March 28, 2017 3:00 p.m.—4:00 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
- Neill Graff-Radford, MD, Mayo Clinic Jacksonville

DOH Staff:

- Bonnie Gaughan-Bailey, MPA, ASQ-CQIA, Administrator, Biomedical Research Section
- Will Crowley, Biomedical Research Section
- Dinithia Sampson, PhD, Advisory Board Liaison, 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. Meeting Minute Approval

Dr. Doty identified the following issues with the previous minutes: a misspelling of Dr. Schaerf's name on page 2, item 4; redundant language in the Annual Report section; and an erroneous conflation of a discussion of Advisory Board membership and roles with a discussion of credential requirements for Principal Investigators, on the bottom of page one in the program membership section.

Dr. Schaerf suggested the minutes be updated to include the need to clarify the eligibility of PIs (Principal Investigators) for grant opportunities and for Board members. Dr. Graff-Radford moved to enact Dr. Schaerf's suggestion to accept the minutes with clarification to be sent to the Department by Dr. Doty. Dr. Schaerf seconded the motion. With no other discussion, the Board voted unanimously to approve the amended minutes.

III. Edits/Updates to FY '17-'18 Research Agenda

No discussion

IV. Edits/Updates to FY '17-'18 FOA

Dr. Schaerf suggested clarification for the definition of Principal Investigator, pointing out that there are two definitions in the language of the FOA (Funding Opportunity Announcement). He then offered new language based on criteria from the NIH (National Institutes of Health): "A principal investigator may be an MD an PhD and MD/PhD or a DO in good standing and judged to have the 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 program or project, comply with all of the requirements of the Ed & Ethel Moore Alzheimer's Disease Research Program, and submit all required reports." Dr. Schaerf noted that Dr. Doty suggested the addition of the phrase "research experience" to the required qualifications. From there he encouraged further discussion and input from the other members, adding that such discussion could facilitate the development of clear qualification requirements for new Advisory Board members.

Dr. Doty continued the discussion of the qualifications for principal investigators, inquiring if people with Master's degrees and specialist degrees should be included. She noted that individuals with Master's degrees often have professional research experience, and that individuals with specialist degrees are referred to as "doctors". Dr. Graff-Radford suggested that they should be included, as such inclusion would facilitate the development of new researchers, but only if they were co-PIs with another researcher with an MD or PhD. Dr. Schaerf inquired whether such inclusion would necessitate a change to the language requiring PIs be full-time faculty members. Drs. Doty and Graff-Radford responded that a Master's degree holder may be a full-time faculty member, but Bachelor's degree holders would not be. Dr. Doty then reiterated the importance of the full-time faculty requirement, based on the policies of other major research grant funding institutions. Dr. Suryadevara agreed that focusing on the full-time faculty status would exclude the less-qualified researchers without excluding PhDs and other skilled researchers.

Dr. Schaerf then put forth a question as to whether an excellent PhD researcher performing clinical work would need a physician as a co-PI. Then, noting that the number of Priority Area1 grants were very low, Dr. Schaerf highlighted a larger question as to whether the language of the FOA was restrictive to the point of discouraging research institutions besides universities from applying. Dr. Doty responded with the suggestion that lawmakers seem to have an interest in prioritizing the involvement of in-state researchers, but do not explicitly prohibit collaboration with out-of-state participants. Bonnie Gaughan-Bailey clarified that funded PIs would need to be licensed researchers within the State of Florida, as the purpose of the legislation was to foster the development of Florida's research infrastructure. Dr. Schaerf then clarified his point, in that he was not referring to out-of-state research institutions, but to Florida entities such as the Alzheimer's Association that could provide valuable insight, but may be discouraged from seeking funding. Dr. Doty responded that the language would encourage collaboration with these institutions, as building institutional relationship is a priority of the grant funding program. Dr. Schaerf agreed with her basic point, but reiterated that the language on eligibility as written on pg. 18 seemed to exclude non-academic institutions even if that was not the intent. Dr. Doty then asked Bonnie Gaughan-Bailey whether the language on pg. 18 was inalterable, to which she clarified that the Department could make whatever changes deemed necessary by the Board.

Dr. Wiltshire returned to the topic of academic qualifications for PIs, noting that a major goal of the funding program was to secure follow-on funding from other sources, particularly the NIH. Since most federal grant funding programs exclude researchers with only graduate level degrees, it would be counter-productive for the Board to fund graduate level PIs. Therefore, she suggested that the Board should emulate NIH language regarding PI qualifications. Dr. Doty inquired whether the NIH considered DOs eligible as well as PhDs and MDs, to which Drs. Wiltshire, Schaerf, and Graff-Radford responded in the affirmative.

