

Questions and Answers from July 8 through July 14

FY 2017-2018 Funding Opportunity Announcement (FOA) James and Esther King Biomedical Research Program (King) Bankhead-Coley Cancer Research Program (Bankhead-Coley)

The following questions were submitted to the Biomedical Research Section at <u>Research@flhealth.gov</u>. When possible, the questions were edited to remove any information specific to an individual's unique research project. Questions have also been edited to make them as relevant to the general pool of applicants when possible.

1. I am submitting an applicant eligibility verification request regarding the Bankhead-Coley Cancer Research Program FOA FY 17-18 on behalf of the Miami Cancer Institute, Baptist Health South Florida. On page 13 of 48, Section II.2. "Eligibility Requirements", the FOA explains that "...applications for biomedical research funding may be submitted from any university or established research institute in Florida." We are interested in submitting an application in response to this FOA and wanted to confirm our eligibility to apply as a research institution. In addition to the FOA, we have already reviewed the cited Florida Statutes in the FOA (Section II.2.A) but were unable to find any additional definition or supplemental information. Could the Program Officer please clarify if we are an eligible applicant?

For the purposes of this funding opportunity, an eligible institution is any entity, such as a university or other organization whose primary goal is to conduct fundamental research, industrial research, or experimental development and to disseminate their results by way of teaching, publication or technology transfer; profits are reinvested in these activities, the dissemination of their results, or teaching.

 Our group would like to get clarification on the following: Background: Eligible Applicants: According to sections 215.5602(5) (a) and 381.922(3) (a), Florida Statutes, applications for biomedical research funding may be submitted from any university or established research institute in Florida. Question: We plan to submit an application for Research Infrastructure for the Miami Cancer Institute, Baptist Health South Florida. Is this lead organization eligible? A brief overview of BHSF and MCI research is below for your convenience. (Overview redacted)

Please see the answer to question number 1.

3. I plan to submit a proposal to the Bankhead-Coley Cancer Research Program, and I have a question on which category I should submit it to. I will use [X] to investigate [Y]. Since these data have been collected by various agencies and hospitals, I do not need to contact any patient directly for any data. Does it still fit the Clinical Research category?

It is the responsibility of the researcher to determine which of the funding mechanisms best fits the research they propose based upon the information provided in the FOA.

4. I may collaborate with another institution, but arrangements may not be final at the time of LOI submittal. If I select "no" collaborations in the LOI, will I be able to include collaborations in the full proposal?

Yes. The section of the LOI that asks for collaborators may be edited in the main application.

5. I am interested in applying for the 2017-2018 Bankhead Coley Bridge grant mechanism. Recently, I submitted a NIH SCORE 1 application which is a multi-year, investigator-initiated, research application that is equivalent to an NIH R type grant. I received a highly competitive impact score and am expected to receive the summary statement within the next few days. Based on the eligibility requirements for the Bridge mechanism, it states that the scientific merit must be high and should be at the 16th percentile or better. However, since the NIH SCORE 1 mechanism does not use percentile ranking, how will I determine whether I am eligible to apply for the Bridge mechanism should my SCORE 1 application result in being unfunded?

We recently published a list of Frequently Asked Questions form past funding cycles on the Program website. Please see the answer to **question 24** in the Bankhead-Coley and James and Esther King Frequently Asked Questions, available on the Program website, or by clicking <u>here</u>.

6. I would like to submit a grant proposal entitled "Prostate and Colorectal Cancer Trials" (partially redacted title) to the Bankhead-Coley Cancer Research Program. Could you please take a look at the abstract and let us know if this project is within the scope of this program? Which grant mechanism would this fit: Discovery Science, Research Infrastructure, or Clinical Research?

All applications must demonstrate a connection to at least one of the cancers listed in the FOA. If the application involves a different cancer than the specific cancers listed, the application must include justification as to how and why the proposal is linked to at least one of the specific cancers listed. It is the responsibility of the researcher to determine whether their project fits the scope of the program, and which of the funding mechanisms best fits the research they propose.

