land;

(6) Deferred giving such as a charitable remainder annuity trust, a charitable remainder unitrust, or a pooled income fund; or

(7) Other items as may be determined by the Oversight Committee.

(e) To the extent that a Grant Recipient of a multiyear Grant Award elects to certify Matching Funds on a Project Year basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year may serve as grounds for suspending reimbursement or advancement of Grant Funds for project costs or terminating the Grant Contract.

(f) In no event shall Grant Award funds for a Project Year be advanced or reimbursed, as may be appropriate for the Grant Award and specified in the Grant Contract, until the certification required by subsection (a) of this section is filed and approved by the Institute.

(g) No later than thirty (30) days following the due date of the FSR reflecting expenses incurred during the last quarter of the Grant Recipient's Project Year, the Grant Recipient shall file a form with the Institute reporting the amount of Matching Funds spent for the preceding Project Year.

(1) The Grant Recipient must provide all documentation, including proof of payment, showing that the Grant Recipient expended the required amount of Matching Funds on the CPRIT project for the preceding Project Year. The Institute will accept a general ledger from public or private institutions of higher education as proof of payment.

(2) The Institute will not review or approve the Grant Recipient's Matching Funds form until the Grant Recipient submits the form and all required documentation.

(h) If the Grant Recipient failed to expend Matching Funds equal to one-half of the actual amount of Grant Award funds distributed to the Grant Recipient for the same Project Year the Institute shall:

(1) Carry forward and add to the Matching Fund requirement for the next Project Year the dollar amount equal to the deficiency between the actual amount of Grant Award funds distributed and the actual Matching Funds expended, so long as the deficiency is equal to or less than twenty percent (20%) of the total Matching Funds required for the same period and the Grant Recipient has not previously had a Matching Funds deficiency for the project;

(2) Suspend distributing Grant Award funds for the project to the Grant Recipient if the deficiency between the actual amount of Grant Funds distributed and the Matching Funds expended is greater than twenty percent (20%) but less than fifty percent (50%) of the total Matching Funds required for the period;

(A) The Grant Recipient will have no less than eight months from the anniversary of the Grant Contract's effective date to demonstrate that it has expended Encumbered Funds sufficient to fulfill the Matching Funds deficiency for the project.

(B) If the Grant Recipient fails to fulfill the Matching Funds deficiency within the specified period, then the Grant Contract shall be considered in default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract.

(3) Declare the Grant Contract in default if the deficiency between the actual amount of Grant Award funds distributed and the Matching Funds expended is greater than fifty percent (50%) of

the total Matching Funds required for the period. The Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract; or

(4) Take appropriate action, including withholding reimbursement, requiring repayment of the deficiency, or terminating the Grant Contract if a deficiency exists between the actual amount of Grant Award funds distributed and the Matching Funds expended and it is the last year of the Grant Contract.

(i) Nothing herein shall preclude the Institute from taking action other than described in subsection (h) of this section based upon the specific reasons for the deficiency. To the extent that other action not described herein is taken by the Institute, such action shall be documented in writing and included in Grant Contract records. The options described in subsection (h)(1) and (2) of this section may be used by the Grant Recipient only one time for the particular project. A second deficiency of any amount shall be considered an event of default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract.

(j) The Grant Recipient shall maintain adequate documentation supporting the source and use of the Matching Funds reported in the certification required by subsection (a) of this section. The Institute shall conduct an annual review of the documentation supporting the source and use of Matching Funds reported in the required certification for a risk-identified sample of Grant Recipients. Based upon the results of the sample, the Institute may elect to expand the review of supporting documentation to other Grant Recipients. Nothing herein restricts the authority of the Institute to review supporting documentation for one or more Grant Recipients or to conduct a review of Matching Funds documentation more frequently.

(k) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.15. Financial Policies Applicable to Grant Awards.

(a) The Grant Recipient is responsible for managing the day-to-day operations of the activities supported by the Grant Award and is accountable to Institute for the performance of the Grant Award, including the appropriate expenditure of Grant Award funds by all parties and all other obligations of the Grant Recipient.

(b) The Grant Recipient must maintain a sound financial management system that provides appropriate fiscal controls and accounting procedures to ensure accurate preparation of reports by the Grant Contract and adequate identification of the source and application of Grant Award funds.

(1) The Grant Recipient may use its established controls and policies, as long as the controls and policies are consistent with requirements described in the Institute's administrative rules, the Grant Contract, and other applicable standards.

(2) The Grant Recipient's system of internal controls should encompass segregation of functions, proper authorization of transactions, proper recording of transactions, limited access to assets, and monitoring of internal controls. The extent to which internal controls are established is dependent upon the nature and size of the organization involved.

