

**Florida Biomedical Research Advisory Council
(Council)**

**July 15, 2009
2:00 p.m. – 6:00 p.m.
Conference Call**

Meeting Minutes

Council Members Present:

Dr. Veena Antony
Dr. Richard Bookman, Chair
Dr. Randal Henderson
Dr. Clarence Brown
Dr. Penny Ralston
Dr. Herbert Weissbach, Vice-Chair

Council Members Absent:

Dr. Myra Hurt
Mr. Albert Latimer
Dr. Mary Lou Sole

Program Staff Members Present:

Mr. Jack Cannon – Lytmos Group
Ms. Hope Davis – Lytmos Group
Ms. Kristin Gandy – DOH, OPHR
Ms. Sherrie Hajek – DOH, OPHR
Dr. Susan Phillips – DOH, OPHR
Ms. Peggy Shults – Lytmos Group
Ms. Cynthia Ulysse – DOH, OPHR
Mr. Chuck Wells – DOH, OPHR

Guests in Attendance:

Mr. Ralph DeVitto – American Cancer Society
Mr. John Fraser – FSU Technology Transfer Office
Mr. Gary Keller – FL Institute for the
Commercialization of Public Research
Mr. Don Webster – American Cancer Society

I. Call to Order & Welcome:

Dr. Bookman welcomed Council members, noting the importance of the full agenda for the meeting and acknowledging the attendance of American Cancer Society leadership as well as guest speakers Mr. John Fraser and Mr. Gary Keller.

II.a. Approval of Minutes:

Minutes of the May 8, 2009 Council meeting were presented. Dr. Ralston moved that *the minutes be approved as presented*. This motion was seconded and passed unanimously.

III. Guest Speaker – Florida Institute for the Commercialization of Public Research:

Dr. Bookman introduced Mr. Gary Keller, pointing out the close alignment between the mission of the Institute and the Program's goal of delivering cures from research. Mr. Keller explained that the Institute was established by the Legislature in 2007 as part of the next stage in developing Florida's technology-based economy. The Institute seeks to take Florida research that is publicly funded and arrange partnerships with seasoned entrepreneurs and early stage-investors to create new products and start-up companies in the state. To do this, the Institute carefully coordinates its efforts through technology transfer offices. Mr. Keller indicated that the Institute is very interested in exploring how it can work with the Program to provide appropriate commercialization support for new technologies emerging from research in tobacco-related diseases/cancer, to support start-ups funded by the Program's Technology Transfer/ Commercialization Partnership (TTCP) grants, and also to serve as a resource to help market the TTCP to small businesses now that they are eligible to apply.

A formal request would have to go through the Institute's Board and any efforts to assess research results supported by Program funding for commercial potential would have to be coordinated through the appropriate institutional technology transfer offices. Mr. Keller offered to consult with Program staff and/or Council to construct specific goals to increase

commercialization and what steps need to take place to bring this to fruition, so that a proposal can be prepared. Mr. Wells suggested that one additional way the two organizations could partner is to develop a program offered to grantees, perhaps at a grantees conference, to provide greater awareness for the keys to successful commercialization, including statewide resources available to support such efforts. Dr. Bookman said the Program's TTCP grants are at least in part intended to increase Florida's share of SBIR funding, and asked Mr. Keller whether this type of support resonates with the charter of the Institute. Mr. Keller agreed that early support for those interested in pursuing SBIR/STTR funding is needed because a funding gap or "valley of death" exists prior to conventional funding that prevents the establishment of start-up companies, appropriate levels of management within a team/business, or even the ability to prepare an application for SBIR/STTR funding. The Institute can serve to match technologies to management and move SBIR/STTR applications forward. Dr. Bookman and Mr. Wells will develop some concrete next steps for exploring a partnership with the Institute.

IV. Guest Speaker – Success Factors for Technology Transfer Mechanisms:

In his presentation, Mr. Fraser briefly explained the flow of translational research from the laboratory to market, and the classic sequential model of development and funding. He stated that there is a need for a program in Florida as a primer to prepare for an SBIR type proposal and other types of funding. He endorsed the recent recommendations of the Council to expand TTCP grant eligibility to Florida small businesses and offer an open application period; he also recommended that reviewers with commercialization expertise be included on the review panels for this mechanism, and that the terms and conditions be tailored to suit the special needs for intellectual property protection and award accountability. He believes an expanded application and review process is appropriate, and advised that the metrics of success will look different from other grant mechanisms – inputs, outputs, and impacts, including stories of success.

