

**COMPLIANCE REVIEW OF GRANT APPLICATION & CPRIT AWARD – CP120015
INSTITUTE FOR APPLIED CANCER SCIENCE AT UTMDACC (the “IACS”)**

Submitted by Larry Plutko, UT System Compliance Officer
June 14, 2012

UT System Compliance Review

On May 26, 2012, Chancellor Francisco Cigarroa directed Vice Chancellor and General Counsel Barry Burgdorf to conduct a comprehensive compliance review of the IACS CPRIT grant application and award (CP120015). The external review would focus solely on whether appropriate grant application policies and processes were followed at UTMDACC. As indicated in detail below, no ill-intent, improper conduct, or any type of conflict of interest or nepotism contributed to any error in the CPRIT grant submission process; however, this report recommends policy revisions, already underway at UTMDACC, to ensure better communication and centralization of the process. The external review was assigned to Larry Plutko, System Compliance Officer. Having completed the inquiry, this reviewer now presents a report of factual findings, conclusions, and recommendations.

Interview Process

On May 29, 2012, Barry Burgdorf and Larry Plutko conferenced with Matt Masek, Vice President and Chief Legal Officer at UTMDACC, to discuss the Chancellor’s mandate for UT System to conduct the compliance review as soon as possible. As a follow-up, Larry Plutko and Matt Masek conferenced on May 30 and developed a process and list of persons to interview.

Janice Sams, Senior Administrative Assistant, UTMDACC Legal Services, quickly and efficiently arranged for the telephone interviews by Larry Plutko, June 5-7, 2012. The following persons were interviewed:

- Eric Devroe, Executive Director, Strategic Alliances, IACS – June 5
- Guilio Draetta, Director, IACS – June 5
- Dan Fontaine, Senior VP, Business Affairs – June 5
- Lynda Chin, Scientific Director, IACS – June 5
- Raymond DuBois, Provost and EVP – June 6
- Wesley Harrott, Executive Director, Research Administration – June 6
- Ronald DePinho, President – June 6
- Matt Masek, Vice President and Chief Legal Officer – June 7

The reviewer wishes to note that he received the highest level of cooperation in arranging for and conducting the interviews. Dr. DuBois, Wesley Harrott, and Matt Masek also provided me with electronic copies of grant applications and associated documents for review.

Factual Findings

1. **IACS Leadership:** Drs. Draetta and Chin, interviewed separately, both reviewed aspects of the \$75 M, five-year, start-up funding for IACS, and the expectation to actively pursue grants and revenue sources through institutional investments, philanthropy and grants, and corporate partnerships. In particular, Dr. Draetta planned to focus on relationships with pharmaceutical companies and Dr. Chin indicated that CPRIT asked her and IACS to actively pursue CPRIT grant funding. Both indicated that Jerry Cobbs, Chief Commercialization Officer at CPRIT, alerted them to the technology incubator proposal submitted by Rice University as a worthwhile application starting point for potential CRPIT grant funding. Several times in the interviews, Drs. Draetta and Chin indicated that CPRIT, through Jerry Cobbs, initiated these discussions and steered them to potential funding.

Dr. Chin indicated that Jerry Cobbs suggested that IACS should incorporate its business plan and update the RFA, originally submitted by Rice University, and merge the two proposals. He indicated that CPRIT just needed a business plan add-on and he did not instruct her or IACS to submit the business plan on CPRIT template forms through the CPRIT portal. Eric Devroe continued the discussions with Jerry Cobbs. These discussions led to UTMDACC simply submitting the business plan via email from Mr. Devroe. Because the CPRIT portal mechanism is the responsibility of Wesley Harrott, who reports to Provost Dr. DuBois, they are, therefore, automatically aware of CPRIT portal submissions when made. They were unaware of the direct submission via email by Mr. Devroe to CPRIT.

Dr. Draetta, in retrospect, felt that the overtures by Jerry Cobbs to submit the business plan via direct email and not through the web portal points to a rift within CPRIT itself. Dr. Chin also indicated, in retrospect, that it would have been best to use the CPRIT web portal but again stated she was not aware of this protocol when the IACS proposal was first submitted. She also mentioned that confusion and further misunderstandings came about since CPRIT unilaterally designated her as the PI in the merged commercialization incubator award.

2. **IACS Business Plan:** Eric Devroe focuses on business and strategy development as well as IACS finances. He came to UTMDACC at the end of December and immediately began laying the groundwork for key projects, including engaging CPRIT as part of the IACS overall business plan. Mr. Devroe became aware of the incubator award via Jacqueline Northcut, CEO, Texas BioAlliance. At the same time that Jerry Cobbs, Chief Commercialization Officer at CPRIT, was reaching out to Dr. Chin, he did the same to Mr. Devroe and further suggested language for an updated incubator RFA, linking the IACS business plan to the one submitted by Rice University.

