December 16, 2014

10:00-3:00 p.m.

Conference call (888) 670-3525

Conference code 2922384719



Orange County Health Department
6101 Lake Ellenor Drive
Orlando, Florida 32809

Biomedical Research Advisory Council **Meeting Minutes**

Biomedical Research Advisory Council members present:

- Daniel Armstrong, Ph.D., University of Miami, Chair
- Charles Wood, Ph.D., University of Florida
- Paul Jacobsen, Ph.D., Moffitt Cancer Center and Research Institute
- David Decker, MD, Florida Hospital
- Al Latimer, BBA, Enterprise Florida, Inc.
- John Wingard, MD, University of Florida
- Penny Ralston, Ph.D., Florida State University (by phone)
- Randal Henderson, MD, MBA, University of Florida (by phone)

DOH Staff

- Celeste Philip, MD, MPH, Deputy Secretary for Health and Deputy State Health Officer for CMS
- Robert Hood, Ph.D., Public Health Research Unit
- Sarah Hofmeister, Public Health Research Unit
- Kevin Bist, Office of Compassionate Use

Members of the Public:

- Thomas George, MD, FACP, CCRAB Chair, University of Florida
- Brenda Porter, MD, Pediatric Neurologist, Stanford University (by phone)

A quorum was present.

The meeting was called to order at 10:05 a.m.

I. Introductions

The Chair welcomed Dr. John Wingard, a new BRAC Senate appointment, to the board.

II. Refractory and intractable epilepsy treatment and research discussion

Per statute: Biomedical Research Advisory Council created under s. 215.5602, Florida Statutes, shall advise the State Surgeon General as to the direction and

scope of research of cannabidiol and its effect on intractable childhood epilepsy and the award of research funding.

The chair introduced Dr. Brenda Porter, a pediatric neurologist from Stanford University as a subject matter expert. She reviewed the science and regulatory background of cannabidiol as treatment for severe epilepsy.

After discussion with the board and Dr. Porter, Charles Wood made a motion that the BRAC recommends the following options, provided these are permitted under statute:

Provide funding for enhanced access to existing trials for Florida residents, to cover costs of enrolling additional patients.
Encourage applications that develop corollary studies to existing trials that address other outcomes such as quality of life, cognitive development, educational attainment, psychological delays, or other significant health concerns.
Permit small n studies by Florida investigators that improve the design of future clinical trials, with a translational focus.

John Wingard seconded the motion.

Total Votes for approval: (Total members voting: 8) Affirmative: 8 Negative: 0 Recusal: 0

III. Cancer Center of Excellence Update

Program staff provided the BRAC with an update on the 2014 Cancer Center of Excellence Cycles 1 and 2 applications and timeframes for the 2015 Cycles.

Dr. Philip thanked the members of the Joint Committee who are participating as evaluators for the Cycle 1 applications.

IV. Collaboration between the BRAC and the Cancer Control and Research Advisory Board (CCRAB) on Statewide Research Plan

Thomas George, MD, FACP, CCRAB chair, presented the members with an overview of CCRAB and summarized the recent changes made to CCRAB from this 2014 legislative session.

Dr. George discussed the following priorities that will be focused in the 2015
Cancer Treatment Plan:
□ Health Disparities
□ Addressing most common cancers
 Childhood cancers as models for survivorship
☐ Establish Florida as a destination for care and research

The CCRAB is striving to have the cancer plan reviewed by CCRAB mid-January, submitted to the State Surgeon General by February 1st, and presented to the Legislature at the beginning of Session.

V. FY 2013/2014 Funding Opportunity Discussion

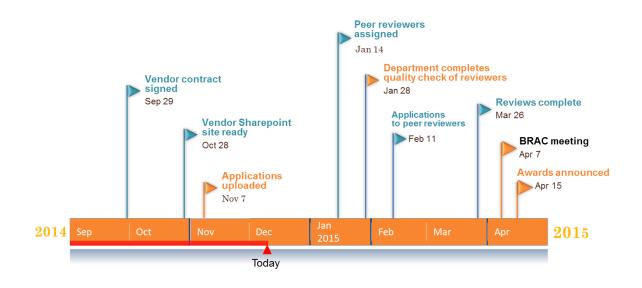
Program staff provided the board with an update on the Funding Opportunity Announcement (FOA) for FY 2014/15, peer review vendor, and timelines for the 2014/15 and 2015/16 FOA.

• There were a total 175 applications submitted to the FY2014/15 FOA:

Mechanism	King	Bankhead-Coley	
Clinical Research		13	22
Discovery Science		43	86
Research			
Infrastructure		3	3
Bridge		0	5
Total		59	116

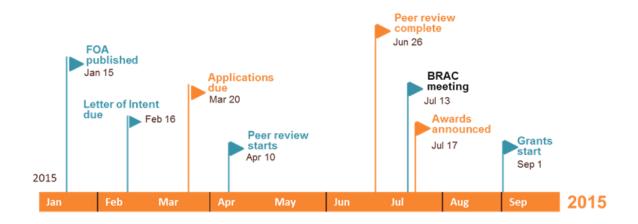
- Peer Review Vendor: Oak Ridge Associated University (ORAU)
 - More money for researchers
 - Admin savings: \$2.5 million over 3 years
 - ORAU \$2.5 million over 3 years
 - Previous vendor \$5 million over 3 years
 - Greater transparency
 - Department audits peer reviewer assignments
 - Rigorous conflict of interest standards
- FY 2014/15 FOA Timeline:

2014-2015 TIMELINE



Potential FY 2015/16 FOA Timeline:

2015-2016 TIMELINE



VI. FY2015/16 Funding Opportunity Announcement Priorities Discussion and Vote

The board reviewed the mechanisms and research priorities for applications submitted to the FY14/15 FOA and timelines provided. The board discussed the possibility of having two submission dates for the FY15/16 FOA: one date for new proposals and another for resubmissions. This would allow researchers to receive their peer review comments from the FY14/15 FOA and revise their proposals. The board asked program staff to check and see if this would be possible with the peer review vendor.

Program staff explained that the peer review process takes approximately 6 months, therefore if the submission deadline was pushed back it would also push back the grant start date.

VII. The chair recognized Dr. Mark Brantly's contribution to the BRAC and publically expressed his appreciation on the behalf of the members of the BRAC. The board members agreed to vote on a co-chair at the next meeting.

VIII. Public comment.

None.

The meeting was adjourned at 2:00 p.m.