

PTSC Webinar Q&A Supplement

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

Response 1: This funding opportunity utilizes the Other Transaction authority 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 Application Review section of the funding opportunity for details on the review process and 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 FOA?

Response 3: No. This funding announcement utilizes the Other Transaction authority 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 4 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 4-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 review process and 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 will be required 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.

Question 9: Is there any more detail on the specific features of software components AoU 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 AoU that the winner would follow/adapt itself to such as Agile, DevOps, etc.?

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 selected awardee(s).

Question 13: Has it been determined that custom development is necessary to achieve the program goals or have platforms - ServiceNow, etc. 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 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 request until the application submission deadline. We encourage prospective applicants to submit questions as early as possible to ensure 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? For example, 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 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? In particular, the current cost of cloud services and the cost of commercial software licenses current 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 proposal. 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 over 350k individuals who have created an account with the program and over 235k individuals who have completed the core protocol. Enrollment is ongoing with a goal of 1M 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 dollars per year.

Question 26: Does the government expect the new awardee(s) to replace the existing patient engagement platforms (mobile app, web portal, etc.)? If no, will the incumbent continue to function as it does today (building and managing the patient engagement platform) even after 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 the incumbent?

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 will be required 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.

Question 28: Does consortium F&A count against the direct cost limitation?

Response 28: For the purpose of this funding opportunity, consortium F&A does not count against the direct cost limitation.

Question 29: What items would be considered during the financial analysis of an organization?

Response 29: There is not a set measure used to determine the financial capability of an organization. Some examples of items that may be requested are as follows: submission of audited or unaudited financial statements, line of credit status, income/loss analysis, plans for the organization to raise capital, calculation of the organization's current ratio, and whether there are any outstanding lawsuits against the organization.

Question 30: Can the Program please provide further information about the architecture and tools used within the current PTSC platform?

Response 30: The All of Us Research Program participant portal supported by the PTSC utilizes an n-tier architecture to provide the participant user experience to include registration, consent, surveys, health data capture, return of information and protocol-based notifications and communications back to the participant. Elements of the architecture include the user-facing applications, server-side application and business rules engine, back-end administration tools, database management solution, and data exchange capabilities, all of which utilize a variety of technologies.

The participant portal user-facing capabilities are provided via mobile applications running on Apple/iOS and Android mobile phones, and via browser-based responsive web experience. The participant portal server-side application and business rules engine, back-end administration tools, and database management solution provide the ability to generate forms, capture data, and enable IRB-protocol based experiences using the embedded business rules framework. Through these backend services, participants receive notifications and communications based on the activities they have completed and new activities available to them. Participant data is shared among internal system components and transmitted to external partners using a messaging infrastructure and standards-based protocols (e.g., FHIR).

The participant portal architecture includes user-facing and server-side applications all of which utilize a variety of technologies. Client-side technologies include - (AngularJs, React, iOS, Android, etc.), webpack for module packaging and bundling, Npm for dependency management, esLint, sonarQube for code quality check, chai, phantomjs, karma, jasmine, mocha for testing, bootstrap, SaSS, PTSC SASS for

CSS, d3, c3 for dynamic graph generation, etc. among many other tools. Server side technologies include - Tomcat for J2EE container, Spring framework, Hibernate for Object Relational Mapping, Redis for Caching, Kafka for messaging, SLF4j for logging, RDS with Aurora for database, S3 for static data storage, Rest over https for client/server, Swagger Tech stack on devops - Jenkin, Nexus, Ansible, Helm Charts, Pingdom, tech stack for logging and auditing, among other tools.

The participant portal integrates with 3rd party partners primarily through industry standard OAuth for authorization and FHIR-based messaging protocols. The participant portal stores all health-related data in a secure health data repository and utilizes a standardize set of data exchange workflows to enable the storage and retrieval of data. Integration with the external data provides are enabled using microservices which subsequently integration with the standardize data exchange workflows and the secure health data repository. PTSC is utilizing many open source libraries in support of its platform engineering, product delivery, and DevOps processes that are well known and used widely.

Question 31: Can the NIH please provide the following information for the PTSC system and Program; average number of daily users, current data types, total data storage for the current PTSC system and daily volume of input/output.

Response 31: Average number of daily users for the portal is variable but ranges from 1,000-1,500 users per day on typical business days and roughly half of those are new user. Communication campaigns can increase daily users dramatically for peak usage days. Current data types include user credentials, consent form responses, user signature image files, consent form PDF files, user profile data, user communication preferences data, survey form responses, wearable device data, audit logs, and user metadata. Current data storage is approximately 9TB including all application and user logs. Data input/output is modest in comparison to the total storage and reflective of the user population and portal functions.

Question 32: Are program director/principal investigator, project manager, and key investigators all considered key?

