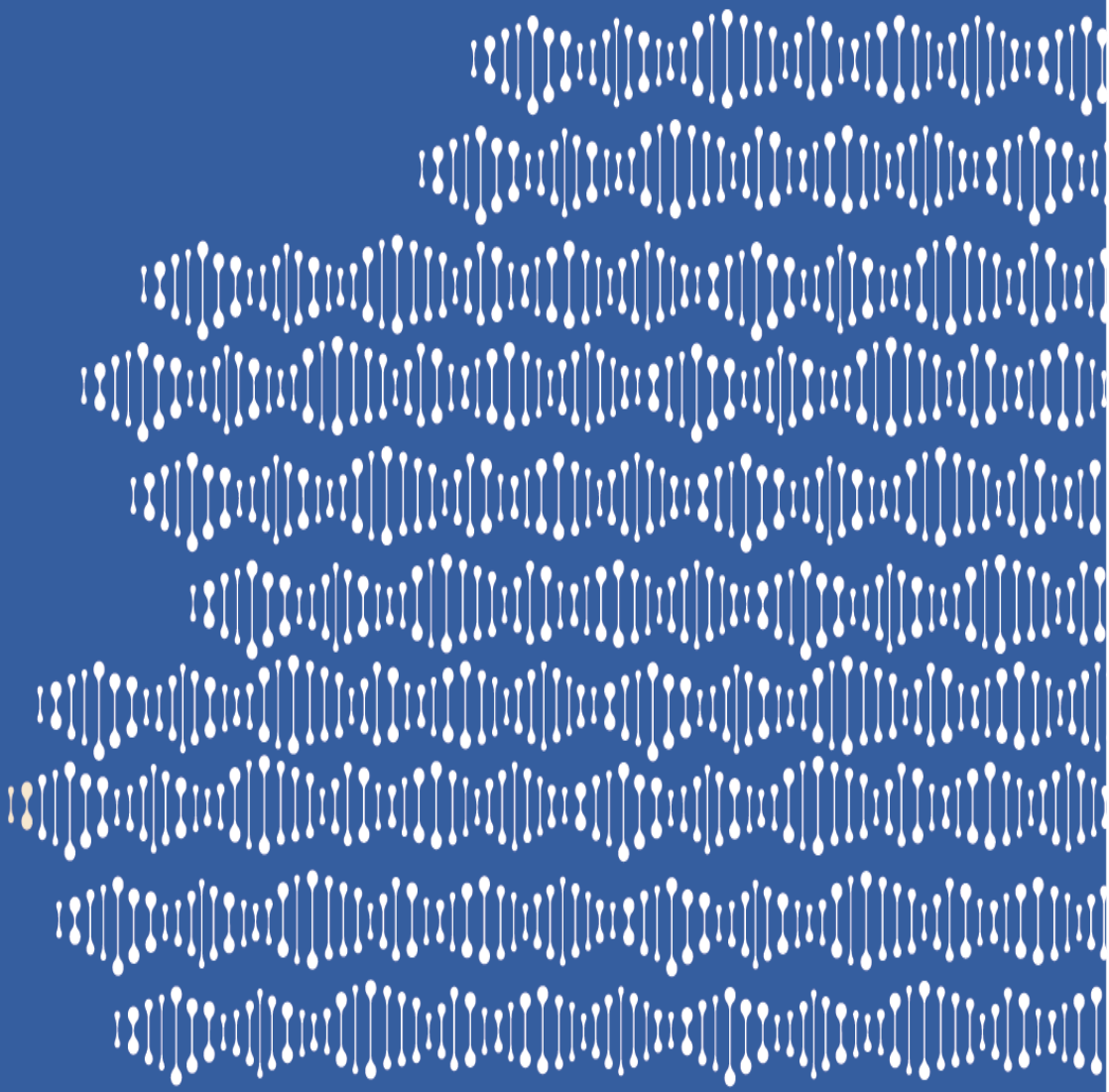
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

January 20, 2015



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

Teacher Retirement System
1000 Red River St. • Austin, Texas 78701
Room: 513E

January 20, 2015
10:00 a.m.

The Oversight Committee may discuss or take action regarding any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any and all purposes permitted by the Act.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from November 19, 2014 meeting — **TAB 1 / p. 3**
4. Contract Terms for Product Development Grants — **TAB 2 / p. 37**
5. Consultation with General Counsel
6. Future Meeting Dates and Agenda Items
7. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Minutes

November 19, 2014

1. Meeting Called to Order

A quorum being present, Dr. Rice called the Oversight Committee to order at 10:04 A.M.

2. Roll Call /Excused Absences

Dr. Rice asked Amy Mitchell, Secretary of the Oversight Committee, to take attendance of the Oversight Committee. All were present except Mr. Holmes. She noted that Mr. Holmes notified CPRIT that he would be unable to attend the meeting.

MOTION:

Dr. Rice asked for a motion to approve an excused absence for Mr. Holmes.

Motion by: Montgomery Seconded by: Mitchell
MOTION CARRIED UNANIMOUSLY

3. Adoption of Minutes from the August 20, 2014, and the September 3, 2014 meetings

Dr. Rice informed the committee that the minutes from the August 20 and September 3, 2014, meetings were in their packets. There were no comments.

MOTION:

Dr. Rice called for a motion to approve the minutes of the August 20, 2014, Oversight Committee meeting.

Motion by: Geren Seconded by: Montgomery
MOTION CARRIED UNANIMOUSLY

MOTION:

Dr. Rice called for a motion to approve the minutes of the September 3, 2014, Oversight Committee meeting.

Motion by: Montgomery Seconded by: Angelou
MOTION CARRIED UNANIMOUSLY

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4. Public Comments

At this time, the Chair recognized Mrs. Nadine Craddick to address the Oversight Committee.

Mrs. Craddick thanked the Committee for letting her speak as a passionate advocate for all children. She spoke about the recommendations of the Advisory Committee on Childhood Cancer (ACCC). The children's grants awarded are promising, but they need more, and she would like to see guidance to applicants to encourage them to apply for juvenile cancer research grants. She noted that the number of children and teenagers with cancer is too low to encourage drug companies to invest. She feels CPRIT is the mechanism to answer the deficiencies. Mrs. Craddick said more research is needed on survivorship to study effects of radiation and chemotherapy. Children and teen cancer patients are having problems later in life and the reason is unknown. She would like to see CPRIT encourage researchers to respond to the RFAs. Mrs. Craddick believes that children are the future of our state and deserve our attention in cancer research; therefore, she hopes more funding opportunities will become available.

After Mrs. Craddick concluded her comments, Dr. Rice informed the committee that no other requests for public comment had been received.

A copy of Mrs. Craddick's comments were distributed to the members and are attached to the minutes.

5. Chief Executive Officer Report

New Employees

Mr. Roberts introduced three new employees: Donald Brandy, Purchaser; Dina Fletcher, Grant Accountant; and Jeff Hillery, Communications Specialist. Dr. Rice welcomed them.

Update on CPRIT

Mr. Roberts reported on where the agency stands one year after the moratorium was lifted.

CPRIT had a challenging landscape:

- 10-month moratorium ended
  - 118 announced grants were pending contracts
  - 17 recommended applications waiting final approval
  - No new applications submitted in previous 11 months
- 51 State Auditor recommendations
- Staff vacancies
- Major legislative changes

CPRIT refocused on Texas' mission

Requests for Applications Issued	29
Applications Received	1,276
Reviewers Appointed	126
Peer Review/Review Council Meetings	62
Program Integration Committee Meetings	4
Grants Awarded	147
Texans Provided Prevention & Control Services	420,738
Texans Received Clinical Services	262,493
Eminent Cancer Researchers Recruited to Texas	30
Patents Issued	18
Patent Applications	41

The number of counties served by Prevention grants increased:

- 2013 – 37 projects (2 statewide)
- 2014 – 59 projects (6 statewide)

CPRIT improved transparency by:

- Having meetings in the Capitol Extension
- Posting the meeting book on the CPRIT website days in advance of meetings
- Making available webcast of meetings in real-time and archiving past webcasts on CPRIT website
- Posting conflict of interest information for each grant cycle on the CPRIT website

CPRIT focused on board governance by:

- Electing Officers
- Adopting a Code of Conduct
- Amending the Board Bylaws
- Creating eight subcommittees
- Activating three advisory committees
- Hiring a CEO plus 13 new employees
- Holding 8 meetings and 38 subcommittee meetings
- Reviewing 15,000 pages of meeting material

CPRIT increased accountability by:

- Implementing 51 of 51 State Audit recommendations
- Overhauling agency rules
- Approving a Compliance Program design
- Mandating ethics training for staff and Oversight Committee members
- Creating dashboard metrics
- Developing Grantee Training Program and focusing on customer service
- Overseeing a robust audit program with
    - 16 Field Audits of Grantees
    - 8 Internal Audits of CPRIT Operations
    - 2 Independent Financial Audits
- Adopting the Agency Strategic Plan for 2015 – 2019
- Approving the 2016-2017 legislative appropriations request

Looking Forward: CPRIT exists to reduce the burden of cancer in Texas

- Our Mission – Create, expedite and enhance the potential for a medical or scientific breakthrough in cancer prevention and cures for cancer.
- Implementing Our Mission – Transparency and accountability in our operations and awarding merit-based cancer prevention and cancer research grants.
- Our Journey – Advancing cancer prevention and treatment one discovery at a time.

