

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

**May 8, 2009
8:00 a.m. – 4:00 p.m.
Courtyard by Marriott - Maitland
1750 Pembroke Drive
Orlando, FL 32810**

Council Members Present:

Dr. Veena Antony
Dr. Richard Bookman, Chair
Dr. Randal Henderson
Dr. Myra Hurt
Mr. Albert Latimer
Dr. Daniel Morris
Dr. Clarence Brown, representing Dr.
Sigurd Normann
Dr. Mary Lou Sole
Dr. Herbert Weissbach, Vice-Chair

Council Members Absent:

Dr. Penny Ralston

Program Staff Members Present:

Ms. Sherrie Hajek – DOH, OPHR
Dr. Susan Phillips – DOH, OPHR (by phone)
Ms. Peggy Shults – Lytmos Group
Mr. Chuck Wells – DOH, OPHR

Guests in Attendance:

None

NOTE: While Dr. Ralston and Dr. Phillips planned to join the meeting by phone, difficulties with the audio-conferencing capability in the meeting room led Dr. Ralston to miss the meeting, and Dr. Phillips was limited in her ability to participate.

I. Call to Order:

Dr. Bookman welcomed Council members and informed the Council that the published agenda would be slightly rearranged to deal with coincident events taking place at the Capitol related to legislation regarding an increase in the state tobacco user fee and a plan to direct a portion of the resulting revenues to the James & Esther King and Bankhead-Coley programs.

II.a. Approval of Minutes:

Minutes of the January 30, 2009 Council meeting were presented. Dr. Hurt moved that *the minutes be approved as presented*. This motion was seconded and passed unanimously.

II.b Public Comments:

Absent members of the public, Dr. Bookman reported that he had received messages from representatives of the American Cancer Society and American Heart Association, and would relay those comments later in the meeting.

III. 2009-2010 Legislative Budget Outcome:

Mr. Wells referred Council members to pp. 98-99 and p. 388 of the Conference Report on Senate Bill 2600, noting that the budget includes \$27.2 million for the James & Esther King program and \$25 million for the Bankhead-Coley program. The difference of \$2.2 million between the two programs is money from the interest on a biomedical set-aside of the Lawton Chiles Endowment Fund (LCEF). He explained why this was lower than the amount projected by Mr. John Benton from the State Board of Administration (SBA) at the January Council meeting. On March 8th, the SBA Board of Trustees voted on a revised payout formula in response to the \$700 million withdrawal from the LCEF in order to preserve their ability to

guarantee fund payouts in perpetuity. Dr. Bookman pointed out that their meeting coincided with the lowest value of the stock market, and the markets are up 20% since then. There is proviso language that directs \$500,000 of the Bankhead-Coley funds to the Brain Tumor Registry program at the McNight Brain Institute, and \$50,000 from the James & Esther King program for collaborative research projects within the state's historically black colleges and universities. Although this proviso language may be unconstitutional, the Department will not be contesting the language this year.

Mr. Wells then reviewed Conforming Bill SB1664, drawing attention to the fact that \$50 million is the maximum amount the Programs may receive (line 86). The actual amount is 2.5% of the total revenue collected throughout the fiscal year for each program. The exact amount will not be known until much later in the fiscal year. In addition, the bill provides for ongoing funding for the King Program in the amount of 5% of the tobacco user fee revenues. Continued funding for the Bankhead-Coley Program is not provided.

The programs are still due to sunset at the end of this fiscal year; the implication is that the Legislature still plans to conduct program evaluations later in the year and must re-enact the Programs in order for them continue. Mr. Wells emphasized the importance of efforts over the last 18 months to do internal program evaluations to prepare for the legislative evaluations. He distributed an analysis of this same bill prepared by Mr. Paul Hull, American Cancer Society, drawing attention to the summary and advising that legislation regarding the Program will be an issue during the 2010 Legislative session. Council members agreed that the increase in the tobacco user fee is a very positive step forward for the State of Florida. Members also acknowledged that, even if for only this year, this significant increase in the state's investment in biomedical research will meet an extremely important need, and it is Council's job is to invest this money wisely.

Upon the arrival of Mr. Latimer at 8:40, the Chair acknowledged the attendance of Dr. Brown as the American Cancer Society representative in place of Dr. Sigurd Normann, who was unable to attend for health reasons. Council members and Program staff introduced themselves to Dr. Brown.

Returning to the agenda topic, Dr. Bookman asked whether there is a problem in making three-year awards, given the uncertainty of future funding. Mr. Wells answered that there is not, because the full amount of a multi-year award is obligated out of current year funding. In addition, as with all state contracts, grant contracts include a statement that funding is contingent upon the availability of funds.

