

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

**June 9, 2009  
3:00 p.m. – 7:00 p.m.  
Conference Call**

**Council Members Present:**

Dr. Veena Antony  
Dr. Richard Bookman, Chair  
Dr. Myra Hurt  
Mr. Albert Latimer  
Dr. Sigurd Normann  
Dr. Penny Ralston  
Dr. Herbert Weissbach, Vice-Chair

**Council Members Absent:**

Dr. Randal Henderson  
Dr. Daniel Morris  
Dr. Mary Lou Sole

**Program Staff Members Present:**

Mr. Jack Cannon – 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:**

None

**I. Call to Order & Welcome:** Dr. Bookman called the meeting to order and welcomed Council members.

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

**II.b. Public Comments:** No members of the public participated in the call.

**III. DOH/OPHR Updates:** Mr. Wells reported that the Department of Health entered into a partnership with the Florida State University College of Medicine to operate FL CURED. Dr. Mike Devine, who has over 40 years of experience in research and technology transfer, will serve as executive director. The work is currently in transition, with current effort focused on the (re)appointment of FL CURED advisory council members whose terms expire November 5. Dr. Ralston is the current Council representative on the FL CURED Council and has expressed interest in continuing. Any member interested in being considered should complete a preliminary questionnaire available at the FL CURED website and/or immediately contact staff.

Dr. Bookman asked Dr. Phillips to explain how actions taken in the recent legislative session are affecting OPHR and the Department of Health. Dr. Phillips responded that while the Florida Biomedical Research Programs are faring well due to the increased allocation from the tobacco user fee, but overall the Department is not. Additional budget reductions are effectively 17%, leading to a need to reduce approximately 200 county health department positions across the state. She said the State Epidemiologist and Division Director for Emergency Management Operations have expressed concerns that, should a disaster occur, the health departments will be significantly understaffed. No changes have been made at the executive level of the Department, including the Surgeon General and Deputy Secretaries.

**IV. Program Evaluation Questions and Answers:** Mr. Wells thanked Council members for their input to date and presented a partial set of draft answers to the anticipated program evaluation questions introduced at the last meeting. He asked for immediate feedback, indicating that a final draft will be circulated for approval once answers for the remaining questions are developed.

**V.a. FY 2009-2010 Special Calls for Grant Applications - Staff recommendations:** Mr. Wells presented a staff recommendations document based on the synthesis of Council discussion during the May Council meeting, and subsequent feedback from individual Council members, which was also presented. Six criteria were used to guide these recommendations including relevance to program goals, efficient administration of the competition, and enough breadth to generate an adequate pool of meritorious proposals. Mr. Wells asked the Council to think about categorizing applications and funding on merit within those categories as opposed to lumping all applications into a single pool. Categories could be based upon any number of factors such as by disease, cure and prevention, basic versus translational science, general population versus health disparities, behavioral versus biomedical, et cetera. The five recommended mechanisms are:

- **Shared Equipment Grants** (*King and Bankhead-Coley*) – similar to the Shared Instrument Grants offered by the Bankhead-Coley Program in 2006
- **RC1 Grants** (*King and Bankhead-Coley*) - meritorious but unfunded NIH Challenge Grants in Health and Science Research (“RC1”) proposals from Florida investigators, limited to specific topics that address the unique goals of each program
- **Technology Transfer/Commercialization Partnership (TTCP) Grants** (*King and Bankhead-Coley*) – similar to the previous TTCP offering, with the following changes: 1) expand eligibility to include Florida-based small businesses as primary awardee and 2) accept applications anytime during a longer open application period, with pre-determined award criteria including merit score
- **Team Science Program (“TSP”) Grants** (*King*)– unchanged from previous offering
- **SPORE Planning Grants** (*Bankhead-Coley*) – unchanged from previous offering

Staff was not in favor of including the following mechanisms in the Special Call, for the reasons noted:

- **Investigator Initiated Grants, limited to Florida researchers who have yet to compete successfully for an NIH R01 grant** – The overriding concern of staff is that this mechanism may not be conducive to funding the most meritorious science directed at achieving explicitly stated primary or secondary goals of the programs. In other words, this may not result in an optimal return on investment for the programs. The Council was divided on this point with the dissenting view being that NIH funding is not necessarily a singular standard for scientific achievement.
- **Post-Graduate Training Grants** – While the planning cycle for the Special Call is too short to accommodate development of this mechanism, the Program may consider fellowships and/or training grants for the FY 2010-11 funding cycle. Staff would like to study and, if appropriate, explore ways to slant the focus toward translational research and/or health disparities. This could include minority supplements, which would enhance critical research capacity considering that cancer burden and smoking prevalence disproportionately affect minority populations.
- **Increased indirect costs to grantee institutions** – It is reasonable to increase the limit on indirect costs from 10% to 15% to be competitive with similar sized grant programs within the private and non-profit funding communities; however, to be consistent with FY2009-2010 grants already awarded, this increase will be implemented in the FY

2010-11 award cycle.

