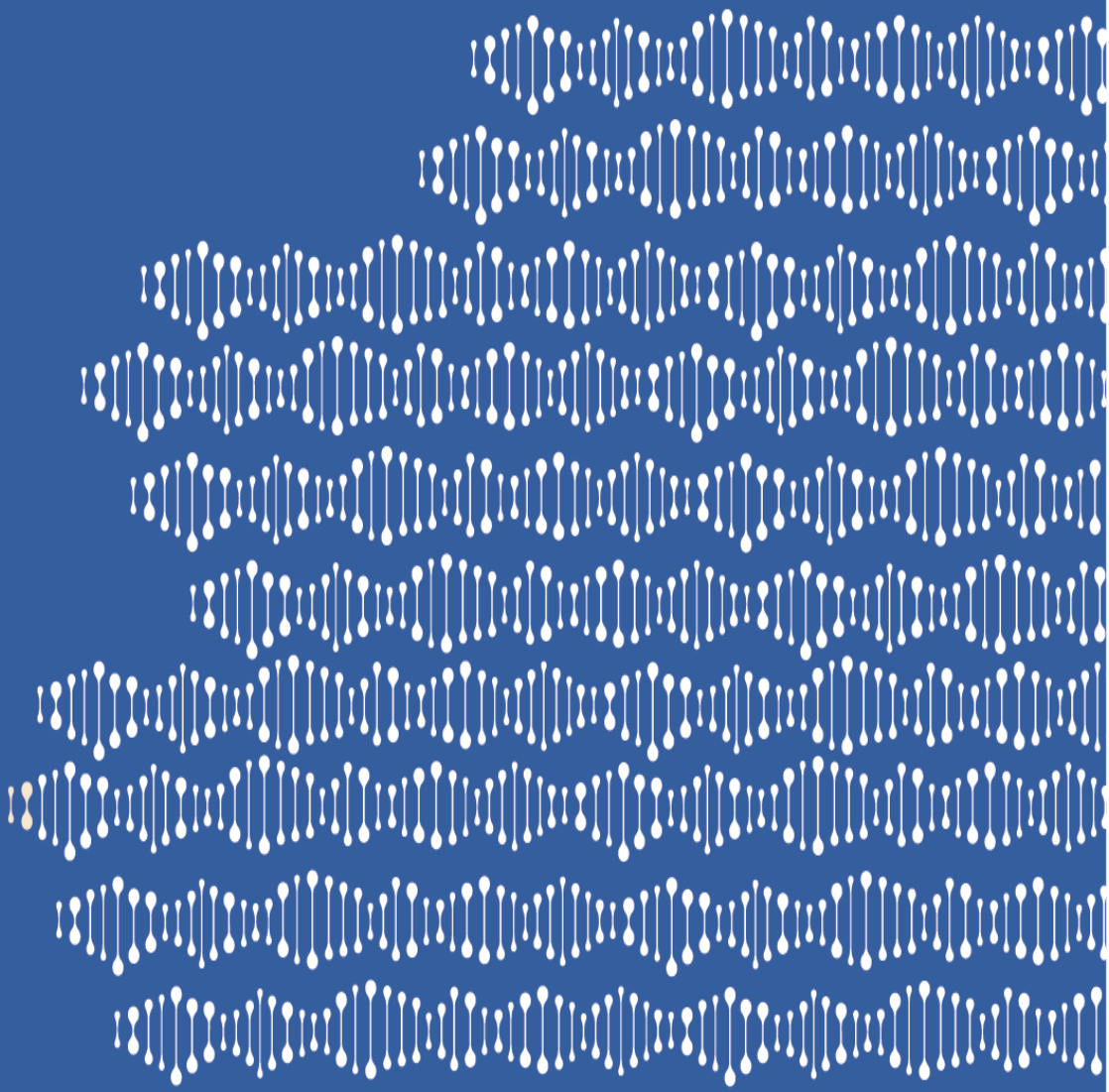
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

September 10, 2015



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Summary Overview of the September 10, 2015, Oversight Committee Meeting

This summary provides an overview of agenda items and background on key issues for Committee consideration at the September 10, 2015, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including CPRIT staff recruitment efforts and other issues as appropriate.

Chief Scientific Officer Report and Grant Award Recommendations
Dr. Margaret Kripke will present the Program Integration Committee's recommendations for recruitment awards.

Grant applications recommended for funding are not publicly disclosed until the Oversight Committee meeting. Supporting information will be made available to board members on September 4, 2015, through a secure electronic portal.

