

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

Meeting Minutes

**September 11, 2007
8:00 a.m. to 4:00 p.m.**

**Enterprise Florida
Main Conference Room
800 North Magnolia Avenue
Orlando, FL 32803
Phone No. 407-956-5600**

BRAC Members Present:

Dr. Veena Antony
Dr. Richard Bookman, Chair
Dr. Randal Henderson
Dr. Myra Hurt
Mr. Al Latimer
Dr. Daniel Morris
Dr. Penny Ralston (via conference call)
Dr. Mary Lou Sole
Dr. Herbert Weissbach, Vice-Chair

BRAC Members Absent:

Dr. Nick Gravenstein
Dr. Sigurd Normann

**Florida Department of Health
Representatives Present:**

Ms. Sherrie Hajek, Programs Manager, OPHR
Dr. Susan Phillips, Director, OPHR
Ms. Peggy Shults, CEO, Lytmos Group
Mr. Chuck Wells, Assistant Director, OPHR

Guests in Attendance:

Mr. Paul Hull, VP, Public Policy, American
Cancer Society
Ms. Sena Black, Sr. VP Marketing, Enterprise
Florida, Inc.

Welcome and Approval of Minutes:

Minutes of the August 7, 2007 BRAC conference call were presented. Dr. Weissbach moved that *the minutes be approved as submitted*. This motion was seconded and passed unanimously.

OPHR Report:

Dr. Phillips presented a summary of the use of state appropriations for FY 06-07 (actual) and FY 07-08 (anticipated) for the James & Esther King Biomedical Research Program and Bankhead-Coley Cancer Research Program. She noted that there is one unfunded fundable application for a Bankhead-Coley New Investigator Research Grant; she explained that this project could be funded from returned funds, but if further budget reductions are later required of the Program, it would mean previously awarded grants would have to be reduced. Several Council members stated their preference that all available resources be used to continue funding investigators. Dr. Sole moved that *the next New Investigator Research Grant be funded*. The motion was seconded and passed unanimously. Dr. Phillips provided a breakdown of administrative expenses reflecting a four percent budget reduction. Dr. Bookman remarked that the information demonstrated "a remarkable sign of program maturity" and cited "frugal stewardship from the Department of Health and Lytmos." Dr. Hurt stated that she was "proud to be associated with this program because there is much better oversight of these grants than there is for other programs, even at the federal level." Dr. Bookman requested that OPHR provide this information to the Council on an annual basis. All agreed that the September meeting is best for this review, given the fiscal calendar and other items of business for BRAC meetings.

Mr. Wells informed the Council that the full impact of the state's current budget reduction activities on the King and Bankhead-Coley programs would not be known until after the rescheduled special legislative session, and that it could be higher or lower than four percent. A recommendation from the Department of Elder Affairs to cut funding for the Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute has sparked a debate around research verses services.

Mr. Wells reported that Dr. Bookman and our senior attorney discussed the proviso language directing King funds to historically black colleges and universities, and in her opinion the only way the program could legally proceed in this direction would be for the statute to be rewritten. Dr. Ralston expressed frustration that politics is preventing the Program from addressing work force under-representation in the life sciences profession, including research. Dr. Bookman stated that, while he has received alternative opinions that differ from the opinion of DOH counsel, it is an undisputed fact that Florida's HBCUs are an underutilized resource. He offered to commit resources from the University of Miami and coordinate the involvement of other state institutions in developing a program to increase the level of collaboration with Florida HBCUs, perhaps in concert with Bankhead-Coley and King research teams. He further suggested that the Council consider other ways to frame a grant mechanism meeting this specific objective within the goal of increasing research capacity. Mr. Wells added that if the real issue was to address disparities in minority health, this is a goal of the Bankhead-Coley program. Language encouraging proposals that address this topic could be added to existing mechanisms or a completely new mechanism around this topic could be created.

Mr. Wells distributed a handout regarding performance measures, and informed the Council of a planned retreat for OPHR and Lytmos staff members that will focus on evaluation and program performance metrics, and improving the ability to readily extract data to monitor performance. Council members provided suggestions about improving performance reporting, such as looking at consistent reporting periods, including the original grantees, and also adding language to the "Terms and Conditions" regarding annual productivity reporting requirements.