- **Grants with a translational emphasis** – More time is needed to rework or replace the Clinical Research Planning Grants, which were previously offered with disappointing results.
- **Competitive continuation funding** – Staff recommends that the Council explore the idea of competitive continuation funding for existing and previous grantees for the FY2010-11 funding cycle.
- **Use of a portion of the administrative budget to advance program goals** - Not a Call-related issue, this topic may be appropriate for more study by one or more Council sub-committees. It may be wise to wait at least one funding cycle to stabilize the program budget.
- **Addressing health disparities** – Because more time is needed to develop a new mechanism, staff agrees this should be a priority topic for the FY 2010-11 funding cycle. We already include language stating “Preference may be given to research proposals that are designed to better understand or mitigate cancer-related health disparities.” This could be changed to a “shall” statement with resulting funding changes.

During discussion of these recommendations, Council considered whether there would be a sufficient pool of TSP and SPORE Planning Grant applications from which to select awards, since the Special Call schedule allows such a short application time for researchers to prepare new proposals. An alternative is to encourage unfunded applicants in the latest competition to draw on their peer review results to modify and resubmit their proposals; however, some Council members stated that this approach is not likely to represent the strongest available science.

Drs. Weissbach and Antony advocated for including the limited Investigator Initiated Grants, saying that there are many research associates and associate professors at Florida’s smaller institutions doing very nice research, but they are having a more difficult time getting R01 funding. Both strongly asserted that lack of R01 funding should not be interpreted as a reflection on the quality of the science being performed. Dr. Bookman pointed out that if the Program chose to offer grants to this population and the peer review scores indicate that the proposed work is not of sufficient quality, the Program would not be obligated to fund any projects. Dr. Weissbach predicted there would be very high peer review scores, higher than the merit review scores for many of the new investigators funded by the Program. Dr. Phillips asked the Council to consider whether providing grants for these projects will make it any more likely that these researchers will go on to win R01 funding. Dr. Hurt expressed a concern about the effectiveness of this mechanism if it is restricted to mid-career investigators that have never obtained major federal funding. Dr. Normann agreed, saying that the New Investigator Research Grant helps researchers working toward tenure. Dr. Weissbach said this would not be intended to take anything away from new investigators. He feels strongly that researchers at Florida’s smaller institutions, with less infrastructure, are at a decided disadvantage in competing for federal funding; he believes the same science performed at a larger institution would earn more federal awards.

Dr. Norman suggested offering funding to investigators at any experience level who want to pursue a novel idea or a new line of research. Ms. Shults said it would be difficult to define eligibility based on this criteria and Dr. Hurt agreed, since Florida State has had many challenges trying to do this.

Several Council members indicated they understood the rationale for not including a post-graduate training grant mechanism in the Special Call, but were in favor of including one in the FY2010-2011 Call for applications.

Dr. Normann asked whether the recommended grant mechanisms would generate a sufficient number of applications to be able to award all available funding. Dr. Bookman projected the likely number of applications and awards for each mechanism, indicating that this would be the case. Dr. Phillips indicated that it would be at least six months before it becomes clear how much the cigarette user fee will generate for the Program to award. The statute states that the Program (combined King and Bankhead-Coley) will receive 5% of the tobacco user fee revenues up to a maximum of \$50 million. Therefore, the state would have to receive \$1 billion in revenues for the Programs to receive this maximum; this is unlikely given the revenue estimates. For planning purposes, she is using a figure of \$40 million (80% of the maximum). Given this insight, the Council recommended trimming the number of mechanisms offered so that a reasonable percentage of applications can be funded.

Dr. Bookman suggested that the Council consider the grant mechanism worksheets prepared for the next agenda item before making final recommendations.

**V.b. FY 2009-2010 Special Calls for Grant Applications – Grant mechanism requirements:**

Ms. Shults led the Council through worksheets defining the following for each of the five staff-recommended grant mechanisms: grant title, statutory relationship, mechanism goal, award amount and duration, applicant eligibility, project eligibility, evaluation criteria, peer review process to be used, and other special requirements.

For the Shared Equipment Grant, she pointed out changes from the 2006 offering, including increasing the limit on the number of applications per institution from two to three, and allowing up to 10% of the cost of the equipment to be used for physical alterations necessary to accommodate the equipment. Dr. Bookman suggested the requirement for the Advisory Committee may be overdone, as such a committee is not always necessary, and when warranted, they will become important well after the end of the one-year grant. Ms. Hajek suggested the five-year post-award reporting be placed on the grantee, rather than an Advisory Committee, and the Council agreed this makes sense.

The recommended TSP and SPORE Planning Grants differed from past offerings only in their limited duration of two years, in keeping with the expected project start date and the limit on the Program's ability to carry forward funds for multi-year awards. Ms. Shults clarified that the TSP Grant would be a King program offering, and SPORE Planning Grants would be a Bankhead-Coley offering.

For the TTCP Grant, applicant eligibility would be expanded to include small businesses that are partnering with academic institutions, requiring each to contribute at least 30% of the total effort with a total of 100% effort between the two entities. In addition, the Program would offer an open application period, with funding up to a predetermined maximum level based on peer review merit scores above a previously established threshold (suggested 2.2 out of 5.0). Unfunded applicants would be able to resubmit a proposal one time. At least two of the five reviewers must have commercialization experience. Dr. Weissbach suggested that the application be expanded to include a business plan.

