



Questions and Answers from July 31, 2018 through August 17, 2018

**FY 2018-2019 Funding Opportunity Announcement (FOA)
James and Esther King Biomedical Research Program (King)
Bankhead-Coley Cancer Research Program (Bankhead-Coley)
Live Like Bella Pediatric Cancer Research Initiative (Bella)**

- 1. Are applicants bound to the other Key Personnel named in the letter of intent, or may they make changes to the list of Key Personnel in the application?**

You MAY make changes to the list of personnel in the main application. During the informational webinar conducted on 8/16/18, it was stated that changes to personnel would not be allowed between the LOI and the main application. This is not entirely correct. You will not be able to make changes to the original list of personnel that was submitted in the LOI, but you will be provided a space to list changes to personnel in the main application.

- 2. Are FL small business entities eligible? We are a recent academic spin-off located in Miami, and conducting clinical trials in the state.**

No, small business entities are not eligible to apply for funding as the lead institution. They can be listed on the application as a collaborating institution, but cannot be the lead.

- 3. I am hoping to compete for a James and Esther King Biomedical Research Program Award through the 'Discovery Science' mechanism.**

I am excited to submit a proposal, but from the guide I am unsure whether or not a Research Program focusing on an 'Infectious' driver of pulmonary/cardiovascular disease, the impact of tobacco use on outcomes, and developing novel strategies to mitigate the negative impacts of tobacco on the outcome of an infectious disease such as influenza fit the focus of your program.

Applications to the James and Esther King Biomedical Research Program must provide a clear explanation of how the project is related to tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease in their grant application. This will become part of the packet that is rated by peer reviewers. Each application is scored on the basis of scientific merit and the goodness of fit with program goals including a demonstrated connection of the research to cancer and tobacco-related disease. Program staff do not provide feedback on goodness of fit during the application process.

- 4. I have a question regarding out of state spending for the Bankhead-Coley mechanism. We typically work through our institution's molecular genomics core facility to conduct whole exome sequencing, a budget item to be proposed in our grant application. However, often, the core does not have the capacity or expertise to complete the work in the most cost-**

effective way, and they often contract with third parties (sometimes out of state) to complete the sequencing. Is it considered an outside service if we are still billed by our core?

Since you will be billed by your core facility, it will not be considered an outside service.

- 5. Section II.A. "Eligible Applicants" shows that the application is submitted by the institution and must identify a Corresponding Principal Investigator. Section II.D. "Duplicate Applications and Overlap Limits" shows that "Eligible applicants can submit one application to the LLB Initiative, one application to the BC program, and one application to the JK program." Is the applicant the institution? Or the institution-PI combination?**

Are multiple applications to the same funding program allowed by the same institution provided they each have a different corresponding PI and are for different projects? For example, could institution ABC submit an one application for Project 1 with PI: Dr. Smith under Bankhead Coley and also submit a second application for an unrelated Project 2 with PI: Dr. Doe under Bankhead-Coley?

Yes, multiple applications to the same funding program are allowed from the same institution provided they each have a different corresponding principal investigator and are for different projects.

- 6. Can you please clarify what information is needed for Section 2 and Section 3 of the LOI if the proposal was not previously submitted? Can I only apply if I have a previously submitted proposal?**

If you did not previously submit a proposal, then answer "no" to the first question in section 3. Question 2 in section 3 is only a required response if you answer "yes" to the first question in the section. We want to know what has changed if the proposal is a resubmission. That is why this section is there. Of course, you are eligible to apply if you have not submitted a proposal before. Please see page 17, "Duplicate Applications and Overlap Limits" for a detailed explanation.

Section 2 of the LOI is general information about your institution's sponsored research official. This is required information for all applications.

- 7. If an application focuses exclusively on leukemia or other blood cancers, but not one of the five cancers, would it qualify for this funding mechanism?**

Yes, you would still be eligible. In previous years, applicants had to demonstrate a connection to one of the five focus cancers listed in the FOA. This year, that language has changed to state on page 5 that, "Priority will be given to applications that address at least one of the following: lung cancer, breast cancer, prostate cancer, colon cancer, or melanoma." So, while priority is still given to applications that address the five focus cancers, other applications are still encouraged. In the case of leukemia and other blood cancers, these applications are emphasized in this FOA, so applications focusing on these cancers are of course eligible.

