

**James & Esther King Biomedical
Research Advisory Council (BRAC)
Regular Session
Meeting Minutes**

**May 4, 2007
8:00 a.m. – 4:00 p.m.
Marriott Tampa Airport
Tampa International Airport
Tampa, FL 33607**

Council Members Present:

Dr. Richard Bookman, Chair
Dr. Ed Block
Dr. Nikolaus Gravenstein
Dr. Randal Henderson
Dr. Myra Hurt (by conference call)
Mr. Albert Latimer
Dr. Daniel Morris
Dr. Sigurd Normann
Dr. Penny Ralston
Dr. Mary Lou Sole
Dr. Herbert Weissbach, Vice-Chair

Florida Department of Health

Representatives Present:

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

Guests in Attendance:

Nina Entrekin – American Cancer Society
Dr. Clyde McCoy, Chair, Florida Center for
Universal Research to Eradicate Disease
Maxine Michael – American Cancer Society
Sue Middleton – Florida Cancer Control and
Research Advisory Board (C-CRAB)

Welcome and Consent Agenda: Minutes of the last meeting were presented. Dr. Gravenstein moved that *the minutes be approved as submitted*. This motion was seconded and passed unanimously.

Special Recognition of Dr. Edward Block: Having received Dr. Block's resignation from the BRAC, Mr. Wells read a letter of appreciation to Dr. Block from the American Lung Association of Florida for his program contributions as their representative. Dr. Block relayed his pride in the accomplishments of the program since its inception, recognized program staff for their important contributions, and expressed confidence the ability of his fellow BRAC members to continue building the value of the program. On behalf of the BRAC and the Department of Health, Ms. Hajek presented him with a plaque as a symbol of gratitude for his service. Dr. Block will be replaced by Dr. Vena Antony as the American Lung Association representative effective July 1, 2007.

Public Comment: Ms. Entrekin stated that she is excited to continue following the progress of the program, noting that she has been involved with the program from its beginning. Sue Middleton, in attendance for the first time, explained that C-CRAB is an advisory council to the Governor and Secretary of the Department of Health and is housed at the Moffitt Cancer Center. Maxine Michael made available to the BRAC the American Cancer Society analysis of HB 7079, which proposes to move and combine all biomedical research funded through the state under an expanded BRAC. While it appeared that it would not be passed by the Senate, it was noted that anything could happen until the conclusion of this session.

Status of Florida CURED Summit: As the designated representative of the BRAC to the Florida Center for Universal Research to Eradicate Disease (FL CURED) Council, Dr. McCoy prefaced his update on FL CURED activities with a brief history of his involvement with the BRAC for its first six years. He emphasized the importance of the support provided by the American Heart Association, American Lung Association, and American Cancer Society (Tri-agencies) in securing stable funding for the program. He thanked the BRAC for allowing him to represent them on the FL CURED Council for the past year.

Dr. McCoy provided a brief introduction to the FL CURED program and the FL CURED Council

for all BRAC members. He shared his enthusiasm for the growing momentum of activities addressing the FL CURED mission of leveraging multidisciplinary statewide collaborations in the pursuit of cures for disease. He relayed how the outcome of the inaugural Summit held last year has led to the plans for this year's Summit to be held August 6-8 in Orlando. The James & Esther King Biomedical Research Program (King Program) and the Bankhead-Coley Cancer Research Program (Bankhead-Coley Program) will be prominently featured during the Summit, with many grantees presenting poster sessions on the research made possible with state support. In addition, the extraordinary effectiveness of the collaboration among the Florida Tri-agencies in securing state funding for biomedical research will be examined as a model for increasing the productivity of related cooperative efforts in the state. Dr. McCoy extended an invitation to Drs. Block, Bookman, and Normann to participate on a BRAC panel presentation. Representatives of key national organizations will also be participating in discussions focusing on accelerating the implementation of effective strategies within Florida that will lead to cures. Dr. McCoy strongly encouraged the other BRAC members to participate in the Summit and take advantage of the opportunity to meet with program grantees. In the ensuing discussion, BRAC members invited more input from Dr. McCoy and the FL CURED Council in identifying mechanisms for grant funding by the Florida Biomedical Research Program.

