

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

**January 28-29, 2007  
Jan. 28, 2:00 p.m. – 6:00 p.m.  
Jan. 29, 8:30 a.m. – 1:00 p.m.**

**4040 Esplanade Way, Room 301, Tallahassee,  
FL 32311**

**Council Members Present:**

Dr. Richard Bookman, Chair  
Dr. Myra Hurt  
Mr. Albert Latimer  
Dr. Daniel Morris  
Dr. Sigurd Normann  
Dr. Penny Ralston  
Dr. Mary Lou Sole  
Dr. Herbert Weissbach, Vice-Chair

**Council Members Absent:**

Dr. Ed Block  
Dr. Nikolaus Gravenstein

**Program Staff Members Present:**

Ms. Sherrie Hajek – DOH, OPHR  
Ms. Stephanie Jackson – DOH, OPHR  
Dr. Susan Phillips – DOH, OPHR  
Ms. Michelle Richardson – DOH, OPHR  
Ms. Peggy Shults – Lytmos Group  
Secretary Ana Viamonte Ros, M.D., M.P.H. – DOH  
Mr. Chuck Wells – DOH, OPHR  
Deputy Secretary. Betsy Wood, R.N., M.P.H. – DOH

**Guests in Attendance:**

Mr. Jim Francis – State Bureau of Administration  
Dr. Robert Hood – DOH, OPHR  
Ms. Megan Kennedy – DOH, OPHR  
Ms. Brenda Olsen – American Lung Association of Florida  
Dr. Alan Rowan – DOH Division of Health Access and Tobacco  
Ms. Judy Taylor-Fischer – DOH, OPHR

**Welcome and Consent Agenda:** As Dr. Bookman's flight was delayed, Dr. Weissbach called the meeting to order at 2:20 p.m. and welcomed council members, staff and guests. Minutes of the last meeting were presented to the Council; Dr. Normann moved that *the minutes be approved as submitted*. This motion was seconded and passed unanimously.

**Staff Report:** In updating the Council on the two pending appointments (ACoS seat and Dr. Sole), Mr. Wells noted that he recently spoke to the House appointments staff and they were optimistic a decision would be reached soon. He apprised the members of staffing changes at the executive level within the Department of Health, noting especially the appointment of Dr. Ana Viamonte Ros as the new Secretary and Florida's first Surgeon General, and Ms. Betsy Wood as Interim Deputy Secretary.

Mr. Wells provided a legislative update that included information about House Bill 555/Senate Bill 750 regarding stem cell research, and also noted the likely inclusion of \$20 million for this purpose in Governor Crist's upcoming budget. Senate Bill 284, appropriating \$15 million to "an independent biomedical organization" was mentioned. As an update on FL CURED, the 2006 annual report was shared.

Mr. Wells provided copies of a recent Florida public opinion study by *Research!America* indicating that not only is there an overwhelming belief that biomedical research is important and a high priority, but also that 59% of Floridians are willing to pay higher taxes to support health research. However, more than half of the respondents were unable to name any organization in the state where medical research is conducted. In the discussion that followed, BRAC members agreed that it is important to more widely promote the accomplishments of researchers

sponsored by the James & Esther King and Bankhead-Coley programs. Toward this effort, recommendations included compiling lay abstracts summarizing the results of all completed projects, and conducting follow-up interviews with past program grantees that can be used in demonstrating the impact of the program's research through a variety of communication channels. In order to maximize the potential of program grants resulting in follow-on funding, council members emphasized that the submission of a related federal proposal should be included as a deliverable in all grant *Terms and Conditions*. Mr. Wells indicated that the Office of Public Health Research is planning to do a marketing campaign next year to coincide with the release of the annual reports.

Ms. Shults provided an update on National Cancer Institute (NCI) certification. The process is informal and a letter is being prepared and should be mailed in the next couple of weeks. Having our programs NCI certified will benefit our grantees who later seek NCI funding for center grants because the funds received through a certified program are counted in the research base in their process for making awards.

**Operations Update:** Ms. Shults provided an overview of the status of 45 active James & Esther King grants as well as the 33 Bankhead-Coley grants that were awarded January 1. She brought to the Council's attention the fact that the majority of 2005 projects involving clinical trials are having patient recruitment problems and identified a list of contributing factors. Council members acknowledged that these factors are common for clinical studies, and agreed with program staff suggestions to increase the focus on study design in the application and review processes, to require new investigators with clinical trial projects to have mentors with clinical trial expertise, and to consider offering in the future a two-stage grant mechanism including a clinical trial planning component. Drs. Sole and Morris volunteered to participate in a subcommittee to review general information about current clinical trial projects to better understand specific cases, and to help staff with a recommendation for one grant that will be seeking a no cost extension.