- 8. For the five cancers, does the FOA only apply to "Resistance to front-line treatments in recurrent disease", or applications that focus on the development of the 5 cancers will also qualify for this funding mechanism?**

The section you are referring to is listing certain types of research that we are trying to target in this funding cycle. This year, "Resistance to front-line treatments in recurrent disease in the five cancers listed" is one of the target areas, but anyone who applies for funding through the

Bankhead-Coley Cancer Research Program will have to choose one of the seven research priorities listed on pages 5 and 6 of the FOA. If you can make a compelling case for research into the development of the 5 cancers under one of the seven research priorities, please do so. Department staff do not provide feedback regarding which research priority or mechanism of support is most appropriate for any given project.

- 9. I tried to register the PI's email in the system, but it wouldn't allow me. I hit the forgot password link and the email sent to her said she doesn't have an account. I registered her name, but I used my email. Will that be an issue?**

The person who will be using the account should register using their own email address. We do not allow multiple users to access a single application, so your PI will have to register for herself using her own email address. All applicants to the James and Esther King Program, Bankhead-Coley Program, or Live Like Bella Initiative will need to register for new accounts for the FY 2018-2019 funding cycle. The Department is using a new intake system for the FY 2018-2019 funding cycle and

- 10. For the general audience abstract that is to be submitted with the LOI, does it need to be verbatim to the one submitted in the body of the grant? Nothing major will change, but she may wish to tweak the language a little.**

As stated in the intake system, the responses provided in the abstract and keywords section will automatically move forward and be included as part of the main application. You will not be able to edit this section after the LOI closes.

- 11. I have question regarding the correct date to submit the request for a letter from Tobacco Free Florida for the JEK grant. In one section of the FOA, it states 8/28/17, but I'm assuming that is outdated from last year? It later states 9/17/18. Can you confirm that the latter date is correct?**

Yes, you are right in assuming that 9/17/18 is the correct date. A correction has been posted to the program website to notify applicants.

- 12. Do character limits in the online application include spaces?**

Yes.

- 13. We will propose to perform translational science using clinical specimens collected from cancer patients undergoing therapy. A clinical trial will not be proposed or funded by the mechanism. Is this in scope with the Clinical Research mechanism? Alternatively should this be submitted to the Discovery Science section?**

Department staff will not provide feedback on which Research Priority or Mechanism of Support is the best fit for any given research proposal.

- 14. Please confirm hematologic malignancies are in scope with the grant.**

The Bankhead-Coley FOA states on page 4 that, "In order to balance the number of grants awarded across Research Priorities, this year the Department will prioritize applications that address the following: [. . .] Research focused on sarcomas, or leukemia and other blood cancers."

15. Does preliminary data within the grant, or the grant in its entirety, become publicly available? If so when?

If funded, the materials submitted in this grant application will become subject to public records laws. Applicants are discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. If the application contains information that the applicant believes constitutes trade secrets or proprietary information or is protected by a specific statutory exemption, it should be limited to the Research Project Plan section. The applicant must clearly identify the information with [brackets] and a footnote that specifies the law that makes the document or information exempt from the public records laws. If a public records request is made involving documents with declarations of confidentiality, the Department will notify the applicant so that he/she may defend the claim in circuit court. The Department of Health will not provide legal representation to assert a confidentiality claim when a public record request is made. Materials submitted with applications that are not funded during this funding cycle will not become subject to public records laws.

16. Although we have made significant improvements that align with reviewer comments on our resubmission, the content has changed and we are not sure whether this should be a new application or a resubmission. If we submit the LOI as a resubmission, will the review committee give us guidance as to how we should submit a future application or will they discard the LOI if they feel it is too different to be a resubmission?

There would be no penalty for submitting as a resubmission even if there have been significant changes to the content. It is the researcher's responsibility to decide whether to submit as a new application or a resubmission. All proposals undergo the same administrative and peer review process regardless of whether the proposal is new or a resubmission.

17. Can you provide guidance and specific instructions on what is required and should be included in a revised application?

Revised resubmissions include all the same components as our other applications. The only difference is that those who revise and resubmit are asked to indicate that their proposal is a resubmission and provide a brief description of how the proposed research differs from previously submitted version(s) of the proposal. You will see these questions in Section 3 of the LOI.

18. Will the new PeerNet intake system allow either: A. A Principal Investigator to add others to the application (to edit/upload documents; review at a central office); B. And/or allow a non-PI to create an application for a PI from an existing letter of intent?