Mr. Roberts announced that because the Capitol meeting rooms will be unavailable during the legislative session, CPRIT Oversight Committee meetings will move to the Texas Higher Education Coordinating Board building, where webcasting for the meetings will be available.

There were no questions for Mr. Roberts.

6. Chief Compliance Officer Report

Dr. Rice recognized Mr. Reisman to present the Chief Compliance Officer Report.

Mr. Reisman started by saying that previously he had reported a considerable number of delinquent reports that needed to be resolved. The staff took a comprehensive approach, with many staff—the legal division, the program managers, grant specialists, grant accountants—working with grantees to clear the reports. Significant progress has been made. He noted that compliance has improved daily as we are working with grantees. At the time of the meeting, there were 18 current financial status reports (FSRs) outstanding. At the past August meeting, he had reported 36 grant projects had not filed their FSRs by the deadline. In August the number of FSRs backlogged as a result of the moratorium was 180, but delinquencies decreased to 25 today. Currently there are six progress reports outstanding, and that number was considerably higher at the last meeting. Also, the "other" reports (inventory reports, historically-underutilized businesses reports, and match certification reports) reported to have 483 delinquencies in August, are down to 66 now. Remaining reports should be filed soon.

For perspective, there are approximately 5,924 reports to be submitted each year, so those 66 outstanding reports represent only 1.1% of all reports.

Dr. Rice asked, for clarity, if that meant that 99% are filed and up to date. Mr. Reisman stated that was correct. He also stated that many reports that were still delinquent were caused by a software problem that would be resolved soon.

Mr. Reisman explained that having worked through most of the delinquent reporting issues has allowed staff to work on other Compliance projects, such as grantee desk reviews on financial reports by grant specialists (12 were in progress at the time of this meeting). These desk reviews allow CPRIT staff to reach out to grantees in a preventive role, as opposed to the reactive role of audits. Additionally, two grantee training sessions

have been conducted as a joint effort between legal, grant accountants and grant specialists, and a webinar was conducted with over 100 grantee participants.

Compliance staff have worked with the Communications staff to produce some short videos. One is currently online concerning relevant rule changes. All grant recipients were notified of its availability.

Dr. Rosenfeld asked if any delinquencies were resisting compliance. Though some of the information is difficult to gather, Mr. Reisman felt all grantees were cooperative.

Dr. Rice said he's seen a couple of the videos and they are excellent and an effective way to provide information.

Mr. Roberts then gave a visual presentation to the Oversight Committee members of "a year in the life of a grantee," that comprised all the reports awardees must provide. Notebooks were displayed that contained all reports required to be summited by a grantee from each of the three programs we have, Product Development being over about 2,200 pages.

Mr. Roberts stated that grantees do ask why CPRIT requires so much more reporting than NIH. Dr. Rosenfeld asked if staff is looking at reducing the requirements. Mr. Roberts said not at this point—CPRIT asks for hard documentation of work performed for the money CPRIT gives, though at some point CPRIT may want to review this in subcommittee. Currently CPRIT reimburses based on work done, where NIH uses a draw-down of funds. Dr. Rosenfeld said there is often value to examining processes and we should be aware of the burdens we put on others. He suggested looking for ways to lessen their burdens without losing oversight.

Dr. Rice asked Mr. Reisman to provide updates on the reporting requirements and on any efforts made by CPRIT to lessen those requirements.

No further discussion on Mr. Reisman's report.

7. Chief Operating Officer Report

Dr. Rice recognized Ms. McConnell to present the Chief Operating Officer's Report.

1) FY 2014, Year End Financial Report
   - CPRIT expended or obligated approximately $2.8 million in Indirect Administration and $9.4 million in Grant Review and Award Operations through the end of fiscal year 2014.
   - CPRIT reported six key performance measures to the Legislative Budget Board; the agency met or exceeded five of the six measures. The measure not met was regarding Product Development and was affected by the moratorium on grants.

2) FY 2015 Operating Budget
   - CPRIT's operating budget for FY 2015 is $297,101,446. With various transfers, approximately $278 million is available for Prevention, Product Development and Research grant awards.

3) Debt Issuance History
   - CPRIT issued $162.5 million in commercial paper notes in FY 2014 through the Texas Public Finance Authority (TPFA).
   - TPFA issued $57.6 million on November 5, 2014.
   - The total amount issued to date is approximately $606.4 million.

Mr. Holmes asked why rent is expected to be reduced in FY 2015 by nearly half. Ms. McConnell stated because CPRIT is moving to state office space as of March so will not be paying rent for Austin office space. The line item that is there is for rent on CPRIT's current location until the agency moved and rent for the Houston office. Mr. Roberts pointed out that CPRIT spent about $1million to renovate the state building space but savings will occur over time.

After some clarifying questions from Dr. Rice, there was no further discussion.

8. Chief Prevention and Communications Officer Report

At this time, the Chair recognized Dr. Garcia, Chief Prevention and Communications Officer, to present the Communications Report.

Dr. Garcia stated the Communications report behind Tab 5 in the meeting packet, and a memo regarding the conference budget and hotel contract behind Tab 14 would be discussed.

Jeff Hillery was introduced as the new Communications Specialist. Dr. Garcia noted that the materials behind Tab 5 summarize the coverage CPRIT has received over the last quarter and include a few of the key articles that resulted from CPRIT's Press releases and working with reporters to secure coverage. Staff will mail out updated Fact Sheets after the meeting in order to include any awards made at this meeting. Additionally, Dr. Garcia announced that a slide bank with current information regarding CPRIT will be sent to members. This information will be updated quarterly after each Oversight Committee meeting.

CPRIT's Annual Report, which staff is currently preparing, is due at the end of January. The content of this report is largely dictated by the Legislature. This year, as a companion piece to the Annual Report, staff is creating an achievements report to highlight work and progress of grantees.

Communications also worked with CPRIT's Compliance Officer to produce training videos.

Finally, Dr. Garcia noted that there will be a panel discussion and 30-minute screening of the Ken Burns documentary *The Emperor of all Maladies: A Biography of Cancer*, to be held in the Capitol Extension Auditorium the evening of March 25. Among invitees to the event will be legislators and cancer advocates.

1) 2015 CPRIT Conference

Dr. Garcia discussed plans for the CPRIT 2015 conference, including the conference budget, which is set out by Dr. Garcia's memo in Tab 14 of the members' meeting book. Registration fees will offset costs, but CPRIT will be responsible for uncovered costs. State regulations prevent CPRIT from paying for food and beverage, but that will be covered by registration fees. Meeting décor costs appear high due to the easels required for poster presentations, not decorations *per se*. CPRIT must guarantee minimums for rooms and food, or an extra fee could be charged if minimums are not met. Staff proposes a full two-day conference on November 9 and 10, 2015. Staff is budgeting for up to four keynote speakers that could be invited with paid travel expenses. Other presenters will also be invited. In addition to keynote presentations, the schedule would include separate, concurrent tracks for Research, Prevention, and Product Development. The venue will be the Renaissance Hotel at the Arboretum. This hotel has been used for the past two conferences and has worked well. A spreadsheet of estimated costs was provided in the meeting books. Highlights are: total estimated costs, $305,000; registration fees will offset a portion of the costs but CPRIT will be responsible for any remaining costs. The largest line items are food and beverage at $132,000 (which will be covered by the registration fees), followed by meeting planning services at $75,000 (based on past experience), and meeting décor at $25,000 ($21,000 is for the poster session). Dr. Garcia stated that Oversight Committee action is necessary to direct CPRIT staff to begin administrative preparations for the conference, including securing the meeting location and locking down a block of rooms for attendees.

Dr. Rosenfeld asked if reviewers for Product Development or Research would attend. Dr. Garcia said they've been invited and attended in the past. But this year, they will not receive assistance to attend as in the past, due to the tight budget. Dr. Rosenfeld asked if grant recipients are required to attend. She said they are strongly encouraged and allowed to use grant funds to send up to two people per project. Some grantees will send additional participants and cover the cost themselves. Dr. Rosenfeld asked if we should require their attendance. She said that would be difficult given their schedules. He asked about the keynote speaker budget. Dr. Garcia said the speaker budget of $12,000 is an aggregate cost for up to four speakers. Dr. Rosenfeld asked if there should be a symposium for university technology transfer offices. She said as conference planning progresses, it would a topic that could be considered. Dr. Rosenfeld asked if there will be a venture symposium (track). Dr. Garcia responded that planning for the program has not begun but asked that he share his ideas as planning progresses.

Mr. Geren clarified that grantees can use CPRIT funds for only two people per project. Dr. Rice asked for an update at each meeting.

Dr. Rice asked if there were any further questions. There were none.

MOTION:

Dr. Rice called for a motion to direct CPRIT staff to proceed to plan a 2015 conference based on the budget estimate provided and to proceed to contract with the Renaissance Hotel based on its response to the RFP issued.

