

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

**August 26, 2008
8:00 p.m. – 1:30 p.m.
Courtyard Marriott Orlando Downtown
730 North Magnolia Avenue
Orlando, FL 32803**

Council Members Present:

Dr. Veena Antony
Dr. Richard Bookman, Chair
Dr. Nikolaus Gravenstein
Dr. Randal Henderson
Dr. Myra Hurt (by phone)
Mr. Albert Latimer
Dr. Sigurd Normann
Dr. Penny Ralston
Dr. Herbert Weissbach, Vice-Chair

Council Members Absent:

Dr. Daniel Morris
Dr. Mary Lou Sole

Program Staff Members Present:

Ms. Sherrie Hajek – DOH, OPHR
Dr. Clara Pelfrey – Lytmos Group
Dr. Susan Phillips – DOH, OPHR
Ms. Peggy Shults – Lytmos Group

Guests in Attendance:

Mr. George Levesque, Florida House of
Representatives
Ms. Carol McKee, H. Lee Moffitt Cancer
Center & Research Institute
Mr. Jamie Wilson, H. Lee Moffitt Cancer
Center & Research Institute

I. Welcome and Call to Order:

a) Approval of Minutes: Dr. Bookman welcomed Council members and acknowledged the guests present. Minutes of the July 9, 2008 Council meeting were presented. Dr. Weissbach moved that *the minutes be approved as presented*. This motion was seconded and passed unanimously.

b) Public Comments: Dr. Bookman stated that the agenda included an opportunity for the guests from H. Lee Moffitt Cancer Center to address the Council later in the meeting, according to their prior request. He invited other comments from members of the public, but there were none.

II. OPHR Report:

Dr. Bookman informed the Council that Mr. Wells was unable to attend the meeting due to illness, and stated that information Mr. Wells had planned to cover on this topic would be rescheduled or emailed after the meeting.

III. Open Innovations – Next Steps:

In Mr. Wells' absence, Dr. Bookman reported that open innovations discussions begun during the FL CURED Summit have continued. He, Mr. Wells, and Dr. Claes Wahlstedt of Scripps Florida have calls scheduled with a number of tech transfer managers from around the state to talk about initiatives going on around the country, all focused on goals closely aligned with this program. The group's objective is to think creatively about ways to make Florida an outstanding location for biomedical researchers, whether working in for-profit or not-for-profit sectors. They are focusing first on sharing information among not-for-profit institutions. They will come back to this Council later with specific ideas and recommendations for changes to the Programs' award *Terms and Conditions* (contract), as agencies such as the National Institutes of Health continue to press toward making sure that publicly funded research is available to the public for non-commercial purposes.

IV. Review of Program Administration Costs:*

For the James & Esther King Program, Dr. Phillips reported that fiscal year (FY) 2007-2008 administrative expenses were approximately \$1 million, which was nearly \$0.5 million less than the 15 percent maximum established in statute. The Office of Public Health Research restricted Program spending in anticipation of a 4 percent budget reduction until the first week of March, when it became clear that the appropriation for the Program was not going to be reduced. This approach allowed a larger share of the total budget of \$9.9 million to be dedicated to grants (\$8.7 million), but also led DOH to leave approximately \$0.35 million in the Biomedical Research Trust Fund.** In the future, DOH can request special budget authority to spend this money. Dr. Normann said this means, unlike unspent funds in the federal budget, this money is not lost, but is still available for use in the future. When asked about the process for obtaining special spending authority, Dr. Phillips (in consultation with Mr. Levesque) explained that she would approach the DOH budget director who would then contact the Governor's office. The request would be considered by the legislative budget commission, who would vote on the request. Dr. Phillips will ask the DOH budget office for the current Biomedical Research Trust Fund balance, and she committed to email this information to Council members. She stated that her budget for FY 2008-2009 is built on the assumption of a 4 percent reduction, with a current forecast of a total shortfall of \$65,000 that would be made up with further tightening of administrative expenses or relinquished grants. The Council encouraged DOH to ensure that all available funds are used to support research, rolling back provisional reductions in initial awards or funding fundable but unfunded grant applications, and Dr. Phillips affirmed her intent to do so.

