PTSC Webinar Q&A

Question 1: *Are our applications expected to follow the traditional Significance, Innovation, and Approach format for NIH grants and scored as such?*

Response 1: This funding opportunity utilizes the Other Transaction Authority (OTA), meaning this is not a grant and standard grant requirements do not apply. Please refer to the Application Instructions section of the funding opportunity regarding application format, components, and page limits. Applicants should refer to the Application Review section of the funding opportunity for details on the review process and the evaluation process.

Question 2: *Can you submit an application for only certain components, or do you have to apply for all?*

Response 2: Please refer to the Application Instructions section of the funding opportunity. Applicants may submit proposals for some or all components based on applicants' capabilities. Programmatic priority will be given to proposals and teams capable of supporting multiple components.

Question 3: *Will there be specific guidance for small businesses (including teaming arrangements) as part of the funding opportunity announcement (FOA)?*

Response 3: No. This funding opportunity utilizes the OTA, meaning this is not a grant or contract. Please refer to the "Eligible Applicants" details in the Eligibility Information section of the funding opportunity. Small businesses are eligible to apply or partner on applications.

Question 4: *How many awards do you anticipate making for the PTSC?*

Response 4: Please refer to the "Anticipated Number of Awards" details in the Overview Information section of the funding opportunity.

Question 5: *Does the multi-PI leadership plan count against the application page limits?*

Response 5: The ASSIST system only allows for the submission of two documents: the multi-PI leadership plan and the application. All applicants must include a leadership structure and management plan within the four pages of the key personnel component; however, the ASSIST system does allow multi-PI applications to submit a separate multi-PI leadership plan that does not count against the four-page limit. The multi-PI leadership plan should specifically address how decisions will be made and conflicts resolved between the PIs.

Question 6: *Who will be on the review panel evaluating the proposals?*

Response 6: A review panel will be convened specifically for the review of the OTA Participant Technology Systems Center funding opportunity. The reviewers will be selected from both NIH staff and extramural research and technical communities, based on subject matter expertise specific to this announcement.

Question 7: *Is there a more detailed scoring criterion? Is there a component that will be weighed as more or less important than another?*

Response 7: Applicants should refer to Application Review section of the funding opportunity for details on the review process and the evaluation process.

Question 8: *Will the current incumbent provide all legacy standard procedures, documentation, open source libraries, data files, and other center management information to the new awardee? If yes, how will this transfer of enterprise information take place?*

Response 8: In the event of a transition of award partners or platforms, the current platform will be supported by the existing PTSC awardee during the period of transition. Collaboration in the transition between existing and new award partners, including all aspects necessary for continuity of operations of existing systems or services support by the current PTSC award for the *All of Us* Research Program, will be required.

Question 9: *Is there any more detail on the specific features of software components All of Us is looking for proposals on? Are there any components related to wearables you all are seeking proposals on?*

Response 9: Applicants should review materials and information provided or linked to within the funding opportunity and program website in order to formulate recommendations and proposed capabilities and innovations to support the program over the five-year award period.

Question 10: *Is there a preferred development methodology/framework in place at All of Us that the winner would follow/adapt itself to, such as Agile or DevOps?*

Response 10: Applicants are free to propose their recommend development methodology to support their application approach and milestones for the *All of Us* Research Program.

Question 11: *Who would be considered the owner of the technology that is developed to support the various components? Would it be the company that is granted the funding?*

Response 11: Please see the Ownership of Data, Software, and Other Products section of the funding opportunity for a full description. NIH will own all rights in data, software, and other products (collectively "Works") made or developed under this award.

Question 12: *Are there performance expectations/service-level agreements (SLAs) for each component area or subcomponent area?*

Response 12: Applicants may define performance capability/expectations or SLAs they expect to support as appropriate within their technical approach or past performance descriptions. Final SLAs will be negotiated between NIH and the selected awardee(s).

Question 13: *Has it been determined that custom development is necessary to achieve the program goals, or have platforms (e.g., ServiceNow) been considered?*

Response 13: Applicants are encouraged to propose their recommended solutions for the components and needs expressed within the funding opportunity.

Question 14: *Who are the existing award partners for the* All of Us *Research Program?*

Response 14: The program has information regarding our award partners available on our website at allofus.nih.gov.

Question 15: *Will you be answering questions previously submitted to the inquiries email address?*

Response 15: Yes. We will respond to questions as received. Please continue to submit any specific questions to the email address provided in the funding opportunity: AllofUsFOAInquiries@nih.gov.

Question 16: *Is there a deadline for questions, and is there a final date when answers will be posted?*

Response 16: We do not have a deadline for questions to be submitted via AllofUsFOAInquiries@nih.gov. We will continue responding to requests until the application submission deadline. We encourage prospective applicants to submit questions as early as possible to ensure a response from the *All of Us* Research Program.

