Addendum #3 to RFA 67-49

Collaborative Research on Health Care Innovation or Traumatic Brain Injury

This addendum is to provide answers to all questions per the RFA Potential Applicant letter.

1. Question: I believe you have a typo in your notification. Your letter states "Your application must arrive in the designated room at the following address no later than 2:30 p.m. on May 25, 2017." This should say May 25, 2016, correct?

   Answer: Applications must arrive in the designated room at the address designated in the cover letter no later than 2:30 p.m. on May 25, 2016. The due date for applications in the cover letter was corrected in Addendum 1 to the RFA.

2. Question: The due date for the full application is indicated as May 25, 2017. I assume it should be May 25, 2016.

   Answer: Refer to Question 1 regarding the due date for applications.

3. Question: I am interested in putting together an application for this RFA but I am confused with the due dates. In the pdf it said that the application is due May 25, 2017 with a start date of January 1, 2017. Please clarify.

   Answer: Refer to Question 1 regarding the due date for applications. The start (effective) date of the grants is January 1, 2017, as stated in section A.8 on page 7 in Part One of the RFA.

4. Question: The e-mail regarding the collaborative health research RFA indicates a Letter of Intent deadline of May 16, 2016; a full application deadline of May 25, 2017 and the Effective Date of the grant being January 1, 2017. Is the full application deadline correct?

   Answer: Refer to Question 1 regarding the due date for the application.

5. Question: The new nonformula RFA says, "An organization may submit only one application as a lead agency in response to this RFA for a collaborative research project on health care innovation or traumatic brain injury." (Underlining is mine.) Given the "or," my interpretation is that we can be lead on only one application that addresses one of the two priorities. We cannot submit an application for TBI and another application for health care innovation. Can you confirm that my reading is correct?

   Answer: This question refers to the first sentence in paragraph 3 in Section A.2 of Part One of the RFA. Addendum 2 to the RFA amended this sentence to read: "An organization may submit only one application as a lead agency in response to this RFA for a collaborative research project on health care innovation and only one application, as a lead agency, for a collaborative research project on traumatic brain injury."

6. Question: I want to clarify the guidelines regarding the number of submissions permitted per institution. Paragraph 3 under Part One A.2 "Who May Apply" states: "An organization may submit only one application as a lead agency in response to this RFA for a collaborative research project on health care innovation or traumatic brain injury. There is no limit to the number of applications in which an organization is listed as a collaborating organization." Are we correct that the "only one application as a lead agency" pertains to each topic? In other words, is my organization allowed to submit one proposal as a

lead for each of the two research priorities included in the RFA: one for Collaborative Research on Health Care Innovation and one for Traumatic Brain Injury. Is that correct?

Answer: Refer to Question 5.

7. Question: Is an organization able to submit one application for each priority? A.2 of the RFA states, "An organization may submit only one application as a lead agency in response to this RFA for a collaborative research project on health care innovation or traumatic brain injury."

   Answer: Refer to Question 5.

8. Question: I am writing to clarify the guidelines regarding the number of submissions permitted per institution. It is our understanding that we are allowed to submit one proposal as the lead for each of the two research priorities on the RFA: one for Collaborative Research on Health Care Innovation and one for Traumatic Brain Injury. Is that correct?

   Answer: Refer to Question 5.

9. Question: I am writing in regard to RFA 67-49 Collaborative Research on Health Care Innovation or Traumatic Brian Injury. Can one of the two major research institutions be outside of PA? We have a possible collaboration between a medium-sized university and one of the major local health systems, but the ideal third collaborative institution is outside of PA.

   Answer: No. As stated in Section A.2 on page 3 in Part One of the RFA, "The applicant and all collaborating organizations (which have a meaningful and substantive role in the research project) must be located in Pennsylvania." An organization is considered to be located in Pennsylvania if it is registered with the Pennsylvania Department of State to do business in Pennsylvania.

10. Question: We have received an invitation to submit an application for the Health Care Innovation/Traumatic Brain Injury RFA67-49. We would be grateful if you could clarify whether the grant application must be submitted by an organization that received the invitation to apply (in this case organization X), or whether the application is open to any Pennsylvania research organization (such as organization Y, organization Z, etc.) that meets the eligibility requirements outlined in the RFA.

    Answer: The Health Research Program e-mailed the RFA to entities on its RFA e-mailing list consisting of more than 1,000 contacts in order to encourage all eligible applicants with capability in health care innovation research or traumatic brain injury research to apply for the funds. Any entity or person that meets the eligibility requirements specified in Section A.2 on page 1 in Part One of the RFA may apply for the funds regardless of the method by which the entity or person becomes aware of the RFA.