Motion by: Mitchell Seconded by: Montgomery

MOTION CARRIED UNANIMOUSLY

9. Program Priorities Project

Dr. Rice recognized Dr. Garcia and Mr. Roberts to take up Item No. 9 on the agenda, the Program Priorities Project.

Dr. Garcia stated that after the September 3, 2014, meeting, a report was drafted and released for public input during October. The feedback received was summarized and included behind Tab 6 in the meeting book, along with comments from the Advisory Committee on Childhood Cancers and LIVESTRONG Foundation. Each program subcommittee reviewed the feedback and had the opportunity to make additional revisions to the draft document. The October draft with red-lined changes was provided behind Tab 6 in the meeting material for the Oversight Committees' consideration.

Mr. Geren stated that recruitment of outstanding cancer researchers to Texas should be influenced by CPRIT's priorities. Dr. Kripke responded that CPRIT priorities are emphasized when recruiting. She stated that discussion has taken place with the Scientific Review Council and Request for Applications (RFAs) will be revised to emphasize that CPRIT is particularly interested in recruiting candidates in specific areas.

Dr. Mulrow asked if annual reporting to the Oversight Committee will be modified to show whether goals and priorities are being met. Mr. Roberts said progress will be reported, though he hasn't thought about exactly how it will be done. He stated it will be discussed in subcommittees. For instance, during the last Prevention Subcommittee meeting Mr. Geren asked staff to identify which priorities were addressed by award recommendations and suggested this be done by all programs. Dr. Rice suggested that each subcommittee should routinely discuss and review how award recommendations address the priorities.

No further discussion or questions occurred.

MOTION:

Dr. Rice called for a motion to adopt the Program Priorities as proposed.

Motion by: Geren Seconded by: Mitchell

MOTION CARRIED UNANIMOUSLY

10. Prevention Program Report and Grant Recommendations

Dr. Rice called on Dr. Garcia to report on the Prevention Program and grant recommendations.

Prevention Program Update

For the update to the Prevention Program, Dr. Garcia referred members to the memo behind Tab 7 in their committee materials.

For the next awards cycle, Dr. Garcia reported that four Prevention RFAs were released in September and are due to close in December. A webinar was held in conjunction with the release of the RFAs to give potential applicants the opportunity to ask questions. Over 100 people signed up for the webinar.

In other activities, staff visited five grantees in the Dallas/Fort Worth area and one in South Texas. Two more site visits were scheduled at Texas A&M University for next week. Dr. Garcia invited Oversight Committee members to join staff on these visits to see the work being done by grantees.

Grant Recommendations

The CPRIT Prevention Review Council has reviewed and recommends awarding five Prevention projects totaling $7,271,233. The RFAs were released March 31 and applications were due July 10, 2014. Peer review of the 16 applications was conducted in October 2014.

The grant recommendations are presented in two slates corresponding to the following grant mechanisms:

1. Evidence-Based Cancer Prevention Services— 4 projects, totaling $5,771,233
2. Competitive Continuation/Expansion Grants—1 project, totaling $1,500,000

Evidence-Based Cancer Prevention Services – For projects that provide the delivery of evidence-based prevention services (e.g., screening, survivorship services). The maximum grant award is up to $1.5 million for up to three years.

There are four Evidence-Based Cancer Prevention Services projects recommended for funding, at a total of approximately $5.7 million. Of the four, two focus on increasing

HPV vaccination rates and screening for cervical cancer and two projects address colorectal cancer education and screening.

Appl. ID	Title	PD	Organization	Total Recommended Budget
PP150004	A multi-pronged approach to increase HPV vaccination rates among adolescents 9-17 years of age from Galveston and Brazoria Counties	Berenson, Abbey	The University of Texas Medical Branch at Galveston	$1,406,919
PP150012	Improving Cervical Cancer Screening and Prevention in the Lower Rio Grande Valley Through Public Outreach, Patient Navigation, and Telementoring	Schmeler, Kathleen M	The University of Texas M.D. Anderson Cancer Center	$1,441,085
PP150009	ACCION for Rural West Texas	Byrd, Theresa L	Texas Tech University Health Sciences Center	$1,467,820
PP150031	Get FIT to Stay Fit. Stepping Up to Fight Colorectal Cancer in the Panhandle	Misra, Subhasis	Texas Tech University Health Sciences Center	$1,455,409

Competitive Continuation/Expansion Grants – For projects that propose to continue or expand highly successful projects previously or are currently funded by CPRIT. The award amount ranges from $150,000 to $1.5 million depending on the type of project proposed.

Of the five applications submitted, one is being recommend for funding.

Appl. ID	Title	PD	Organization	Total Recommended Budget
PP150025	Continuation and Expansion of Texas A&M's Colon Cancer Screening, Training, Education and Prevention Program	McClellan, David A	Texas A&M University Health Science Center	$1,500,000

Dr. Garcia noted that with these five grants, 89 percent of Texas counties are covered (225 out of 254) with a specific project for their county. There are also two statewide projects which are accessible to every county so, technically, CPRIT prevention projects cover every county.

Mr. Montgomery asked Dr. Garcia if she knew what percentage of the actual population is covered by prevention projects. She said she did not have the information with her but would research it.

Dr. Rice pointed out a typographical error on slide 5 in the presentation: the total budget for PP150009 (Texas Tech University Health Sciences Center) was incorrect on the slide deck in the presentation, but was correct in the members' meeting book. The correct number is $1,467,820 and is the number approved by the Program Integration Committee. This will be corrected before the meeting information is posted on the website.

Dr. Rice pointed out that the pedigrees for the award recommendations were under Tab 7 of the meeting book. There were no further questions or comments on Dr. Garcia's presentation of the slates.

Compliance Certification

Dr. Rice called on Mr. Reisman to present the Chief Compliance Officer report. Regarding the Evidence-Based Prevention Award Slate and the Continuation/Expansion Grants Award Slate Applications. Mr. Reisman stated that he had conferred with staff at CPRIT and SRA, International (CPRIT's contracted third-party grant administrator) and studied the supporting grant documentation including Third-Party Observer Reports for the Peer Review Meetings, and is satisfied that the application review process that resulted in the five grants recommended followed applicable laws and agency administrative rules. He then certified the two award slates, the Evidence Based Cancer Prevention Award Slate and the Competitive Continuation/Expansion Grants Award Slate for Oversight Committee approval.

CONFLICT OF INTEREST NOTIFICATIONS

Dr. Rice noted for the record that Oversight Committee members have reported conflicts of interest with some of the applications to be considered. Specifically, Ms. Mitchell reports conflicts with applications submitted by the following institutions:

- The University of Texas Medical Branch at Galveston
- The University of Texas M.D. Anderson Cancer Center
- Texas Tech University Health Sciences Center
- Texas A&M University Health Science Center

In accordance with CPRIT's rules, Ms. Mitchell is recused from the discussion or action on these applications.

Dr. Rice stated the list of the application ID numbers that members report conflicts with was included in their meeting packets and that he would sign the list and require that the list be included in the certified copy of the minutes for this meeting.

Dr. Rice asked if there were any other conflict of interest declarations for Oversight Committee members that had not been previously noted. None was heard.

APPROVAL PROCESS – Evidence-Based Cancer Prevention and Competitive Continuation/ Expansion Grant Awards

Dr. Rice stated that members had the list of applications and grant amounts recommended by the Program Integration Committee (PIC) for Evidence-Based Cancer Prevention and Competitive Continuation/Expansion grant awards.

He noted that the PIC's recommendation would be approved if two-thirds of the Oversight Committee members present and able to vote approved the PIC's funding recommendations. Rather than taking up each recommendation individually, Dr. Rice asked for a vote for the awards and award amounts as listed on pages 3 and 4 of the letter from the PIC Chair dated November 5, 2014.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for Evidence-Based Cancer Prevention Services grant awards.

Motion by: Montgomery Seconded by: Mulrow
MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell abstained from voting.

MOTION:

Dr. Rice called for a motion to approve the PIC's recommendation for a Competitive Continuation/Expansion grant award to the Texas A&M University System Health Science Center in an amount not to exceed $1.5 million.

Motion by: Montgomery Seconded by: Mulrow
MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell abstained from voting.

MOTION:

Having approved the PIC recommendations for the prevention grant awards, Dr. Rice called for a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff and to authorize the Chief Executive Officer to sign the contracts on behalf of CPRIT.

Motion by: Montgomery Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

11. Chief Scientific Officer Report and Grant Award Recommendations (1:25)

Dr. Rice recognized Dr. Kripke to present the Chief Scientific Officer Report and Grant Award Recommendations.

Scientific Research Program Update

Dr. Kripke stated that the October 27-November 11 round of Peer Review Meetings was successful. Staff is currently analyzing data to determine the success rate of various RFAs. This is the first time targeted RFAs were offered so staff wants to see the response and funding success rate. Those recommendations will be presented at the February meeting for Oversight Committee approval.

Dr. Kripke said FY 2015 second round of RFAs for High-Impact/High-Risk Grants, Core Facilities Awards, and Multi-Investigator Awards had just closed, and the applications from those will be distributed to the various review committees. CPRIT received an unusually high number of applications: 42 Multi-Investigator Awards, each one of which could have up to 5-8 projects included.

