Questions and Answers from October 21 through October 28

FY 2016-2017 Funding Opportunity Announcement (FOA)
Zika Research Grant Initiative

1. Is a non-Florida component/investigator possible if the grant has a Florida PI and is submitted from an FL institution?

Yes.

2. Is there some budgetary upper limit on a non-FL institution?

From page 17 of the FOA:

> Activities funded through this competition must occur in Florida. All work (effort) must occur and funds must be spent in Florida at the applicant organization and any collaborating entities. However, the Department may make exceptions if the service is essential and only provided outside Florida, and if the amount is less than 10 percent of the requested amount.

3. As outlined in the "Notice of Funding Opportunity", the research you will be sponsoring is limited to dealing with the disease and does not include concerns about preventative steps that are being taken. We are concerned about the human health implications of insecticide spraying, in particular, upon vulnerable populations. Is there any avenue within this funding opportunity for such a research project to be considered for funding?

The Department does not provide feedback to prospective applicants. Question 24 in our Frequently Asked Questions (http://www.floridahealth.gov/provider-and-partner-resources/research/_documents/zika-research-faq.pdf) addresses this issue. It is the responsibility of the researcher to determine whether or not their project fits the goals and research priorities outlined in any given funding opportunity issued by the Florida Department of Health Biomedical Research Section. Similarly, the researcher must decide which of the funding mechanisms best fits their research goals.

4. Is the vaccine research priority limited to Phase II clinical trials?

From page 5 of the FOA:

> Participate in Zika vaccine Phase II clinical trial studies for advancing the overall progress of promising vaccines (or other prevention technologies) being developed [. . .] In addition, researchers can propose the development of other methods for the prevention of Zika virus prevention.

It is the researcher's responsibility to determine how their proposed project would fit within the research priorities presented in the FOA. Researchers may submit proposals focusing on other methods of Zika virus prevention so long as they are able to draw a clear connection between their proposed research and the research priority under which they are applying.

5. I am planning to submit a proposal on [X], but I am a bit confused about deciding which mechanism of support (Rapid Pilot OR Investigator Initiated) our proposal would fall under? Can you please elaborate more than what type of projects fall under Rapid or Investigator Initiated? Can one project fall under both mechanisms?

The applicant must decide which mechanism of support best fits their research. The descriptions of each mechanism of support are intended to describe in broad terms the types of research that would fall under each support mechanism. These descriptions are open to interpretation, and it is the responsibility of the applicant to make a clear case for how their research would fit within the support mechanism category they choose.

The researcher must choose one mechanism of support. Projects may not fall under multiple mechanisms of support.

6. Clinical trials are very expensive. Why is there an imposed limit on the total funding request amounts when we know the study may be pivotal and do not want to compromise the study?

The funding request amounts were established by the Biomedical Research Advisory Council (BRAC). It is the standard practice for all funding opportunities offered through the Florida Department of Health Biomedical Research Section to have limits on total funds requested.

7. We will not be able to perform human challenge trials and lack sufficient cohorts to perform a Phase II trial here in Florida. Can we submit Phase I studies on strong front runner vaccine candidates?

The Department does not provide this kind of feedback to prospective applicants. Please see the answer to question number three.

8. Is field site development permitted for Phase II with established agreements and unique footprint in an endemic country?

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9. Is the overhead capped at 10% according to previous policy?

Please refer to the following excerpt regarding indirect costs (overhead) from page 17 of the FOA:

> Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 15 percent of the direct costs requested. Indirect costs are those costs that are incurred for the joint or common benefit of several separate organizational or financial components (cost centers) of an organization, which specifically or readily cannot be identified to a particular cost center, project, or program.

Fifteen percent is the standard limit for indirect costs placed upon all grants awarded by the Department of Health Biomedical Research Section.

10. We are planning to submit a grant for Zika research initiative opportunity. The idea that will be presented in this grant is protected by the provisional patent that we have filed through the [redacted]. Under this circumstance how do the patents, copyrights, and royalties defined in the Zika initiative document apply? Can you please explain the rights of the State of Florida if the patent is already filed? Also if only the disclosure is filed how would the patent rules apply as stated in this initiative?

Please refer to Section II number 6 found on page 18 of the FOA. This section elaborates on requirements for protecting intellectual property. The Department cannot provide legal advice to prospective applicants. Please consult with your institution's general council regarding the application of Florida's public records laws to the provisional patent and the potential effects of public disclosure of the provisionally patented invention during the 12-month provisional application pendency period.