(3) The Grant Recipient's accounting system must conform to Generally Accepted Accounting Principles applicable to state and federal grant funds and conform to the standards for financial management set forth in the Texas [~~Uniform~~] Grant Management Standards (TxGMS).

(4) The Institute may review the adequacy of the financial management system of any Grant Recipient to ensure that the system is appropriate to fulfill the Institute's administrative rules, the Grant Contract, and other applicable standards.

(c) The Grant Recipient shall use cash basis accounting when reporting expenses to be reimbursed with Grant Award funds.

(1) A Grant Recipient utilizing an accrual basis of accounting in its normal operations must present expenses on a cash basis and reflect actual costs incurred during the payment period.

(2) A subcontractor is not required to record the adjustment in the general ledger; the adjustment should be documented by memo entries along with a reconciliation of the expense reported to the Institute and the expense recorded to the general ledger.

§703.24. Financial Status Reports.

(a) The Grant Recipient shall report expenditures to be reimbursed with Grant Award funds on the quarterly Financial Status Report form. The Grant Recipient must report all expenses for which it seeks reimbursement that the Grant Recipient paid during the fiscal quarter indicated on the quarterly Financial Status Report form.

(1) Expenditures shall be reported by budget category consistent with the Grant Recipient's Approved Budget.

(2) If the Grant Recipient seeks reimbursement for an expense it paid prior to the period covered by the current quarterly Financial Status Report but did not previously report to the Institute, the Grant Recipient must provide a written explanation for failing to claim the prior payment in the appropriate period.

(A) The Grant Recipient must submit the written explanation with any supporting documentation at the time that the Grant Recipient files its current Financial Status Report.

(B) The Institute shall consider the explanation and may approve reimbursement for the otherwise eligible expense. The Institute's decision whether to reimburse the expense is final.

(3) All expenditures must be supported with appropriate documentation showing that the costs were incurred and paid. A Grant Recipient that is a public or private institution of higher education as defined by §61.003, Texas Education Code is not required to submit supporting documentation for an individual expense totaling less than $750 in the "supplies" or "other" budget categories.

(4) The Financial Status Report and supporting documentation must be submitted via the Grant Management System, unless the Grant Recipient is specifically directed in writing by the Institute to submit or provide it in another manner.

(5) The Institute may request in writing that a Grant Recipient provide more information or correct a deficiency in the supporting documentation for a Financial Status Report. If a Grant Recipient does not submit the requested information within five (5) business [~~21~~] days after the request is submitted, the Financial Status Report may [~~will~~] be disapproved by the Institute.

(A) Nothing herein restricts the Institute from disapproving the FSR without asking for additional information or prior to the submission of additional information.

(B) Nothing herein extends the FSR due date.

(6) The requirement to report and timely submit quarterly Financial Status Reports applies to all Grant Recipients, regardless of whether Grant Award funds are disbursed by reimbursement or in advance of incurring costs.

(b) Quarterly Financial Status Reports shall be submitted to the Institute within ninety (90) days of the end of the state fiscal quarter (based upon a September 1 - August 31 fiscal year). The Institute shall review expenditures and supporting documents to determine whether expenses charged to the Grant Award are:

(1) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(2) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(c) A Grant Award with a Grant Contract effective date within the last quarter of a state fiscal year (June 1 - August 31) will have an initial financial reporting period beginning September 1 of the following state fiscal year.

(1) A Grant Recipient that incurs Authorized Expenses after the Grant Contract effective date but before the beginning of the next state fiscal year may request reimbursement for those Authorized Expenses.

(2) The Authorized Expenses described in paragraph (1) of this subsection must be reported in the Financial Status Report reflecting Authorized Expenses for the initial financial reporting period beginning September 1.

(d) Except as provided herein, the Grant Recipient waives the right to reimbursement of project costs incurred during the reporting period if the Financial Status Report for that quarter is not submitted to the Institute within thirty (30) days of the Financial Status Report due date. Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.

(1) For purposes of this rule, the "Financial Status Report due date" is ninety (90) days following the end of the state fiscal quarter.

(2) The Chief Executive Officer may approve a Grant Recipient's request to defer submission of the reimbursement request for the current fiscal quarter until the next fiscal quarter if, on or before the original Financial Status Report due date, the Grant Recipient submits a written explanation for the Grant Recipient's inability to complete a timely submission of the Financial Status Report.

(3) A Grant Recipient may appeal the waiver of its right to reimbursement of project costs.

(A) The appeal shall be in writing, provide good cause for failing to submit the Financial Status Report within thirty (30) days of the Financial Status Report due date, and be submitted via the Grant Management System.

(B) The Chief Executive Officer may approve the appeal for good cause. The decision by the Chief Executive Officer to approve or deny the grant recipient's appeal shall be in writing and available to the Grant Recipient via the Grant Management System.