Mr. Wells reported that the total amount of funding requested in the most recent competition was approximately \$20 million for each program, and the Program is unlikely to fund all requests based on merit. Consequently, there will be a need to conduct a Special Call for Applications for FY2009-2010 funding.

IV.b. and V.b. Available Funds:

Mr. Wells distributed a calculation of available FY 2009-2010 funding for the King and Bankhead-Coley programs. The Bankhead-Coley program started with \$25 million. After deducting 10% for administrative costs, \$500,000 for the proviso language, and restoring all four of the FY2008-2009 New Investigator Research grants that were cancelled early due to mid-year budget reductions, the balance would be \$21,138,748. The King Program started with \$27.2 million and ended with \$22,820,000 after subtracting 15% administrative costs, \$50,000 proviso language,

and \$250,00 for FL CURED

Mr. Wells relayed Dr. Phillips' suggestion that the Program also restore the percentage reductions made to the remainder of the FY2008-2009 multi-year grants. This would result in new totals of \$20,407,184 for Bankhead-Coley grants and \$22,176,597 for King grants.

Dr. Bookman credited the voluntary health organizations with tremendous effort in support of directing the available biomedical research funding to these two programs, especially Paul Hull with the American Cancer Society and James Mosteller with the American Heart Association. On behalf of the Council, he extended a huge "thank you" for their roles in helping make this large amount of funding possible.

Mr. Wells explained why the exact funds available for grants would not be known until much later in the fiscal year. He proposed that the Council, when making their funding recommendations, establish a fundable threshold within each mechanism. Then, the Program would be able to make additional awards to fundable but unfunded applications later in the year. The Council agreed that the concept of merit-based awards would not be sacrificed in favor of making sure all available funds are awarded.

IV.a. Funding Cycle Observations & Statistics (King Program):

Ms. Shults presented data on the number (58) and type of applications received in this competition without disclosing the specific applicants or institutions. The Program ruled six applications ineligible due to their failure to meet requirements stated in the Call for Applications. Applications were received from 14 institutions, including three first-time participants, Lake Erie College of Osteopathic Medicine, Miami Children's Hospital, and Nemours Children's Clinic.

Scripps Florida submitted only one application; Ms. Shults reported earlier feedback from Scripps that the Program's relatively low allowance for indirect costs (currently 10% versus federal rates of up to 50%) is a disincentive to apply. Several Council members echoed a concern that it has become increasingly difficult for Florida institutions to cover real, indirect costs associated with every research project. This includes the infrastructure necessary to support the work, such as pre-award assistance, post-award accounting, animal health facilities, laboratory space and utilities, and undergraduate and graduate education activities. Institutions must make up this gap from the healthcare margin and philanthropic contributions, both of which have been shrinking.

Ms. Shults explained the peer review process used to evaluate the scientific merit of submitted applications. For the King program, 164 subject matter experts from outside Florida evaluated the applications. Depending on the type of grant, between five and seven scientific peer reviewers independently assessed each application, with the highest and lowest scores dropped before calculating an average rating. For Bridge grants, the federal peer review score was used, with one scientific peer reviewer assigned to each proposal to evaluate the strength of the relationship of the proposed work to tobacco and the feasibility of the proposed work, given the requested time and funding.

IV.c. Application Scoring Review and Recommendations (King Program):

Ms. Shults presented a list of applications ranked by merit score within each grant mechanism. Applications were identified only by a randomly assigned number. She also mentioned that peer review reports will be available to the applicants shortly after the Council meeting.

The Council considered Bridge Grant applications first. Dr. Bookman pointed out that his knowledge of past NSF funding practices indicated that the peer reviewer ratings provided for one application would rank it far below the likely federal funding pay line, and several other Council members agreed. However, the other 3 Bridge applications likely meet the criteria.

After discussion, the Council considered a funding scenario totaling \$10,025,675, broken out follows:

- Team Science Program Grants scoring better than 2.0 (3 of 6 applications)
- New Investigator Research Grants scoring better than 2.2 (18 of 38 applications)
- Technology Transfer/Commercialization Partnership Grants scoring better than 2.0 (1 of 3 applications)
- Bridge Grants ranking higher than the 30th percentile (3 of 4 applications)

Dr. Weissbach moved that *this funding scenario be adopted as the Council's formal recommendation*. The motion was seconded. During discussion, members confirmed that there were no exceptions to the funding rules proposed. The motion was brought to a vote and passed unanimously.

