Questions and Answers from Informational Webinar

7/15/20

1. If a person re-applies, should they include a rebuttal statement that summarizes the changes in response to the reviewers?

Yes, you should identify the application as a resubmission. There is a section in the application that address re-submissions where this should be stated. Look at FOA for how you should address the resubmission.

2. What is the purpose of the Level 2 Background and Drug Screening? Who is being screened, the researchers or participants?

This is a State of Florida requirement that is in place for all contracts. This requirement had not been applied previously to Biomedical Research Grants, but midyear FY19-20 it was implement as a requirement. This is specific to individuals that are working with human subjects. There is a form that grant managers complete to determine if a Level 2 Background and Drug Screening is necessary once you receive the award, but it is best to put this screening in the draft budget. This is a safeguard to assure the safety of human subject participants and co-workers. Screening is specific to key research staff.

3. Can you be a Co-Investigator on more than one grant application for a research program?

Yes, you can, unless it is going to result in Commitment Overlap. This definition is found in the FOA: **Overlap, Commitment:** Commitment overlap occurs when any project staff has time commitments exceeding 100 percent. This is the case whether or not the grant includes salary support for the effort. While information on other support is only requested for the Corresponding Principal Investigator, no individual on the project may have combined commitments in excess of 100 percent.

4. Will studies on patients/family financial burden of Alzheimer's Disease be included for consideration?

For you to make that determination, in the mechanism of support and research priorities section of the FOA, the explanations of possible study areas are given in detail.

5. One of the goals of this program is to "stimulate economic activity in the state in areas related to Alzheimer's Disease research," can you give an example of the economic activity mentioned here?

That statement came from the research priorities developed by the Alzheimer's Disease Advisory Council, at the time a newer research program. It was important to build an AD research infrastructure within the state of Florida for Alzheimer Disease.

- 6. Could you talk about the specific requirements for priority area 5 (postdoctoral fellowships) of the Ed and Ethel Moore Alzheimer's' Debase program.

 Building the next generation of researchers is important, that is the intent of the priority area. Refer to the FOA.
- 7. Can Cloud Computing resources be included for funding in the grant, for example Good Cloud/Microsoft Azure?

The answer is yes but as you know the Cloud is not always secure. Be cautious using the Cloud for Personal Health Information.

- 8. Can you talk about the Research Infrastructure mechanism for Bioinformatics? It is intended to build resources that will be available to other researchers as well.
- 9. With regards to the Bankhead-Coley & Live like Bella "high-risk, high reward" basic science grants, what are the applications limits for these? In other words, how long should the application be? Do they generally include 2 or 3 specific aims?

This was intended to be shorter term research grants, novel ideas, and wanting to try ideas out. The funding level is lower and maximum duration of five years. This can be found in the Mechanism of Support Section.

10. Are animal studies allowed for all these funding mechanisms? Animal studies are allowed for all funding mechanisms.

11. Can an application request funding to analyze data and stored biomarkers already collected?

This is allowable. Refer to the FOA.

12. If there is already collected patients' histology data will be analyzed, can we apply for the Discovery Science mechanism, or would it have to be Clinical Research mechanism?

Using already collected data does not exclude you from applying for a grant. Department staff will not make a determination on which Mechanism of Support you should apply for.

13. For the Research Infrastructure, for the scientific advisory process from at least four universities, do these universities all need to be in Florida?

Yes, all universities need to be in the state of Florida. For an out-of-state PI on your proposal you need to comply with the 10% out-of-state funding cap as stated in the FOAs. The Corresponding Principal Investigator must be located in-state.

14. For Ed and Ethel Moore Alzheimer's Disease Research Program priority area 5, is a research project part of the application/budget or is the focus primarily on the training plan?

This can be for either of these sections

15. Can a project be submitted as a re-submission 2 funding cycles? E.g. initial application FY 18-19, re-submitted 19-20, could we re-submit?

A project can only be resubmitted once.

16. We are submitting a letter of intent for a grant under the Ed and Ethel Moore Alzheimer's Disease Research Program, which includes a principal investigator as a mentor and a few co-mentors. Would they be classified as collaborators or personnel?