(C) The Chief Executive Officer's decision to approve or deny the Grant Recipient's appeal is final, unless the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision by the Oversight Committee.

(D) The Grant Recipient may request that the Oversight Committee reconsider the Chief Executive Officer's decision regarding the Grant Recipient's appeal. The request for reconsideration shall be in writing and submitted to the Chief Executive Officer within 10 days of the date that the Chief Executive Officer notifies the Grant Recipient of the decision regarding the appeal as noted in subparagraph (C) of this paragraph.

(E) The Chief Executive Officer shall notify the Oversight Committee in writing of the decision to approve or deny the Grant Recipient's appeal. The notice should provide justification for the Chief Executive Officer's decision. In the event that the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision, the Chief Executive Officer shall provide the Grant Recipient's written request to the Oversight Committee at the same time.

(F) The Grant Recipient's request for reconsideration is deemed denied unless three or more Oversight Committee members request that the Chief Executive Officer add the Grant Recipient's request for reconsideration to the agenda for action at the next regular Oversight Committee meeting. The decision made by the Oversight Committee is final.

(G) If the Grant Recipient's appeal is approved by the Chief Executive Officer or the Oversight Committee, the Grant Recipient shall report the project costs and provide supporting documentation for the costs incurred during the reporting period covered by the appeal on the next available financial status report to be filed by the Grant Recipient.

(H) Approval of the waiver appeal does not connote approval of the expenditures; the expenditures and supporting documentation shall be reviewed according to subsection (b) of this section.

(I) This subsection applies to any waivers of the Grant Recipient's reimbursement decided by the Institute on or after September 1, 2015.

(4) Notwithstanding subsection (c) of this section, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding Financial Status Report(s). The approval shall be in writing and maintained in the Grants Management System. The Chief Program Officer's approval may cover more than one Financial Status Report and more than one fiscal quarter.

(5) In order to receive disbursement of grant funds, the most recently due Financial Status Report must be approved by the Institute.

(e) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§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 of this title (relating to Financial Status Reports).

(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 Texas [~~Uniform~~] Grant Management Standards (TxGMS) [~~(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 the 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 an individual employed by the Grant Recipient. Professional association fees or dues for the Grant Recipient's membership in business, technical, and professional organizations may be allowed, with prior approval from the Institute, if:

(A) the professional association is not involved in lobbying efforts; and

(B) the Grant Recipient demonstrates how membership in the professional association benefits the Grant Award project(s).

(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 the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative's salary or the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.

(A) 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.

(B) Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.

(16) Fundraising.

(17) Tips or gratuities.

(f) Pursuant to Texas Health and Safety Code Section 102.203(b) the Institute may authorize reimbursement for one or more of the following expenses incurred by a cancer clinical trial participant that are associated with participating in a clinical trial and included in the Grant Recipient's Approved Budget:

(1) transportation, including car mileage, parking, bus fare, taxi or ride hailing fare exclusive of tips, and commercial economy class airfare within the borders of the State of Texas;

(2) lodging; and

(3) any cost reimbursed under a cancer clinical trial participation program established pursuant to Texas Health and Safety Code Chapter 51 (relating to Cancer Clinical Trial Participation Program).

(g) 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: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

SUBJECT: CHIEF OPERATING OFFICER REPORT

DATE: AUGUST 7, 2022

CPRIT Financial Overview for FY 2022, Quarter 3

FY 2022, Quarter 2 Operating Budget

In FY 2022, CPRIT has a budget of $4.9 million in Indirect Administration and approximately $16.1 million budgeted in Grant Review and Award Operations. The Grant Review and Award Operations budget includes the majority of the agency's vendor contracts which support grant award and administration, including the $9.6 million contract for grant management support services with GDIT.

Approximately 71 percent of the $4.9 million budget for Indirect Administration has been expended or is committed in contracts. Of the $16.1 million budget for Grant Review and Award Operations, approximately 91 percent has been expended or is committed in contracts.

CPRIT received $209,687 in revenue sharing payments during the third quarter. This amount includes the receipt of a quarterly royalty payment for $27,550 from Merck & Co., Inc. from the sales revenue of WELIREG™ (belzutifan). Merck notified CPRIT that there is a royalty payment of approximately $40,033 from WELIREG sales during the second calendar quarter of 2022.

Revenue sharing payment deposits from CPRIT's inception total approximately $7.7 million through the end of May 2022.

FY 2022, Quarter 3 Performance Measure Report

CPRIT reported on its two quarterly key performance measures to the Legislative Budget Board. During the first quarter, there were no company relocations to the state. CPRIT served 204,599 people through its prevention and control grants for a total of 604,129 people served through the third quarter, more than three-quarters of the 700,000-person served annual goal.