Mr. Geren asked if a good response occurred with the other grant mechanisms and Dr. Kripke answered affirmatively. Core Facility Awards are limited to one per institution and eleven were submitted. The High-Impact/High Risk grants also have a limited number that can be submitted per institution—100 were received, a normal amount for that grant mechanism.

Dr. Kripke noted that the Advisory Committee on Childhood Cancers (ACCC) had a productive September meeting. There was a discussion about CPRIT priorities and how to implement them. The ACCC also worked on its charter for approval later in this meeting and a whitepaper with recommendations to the Oversight Committee for the Priorities Project.

Mr. Geren noted that Mrs. Craddick had encouraged CPRIT to solicit applications from the pediatric cancer research community. He asked if there was a reason why pediatric researchers seem less aggressive in seeking out support. Dr. Kripke said many of the pediatric researchers are also clinicians with less time available to compete than scientists without clinical responsibilities. She said this applies to clinical research in general. The ACCC pointed out that since Core Facilities Awards are limited to one per institution, the

institution decides which applications advance. Their concern is that pediatrics often lose under those circumstances. The ACCC suggested that more than one application per institution be permitted if they include applications in CPRIT's priority areas. This suggestion will be taken up with the Research Subcommittee. Another ACCC suggestion was to have a Multi-Investigator award targeted at childhood cancer. The first step has been taken with an Individual Investigator RFA targeted at childhood and adolescent cancer. These suggestions will be considered to help pediatric researchers be more competitive. In response to Dr. Rice's question, she stated that the Individual Investigator RFA just went through peer review.

Dr. Rosenfeld said that as he has attended cancer conferences, he notes that the reputation of CPRIT has gone up tremendously over the past year, much of that due to Dr. Kripke's and Mr. Roberts' efforts. He wondered if it would be worthwhile to develop an abstract about CPRIT to present to the American Society of Clinical Oncology (ASCO). Dr. Kripke said the other logical association to which such an abstract could be submitted was to the American Association for Cancer Research, but was not certain if nationally they would be interested in Texas-specific research, though she believed the granting program is of interest to the cancer research community. She said she would prefer to be "invited" by an organization to participate on a panel or make a presentation, rather than submit an abstract. Dr. Rosenfeld said the two were not mutually exclusive. Mr. Roberts said that the agency is now in a position to being proactive in giving out information about what Texas is doing in cancer research. He said the new Communications Specialist has been tasked with finding ways to do this. Dr. Kripke believes the peer reviewers are our best marketing group because they see the process first hand and the quality of the grants that are being funded.

Dr. Mulrow asked Dr. Kripke to discuss Core Facility grants and the fact that they are limited to one per institution and whether that means an institution cannot apply for another until the current multi-year grant is completed. Also, she asked if CPRIT proactively identifies areas where it would benefit the State of Texas to have a core facility. Dr. Kripke responded Core Facility grants are for five years and that CPRIT has not set requirements in the past as to what the facilities should do. She pointed out that the institutions are allowed only one application per cycle but institutions can apply a new one while a previous one is still active.

To show that a core facility grant is successful, Dr. Mulrow asked if they are required to show they are delivering services across Texas or beyond the institution's location. Dr. Kripke said they are variable, since some are within an institution, and others are regional and thus may provide a core service not only for their institution but surrounding areas as well. It's up to the applicant to identify their service, but strict criteria exist for evaluating who receives grants, part of that being who the users of the service will be and how broadly it will be used. The productivity of scientists and physicians using the core is what is evaluated—are they producing papers in quality journals and do they use the core facility to further their work and obtain more funding for their research scientists. Dr. Rice inquired when the evaluation takes place. She stated the evaluation occurs at the time of the application, annually through progress reports, and at the end of the grant

through a final report. If the institution applies for a competing renewal, it must report accomplishments in the last grant period.

Dr. Rosenfeld asked why the ratio of Academic awards to Product Development awards is high. Mr. Roberts stated that there are several reasons. First, because Research grants began prior to Product Development grants, there are now more Research grants. Secondly, there are fewer Product Development grant applications versus Research grant applications. Additionally, there are several Product Development grant contracts pending the committee's approval of contract terms. When the contracts are signed, it will impact the funding ratio somewhat, though still not enough to make them equal in dollars or number.

Grant Recommendations

Dr. Kripke stated that in the last few months the Scientific Review Council had reviewed 10 applications for Recruitments awards. There were three application reviews for established investigators: two were recommended but one was withdrawn yesterday. This withdrawal substantiates what has been discussed before—these researchers are being competitively recruited. This makes the total amount of recommendations $24 million (instead of the $30 million in Dr. Kripke's memo to the Oversight Committee regarding Recruitment awards). There are now three Rising Star applications and three First-Time Tenure-Track Faculty Members applications being recommended for funding.

Recruitment Grant Award Recommendations

Application ID	Nominator Organization	Candidate	Mechanism*	Budget Requested
RR150013	The University of Texas M. D. Anderson Cancer Center	Dr. Marcin Imielinski	RFT	$2,000,000
RR150009	Baylor College of Medicine	Dr. Xi Chen	RFT	$2,000,000
RR150005	Baylor College of Medicine	Dr. Melanie Samuel	RFT	$2,000,000
RR150010	The University of Texas Southwestern Medical Center	Dr. Robert Mattrey	REI	$6,000,000
RR150015	The University of Texas Southwestern Medical Center	Dr. Samara Peck-Peterson	RRS	$4,000,000
RR150016	The University of Texas Southwestern Medical Center	Dr. Andres Leschziner	RRS	$4,000,000
RR150017	The University of Texas Southwestern Medical Center	Dr. Issam El Naqa	RRS	$4,000,000

*RRS = Recruitment of Rising Star, RFT = Recruitment of First Time Tenure Track, REI = Recruitment of Established Investigator

Compliance Certification

Dr. Rice called on Mr. Reisman to present the Chief Compliance Officer report. With regard to First Time Tenure Track Faculty Members awards slate, Rising Star awards slate, and the Recruitment of Established Investigator awards slate, Mr. Reisman stated that he had conferred with staff at CPRIT and SRA, and studied the supporting grant documentation including Third-Party Observer Reports for the Peer Review Meetings, and is satisfied that the application review process that resulted in the seven grants recommended followed applicable laws and agency administrative rules. He then certified these three award slates for Oversight Committee approval.

CONFLICT OF INTEREST NOTIFICATIONS

Dr. Rice noted for the record that Oversight Committee members have reported conflicts of interest with some of the applications to be considered.

Specifically, Ms. Mitchell reported conflicts with applications submitted by the following institutions:

- The University of Texas M.D. Anderson Cancer Center
- The University of Texas Southwestern Medical Center
- Baylor College of Medicine

Dr. Rice stated that in accordance with CPRIT's rules, Ms. Mitchell was recused from the discussion or action on the applications where she reported a conflict of interest.

Dr. Rice referred members to their Oversight Committee meeting books for the list of application ID numbers for applications with which members reported conflicts. He stated that several copies of this list were also made available for the public. Dr. Rice stated he would sign the list at the end of this meeting and require that the list be included in the certified copy of the minutes for this meeting.

Dr. Rice asked if there were any other conflict of interest declarations for Oversight Committee members that had not been previously noted. There was no other conflict.

APPROVAL PROCESS – Recruitment Grant Awards

Dr. Rice stated that members now have seven applications and grant amounts recommended by the PIC for Recruitment grant awards.

The PIC's recommendations, excluding the recommendation for RR150012, will be approved if two-thirds of the Oversight Committee members present and able to vote approve the PIC's funding recommendations.

Rather than taking up each recommendation individually, Dr. Rice asked for a vote for the awards and award amounts as listed on page 2 of the letter from the PIC Chair dated November 5, 2014.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for recruitment grant awards and award amounts.

Motion by: Angelou Seconded by: Montgomery
MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell abstained from voting.

MOTION:

Having approved the PIC recommendations for Recruitment grant awards, Dr. Rice called for a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff and to authorize the Chief Executive Officer to sign the contracts on behalf of the Institute.

Motion by: Angelou Seconded by: Montgomery
MOTION CARRIED UNANIMOUSLY

APPROVAL PROCESS – Additional Funding Consideration for Two Research Awards (RP130256 and RP130397)

Dr. Rice advised members they had a recommendation from the Scientific Review Council Chair, Dr. Richard Kolodner, to approve additional grant funding be awarded for two CPRIT grantees that were previously ratified for Core Facilities Awards in 2012.

Dr. Rice called on Dr. Kripke to lay out the recommendation.