Interim Chief Product Development Officer Program Report
Kristen Doyle will provide an update on the Product Development Research Program. Ms. Doyle will also discuss a proposed contract extension for Cell Medica (CP120036).

Changes to Agency Administrative Rules
Ms. Doyle and Cameron Eckel, staff attorney, will present proposed changes to the agency's administrative rules. Proposed rule changes to T.A.C. §§ 703.12 and 703.22 are recommended to be published in the *Texas Register* for public input.

- The change to § 703.12 clarifies that cancer prevention grantees may spend some grant funds on indirect expenses, but are subject to the same limitation as cancer research grantees. New rule § 703.22 creates a compliance training requirement for new grantees and an annual compliance training component for all grantees with active CPRIT grants.

Changes to CPRIT's Code of Conduct
Ms. Doyle will present three non-substantive changes to page 9 of the Code of Conduct for approval. The changes correct typographical errors.

Ethics Training
CPRIT's administrative rules require Oversight Committee members to participate in periodic Compliance Program training. Vince Burgess will lead the compliance training, which focuses on CPRIT's Code of Conduct and applicable statutory provisions.

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Oversight Committee Meeting Agenda

Texas State Capitol Extension
1400 N. Congress Avenue, Austin, Texas 78701
Room E1.012

September 10, 2015
12:00 p.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. Public Comment*
4. Chief Executive Officer Report **TAB 1**
5. Chief Scientific Officer Report
    - Grant Award Recommendations
6. Chief Product Development Officer Report **TAB 2**
    - CP120036 Contract Extension
7. Proposed Amendments to 25 T.A.C. Chapter 703 and Authorization to Publish in the *Texas Register* **TAB 3**
8. Proposed Amendments to CPRIT Code of Conduct **TAB 4**
9. Subcommittee Business
10. Ethics Training
11. Consultation with General Counsel
12. Future Meeting Dates and Agenda Items
13. Adjourn

** Anyone wishing to make 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.*

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MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 4, CHIEF EXECUTIVE OFFICER REPORT
DATE:	AUGUST 31, 2015

As of this writing the Chief Executive Officer Report for the September 10, 2015, Special Oversight Committee will consist of the following items:

- Status of selected CPRIT staff personnel recruitments, and
- Funds available for grant awards in FY 2016

Other topics may be added as warranted.

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CPRIT has awarded **915** grants totaling **$1.352 billion**

- 146 prevention awards totaling $142.2 million
- 769 academic research and product development research awards totaling $1.210 billion

Of the $1.210 billion in academic research and product development awards,

- 32.5% of the funding ($393.5 million) supports clinical research projects
- 26.7% of the funding ($322.8 million) supports translational research projects
- 22.9% of funding ($276.5 million) supports recruitment awards
- 15.5% of the funding ($187.9 million) supports discovery stage research projects
- 2.4% of funding ($29.5 million) supports training programs.

CPRIT has 10 open Requests for Applications (RFAs)

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

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MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS** **WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER**
From:	**KRISTEN DOYLE, GENERAL COUNSEL AND INTERIM CHIEF PRODUCT DEVELOPMENT OFFICER**
Subject:	**CONTRACT EXTENSION – CP120036**
Date:	**SEPTEMBER 3, 2015**

Summary and Recommendation:

I recommend that the Oversight Committee authorize Mr. Roberts to approve a contract extension for up to one year so that Cell Medica may complete the work on its CPRIT-funded project. The request comes before the Oversight Committee for approval because Cell Medica failed to request a contract extension within the time period specified by CPRIT's administrative rules. However, the company's failure to do so appears to be the result of Cell Medica's reliance upon advice from CPRIT staff that was incomplete or incorrect. Cell Medica is programmatically and fiscally up to date and has approximately $2.7 million in unspent grant funds. Approving the contract extension provides the company with time to complete the approved work of the grant project.

Background:

Cell Medica Inc. is the U.S. subsidiary of Cell Medica Limited. Cell Medica is a cellular therapeutics company developing cellular immunotherapy products for infectious diseases and cancer. The company was approved for a $15.6 million award at the March 2012 Oversight Committee meeting. CPRIT funding supports activities leading to FDA approval of cell therapies for the treatment of cancers associated with the Epstein Barr virus and for the treatment of cytomegalovirus infections in patients following bone marrow transplants. Cell Medica's U.S. headquarters are in Houston, which facilitates the company's research collaboration with Baylor College of Medicine, Texas Children's Hospital and Houston Methodist Hospital. During the course of its project, Cell Medica has received regulatory and ethical approvals for clinical trials in the U.S., U.K., France, Germany and South Korea. The company also received U.S. orphan drug status for treatment in non-Hodgkin lymphoma. Baylor College of Medicine, Texas Children's Hospital and Houston Medical Hospital have treated more than 250 patients with research prototypes of this treatment and report promising clinical results across a range of malignancies.