11. Question: Is it possible to get some idea of the approximate amount of money that could be available for each project, as that would greatly help in planning an application that involves collaborative work among several different institutions? Alternatively, is it possible to share the total amount of money available and the number of grants that will be awarded? Any guidance along these lines would be extremely helpful in planning a realistic application.

    Answer: As stated in section A.1 on page 1 in Part One of the RFA, "The Department has between $10 and $11 million to fund collaborative research projects that are consistent with the research priorities listed in the Preface. The Department expects to award three grants, and expects awards not to exceed $4 million."

12. Question: I just wanted to clarify whether any Pennsylvania organization that meets the eligibility requirements can apply for this RFA, or whether application is only by invitation. In other words could organization X and/or organization Y apply for these funds instead of – or in addition to – organization Z?

    Answer: Any entity or person that meets the eligibility requirements specified in Section A.2 on page 1 in Part One of the RFA may apply.

13. Question: Have you determined how the money will be divided?

    Answer: No.

14. Question: The new RFA67-49 says, "An organization may submit only one application as a lead agency in response to this RFA for a collaborative research project on health care innovation or traumatic brain injury." (Underlining is mine.) Given the "or," is the correct interpretation that our organization can be lead on only one application that addresses one of the two priorities? We cannot be the lead on an application for TBI and be the lead on another application for health care innovation—we must choose one, correct?

    Answer: Refer to Question 5.

15. Question: How long will it take before answers to the questions posed at the pre-application conference on 2 May are posted at www.emarketplace.state.pa.us?

    Answer: May 9th

16. Question: This question consists of two parts. On pages 1-2 of RFA67-49 under Who May Apply it states: "Although one applicant must be designated on the application as the lead agency, the collaborative research project must consist of at least two organizations that have joined together for the purpose of this RFA to conduct research on the research priority listed in the preface of this RFA…At least two of the collaborators must be major research institutions which are located in Pennsylvania."

    (16a) Could you please advise as to the criteria for designating an organization as a "major research institution"?

    Answer: The requirement that two of the collaborators be major research institutions is based on guidance contained in the research priorities. On pages v and vi in the Preface to the RFA, the research priorities for health care innovation and traumatic brain injury contain the statement: "At least two of the collaborators must be major research institutions." All research proposals must be consistent with the research priorities. The Department will not define what is considered to be a major research institution. The peer reviewers, who will review and rank the proposals, will determine the extent to which proposals are consistent with all of the guidance and requirements contained in the research priorities.

    (16b) Center X, a nonprofit research organization, housed within Division Y, is interested in submitting a response to this RFA with University Z (a separate institution) as a collaborator, but we are not sure if the Center meets the criteria for a major research institution.

    Answer: Refer to the answer to the previous question.

17. Question: Are state government agencies eligible to apply for RFA67-49

    Answer: No, in accordance with Act 2001-77, the Tobacco Settlement Act, which authorizes funding for the health research program, state governmental agencies are not eligible to apply for health research funds.

18. Question: The proposal due date is listed as May 25, 2017. Should this be May 25, 2016? It looks like the effective date for the grant will be January 1, 2017.

    Answer: Refer to Question 3.

19. Question: For TBI, how are the evaluation criteria scored?

    Answer: According to Section B.2 in Part One of the RFA, "Each application will be evaluated individually against the following criteria: scientific and technical merit on the basis of scientific need, scientific method, research design, adequacy of the facility and qualifications of the research personnel." Each application will receive an overall score based on all of the criteria considered together. Scores are not assigned separately to each criterion.

20. Question: We are a diagnostic company, with strong TBI collaborations with clinicians. How do we best identify additional collaborators, e.g., in neurodegenerative disorders?

    Answer: The list of persons who attended this pre-application conference and their contact information is included after Question 51.

21. Question: Do you anticipate 2 of the 3 awards in TBI or in the other topic ("healthcare innovation")?

    Answer: The Department expects to fund three applications, but cannot predict how many will be selected for traumatic brain injury or for health care innovation.

22. Question: Would you consider supporting a project that aims to assess the cost-effectiveness of an alternative model of service by paying for that alternative model within the confines of the project?

    Answer: The Department cannot answer whether a particular research is consistent with the research priorities as stated on pages iv-vi in the Preface to the RFA. The peer reviewers, who will review and rank the proposals, will make the determination as part of the evaluation process, as described on page 7 in Part One of the RFA. However, you may submit the proposal for consideration.