Dr. Kripke noted that the members had the history of the recommendation in their meeting book materials. The two grants were previously reviewed by the Scientific Review panels but not fully funded—both were given a reduced budget and one was given a reduced timeline. There was an indication that a CPRIT employee had inappropriately participated in a discussion of the grants during the review process. Therefore, the previous Compliance Officer had brought this to the Oversight Committee in December 2012 with the recommendation that these grants be re-examined after the first year and consideration given to adding funding they were not originally awarded at a later date. The review has now taken place and both are recommended for additional funding. For the Core Facilities Award for Baylor College of Medicine, the Scientific Review Council has recommended that full funding be restored, which means adding $1.6 million to their award, to bring them to a total of $5.3 million. For MD Anderson, the recommendation is that they receive an additional $2.8 million, bringing their total award to $4.5 million. This amount is not as much as the original request but is consistent with reviewers' assessment. Along with the additional funds, the reviewers voted to extend the granting period five years in total, consistent with

the grantee's original timeline. Since this is additional funding, it will require Oversight Committee approval to move forward.

Dr. Rice asked if there were any further questions. There were none. He then stated that approving the recommendation for these two awards will result in additional grant funding. CPRIT's General Counsel advised that an Oversight Committee vote is necessary to increase grant funding above the amount originally approved for these awards.

Dr. Rice noted that Ms. Mitchell had a conflict of interest with regard to these recommendations and will abstain from voting on the recommendations. There were no other conflicts.

MOTION:

Dr. Rice asked for a motion to approve the Scientific Review Council's recommendation to increase the grant funding for RP130256 to $5.3 million.

Motion by: Montgomery Seconded by: Mulrow
MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell abstained from voting.

MOTION:

Dr. Rice asked for a motion to approve the Scientific Review Council's recommendation to increase the grant funding for RP130397 to $4.5 million and to increase the grant term to five years.

Motion by: Montgomery Seconded by: Angelou
MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell abstained from voting.

12. Chief Product Development Officer Report and Grant Recommendations

Product Development Update

Dr. Rice called on Dr. Goodman to present his update. An Advisory Committee on Product Development was created and has begun advising the Oversight Committee Subcommittee on Economic Terms. A CPRIT Revenue Sharing Policy Briefing Document was communicated to both these Committees. As of this writing, a timeframe to complete the Subcommittee's task has not been established.

The most recently completed RFA for Established Company, New Company and Relocating Companies yielded 30 grant applications. Seventeen of those companies were

chosen for onsite presentations. The Product Development Review Council recommended nine of those companies for business and IP due diligence. It is expected that several of the applications will be brought before the next Oversight Committee.

Product Development Grant Recommendations:

Early Translational Research Awards (ETRA)

ETRA grants support products that bridge the gap between promising research in the laboratory and the actual development of products that are licensable, or new companies that can be formed based on university research. To accomplish this, applicants must put together a business plan that can be sent to venture capitalists or other sources of funding to announce their product. The ETRA program was recently transferred from the Research Program to the Product Development Program in order to have reviewers who are more business-oriented look at the applications to determine their translational viability.

The RFA was released in May and peer review took place in October. There were 46 applications submitted. After scientific review, 20 Early Translational Grants were recommended by the Product Development Review Council and Program Integration Committee for approval by the Oversight Committee. These applications are described in a separate memorandum. Six of these involve new therapies, and seven refer to new targets being investigated (two deal with biomarkers and five with immunotherapy).

Dr. Rosenfeld said he would like to see the ETRAs transferred back to the Scientific Research Program if they continue to be formulated this way. He said this is not to comment on their merit but these program are very early and really not directly Product Development. He asked that the Oversight Committee consider that there be no further ETRAs until there is a discussion between the Product Development Subcommittee and the Scientific Research Subcommittee to determine the appropriate program to be issuing these grants.

Dr. Rice stated that Dr. Rosenfeld's comments warranted further discussion between the subcommittees. Also, he would like to have that conversation without interrupting the pace of RFAs already anticipated. Dr. Goodman said the next group of RFAs for companies will be released in December, with another RFA anticipated release in March 2015 on ETRAs. Mr. Roberts stated that the March time frame would give time to discuss Dr. Rosenfeld's concerns. Dr. Rosenfeld asked for assurance that no additional RFAs will go out on ETRAs until there has been a discussion and activity at the Oversight Committee level. Mr. Roberts gave his assurances that no ETRA RFAs would be issued without resolution of this issue.

Early Translational Research Awards Slate

DP150051
Targeting the DC-HIL Receptor for Anti-Cancer Immunotherapy
(University of Texas Southwestern Medical Center, Kiyoshi Ariizumi, $1,163,655 requested)

DP150052
High-Throughput Flow-Proteometric System in Screening Functional Complexes as Cancer Biomarkers
(M.D. Anderson Cancer Center, Mien-Chie Hung, $1,359,649 requested)

DP150055
Druggable Targets That Regulate the Antitumor Activity of ER-beta
(University of Texas Health Science Center at San Antonio, Rong Li, $1,998,444 requested)

DP150056
New Antibody Therapy for Treating Leukemia
(University of Texas Southwestern Medical Center, Chengcheng Zhang, $2,000,000 requested)

DP150059
Blood-Based Markers for Screening and Early Detection of Colorectal Neoplasia
(M.D. Anderson Cancer Center, Robert Bresalier, $1,693,599 requested)

DP150061
Preclinical Development of a Therapeutic Enzyme for Immune Checkpoint Inhibition in Cancer
(University of Texas at Austin, George Georgiou, $1,790,486 requested)

DP150064
Novel Separase Inhibitors to Treat Refractory Breast Cancer
(Baylor College of Medicine, Debananda Pati, $2,000,000 requested)

DP150065
Development of a Novel K-Ras Therapeutic
(University of Texas Health Science Center at Houston, John Hancock, $1,511,840 requested)

DP150069
Oral Stat3 Inhibitor as Targeted Treatment for Triple-Negative Breast Cancer
(Baylor College of Medicine, David Tweardy, $1,999,569 requested)

DP150074
Inhibitors of Hydrogen Sulfide Biosynthesis: Preclinical Development of Novel Colorectal Cancer Therapies
(University of Texas Medical Branch at Galveston, Mark Hellmich, $1,605,119 requested)

DP150077
Targeting the SWI/SNF Chromatin-Remodeling Complex in Liver Cirrhosis and Hepatocellular Carcinoma
(University of Texas Southwestern Medical Center, Hao Zhu, $1,357,880 requested)

DP150083
NKT Cell Platform for Cancer Immunotherapy
(Baylor College of Medicine, Leonid Metelitsa, $1,928,220 requested)

DP150086
Therapeutic Targeting of Skp2/Ck1 to Restore Nuclear p27
(Texas A&M University System Health Science Center, Cheryl Walker, $1,999,979 requested)

DP150087
Pre-IND Development of OxaliTex
(University of Texas at Austin, Jonathan Sessler, $1,464,504 requested)

DP150091
Selective Tumor Delivery of Anti-cancer Agents in Ovarian Cancer Therapy
(University of North Texas Health Science Center at Fort Worth, Andras Lacko, $742,048 requested)

DP150093
Targeting an Elusive Foe: Development of K-Ras Inhibitors
(University of Texas Health Science Center at Houston, Alemayehu Gorfe, $1,969,826 requested)

DP150094
Genetic Engineering of T Cells as an "Off-the-Shelf" Therapy for Leukemias and Lymphomas
(M.D. Anderson Cancer Center, Laurence Cooper, $1,992,245 requested)

DP150096
ESR1 Coregulator Binding Site Inhibitors (ECBIs) as Novel Therapeutics to Target Hormone Therapy Resistant Metastatic Breast Cancer
(University of Texas Health Science Center at San Antonio, Ratna Vadlamudi, $1,992,460 requested)

DP150099
Immunotherapy Targeting Triple Negative Breast Cancer Using NY-ESO-1-Specific TCRs and Blockade of Immune Suppression
(Methodist Hospital Research Institute, Rongfu Wang, $1,592,992 requested)

DP150102
Image-Guided Smart Laser Knife for Cancer Surgery
(University of Texas at Austin, Thomas Milner, $1,694,460 requested)

Compliance Certification

Dr. Reisman stated that with regard to Product Development awards, he conferred with staff at CPRIT and SRA International (SRA), and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. He stated that he was satisfied that the application review process that resulted in the Early Translational Research Product Development awards slate recommended by the Chief Executive Officer followed applicable laws and agency administrative rules. Mr. Reisman certified these award slates for the Oversight Committee's consideration.

CONFLICT OF INTEREST NOTIFICATIONS

Dr. Rice noted for the record that Oversight Committee members have reported conflicts of interest with some of the applications to be considered.

Specifically, Ms. Mitchell reports conflicts with applications submitted by the following institutions:

- The University of Texas M.D. Anderson Cancer Center
- The University of Texas Southwestern Medical Center
- The University of Texas Health Science Center at San Antonio
- The University of Texas at Austin
- Baylor College of Medicine
- The University of Texas Health Science Center at Houston
- The University of Texas Medical Branch at Galveston
- Texas A&M University System Health Science Center
- University of North Texas Health Science Center at Fort Worth
- Methodist Hospital Research Institute

In accordance with CPRIT's rules, Ms. Mitchell was recused from the discussion or action on these applications.

Dr. Rice explained that a list of the application ID numbers with which members reported conflicts has been provided. Dr. Rice will sign the list at the end of this meeting and require that the list be included in the certified copy of the minutes for this meeting. He

then asked if there were any other conflict of interest declarations for Oversight Committee members.