CPRIT acquired equity ownership in Cell Medica in accordance with CPRIT's contractual revenue sharing requirements. Although the grant contract's effective date was June 1, 2012, the equity agreement negotiations added several months to the contract execution process, which in turn delayed the company's initial progress. In addition, Cell Medica experienced a delay in starting its Phase I clinical trial in 2014. Company representatives had several discussions with CPRIT's former accounting director over the course of the grant about extending the contract term into a fourth year and was assured that the company would be able to "carry forward" unspent grant funds past the May 31, 2015, termination date into a fourth year. According to the company, representatives raised the issue more than once with the former Chief Product Development Officer, most recently when he visited the company in early May. The former Chief Product Development Officer reiterated that Cell Medica would be able to carry forward the unspent funds into a fourth project year.

CPRIT's administrative rule T.A.C. § 703.14 allows grantees to seek more time to complete work on the grant project if they submit a written request to the agency within six months of the termination date of the contract. The additional time is referred to as a "no cost extension." As long as the grantee has filed all required fiscal and progress reports, the no cost extension request is granted and six months are added to the contract termination date with the remaining funds carried forward into another project budget year. If the grantee needs more than six months to complete the project work or requests a second no cost extension, then the grantee must show good cause. No cost extensions are submitted via CPRIT's electronic grant management system.

Cell Medica representatives report that they did not know that there is an established process for extending the grant contract term and relied upon the advice of CPRIT staff that they would be able to carry forward funds into a fourth year. Had they known about the process, the company contends that they would have used it to request the additional time for completing work on the project. As of the termination date of the contract, Cell Medica has not spent $2.7 million of the $15.6 million award. If the grant contract term is extended, Cell Medica will spend the remaining funds on product manufacturing to support completion of clinical trials and continued development of combination therapies. This expansion is expected to result in hiring eight additional people in Houston.

Discussion:

Had Cell Medica followed CPRIT's established process for requesting a no cost extension prior to the termination date of the contract, the request would have received routine approval because the project was up-to-date fiscally and making appropriate progress as judged by CPRIT's expert reviewers. Although CPRIT staff publicized the no cost extension process in our newsletter notifications and in webinars, the company was not advised of the process when it sought advice from its primary CPRIT staff contacts. Both former CPRIT staff members correctly identified what would happen *once the no cost extension request was approved* – that the remaining funds

would be carried forward and a fourth budget year would be created in the system – but this was incomplete.

CPRIT staff do not retain the authority to approve the extension pursuant to our established process because of the late request. The Oversight Committee is statutorily responsible for approving grant contracts and has the authority to authorize an extension of time associated with a grant contract it has approved. Extending the time available for Cell Medica to complete its approved project is consistent with the project's scope of work and CPRIT's mission. No cost extensions are routinely approved for CPRIT grantees in similar situations that need additional time to complete work on grant projects.

If the no cost extension is not approved, Cell Medica would be required to return the unused grant funds. However, this process may be complicated by the fact that CPRIT holds equity in the company. It is unclear whether a return of grant funds will result in a diminution in CPRIT's equity interest and may require extensive negotiation.

Recommendation:

I recommend that the Oversight Committee authorize Mr. Roberts to approve a no cost extension for the Cell Medica contract that changes the termination date of the contract to May 31, 2016. Approving the contract extension provides the company with time to complete the approved work of the grant project and expend the remaining $2.7 million in CPRIT grant funds.

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INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**KRISTEN DOYLE, GENERAL COUNSEL** **CAMERON ECKEL, STAFF ATTORNEY**
Subject:	**PROPOSED RULE CHANGE T.A.C. § 703.12 AND NEW RULE T.A.C. § 703.22**
Date:	**SEPTEMBER 3, 2015**

Summary and Recommendation

CPRIT's legal and compliance staff recommend that the Oversight Committee approve two administrative rules changes for publication in the *Texas Register*. The first proposed rule change (§ 703.12) clarifies that prevention grantees may spend up to five percent of their grant funds on indirect costs. This change was suggested by the Prevention Program staff in response to concerns raised by potential applicants. The second rule change is a new rule (§ 703.22) regarding required grantee compliance training. The new rule is proposed to address an internal auditor finding. The proposed rules changes and any comments received from the public will be brought back to the Oversight Committee in November before the rule changes are officially adopted. Text of both rules and the proposed preamble are attached. The proposed changes were reviewed by the Board Governance subcommittee, which recommends Oversight Committee approval.