The Council sought input from Mr. Levesque concerning likely legislative responses to the current state revenue shortfall. He said that, while he can't speak to specific appropriations, revenues are down \$1.7 billion this year, and the forecast indicates a deficit of \$2.5 billion next year. Elected officials will first look for revenue replacement, but failing that, must comply with a constitutional requirement to balance the budget. There is a 1 percent holdback on quarterly distributions now. The Governor's plan includes advancing transportation and infrastructure spending, which may help. For the current year, Mr. Levesque does not expect further budget changes before the November elections.

Dr. Bookman stated that the state is getting good value for the portion of administrative expenses being spent on the Lytmos contract, and Dr. Phillips and Ms. Hajek agreed.

Dr. Phillips presented a similar breakdown of spending and budgets for the Bankhead-Coley Program, with roughly \$0.7 million out of \$9 million spent on administrative expenses in FY 2007-2008. Because there were no fundable-but-unfunded Bankhead-Coley grant applications that year, relinquished Bridge Grants led to the return of \$0.5 million to the Biomedical Research Trust Fund. She clarified that Florida statute requires money in this fund to be used for the Program. When asked how the Program would address a deficit if it arose, she responded that current grants would be reduced by a percentage to be taken out of second and/or third year budgets. Dr. Phillips noted that administrative expenses for the Bankhead-Coley Program are capped at 10 percent, while the King Program allows up to 15 percent. For this reason, expenses that benefit both Programs (such as Council meetings) are allocated with a greater share charged to the King Program. She expressed her hope that these administrative caps would not be further reduced, even though both Programs have been under-spending in this category, because there are many ideas for additional future programmatic support that could be extended to grantees to increase their success in obtaining additional funding. Dr. Bookman said that as these programs have matured, the Council and staff are ready to supplement grants

with more programmatic content, and the costs for this support should not be classified as administrative expense. Dr. Bookman asked about the percent of administrative expense spent by the National Institutes of Health and private foundations. Dr. Phillips said she thought Mr. Wells had relevant data on this topic, and if so, she would ask him to send this information to Council members.

Council members thanked Dr. Phillips for the report, and asked that it be included on the Council agenda on an annual basis.

Dr. Hurt joined the meeting at this time by teleconference.

****Updated Financial Report – attached –** For the James & Esther King Program, fiscal year (FY) 2007-2008 administrative expenses were approximately \$1.13 million; actual grants awarded (minus relinquished awards) totaled \$8.55 million; leaving \$0.35 million to be retained in the trust fund. Estimations for the 2008-2009 FY are \$1.24 million for administrative expenses, \$8.42 million awarded to grants, and \$0.24 million retained in the trust fund. TSP grant reductions will be returned to the grantees and if any grantees relinquish their grants, another grant will be awarded. For the Bankhead-Coley Program, FY 2007-2008 administrative expenses totaled \$0.73 million and grants awarded (minus relinquished grants) totaled \$7.76 million, thereby returning \$0.5 million to the trust fund. Estimations for the 2008-2009 FY are \$0.81 million for administrative expenses, \$8.1 million awarded to grants, and \$0.85 million retained in the trust fund. SPORE grant reductions will be returned to the grantees and if any grantees relinquish their grants, another grant will be awarded.

V. Operations Report:

Ms. Shults introduced Dr. Clara Pelfrey, Lytmos Scientific Review Officer.

a) Status of Current Grants; b) Overview of Progress Analysis: Ms. Shults provided a brief breakdown of the current portfolio of grants for both the King and Bankhead-Coley Programs. She described the process used by Lytmos and OPHR to review grantee progress, both administratively and scientifically, and then characterize the status of each grant at specific points in time using a subjectively-assigned green/yellow/red color-coding scheme. These ratings are used by Program staff, and not released, to determine where follow-up grant management actions are necessary. For both administrative and scientific performance, Ms. Shults explained the criteria for each category, along with the general action plans followed by Lytmos and OPHR when a grant is classified as anything other than in good standing (green). She then presented charts summarizing the classifications of all active King and Bankhead-Coley grants as of July 1, 2008. For the King Program, 90 percent of the grants were in good administrative standing and 83 percent were near or ahead of their project objectives (good scientific standing). For the Bankhead-Coley Program, 82 percent were in good administrative standing and 85 percent were near or ahead of their project objectives. She reported that staff was working closely with principal investigators of all grants not in good standing, and several had resolved outstanding issues as of the date of the meeting. Grantee performance is factored into decisions to continue multi-year grants and allow no-cost extensions, with one King grant awarded a conditional continuation (now in good standing), and one Bankhead-Coley grant denied a no-cost extension. Ms. Shults then directed Council members to a CD in each of their notebooks. The CD contains details regarding each of the active grants, including an index with administrative and scientific progress status indicators, project summaries from the original applications, and progress report overviews as submitted by the grantees.