Debt Issuance History

CPRIT did not have any general obligation bond transactions during the third quarter. The last general obligation bonds issued at the end of November 2021 for $582,315,000 included $144.8 million of new money proceeds that covered the agency's second and third quarter tranches for FY 2022.

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

FY 2023 Contract Renewals Under $100,000

CPRIT intends to renew contracts for the following services in FY 2023:

- Financial audit services with McConnell and Jones, LLP for $41,000 and
- Outside counsel services with Norton Rose Fulbright for $95,000.

CPRIT also plans to renew the peer review monitoring contract with Business & Financial Management Services for FY 2023 and anticipates that contract amount will be less than $100,000. I will update this information during the Oversight Committee meeting.

2023 Conference Update

CPRIT staff has a recommendation to award a contract for a conference venue in Galveston for Oversight Committee approval at this meeting. Should the Oversight Committee approve this contract, the 2023 CPRIT Innovations VI Conference will take place on October 2-3, 2023, at the Moody Gardens Hotel, Spa and Conference Center on Galveston Island, Texas.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of May 31, 2022

Indirect Administration (B.1.1.)

		2022 Appropriated	2022 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,847,425	$ 1,847,425		$ 984,255	863,170	53%	$ 984,255	$ 863,170
1002	Other Personnel Costs	38,785	38,785		18,698	20,087	48%	18,698	20,087
2001	Professional Fees and Services	1,808,662	1,953,603		1,723,537	230,066	88%	1,723,537	230,066
2003	Consumable Supplies	24,000	24,000		4,318	19,682	18%	4,318	19,682
2004	Utilities	58,600	58,600		35,394	23,206	60%	35,394	23,206
2005	Travel	45,000	45,000		38,882	6,118	86%	38,882	6,118
2006	Rent-Building	11,000	11,000		9,705	1,295	0%	9,705	1,295
2007	Rent-Machine and Other	32,172	32,172		21,411	10,761	67%	21,411	10,761
2009	Other Operating Expenses	1,062,737	1,057,261		786,166	271,095	74%	786,166	271,095
	Subtotal - Indirect Administration (B.1.1.)	**$ 4,928,381**	**$ 5,067,846**	**1.70%**	**$ 3,622,366**	**$ 1,445,480**	**71%**	**$ 3,622,366**	**$ 1,445,480**

Grant Review and Award Operations (A.1.3.)

		2022 Appropriated	2022 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 3,505,873	3,378,737		$ 2,965,284	$ 413,453	88%	$ 2,965,284	$ 413,453
1002	Other Personnel Costs	45,000	172,136		172,136	(0)	0%	172,136	(0)
2001	Professional Fees and Services	12,419,373	12,780,100		11,867,388	912,712	93%	11,867,388	912,712
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	13,212		13,212	0	100%	13,212	0
2005	Travel	45,000	45,000		9,303	35,697	21%	9,303	35,697
2009	Other Operating Expenses	71,649	70,437		14,755	55,682	21%	14,755	55,682
	Subtotal - Grant Operations (A.1.3.)	**$ 16,098,895**	**$ 16,459,622**	**5.53%**	**$ 15,042,078**	**$ 1,417,544**	**91%**	**$ 15,042,078**	**$ 1,417,544**

Grants

		2022 Appropriated	2022 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 27,670,031	$ 27,709,605		$ 13,189,929	$ 14,519,676	48%	$ 13,189,929	$ 14,519,676
4000	Grants - Research (A.1.1.)	251,353,693	$ 248,235,661		128,154,393	$ 120,081,268	52%	128,154,393	120,081,268
	Subtotal - Grants	**$ 279,023,724**	**$ 275,945,266**	**92.76%**	**$ 141,344,322**	**$ 134,600,944**	**51%**	**$ 141,344,322**	**$ 134,600,944**
	Grand Totals	**$ 300,051,000**	**$ 297,472,734**	**100.00%**	**$ 160,008,766**	**$ 137,463,968**	**54%**	**$ 160,008,766**	**$ 137,463,968**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of May 31, 2022

	5/01/2022-5/31/2022	AY 21 Year to Date as of 5/31/2022
Beginning Balance : 9/01/2021		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance: 5/31/2022		**$ 600,506.00**

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds ($303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of May 31, 2022

		5/01/2022-5/31/2022	AY 21 Year to Date as of 5/31/2022
Beginning Balance : 9/01/2021			**$ 39,573.54**
Increases:			
(1)	License Plate Revenue Received	$ 531.65	$ 5,267.34
	Interest	$ 21.17	$ 111.46
Total Increases		**$ 552.82**	**$ 44,952.34**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		-	-
Total Reductions		**$ -**	**$ -**
Ending Balance: 5/31/2022			**$ 44,952.34**