Mr. Wells informed the Council that the Department sought Mr. Fraser's recommendations for improving the TTCP mechanism some time ago, and credited him with the ideas behind many of the changes already being made in the Special Call for Applications.

Council members asked for confirmation that the Program is permitted in statute to allow small for-profit businesses apply for and lead grants, and Mr. Wells confirmed that it is. In the opinion of Department counsel, the term "institution" should be interpreted in light of the Program's statutory goals, and since commercialization is one of the Program goals, businesses should be eligible for certain grant types.

Mr. Fraser was asked to explain his recommendation that commercialization plans be required for a TTCP application, when the Program expects these projects to be very early stage, not yet ready for SBIR funding. He clarified that his point is to encourage TTCP applicants to start thinking about commercialization and demonstrate to reviewers that they are laying the foundation for potential commercial partnerships. Mr. Fraser offered to present the next draft of the Call for TTCP applications to his colleagues at an upcoming technology transfer officials meeting and provide feedback regarding the specific information required from applicants and reviewer criteria. Dr. Bookman asked whether Mr. Fraser believed the Program should require a small business to have an academic partner, and Mr. Fraser answered yes.

V. DOH/OPHR Updates:

Mr. Wells congratulated Dr. Ralston on her reappointment to the Council, and said there is no news yet on the Department's request that Dr. Weissbach be reappointed to the Biomedical Research seat.

Mr. Wells reported that he was working through the Florida Research Consortium, BioFlorida,

Mr. Keller's Institute, and Mr. Fraser and other technology transfer officials to broaden the distribution of the pre-announcement of the FY2009-2010 Special Calls, and would do the same when the Calls are released.

V.a. Active Grants Portfolio:

Mr. Wells presented a current Active Grants Report, showing how 127 grants valued at roughly \$47.5 million are broken down by fiscal year of award and grant mechanism. The report demonstrates the newer in-house capabilities towards program evaluation and performance measurement. Efforts towards program evaluation started two years ago in anticipation of the upcoming Program Re-enactment (Sunset) Review.

V.b. Sunset Review Update:

The legislative staff charged with doing the review has scheduled a meeting with OPHR on July 22nd in Tallahassee to begin the process. Program staff is finalizing the set of anticipated questions and answers in preparation for the meeting.

V.c. Program Evaluation:

Ms. Ulysse presented a collection of performance measures currently being tracked by the Program and said she is preparing a demonstration of the internal grantee database at the August Council meeting. Dr. Phillips pointed out that this effort is a critical part of program management that the Program has not had before, and is beyond the data that Lytmos collects. Beyond answering questions for the legislative review, it will help the Program evaluate fiscal, operational, and outcome-related issues to measure Program performance and drive continuous improvement including strategic planning. Ms. Gandy shared an outline of an internal Program Evaluation report regarding the King program that is approximately 75% complete. Once completed, a similar internal evaluation will be conducted of the Bankhead-Coley Program. She presented the second draft of a logic model for Council feedback. Dr. Weissbach recommended that drug biologics, devices, and protocols should be an intermediate outcome, rather than short-term. Dr. Brown recommended that an invention disclosure, Investigational New Drug (IND) filing, or patent should be considered an initial outcome.

VI. FY 2009-2010 Special Calls for Applications:

When asked about new estimates of revenue from the tobacco user fee, Dr. Phillips said that, while the tobacco fee has only been in place for 15 days, she has heard that related revenue is running slightly ahead of the forecast. She recommended that the Program still plan on about \$40 million total this fiscal year (80% of the possible amount), and wait to consider the first quarter data that will be released before award decisions must be made for the Special Calls.