Dr. Bookman expressed a concern regarding handing this information, some of which may be proprietary, out at this meeting, and stated his opinion that this differs from the concept of open innovation, in which published information is shared. Dr. Phillips stated that grant contract files and progress reports are public information, and that it is the grantee's responsibility to identify proprietary information. Ms. Shults pointed out that, of the CD contents, the project summaries/abstracts are already posted on www.floridabiomed.com, the progress summaries are typically only a few paragraphs in length and are unlikely to contain sufficient detail to jeopardize proprietary information, and the peer review comments are limited to those addressing overall feedback. Dr. Ralston stated that, she objects to the inclusion of the performance ratings. It is an internal matter; names and universities are disclosed. When asked if the ratings are open, Dr. Phillips responded that if someone asked for any records pertaining to a specific grant, DOH would first ask the grantee to identify any portion of the records that merit protection from disclosure based on meeting the State's definition of "confidential." If successfully defended, DOH would redact this information before releasing copies to the public. Dr. Gravenstein said he thought the information validated the degree of Program oversight devoted to grantee performance, and this should be reassuring to the State.

Dr. Weissbach asked Program staff to consider whether the time and cost spent on annual performance assessment is worthwhile, noting that he has seen many cases in which annual progress reports show more progress than has actually been made. Dr. Bookman proposed that annual reviews might not be necessary for grants with more experienced investigators (such as Team Science Program Grants), but he said he believed new investigators likely benefit a great deal from the feedback. Dr. Phillips said the Lytmos performance reviews have identified a number of cases in which grantees were having trouble, most of which were resolved successfully. She also cited the value of site visits as another source of performance information, and Dr. Weissbach agreed. Dr. Pelfrey said she has found having progress reports helpful in preparing for the site visits, and in some cases, progress has been more evident in the visits than in the written reports. Dr. Ralston observed that this process plays an important role in the formative evaluation of the Programs, and although it may be tedious, it is likely to be meaningful to legislative committees and others who want to see that the Council and OPHR are serving as good stewards of the Program.

Dr. Antony asked if the Program follows-up on past grantees, because often it is 2-3 years after the grant ends before substantial results are published. Dr. Phillips responded that the Program does an annual survey of previous grantees, but that a low response rate means a more systematic method of follow-up is also needed.

Several Council members advised Program staff to be clear in informing grantees on the progress report form that, unless information they disclose in their report is identified as proprietary and meets the statutory definition of "confidential," it is subject to Florida Sunshine Laws and open to the public should a public records request be made. In addition, Dr. Ralston urged Program staff to inform grantees that evaluative information, such as the peer review reports and grant status indicators, may also be treated as public record. Council members also requested that a long-term follow-up of grantee performance be placed on a future agenda.

c) Annual Report Plans: Ms. Shults informed the Council of the preliminary plans for the 2008 annual reports for the King and Bankhead-Coley Programs, and provided a development and production timeline. During this interval, Lytmos will work more closely with the Council members who volunteered during the July meeting to help with these reports.