Mr. Wells presented an overview of the reenactment process tied to the 2010 program review by the Legislature. He noted that the Calls for Applications being planned in this meeting will represent the last Calls that will produce measurable results before the scheduled 2010 Program Review, which could be initiated as early as May 2009. Mr. Wells informed the Council that OPHR is preparing a customer service survey of current and former Program participants to stimulate process improvements. This discussion concluded with a request to Mr. Wells for another briefing prior to May 2009 to prepare BRAC members for interviews related to the program review.

FL CURED Representative:

Mr. Wells described the duties required of the BRAC representative to the FL CURED Council. As there were no volunteers or nominations during the meeting, he invited members to contact him after the meeting.

Future Meeting Schedule:

Ms. Hajek presented a suggested calendar for future BRAC meetings. Dr. Morris spoke in favor of holding meetings at other locations of special interest (like today's at the Enterprise Florida headquarters) for the educational value. Dr. Hurt offered to arrange meeting space at FSU for the January meeting. After discussion, the Council agreed to the following dates:

- Friday and Saturday, January 18-19, 2008 (face-to-face)
- Friday, May 16, 2008 (face-to-face)
- Wednesday, July 9, 2008 (conference call)
- Tuesday, August 26, 2008 (face-to-face)
- Friday and Saturday, January 16-17, 2009 (face-to-face)
- May 2009 Program Review (conference call)

Operations Report:

Ms. Shults provided a high-level overview of the status of the 58 active James & Esther King grants, noting that one New Investigator Research grant was conditionally renewed, and the 46 active Bankhead-Coley grants. She reported that 13 Bridge Grant awardees of both programs have relinquished their awards after successfully obtaining federal funding.

In response to questions from the Council, Dr. Phillips explained that unused funds from the current fiscal year could be used to fund other unfunded fundable applications from this year; however, unused or relinquished funds from prior year appropriations remain in the Biomedical Research Trust Fund. In order to use these funds for other awards, OPHR must first request spending authority from the Legislative Budget Commission. Dr. Phillips stated her belief that this authority would likely be granted if the Program demonstrated that the available funds during a given year were insufficient to support the number of highly rated proposals at hand.

As a follow-up to a previous Council request, Ms. Shults described recent changes to grantee progress report forms that will collect brief cumulative summaries of scientific progress for active projects. She will share these summaries with the Council in the future to provide a better understanding of the current state of all sponsored projects.

Ms. Shults presented a flowchart illustrating the current process for making peer review assignments as an aid for ongoing Council considerations regarding the process for conducting peer review of applications. She reported receiving feedback during recent site visits in favor of allowing applicants to name individuals they wish to exclude from the review panel in their application. Lytmos is willing to add this feature to the online application, and Council members agreed this would be an improvement.

An update on the schedules and planned content for the 2007 annual reports for the King and Bankhead-Coley program concluded Ms. Shults' presentation. Council members agreed to provide feedback on first drafts of each document, paying particular attention to recommendations for change(s) to current policy.

Public Comments:

Because so many of the BRAC members are relatively new, the Chair invited Mr. Paul Hull to give a quick overview of the legislative history of the James & Esther King and Bankhead-Coley programs. Mr. Hull worked for Senator King around the time of the tobacco settlement and the establishment of the biomedical set-aside within the Lawton Chiles Endowment Fund. He stated that when the James & Esther King program was founded, the objective was not only to make it successful, but also to eventually expand it. In 2004, after going to work for the American Cancer Society, Mr. Hull authored the original legislation that eventually became the Bankhead-Coley Program. The final legislation looked different from the original and complicated deals had to be made, but funding for 5 years through 2010 resulted. While funded at a much lower level than originally sought, and restricted to peer-reviewed grants only, it still represents a big opportunity for both programs to move forward. In his capacity with the American Cancer Society, he is prepared to fight for both programs. From the perspective of the cancer community, he is pleased with the grant mechanisms that the Program offered in the first two Bankhead-Coley Calls for Applications and is glad the Council is discussing initiatives to address the goal of increased participation in clinical trials. As the Johnnie Byrd Center was a part of the original deal making, Mr. Hull echoed the opinion that research could be a topic during the upcoming special session and should be watched carefully.

