May 25, 2017 2:00 p.m.—3:00 p.m.



Conference call (888) 670-3525 Conference code 5311418626

Alzheimer's Disease Research Grant Advisory Board Meeting Minutes

Alzheimer's Disease Research Grant Advisory Board Members in Attendance:

- Leilani Doty, PhD, University of Florida, Chair
- Frederick Schaerf, MD, PhD, Neuropsychiatric Research Center of Southwest Florida
- Niharika Suchak, MBBS, MHS, FACP, Florida State University
- Uma Suryadevara, MD, University of Florida
- Jacqueline Wiltshire, PhD, University of South Florida, Assistant Chair
- Ranjan Duara, MD, Mount Sinai Medical Center

DOH Staff:

- Will Crowley, MSP/MPA, Biomedical Research Section
- Teresa Mathews, MPA, MSW, Biomedical Research Section

Members of the Public: None

A quorum was present. Board members received all pertinent meeting materials. Board members participated via conference call and could actively and equally participate in the discussion.

I. Introductions and Meeting Overview

Dr. Doty provided an overview of the meeting agenda. Board members introduced themselves.

II. Approval of Prior Meeting Minutes (March 28, 2017)

Dr. Wiltshire moved to approve the minutes with Dr. Doty's corrections. Drs. Schaerf and Suryadevara seconded the motion. By unanimous vote, the Board voted to approve the minutes.

III. Edits/Updates to the FY '17 – '18 FOA

Dr. Doty informed the Board that, while both chambers of the Florida legislature have signed off on the budget, Governor Scott had yet to do so, and therefore the \$5 million in funding was not yet a certainty. Further, she informed the Board that the request for statutory change to permit the use of up to 10% of the research funds for administrative expenses would likely not be granted.

Dr. Doty then turned to the funding metrics provided by the Department, calling attention to the fact that only a single grant had been funded in Priority Area 1. In contrast, Priority Area 2 saw 18 funded grants. Dr. Doty requested input from the Board members for how to address this disparity. Dr. Duara then requested that the Department provide data on the award rate by priority area to supplement the funding metrics. Dr. Doty agreed with this request, and added that the National Institutes of Health has been increasingly concerned with a dearth of new investigators attracting funding, as more experienced scientists are out-competing them. She suggested that the Ed & Ethel Moore Alzheimer's Disease Research Grant Program could have a similar problem, and such additional data could lead to a solution. Department staff agreed to provide the requested data before the following board meeting.

Dr. Doty then shifted to the content of the FOA. In the section describing the priority areas, she suggested that the phrase "care management" be added to encourage applications that address therapies, and language indicating that consortium grant applications are

encouraged for maximum return on state funding. She also suggested additional language to expand non-pharmaceutical therapies, driver safety assessment, and behavioral modification techniques. Dr. Schaerf suggested additional examples of non-pharmacological interventions, such as diet or bright light therapy. Department staff suggested that the addition of "care management" may be beyond the statutory scope of the program. Dr. Doty responded that care management is traditionally considered an element of treatment, and Dr. Duara suggested that the addition would be consistent with the apparent spirit of the statute. Department staff maintained that because the language was taken directly from statute, and divergence would likely require clearance from Legal before adoption.

Dr. Duara suggested that the Board address the significant overlap between Priority Areas 1 and 2. Dr. Schaerf agreed that the priority area descriptions could all benefit from a redesign, but suggested that such efforts be postponed until after the next grant cycle. Dr. Doty agreed, maintaining that it was essential that the Board finalize the FOA as soon as possible, and that such a program redesign would likely be a highly time-intensive process.

The Board then discussed the addition of Focus Area 3.6, which would address care management over the course of decline. Dr. Suryadevara suggested that the description be expanded and supplemented with examples. Dr. Doty agreed to provide such language. Dr. Schaerf then addressed the title of Focus Area 3.7, Normative Neuropsychological Database, suggesting it may be misleading. Dr. Doty agreed and requested that Department staff keep track of such suggestions for the Board to discuss after the upcoming grant cycle.

Dr. Doty then suggested the addition of the word "cardiac" to language discussing vascular risk factors in Priority Area 4. Dr. Suchak and Dr. Duara both suggested the use of "cardiovascular" instead, to which Dr. Doty agreed.

Dr. Doty then brought up the issue of comparable terminal degrees as addressed in the background section of Priority Area 5. Dr. Schaerf agreed that the use of the broader phrase was appropriate, given the diversity of academic background of potential future Principal Investigators. Dr. Schaerf then brought up the issue of multiple, possibly inconsistent definitions of eligibility requirements for Principal Investigators. He suggested that a single definition be offered, and other sections that discuss eligibility should reference it instead of giving another definition. He also read aloud a draft of a definition based on NIH language: "An individual with the skills, knowledge, and resources necessary to carry out the proposed research as well as possessing personal interest, commitment, and expertise, consistent with the goals of the Ed & Ethel Moore Alzheimer's Disease Research Program. A Principal Investigator must hold a research or health professional doctoral degree (i.e. PHD, MD, MD/PHD, DO/PHD, DO, DNP, or DNS) or equivalent, and be in good standing and judged to have appropriate training, level of authority and responsibility to direct the program or project outlined in the grant application to the Ed & Ethel Moore Alzheimer's Disease Research Program. The Principal Investigator is responsible to ensure the proper conduct of the research program or project, comply with all the requirements of the Ed & Ethel Moore Alzheimer's Disease Research Program and submit all required reports. The one individual designated by the applicant organization to direct the project to be supported by the grant, the Principal Investigator is responsible and accountable to applicant organization officials for proper conduct of the project. The Principal Investigator must have research experience and the time commitment so as to supervise the project directly and in person." Dr. Schaerf suggested that this section captured much of the essential points discussed by the board, but acknowledged that it did not address US citizenship, state licensing requirements, Veterans' Administration eligibility, and other nuances.

Dr. Shaerf then pointed out that while the FOA states that the Board chooses the ad hoc scientific merit reviewers, this does not accurately reflect the current practice, which is closer to recommending reviewers to Department staff. The Board agreed to include language that indicates that the Board will recommend reviewers with appropriate expertise to Department staff, who will then follow up with those individuals. Similarly, he highlighted the statement of reserving the right on behalf of the Department to disqualify applications, suggesting the addition of language requiring Department staff to inform or seek approval from the Board. Teresa Mathew clarified that this language came from the Legal staff, and pertains only to administrative issues, not to scientific merit, but agreed that such information could be reported to the Board in the

future. The Board also agreed to clarify that researchers with the Veterans' Administration can be collaborators or Co-Principal Investigators, but cannot be Principal Investigators.

Dr. Duara made a motion to accept all the above recommended changes to the FOA. Dr. Wiltshire seconded the motion. The Board passed the motion unanimously.

IV. Edits/Updates to the FY '17 – '18 Research Agenda

V. Program Update

a. Membership

Dr. Doty informed the Board on behalf of Bonnie Gaughan-Bailey that the open seats have not been filled, but that the Board will be updated as soon as any activity occurs.

b. Grant Execution No discussion.

VI. Public Comment

None.

The meeting was adjourned at 3:04 p.m.