V.a. Funding Cycle Observations & Statistics (Bankhead-Coley Program):

Ms. Shults presented information about the collection of 65 Bankhead-Coley proposals received. The majority of the requests were for New Investigator Research Grants (57%), followed by Bridge Grants (37%) and SPORE Planning Grants (6%). No applications were received for Clinical Research Planning Grants. Thirteen institutions submitted proposals, including two for the first time: University of West Florida and Florida Hospital Cancer Institute. Not counted in the total were two applications ruled ineligible, one for being substantially incomplete, and the other a Bridge Grant application that failed to meet the eligibility requirement. A total of 116 scientific peer reviewers from outside Florida evaluated the proposals. New Investigator Research Grant applications were evaluated by five reviewers and seven reviewers examined each SPORE Planning Grant proposal. The federal peer review score was used as the measure of scientific merit for Bridge Grant applications, but one peer reviewer assessed the cancer-relatedness of each proposal, the strength of any case made for a special focus on disparate groups, and the feasibility of the proposed work, given the requested time and funding.

V.c. Application Scoring Review & Recommendations (Bankhead-Coley Program):

The Council considered the full list of Bankhead-Coley proposals, ranked by scientific merit score, with annotations made for proposals that specifically addressed the special needs of disparate groups. The Council recommended applying similar pay line thresholds as recommended for the King program, requiring \$11,380,472 in total funding for the following portfolio:

- SPORE Planning Grants scoring better than 2.0 (2 of 4 applications)
- New Investigator Research Grants scoring better than 2.2 (15 of 36 applications)
- Bridge Grant applications below the 30th percentile or with federal scores of 2.0/200 or better (22 of 22 applications)

Dr. Brown moved that \$11,380,472 be awarded in grants. The motion was seconded and, without further discussion, the motion passed unanimously.

Dr. Antony moved to restore funding to the four New Investigator Research (NIR) Grants that were canceled early due to the FY 2008-2009 budget reduction. The motion was seconded and passed unanimously.

Dr. Weissbach made a motion to restore all percentage reductions to all [FY2008-2009] King and Bankhead-Coley [multi-year] grants, including the newly restored NIR Grants, equating to approximately \$1.4 million. The motion was seconded. Mr. Latimer asked if the two figures Mr. Wells presented during his report on the available funds (\$731,564 and \$643,403) were for this purpose, and Mr. Wells confirmed that this was his intent, although the numbers may not be exact. The motion passed unanimously.

Dr. Morris asked for a summary of the total amount of funding just recommended, and it was agreed to be approximately \$23.6 million. This leaves approximately \$9.0 million for Bankhead-Coley grants and \$10.1 million for King grants to be awarded based on a Special Call for Applications.

VI.a. Council Re-Appointments:

There is no further word from the Governor or Senate President on Council reappointments, most likely due to the demand for their attention in the current session.

Dr. Morris has informed OPHR that he wishes to serve only one term. Mr. Wells expressed appreciation to Dr. Morris for his service and presented him with an award. Dr. Morris said he has found this experience to be extremely important for him as a practicing oncologist. He realized how little he knew about biomedical research and how it relates to clinical medicine. He reported speaking to the state society of oncology about the Program and met with his local legislators about importance of these efforts, and said he hopes to continue his relationship in another way. Several members stated that the perspective Dr. Morris has brought to the Council is unique, with a focus and expertise in clinical trials that will last beyond Dr. Morris's appointment. They offered their thanks to Dr. Morris for his contribution, which they characterized as important and substantial.

Mr. Wells noted that Dr. Ralston has also completed her three-year term, that she is willing to serve another term, and that OPHR has an award for her to be delivered to her in Tallahassee.

VI.b. FL CURED Update:

Mr. Wells briefly explained the nature of service to FL CURED as an advisory council member. He pointed out the Preliminary Questionnaire for FL CURED Advisory Council Appointments, and said the form is also available on the FL CURED web site. If any of the Council members or colleagues are interested in service to FL CURED, they should fill out the preliminary questionnaire, and Mr. Wells will follow up to collect more complete information. Dr. Ralston is the current Council representative to FL CURED, two years into her four-year appointment.

VI.c. Update BRAC Contact Information:

Ms. Hajek collected updated contact information from Council members.