Discussion

§ 703.12

CPRIT's administrative rules permit Academic Research and Product Development Research grantees to spend up to five percent (5%) of grant funds on indirect costs associated with the grant projects. This is consistent with the statutory restriction on indirect costs paid for with cancer research grant funds. (*See* Tex. Health & Safety Code § 102.203(c).) However, both the statute and CPRIT's administrative rules are silent with regard to allowable indirect costs for prevention grants. Currently, the Prevention Program prohibits prevention grantees from expending any grant funds on indirect expenses.

CPRIT's Prevention Program staff have received feedback suggesting that the inability to spend any grant funds on indirect expenses may be a hardship for potential prevention grantees and may cause potential applicants to not submit grant proposals. The proposed change clarifies that

prevention grantees may spend some grant funds on indirect expenses, but subjects the prevention grantees to the same limitation imposed on research grantees.

§ 703.22

The proposed new rule implements the internal auditor's recommendation that CPRIT establish a mandatory compliance onboarding program for new grantees as well as periodic compliance training for all grantees. The new rule establishes an "initial compliance training program" for grantees receiving their first grant on or after September 1, 2015. The proposed rule also establishes an annual compliance training program requirement for all grantees with at least one active grant. Grantees must complete the annual training by November 1, 2016, and then by that date every year thereafter. Failure to the complete the required training may result in withholding disbursement of grant funds. The Chief Compliance Officer is responsible for designing the initial and annual compliance training programs, which are expected to be some combination of on-site training (particularly for the initial compliance training program) and web-based training.

The Board Governance subcommittee members reviewed the proposed changes on September 3, 2015, and recommends Oversight Committee approval for publication in the *Texas Register*.

Next Steps

The proposed rule change and new rule will be presented to the Oversight Committee at the September 10, 2015, meeting for consideration. If approved, the proposed rule changes will be published in the *Texas Register* and posted on CPRIT's website. Public comment will be accepted for 30 days following publication. The final order will then be presented at the November 19th Oversight Committee meeting.

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MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**KRISTEN DOYLE, GENERAL COUNSEL**
Subject:	**NONSUBSTANTIVE CHANGES TO CPRIT'S CODE OF CONDUCT**
Date:	**SEPTEMBER 3, 2015**

I recommend that three non-substantive changes be made to CPRIT's Code of Conduct to correct typographical errors. The errors appear on page 9 of the Code of Conduct (attached). The revised Code of Conduct will be posted on CPRIT's website.

(b) The personal friend or colleague, or a Relative of the personal friend or colleague, is not an employee or the member of the governing board of an entity receiving or applying to receive money from CPRIT; and

(c) The Oversight Committee Member, the PIC Member, or the Employee has no reason to believe that the gift or consideration is being offered through the personal friend or colleague as an intermediary; and

(3) payments to which the Oversight Committee Member, PIC Member, or Employee is lawfully entitled in a capacity other than the individual's official status;

(4) a political contribution as defined by Title 15, Election Code;

(~~7~~5) items issued by CPRIT or other governmental entities to the Oversight Committee Member, PIC Member, or Employee that allow the use of property or facilities owned, leased, or operated by CPRIT or other governmental entity;

(6) food, lodging, transportation, or entertainment accepted as a guest with the donor present, and, if the ~~done~~ donor is required by law to report those items, reported by the ~~done~~ donor in accordance with that law;

(7) Lodging, transportation, and meals described by Chapter 36, Section 36.07(b) (Acceptance of Honorariums), Penal Code;

(8) books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of an Oversight Committee Member, Employee, or PIC Member and that are accepted by the individual on behalf of CPRIT for use in performing the individual's job duties; and

(9) registration or admittance fees for seminars, conferences, or other sponsored events that may involve entertainment or recreation. If the seminar, conference, or other sponsored event is hosted or paid for by a business entity or organization applying for or receiving CPRIT funds, prior written approval to attend the event is required and the entity sponsoring or paying for the event must attend. For Oversight Committee Members, approval may be provided by the Oversight Committee chair (or vice chair if the chair is seeking approval). For a PIC Member or Employee, approval may be provided by the CEO (or the Oversight Committee chair if the CEO is seeking approval.)

C. Gifts or Consideration from Lobbyists

An Oversight Committee Member, PIC Member, or Employee shall immediately report to the Chief Compliance Officer any gift or consideration if the gift or consideration is provided by a