Dr. Phillips acknowledged Dr. McCoy's leadership in moving FL CURED forward and in well-representing the interests of the BRAC on the FL CURED Council, and offered appreciation on behalf of the Department of Health. Dr. McCoy then excused himself to leave for another commitment.

After recognizing that Dr. McCoy's appointment as the BRAC representative to the FL CURED Council is due to expire in September, Dr. Weissbach moved that *Dr. McCoy's services as the BRAC representative is extended for another year*. This motion was seconded. During discussion, Dr. Norman recommended that *Dr. McCoy's appointment as the BRAC representative should be extended to two years*. Dr. Weissbach seconded the amendment, and noted that FL CURED funds do not provide for expense/travel reimbursement for FL CURED Council members. The amendment passed unanimously. Dr. Phillips offered to put forth a legislative recommendation for a budget increase to allow FL CURED Council member travel expenses to be reimbursed. Mr. Latimer requested that, prior to voting on the two-year term for Dr. McCoy, a general policy be established for a consistent term for the BRAC representative to the FL CURED Council. It was agreed that there was no desire to impose a term limit, so that if the BRAC wished, a representative could be appointed to consecutive terms. With no further discussion, the Chair called the question on Dr. Weissbach's amended motion, which carried unanimously. The BRAC then entertained Mr. Latimer's motion that *a consistent term of two years is established for the BRAC representative to the CURED Council*. Mr. Wells offered a clarification that this representative serves at the pleasure of the BRAC, which means term limits would not apply. Dr. Block raised a concern about expecting the BRAC representative to travel without reimbursement for two years; Dr. Phillips agreed to verify whether or not these expenses could be covered by the program. Dr. Block seconded Mr. Latimer's motion, which then passed unanimously.

Staff Report: Mr. Wells reported fiscal year 2007-08 state funding appropriations in the amount of \$9 million for the Bankhead-Coley Program, of which \$8.1 is available for grants after deducting 10% for expenses as allowed in statute. The King Program received \$6 million in appropriations and \$3.9 million in interest from the Lawton Chiles Endowment Fund, totaling \$9.9 million. Proviso language in the spending bill again requires the awarding of \$50,000 for collaborative biomedical research at the state's historically black colleges and universities. After deducting 15% for expenses, \$250,000 for FL CURED as required in statute, and the \$50,000 in proviso, \$8.115 million is available for grants¹.

Dr. Phillips reported on the process that was used last year to offer \$50,000 in awards, with the

end result being that only \$25,000 was disbursed. These funds are counted as part of administrative expenses. She solicited input from the BRAC to help create an initiative that will be more in-line with the program's goals. Drs. Ralston, Gravenstein, and Bookman volunteered to work with program staff to further develop a process that may be more effective and could potentially leverage additional federal monies.

Mr. Wells noted that the current collection of 75 active grants will grow to more than 100 with the next batch of awards, and program staff is continuing to take measures to ensure that consistent processes and resources are in place to handle the increasing volume, including renewing the current Lytmos contract for another three years.

Many changes in leadership are occurring at the Department, as expected, following Governor Crist's inauguration. Jean Kline, R.N., M.P.H.; was recently appointed as Deputy Secretary, replacing Nancy Humbert. She will attend the FL CURED Summit and will likely attend the BRAC meeting in January 2008. The BRAC recommended advancing the planned meeting schedule in order to discuss legislative issues sooner, so the program might enjoy stronger legislative support by the beginning of the next session. It was agreed to plan a council meeting in August in conjunction with the FL CURED Summit and to invite both Secretary Viamonte Ros and Deputy Secretary Kline.

