

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

**July 9, 2008
3:30 p.m. – 6:00 p.m.
Conference Call**

Council Members Present:

Dr. Veena Antony
Dr. Richard Bookman, Chair
Dr. Myra Hurt
Dr. Daniel Morris
Dr. Sigurd Normann
Dr. Penny Raiston
Dr. Mary Lou Sole
Dr. Herbert Weissbach, Vice-Chair

Council Members Absent:

Dr. Nikolaus Gravenstein
Dr. Randal Henderson
Mr. Albert Latimer

Program Staff Members Present:

Mr. Jack Cannon – Lytmos Group
Ms. Hope Davis – Lytmos Group
Ms. Sherrie Hajek – DOH, OPHR
Dr. Clara Pelfrey – Lytmos Group
Dr. Susan Phillips – DOH, OPHR
Ms. Peggy Shults – Lytmos Group
Mr. Chuck Wells – DOH, OPHR

Guests in Attendance:

None

Welcome and Approval of Minutes:

Dr. Bookman welcomed Council members. Minutes of the May 18, 2008 Council meeting were presented. Dr. Weissbach requested that in the notes under the heading "Discovery - Article Review" the word "impossibility" be changed to "difficulty." Dr. Weissbach moved that *the minutes be approved with this revision*. This motion was seconded and passed unanimously.

OPHR Report:

Mr. Wells reported that the State is continuing to watch declining revenues, and one percent is currently being held back from State agency quarterly appropriations, in keeping with an executive order from the Governor. However, the Florida Legislature would have to approve any reductions to the King and Bankhead-Coley programs, since funding is specifically authorized in statute. Dr. Bookman asked for and received confirmation that the FY2008-2009 awards are the same as recommended by the BRAC in the May meeting – including a three percent reduction for SPORE Grants and a five percent reduction for TSP Grants, with no funds taken from the administrative allocation.

Open Innovations – Next Steps:

In a report to the Council regarding the recent FLCURED Summit, Mr. Wells began by recognizing the outstanding job done by Dr. Bookman as facilitator and member of the Summit program planning committee. He described the Summit as extremely successful, bringing together more than 65 attendees. John Wilbanks, who travels around the country making presentations on behalf of Science Commons, and who was the keynote speaker, told him this was the largest gathering of scientists/researchers to discuss open innovation that he had seen. Mr. Wells stated that this validated FLCURED's role as a convener of Florida's biomedical research community. At the Summit, several King and Bankhead-Coley grantees made poster presentations and the FLCURED Council honored Dr. Clyde McCoy with the inaugural Jim King Leadership Award.

Even though FLCURED Council members found it hard to identify next steps during their post-event meeting, they felt the discussion was a good beginning and are committed to continuing the dialog. They specifically noted the high transactional costs of sharing information and that open innovation is a different business model that will require some new infrastructure. They also agreed that the technology transfer offices, notably absent from the Summit, must be engaged. A new website has been created in order to continue the conversation. In addition, a video recording of the Summit will be posted on the newly created site www.virtualcured.org.

Mr. Wells suggested that the Council invite John Wilbanks to the August meeting to talk about next steps. He relayed Mr. Wilbanks' statement regarding the special role of funders in encouraging open innovation, and he offered to share Howard Hughes Medical Institute policies on open innovation with the Council as a model of what funders can do. He concluded by emphasizing the importance of alerting the Florida research community regarding potential policy changes in this area and seeking their feedback for consideration as further policies are advanced.

Dr. Morris said that he found the FLCURED Summit to be very exciting, noting especially that the changes needed are not intuitive. He came away inspired and cited Mr. Wilbanks' example of how patent disagreements almost prevented the invention of the airplane. Dr. Hurt related comments from a number of researchers who attended regarding the major hurdles in navigating the IRB process. She also relayed that Mr. Wilbanks has accepted an invitation to speak at the FSU Medical School Grand Rounds on October 16th, and invited Council members and Program staff to attend. Dr. Bookman elaborated on Dr. Morris's point on patents and discussed IP bundling as a way to overcome the plethora of very specific, interrelated research patents. He noted that several members of the FLCURED Council are interested in exploring the possibility of gathering intellectual property from FL research institutions and offering preferred terms to Florida-based companies. He would also like to see a change in the King and Bankhead-Coley contracts to support information sharing for non-commercial purposes. He mentioned www.ibridgenetwork.org as a possible source of information.

NIH Peer Review Process Changes and Discussion:

To stimulate thinking about any desired changes in the peer review process for the next competition, Ms. Shults presented highlights of the changes the National Institutes of Health (NIH) are making in their proposal application and peer review processes. Ms. Shults drew attention to several NIH changes for consideration by the BRAC, including:

- 1) modifying the rating system to focus on specific review criteria such as impact, investigator(s), innovation/originality, project plan/feasibility, and environment;
- 2) adopting a seven-step scoring model and providing applicants with scores for each criterion;
- 3) considerably shortening applications and allowable appendices and restructuring them to fit the review criteria;
- 4) implementing a standardized reviewer training program; and
- 5) developing metrics for monitoring review performance.

The goal of the discussion that followed was to identify additional information needed at the August Council meeting in order to make informed decisions about changes that will improve the quality of peer reviews.

Several Council members endorsed shortening applications as a timesaver to applicants and

peer reviewers.