Mr. Devroe was insistent that CPRIT only wanted a business plan for an incubator, which did not require any scientific justification. The principals involved with the submission of the IACS grant proposal at UTMDACC had no reason to believe that this was anything other than an appropriate procedure for a commercialization grant opportunity as opposed to a more traditional, for CPRIT, research grant. Mr. Cobbs indicated that Mr. Devroe should simply submit the business plan by email rather than through the CPRIT portal. Thus, while Dr. DuBois and Wesley Harrott were not aware, the direct email submission was not done to

intentionally circumvent any UTMDACC procedures. Mr. Devroe also indicated that he had discussed the business plan with the Provost at Rice University. Mr. Devroe, in retrospect, added that an internal dispute was unfolding at CPRIT and the grant application got unwound because of it. He mentioned that, in the event of a resubmission to CPRIT, he would use the standard CPRIT forms and work with the Provost office in order to resubmit through the CPRIT web portal.

3. **Provost Office:** Dr. DuBois indicated that since the inception of CPRIT, hundreds of grants have been submitted and the CPRIT web portal was always used. Wesley Harrott, who reports directly to Dr. DuBois, has oversight for the portal and checks for proper formatting, salary guidelines, and budget considerations so there is a standard way for proposals to go forward and, hopefully, enhance chances for success. Mr. Harrott serves as the Application Signing Official and “pushes the submission button,” as Dr. Dubois described it, on behalf of UTMDACC and the Provost Office.

Dr. DuBois indicated that information on the Texas Life Sciences Incubator Infrastructure Award had gone out under his auspices on February 21, 2012, to all faculty and departments including the process for submission to CPRIT. This communication did go to IACS, including Drs. Chin and Draetta. Dr. DuBois forwarded an email to me, dated April 18, 2012, from Eric Devroe to Israel Ramirez and Joseph Gordon (cc: Wesley Harrott), members of Mr. Harrott’s staff which states:

“As you have certainly gathered, this entire CPRIT engagement was likely an exception to standard rules and channels. I am attaching documents that I sent directly to Jerry Cobbs (Chief Commercialization Officer) at CPRIT.”

This documentation is attached to this report but the above excerpt is noteworthy, according to Dr. DuBois, for it points out that Mr. Devroe did interpret the overture from Jerry Cobbs as an exception to submitting the proposal through the CPRIT web portal. Dr. Dubois clearly pointed out that he did not see any deliberate or malevolent intent present but attributed it to Mr. Devroe’s newness at IACS combined with “Guilio, Lynda, and Mr. Devroe getting caught up with the advice of Jerry Cobbs.” Dr. Dubois also feels that CPRIT needs to clarify why IACS was not expected to follow the web portal protocol pointing to a procedural breakdown at CPRIT. However, Mr. Devroe’s email does indicate he knew there was a standard protocol but it was not followed in this case. Dr. DuBois was unaware of any instructions from CPRIT to Mr. Devroe to submit the incubator grant proposal directly by email.

Subsequently, I spoke with Wesley Harrott on the points noted by Dr. DuBois. Mr. Harrott indicated that confusion resulted because there was no Application Signing Official listed on the incubator grant (CP120015). He first heard of the \$20M grant on March 29, 2012. At that time, Mr. Devroe requested accounts be set up so that IACS could access and spend the grant funds. This led to Mr. Devroe forwarding the grant documentation to Mr. Harrott to review with Dr. DuBois. Mr. Harrott felt it was unusual that the RFA did not follow the web portal protocol but also agreed that he did not interpret this as deliberate but rather confusion on how commercialization and accompanying business plans fit into the mechanisms set up

by the Provost Office. He indicated that his office needs to act as the central clearinghouse for grant submission otherwise there will be further breakdowns in communication and processes. Mr. Harrott also indicated that Dr. DePinho, Dan Fontaine, and Dr. DuBois are working on a policy and guidelines to ensure proper and official handling of all grant submissions at UTMDACC in light of the IACS CPRIT controversy. Matt Masek is assisting with this effort to ensure the central clearinghouse model.

4. **Business Affairs:** Dan Fontaine indicated that he became aware of the grant controversy but knew that Eric Devroe, Dr. Chin, and Dr. Draetta and other IACS staff were working together to match the Rice University proposal. However, he did not get involved until the controversy made the newspapers at the end of May. Mr. Fontaine feels that Mr. Devroe was new to the scene but should have utilized the web portal through Mr. Harrott's office. Mr. Fontaine did not feel that Mr. Devroe or anyone else at IACS was purposely trying to bypass the protocol but there was clearly a need to "hit the refresh button" and shore up the policy and guidelines. He affirmed the effort, alluded to by Wesley Harrott, to update the policy so that the Offices of President, Provost, and Business Affairs are all in alignment.

Mr. Fontaine stated that there are lessons to be learned from this controversy: (1) use the official portal provided by the granting agency at all times and (2) if you cannot find a portal or instructions, contact the agency and specifically ask for instructions. He explained that Mr. Harrott is a procedural person and "superb backstop" and must continue to be the key "go-to," especially as we venture into more commercialization grants.