23. Question: Just to clarify, may an institution submit one application for each research priority? (one application for health care innovation and one for TBI?)

    Answer: Yes. Refer to question 5.

24. Question: Would you please provide any specific requirements around minority partnerships and student training?

    Answer: On pages v and vi in the Preface to the RFA, the research priorities contain the following statement regarding minority partnerships: "Collaboration with a minority-serving academic institution or a minority-serving community-based organization in Pennsylvania is strongly encouraged, and should include the mentoring and training of students." All research proposals must be consistent with the research priorities. The peer reviewers, who will review and rank the proposals, will determine the extent to which proposals are consistent with all of the guidance and requirements contained in the research priorities.

    Item A.3.c on pages 3-4 in Part One of the RFA describes the requirements for minority student training. The Department will not elaborate further on the minority student training requirements.

25. Question: There is a focus on rural populations in the RFA. How is rural defined?

Answer: This question refers to the following statement contained in the research priorities: "The research should hold the potential for addressing the health needs of underserved segments of the population, including rural, urban, racial/ethnic minorities, or older adults and other high risk Commonwealth populations." If the application addresses the health needs of a rural population, the application should include a definition of "rural" and an explanation of how the targeted population meets the definition. The peer reviewers, who will review and rank the proposals, will determine the extent to which proposals are consistent with all of the guidance and requirements contained in the research priorities.

26. Question: If our budget varies year to year because of phased aims, how should that be handled on the budget forms, which appear to only ask for one budget?

    Answer: Only one budget may be submitted. The budget must include all proposed expenditures for the duration of the grant. The applicant must determine the grant period, which may not exceed 48 months. The applicants must determine the best method for producing one budget for entire grant period.

27. Question: Can the minority serving academic institution refer to a secondary school (e.g., high school) or does it only mean a collegiate institution?

    Answer: The minority students to be trained must be college students as specified in Section A.3.c on page 3 in Part One of the RFA. The requirements for minority training must be achieved by one of three ways as explained on page 3 in Part One of the RFA.

28. Question: Will the salary cap increase to match the 2016 NIH salary cap of $183,300?

    Answer: No. As stated on page 6 in Part One of the RFA, "For the duration of the Grant Agreement, hourly rates and fringe benefit rates for all personnel except union-covered positions cannot be increased above the rates specified in the Grant Agreement. Hourly rates and fringe benefit rates may be increased only for union-covered positions and only when those increases are negotiated as part of an approved collective bargaining unit agreement that was put into place after the Grant Agreement was approved."

29. Question: Is the NIH Biosketch (5 page limit) acceptable?

    Answer: The NIH biosketch format is acceptable, but the biosketch should not exceed four pages as stated in Item XV of Appendix A, Attachment 2.

30. Question: Can IRB approval be submitted after award and before starting the project?

    Answer: IRB approval is not required at the time the application is submitted to the Department. However, all research involving human subjects must be approved by the applicant's IRB *prior to the initiation of the research involving human subjects and prior to the use of grant funds* to pay for research involving human subjects, as stated in item i on page 16 in Part One of the RFA.

31. Question: Are hypotheses required for each specific aim?

    Answer: No. If hypotheses are not appropriate for a specific aim, they should not be included.

32. Question: Are biosketches required to be formatted using the most recent guidelines from NIH?

    Answer: No. Applicants must provide the information requested in Item XV of Appendix A, Attachment 3. As stated in Item XV, "There is no required format for providing the information. NIH grant application biosketches are compatible with the required information and may be used."

33. Question: Do we need to complete any of the information regarding IRB submission prior to receipt of award?

    Answer: If the research project involves human subjects and has not been approved or exempted from review by applicant's IRB, Appendix D, Attachment 4 should not be submitted when the application is submitted to the Department. The Department will award funds regardless of the status of the submittal of this form. However, if the research involves human subjects, the applicant must obtain approval of the research from the applicant's IRB and submit to the Department Appendix D, Attachment 4 and documentation of the applicant's IRB approval *prior to the initiation of the research involving human subjects and prior to the use of grant funds* to pay for research involving human subjects.

    Also, item XVIII of Appendix A, Attachment 3, which must be submitted as part of the grant application, requires detailed information on how the applicant will protect human subjects during the research project.

34. Question: If a proposal includes money in the budget to create new or further develop existing health information technology, would this budget item be considered "infrastructure"?

    Answer: No. Refer to the definition of infrastructure on page 5 in Part One of the RFA.