Dr. Bookman stated that the American Heart Association has begun using junior faculty as peer reviewers. He suggested this might be a source of new reviewers, and that a peer reviewer mentoring program might be worth exploring.

There was discussion about collecting information about peer reviewer performance, both in terms of peer reviewers who consistently score high or low compared to the other peer reviewers on the same proposals and in terms of peer reviewers who consistently give the same score to all applications. Dr. Pelfrey stated that Lytmos currently reads all peer review comments to assure that reviewer comments align with their scores.

Mr. Wells pointed out that an unintended consequence of using fewer peer reviewers in the most recent competition was a difficulty in resolving significantly different reviewer opinions regarding tobacco-relatedness. Ms. Shults reminded Council members that the National Cancer Institute endorsed the independent peer review process used during the 2007 competition, in which the highest and lowest scores were excluded in calculating the scientific merit scores. Dr. Weissbach reiterated his belief that the quality of the peer reviews would be improved by allowing reviewers with different opinions to reconsider their scores in light of the other reviewers' observations. Dr. Phillips explained that, in the opinion of the Department's legal counsel, doing so constitutes a violation of Florida Sunshine law. Dr. Bookman sought and received Dr. Phillips' permission to revisit the issue with counsel.

FY 2009-2010 Call for Grant Applications:

Ms. Shults solicited suggestions from the Council for preparatory research by staff that would help in forming recommendations for the major components of the Call during the August Council meeting. Dr. Pelfrey reported that during site visits, she has received requests from grantees for longer periods of support. Several members expressed a concern that longer, larger awards would reduce the total number of awards. Council members discussed various ways of expanding the use of no-cost extensions and variations of the Bridge grant mechanism to provide additional support to new investigators, and asked staff to bring recommendations to the August meeting.

Mr. Wells proposed an investigator-initiated mechanism for proven program investigators. Dr. Bookman advised against inviting Florida investigators to become dependent on state funding, but rather suggested they should be encouraged to enter into federal funding competitions. Dr. Hurt supported this position. Dr. Weissbach stated that, while some institutions may be able to bridge funding gaps for new investigators, not all can afford to do so. Dr. Bookman further suggested that federal proposal submission become a deliverable for New Investigator Research grants; that the submission be due by the end of the second year of the grant so that results would be available during the third (and final) year of the grant; and then a bridge grant application could be submitted by the grantee in order to increase continuity of funding. A suggestion was made to allow grantees to use a no cost extension for the purpose of federal proposal submission. Ms. Shults agreed to compile data regarding funds carried by New Investigator Research grants into no-cost extensions, taking into account changes in the total award amounts over the years.

Dr. Norman proposed that Team Science Program (TSP) grants be extended to an optional three years with the same amount of money, as it is for the Bankhead-Coley SPORE Planning Grants. As a past TSP grant recipient, Dr. Antony supported this change. Dr. Sole cited

additional challenges faced by TSP projects involving human subjects research. Dr. Bookman stated that he would be much more supportive of more time for TSPs if more money was involved. To help the Council arrive at consensus on this matter, Ms. Shults agreed to provide data regarding the frequency of no-cost extensions for TSPs and the historical amount of funding carryover.

Finally, Ms. Shults reminded Council members that the Bankhead-Coley Special Emphasis Project grantees are scheduled to make presentations to the Council during the January 2009 meeting, providing information for decision-making thereafter.

Terms and Conditions – Financial Conflict of Interest of PI Discussion:

Dr. Bookman posed a question for Council members regarding whether a change should be made to the Terms & Conditions (grant contract) to require disclosure of principal investigator financial interests that could be construed as conflicts of interest. For example, an investigator undertakes a research program into a drug to treat a certain cancer, and also receives speaker fees from a drug company that owns or licenses the intellectual property for this molecule. Dr. Weissbach said the same financial interest disclosure is now required by many journals. Mr. Wells stated that research he has done on NIH policy regarding this topic led him to conclude that this is a hole in the Program's current process that can be easily fixed. NIH imposes financial interest disclosure requirements on the funded institution for all grants except SBIRs and SBTTs, and all institutions likely to be funded by this Program already must comply. This means that adding a similar Program requirement would not increase the regulatory burden for Florida's institutions. However, there are administrative implications for the Program from application to grant closure, such as verification of compliance with NIH, creation of financial disclosure form(s), post-award administrative reviews, annual updates in progress reports, and verification during site visits. Council members were in favor of taking this to the next step, and asked staff to fill in details for Council approval at the August meeting.

Program Annual Reports:

Ms. Shults reported that Lytmos is beginning the planning process for the Program's annual reports. The Bankhead-Coley report must be delivered by December 15th, and the James & Esther King report is due by February 1st. She solicited general ideas and messages. Dr. Bookman recognized outstanding work done by Lytmos and OPHR in past annual reports, and said he could cite no deficiencies to be corrected in the next issues. Ms. Shults asked for Council volunteers to provide more detailed feedback on early plans and drafts, and identified mid-September through November as the interval of commitment for both reports. Drs. Weissbach, Bookman, Hurt, Sole, and Ralston offered to assist.

Open Discussion and Closing:

No additional discussion items were introduced. After a motion for adjournment was seconded and passed unanimously, the meeting ended at 5:05 p.m.

Respectfully submitted on behalf of Dr. Richard Bookman, Chair

Handwritten signature of Chuck Wells, dated 9-2-08.

Chuck Wells, Assistant Director
Office of Public Health Research