The scientific merit of RC-1 applications will be determined by the outcome of the federal peer review process. Dr. Antony pointed out that NIH is using the new NIH scoring system of 1-9. Dr. Bookman also endorsed the suggested limits on the numbers of applications and awards per institution, but he is not sure whether percentile scores will be provided. Ms. Shults agreed to check with NIH's Center for Scientific Review to understand their plans to communicate scores

to applicants, so that the Call can be clear in defining project eligibility. Dr. Phillips presented the list of NIH high-priority targets, approximately 42 of which staff has identified as meeting Program goals, and asked Council members to identify any other topics that the Program should also highlight. Council members asked whether there is a risk to allowing applicants to submit RC-1 applications in any of the NIH priority areas and defending their cancer or tobacco relationship. Ms. Hajek and Dr. Phillips stated their preference for emphasizing the program's interest in specific tobacco- and cancer-related topics, rather than accepting applications for which these relationships may be a stretch or an afterthought. After discussion, a compromise was reached in which applications will be accepted for any of the NIH priority topics and the applicant must clearly refer Program peer reviewer(s) to the location in the NIH proposal where the tobacco- or cancer-relatedness is discussed/shown.

**V.c. FY 2009-2010 Special Calls for Grant Applications – Call for Applications release schedule:** Ms. Shults presented a proposed schedule for Special Call funding cycle, with a separate Call for each mechanism offered. This approach provides the capability of setting different due dates for each mechanism. She said there are administrative advantages to starting projects at the beginning of a quarter, with a quarterly reporting schedule that coincides with existing grants. When asked whether an exception might be made for the one-year Shared Instrument Grants since there is a benefit to announcing these awards as soon as possible, Ms. Shults agreed. She asked if six weeks is sufficient for applicants to prepare an application for this grant, and several Council members agreed that it was. Dr. Bookman emphasized that the awards should be announced as soon as possible due to ongoing cuts at institutions, even if the grant start date is slightly delayed for administrative purposes.

Ms. Shults said the schedule for the TSP and SPORE Planning Grants was longer in order to allow more time for proposal preparation, and grants would not begin until April 1<sup>st</sup>. Dr. Bookman suggested that there may not be a sufficient amount of money left to make these awards, and questioned whether these two mechanisms should be part of the Special Call portfolio. Because 2% of the top scoring RC-1 proposals in the nation are likely to be funded, this will be a unique opportunity for the Program to support Florida projects ranking among the top projects in the country. Once again, the Council weighed the advantages and disadvantages of allowing unfunded TSP and SPORE applicants from the last competition to resubmit revised applications. Dr. Hurt observed that to consider this option is to open the Council to criticism over possible perceptions of conflict of interest and bias now that the identity of unfunded applicants is public knowledge.

Ms. Shults acknowledged that the schedule presented does not include the limited Investigator Initiated grant mechanism, and that it would likely follow the schedule for an 11-week application period.

Dr. Bookman called for a motion regarding the Council's recommendation for the Special Call. Dr. Hurt moved that *the Program issue a Special Call including the RC1, SIG, and TTCP grant mechanisms*. The motion was seconded, and after no further discussion, the motion passed unanimously.

**VII. Preliminary Planning for the FY 2010-2011 Call for Grant Applications:** While there are many unknowns about available funding for the next fiscal year, Council agreed to go forward with an assumption that approximately \$40 million will be available, split relatively evenly between the two programs. They also recommended conducting one funding cycle with a sufficient number of mechanisms to ensure an adequate pool of highly meritorious projects. After discussion, they agreed on the following preliminary recommendations:

- New Investigator Research Grant
- Bridge Grant
- Technology Transfer/Commercialization Partnership Grant
- SPORE Planning Grant (Bankhead-Coley only)
- Team Science Program Grant (King only)
- Post-Graduate Training and/or Fellowship Grant
- Grant for projects with translational emphasis
- Grant for projects addressing health disparities

Staff will develop draft grant mechanism worksheets for each of these recommendations for Council consideration. Dr. Bookman offered to help shape a mechanism around the health disparities topic, citing as a potential model a recent grant offered by the National Center on Minority Health and Health Disparities, "Community Participation in Health Disparities Intervention Research, Planning Phase (R24)."

Mr. Wells presented a summary of the report entitled, "Venture Philanthropy Strategies to Support Translational Research" circulated in advance of the meeting, and Council agreed to give this further consideration at the July meeting.

**VIII. Open Discussion:** Council members agreed that the November 17<sup>th</sup> meeting will be held in Tampa, with a 10:00 a.m. start, and the August meeting will be held in either Orlando or Tampa. Staff will follow up with more details.

**IX. Adjournment:** The meeting was adjourned at 6:40 p.m.

Respectfully submitted on behalf of Dr. Richard Bookman, Chair



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Chuck Wells, Assistant Director  
Office of Public Health Research