Question 17: *Page 7 of the FOA describes the responsibilities of the HPOs and the PTC in recruiting and engaging with participants. Does this suggest that the role of the PTSC in developing "innovative technology solutions to support engagement, enrollment, and retention of diverse participants" is confined to technical implementation of the strategies developed by the HPOs and PTC? Or is the government expecting a more collaborative interaction between the groups with the ability of the PTSC to also contribute non-technical engagement and retention expertise and solutions?*

Response 17: The PTSC awardee(s) will collaborate with consortium partners in the development of protocols and strategies to support engagement, enrollment, and retention. Ultimately, the PTSC will support the technical implementation of systems necessary to enable these strategies. The PTSC will not be engaged in outreach and enrollment efforts directly but will support all system requirements needed for partner success.

Question 18: *Does the current platform include commercial, off-the-shelf software packages already licensed to the* All of Us *Research Program at large or the PTSC in particular? If yes, could we obtain a list of such?*

Response 18: The current platform uses a combination of licensed services or products and custom-coded software to meet the requirements of the program and implement our research protocol linked within the funding opportunity. Applicants should consider the needs or requests for innovation expressed within the funding opportunity as they develop their proposals, including technical approach, past performance, and cost proposals. We anticipate an opportunity to explore and collaboratively revise technical approach with partners at the time of award.

Question 19: *Are there artifacts and documentation available that describe the technology and architecture of the current platform, including dependencies of third-party software? This information would assist us in deciding whether to "extend and enhance current All of Us PTSC systems or to replace them with alternative systems."*

Response 19: The current platform uses a combination of licensed services or products and custom-coded software to meet the requirements of the program and implement our research protocol, linked within the funding opportunity. Applicants should consider the needs or requests for innovation expressed within the funding opportunity as they develop their proposals, including technical approach, past performance, and cost proposals. We anticipate an opportunity to explore and collaboratively revise technical approach with partners at the time of award.

Question 20: *In the FOA, the government cites two types of software: "customized open source" and "off the shelf." Will alternative software licensing modalities be considered (e.g., customized software for which the source code is not open source)?*

Response 20: Alternative software licensing modalities, either in whole or in part, will be considered and should be documented within the proposal. Please also see the Ownership of Data, Software, and Other Products section of the funding opportunity for a full description. NIH will own all rights in data, software, and other products (collectively "Works") made or developed under this award.

Question 21: *To support the requirement in the FOA for operations and maintenance (O&M) of the current platform for as long as 12 months, could the government share high-level labor-level-of-effort metrics for the current platform?*

Response 21: In the event of a transition of award partners or platforms, the current platform will be supported by the current PTSC awardee during the transition period for the new PTSC award(s). Collaboration in the transition will be required for any new award partner(s) in the event of a transition of award partners.

Question 22: *Could the government share high-level other direct cost information for the current platform, particularly the current cost of cloud services and the cost of commercial software licenses incurred on a yearly basis?*

Response 22: Applicants should consider the needs or requests for innovation expressed within the funding opportunity as they develop their cost proposals based on their assumptions and technical proposals. Current costs for cloud services are driven by our research protocol, user population, and operational or security requirements. As indicated during the December 16, 2019, informational webinar, we currently have more than 350,000 individuals who have created an account with the program and more than 235,000 individuals who have completed the core protocol. Enrollment is ongoing, with a goal of one million or more participants over the coming years. The protocol and survey data are linked within the funding opportunity for reference. We anticipate that the study will add an increasing number of data types over the award period. General privacy and security requirements are also documented within the funding opportunity.

Question 23: *In the FOA, page 8, Section "Component 1," it specifies "staffing requirements to support separation of duties for security and privacy operations and compliance." We understand that the separation of duties is between the personnel in charge of security/privacy operations and the personnel in charge of ensuring compliance with the security/privacy requirements, as opposed to separation of duties between personnel in charge of security and personnel in charge of privacy. Is this correct?*

Response 23: Your understanding is correct. Thank you for the question for clarification.

Question 24: *Can a non-domestic company apply for this funding announcement?*

Response 24: Non-domestic entities are not eligible to apply. Please see the funding opportunity for additional clarifications.

Question 25: *Please clarify the yearly direct cost amount.*

Response 25: Depending on the availability of funds, the direct costs should not exceed $25 million per year.

Question 26: *Does the government expect the new awardee(s) to replace the existing patient engagement platforms (e.g., the mobile app, the Web portal)? If no, will Vibrent continue to function as it does today (building and managing the patient engagement platform) even after the new PTSC award(s) is/are awarded?*

Response 26: The funding opportunity is an open competition. Applications will be reviewed on their merit and responsiveness. Please refer to the Application Instructions section of the funding opportunity. Applicants may submit proposals for some or all components based on applicants' capabilities. Programmatic priority will be given to proposals and teams capable of supporting multiple

components. Please also refer to the "Anticipated Number of Awards" details in the Overview Information section of the funding opportunity.

Question 27: Will new awardees have access to the source code and systems currently managed by Vibrent?

Response 27: In the event of a transition of award partners or platforms, the current platform will be supported by the existing PTSC awardee during the period of transition. Collaboration in the transition between existing and new award partners, including all aspects necessary for continuity of operations of existing systems or services support by the current PTSC award for the *All of Us* Research Program, will be required.