VI. Break

VII. King Program FY 2009-2010 Call for Grant Applications:

Ms. Shults reminded the Council of the set of grant types/mechanisms offered in the last Call for Applications, including the amounts and durations. Several Council members spoke in favor of repeating the same grant mechanisms in the next competition.

a) Application Revisions: Dr. Weissbach advocated shortening the applications as a beneficial change for the applicants as well as reviewers, as NIH will soon be doing. Dr. Antony recommended waiting until this is implemented at the federal level, especially by the National Institutes of Health (NIH). Dr. Bookman agreed, saying that it will be important to make sure the emphasis is adjusted at the same time that pages are reduced. Dr. Gravenstein moved *that the NIR application be shortened from 20 to 15 pages*. After the motion was seconded, there was discussion about training and preparation for principal investigators. The motion failed seven to two. However, Council members agreed to monitor the NIH application reduction initiative for future applicability to this Program.

b) New Investigator Definition:* After discussion regarding potential changes to eligibility for New Investigator Research (NIR) Grants, Dr. Normann moved that *the maximum number of years since first full time faculty appointment be increased from five to six*. During discussion, Dr. Antony asked Council members to consider a funding mechanism for mid-career investigators who are having trouble getting federal funding. Dr. Bookman described the Program's experience offering Investigator Initiated Research Grants in 2001, when a very large number of applications were received. He explained that the amount of money available to the Program is not sufficient to open the competition up to large numbers of more experienced investigators. The motion was seconded and passed unanimously.

The Council recommended that Program staff rely on the NIH definition of Co-PI (i.e., equally responsible independent investigator) when ruling on an applicant's prior research experience. There is a distinct difference between a Co-PI and a key personnel.

c) NIR Deliverables: Rather than requiring new investigators to submit proposals for follow-on funding as a deliverable in their Award Terms and Conditions (contract), Council members agreed it would be best to ask NIR awardees to describe their progress in submitting proposals to federal and/or national peer reviewed competitions on their annual progress reports.

d) Institutional Affiliate Definition: The Council invited Ms. McKee and Mr. Wilson from H. Lee Moffitt Cancer Center & Research Institute to address the Council regarding their request that the Program no longer treat H. Lee Moffitt Cancer Center as an affiliate of the University of South Florida. In his statement, Mr. Wilson noted that Moffitt is the only Florida-based Comprehensive Cancer Center, and emphasized the following key facts:

- Moffitt reports directly to the Florida Board of Governors, according to section 1004.43, *Florida Statutes*
- Moffitt has a governing Board, on which The University of South Florida has one member
- Moffitt has its own Federal Employer Identification Number as an independent non-profit corporation
- Moffitt is directly funded by the Department of Education
- Moffitt pays its employees directly

He stated that while Moffitt has affiliations with many hospitals, physicians groups, universities, and research institutions, it is not an affiliate of any other organization. It does not currently offer any degrees, but if authorized by the Board of Governors, it could do so.

During discussion, Dr. Normann suggested that the Program needs to look at issues of governing authority in order to determine independence. Dr. Bookman thanked Ms. McKee and Mr. Wilson and said the Council and Program staff, in consultation with the DOH attorney, will consider this information and make appropriate revisions to the definition of “affiliate” in the upcoming Call for Applications.

e) TSP/SPORE – Inter-institutional Provision: Dr. Normann raised a concern that the limit of one Team Science Program (TSP) application per institution has hindered inter-institutional collaborative applications. Other Council members agreed, but pointed out that the potential number of applications could be large, and the Program’s limited funds only allow a small number of awards. Dr. Bookman suggested changing the limit to allow each institution to submit one TSP application on its own and additionally to serve as a collaborator on one inter-institutional TSP application. Collaborative applications should require equivalent matches from each participating institution. Rather than entertaining a motion on this topic, Dr. Bookman suggested Program staff investigate this possibility further, draft changes to the Call for Application TSP language, and solicit Council members’ feedback via e-mail.

Dr. Hurt left the meeting.

f) Grant Periods, Including No Cost Extensions: Ms. Shults shared data regarding the frequency and duration of no-cost extensions and the amount of unspent funds at grant conclusion. Dr. Normann moved that *the Program extend the duration of TSP grants to three years (at the grantee’s discretion) without additional funding.* As Principal Investigator of a previous TSP grant, Dr. Antony echoed the value of making this change. The proposal was seconded and passed unanimously.