James & Esther King Biomedical Research Program FY 2008-2009 Call for Grant Applications:

The Council was reminded that with the budget crisis still unresolved, additional mechanisms or major changes to existing mechanisms would increase administrative costs undesirably.

As a follow-up to a previous Council request, Ms. Shults reported on the productivity of past Small Business Technology Transfer (SBTT) Grants. Four of nine recipients since 2003 have raised at least \$2,000,000 in follow-on funding to support further research and development, and are actively pursuing commercialization. Several members expressed satisfaction with this return on the Program's original investment for all nine of just over \$700,000. She also shared the results of interviews with previous grantees and a survey of technology transfer offices across the state which yielded a number of potential improvements.

Ms. Shults presented the Council with feedback regarding two of the current mechanisms. Several institutions have asked for relaxation of the limit of one Team Science Program (TSP) application per institution, citing great difficulty in managing internal competitions prior to the application deadline. Several members pointed out that this is a requirement of many other programs, and reaffirmed their desire to continue the limit of one award per institution. In addition, the Council wished to avoid the additional peer review costs if more than one application per institution were allowed. Additionally, this could result in funding a proposal with a lower merit score to avoid awarding two or more projects to a single institution. After discussion, Council members declined to change this requirement. A similar suggestion to allow more than one Bridge Grant application from a single investigator likewise failed to win support from the Council.

After Council members considered the application response and grant performance to date against the statutory goals, and in light of budget constraints, Dr. Sole moved that *the Program replicate the grant mechanisms offered in FY 2007-2008*. The motion was seconded. During discussion, Dr. Weissbach advocated for including the SBTT Grant as a fourth mechanism. The motion failed by a vote of three to five. Dr. Sole then moved that *the Program replicate the grant mechanisms offered in FY 2007-2008 and also reinstate the SBTT Grant as a fourth mechanism using the 2006 criteria*. The motion was seconded and passed by a vote of seven to two.

In light of budget constraints, Ms. Shults asked the Council to reconsider its earlier recommendation to conduct a pilot in parallel with the traditional peer review process during the upcoming competition. She suggested two possible paths, with the first being to continue with the status quo. An alternative, still expected to be more costly than the status quo but less costly than a pilot, would be to reduce the number of peer reviewers assigned to a proposal by two, and add a secondary evaluation step in cases where the standard deviation of reviewer ratings is equal to or greater than 1.0. In these cases reviewers would be asked to read their cohort's reviews and, if sufficiently persuaded by alternative viewpoints, modify their rating and review. Dr. Sole moved that *the review process be modified to use the average rating of three reviewers for SBTT and New Investigator Research Grants and five reviewers for TSP Grants. If the standard deviation of reviewer ratings is greater than or equal to 1.0 for any proposal, that review panel will be provided a second chance to adjust their scores, if persuaded to do so*. This motion was seconded. During discussion, there was consensus that reviewers should be allowed to change their original comments as well as their initial rating. The motion then passed unanimously. Dr. Hurt moved that *the same process be adopted in peer reviewing the next round of Bankhead-Coley grants*. The motion was seconded and passed unanimously.

Ms. Shults informed Council members they would be asked to review a draft of the Call for Grant Applications in late October before its anticipated release in mid-December. At this point Dr. Ralston departed the meeting.

Enterprise Florida Presentation:

After lunch, Ms. Sena Black provided a brief overview of the activities of Enterprise Florida within the life sciences sector, including a \$4 million fund for commercialization to aid specifically in business formation rather than research and development. Florida is building critical mass, as evidenced by the fact that only 30 biotech companies existed in Florida five years ago, but today there are over 100. She encouraged the Council to review the *Florida Life Sciences Road Map*, a recent publication from the Milken Institute available at the Enterprise Florida website – www.eflorida.com/lroadmap.