Ms. Shults presented a summary document outlining significant changes from previous Calls for the same grant mechanisms and further clarifications on the new Florida RC1 grant mechanism. The Council accepted these changes and clarifications, with the following additional feedback:

- Florida RC1 grant applications must clearly show tobacco/cancer relatedness, but it is not a requirement that the qualifying NIH RC1 application specifically mention a tobacco or cancer relationship.
- Florida RC1 principal investigators' percent effort cannot be less than stated in the NIH RC1.

- The qualifying federal merit score for NIH RC1 proposals should have an overall impact score of less than 40, based on the new NIH 10-90 scoring system, where 10 is the best possible score. This could be roughly equivalent to the top third of applicants. Because it is not yet clear how NIH will report scientific merit scores, the Call should include language that the Department reserves the right to change these guidelines, and applicants should monitor the Program web site. Also, depending on the number and quality of Florida RC1 applications received, the Program may elect to exclude applications with lower scoring NIH RC1 proposals from peer review.
- The direct cost budget in a Florida RC1 application must be the same or less than that in the NIH RC1 proposal; the Program will not permit an increase in direct costs to compensate for the Program's lower (than NIH) indirect cost allowance.
- Shared Instrument Grants will include a requirement that the instrument must be operational by the end of the grant period, as evidenced by a deliverable consisting of a reports from named users of the instrument on their use of the equipment to date.
- Shared Instrument Grant awards may include up to \$50,000 for required physical alterations in order to accommodate the instrument, with a maximum award limit of \$500,000; all budget entries for physical alterations must be justified in the application, and the evaluation questionnaire should ask reviewers to include the merits of this budget component in their assessments.
- On a TTCP application, if a small business is the applicant and the principal investigator is less than fully employed by that business, he/she must disclose any other employer(s). For purposes of this application, "full employment" is intended to reflect full-time effort, whether or not the individual receives monetary compensation.
- The minimum fundable TTCP application scores are 2.2 out of 5.0 for merit and 2.5 out of 5.0 for tobacco-relatedness.
- For TTCP grants, the Program expects to dedicate up to \$1 million in FY2009-2010, but reserves the right to change this amount depending on the availability of funds and the merits of the applications received.

Ms. Shults referred Council members to drafts of each of the Special Calls included in the set of documents emailed prior to the meeting, and asked for any further feedback not later than close of business on Friday, July 17th.

VII. Program Annual Reports:

Ms. Shults reported that Lytmos is beginning work on the 2009 King and Bankhead-Coley annual reports, and asked for input from the Council on the most important messages to be communicated in this year's reports. The consensus was that the content should include a discussion on how the Program is rising to the challenge of the expanded funding from the tobacco user fee. Dr. Ralston recommended first presenting the successes of the program, and follow with the point that it is because of the program's strong reputation that it was given the additional money. Ms. Shults asked for volunteers to serve as sounding boards for early report plans and materials, and Drs. Weissbach and Brown agreed to assist.

IX. FY 2010-2011 Calls for Grant Applications:

Mr. Wells presented a position paper he authored for the Council's consideration, entitled "FY2010-11 and Beyond Call for Grant Applications," in which he challenged the Council to reflect on the Program's internal program evaluation, the outcome of the impending Legislative

evaluation, the maturing of the program, and national trends altering the biomedical research landscape, to study and make recommendations for a short and long-term translational research strategy. He recommended forming an ad hoc committee of the Council for these purposes. Mr. Wells proposed 11 specific items, including eight possible grant mechanisms, for committee consideration, with the short-term horizon being defined as the FY2010-11 Call for Applications. For planning purposes, only five mechanisms per program can be offered each year, of which only three can be new.

During discussion, Dr. Bookman urged the importance of identifying what the unique role of public funding should be, noting that there is no money for wellness. Dr. Weissbach posited that the Program should seek ways to look at high risk proposals, which often have no preliminary data. Dr. Phillips injected that comparative effectiveness studies to learn which treatments are most effective have value because they are closer to the treatment end of the research continuum.

Dr. Phillips echoed Mr. Wells' challenge to the Council to place a priority on longer term strategic planning, especially now that the Program has more resources with which to work.