g) Submission Deadline Procedures: Regarding application submission deadline enforcement, Ms. Shults and Dr. Phillips informed the Council of general circumstances surrounding late applications in the most recent competition. Dr. Bookman acknowledged that these were applications from the University of Miami, and explained that a number of scientists had done a tremendous amount of work on these proposals, and administrative failures at the end caused this effort to be wasted. He asked for the opinions of other Council members regarding whether it is in the best interests of the State in the future to relax the enforcement of the submission deadline. Dr. Phillips explained that many support options are available to applicants who notify the Program of last minute problems, and accommodations have been made in the past when it would not result in unfair advantages to applicants. Dr. Antony stated her position that institutions should enforce their internal deadlines in order to avoid late applications. Dr. Normann stated he felt comfortable leaving it to Program staff to evaluate individual cases for not meeting the deadline, and didn’t believe a lot of guidelines are required. Dr. Bookman suggested that language in the upcoming Call for Applications emphasize the importance of calling the support phone number *immediately* if problems are experienced near the application deadline.

h) Mechanisms to be Offered: The same mechanisms as last year will be offered this year.

VIII. Break for Lunch:

Because the meeting was running ahead of schedule, the Council agreed to continue working without a break in order to finish early.

IX. Bankhead-Coley Program FY 2009-2010 Call for Grant Applications:

a) CRP Eligibility Requirements: Ms. Shults reported that only two Clinical Research Planning Grant applications were received, and no grants were awarded because both applications were deemed ineligible. Ms. Shults suggested that more applications might be received if the CRP were open to investigators at all levels, not just new investigators. The Council recommended offering this grant for one more year to test whether this is a viable mechanism, retaining the new investigator eligibility requirement.

b) Mechanisms to be Offered: Dr. Normann recommended the Program encourage SPORE Planning Grant applications to request three years of funding. Dr. Bookman pointed out that applicants for this mechanism are not necessarily all starting at the same level of readiness, and two years may be more appropriate for some teams.

No further changes to the Bankhead-Coley grant mechanisms were made by Council.

X. Peer Review Process:

Dr. Phillips apologized to the Council for not realizing sooner that the two-stage review process recommended by the Council for the last competition would be a violation of Florida Sunshine Laws. She read an e-mail she received from DOH attorney Jan Myrick confirming this interpretation. She also confirmed that section 215.5602, *Florida Statutes* specifically requires the peer review panels to be subject to Sunshine Law. When Council members asked about the possibility of obtaining a formal exemption for the peer reviews, she and Mr. Levesque explained the process that would be required: OPHR submits a legislative proposal to the DOH Legislative Planning office, DOH Legislative Planning chooses a maximum of fifteen (out of over 100) proposals to send to the Governor's office, and then the Governor's office chooses five to send to the Legislature. With the generally broad interpretation of the Sunshine Law and the DOH's focus on proposals that foster provision of direct health care services, the chances of such a proposal making it out of DOH would probably be very slim. All agreed this was not a feasible alternative. Dr. Bookman asked DOH and Lytmos to explore the workload, time, and cost, and other implications of publicly noticing peer reviews. Dr. Phillips agreed to discuss this option once more with the DOH attorney, to consult with Lytmos regarding the extra costs associated with such changes, and to report back to the Council.

The Council recommended that the FY 2009-2010 Calls for Applications be prepared with the assumption of a peer review process (the same as used in FY 2007-2008) consisting of independent reviews, with merit scores determined by calculating average scores after dropping the highest and lowest. Council also recommended against making any changes to the process during this year's competition.

Ms. Shults directed Council members' attention to a copy of an e-mail received from Dr. Clyde

McCoy* regarding evaluation of the Program's current peer review process. The Council asked Program staff to invite Dr. McCoy to the January Council meeting to discuss the issues presented.