Note:

Balance forward from 2021 License Plate $39,573.54

14-5

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of May 31, 2022

		5/01/2022-5/31/2022	AY 21 Year to Date as of 5/31/2022
Beginning Balance : 9/01/2021			**$ 11,246.90**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ 23,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ -	$ -
(4)	Conference Registration Fees-Credit Card	$ -	$ -
Total Increases		**$ -**	**$ 23,000.00**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ -	$ -
	Refund-Application Fees	$ -	$ -
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 5/31/2022			**$ 34,246.90**

Forward balance for FY 2021 is $11,246.90
Application Fees

Cancer Prevention and Research Institute of Texas

Interest & Sinking Fund Account - 5168

As of May 31, 2022

		5/01/2022-5/31/2022	AY 21 Year to Date as of 5/31/2022
Beginning Balance : 9/01/2021			**$ 2,525,531.25**
Increases:			
(1)	Revenue Sharing / Royalties	$ 161,824.84	$ 2,684,657.03
(2)	Reconciled previous FY for double entry	$ -	$ (781,435.16)
Total Increases		**$ 161,824.84**	**$ 4,428,753.12**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 5/31/2022			**$ 4,428,753.12**

Balance forward from FY 2021 is $2,525,531.25

(2) Reconciled previous for double entry FY 2018 ($734.53) FY 2019 ($236,024.48) 2020 ($531,764.33) FY 2021 ($12,911.82) = ($781,435.16)

Cancer Prevention and Research Institute of Texas
FY 2022, Quarter 3 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	700,000	203,604	195,926	204,599	-	604,129	86.30%
Number of Entities Relocating to TX for Cancer Research Related Projects	1	0	0	0	-	0	0.00%
Annual Age-adjusted Cancer Mortality Rate	143.0	N/A	N/A	N/A	N/A	0	0.00%
Number of Published Articles on CPRIT-Funded Research Projects	1,000	N/A	N/A	N/A	N/A	0	0.00%
Number of New Jobs Created and Maintained	3,000	N/A	N/A	N/A	N/A	0	0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT prevention grantees have continued to be successful at delivering cancer prevention education and clinical services to more people than they anticipated, stretching their CPRIT-grant funds further to serve Texans. They have resumed providing cancer prevention clinical services, such as mammograms and colonoscopies, following COVID-19 precautions which include the use of COVID-19 tests and extra safety precautions.
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas. Therefore, the results vary. A company must meet 4 of CPRIT's 7 criteria for a relocation to be considered complete.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,800,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2016		August 29, 2016	$ 60,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 277,300,000				
2017	$300,000,000	October 19, 2016	$ 58,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		January 5, 2017	$ 58,900,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		February 8, 2017	$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded $269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				$ 222,900,000				
2018	$300,000,000	September 29, 2017	$ 68,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		March 8, 2018	$ 99,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		July 11, 2018	$ 55,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 222,200,000				
2019		September 21, 2018	$ 222,200,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded $222.2M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.720632%
2019	$300,000,000	September 21, 2018	$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.720544%
2019		March 28, 2019	$ 77,725,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.90% - 2.55%
2019		July 12, 2019	$ 54,000,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.95% - 2.35%
				$ 207,700,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2020		September 16, 2019	$ 64,300,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 2.10%
2020		January 9, 2020	$ 52,000,000		Commercial Paper Notes	Series A, Taxable		
2020		April 23, 2020	$ 237,720,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2020	Par amount of refunding: Refunded $248.025M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	$ 115,000,000		G.O. Bonds	Taxable Series 2020	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	$ 119,750,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2020	Par amount of refunding. Refunded $120.525M of Taxable Series 2011	
				$ 231,300,000				
2021	$300,000,000	September 11, 2020	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
2021		January 14, 2021	$ 59,000,000		Commercial Paper Notes	Series A, Taxable		
2021		April 29, 2021	$ 68,900,000		Commercial Paper Notes	Series A, Taxable		
2021		August 12, 2021	$ 57,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 260,300,000				
2022	$300,000,000	September 28, 2021	$ 87,000,000		Commercial Paper Notes	Series A, Taxable		
2022		November 18, 2021	$ 334,745,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2021B	Par amount of refunding: Refunded $347.300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		November 18, 2021	$ 139,565,000		G.O. Bonds	Taxable Series 2021B	New money proceeds of $144.800M	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		November 18, 2021	$ 108,005,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2021B	Par amount of refunding: Refunded $108.660M of Taxable Series 2014B	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
				$ 231,800,000				
TOTAL ISSUED TO DATE				**$ 2,447,100,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	2023 CPRIT INNOVATIONS CONFERENCE VENUE CONTRACT
DATE:	AUGUST 8, 2022

Recommendation

CPRIT staff recommends that the agency award a contract to the Moody Gardens Hotel, Spa and Convention Center (Moody Gardens Hotel) on Galveston Island, Texas, for an estimated cost of $202,157 for conference meeting space and food and beverage catering. In addition, there will be an estimated cost of $52,103 for audiovisual services through the Moody Gardens Hotel's in-house audiovisual provider, Encore. The audiovisual services will be contracted separately with the provider but are part of the overall conference venue proposal price for this property of $254,260.