5. **President DePinho:** Dr. DePinho recalled that many IACS team members were asked to give presentations to the biotech community in Houston early on after IACS's formation. Additionally, CPRIT reached out to IACS leadership to solicit interest in joining the incubator proposal submitted by Rice University. This request resulted in the creation of a business plan, written by Eric Devroe, who as indicated earlier sent it via email to CPRIT per instructions from Jerry Cobbs. Dr. Draetta assigned Dr. Chin the lead on the incubator grant proposal but it was CPRIT who designated her as PI. Dr. DePinho indicated that Mr. Devroe is new in his role at UTMDACC but did not believe anything nefarious was at play in making the email submission as requested instead of going through the customary web portal.

Dr. DePinho also confirmed that he, Dan Fontaine, and Dr. DuBois were working on procedural changes to policy in order to deal with commercialization proposals. However, he intends to continue using the existing structures in place with Wesley Harrott serving as the Application Signing Official so that the central clearinghouse model is continued as the exclusive means to submit a CPRIT grant proposal.

6. **Conclusions:**
 - a. Based on the interviews and review of documents and grant proposals, this reviewer concludes CPRIT, through its Chief Commercialization Officer, Jerry Cobbs, made a number of overtures to IACS leaders to submit a proposal which would merge with the incubator proposal submitted earlier by Rice University. The Provost Office, through

Wesley Harrott, had circulated instructions on commercialization awards on February 21, 2012, which did route to IACS leadership, namely Dr. Draetta, Dr. Chin, and Eric Devroe. It appears that in the rush to respond and as directed by Jerry Cobbs, IACS, through Mr. Devroe, submitted the business plan for the commercialization grant to CPRIT by direct email with attachments and did not employ the official CPRIT web portal with use of standard CPRIT forms and Application Signing Official (ASO) attached. This procedure resulted in a departure from the customary CPRIT grant submission process and, accordingly, notice of the grant's submission failed to reach the Provost's Office.

- b. CPRIT did not reject the email application from Eric Devroe and it did not make a follow-up request to submit the same through the CPRIT web portal. This points to an internal breakdown at CPRIT in its grant acceptance and handling process and brings into question why CPRIT did not have checks and balances in place to redirect the submission process. UTMDACC did not receive any notice from CPRIT that anything was amiss or inappropriate about this commercialization proposal and it was reasonable for UTMDACC personnel to assume it was an appropriate submittal process for a commercialization grant proposal as opposed to a research grant.
- c. UTMDACC Institutional Policy #ADM0255 states:

“It is the policy of The University of Texas MD Anderson Cancer Center that an MD Anderson employee may not have a direct or indirect interest, including financial and other interests, engage in a business transaction or professional activity, or incur any obligation of any nature that is in substantial conflict with the discharge of the employee's duties.”

This reviewer questioned each person about allegations of conflicts of interest and whether they could identify actions or activities, which constitute conflicts of interest, including the presence of nepotism. No conflicts of interest were identified in this review and there exists no basis to reasonably allege such conflicts exist. No documents reviewed pointed to any type of conflict of interest, including nepotism.

Recommendations

As a result of this compliance inquiry of CPRIT Award CP120015, this reviewer offers the following recommendations:

1. **Resubmission of IACS Proposal to CPRIT:** UTMDACC is currently reevaluating its original grant application to CPRIT and plans to resubmit a revised application, which considers research and business elements. The revised application will entail a joint scientific and commercialization review. IACS will work directly with the Provost Office and Application Signing Official to process the revised application through the CPRIT web portal. This reviewer endorses the resubmission plan.

2. **Education:** Due to the organizational complexity of UTMDACC, education “to the policy” is advised. The organization must employ novel and effective ways to educate and assure compliance with policy and procedures on grant submission. Special in person, mandatory orientation programs for new entities, such as IACS, are advised.
3. **CPRIT:** UTMDACC and CPRIT leadership need to jointly meet as soon as possible so that CPRIT can clarify its procedures on the submission of commercialization grants so as to avoid further breakdowns in communication and processes. Such clarification by CPRIT would not only benefit UTMDACC and other UT System institutions but all public and private entities located throughout Texas.
4. **Policy and Process:** As UTMDACC already has undertaken, it is imperative that UTMDACC update and enhance policy and procedures related to grant submission and clearly communicate such enhancements, especially with the expansion of commercialization opportunities at IACS and other areas of the institution to ensure a uniform, consistent, and centralized grant submission process regardless of purpose.
5. **Management of Conflicts of Interest:** Despite the fact that no conflicts of interest internal to UTMDACC were found, we suggest a review of all policies to guard against outside influences causing UTMDACC to make decisions, which interfere with the objective exercise of its official and public duties and responsibilities. The UT System has recently reviewed and updated policies governing financial interests, management, and reporting of individual financial conflicts of interest in research. This reviewer recommends that UTMDACC and all UT System institutions conduct a review of institutional conflicts of interest policies so that our institutions can effectively manage the complexities of ensuring right relationships with all outside organizations. The goal is to be transparent at all times and maintain the public trust.

Attachment