

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

**August 31, 2009  
1:00 p.m. – 4:30 p.m.  
Conference Call**

**Meeting Minutes - Final**

Council Members Present:  
Dr. Veena Antony  
Dr. Richard Bookman, Chair  
Dr. Clarence Brown  
Dr. Randal Henderson  
Dr. Myra Hurt  
Dr. Edith Perez  
Dr. Penny Ralston  
Dr. Mary Lou Sole  
Dr. Herbert Weissbach, Vice-Chair

Council Members Absent:  
Mr. Albert Latimer

Program Staff Members Present:  
Mr. Jack Cannon – Lytmos Group  
Ms. Hope Davis – Lytmos Group  
Ms. Glenda Sapp – Lytmos Group  
Ms. Sherrie Hajek – DOH, OPHR  
Dr. Susan Phillips – DOH, OPHR  
Ms. Peggy Shults – Lytmos Group  
Mr. Chuck Wells – DOH, OPHR

Guests in Attendance:  
Ms. Shira Kastan – University of Miami  
Mr. Paul Hull – American Cancer Society

**I. Call to Order & Welcome:**

Dr. Bookman called the meeting to order, and welcomed new Council member Dr. Edith Perez. At Dr. Bookman's invitation, Dr. Perez shared information about her background.

**II.a. Approval of Minutes:**

Minutes of the July 15, 2009 Council meeting were presented. Dr. Weissbach moved that *the minutes be approved as presented*. This motion was seconded and passed unanimously.

**III. DOH/OPHR Updates:**

Mr. Wells reported that Dr. Weissbach disclosed a potential conflict of interest to the Department in late July. Dr. Weissbach is aware of an individual who wishes to apply for a Technology Transfer/Commercialization Partnership (TTCP) Grant that involves patented intellectual property belonging to Dr. Weissbach. Mr. Wells discussed the matter with Department counsel, who advised that proper conflict management is for Dr. Weissbach to refrain from all further Council discussion on TTCP evaluation criteria or funding decisions. Mr. Wells pointed out that Dr. Weissbach is already insulated to a degree due to the Counsel's prior recommendation of rule-based funding for TTCP grants based on minimum peer review scores. Mr. Wells also acknowledged that being on the Council should not prevent members from conducting normal business and that the first action involving conflict of interest is disclosure.

**III.a. Re-enactment Review Update:**

As part of the mandated legislative review, a staff member associated with the Senate Committee on Health Regulation, Sandra Stovall, J.D., C.P.A., met with OPHR and DOH legislative staff in July. In a follow-up meeting with Department counsel, Ms. Stovall made it clear that the Program must promulgate an administrative rule. Mr. Wells explained that a rule is an administrative code that interprets a statute. In order to retain a reasonable level of Program agility, OPHR will propose a rule designed to be as general as possible. The legislative evaluation report is due September 1.

**III.b. Strategic Planning Retreat:**

Mr. Wells explained that the reason for the delay in holding the strategic planning session was the length of time needed to identify and engage the services of a suitable facilitator with relevant expertise related to biomedical research. Following state procurement rules, which require competitive bid for purchases over \$25,000, OPHR solicited bids and has narrowed the list of

qualified respondents to two individuals; the selection of the facilitator should be announced within a week. Current plans call for the retreat to take place at the end of October, preceded by a series of five conference calls for pre-work to lay the foundation for the retreat. There is a chance that the meeting could be pushed back to coincide with the November Council meeting.

#### **IV. Status of Special Calls**

Ms. Shults reported current application registrations numbered 14 for the King program, and 12 for Bankhead-Coley; of the 26, 16 are for RC1 applications. Two applications have been submitted, one RC1 and one TTCP.

##### **IV.a. RC1 Eligibility:**

Ms. Shults reviewed the final eligibility criteria for Florida RC1 applications, which was changed from the original plan based on emerging information about the preliminary scoring and panel review process in the federal competition. Reports indicate that only about 10 percent of all federal RC1 applications were sent to full panel review. The other 90 percent only received the initial review. Our criteria are that the application must have received an average score of better/less than 4.0 from the initial three reviewers, regardless of whether it went to full panel review.

Dr. Bookman said there are anomalies in the federal peer review, such as criteria ratings from only two preliminary reviewers rather than three. Another issue is whether the best approach is to use the arithmetic average of all five criteria ratings equally, or to apply weighting factors that would emphasize certain criteria over others (for example, significance and innovation more than environment). Dr. Bookman solicited Council feedback, and none was offered. He then asked Lytmos to go forward with a straight arithmetic average of all criteria ratings and to prepare recommendations for any anomalies for Council consideration during the funding meeting.

#### **V. FY 2010-2011 Calls for Grant Applications:**

Mr. Wells introduced this topic by reminding the Council of prior discussions in which the planned mechanisms were narrowed to:

- continuing the New Investigator Research (NIR) grant
- Continuing the Technology Transfer/Commercialization Partnership (TTCP) grants
- offering a new hybrid of the Team Science Program (TSP) and SPORE Planning Grant
- offering some type of postgraduate fellowship
- offering something in the areas of health disparities and translational (especially clinical trials) research

Based on the discussion of more concrete definitions at the July Council meeting as well as limitations in the time to execute new mechanisms, Program staff is proposing three new mechanisms in addition to the NIR and TTCP. Program staff is looking for affirmation from the Council that these are moving in the right direction.