Dr. Rosenfeld stated he had a conflict with application DP150069, Baylor College of Medicine. In accordance with CPRIT's rules, Dr. Rosenfeld was recused from the discussion or action on this application.

CONSIDERATION OF EARLY TRANSLATIONAL RESEARCH AWARD GRANTS

Dr. Rice reported that the Program Integration Committee recommended 20 Early Translational Research applications for Product Development awards. Rather than taking up each recommendation individually, Dr. Rice said the committee would vote on the awards and award amounts as listed on pages 5 and 6 of the letter from the PIC Chair dated November 5, 2014, excluding DP150069. That award would be voted upon separately.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for Early Translational Research awards and award amounts, excluding DP150069.

Motion by: Geistweidt Seconded by: Mulrow
MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell had abstained from voting.

MOTION:

Dr. Rice called for a motion to approve the PIC's recommendations for Early Translational Research award and award amount for application DP150069.

Motion by: Montgomery Seconded by: Geren
MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell and Dr. Rosenfeld abstained from voting.

MOTION:

Having approved the PIC recommendations, Dr. Rice called for a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff and to authorize the Chief Executive Officer to sign the contracts on behalf of the Institute.

Motion by: Montgomery Seconded by: Angelou
MOTION CARRIED UNANIMOUSLY

13. Appointments to Scientific Research and Prevention Program Committees

Dr. Rice presented, on behalf of Ned Holmes, the Nominations Subcommittee recommendations related to the Chief Executive Officer's new appointments to the Scientific Research and Prevention Programs Committees. Dr. Rice stated the Nominations subcommittee met on November 14 and recommended approval of the CEO's two appointments to CPRIT Scientific Research Program and Prevention Program Committees.

There were no questions or discussion by members.

MOTION:

Mr. Rice called for a motion to approve the Chief Executive Officer's appointments to the Scientific Research and Prevention Program Committees.

Motion by: Geistweidt Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

14. Personnel Action – Process for Annual Review of CEO

Dr. Rice referenced Tab 11 in the members' meeting book. He stated it is best practice to have a performance review of the Chief Executive Officer. The Board Governance Committee has been asked to execute that process. This process will occur annually going forward.

There was no further discussion.

15. Internal Audit Reports

Dr. Rice recognized Ms. Pryia Sarjoo (Principal, Grant Thornton) CPRIT's internal auditor, to present the audit reports.

Ms. Sarjoo explained that she will summarize the detailed reports, which committee members have in their meeting book. She pointed out that the Audit Subcommittee had reviewed and recommended approval all the reports. The audits performed were:

- Expenditure Audit
- Third-Party SRA Managed Information Systems Audit
- Governance Audit
- Information Technology Audit
- Grants Management Audit

Ms. Sarjoo noted that the Expenditure Audit and Third-Party SRA Managed Information Systems Audit had been reviewed at CPRIT's August Oversight Committee meeting,

therefore she would only cover the Governance, Information Technology, and Grants Management Audits. (Ms. Sarjoo's presentation is attached to these minutes.) She stated that most of these issues have been discussed already and, with the permission of the committee, she would rely on their reading of the audits themselves. Dr. Rice stated that the audits had been discussed in the Audit Subcommittee and they would reserve their comments for the end of her presentation. He stated that CPRIT staff will put the audit findings and recommendations into a spreadsheet to update for each committee meeting to allow Oversight Committee members to keep track of progress quarterly instead of waiting until the next internal audit report so issues may be addressed as they arise. This information will also be used to compare year to year progress.

Dr. Rice asked Mr. Angelou to provide the Audit Subcommittee recommendations for the audits.

Mr. Angelou stated the Audit Subcommittee met on November 10 to discuss the three internal audits and the six field audits of grantees that were complete at the time of the meeting. Subsequent to the November 10 meeting, the Audit Subcommittee reviewed and approved the additional four field audits. The Audit Subcommittee recommends accepting the audits.

Dr. Rice called for questions or discussion. There were none.

MOTION:

Mr. Rice called for a motion to accept the Governance Internal Audit Report, the Grants Management Internal Audit Report, the IT Internal Audit Report and the ten grantee field audits.

Motion by: Angelou Seconded by: Montgomery
MOTION CARRIED UNANIMOUSLY

Dr. Rice noted that the audits will be posted to the CPRIT website.

16-18. Internal Audit Plan for FY 2015 and Services Contract

Internal Audit Plan for FY 2015

Ms. Sarjoo explained that, after the Oversight Committee approval, the FY 2015 Internal Plan is included in the FY 2014 Internal Audit Report. The planned audits are:

Internal Audit Area	Description
Grants Management	This internal audit will consider whether controls are in place to help validate that the grant application process and the subsequent review of programmatic and financial activities are operating effectively.

Expenditures	This internal audit of expenditures will consider whether controls are in place to help validate that the Agency's internal expenditure process and controls are operating effectively to mitigate the risk of fraudulent activity.
Information Technology	This internal audit will help validate that the Agency's IT environment is compliant with Texas Administrative Code and will determine whether general computer controls are in place and operating effectively.
Grantee Field Audits	Internal audits of various grantees will help validate if the grantees have a clear understanding of CPRIT's policies and procedures and will review whether CPRIT funds have been used in accordance with the established guidelines.
Ad Hoc	To be determined by Management or the Audit Subcommittee.

Dr. Rice called on the Audit Subcommittee chair, Mr. Angelou, to give the subcommittee's recommendation.

Mr. Angelou stated the Audit Subcommittee met on November 10 to discuss the report. The Audit Subcommittee recommends accepting the FY 2014 Internal Audit Report and approving the FY 2015 Audit Plan.

MOTION:

Dr. Rice called for a motion to accept the FY 2014 Internal Audit Annual Report.

Motion by: Angelou Seconded by: Montgomery
MOTION CARRIED UNANIMOUSLY

MOTION:

Dr. Rice called for a motion to approve the FY 2015 Audit Plan.

Motion by: Angelou Seconded by: Montgomery
MOTION CARRIED UNANIMOUSLY

Internal Audit Services Contract

Dr. Rice called on Ms. McConnell to present the recommendation for contracting for the FY 2015 internal audit services.

Ms. McConnell directed the members to a memo behind Tab 13 regarding internal audit contracting. CPRIT will procure the services through the Comptroller's Texas Multiple Awards Schedule (TEXMAS) program for certified public accounting firm. She stated that CPRIT anticipates continuing with Grant Thornton, LLP, as the agency audit firm. The cost is expected to be similar to 2014, approximately $200,000. Staff requested approval for a contract for internal audit services not to exceed $200,000 and contingent upon Legislative Budget Board approval.

MOTION:

Dr. Rice called for a motion to authorize CPRIT to execute a contract for internal audit services for FY 2015 not to exceed $200,000 upon appropriate approval from the Legislative Budget Board.

Motion by: Montgomery Seconded by: Angelou
MOTION CARRIED UNANIMOUSLY

19. Biennial Conference Contract

Dr. Rice stated that the Biennial Conference was discussed earlier in the meeting and no further action was needed.

20. Advisory Committee on Childhood Cancers Charter

Dr. Rice told members that Dr. Kripke had discussed the work of the Advisory Committee on Childhood Cancers earlier in the meeting. He understood that the Board Governance subcommittee had reviewed the proposed charter and recommended approval.

MOTION:

Dr. Rice called for a motion to approve the charter for the Advisory Committee on Childhood Cancers.

Motion by: Rosenfeld Seconded by: Montgomery
MOTION CARRIED UNANIMOUSLY

21. Advisory Committee on Product Development

Dr. Rice advised members that at the last meeting, the Oversight Committee directed CPRIT staff to create an advisory committee to provide advice related to product development issues. Mr. Roberts discussed the first meeting of the Advisory Committee on Product Development in his CEO report. Dr. Rice then called Mr. Roberts to present the nominees to the Advisory Committee on Product Development.

Mr. Roberts reported that he asked members of the Oversight Committee to provide membership suggestions for this committee. He also solicited recommendations from other contacts familiar with CPRIT's mission. The recommendations presented below consist of individuals from the venture capital, university technology transfer, and non-profit sectors, all with experience in the bio-life sciences. He anticipated another two or three recommendations to be presented at the next meeting.

Nominees - Advisory Committee on Product Development			
Bruce Butler	Ph.D., Physiology and Biophysics, University of Texas Medical Branch	Vice President, Research & Technology; Director, Office of Technology Management	The University of Texas Health Science Center at Houston
Kevin M. Lalande	BS, MBA Harvard	Managing Director	Santé Ventures
Martin Lindenberg	MD, Wits Medical School; MBA, BSci Univ. of Witwatersrand	Partner	Newport Board Group
Bruce Mackler	Ph.D., Immunology/Microbiology, University of Oregon Medical School; MS, Immunology/Microbiology, Penn State University; JD, South Texas School of Law	Board member of 3 companies, Venture Partner, FDA Advisor	Board member: Prairie Plant Systems, Inc.; OncoFluor, Inc.; Immunomic Therapeautics, Inc.; Venture Partner: TVM-Capital
Jonathan MacQuitty	Ph.D., Chemistry, University of Sussex; MBA, Stanford	Partner	Abingworth
George McLendon	Ph.D., Inorganic Chemistry, Texas A&M; BS, The University of Texas at El Paso	Provost, Rice University; Co-Director, Texas Medical Center Accelerator (TMCx)	Texas Medical Center Acclerator
Debra Peattie	Ph.D., Biochemistry & Molecular Biology; MBA, Harvard	Entrepreneur in Residence	GlaxoSmithKline
Emma Schwartz	BA, Stanford; MPH, UCLA	President	Medical Center of the Americas Foundation
James (Jamie) Topper	M.D., Ph.D. (Biophysics), Stanford	General Partner	Frazier Healthcare

Dr. Rice stated that the Nominations Subcommittee met on November 14, 2014, to discuss the nine nominees for the Advisory Committee on Product Development and recommended that the Oversight Committee accept the members as listed in the members meeting book.