King Program Grant Funding Decisions on FY07-08 Call for Grant Applications: Ms. Shults presented statistics regarding the applications submitted for funding in response to the most recent *Call for Applications* and described the peer review process used. Without identifying the institutions or investigators, she presented the BRAC with two questionable eligibility cases for recommendation. After discussion about both matters, Dr. Block moved that *a one-year [NIH] STTR application should not be considered for Bridge Grant funding*; the motion was seconded and passed unanimously. Dr. Block then moved that *a Bridge application for an NSF proposal [assigned a rating of Superior but without a percentile or numeric rating] meeting all other specified criteria should be considered eligible*. This motion was seconded, and passed ten to one. Ms. Shults then explained the process for collecting reviewer opinions regarding the tobacco-relatedness of each application, and solicited a BRAC recommendation regarding a policy for sufficiency. Dr. Block moved that *applications must earn an average tobacco-relatedness score of less than 3 [on a scale of 1 to 5] to be qualified for funding*. The motion was seconded and passed unanimously.

In discussing the list of applications ranked by scientific merit scores within grant type, BRAC members agreed that reductions in award amounts may be appropriate in order to fund the highest number of qualifying grants. Program staff indicated that it will be possible to make up a portion of a funding shortfall by contributing funds from administrative expenses. Dr. Bookman recommended that the BRAC be aware of the components of administrative expenses, and asked that program staff provide a high level overview at the next meeting. Dr. Block moved that the program fund the top two Team Science Program (TSP) applications, the top 14 New Investigator Research (NIR) applications, and all eligible Bridge applications. This motion was seconded and passed unanimously. Council recommendations totaled \$8,349,999 thereby exceeding the amount budgeted for grants.²

Dr. Sole then moved that *if a shortfall exists, program staff should first look for administrative margin, and then reduce funding for TSP and/or Bridge grants by not more than 10%, but no reductions shall be made to NIR awards*. This motion was seconded and passed unanimously. Next, Dr. Sole moved that *if one NIR grant falls out, reductions to other awards shall first be removed; if more funding becomes available, qualified NIR applications through #21 shall be considered fundable*. This motion was seconded and passed unanimously.

Bankhead-Coley Program Grant Funding Decisions on FY07-08 Call for Grant

Applications: Ms. Shults presented statistics regarding the applications submitted for funding in response to the most recent *Call for Applications* and described the peer review process used. Without identifying the institutions or investigators, she presented the BRAC with two questionable eligibility cases for recommendation. After discussion on both matters, Dr. Weissbach moved that *a one year concept grant does not meet the definition of R-type for Bridge Grant funding*. This motion was seconded and passed unanimously. In the second case, the BRAC agreed that an applicant may not request Bridge grant funding for the portion of a federally funded project that was removed due to a budget reduction, and indicated no motion was required. Council members requested clarification on the feasibility ratings assigned during the peer review process. After re-examining the question posed to reviewers, it was agreed that the feasibility rating should not be considered in making Bridge Grant funding decisions in this cycle, and the question should be changed before the next peer review to differentiate between the overall achievability of the project and the likelihood that the planned work can be completed within the stated time frame.

Dr. Block moved that the top two SPORE applications, the first Special Emphasis Project (SEP) application, the top nine NIR applications, and all qualified bridge applications (nine) be funded. The motion was seconded. After considerable discussion, Dr. Norman moved that both SEP applications be funded. This amendment was seconded and passed six to five. BRAC recommendations totaled \$8,091,216.³ Dr. Sole then moved that *the next three eligible NIR applications (through applicant #12) in the ranking should be considered fundable*. The motion was seconded and passed unanimously.

Dr. Bookman asked that the guidelines for Bridge Grants be clarified in future calls for applications to tie awards to federally recommended direct costs. Ms. Shults concluded by briefly reporting the outcome of a survey of peer reviewers regarding willingness to participate in a secondary review step and described a possible solution for resolving cases with a large standard deviation in ratings of overall scientific merit.

Legislative Update: Mr. Wells provided BRAC members with information regarding Florida House Bills (HB) 1065/2496 (Stem Cell Research), 1555 (Cigarette Tax), and 7079 (Biomedical Research). The BRAC expressed serious concern about the implications of HB 7079, noting that it posed many threats to the momentum being built with the current programs and presented significant legal issues regarding the method of making competitively awarded research grants. BRAC members agreed to place a high priority on proactively educating members of the legislature about the programs and the national environment for biomedical research funding well before the start of next year's session. Mr. Latimer informed the BRAC about the Innovation Fund through Enterprise Florida. Dr. Bookman shared information about an upcoming meeting he will attend in Washington D.C. with medical center leaders.