No. Multiple users are not supported by the new PeerNet system and a non-PI cannot create an application for a PI from an existing letter of intent unless the PI shares his/her user credentials. This is not recommended, but it is a possible work around.

19. Both the Bankhead Coley and James & Ester King grant mechanisms state that "Applications for high-risk, high –reward, or highly innovative pilot projects will also be considered for funding at \$100,000/year for three years for Discovery Science, and \$150,000/year for five years for Clinical Research." Will these applications be reviewed based on the same criteria as a full/non-pilot application? For example, will less emphasis be placed on preliminary/previous work, and more on innovation and potential for a larger boost in science? If so, are there different areas in the pilot applications that should be emphasized?

All of the applications we receive go through the same peer review process. All applications receive an initial review by three individual peer reviewers. Those that score within the top 25-

30% in the initial round of review progress to the panel review stage where applications are assigned to panels of 6 to 15 reviewers discuss and score the applications. The score summaries for the applications that progressed to the panel stage are presented to our Biomedical Research Advisory Council. The Biomedical Research Advisory Council makes recommendations on funding based on the blinded results of peer-review. The BRAC will also consider other programmatic interests, such as the availability of funds, and Program goals and preferences to form a funding recommendation for the State Surgeon General.

- 20. How much importance is placed on collaborations with other Florida institutions? Although it is clear that collaboration is a bonus, is it helpful to collaborate with more than 1 institution? Also, aside from Florida collaborations, is there a downside or de-emphasis on collaboration with non-Florida institutions (assuming the that PI is at a Florida institution).**

It is difficult to quantify this. There is a section in the application where applicants are asked to describe the facilities and other resources that will be available for the research. Peer reviewers are asked to score the institutional support, equipment, and other physical resources available and how they would contribute to the success of the project. One of the main goals of these grant programs is to expand cancer research capacity in Florida, so building up a network of collaborations in the state is always of interest. You are not barred from including collaborators from institutions outside of Florida, but you would be limited in how much of your budget could go to out-of-state collaborations. You are allowed to use up to 10% of your grant budget for out of state expenses. If funded, the Department must approve any budgeted out-of-state contracts.

- 21. For the J&E King applications, the description for the priority area of screening specifies: "Improve screening accuracy, detection of high risk subgroups, and/or improved implementation of a cancer screening program that results in an increase in early detection or prevention". Would an application to develop and assess an intervention to improve decision making about lung cancer screening and increase adherence to screening over time fit within this description?**

Department staff will not provide feedback on which Research Priority or Mechanism of Support is the best fit for any given research proposal.

- 22. Can resubmission be submitted as a new application rather than a resubmission? This would be a first resubmission and there would be changes to the application. The initial application was highly scored by the primary reviewers (score under 2.5) but scored 3.5 on panel review with no feedback from panel review that would help to improve the application for resubmission. Would there be any benefit to resubmit rather than submit as new? As new application, would it be ok to change from one program to another (e.g. BC to JEK if priorities in that program this year are different and may favor this application)?**

Yes, you can resubmit as a new application. There would be no advantage one way or another in applying as a resubmission or as a new application. All applications, regardless of whether they were resubmissions, are subject to the same level of scrutiny during the peer review process. The only difference is that you are given the opportunity to address peer reviewer feedback and explain what has changed in your resubmission if you decide to apply as a resubmission. If you wish to use an unfunded BC application from a previous year, you can change it to JEK if you think it is a better fit. Please keep in mind the duplicate applications and overlap limits found in the FOA.

- 23. I am planning to submit an LOI followed by a proposal in response to the Bankhead-Coley FOA. I am confused about the priority areas that are listed in the FOA. On page 4 (appended below), it appears that one of the priority areas just for this year is sarcomas and blood cancers. Yet, on page 5, the FOA also states (appended below) that priority will be given to applications addressing lung, breast, prostate, colon cancers and melanomas. My proposal aims to develop a new cancer therapy that could target blood cancers or non-hematologic cancers (of breast, lung, etc) depending on how the proposed therapeutic is engineered. Should I be tailoring my proposal towards hematologic or non-hematologic cancers?**

Page 4: In order to balance the number of grants awarded across Research Priorities, this year the Department will prioritize applications that address the following:

- 4. Research focused on sarcomas, or leukemia and other blood cancers.**

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.