Dr. Rice asked for further comments and none were heard.

MOTION:

Dr. Rice called for a motion to approve the members of the Advisory Committee on Product Development.

Motion by: Montgomery Seconded by: Angelou

MOTION CARRIED UNANIMOUSLY

22-23. Final Order Approving Amendments to 25 T.A.C. Chapters 701-703 and Proposed Amendments to 25 T.A.C. Chapter 703 and Authorization to Publish in the Texas Register

Dr. Rice called on Ms. Doyle, General Counsel, to present the changes for approval.

Final Order Approving Amendments to 25 T.A.C. Chapters 701-703

Ms. Doyle described the rulemaking process. First the Oversight Committee approves proposed rules for publication in the *Texas Register*, and CPRIT seeks public comment. Any public comment received is incorporated and the proposed rules are presented to the Oversight Committee again to adopt the rules, at which time they become final. Item 22 is to adopt final rules. At the August meeting the Oversight Committee considered one new proposed rule and two proposed rule changes. The new rule adopts a process for the public to request that the agency initiate a rule-making, which is a standard requirement. One of the proposed rule changes deals with audits for public and private institutions, recognizing that these institutions could satisfy the audit requirements that CPRIT has by obtaining a program-specific audit for agreed upon procedures and engagements. The other change is to the matching funds rule, providing additional clarification on how subcontractor funds, if they are also contributing to a project, can be counted to meet matching funds requirements. CPRIT published these rules for public comment and received no comments. The Oversight Committee has a memo from the Board Governance subcommittee recommending that the Oversight Committee approve these rules and adopt them as final rules.

MOTION:

Dr. Rice called for a motion to approve the final orders adopting CPRIT's rule changes and to direct staff to file the orders with the Secretary of State.

Motion by: Montgomery Seconded by: Angelou

MOTION CARRIED UNANIMOUSLY

Proposed Amendments to 25 T.A.C. Chapter 703 and Authorization to Publish in the Texas Register

With regard to Item 23, Ms. Doyle stated CPRIT is starting the rule-making process for three rule changes. She noted that on the back page of the memo from the Board Governance subcommittee (behind Tab 18), is a summary of the changes to be made. One proposed change is allows the Chief Compliance Officer to observe and report the grant review process, and to inform the Oversight Committee at the time of the grant certification process. CPRIT currently uses a third party contract for this service. This change adds the Chief Compliance Officer to individuals able to perform that service. He currently does so for the Program Integration Committee and can serve as a backup for the third party contractor if it is unable to do so. Another proposed change is to the matching funds rule. This was briefly referred to in the Internal Audit presentation. Institutions are now able to use their indirect cost rate as a credit for the matching funds requirement and, therefore, there is clarification necessary to make sure the grantees understand what they need to do in terms of reporting to CPRIT, and in interpreting some of the statutory requirements. These rules changes will be released for public comment, and will be brought back at the in February Oversight Committee meeting with any comments received, incorporated into a final order.

Dr. Rice asked for any question or comments and there were none.

Dr. Rice stated that members have a memo in their packet from the Board Governance subcommittee recommending approval of the proposed changes.

MOTION:

Dr. Rice called for a motion to instruct staff to publish the proposed Chapter 703 rule amendments in the *Texas Register* in accordance with the requirements of the Administrative Procedure Act.

Motion by: Montgomery Seconded by: Angelou

MOTION CARRIED UNANIMOUSLY

24. Subcommittee Business

Diversity Subcommittee Report

Dr. Rice called on subcommittee chair, Dr. Mulrow, to give the report.

Dr. Mulrow stated the subcommittee met on November 7 and discussed research training grants. She said they have some ideas to focus on training for groups under-represented in medicine and research science but no firm action to recommend at this time.

Dr. Rice asked if any other subcommittee business needed to be discussed at this time and there was none.

25. Consultation with General Counsel

This agenda item was not taken up.

26. Future Meeting Dates and Agenda Items

Dr. Rice stated the next regular Oversight Committee meeting is scheduled for February 18, 2015, at 10:00 a.m. CPRIT staff will circulate a tentative agenda prior to the meeting.

Dr. Rice said a special meeting may be called before the February meeting to discuss revenue sharing terms for Product Development awards. Mr. Roberts asked the members to consider what date they might be available, should that meeting need to be scheduled. He stated the three most viable dates were January 8, January 9, and January 20. Dr. Rice asked if contracts were on hold until the committee comes to a decision and Mr. Roberts affirmed that was so. After discussion with the members, it was decided that January 20 would allow the most members to be present since all would be available except Mr. Geren. Mr. Roberts said he would send calendar appointments to hold January 20.

Mr. Geren asked if there was any information they needed before the legislative session starts in January. Mr. Roberts stated he had met with several members and is trying to set additional appointments now that legislators are coming back into town. He doesn't have any indications at this time of any legislator interested in amending CPRIT's statute. The Legislative Budget Board recommendation will probably be made public the first week or two of January.

27. Adjourn

There being no further business, Dr. Rice called for a motion to adjourn.

Motion by: Geren Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

Meeting adjourned at 1:35 P.M.

_____ _____

Signature Date

TAB 2

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**SUBCOMMITTEE ON ECONOMIC TERMS (PETE GEREN, AMY MITCHELL, WILL MONTGOMERY, CRAIG ROSENFELD)**
Subject:	**DEVELOPMENT OF STANDARD REVENUE SHARING TERMS FOR PRODUCT DEVELOPMENT CONTRACTS**
Date:	**JANUARY 13, 2015**

RECOMMENDATION

The Oversight Committee Subcommittee on Economic Terms unanimously recommends Oversight Committee approval of the attached "Product Development General Contract Term Sheet". The contract terms proposed were developed by CPRIT staff with significant input from the newly formed Advisory Committee on Product Development and the Subcommittee on Economic Terms.

These terms provide revenue income to the state from products and services developed with CPRIT grant funds. The terms fall within accepted venture capital industry parameters as moderated by CPRIT's complex purposes stipulated in Article III, Section 67(1) of the Texas Constitution and V.T.C.A., Health & Safety Code Chapter102.002.

PROCESS

The Oversight Committee (OC) adopted staff recommended standard terms for use in contracting with new product development awardees on May 21, 2014. Subsequently, questions were raised about the terms by companies ready to finalize contracts with CPRIT and additional questions were raised by OC members. Upon further discussion by the OC at its August 20 and September 3, 2014, meetings, a staff suggestion was approved to create a new *ad hoc* advisory committee specifically for product development to assist in developing revised contract terms for review by a new OC subcommittee on economic terms (in this case product development contracts) for adoption by the full OC. Advisory committees have been used by CPRIT to provide expert advice on issues such as university research and childhood cancer.

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The goal of this process was to establish general product development terms for use by CPRIT that met the following major criteria:

- Simple and understandable
- Provides the State of Texas with a fair and reasonable rate of return on its investment in keeping with:
    - Its role as a provider of financing only
    - Its goals of stimulating company formation and job growth in Texas, and
    - Its lower cost of capital in comparison with other investors
- Facilitates state participation in any blockbuster returns on a product developed with CPRIT funds
- Within a range of venture capital and non-profit industry standards, and
- Does not deter follow-on investment in the company by corporate or venture capital investors.

CPRIT staff solicited recommendations for members of the new Advisory Committee on Product Development from numerous sources, including individuals familiar with CPRIT and the national venture capital industry as well as Oversight Committee members. From these recommendations, staff identified a panel of nine members from across the United States with impressive academic credentials and significant experience in the venture capital, economic development, and technology transfer sectors. This panel was formally established by the OC at its November 19, 2014, meeting.

The Advisory Committee on Product Development (ACPD) met by teleconference on November 6, 2014, to discuss CPRIT's criteria and, based on their experience, what CPRIT should expect from revenue sharing and other terms with product development grantees. The ACPD teleconferenced again on January 7, 2015, to respond to a staff proposal developed from the first teleconference and several one-on-one discussions between staff and individuals from the ACPD. Members of the OC Subcommittee on Economic Terms participated in both teleconferences of the ACPD.

On January 10, 2015, the OC Subcommittee on Economic Terms teleconferenced and approved the staff proposal that had received favorable review from the ACPD.

The OC Subcommittee on Economic Terms believes the attached proposal addresses all desired criteria stipulated above and recommends approval by the full Oversight Committee.