Ms. Shults also reported on the 2007-2008 Call for Applications process. As of 1/25/07, a total of 63 applicants had registered to apply for grants for the two programs, with nearly 30 days left before the application due date. Call question and answers are soon to be posted. Council input was solicited on a potential modification to the Call regarding summary statements from previous federal grant competitions. Currently, summary statements must be included in the grant application for bridge grants. Recently concluded competitions have sent web notifications to applicants including their score/percentile ranking, while the summary statements will likely arrive after the close of our competition. After discussion, it was concluded that web notifications can be substituted for the purposes of the application process as long as equivalent key information is contained. Amendments to the Calls will be issued.

**Comments from the Secretary:** Dr. Viamonte Ros made a special effort to make an appearance at the meeting on a Sunday afternoon only a few days after her appointment. She expressed her interest in becoming more familiar with the James & Esther King and Bankhead-Coley programs and offered her full support to the Council and program staff in ensuring the success of both programs. On behalf of the Council, Dr. Bookman advocated for the consolidation of advisory, oversight, and program management responsibilities for all Florida biomedical research grant programs within the scope of the BRAC and the Office of Public Health Research in order to maximize efficiency and ensure the consistent use of best practices in grant making.

**Scientific Peer Review:** To facilitate an examination by the BRAC of the scientific peer review process used to select applications for award, Ms. Shults presented information regarding the advantages and disadvantages of using smaller review panels, which are more conducive to

secondary review discussion and consensus-building, versus using larger numbers of independent reviewers, who have no opportunity for dialog. Dr. Weissbach raised concerns that the current process of discounting the high and low scores for scientific merit (which is intended to compensate for the lack of interaction among reviewers) may discount very relevant feedback from qualified reviewers, and stated his belief that if the reviewers had the opportunity to read each others contributions, they may wish to change their scores. He further postulated that perhaps the two methods could somehow be combined. After discussion regarding the feasibility of making a process change to allow for secondary review consideration, Dr. Sole moved that *the program conduct a pilot peer review project that adds a second round of review for a subset of grant applications, allowing reviewers to change their scores if they wish after reading preliminary review comments. The program will use the first scores to make actual funding decisions and compare the outcome of the second round to see how the scores might have changed.* The motion was seconded and passed unanimously.

Ms. Shults also introduced the possibility of assigning weights to the components of the evaluation criteria, substituting a calculation of a scientific merit score based on reviewer responses to specific questions, rather than, or in addition to, soliciting subjective overall ratings from reviewers. There was not a consensus among the council members to move aggressively in this direction; however, Dr. Bookman volunteered to work with program staff to further evaluate this concept.

Finally, Ms. Shults shared copies of the proposed review questions for each of the grant mechanisms currently offered, and asked for Council feedback, with special attention to the new SPORE Planning Grant and Special Emphasis Projects. Members agreed to provide feedback via email after the meeting.

*This concluded the business of the first day, and the meeting resumed with a call to order by Dr. Bookman at 8:30 a.m. on Monday morning.*

**Public Comment:** Ms. Olsen of the American Lung Association stated that, as a tri-agency member and supporter of the program from the beginning, she is extremely pleased with how it has grown. She expressed optimism for support from the new administration, and noted the passage of Amendment 4, restoring funding to the tobacco prevention program, as earlier intended. She and her colleagues are continuing to seek more money for biomedical research and to find ways to enhance the program. Dr. Bookman echoed her comments regarding the new administration, and stated that he has personally observed an exceptional spirit of cooperation between Senate President Pruitt and House Speaker Rubio.

**Comments from the Interim Deputy Secretary:** Deputy Wood complimented the BRAC and program staff on the management of the King and Bankhead-Coley programs, characterizing current processes as “stellar.” She pledged her support for as long as she holds this interim appointment.

**Legislative Affairs:** Mr. Wells noted that Governor Crist’s budget would be released within the next several days, and Council members solicited and received confirmation from program staff that, while it is not permissible to lobby for a vote on specific legislation, it is within the scope of their responsibilities to support the Governor’s biomedical initiatives/emphasis by educating members of the public and the legislature about Florida biomedical research programs.

Council members advocated a position that the BRAC, with the possible addition of two new members representing an adult stem cell researcher and a medical ethicist, would have the capacity to advise the department on a new stem cell research program, if passed. This would avoid duplication of effort and ensure that fair decisions could be made regarding different

programs. Mr. Latimer moved that *the Council author a letter to the appropriate state lawmakers affirming the members' willingness to support all state government initiatives including grant-based research.* The motion was seconded and passed unanimously.