Dr. Schaerf then brought up the exclusion of the VA from eligible research institutions. Bonnie Gaughan-Bailey clarified that this exclusion was not statutory, but rather was decided by the Board in the previous year. Dr. Graff-Radford expressed concern that the VA was excluded from eligibility, to which Dr. Doty responded that the VA may still collaborate on funded research projects. She noted that the exclusion of the VA from funding eligibility reflected an apparent separation between VA systems and non-VA systems. Dr. Schaerf echoed Dr. Graff-Radford's concern with the exclusion of the VA. Dr. Doty discussed that federal support was available for VA research. Dr. Schaerf then suggested that the VA could provide valuable insight due to their access to affected populations. Dr. Graff-Radford echoed this point, suggesting that the Board fall on the side of inclusiveness rather than exclusiveness. He also posited that DOD (Department of Defense) support for the VA was not as problematic as others may think. Dr. Wiltshire voiced further support for including the VA, citing their unique level of access to longitudinal data. Drs. Schaerf and Graff-Radford expressed interest as to the origins and rationale for the exclusion. Dr. Suchak then stated her objection to including the VA, suggesting that state funding should prioritize state research infrastructure over federal institutions. She acknowledged the VA's extensive access to valuable data, but reiterated that the VA could still be listed as a collaborating institution under the eligibility language as written. Dr. Graff-Radford then repeated his interest in being as inclusionary as possible, noting that while the VA is a federally-supported institution, its researchers are still an important part of the scientific community in Florida, and further suggested that their inclusion would result in higher quality submissions by increasing competition. Dr. Doty then suggested that the Department further explore the issue and report back to the Board.

The Board then shifted discussion to the FY '17-'18 FOA agenda. Dr. Schaerf pointed to the description of Priority Area 3, suggesting that the consortium requirement might discourage applicants from addressing Focus Area 3.5 Expert Diagnosis Systems and 3.6 Normative Neuropsychological Database, both of which are needed. He inquired whether those focus areas might be better off under a different priority area that was more inclusive. Dr. Graff-Radford responded that those two focus areas are appropriately listed under Priority Area 3 because the intent was to get the MDCs to work together. Dr. Schaerf then suggested that these concepts could be repeated in other non-consortium priority areas. He stated his underlying interest was to find a way to increase the number of Priority Area 1 applications. Dr. Doty suggested that Focus Area 3.3 Treatment Protocols should involve some sort of consortium, but that Focus Area 1.1 or 1.2 could accommodate treatment protocols. She also acknowledged that there were several focus areas in Priority Area 3 that were repeated under other priority areas without the consortium requirement. Dr. Schaerf reiterated his suggestion that Priority Area1 be broadened to encourage more applications. Dr. Graff-Radford suggested that a lack of good scientists working in areas that would fall under Priority Area 1. Dr. Doty stated that transitional research and caregiver research were lacking in the applications that were received, suggesting there should be more efforts to reach out to pragmatic researchers and spreading the word. She then suggested that the language of Priority Area 3 and Priority Area 4 be clarified to communicate their purpose more accurately.

Dr. Doty then turned to the schedule of important dates. She suggested that there should be an announcement to be on the lookout for the FOA listed in the schedule. Bonnie Gaughan-Bailey responded staff would make sure to add such an announcement. Dr. Doty suggested that an individual announcement for this FOA alone would likely generate more interest. She then pointed out that the language was confusing on page 16, Table 1: Schedule of Important Dates, in the third row regarding important information. Dr. Doty also suggested a third round of questions and answer, and more than a week after that to submit their Letter of Intent. Bonnie Gaughan-Bailey pointed out that in the previous year, the legislative session started early enough to release an FOA before the end of the fiscal year. She stated that she had inquired whether the Department could send out the FOA before the official budget is released. Dr. Doty suggested some possible dates for the timeline of events. She then inquired whether there had been any productive discussion regarding the 10% administrative budget that had been recommended in the previous year's annual report. Bonnie Gaughan-Bailey responded that the Department had not heard anything regarding that recommendation.

V. Annual Report

No discussion.

VI. Program Update

a. Membership

Bonnie Gaughan-Bailey stated that two applications for the vacant Board seats were in the Surgeon General's office for review, and that interview appointments were being made. b. **Grant Execution**

No discussion.

VII. Public Comment

None.

The meeting was adjourned at 2:08 p.m.