35. Question: Is there a page limit for letters of support?

    Answer: No

36. Question: Can a single letter of support be submitted to represent all collaborating entities within a larger organization? For example, one letter from research institute X for all 3 departments that are in the research institute?

    Answer: The lead applicant is the legal entity that will receive all grant funds and be responsible for the fiscal aspects and all other aspects of this grant (Section A.2 in Part One of the RFA) . Collaborating organizations must be separate institutions and should be included in the budget as subcontractors. If institute X is the lead applicant, letters of support from departments that are part of institute X are not required and should not be submitted. If institute X is a collaborating organization, only one letter of support is required from institute X and should be submitted. A letter of support is required for subcontractors and consultants, as explained in items XXI and XXII of Appendix A, Attachment 3.

37. Question: Are there any restrictions on percentage of budget for consultant time?

    Answer: No, however all budget items must be adequately justified in item XIV of Appendix A, Attachment 3.

38. Question: Any restriction on participation of entities or consultants outside of PA?

    Answer: The out-of-state restrictions are specified in detail in Section A.2 in Part One of the RFA.

39. Question: If you have the answers to the questions before May 9, will you post them sooner?

    Answer: Yes

40. Question: Is it possible, based on peer review, that all projects awarded will be within one of the two priorities?

    Answer: Yes

41. Question: The RFA states that multiple PI's are acceptable. May the multiple PI's be from the same institution?

    Answer: Yes.

42. Question: Is a hypothesis required for all RESEARCH aims (i.e., aims other than the minority training aim)?

    Answer: Refer to Question 31.

43. Question: Regarding the budget, what is the indirect rate?

    Answer: As stated on page 5 in Part One of the RFA, "Indirect costs must not be charged against items in Categories II and III of the budget (Consultant and Subcontract Services). A subcontractor also must not charge indirect costs against items in Categories II and III. The Department does not specify which budget categories can be included in indirect costs. The indirect costs specified in Appendix C - Budget must not be greater than 20 percent of the sum of total direct costs less Categories II and III of the budget (Consultant and Subcontract Services) costs. Indirect costs must be supported by a uniform method to equitably allocate and distribute indirect costs across all projects. The applicant must be able to support the indirect cost rate with an allocation plan if requested. The indirect cost rate cannot be increased at any time for the duration of the Grant Agreement."

44. Question: What about annual directs?

    Answer: The RFA requires submission of one budget for the entire grant period. The indirect cost rate cannot be increased at any time for the duration of the Grant Agreement.

45. Question: What types of FTEs can it support?

    Answer: Limitations on Use of Funds including any requirements related to personnel are specified in Section A.4 in Part One of the RFA. All positions must be adequately justified in item XIV of Appendix A, Attachment 3.

46. Question: Any restrictions on how money can be used?

    Answer: Yes. Refer to Section A.4 in Part One of the RFA.

47. Question: To evaluate cost-effectiveness of a new service delivery model, we would like to ask the state to alter its current coverage position/policy. Would this be feasible?

    Answer: The Health Research Office, which is administering the nonformula funds and the award of grants in response to this RFA, cannot answer this question. This question must be directed to the various state offices and agencies or federal agencies or both state and federal agencies which have the authority to alter current policy. As specified on page 13 of Appendix A, Attachment 3, the research plan should describe new methodologies, prior research, and preliminary studies, and pilot studies that have been conducted to test and refine methods proposed in the application.

48. Question: How were the grant topics originally selected and formulate?

    Answer: The Department of Health established the research priorities in conjunction with the Health Research Advisory Committee in accordance with the requirements in Act 2001-77.

49. Question: Should biosketches include other support?

    Answer: Yes

50. Question: Is hand delivery suggested?

    Answer: The Department does not recommend any particular delivery method. Applicants should choose whichever method provides for submittal of the application by 2:30 p.m. on May 25, 2016 at the address listed in the cover letter to the RFA. Late applications will not be accepted regardless of the reason.

51. Question: How are expert reviewers identified?

    Answer: Peer reviewers must meet the requirements of the Tobacco Settlement Act, Act 2001-77, i.e., they must be nationally recognized physicians, scientists or researchers from the same or similar discipline as the research grant proposal under review. They will be selected from outside of Pennsylvania to minimize the potential for conflict of interest. There will be at least two separate peer review panels, one for traumatic brain injury and one for health care innovation. For the traumatic brain injury panel, the reviewers will be experts on traumatic brain injury research. For the health care innovation panel, the reviewers will be experts on health care innovation research.

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