

October 12, 2016  
3:00 PM to 5:00 PM



Conference call # (888) 670-3525  
Conference code 5311418626

Biomedical Research Advisory Council  
Meeting Minutes

---

Board Members Present:

Richard Nowakowski (Vice Chair)  
Charles Evans Wood  
John Wingard  
Abubakr A. Bajwa  
David Decker  
Susan Vadaparampil

Board Members not in Attendance:

Daniel Armstrong (Chair)  
Barbara Centeno  
Stephen Gardell  
Allison Eng-Perez

Department of Health Staff:

- Shannon Hughes, Division Director, Community Health Promotion
- Philip Cavicchia, PhD, Director, Public Health Research Unit
- Bonnie Gaughan-Bailey, MPA, ASQ-CQIA, Administrator, Biomedical Research Section
- Teresa Mathew, MSW, MPA, Advisory Council Liaison, Biomedical Research Section
- Will Crowley, MSP/MPA (Candidate), Biomedical Research Section

Representatives from the National Institutes of Health:

- Cristina Casseti, Ph.D., Translational Science Program Director
- Robert Eisinger, Ph.D., Acting Director of the Office of AIDS Research

Representatives from the Department of Health and Human Services:

- Rick Bright, PhD, Director of Influenza and Emerging Infectious Diseases Division
- Laura Gibson
- Bob Walker

A quorum was present. The meeting was called to order at 3:05 p.m. Board members received all pertinent meeting materials. Board members participated via conference call and could actively and equally participate in the discussion.

**I. Introduction and Meeting Overview**

Dr. Nowakowski provided an overview of the meeting agenda and asked the guests from the National Institutes of Health and Department of Health and Human Services to introduce themselves.

## **II. Approval of Prior Meeting Minutes**

Dr. Wingard made the motion to approve the September 27, 2016 meeting minutes. Dr. Deckerd seconded the motion. Total votes for approval: (Total members voting: 6) Affirmative: 6, Negative: 0, Recusal: 0.

## **III. Discussion of PowerPoint presentation slides provided by the Department of Health and Human Services**

Dr. Nowakowski invited Rick Bright to provide a brief overview of the PowerPoint Presentation titled, "Current USG Investments in Zika Virus Medical Countermeasures." A copy of this presentation is available on the Zika Research Grant Initiative website at <http://www.floridahealth.gov/provider-and-partner-resources/research/zika-research.html>.

The presentation focused on the current state of research regarding Zika diagnostics, vaccine development, and therapeutics. The presentation also covered opportunities for further research in the state of Florida.

Dr. Nowakowski asked about the availability of reagents. Would this information be available on the HHS program website? Rick Bright answered that there are a number of reagent sources, however availability is limited based upon the high level of demand.

Expanded clinical network for clinical trial vaccines. Dr. Nowakowski asked how to find partners for clinical trials. Rick Bright said that Bob Walker and Laura Gibson would be able to direct interested parties. Each individual manufacturer reaches out to specific sites. Weaving together a Florida-based consortium of sites would be very helpful. Site Management Organizations (SMOs) and Contract Management Organizations (CMOs) are a resource for guiding interested parties toward building partnerships.

Dr. Wingard asked whether the BRAC would want to put language into the FOA stating that the Department would encourage unique and novel research that is not being sponsored by HHS or NIH.

Bonnie Gaughan-Bailey asked how to outline the process to researchers who would want to be a clinical site. There is no formal registration process for becoming a Phase II clinical site. SMOs often handle making the connections between clinical studies and potential research sites. CMOs also handle contract management in these situations.

There was some discussion of the types of research that NIH and HHS think would be most beneficial to furthering the study of this virus.

## **IV. Review of Draft Research Priorities and Mechanisms of Support**

BRAC members discussed whether there should be a limit on the number of applications per PI, per university, or by research priority. Dr. Vadaparampil suggested that this FOA maintain a similar limit as what is used in the FOAs for Bankhead-Coley and King. This limit would allow one application per PI, but would not limit the number of applications by research priority or by university. Furthermore, an individual would be permitted to serve in a collaborating role on any number of proposals. Dr. Vadaparampil made the motion to vote on this option. Dr. Wingard seconded the motion. Total votes for approval: (Total members voting: 6). Affirmative: 6, Negative: 0, Recusal: 0.

Members reviewed the language for the Research Priorities and Mechanisms of Support. Dr. Decker moved to accept the Research Priorities and Mechanisms of Support. Dr. Wingard seconded the motion. Total votes for approval: (Total members voting: 6). Affirmative: 6, Negative: 0, Recusal: 0.

Members voted to accept the FOA with any edits the Department deems necessary during the routing process. Dr. Vadaparampil made the motion. Dr. Decker seconded the motion. Total votes for approval: (Total members voting: 6). Affirmative: 6, Negative: 0, Recusal: 0.

#### **V. Discussion of Timeline and Next Steps**

Bonnie Gaughan-Bailey provided an overview of the most recent timeline and the next steps in the funding cycle. The FOA is scheduled to be published to the program website by October 21, 2016. The online application system will begin accepting Letters of Intent on or around October 21, 2016. The deadline to submit a LOI is November 10, 2016. The online application system will open for the main application on or around November 14, 2016. The main application will close on December 5, 2016. The BRAC will hold an in-person meeting to review the peer review results for applications on January 12, 2017 and the BRAC chair will call the State Surgeon General to present the BRAC's funding recommendations on January 13 or January 17. The press release will be issued shortly after the State Surgeon General finalizes the list of research grant recipients. Grants will be executed by January 30, 2017.

#### **VI. Public Comment**

There were several requests for copies of the slides from the NIH presentation. The presenters expressed a desire to redact proprietary information before the slides are shared with the public. Department staff will coordinate with the presenters and will provide the public with the edited version of the NIH presentation.

The meeting concluded at 4:37 p.m.