Bankhead-Coley Cancer Research Program FY 2008-2009 Call for Grant Applications:

As a follow-up to a previous Council request, Ms. Shults reported further on Clinical Trial Planning Grants (R34) offered by the National Institutes of Health based on her conversations with three NIH program managers. Each reported very favorable results and continuing strong support for this type of award. One notable observation relayed to her was that, on average, 3 of 10 planning grants produce successful clinical trials. A planning grant should be for one year and around \$100,000 – \$150,000.

Dr. Morris delivered a report on some of the weaknesses of clinical trials from a patient perspective, backed by several articles included in the meeting materials. He expressed great concern regarding the ethics of randomized treatments based on his experience as a practicing community oncologist and called for temperance. All clinical trials should not be blindly supported, but rather those that benefit the treated patient first and foremost. Generally speaking, enrollment is low because patients don't want to enroll. The litmus test is, "would I enroll myself or a family member in this randomized clinical trial?" Dr. Morris argued that the importance of clinical trials has to be balanced against the need to fund basic science research for drug discovery as well as the realities of clinical practice.

Dr. Henderson noted that all new drugs need to go through clinical trials for approval and widespread use, and supporting this process of research and treatment is called for in statute. He expressed a concern that new therapies and drugs will not find their way into the clinic without trials, but readily acknowledged the need for high quality trials. Moreover, this is what the Legislature will judge us on – did we do what the statute directed us to do?

Dr. Hurt reminded her colleagues that this discussion began with a concern that a number of the program grants involving clinical trials have not gone well, stating that the Council's task is to find the best way to support high impact projects. After the Council solicited his input, Mr. Hull stated that the impetus for the Florida Dialog on Cancer (FDOC) and the Bankhead-Coley Program was a desire in state government to ensure that Floridians have access to the best care, and that clinical trials, for many, are the only hope. He acknowledged that having only \$9 million per year makes setting priorities very difficult, but he explained that Council members were appointed based upon their knowledge about the best way to make this happen.

At the last BRAC meeting, Dr. Henderson agreed to draft a mechanism proposal for infrastructure support of clinical trials. He presented two draft mechanisms. The first, entitled "Special Emphasis Project – Florida Cancer Clinical Trials Information and Matching Service" would create the infrastructure for information and matching, and the second, entitled "Florida State-wide Cancer Trials Network" would create the infrastructure for a clinical trials network.

As background, Dr. Henderson provided information about the Florida Dialogue on Cancer (FDOC), their involvement in the creation of the Florida Cancer Council (FCC) and the effort to advance the goal of increased participation in clinical trials. To this end the FDOC also created the Florida Cancer Trials, Inc. (FCT), a non-profit that supports a clinical trials database and

matching service www.floridacancertrials.com. He answered questions regarding the difference between this resource and the national clinical trials registry, www.clinicaltrials.gov, sharing a handout that cited shortcomings of the federal database. He spoke in favor of funding projects that not just research patient participation, but take action to increase participation. Increases in accrual rates can and should be a metric reported to the Legislature during the 2010 program review. Only Florida and New Jersey have such a system in place and the FCT claims to have 95% of all Florida cancer clinical trials in its database. Eighty percent of all patients receive treatment in the community, not at academic health centers. Dr. Henderson's second proposed mechanism for a statewide cancer trials network spawned from his past work as President of the Florida Association of Clinical Oncologists (FLASCO), where a fledgling network has been created. In response to concerns over qualitative issues pertaining to trials in the database, Dr. Henderson indicated that the database and network would serve as a vehicles to push high quality trials out to Florida communities and then the practicing oncologists, by virtue of their referrals, would ultimately decide which were worthy of patient enrollment.