The pricing for catered food and beverage is based on an estimate of 750 conference attendees, so the actual cost of the contract with the hotel could increase if attendance exceeds the estimate of 750 conference participants.

Background

CPRIT received several proposals in response to the agency's request for proposal (RFP) for a 2023 conference venue issued earlier this year in February 2022. After evaluating the proposals, the primary factor that led to the choice of the Moody Gardens Hotel was the available conference dates of October 1-3, 2023, with October 1, 2023, being a move-in and set up day. This period of days achieves the goal to maximize attendance from CPRIT grantees of which the majority are academic institutions because the dates occur during the middle of the fall semester, not the beginning or end.

Other factors that were considered are the concessions and discounts offered including a waiver of $23,500 in meeting space costs if we meet certain guest room night and catered food and beverage targets. Additional concessions include complimentary self-parking, complimentary wireless in the guest and meeting rooms, and a complimentary guest room for every paid 40 guest rooms. An advantage of the Moody Gardens Hotel is that the guest and meeting rooms are housed in one property.

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

The Galveston Island Convention & Visitors Bureau is also offering CPRIT a $3,000 sponsorship based on the conference meeting at least 80% of the requested guest room nights in the original RFP and execution of a contract before October 30, 2022.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	FY 2023 SERVICE CONTRACT RENEWALS APPROVAL
DATE:	AUGUST 8, 2022

Recommendation

CPRIT staff recommends the Oversight Committee approve the following contract renewals for FY 2023 with:

- Weaver and Tidwell for $186,000 to provide internal audit services and
- The Perryman Group for $195,000 to perform an economic assessment of the cost of cancer in Texas.

The contract costs for consideration are not-to-exceed amounts, and payment is based on the delivery of actual services through time and materials expended by the vendor or as a fee for service based on the delivery of a report.

Background

Internal Audit Services Contract Renewal

In FY 2023, the proposed internal audit plan includes one audit and two audit advisory engagements. The audit will cover IT general controls. One of the two audit advisory engagements will evaluate CPRIT's post-award compliance program and the other will assist CPRIT in developing a service contract risk assessment. The plan also includes follow-up procedures on contract compliance.

CPRIT would be exercising the third and final contract renewal.

Economic Assessment of the Cost of Cancer in Texas Contract Renewal

The report produced by The Perryman Group provides CPRIT with the statutorily required cost of cancer in Texas measurement and measurement of key economic performance indicators based on CPRIT funding and program impact. The information produced in this economic assessment is used in CPRIT's annual report.

CPRIT would be exercising the third and final contract renewal.

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

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
FROM:	TRACEY B. DAVIES, CHIEF STRATEGIC INITIATIVES OFFICER; CHIEF INTELLECTUAL PROPERTY OFFICER
SUBJECT:	CPRIT IP REPORTING PROJECT UPDATE
DATE:	AUGUST 2, 2022

CPRIT Intellectual Property Data Collection Streamlining and Standardization

I. Executive Summary

CPRIT worked with the 15 institutions receiving the most academic research grants to implement a streamlined and standardized reporting process and system to better track and understand the amount and nature of intellectual property generated from CPRIT grant activity. Implementation of this program for these institutions should be substantially complete during the 4th quarter of 2022.

II. Background

CPRIT collects data related to the generation of intellectual property ("***IP***") as the result of CPRIT -funded academic and product development research activity. These data are valuable for several reasons, including:

(1) IP generation is one measure of how our funded research leads to new and useful information related to understanding, preventing and treating cancer. As a result, it is also a measure of the benefit of CPRIT-funded activity to Texas.

(2) In the area of cancer prevention, diagnosis and treatment, protectable IP (typically in the form of patents) is a necessary component for any scientific advancement or invention to be commercialized for the benefit of patients. Understanding what IP is generated from CPRIT-funded activity provides some visibility into the potential of CPRIT-funded activity to concretely benefit patients.