Mr. Wells directed the Council's attention to two documents sent out before the meeting regarding translational research and affirming that the Program is moving in the right direction. Dr. Perez strongly advocated moving towards translational research that will directly improve the health of human beings. Dr. Bookman urged finding a balance so that there will be enough basic science to move discoveries into the clinic.

Dr. Phillips confirmed that the limit on indirect expenses will be increased to 15 percent for FY 2010-2011.

##### **V.a. Grant Mechanisms:**

Ms. Shults presented worksheets for three new grant mechanisms: Postdoctoral Research Fellowship (PRF), Research Project Grant (RPG), and Collaborative Research Program (CRP). The Council discussed each, making the following recommendations:

**Postdoctoral Research Fellowship (PRF) –**

The PRF worksheet sparked discussion on the length of time available for the award. Because four years since award of terminal degree may not be long enough for an M.D. to attain independence, clinical training time will be exempted. Also, the fellowship stipend amount will increase depending on the length of clinical training since terminal degree, to a maximum of perhaps \$65,000 plus benefits. Dr. Bookman and Program staff will jointly develop tables for variable award duration and amounts. There was also discussion on whether the PRF should be available for basic science, with some members feeling strongly on both sides of the issue. This issue will be discussed further in the upcoming strategic planning meeting.

**Research Project Grant (RPG) –**

The grant will be similar to an NIH R01 and the early Program grants called IIRs, but it must be more narrowly focused than the IIR in order to limit the number of applications. There was discussion regarding the focus the language “must deal directly with humans.” Concern was expressed that if projects are limited to clinical trials, there may not be a sufficient pool of applications. The focus will be reworded to better express the intent for human subjects research, possibly as defined by needing IRB approval. The Call language will also be made more clear regarding the funding risk for years four and five since only three years worth of funding can be carried forward. Both translational and health disparities topics will be offered for the King and Bankhead-Coley Programs, and community-based research will be explicitly included. A recommendation was made for the grant to be funded at \$287,500 per year including 15% indirect costs.

The meeting was suspended for a brief break.

**Collaborative Research Program (CRP) –**

The goal of the CRP is to take the best of the SPORE Planning grant and the Team Science Grant and combine them into one mechanism that will require both collaboration and have a clinical component. The acronym of this mechanism will be changed to avoid confusion with the previously offered Clinical Research Planning Grant. After discussion, it was determined that project eligibility should not require the establishment of a core facility, developmental funds, or career development activities, although these could be permissible uses of funds if justified in the proposal. In-kind contributions from an institution will be counted toward the match requirement. The 25 percent match requirement applies to direct costs only, and is intended to ensure that each collaborating institution is significantly committed to the project. To encourage more inter-institutional applications, limit the number of intra-institutional proposals to two, with no limit placed on the number of inter-institutional applications. The grant amount will be up to \$1.5 million, including indirect costs, over three years.

Program staff agreed to make appropriate changes to these worksheets and distribute them to Council members for individual comment before drafting full Calls for Applications based on them.

**V.b. Peer Review:**

Ms. Shults recommended that the scoring system to be used in the FY 2010-2011 peer review process be modified to match the new nine-point scoring system (whole numbers only) in use by the National Institutes of Health (NIH), and Council members agreed. Ms. Shults said the review questions will also be adjusted, where appropriate, to reflect recent changes in NIH evaluation criteria for assessing scientific merit. Because these questions will be documented in each of the Call for Applications, the Council will have an opportunity to comment on them along with the

rest of the Call contents.

**V.c. Other Changes:**

Ms. Shults said that NIH has also announced an impending reduction in the overall length of its grant applications. However, because this change has not yet been widely deployed by NIH, the Council recommended making no significant changes in application length at this time.

**VI.a. Public Comment:**

Dr. Bookman invited members of the public to speak. Mr. Hull was no longer on the call, so Dr. Brown reported on his behalf that the American Cancer Society is planning a legislative summit in November to address the re-enactment of the King and Bankhead-Coley Programs. It would be helpful for Council members to attend, if possible. Dr. Brown will ask Mr. Hull to send details to Mr. Wells and Dr. Bookman. Dr. Bookman offered to solicit the participation of the American Heart Association and American Lung Association as well.

Ms. Kastan said she had no comments.

**VI.b. Future Meeting Dates:**

It was agreed that the strategic planning session and the Council meeting to determine funding recommendations for the FY 2009-2010 Special Calls for Applications should be combined in an in-person meeting. Options were narrowed to either November 17-18 or November 12-13, in Tampa or Orlando. Program staff will follow up with details as soon as possible.

Council meetings are now being posted in the Florida Administrative Weekly.

**VII. Adjournment:**

Dr. Sole moved that *the meeting be adjourned*. The motion was seconded and approved unanimously. The meeting was adjourned at 4:18 p.m.

**Respectfully submitted on behalf of Dr. Richard Bookman, Chair**



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