7. I'm wanting to get the page/word limits for the various sections of the Bankhead-Coley FOA Application. I'm assuming that the only way to do that is to submit the LOI? Once I submit the LOI, can I still make changes before the due date?

We recently published a list of Frequently Asked Questions from past funding cycles on the Program website. Please see the answer to **question 31** in the Bankhead-Coley and James and Esther King Frequently Asked Questions. You may view this document by clicking <u>here</u>. I believe that this question addresses your inquiry regarding the page/word limits for various sections of the application.

In keeping with the FOA, the main application will not be available to applicants until August 25, 2017 (please see page 11 of the FOA, Schedule of Important Dates). Submitting the LOI early will not give you early access to the main application. After you submit the LOI, you may return to edit/update it until the LOI submission deadline. If you decide to do so, it will no longer retain "submitted" status. You will be required to review and submit the LOI again in order for it to be considered. Failure to "submit" an updated LOI will result in loss of submission.

8. In order to resubmit an application, would we be allowed to provide a 1page introduction (in NIH style) to address the criticism from the previous review?

There is a question in the LOI regarding grant resubmission. If you indicate that the application is a resubmission, you will be prompted to provide a brief explanation of how your resubmitted application addresses concerns raised by peer reviewers when the proposal was initially submitted. This explanation may

be edited during the main application stage if you decide that the response you submitted during the LOI stage was not adequate.

9. Can I access reviewer comments from a previously submitted application through the online system?

No. Reviewer comments for previously submitted applications that were not funded are not currently saved in the online system. Comments were, however, sent out to unfunded applicants shortly after awards were announced. If you would like for your comments to be resent to you, that is not a problem. Please send your request to <u>Research@flhealth.gov</u> and include the title of the application and the full name of the individual listed as the PI on the application.

10. Are FL VA facilities able to participate in the program funding calls this year?

Yes.

11.Can a discovery science proposal have Co-Principal investigators on the proposal?

Any application to the Bankhead-Coley Cancer Research Program or the James and Esther King Biomedical Research Program may include multiple Principal Investigators. They may be multiple Principal Investigators on a project, however, there can only be one Corresponding Principal Investigator per project. The Corresponding Principal Investigator is the individual designated by the applicant organization legally responsible to direct the grant project.

12. Is it allowable to include general letters of support from collaborators on the project that are NOT letters from The Tobacco Free Florida Program or a FL Dept. of Health program office? If yes, do we upload them under the "Letters of Support" upload?

Yes, you may provide additional letters of support from collaborators. Upload them as a single document in the upload field dedicated to "Images, Tables, and Graphs". This upload field can accommodate only one PDF, so if you plan to also include images, tables, or graphs, you will need to combine these into a single PDF with your letters of support.

13. It looks like that research that we are considering will be eligible to both programs, and I am trying to figure out whether we can submit a similar

application to both programs, or should we choose only one. If we can only submit to one program, what are the criteria to find out optimal fit?

Please see the answer to question 22 in the Bankhead-Coley and James and Esther King Frequently Asked Questions. You may view this document by clicking <u>here</u>. I believe that this question addresses your inquiry regarding submission of the same or similar application to both programs. Please see the answer to question number 42 in response to your question regarding optimal fit.

14. Is there a cover page for transmittal of the proposal similar to the NIH format?

No.

15. Do we have to indicate if we are submitting a grant proposal for resubmission and if so, what is the process?

Yes. Please see the answer to question number 7 above.

16. On page 29, Section 5.A. of the FOA for Bankhead-Coley, the section reads, "The "Terms and Conditions" are non-negotiable and acceptance is required as part of the grant award process."
Is the sample Terms and Conditions Template, which is included with the FOA as Appendix 4, representative of the terms and conditions grantees will be required to sign?

The Terms and Conditions Template which is included with the FOA as Appendix 4 is largely representative of the terms and conditions grantees will be required to sign. The version contained in the FOA is consistent with the Terms and Conditions that grantees received in FY 2016-2017. This document is reviewed by the Department's legal counsel each year, and It is possible that the version of the Terms and Conditions a grantee receives for a FY 2017-2018 grant may contain minor changes.