You may apply for funding for hematologic or non-hematologic cancers. In previous years, the Bankhead-Coley FOA contained the following language: "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." This year, the FOA is opened up to other cancers as well, so the language has been changed to say, "Priority will be given to applications that address at least one of the following: lung cancer, breast cancer, prostate cancer, colon cancer, or melanoma." These cancers (as well as sarcomas, leukemia, and other blood cancers) are receiving priority in this year's application cycle, but research covering other cancers will not be disqualified.

- 24. The JEK call states that:**

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. Prevention and treatment research evaluating programs for tobacco use reduction and prevention.**

Does it mean that the department will potentially fund grants that scored lower but address these priorities? How is it determined which applications address these areas? Is there a box to check in the application system?

All applications receive an initial review by three individual peer reviewers. Those that score within the top 25-30% in the initial round of review progress to the panel review stage where applications are assigned to panels of 6 to 15 reviewers discuss and score the applications. The score summaries for the applications that progressed to the panel stage are presented to our Biomedical Research Advisory Council. The Biomedical Research Advisory Council makes recommendations on funding based on the blinded results of peer-review. The BRAC will also consider other programmatic interests, such as the availability of funds, and Program goals and preferences to form a funding recommendation for the State Surgeon General. The priorities stated in the FOA will inform their decisions in preparing a funding recommendation.

- 25. I would like to put my application under high risk, high-reward category or highly innovative projects (funding at \$100,000/year for three years for discovery science). Will the previous page limitations you mentioned apply to this category as well or any changes to the criteria for this program.**

The same page limitations will apply. All applications will be peer reviewed using the same criteria. All applications receive an initial review by three individual peer reviewers. Those that score within the top 25-30% in the initial round of review progress to the panel review stage

where applications are assigned to panels of 6 to 15 reviewers discuss and score the applications. The score summaries for the applications that progressed to the panel stage are presented to our Biomedical Research Advisory Council. The Biomedical Research Advisory Council makes recommendations on funding based on the blinded results of peer-review. The BRAC will also consider other programmatic interests, such as the availability of funds, and Program goals and preferences to form a funding recommendation for the State Surgeon General. The priorities stated in the FOA will inform their decisions in preparing a funding recommendation.

- 26. The application I am submitting is a revised version of an R01 submitted to NIH and reviewed and scored, but wasn't at or below 16%tile (received 21%tile) so not eligible for bridge funding. Is it necessary to include the information that a version of this application was previously reviewed by NIH? And if yes, should I include summary statement and detail how I responded to the criticisms? The application will also differ from the NIH submission in focus (more emphasis on smoking/carcinogen-caused cancer) and size (due to different budget size/length of time).**

If you are not applying for a Bridge grant then it is not necessary to say that it was submitted to NIH as an application for federal level funding. This information is only necessary for Bridge grant applications and will not be reviewed if submitted in connection with applications for other funding mechanisms.

- 27. This application proposes analysis of already collected patient tumors and patient/tumor information. Personnel listed as collaborators on the application collected this tissue using a Mayo IRB, but I am not on the IRB protocol. The tissue will not be collected specifically for my proposed studies. I and my staff will analyze tissue by IHC and DE-IDENTIFIED patient/tumor data for correlation with IHC data. I and my staff will not have access to the patient identifiers. In the case of NIH, this study would be considered "no human subjects" as described by "exemption 4". I assume this is also the case for the Florida research grants (King and Bankhead-Coley), in which case I will say "no human subjects". Is this correct? If it is considered "human subjects research" what process do I take to describe this research properly for the application, and fulfill the requirements for the Florida research funding, given that the tissues and information have already been collected?**

If human subjects will be used at any time during the research, you should respond "yes" to the prompt in the main application which says, "If activities involving human subjects are planned at any time during the proposed project at any site, check 'Yes'. Check 'Yes', even if the proposed project is exempt from Regulations for the Protection of Human Subjects. Otherwise, check 'No'." Even if you believe your research is exempt, you should answer "yes". The human subjects section of the main application includes questions regarding the use of and protections for human subjects. Peer reviewers provide feedback on the use of and protections for human subjects in the peer review comments. You may also explain in this space that you are not on the IRB protocol, but that your collaborators who will be collecting the tissue are on the protocol.