Dr. Bookman asked Council members for their views on forming a task force to flush out short- and long-term strategies for translational research and come back with recommendations to the full Council. Dr. Brown said he is willing to serve on such a task force, and left the meeting due to another commitment [5:10 p.m.]. Dr. Ralston said she felt the work of coming up with a broader plan should be the work of the full Council, rather than a subcommittee and that focusing on a translational research agenda before conducting strategic planning seemed out of order. Dr. Bookman stated that there might be overlap between planning the upcoming FY2010-2011 calls and long-term strategic planning. Dr. Phillips suggested that the task group could help shape short-term objectives that could be fleshed out by the entire Council during the August meeting. Among the items on Mr. Wells' list, this might include post doctoral fellowships with a clinical emphasis, a hybrid TSP/SPORE mechanism, an investigator initiated research grant with targeted clinical/translational requirements, and re-engineering the peer review process to support a translational/commercialization model. These changes could include recruitment of peer reviewers with appropriate experience, weighting factors in scoring sections of proposals to arrive at an overall score, and a less conservative mindset so that higher risk proposals are not at a disadvantage to safer, more incremental proposals. Council members noted that trends in clinical research are shifting away from academia, and a more appropriate clinical research mechanism would require five years – two years longer than the Program can currently carry forward funds for multi-year grants. Mr. Wells offered a suggestion for how the Program might work within that limit by funding the first three years from the award year budget and subsequent years from the fourth year's budget.

Mr. Wells stressed the importance of long-term strategic planning showing a clear vision for how to utilize the increased funds allocated to the Program. Dr. Phillips pointed out that previous strategic planning was based on the assumption of less than \$10 million per year. Now we need to plan with the assumption of maintaining or exceeding the current allocation and seek out research projects that will show more immediate gains in prevention, diagnosis, treatment, and cures. Dr. Ralston suggested that long-term planning should include planning the FY2010-2011 Calls; however, mechanisms must be finalized by the end of August in order to meet Call deadlines and this may not fit with a full strategic planning endeavor.

Dr. Bookman sought consensus among the Council for how best to develop a new strategic plan, which produced a tentative plan for the full Council to participate in a two-day retreat, possibly as an expansion of the planned August 31st meeting. Dr. Bookman asked for Council volunteers to join him and Program staff in preparing for this strategic planning session, with weekly phone calls leading up to the meeting. These would be publicly noticed meetings. Drs. Antony, Bookman, Brown, and Weissbach agreed to participate, and Council members suggested that

Dr. Hurt and Mr. Latimer be approached about their willingness to participate as well. There was also consensus that Program staff would prepare mechanism worksheets and proceed with planning for the FY2010-2011 Calls.

Dr. Bookman expressed his appreciation to Dr. Phillips and Mr. Wells for calling attention to the unique opportunity and responsibility at this time to step back and make sure Program actions are thoughtfully aligned with Program goals.

X. Open Discussion:

Ms. Shults cited the recent NIH Clinical and Translational Science Award (CTSA) in the amount of \$26 million to the University of Florida as an important win for the State's biomedical research community. Council members noted that NIH does not pay for all they ask grantees to do, and perhaps there will be a role for this Program to play in leveraging this major federal award.

X.a Public Comment:

Mr. DeVitto said he was thrilled with getting the \$1 surcharge to the tobacco user fee, and said he would make getting the Program reauthorized a top legislative priority for his organization. The American Cancer Society is planning a summit later this year to focus on the upcoming Legislative Session. He encouraged Council members to attend, and will provide more information very soon. Mr. DeVitto commended the Council for their vision and for thinking big. He said he did not believe \$50 million is the end, as the Legislature has to see funding biomedical research in a positive light. He urged Council to make Program work visible to the Legislature and emphasized the fundamental principles of the Program. Mr. DeVitto closed by suggesting that capping awards to individual institutions raises a concern about whether the Program really is funding the best science; that the Program should continue to fund the best peer-reviewed competitive science that comes forward.

X.b. Future Meeting Dates:

Program staff will follow up with Council members after the meeting regarding dates for the strategic planning session. The May 2010 meeting will be planned for the 21st in Tampa.

XI. Adjournment: The meeting was adjourned at 5:52 p.m.

Respectfully submitted on behalf of Dr. Richard Bookman, Chair

 9-14-09

**Chuck Wells, Assistant Director
Office of Public Health Research**