VII. Grant Continuation Status Report:

Ms. Shults reported that, of 52 active King grants, 13 are completing in June and 8 have requested no-cost extensions. Of 34 Bankhead-Coley active grants, 2 are completing in June and 9 have requested no-cost extensions. Progress reports were due April 15th, and Lytmos scientific peer reviews and recommendations are due by June 1st. Ms. Shults indicated that, based on early feedback, there may be one New Investigator Research Grant that will require a plan for improving progress. For Dr. Brown's benefit, Dr. Bookman and OPHR staff briefly explained policies and procedures the Program uses to monitor the progress of these grants. Ms. Shults said two site visits originally scheduled for February and June were cancelled due to earlier budget cuts, and that this year's recommendations for grant continuations would be made without the benefit of this information. If possible, these site visits will be picked up again in the coming year. Dr. Bookman asked that Council members be advised of the site visit schedule once it is determined.

VIII. Program Evaluation:

Ms. Hajek shared the results of a 2009 Application Process Survey. Survey recipients were individuals who registered to apply for a FY 2009-2010 grant. There was a 57% response rate, and overall, registrants were very satisfied:

- 97% agreed that the Call provided a clear explanation of PI eligibility
- 93% agreed that the Call provided a clear explanation of project requirements
- 68% referred to the Q&A on the web site, 7% were not aware of the Q&A
- 90% of those who used the Q&A found them helpful
- 84% were satisfied or very satisfied with assistance from Lytmos (11% replied "not applicable")
- 97% would apply again in the future, if eligible

Compared to the application requirements of other funding sources, respondents rated the Florida Biomedical Research Programs as comparable to NIH, but more difficult than non-profit sources.

Based on survey results and comments, the focus of the Program's short-term improvements are:

- Consider changing the interface to allow sectional uploading similar to the NIH system and separating out instructions by mechanism to reduce confusion
- Address page limit and file size concerns and improve the clarity of this information within the Call for Applications
- Explore possible improvements to the Q&A process and timelines to reduce the delay between the ask and the answer
- Review the application requirements related to key personnel and other support to reduce paperwork requirements and streamline the process

Ms. Hajek said OPHR has plans to conduct additional surveys to learn more about opportunities for program improvement. One will target past applicants to collect outcome information. Council members advised making it clear that the purpose for this request is for program evaluation due to the impending sunset of the programs' enabling statutes. Other customer satisfaction surveys

will target administrative office personnel at grantee institutions, grantees, and Council members. Dr. Bookman suggested sending letters to the top executives at each institution asking for feedback for and support in the upcoming legislative program evaluation. Dr. Hurt suggested including a summary of the dollars and number of grants the institution has received over the history of the Program. Dr. Weissbach suggested asking how this money led to other revenue for the institution.

Ms. Hajek shared a timeline of Performance Measurement and Program Evaluation activities. OPHR is very close to having a database of outcome data and is developing a set of performance standards. She presented a logic model of inputs, activities, outputs, and outcomes at the initial, intermediate, and long-term stages. Council members recommended expanding the activities listed beyond awarding grants annually through a competitive peer reviewed process, as the first and foremost Program activity is designing mechanisms to achieve statutory goals and monitoring the progress of existing awards. They also advised including stimulation of economic activity, especially as scientific workforce development. Dr. Bookman suggested adding to the outputs the number of distinct Florida institutions sponsored throughout the Program's history. Ms. Hajek said the Program is at the level of measuring initial outcomes, and the next step is to focus on measuring our progress against intermediate outcomes. The Council suggested publication citation history as a potential metric for expanding the foundation of biomedical knowledge, and Dr. Bookman offered the assistance of people on his staff to help with data collection. He also offered to help with studying the long-term impact of the Program's support for past grantees, especially new investigators. Dr. Henderson emphasized the importance of including patient participation in clinical trials, especially disparate populations, in the logic model for the Bankhead-Coley program. Dr. Bookman recommended that the program not shy away from self-criticism in program evaluation.

The Council broke for lunch.

Upon return, Dr. Antony asked that OPHR announce the funding decisions as soon as possible, because many of the institutions are preparing to make staff reductions, and these awards are likely to save jobs. Ms. Hajek committed to accelerate the notices as much as possible.

The Council was notified that the conforming bill (SB1664) had now passed both the Senate and the House, moving on to the Governor.

VIII. Program Evaluation (continued):

Mr. Wells presented a list of anticipated questions about the program to anticipate what might be asked during the legislative program evaluation from a risk communication perspective. OPHR will draft answers and then circulate to the Council for feedback. With appropriate revisions, these will then be distributed to help Council members, Lytmos, and program staff prepare for inquiries they may receive. Dr. Henderson read a list of questions he would like to add regarding the outcomes of the Bankhead-Coley program, and he agreed to email them to Mr. Wells. Council members agreed to provide further feedback by close of business on Friday (May 15th).