If they are included in the budget for the project you can include them as personnel. If not, collaborators are fine as well.

- 17. For the Research Infrastructure Grant for Bioinformatics, can we use request funds to purchase cloud computing resources such as Google Cloud/Microsoft Azure? Hi, the answer is yes but the Cloud is not always secure. So, be cautious in using the Cloud for Personal Health Information.
- **18.** For the Research Infrastructure Grant, can we request funds to hire a technician or a postdoc? Yes, staffing is permissible and common place. You should build your budget based on what is needed to complete the research aims.
- 19. For the Research Infrastructure Grant, how should be go about describing the community advisory process? Any advice on this will be much appreciated. You would need to document who is part of the community advisory process and their role.
- 20. For the Research Infrastructure Grant, for the scientific advisory process from at least 4 universities, do these universities all need to be in Florida? I know collaborators need to be in Florida, but what about scientific advisors? Yes, the universities must be in Florida. A subcontract with an out of state vendor/advisor is rare and limited. Refer to the FOA for restrictions. For an out-of-state PI/collaborator on your proposal you need to comply with the 10% out-of-state funding cap as stated in the FOAs. The Corresponding Principal Investigator must be located instate.
- 21. Can you please let me know about the High Risk, High Reward?

The High-Risk, High-Reward grant applications catalyze scientific discovery by supporting highly innovative research proposals that, due to their inherent risk, may struggle in the traditional peer review process despite their transformative potential. Program applicants are encouraged to think outside-the-box and to pursue trailblazing ideas in any area of research relevant to the Funding Opportunity Announcement. High-Risk, High Reward grant applications have the potential for broad impact.

- 22. Could you clarify two sections within this funding opportunity announcement?
 Although page 4 indicates that sarcoma research will be given priority, page 5 indicates it will not (see cut-and-pasted text below)
 Quote from Page 4:
 - "To balance the number of grants awarded across Research Priorities, this year the Department will prioritize applications that address the following:"
 - 1. Reduction of mortality and morbidity as related to health disparities;
 - 2. Improve screening accuracy and detection in high risk groups;
 - 3. Resistance to front-line treatments in recurrent disease in the five cancers listed:
 - 4. Research focused on sarcomas, or leukemia and other blood cancers;
 - 5. Examine the relationship between obesity and cancer, cancer treatment responsiveness, and cancer treatment-related morbidities.

Quote from Page 5: "Priority will be given to applications that address at least one of the following: lung cancer, breast cancer, prostate cancer, colon cancer, or melanoma."

In regard to the slight difference in the two priority references, you should consider applying for research in any of these areas in which you feel you have the most advantage.

23. I am currently on H1B visa and do not have a permanent residency. This rules out the possibility of me being the primary PI. But, will my visa status allow me to be a co-PI for this application?

If you refer to the FOA, page 16, "Each application must identify a Corresponding Principal Investigator. The Corresponding Principal Investigator must be a U.S. citizen or permanent resident as pursuant to pursuant to §274A(e) of the Immigration and Naturalization Act (8 U.S.C. 1324a), section 101 of the Immigration Reform and Control Act of 1986, and Florida Executive Order 11-02. There may be multiple principal investigators on a project, and non-U.S citizens can serve as collaborators or members of a research team."

As such you can be a Co-PI on a project, as long as, the Corresponding Principal Investigator satisfies the necessary requirements.

24. Me and my team are planning to submit an application to the program focusing on stem cell therapy for stroke. From the FOA, I understand that tobacco-related illnesses will be given priority this year. Although stroke is one of the tobacco-related conditions, our project currently does not have a direct component of "tobacco use" in our model. But is focused entirely on stroke, generally speaking. Can you confirm if we will still be considered or does the project submission has involve a direct tobacco use component?

On page 15 of the Funding Opportunity Announcement, you will find the following wording:

II. ELIGIBILITY AND APPLICATION REQUIREMENTS

1. Tobacco-Relatedness

All applicants must clearly demonstrate how the proposed project is relevant to tobaccorelated cancer, cardiovascular disease, stroke, and pulmonary disease. Proposals that do not or cannot demonstrate the relatedness between tobacco use and the proposed project will not be funded."