After Dr. Henderson's presentation, Ms. Shults suggested the Council consider which of the grant mechanisms offered in FY 2007-2008 to repeat in the coming Call for Grant Applications. Several members agreed the Special Emphasis Project should not be offered again. Referring the Council to the goals listed in Florida statute, Mr. Wells commented that none of the existing mechanisms specifically addresses the third goal of reducing the impact of cancer on disparate groups. He asked the Council to consider having Program staff flag projects that address disparate groups when presenting applications for funding. Mr. Latimer stated that, as long as the Council follows policy consistently in periodically reevaluating the mechanisms offered against Program goals, it couldn't be faulted for not already addressing all goals; however, he believes it is not acceptable to postpone addressing the needs of disparate groups. He suggested adding a question to the application and evaluation forms regarding the involvement of or a focus on disparate groups. This suggestion was endorsed by others, so that when all else is equal, the Council may give preference to projects that specifically address the needs of disparate groups. Dr. Weissbach spoke against providing Program funds for a clinical trial database, since this resource already exists in Florida. Dr. Henderson stated that the FCT will not have any sustaining funding when the SEP Grant runs out.

In the interests of time, Dr. Bookman asked for a motion regarding the next grant mechanisms to offer. Dr. Hurt moved that *the Program continue to offer Bridge, New Investigator Research, and SPORE Planning Grants, with the addition of specific application and review questions regarding relevance to disparate groups that will allow the Council to separately identify and give preference to projects reducing the impact of cancer on disparate groups*. This motion was seconded, and then passed with a vote of six to one; Dr. Morris abstained. At this point, Dr. Hurt departed the meeting.

It was determined that one more mechanism could be considered for the 2008-09 Call for Applications. Dr. Henderson proposed the mechanism supporting a clinical trials database and matching service be considered. He reasoned that it was a tangible service in keeping with s. 381.921(2) and that the Florida Cancer Trial, Inc., currently receiving grant funds through Bankhead-Coley, and others could apply. Drs. Bookman and Morris inquired about the institutional home for the network and matching service and Dr. Henderson's relationship respectively. Because Dr. Henderson is on the Board of Directors for the network, concern was raised about the perception of a conflict of interest. Dr. Henderson explained that he had discussed whether or not he should resign from either FCT, Inc. and/or FLASCO with Mr. Wells earlier in the year and was told "no." Dr. Phillips expressed that she did not believe this violated the conflict of interest statutes, which involve voting at the time of an award but also was concerned about the perception. Moreover, Dr. Phillips questioned the wisdom of offering a

mechanism that might create a duplicative service where one already exists. Moreover, Dr. Morris felt that www.clinicaltrials.gov substantively already fulfilled this need. Dr. Bookman asked that any further discussion be tabled until such time as staff researched conflict of interest further and he had a chance to review that. Dr. Bookman thanked Dr. Henderson for his forthrightness and acknowledged that Dr. Henderson had sought consultation in advance to avoid any real or perceived conflict. Staff also agreed to see if a competitive bid process such as an Invitation to Negotiate (ITN) might be a preferred and acceptable vehicle to support s. 381.921(2).

On a related note, Dr. Phillips suggested that the Program needs a mechanism by which it could offer additional funding to grantees with exceptional results; after their existing award ended. Dr. Bookman asked if the Program could use relinquished Bridge Grant money for this purpose, and Dr. Phillips agreed to investigate this further.


Dr. Bookman spoke in favor of offering a Clinical Trial Planning Grant, similar to the NIH R34, for one year of support at \$100,000 to organize a study. Dr. Sole strongly recommended including the collection of pilot data. Mr. Wells reported that OPHR has recently learned it is possible to offer four-year awards without the possibility of no-cost extensions. This would make it possible to insert a one-year planning period at the beginning of a three-year New Investigator Research Grant if the application was for clinical research. Discussion ensued as to how clinical would be defined. The consensus was that the research should involve "intact, breathing humans."

Dr. Sole moved that *the New Investigator Research Grant be modified to include a clinical trial planning period, not to exceed 12 months and \$100,000, followed by three years of funding to execute the project.* Dr. Weissbach seconded Dr. Sole's motion, and the motion passed unanimously. Staff was asked by the Chair to flesh out the Call for Applications in response to the recommendations of the Council, including key definitions, and asked that a teleconference be held to give final approval.

Open Discussion and Closing:

Dr. Weissbach moved that *the meeting be adjourned.* The motion was seconded and all members voted in favor. The meeting was adjourned at 3:40 p.m.

Respectfully submitted on behalf of Dr. Richard Bookman, Chair

 1-23-08

Chuck Wells, Assistant Director
Office of Public Health Research