Questions Submitted during the August 16, 2018 Informational Webinar

- 1. Do you fund research areas other than those related to cancer?**

While the Bankhead-Coley program and the Live Like Bella initiative focus solely on Cancer, the James and Esther King Program funds research into both cancer and tobacco-related disease. DOH also awards grants for Alzheimer's research through the Ed and Ethel Moore Alzheimer's Disease Research Program. We will have another informational webinar for the Ed and Ethel Moore grants in the near future.

2. Is there a research application template for FL-DOH Bankhead Coley research grant?

There is no template. The online system includes instructions for each section of the application and all application components are outlined in the FOA.

3. Do you use NIH-templates?

We use the NIH template for biosketches. We do not use any other NIH templates.

4. Where do we get information on page limit etc.? Page 27 of 57 (Bankhead FOA) has font size but not page limit etc.

Please see the document titled, "Frequently Asked Questions: FY 2018-2019 Funding Opportunity Announcement (FOA)," on our program website at <http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/colelyfoa.html>. Question number 32 on page seven of the document contains a full list of page and character limits for each section of the application.

5. Where could we find a list of funded grants from the past?

<http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/list-of-active-research-projects/index.html>

6. Could you please elaborate more on the second round of review? How are the reviewers selected? Are they the initial reviewers?

Peer reviewers in the second round of peer review were reviewers in the initial round of review. Peer reviewers are selected from a pool of highly qualified experts and are paired with applications that fit with their area of expertise. Our peer review vendor (Oak Ridge Associated Universities) completes the recruitment and assignment of peer reviewers based upon the LOI submissions. All peer reviewers are located outside the state of Florida and sign conflict of interest forms to ensure the integrity of the peer review process.

7. For resubmissions, are the reviews of the original application sent to the reviewers along with the resubmitted application?

This is not part of our review process at this time. Resubmissions are subject to the same level of scrutiny as new submissions.

8. During the panel review are all applications reviewed and scored together by all reviewers of the select 25-30% of grants or only by the reviewers that specialize in the field of application?

After the Biomedical Research Advisory Council determines the percent of applications that will progress to the panel stage, our peer review vendor creates panels based upon the subject areas represented in these applications. The panels are made up of reviewers who participated in the initial round of review.

9. Can you provide guidance and specific instructions on what is required and should be included in a revised application?

Revised applications contain all the components present in new applications. The only difference is that revised applications contain a brief section where the Corresponding Principal Investigator responds to prior reviewer comments and explains how the resubmitted application differs from the previously submitted version of the application.

10. Will the new PeerNet intake system allow either: (1) A Principal Investigator to add others to the application (to edit/upload documents; review at central office); or (2) a non-PI to create an application for a PI from an existing letter of intent?

No, the current PeerNet system does not support adding multiple users to a single application. We encourage the PI to act as the primary user and complete the application for him/herself.

11. Where might I find the character limitation information for grant sections?

Please see the document titled, "Frequently Asked Questions: FY 2018-2019 Funding Opportunity Announcement (FOA)," on our program website at <http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/coleyfoa.html>. Question number 32 on page seven of the document contains a full list of page and character limits for each section of the application.

12. What is the link for frequently asked questions?

<http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/coleyfoa.html>

13. What is the definition of buying the cards in "Bulk: I may need 20-30 cards per, month can I buy that amount once a month?"

Yes, that is acceptable. We want to ensure that there is no stockpile of gift cards that is built up over time. If you will use 20-30 cards per month, please purchase what you will need.

14. Character counts with or without spaces?

Character counts include spaces.

15. Are consultants considered key personnel?

Key personnel are defined as, and should be limited to, individuals who contribute to the scientific development or execution of the project in a substantive way, whether or not salaries are requested. If the consultant will be contributing to the scientific development/execution of the project, then they would be considered key personnel.

16. In the research project/plan section-does the 68,000-character reference for the "research strategy"- Does that apply to significance, innovation, and approach portions only? Are the citations and bibliography included here for the character count?

The 68,000-character reference for the "research strategy" is for the sections where the applicant describes the significance, innovation, and approach of their project. The bibliography is an upload field with no page or character limit.

17. For the personnel section of the LOI do you mean only key personnel? Also, is the personnel not editable in the application. The instructions in the portal of the LOI said this section cannot be edited.

You MAY make changes to the list of personnel in the main application. During the informational webinar conducted on 8/16/18, it was stated that changes to personnel would not be allowed between the LOI and the main application. This is not entirely correct. You will not be able to make changes to the original list of personnel that was submitted in the LOI, but you will be provided a space to list changes to personnel in the main application.