Future Meeting Schedule: The BRAC agreed to hold the next meeting in Orlando in conjunction with the FL CURED Summit, so that members may take advantage of the synergies presented by both events. The conference call previously planned for July will not be held, but may be held in September. No date was set.

Grant Continuations Status Report: Among the 43 active King Program grants, Ms. Shults reported that continuation requests were received for 25 multi-year awards, and 12 investigators with projects scheduled to be completed by June 2007 requested no-cost extensions. She indicated that annual grantee progress reports received in mid-April were still undergoing peer review and Lytmos recommendations for disposition of continuation and no-cost extensions would be provided to DOH within a few weeks. If warranted, a non-conflicted subcommittee of

the BRAC would be commissioned to consider special cases.

BRAC members indicated a desire to better understand the level of progress being made by grantees in funded projects. In addition to the information contained in the annual reports, Program staff agreed to investigate an efficient process and timetable for summarizing scientific progress on all active grants for BRAC review.

Clinical Research Project Review Subcommittee Report: Ms. Shults reported the recommendations of a BRAC subcommittee, consisting of Drs. Sole, Hurt, and Morris, regarding their reviews of patient recruiting difficulties being encountered by seven 2005 King Program projects involving clinical trials. Regarding the specific projects, their independent feedback favored allowing one TSP to complete the project and then decline a request for an extension, watching very closely an NIR project on hold due to identification of a conflict by an IRB, and allowing the other projects to proceed although the aims are overly ambitious and/or the progress is slow. More general observations supported continuing to sponsor clinical research projects while making process changes such as clarifying requirements in advance of the award, increasing the clinical research expertise on associated review panels, and perhaps developing a grant mechanism to assist with planning a clinical research project. In the discussion that followed, Dr. Henderson volunteered to share procedures and criteria that he has seen used successfully in annually reviewing actively-accruing protocols; program staff will distribute this information to the BRAC.

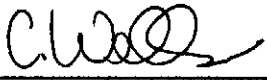
Strategic Planning: Mr. Wells reported that at a program staff level, attention is being given to growth management issues, public relations and marketing, and preparing for the 2010 legislative review. Several BRAC members advocated the importance of relationship building and outreach efforts during the coming year, targeting both members of the legislature and the state's research community. Specific tactics suggested included an open house at DOH offices, a grantee survey regarding customer service satisfaction, continued advocacy through the voluntary health agencies, and increased institutional interaction at site visits. Dr. Bookman volunteered to organize a cooperative VP Research group to promote cross-institutional dialog about program operations and strategies.

Mr. Wells pointed out that the grant mechanisms offered ultimately reflect the primary strategies for achieving the statutory goals. He distributed information about the King and Bankhead-Coley programs relating past and current mechanisms to the statutory goals, and asked BRAC members to consider what may still be needed before the next BRAC meeting, during which the grant mechanisms to be offered in the 2008-2009 Calls for Applications will be determined.

Dr. Bookman expressed his opinion that making significant progress against the ambitious goals established for these programs will require more resources than are presently available. He reiterated his view that the combined budget for these two programs should be \$40 million at a minimum, and he stated his confidence in the capacity of the program's business processes and staff to handle more responsibility.

Open Discussion and Closing: The meeting was adjourned at 3:31 p.m. EST.

Respectfully submitted on behalf of Dr. Richard Bookman, Chair

 8/27/07

Chuck Wells, Assistant Director
Office of Public Health Research

¹ The actual amount available for grants should have been reported as \$8.365 million. Historically, the FL CURED appropriation has been considered part of the 15% deducted for expenses, as has the proviso amount of \$50,000.

² After the meeting an error was discovered in the funding spreadsheet, which increased the funding recommendations total by an additional \$400,000.

³ After the meeting an error was discovered in the funding spreadsheet, which increased the funding recommendations total by an additional \$56,993.