(3) Contractually, in accordance with our statute, CPRIT takes a revenue-sharing interest in revenue generated from any CPRIT grant-funded research activity. Revenue generally stems from licensing of IP created as the result of CPRIT grant-funded research.[1]

[1] This revenue-sharing typically takes one of two forms: (1) for academic research grants, CPRIT receives a share (typically 10%) of money the recipient institution receives from commercialization of grant-generated inventions; and (2) for product development research grants, CPRIT receives a royalty on revenue from commercialization of the CPRIT grant-funded product (typically 3% to 5% of revenue until a multiple of the grant award is reached, and then a much smaller royalty, 0.5% for example, until exclusivity expires on the product that is commercialized).

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

Historically, CPRIT tracks intellectual property generation from CPRIT-funded research in two ways:

(1) Through self-reporting by grant recipient PIs as they fill out grant summary reports for CPRIT. This tracking allows CPRIT to maintain tallies of patents generated as the result of grant research, and licenses granted to those patents by recipient academic research institutions.
(2) Per the grant contracts, Grantee institutions' technology transfer and/or licensing departments report to CPRIT regarding IP disclosures, patent prosecution events, and IP licensing activity related to CPRIT-funded research.

This reporting allows CPRIT to track overall numbers of patents, licenses, and related activity to date.

III. Opportunity to Optimize the Value of IP Reporting to CPRIT

As CPRIT has matured into its second decade, we have determined that streamlining and standardizing IP reporting can achieve various additional benefits to CPRIT, and to Texas.[2] Potential benefits from streamlining and standardizing grantee IP reporting processes include:

(1) Minimize occurrences of under-reporting.
(2) Minimize occurrences of reporting in a way that does not allow correlation between the IP activity and the related grant that funded the IP.
(3) Eliminate questions or confusion by grantee institutions regarding what information CPRIT wants reported on a regular basis.
(4) Provide a format for reported information that can be reliably and flexibly used by CPRIT to (1) better understand the IP volume and quality from CPRIT-funded research activity; (2) allow CPRIT to become a potential additional resource for entities seeking IP commercialization opportunities; (3) manipulate the data for analysis and use for a variety of purposes to be determined in future.

IV. Work to Date

This project has focused primarily on optimizing the reporting from institutions receiving the bulk of awarded academic research grants (rather than recipients of product development research grants).[3] After conducting extensive evaluations of the reporting history of each of the

[2] Contributing factors for challenges and deficiencies in current reporting include: (1) the total number of grants over time has increased, making tracking of detailed information cumbersome; (2) reporting expectations and approaches by each grantee institution has been idiosyncratic, resulting in CPRIT receiving different levels of information from each institution and in different formats; and (3) reporting has not been standardized to ensure that the reporting is consistent, or consistently or accurately correlates to the grant that gave rise to the relevant IP upon which the institution is reporting, thereby confounding CPRIT efforts to accurately track IP associated with any particular grant.

[3] There are various reasons for this, including that (1) base IP is already formed when companies come to CPRIT seeking product development grants, and (2) a primary goal of tracking IP generation is to evaluate the commercialization potential of that IP; the product development grant recipients are already engaged in commercialization of the relevant IP.

15 recipient institutions that make up this group, and consideration of the use to which we would like to put the information reported, we have developed a list of 12 items we expect recipient institutions to report to us on a regular basis:

1. Institution-Specific Identifiers and CPRIT Grant IDs
2. Invention Disclosure Reports and Invention Descriptions
3. Provisional Patent Applications
4. PCT Patent Applications
5. U.S. Utility Patent Applications
6. U.S. Patent Classifications
7. U.S. Issued Patents
8. Commercial Activity (e.g., Draft and Final License Agreements)
9. Infringement of CPRIT-Funded IP Rights
10. Royalty Payments and Royalty Reports
11. Decisions to Abandon, Disclaim, Waive, or Assign IP Rights
12. Commercial Development Plans

We also developed a specific file naming and format convention for each of these 12 items, and individually tailored tools for each institution to facilitate their ability to clearly identify the items to be reported, to save them in the standards format, and to name them according to the standardized naming convention.

Each of the 15 institutions has received this information and is working with us to simultaneously (1) implement the streamlined and standardized reporting, effective immediately, for reporting of all future IP events; and (2) ensure reporting for past IP events is sufficiently comprehensive to identify any gaps due to the prior idiosyncratic nature of the reporting methods.

V. Next Steps

We hope to have the streamlined and standardized reporting system implemented by all institutions by the end of 3Q 2022, and to have most past reporting deficiencies identified and addressed by early Q4, 2022.

Additionally, we want to identify the best external database to house the information for the long term that will enable both internally facing and externally facing use and provide a searchable database for anyone interested in seeing non-confidential information regarding the generation of IP and the commercialization of IP resulting from CPRIT-funded grant activity.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: MARK DALLAS LOEFFLER
SUBJECT: COMMUNICATIONS UPDATE
DATE: AUGUST 8, 2022

These are the highlights of CPRIT Communications efforts since the most recent Oversight Committee meeting in May.