Council members recommended comparing the Florida Biomedical Research Program to other state-funded programs.

IX. Special Call for Applications:

Ms. Hajek asked the Council to keep program statutory goals in mind, different for each program,

when considering the grant mechanisms to be offered in the Special Call for Applications. Mr. Wells reminded the Council that the first Bankhead Call was released within 60 days, award decisions were made by late November, and grants started on January 1st. He suggested that a similar timeline be established for the next Call this year. He proposed that the Council first brainstorm a list of possible grant mechanisms and then seek consensus on a prioritized list.

Ms. Shults suggested factors to keep in mind when developing a successful accelerated Call for Applications (Call):

- readily definable mechanisms to simplify the Call preparation
- simple application processes for applicants
- simple peer review processes

Council discussion produced the following prioritized list of 6 possible grant mechanisms:

1. **Equipment/core/research infrastructure facilities** -- not limited to unfunded S10 applications because they favor large institutions; must have proven tobacco/cancer relationship; must be necessary for ongoing grants; limit 2 per institution; offer for both programs; maximum \$500K award for one year
2. **Investigator Initiated Grants** -- grants to be qualified by research interest or translational focus; alternately, target investigators who have not yet had an NIH R01 award; this mechanism is likely to have more appeal to smaller institutions and more diverse disciplines will be eligible to apply; there was some concern that there may not be many applications; maximum \$450K award, \$150K/yr for 3 years
3. **Postgraduate Training Grants** -- similar to NIH T32 with adjusted review criteria so as not to disadvantage smaller institutions. Awards should be for 2-3 years; independent fellowships for mentored research and training for post-graduate students in nursing, pharmacy, and social science, as well as clinical fellows; a specified minimum percent effort as in the National Research Service Award guidelines. This grant may tilt toward the large institutions. All agreed that this mechanism will require a lot of development/administrative work. The application may require CVs that represent the type of applicants expected; maximum \$300K award, \$50K/yr per slot for 2 slots for 3 years
4. **RC1 Challenge Grants** -- using an approach similar to the Bridge Grant for high-scoring but unfunded Florida proposals to the federal solicitation offering challenge grants. Federal peer review scores are expected by the end of July. The Program can designate specific program topics tied to tobacco and cancer and set a federal score threshold for eligibility. Perhaps limit the number of applications per institution to ten; also limit the number of awards per institution; maximum \$1 million award, \$500K/yr for 2 years
5. **Across the board enhancement to indirect costs to 15%** -- due to the difficult economic climate for Florida's research institutions; and proportionately increase the value of the grants so the investigators don't have to cover the increase
6. **Consider creative use of a portion of the administrative budget to:**
 - a. facilitate collaboration among grantees
 - b. extend Florida Clinical Trials Network (database and matching service) beyond cancer trials; perhaps in tobacco-related disease
 - c. support online resource for grantee/researcher networking

Also discussed, but agreed to be of lower priority:

- A translational mechanism targeting all experience levels; the Program would need to narrow the focus because “translational” can be very broadly interpreted.
- Reissue the same Call for New Investigator Research Grants, Team Science Program Grants, and SPORE Planning Grants
- A new Bankhead-Coley mechanism intended to reduce burden of disparities; because this would require research and additional planning, this may be more appropriate for the FY2011 Call for Applications. Council members agreed they would like to review the status of funding addressing this topic at a future meeting, and use the basis of this information to shape a potential new mechanism.
- Allow start-up companies to apply for grants, partnering with institutional/academic researchers
- Clinical Planning Grants for investigators at all experience levels
- Competitive continuation funding for current grantees based on merit
- Projects involving promising intellectual property that is facing valley of death, needing help getting to next level
- Directed requests for applications in high priority topics, perhaps requiring collaboration

All agreed that the next step is to flesh out these mechanisms and review them in a Council meeting to be held via conference call in early June. Ms. Shults directed the Council to a form in the notebook to be used to construct each mechanism. She agreed to email meeting notes from this agenda topic to Council members, along with an electronic copy of the grant mechanism work sheet, along with a request for feedback, within the next few days.

X. Open Discussion and Closing:

Dr. Morris moved that *the meeting be adjourned*. The motion was seconded and passed unanimously. The meeting adjourned at 4:20 p.m.

Respectfully submitted on behalf of Dr. Richard Bookman, Chair

 6/22/09

Chuck Wells, Assistant Director
Office of Public Health Research