**Department of Health IRB:** Dr. Hood, Director of the DOH Ethics and Human Protections Program, introduced himself and Ms. Kennedy, the DOH IRB Administrator, to the Council. He reported on recent improvements to streamline the DOH IRB review process, including the adoption of an online system and the addition of a second committee, resulting in two meetings a month. In total, the current workload of the IRB includes 87 protocols under full review and 107 under expedited review. They are actively recruiting additional members for the committees and welcomed referrals from the Council. On behalf of the BRAC, Dr. Bookman commended Dr. Hood and his staff for the noticeable improvements in the DOH IRB approval process.

**Status of Lawton Chiles Trust Fund:** Mr. Francis distributed copies of the 2005-2006 *Investment Report for the State Board of Administration* and a report on the actual endowment contributions and distributions from 1999 through June 30, 2007 along with projections through 2008-2009. Strong market performance has enabled the fund to recover to 100% of its initial principal. Current forecasts call for net biomedical distributions in FY2007-08 and FY2008-09 of approximately \$3.9 million and \$4.3 million per year, respectively.

**Tobacco Prevention Program:** Dr. Rowan, Director of the DOH Division of Health Access and Tobacco, shared the highlights of the current plans for utilizing the \$57 million now allocated for the prevention of tobacco use. This plan was developed after consulting other tobacco prevention programs in Colorado, California, and New York. Early efforts focused on creating a program infrastructure to support the investment of the larger fund. He reported that 39 counties are receiving awards to hire tobacco prevention specialists, 28 others are receiving money for expenses, and \$20 million will be used to prepare marketing media using best practices defined by the Centers for Disease Control. The goal is to implement a comprehensive, evidence-based program focused around Centers of Excellence in prevention, cessation, and second-hand smoke.

**Program Performance Measures:** Mr. Wells reviewed section 20.016, *F.S.* on program review in order to begin preparations for the upcoming 2010 legislative review. Council discussion produced for consideration a list of performance measures against the goals listed in Florida statutes. Specific possible measures include gathering data on the number and amount of additional funding applications and awards to program grantees based on program project accomplishments, patents, peer-reviewed papers, citations of papers, and presentations. Additional metrics include university invention disclosures, licensing agreements and revenues, number of start-up companies, and sponsored investigators continuing to conduct research in Florida, especially pertaining to tobacco-related diseases. While these were agreed to be quantifiable results, members strongly advocated for the use of investigator success stories as a means of communicating the impact of program grants. Council members were asked to consider whether it was feasible to establish targets, although this was universally acknowledged to be difficult to do while still adequately reflecting the impact of the program.

**Strategic Planning:** Mr. Wells reviewed the interest of program staff in collecting feedback from the BRAC during the January meeting each year to help establish the future direction of the program. He went on to define a strategic planning horizon that involves short, medium, and long-term plans. He suggested that the 2007-2008 grant portfolio selection and the development of the 2008-2009 calls fall within the category of short-term; medium term plans include program input into 2008-2009 budget and biomedical research legislation as well as the 2009-2010 calls; he described long-term as 2010 and beyond. Ms. Shults asked for feedback from Council members regarding the *Strategic Visioning Report* previously prepared by the BRAC for the

James & Esther King Biomedical Research Program, as updated in January 2006. Besides including the Bankhead-Coley Program in the scope of the strategic plan, members suggested that overarching goals be established at the level of the Florida Biomedical Research Program, with more specific goal sets for each of the two named programs. Dr. Bookman challenged the Council with a vision of a state commitment amounting to 10% of NIH awards to Florida (approximately \$40 million) and recognition as the gold-standard for state-run competitive biomedical research grant programs. In order to make this vision a reality, members suggested emphases on improving the quality of applications, supporting the best science, supporting clinical studies, and marketing the programs and sponsored research. Ms. Shults offered a chart, patterned after the strategic planning table used annually by NIH, as a tool for mapping specific plans and objectives to the goals provided in Florida statutes. Program staff accepted responsibility for translating ideas from this discussion into a first draft of a strategic plan for review by the Council during its regular session in May.

**Future Meeting Schedule and Closing:** Members agreed that the next meeting will take place in Tampa on Friday, May 4<sup>th</sup>, with a possible extension to Saturday if necessary. Program staff will circulate a poll to schedule the balance of the 2007 BRAC meetings and inform council members of related events for possible attendance. The meeting was adjourned at 1:00 p.m. EST.

Respectfully submitted on behalf of Dr. Richard Bookman, Chair

 7/9/07

Chuck Wells, Assistant Director  
Office of Public Health Research