

National, State, and Local Engagement Partner Funding Opportunity (OT2) Q&A

- 1. Q: May applications include more than one PI from one organization?
 - A: Yes, but one of these PIs must be listed as the contact PI.
- 2. Q: Is the 25-page limit for each category?
 - A: No, the page limit for the application is 25. A one-page cover letter is allowed and will not count against the 25-page limit. Details on this requirement are provided in the "Required Application Instructions" section.
- 3. Q: May we use charts/graphs?
 - A: Charts/graphs may be utilized in the application submission. The total application submission must not exceed the stated 25-page limit. Appendices are not permitted.
- 4. Q: Will you provide the names of the incumbents?
 - A: All of our current award partners are listed on our <u>website</u>.
- 5. Q: Are senior managers allowed to bill up to the max salary level on direct cost and also have income from G&A for their management responsibilities of the organization?
 - A: Salary support requested must be compliant with the NIH Salary Cap.
- 6. Q: Is this funding opportunity aiming to expand the existing group of National Community Engagement Partners (NCEP) **OR** if this is a different/new group of awardees separate from NCEPs?
 - A: Current awards under the OT-PM-17-002 funding opportunity expires on June 30, 2021. Any interested applicants, including current engagement partners must submit an application for this OTA-20-009 funding opportunity to be considered.
- 7. Q: In the FOA OTA-20-009 we are encouraged to partner in our submissions. If we do so, are we allowed to ask for up to \$1.5 million per applying partner or is that the total for the whole partnership?
 - A: The whole partnership may submit only one application. The total budget should not exceed \$1.5 million per year in direct costs.
- 8. Q: Are existing awardees, subawardees, and champions eligible for this opportunity?
 - A: Yes, any applicant that meets the eligibility requirements outlined in the Funding Opportunity is eligible for this opportunity.

- 9. Q: Will the awardees for this opportunity be selected by regions in the US?A: No, it is not based on regions.
- 10. Q: How will the activities of this awardee differ from the current Engagement and Retention Innovators, and the Community Engagement Partners?
 - A: These different awards aim to achieve different goals and objectives. Please reference the funding opportunity announcements provided in the FO.
- 11. Q: How are the activities across all four related funding notices coordinated (to avoid redundancy and share best practices)? Is NIH the overall coordinator or is that another funded entity?
 - A: NIH has the overall oversight to ensure redundancy and share best practices when applicable.
- 12. Q: What are the current lessons learned (successes and failures) in engagement and retention?
 - A: Each awardee are the experts and inform the program in ways to engage their respective communities. The selected awardees will share the concerns of their communities with the program, which will help us develop ways to overcome communities' distrust of the research enterprise, and to assist people in making informed decisions about participation.
- 13. Q: How is NIH defining a "Small Business" for this funding opportunity?
 - A: Generally, NIH defines a "Small Business" as the following: https://sbir.nih.gov/about/eligibility-criteria. For the purpose of this FOA, no special consideration will be given to small businesses.
- 14. Q: Is there an associated NAICS code or other size standard?
 - A: Currently there is no NAICS code and it's not required to submit an application. If this changes or if additional information is needed, we will reach out to you.
- 15. Q: Are there any formatting guidelines NIH expects offerors to follow for the Technical Approach, Past Performance, Key Personnel, or Cost Proposal, outside of the identified page limits for each?
 - A: No, there are no formatting guidelines.
- 16. Q: Is NIH looking for specific past performance references or more of a general narrative on the organization's experience providing these services?
 - A: Applicants should provide relevant past performance. Each applicant should be an expert and experienced organization with a proven track record in similar work that can assist the program in some or all tasks and subtasks in this funding opportunity. Programmatic priority will be given to proposals and teams capable of supporting multiple components.

- 17. Q: Does NIH require resumes to be submitted for proposed Key Personnel?
 - A: Resumes are not required. Applicants should provide brief biosketches of key personnel.
- 18. Q: We are considering submitting a fixed price application. We do not have a NICRA or any other reviewed indirect rates.
 - A: An indirect cost rate agreement isn't necessary to apply for this Funding Opportunity. If you request an indirect cost reimbursement, NIH will review your request and will respond to it accordingly. Any indirect costs that are not including in the application, should be clearly identifiable.
- 19. Q: When you state that there is \$1.5 million per awardee per year available for "applicant direct costs," does that mean that a fixed price application may not exceed \$1.5 million per year?
 - A: Yes, a fixed price application could exceed the \$1.5 million, however there should be a clear breakdown. If the direct costs exceed the \$1.5 million direct cost cap, the application will be considered nonresponsive to the FOA.
 - a. Q: Would the total reimbursement for a cost type applicant be \$1.5 million per year as well?
 - A: See response above. We do not have any examples to share at this time.
 - b. Q: Can you please provide more detail, or an example, of a compliant cost proposal?
 - A: As mentioned, we are considering providing a fixed price application. We can show fixed price by milestone but are not sure what "cost allocated" would mean for a fixed price proposal.
 - You may submit a fixed price application and you may show the fixed price by milestones; however, there should be a clear breakdown of the direct/indirect costs that are being requested. The fixed price by milestone approach will still be subject to the \$1.5 million direct cost cap.
- 20. Q: Is the "wearables" portion mandatory? We work with a network of underrepresented patients, however, most of them do not have access to Fitbit, etc.
 - A: No, the wearable portion is not mandatory.
- 21. Q: Our high school research program includes RNAseq analysis. Would there be RNAseq data included in addition to DNAseq?
 - A: *All of Us* Research Program will be doing RNAseq, but the data will not be generated until at least 2022.
- 22. Q: Can a funded HPO submit in partnership with other community organizations?
 - A: Yes. Any applicant that meets the eligibility requirements outlined in the Funding Opportunity is eligible for this opportunity.