XI. Terms and Conditions Changes:

a) Financial Conflict of Interest of PI – Implementation Plan: Ms. Hajek reported that Mr. Wells is working on an implementation plan to include a financial conflict-of-interest disclosure clause that aligns the Program's Terms and Conditions more closely with that used by NIH.

b) Intellectual Property Clause: Regarding the intellectual property clause, Program staff are reviewing it against the Bayh-Dole Act and working with Mr. David Day, Director of Technology Transfer at the University of Florida regarding his requested changes. Staff will also communicate with other sponsored research and technology transfer offices in order to best meet customer needs.

c) No Cost Extension Policy: Ms. Hajek informed the Council about planned changes to the no-cost extension policy. First, the final quarterly distribution of funds will be withheld until all deliverables have been received from the grantee, including the final progress report. This applies to all grants, with or without no-cost extensions. This change is intended to encourage more timely delivery of final grant reports and is a state of Florida contract requirement. Secondly, no-cost extensions for three-year grants will be limited to six months. This change is necessary because all money must be distributed within four years (48 months) of the initial allocation, or it is lost to the grantee (returns to the Biomedical Research Trust Fund). For three-year grants with no-cost extensions, there is a risk that grantees may not receive all their funds unless they submit all final deliverables no later than three months before the end of the fourth year. One- and two-year grants may still request no-cost extensions of up to one year.


XII. Future Meetings and Council Contact Information:

Future Council meetings are planned for Friday, January 30, 2009 in Tallahassee; Friday, May 8, 2009 (location to be determined); Wednesday, July 15, 2009 (conference call); Monday, August 31, 2009 (location to be determined); and Friday, January 22, 2010 in Tallahassee. Ms. Hajek asked Council members to review and update contact information on file.

XIII. Open Discussion and Closing:

No additional discussion items were introduced. After a group photo was taken of the Council, the meeting adjourned at 1:30 p.m.

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

 2-4-09

Chuck Wells, Assistant Director
Office of Public Health Research

James & Esther King Biomedical Research Program (as of September 30, 2008)	FY 07-08 Actual Expenditures	FY 07-08 Estimated Budget	FY 08-09 Estimated Budget
Appropriation			
Appropriation (General Revenue)		\$5,936,591	\$6,000,000
Appropriation (Trust Fund)		\$3,963,409	\$3,900,000
Total Appropriation		\$9,900,000	\$9,900,000
Grant Awards			
Initial Research Grants Awarded	\$8,749,999	\$8,749,999	\$8,418,749
Grants Relinquished	-\$199,977		
Actual Research Grants Awarded	\$8,550,022	\$8,749,999	\$8,418,749
Under(Over) Budget	(\$135,022)	(\$334,999)	(\$3,749)
Expenses (Maximum 15% of Appropriation)			
FL CURED	\$33,463	\$40,000	\$250,000
Lytmos Contract COOD9	\$626,364	\$602,140	\$602,135
Honorarium	\$53,225	\$75,000	\$72,500
FDOH Personnel Expenses	\$170,354	\$205,597	\$207,699
Other Expenses	\$114,868	\$82,201	\$108,690
Administrative Expense Allocated to Grants	\$135,022	\$0	\$0
Total Administrative Expenses	\$1,133,296	\$1,004,938	\$1,241,024
Under(Over) Budget	\$351,704	\$480,062	\$243,976
Appropriation Balance	\$216,682	\$145,063	\$240,227

Bankhead-Coley Cancer Research Program (as of September 30, 2008)	FY 07-08 Actual Expenditures	FY 07-08 Estimated Budget	FY 08-09 Estimated Budget
Appropriation			
Appropriation (General Revenue)		\$9,000,000	\$9,000,000
Appropriation (Trust Fund)		\$0	\$0
Total Appropriation		\$9,000,000	\$9,000,000
Grant Awards			
Initial Research Grants Awarded	\$8,148,209	\$8,148,209	\$8,100,000
Grants Relinquished	-\$386,638	\$0	\$0
Actual Research Grants Awarded	\$7,761,571	\$8,148,209	\$8,100,000
Under(Over) Budget	\$338,429	(\$48,209)	\$0
Expenses (Maximum 10% of Appropriation)			
Lytmos Contract CO0D9	\$560,641	\$540,865	\$540,870
Honorarium	\$24,200	\$75,000	\$63,000
FDOH Personnel Expenses	\$95,166	\$128,050	\$141,335
Other Expenses	\$50,002	\$64,056	\$69,521
Administrative Expense Allocated to Grants	\$0	\$48,209	\$0
Total Administrative Expenses	\$730,009	\$856,180	\$814,726
Under(Over) Budget	\$169,991	\$43,820	\$85,274
Appropriation Balance	\$508,420	(\$4,389)	\$85,274