FY 2022 ANNUAL REPORT

- Investigating new interactive tools for Annual Report (which is web-based) to illustrate how CPRIT is achieving our mission statewide
- Collaborating with contributors from the programs to develop content
- IT is working on Annual Report website; modernizing design elements

MEDIA RELATIONS

- *Houston Chronicle* story regarding Houston biotech industry published; included mention of CPRIT.
- Responded to Houston Methodist publication request for information on CPRIT grantee
- Posted and distributed media advisories and press releases related to CPRIT programs and news:
    - June 23 - Notice Regarding FY22 and FY23 Academic Research Program Budget
    - June 24 - CPRIT Product Development Program Applications for FY 2023 Awards
    - July 21 - MEDIA ADVISORY: CPRIT and Carson Leslie Foundation "Researcher RoundUp" brings best childhood cancer researchers to Dallas
    - July 22 - PR: CPRIT and Carson Leslie Foundation Dallas event rounding up best childhood cancer researchers
    - August 8 - CPRIT CEO Roberts Endorses Bertagnolli NCI Appointment

WEBSITE

- Posted Academic Research Recruitment RFAs

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

- Added Academic Research Budget update news brief
- Expanded Product Development program landing page, including FAQs and RFAs
- Added Product Development RFAs news brief to link to new landing page
- Provided edits and added 2023 – 2027 CPRIT Strategic Plan to website

PUBLICATIONS

- Created new publications for Product Development program; modified "What Is CPRIT" and "Momentum" report to highlight PD program and add QR codes to take readers to CPRIT website for more information.
- Developing updated graphic to illustrate Product Development investment in drug development process.

SOCIAL MEDIA

- Posted extensive coverage of 2022 Second Annual Researchers' RoundUp; many posts over three days (far more than other hosts)
- Created posts to spotlight CPRIT grantees, programs and outreach

STATISTICS

Social Media from February 17 to May 17

Facebook	Twitter	LinkedIn
6.57% engagement rate	**3.22%** engagement rate	**6.29%** engagement rate
1,100 Fans	3,100 followers	1,500 followers
Top Post: **266.67%** engagement (4/4)	Top Tweet: **3,715** impressions (4/4)	Top Post: **5,551** impressions (4/5)

Social Media from May 19, 2022 to August 4, 2022

Facebook	Twitter	LinkedIn
15.71 % engagement rate **(▲increase 9.14 %)**	2.36% engagement rate (▼slight decrease 0.88%)	4.47% engagement rate (▼ decrease 1.88%)
1,100 Fans	3,100 followers	1,500 followers
Top Post: **900% engagement** (5/18)	Top Tweet: **9,811 impressions** (5/25)	Top Post: **2,855 impressions** (5/27)

Website Hits and Visitors May 18 to August 4

Users	New Users	Sessions (Visits)	Pageviews	Pages / Session
17,570	**16,357**	**24,144**	**52,687**	**2.18**

Oversight Committee Meetings and Standing Subcommittees Meetings FY 2023

September 2022

Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
				1	2	3
4	5	6 PIC Meeting CPRIT Staff Only Portal Opens	7	8 Academic Research Product Development	9	10
11	12	13	**14 Special Oversight Committee Meeting**	15	16	17

November 2022

Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
		1	2 PIC Meeting CPRIT Staff Only	3 Portal Opens Board Governance	4	5
6	7 Audit	8 Prevention	9 Academic Research	10 Product Development	11	12
13	14	15	**16 Oversight Committee Meeting**	17	18	19

February 2023

Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
			1 PIC Meeting CPRIT Staff Only	2 Portal Opens Board Governance	3	4
5	6 Audit	7 Prevention	8 Academic Research	9 Product Development	10	11
12	13	14	**15 Oversight Committee Meeting**	16	17	18

May 2023

Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
	1	2	3 PIC Meeting CPRIT Staff Only	4 Portal Opens Board Governance	5	6
7	8 Audit	9 Prevention	10 Academic Research	11 Product Development	12	13
14	15	16	**17 Oversight Committee Meeting**	18	19	20

Oversight Committee Meetings and Standing Subcommittees Meetings FY 2023

August 2023

Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
		1	2 PIC Meeting CPRIT Staff Only	3 Portal Opens Board Governance	4	5
6	7 Audit	8 Prevention	9 Academic Research	10 Product Development	11	12
13	14	15	**16 Oversight Committee Meeting**	17	18	19

Note: Unless the subcommittee members agree to a different time, all subcommittee meetings will begin at 10:00 a.m. Members of the Audit and Program subcommittees should allocate 1.5 hours for a meeting. All others subcommittee meetings require one hour.