- 23. Q: Is there contact information to follow up after the webinar?
 - A: Please send your questions to <u>AllofUsFOAInquiries@nih.gov</u>.
- 24. Q: Can you please talk more about your vision for the research work participants would be expected to bring to the table?
 - A: When a participant decides to join *All of Us*, the participant will be asked to share different kinds of information over time. Please see the <u>FAQ page</u> on our website for more information.
- 25. Q: Other than being "engaged" what specifically are you asking from: 1) individual participants and 2) organizations that might help enroll participants?
 - A: Please see the answer to questions 24 for what the *All of Us* is asking from our participants.
 - In reference to how community partners under this award might help in the enrollment efforts, the NIH solicits proposals from organizations to serve as engagement partners for the *All of Us* Research Program. To ensure that the *All of Us* data reflects the diversity of the country, the program needs to mobilize and collaborate with trusted organizations, intermediaries, and influencers to engage and facilitate enrollment and retention of UBR communities.
- 26. Q: What will participating individuals and organizations actually do? What's in it for them?

A: Volunteers who are interested in joining the program can visit the program's enrollment website: https://www.joinallofus.org.

The NIH solicits proposals from organizations to serve as engagement partners for the *All of Us* Research Program. To ensure that the *All of Us* data reflects the diversity of the country, the program needs to mobilize and collaborate with trusted organizations, intermediaries, and influencers to engage and facilitate enrollment and retention of communities who are underrepresented in biomedical research. The *All of Us* Research Program is not medical treatment. You will not get direct medical benefit from taking part in the *All of Us* Research Program. That said, you may indirectly benefit from taking part in the *All of Us* Research Program. For example, we will give you ways to see the information you share with us and the information we learn about you. This information may be interesting to you. You may learn about your health. If you choose, you will be able to share your *All of Us* Research Program information with your health care team. You will have the option to learn about additional research opportunities. Finally, you will be helping researchers make discoveries that may help future generations.

- 27. Q: Do you want us to propose recruitment in diverse populations by our team at several sites and would you have a target recruitment target? Or do we simply propose the piloting of methods and design of methods and tools?
 - A: It is up to the applicants to decide how to best meet the requirements. Each applicant should be an expert and from experienced organizations with a proven track record in some or all tasks and subtasks in this FO. Please refer to the FO for details.
- 28. Q: Page 6 of the FOA notes that "Each applicant should be expert and experienced organizations with a proven track record in similar work that can assist us in some or all tasks and sub-tasks in this FO. Programmatic priority will be given to proposals and teams capable of supporting multiple components". Please confirm that applicants may respond to specific tasks in their application or must applicants address all tasks?
 - A: Each applicant may respond to specific tasks in their application. Each applicant should be an expert and from experienced organizations with a proven track record in some or all tasks and subtasks in this FO.
- 29. Q: If an organization is a partner on one application as a subcontractor, is that organization still eligible to apply to the *All of Us* grant program, provided that the scope of the project is not the same between the two applications?
 - A: Yes. Eligible organizations may submit only one application. Applicants may opt to partner with other organizations on a single application submission. NIH encourages applicants to partner to provide the best response to the FO. Applications shall include sufficient detail to allow the Government to assess the applicant's capabilities to provide the requested services.
- 30. Q: We have a consortium of health centers that we currently work with. Does this opportunity allow for awardees to add additional members to their consortium to expand our reach after funds have been awarded, or would consortium participants be limited to those members listed in our application?
 - A: Decisions regarding the potential to add additional consortium participants after award would be subject to NIH approval based on the scope of work and justification provided.
- 31. Q: Would a small biotech company that is not eligible for STTR/SBIR opportunities be eligible to apply for the OTA-20-009? We are a US based company that is funded >50% by a non US company?
 - A: A for-profit company that does not meet the Small Business requirements would be eligible to apply. However, foreign entities are not eligible to apply so depending on the level of authority and ownership of the foreign company, the company may be deemed foreign controlled-foreign owned and may not be eligible.

32. Q: We have a few questions around the following underlined language in the funding opportunity document:

Anticipated Number of Awards (p. 2)

NIH intends to fund at least 6 awards in FY 2021. <u>Applicants may opt to partner with other organizations on a single application submission.</u> Other applications may be awarded dependent on applications received and funding availability.

Required Application Instructions (p. 2)

Eligible organizations may submit only one application. Applicants may opt to partner with other organizations on a single application submission. NIH encourages applicants to partner to provide the best response to the FO. Applications shall include sufficient detail to allow the Government to assess the applicant's capabilities to provide the requested services.

Does this mean that each applying organization can only submit one application, regardless of whether or not they are teamed with other organizations? Or, can an organization be a part of multiple teams, effectively as a "subcontractor," and be included in multiple applications? In other words, can we submit one application ourselves, but also be included as a team member on another application?

A: Please see response to question 29.