PRODUCT DEVELOPMENT GENERAL CONTRACT TERM SHEET

Revenue Sharing: Until 4X the amount of the grant monies distributed to the grantee is paid to Texas, the revenue sharing percentage for all products and services subject to revenue sharing shall be:

- 3% of Revenue for Cumulative Revenues greater than $5 million and less than $500 million,
- 4% of Revenue for Cumulative Revenues of $500 million or more but less than $1 billion, and
- 5% of Revenue for Cumulative Revenue of $1 billion or more.

"Cumulative Revenue" is the sum of all Revenue in all years and quarters up to the quarter in which the revenue sharing is being paid. The definition of "Revenue" is given below.

Stacking Provision: The above revenue sharing percentages may be diminished by 0.5% for every one percent of royalty necessary to be paid to a third party to sell a product or service, but in no case shall be reduced to less than one-half of what would otherwise be due.

Continuing Royalty: After 4X the amount of the grant monies distributed to the grantee is paid to Texas, the revenue sharing percentage for all products and services subject to revenue sharing shall be reduced to 0.5%, but cannot be reduced further by any provision for stacking or adjustment.

Equity: Nothing herein prohibits CPRIT from negotiating an equity share in addition to or in lieu of revenue sharing or continuing royalty terms when deemed appropriate by the Oversight Committee and a company.

Termination of Revenue Sharing: All revenue sharing obligations under the contract for any particular Commercial Product or Commercial Service in a given venue shall terminate for that Commercial Product or Commercial Service in that venue when there is not, or there no longer exists, any governmental grant of exclusivity for the Commercial Product or Commercial Service in that venue.

Definition of Revenue: "Revenue means the gross consideration, whether cash or non-cash (for example, but not by way of limitation, securities, direct equity interest, indirect equity interest, trade or barter considerations, and the like), received from Sales to a Third Party by RECIPIENT or its licensees (including

without limitation, any milestone fees, license fees, sublicense fees, or assignment fees), net of: (a) trade or quantity discounts or rebates, credits, allowances or refunds given for rejected or returned Commercial Products or Commercial Services, (b) any sales, value-added or other tax or governmental charge levied on the sale, transportation or delivery of a Commercial Product or Commercial Service (but excluding any income tax owed by the RECIPIENT or its licensees), and (c) any separately stated charges for freight, postage, shipping, and insurance. The foregoing notwithstanding, any consideration: (i) received and used by RECIPIENT or its licensees for the purposes of research or development, or (ii) received from Sales made solely in the performance of clinical trials designed to obtain regulatory approval for a Commercial Product or Commercial Service, or (iii) received by RECIPIENT or its licensees from Sales made for compassionate use where no profit was obtained by RECIPIENT or its licensees shall not be included in this term."

CPRIT will make it clear in the final contract document that there will be no revenue sharing of milestones or other monies prior to the approval of a Product.

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These are standard terms that will be applicable to most Product Development grants. However, special circumstances, at CPRIT's determination, may justify individually negotiating one or more terms with the grantee at the time of or following execution of the award contract.

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**THOMAS GOODMAN, CHIEF PRODUCT DEVELOPMENT OFFICER**
Subject:	**PRODUCT DEVELOPMENT CONTRACT TERMS RATIONALE**
Date:	**JANUARY 13, 2015**

SUMMARY

The proposed contract terms were developed with significant input from staff and the newly formed Advisory Committee on Product Development. As a whole, the terms fall within accepted venture capital industry parameters as moderated by CPRIT's complex purposes stipulated in Article III, Section 67(1) of the Texas Constitution and V.T.C.A., Health & Safety Code Chapter102.002. The Oversight Committee Subcommittee on Economic Terms, in a separate memorandum to the Oversight Committee, recommends adoption of a "Product Development General Contract Term Sheet".

BACKGROUND

CPRIT's statute requires that the Oversight Committee establish standards requiring all grant awards to be subject to an agreement that allows the state to share in the proceeds realized from projects undertaken with grant funds. The standards should balance the state's opportunity to benefit through revenue sharing with the need to ensure that medical research is not unreasonably hindered and should not remove the incentive for further development.

The Subcommittee on Economic Terms established a goal for standard revenue sharing terms for product development grants to meet the following major criteria:

- Simple and understandable
- Provide the State of Texas with a fair and reasonable rate of return on its investment in keeping with:
    - Its role as a provider of financing only (vs. other assistance provided by VCs including access to network leads for additional capital, business and technical guidance, board members, etc.)
    - Its goals of stimulating company formation and job growth in Texas, and
    - Its lower cost of capital in comparison with other investors

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- Facilitate state participation in any blockbuster returns on a product developed with CPRIT funds
- Fall within a range of venture capital and non-profit industry standards, and
- Do not deter follow-on investment in the company by corporate or venture capital investors.

EXPLANATION OF MAJOR TERMS

Revenue Sharing - CPRIT's proposed return of 4X the amount of funds invested by CPRIT provides a fair and reasonable yield on the state's investment by taking into account its statutory public mission to accelerate development of cancer treatments and cures and stimulate company formation and job growth in Texas.

- The proposed 4X return is within the appropriate range of industry standards and recognizes CPRIT's role vis-à-vis the company. Generally, successful venture capital industry returns fall within a range of 3X-7X the amount of funds invested with anything above 8X considered excellent and 10X as outstanding. Most venture capital investments are unsuccessful or return little. As an investor, CPRIT provides little else to the company beyond financing. The infusion of capital is of paramount importance, however, venture capitalists may also provide additional resources valuable to the early stage company. These resources include access to the VC's network of other investors and experts that provide valuable business and regulatory guidance to navigate early stage development hurdles. Another distinction between the state and VC as investors is that the state benefits in other ways beyond cash returns when a company successfully develops a device or therapeutic. These benefits include a growing tax base and creation of high-quality jobs in the state. In contrast, the VC's primary and likely sole interest is a capital return when a company in its portfolio successfully develops a product. Job growth and other economic considerations have little or no value to the VC and therefore are not accounted for in terms of the potential return on investment.

- Two other issues related to revenue sharing are worth noting. First, the proposed terms provide that Texas begins receiving its revenue sharing payments in steps once the grantee company has product sales exceeding $5 million. This is a sensible approach that allows the company to preserve early cash for product development, approval, and product launch. Second, the proposed terms increase the revenue sharing amounts in steps. This simple accommodation allows for the same set of terms to apply to all companies CPRIT funds, despite differences among the type of products developed. Generally, companies that develop research products or diagnostics have more modest sales (less than $500 million) compared to successful drug developers (billions in sales).

CPRIT receives greater return on companies with greater sales. Incorporating steps into the revenue sharing provisions allows for flexibility for all companies.

Stacking Provisions: Adjusting CPRIT's proposed revenue sharing percentages to recognize existing license agreements facilitates needed follow-on funding while preserving a reasonable rate of return for CPRIT.

- Companies must pay royalties to use non-company owned patented products or techniques to develop new product. Due to the technical complexity of product development in biotechnology, it is common that a single drug will have several inputs with various proprietary rights attached. Royalty stacking occurs when the company must pay royalties to more than one entity; the obligations are "stacked" on one another. Unless stacking is taken into account by early investors, potential follow-on investors could be discouraged from providing needed additional financing due to a decreasing amount of product sale revenue available as income to them. Failure to adjust for royalty stacking hurts the initial investor and may be the reason a promising technology is never ultimately developed.

- The proposed terms accommodate revenue-stacking concerns. Many products developed with CPRIT funding will also be subject to existing license agreements and other proprietary rights. In those cases, CPRIT will allow its revenue sharing to be diminished by these prior agreements so that the burden on return to the company is reduced. However, in order to preserve a reasonable level of return to Texas, the proposed terms incorporate a floor below which the percentage of revenue sharing due to CPRIT cannot be diminished.

Continuing Revenue Sharing (Blockbuster Provision): In addition to a 4X return on investment, the proposed terms preserve the state's participation in any "blockbuster" product developed with CPRIT funding.

- The proposed terms include a continuing revenue-sharing obligation that requires the company to pay CPRIT one-half percent (0.5%) of revenue even after the company has fulfilled its obligation to pay 4X the CPRIT grant amount. The continuing royalty is not reducible by stacking or other adjustments and ensures the state's participation in revenue from a runaway success.

Termination of Revenue Sharing: The proposed terms end the revenue sharing obligations once all governmental grants of exclusivity terminate. Doing so ensures that Texas companies are not disadvantaged when it becomes possible for competitors to enter the marketplace.

- An early stage company created largely through innovation has its products or intellectual property protected for a period of time with governmentally sanctioned rights to exclusivity, e.g., patents, orphan drug status. When the protection period ends, competitors can and do enter the market niche if the product is successful. The proposed term is a typical and expected provision in licensing agreements and enhances a major CPRIT goal to grow and expand the biotech industry in Texas by starting new companies based on innovative products and attracting existing ones to Texas.

Revenue Definitions

- Definitions are those used in existing CPRIT contracts.
- No pre-revenue monies to be paid. CPRIT will clarify that no revenue sharing of milestones or other monies prior to the approval and sale of a product will be required.