17.I am interesting in submitting a grant proposal (Clinical Research) in response to the Bankhead-Coley FOA. I have a question regarding the types of cancer eligible for this FOA. The FOA states that "All applications, regardless of research priority, must indicate a relationship to at least one of the following: lung cancer, breast cancer, prostate cancer, colon cancer, or melanoma". I am interested in myelodysplastic syndrome (MDS), which frequently occurs following cancer treatment with radiation alone or

combined with chemotherapy. Is research related to MDS eligible for this FOA?

Grant applications must be responsive to one of the research priorities listed in this Funding Opportunity Announcement. All applications, regardless of research priority, must indicate a relationship to at least one of the following: lung cancer, breast cancer, prostate cancer, colon cancer, or melanoma. Applications submitted to the James and Esther King Biomedical Research Program have the additional option of tobacco-related diseases. If the application involves a different cancer than the specific cancers listed, the application must also include justification as to how and why the proposal is linked to at least one of the specific cancers listed.

18. We are planning to apply for a Bankhead Coley Infrastructure Grant and we have the following questions:

A. Is it required that all four institutions of the Scientific Advisory committee be located in Florida, or can they be from other states?

As stated in the FOA, one of the Program's goals is to significantly expand cancer research capacity in Florida. To that end, Program funds are targeted toward Florida-based institutions. An application may, however, allow for less than 10% of the overall award for services provided outside of Florida. If awarded, the Department reserves the right to: 1) require further justification, 2) reject any disallowed costs, and 3) request new/revised budgets as it deems necessary.

The text below is copied and pasted from the section of the FOA regarding Allowed Direct Costs.

Work Must Occur in Florida:

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.

B. Is there a limit on the amount we can budget for equipment purchase?

There is no limit on the amount you can budget for the purchase of equipment. You must provide justification of the purchase in your budget narrative. If awarded, the Department reserves the right to: 1) require further justification, 2) reject any disallowed costs, and 3) request new/revised budgets as it deems necessary.

19. Who should the Letter of Intent be addressed to?

Please see the answer to question 11 in the Bankhead-Coley and James and Esther King Frequently Asked Questions. You may view this document by clicking <u>here</u>. Although the question focuses on submission of the main application, it also addresses your inquiry regarding submission of the LOI. The LOI is submitted through the application intake site. It is an online fillable form so there is no need to address it to anyone. You may access the online system for the James and Esther King Biomedical research program at <u>https://apps.orau.gov/FLDOH_King/Account/Login</u>.

20. For the scope of supported research on "tobacco-related diseases" or "diseases resulting from tobacco use", the two terms widely used in the FOA, are they only limited to "tobacco related cancer, cardiovascular disease, stroke, and pulmonary disease"?

Yes.

21. The #4 and #5 of the eight supported research priorities on "tobacco use" and "obesity" can fall beyond "tobacco related cancer, cardiovascular disease, stroke, and pulmonary disease". Are they still qualified for the support?

From the FOA: "All applications, regardless of research priority, must indicate a relationship to at least one of the following: lung cancer, breast cancer, prostate cancer, colon cancer, melanoma, or other tobacco-related diseases." This FOA's focus on tobacco related disease is specific to cardiovascular disease, stroke, and pulmonary disease. Applications submitted to the priorities for "tobacco use" and "obesity" must adhere to these guidelines.

22. Is preliminary data required for application in the "discovery science" type of support?

No.

23. Can you confirm the page/word limitations of LOI and full application?

The LOI is a simple fillable online form. There are no large text fields or page limits. If you are resubmitting an application that was not funded in previous competitions, you will be asked to provide a 2,100-character explanation of what

has been revised in response to peer reviewer feedback. You must also include a general audience abstract of up to 3,500 characters.

For a list of page/character limits in the main application, please see the answer to question number 31 in the FY 2017-2018 Bankhead-Coley and James and Esther King Frequently Asked Questions. You may access this document <u>here</u>.