Response 32: Designation of Key Staff/Investigators is at the discretion of the applicant. Additional staff can be named in the application and included in the budget but not designated as Key Staff, including those that will make significant time, scientific or technical contributions to the project's success.

Question 33: How many key investigators are currently on the project?

Response 33: Structure of the current awardees budget and award management approach are not public information. Designation of Key Staff/Investigators is at the discretion of the applicant.

Question 34: Does the government require any particular certification for the key individual with primary responsibility for information systems security oversight?

Response 34: Applicants should use their discretion regarding selection of individuals with the experience to support security implementation steps leading toward operational readiness and Authority to Operate (ATO), and ongoing systems oversight for a FISMA Moderate cloud enterprise.

Question 35: What kind of transition period will be allowed between the incumbent and the incoming contractor?

Response 35: Please review the Funding Opportunity Purpose section of the funding announcement for details. Any alternative systems would need to be implemented in collaboration with All of Us consortium award partners, with full security controls, within 6 to 12 months of the award.

Question 36: If there is more than one awardee, how will the awardees work together?

Response 36: In the event of multiple awardees, all awards issued under this funding opportunity will collectively represent the All of Us Participant Technology Systems Center (PTSC). At the time of award, terms and requirements associated with collaboration between PTSC awardees will be addressed within the notice of award. It is expected that operational management between NIH and award partner(s) will be established based on a combination of award terms and award milestones.

Question 37: The Application Instructions state, on page 3, that "eligible organizations may submit only one application" and that "the application package must not exceed 40 pages in total". Please confirm that if our firm is addressing all 5 components, we may not exceed 40 pages and we may only submit one application.

Response 37: The application cannot exceed 40 pages

Question 38: May we include a Cover Page and Table of Contents, without those being included in the 40 page count?

Response 38: Per the funding announcement, "A 1-page cover letter is allowed and will not count against the 40-page limit. It will be included with the application material provided to reviewers. Appendices are not allowed." An allowance for the table of contents was not given in the funding opportunity.

Question 39: On page 3 you state "The application must list other key investigators and identify the individual with primary responsibility for information systems security oversight (LOE 50%)". Is the LOE of 50% referring to the Information Systems Security Oversight person only, or is that referring to the other key investigators as well?

Response 39: The 50% LOE refers to the primary Information Systems Oversight person.

Question 40: Is the data that is collected from third parties restricted and/or 'filtered' in anyway? Is it a 'data dump' at the patient-level? In what ways has the data been filtered? I.e. what has been removed vs. retained?

Response 40: Data access from participant authorized data sharing from third party systems, such as wearable sensors or electronic health records, will follow standards-based data authorization processes and data formats and types will be consistent with those systems available APIs.

Question 41: Will we be granted access to any data at the patient level (e.g. free-text doctors notes from EHR) that has not been anonymized?

Response 41: Data access from participant authorized data sharing from third party systems, such as wearable sensors or electronic health records, will follow standards-based data authorization processes and data formats and types will be consistent with those systems APIs.

Question 42: Will we have control over standing up test environments to build test applications and run data analysis (across real patient data) to optimize performance? or will this be governed by NIH or researchers or partners?

Response 42: Non-production environments will never have access to All of Us participant data of any type. Access to and use of participant data is strictly controlled and limited to essential use cases. Simulated data would need to be used to test analytics or system performance.

Question 43: In short - how much are we in charge/control of the decisions and activities aimed at improving and supporting "engagement, enrollment, and retention of diverse participants" vs. other stakeholders (e.g. NIH).

Response 43: The PTSC will work with consortium partners collaboratively. Ultimately the PTSC will support enrollment, engagement and retentions through delivery of the systems, services and content described within the funding opportunity. Innovation within these areas are welcome and will be vetted through consortium governance.

Question 44: It is our understanding that the Data and Research Center (DRC), will provide a set of analysis tools for DRC users; Component 5 of the PTSC FOA states prospective vendors should propose "analytics tools and services to support real-time visibility for study staff into cohort, sub cohort, and individual participant status, activity, and engagement with the All of Us protocol(s)". Can we be told what sort of analysis tools already exist in the DRC and what their focus is so that efforts are not duplicated for the PTSC?

Response 44: The DRC received all data necessary to support the program's mission to serve as a research resource which includes data types provided by the PTSC (such as surveys), as well as other data shared from additional program partners. However, currently there are many types of data, such as

participant communications and application utilization, that characterize participants level of engagement with the program over time. These data are essential to program and protocol improvement.

Question 45: Can an application include multi-PIs from different organizations?

Response 45: Yes. Prior to any potential award, NIH would work with the applicant to ensure the proper understanding as well as written assurances are established between the applicant organization and any named PIs that are not employed by that organization. The cover letter or multiple PI leadership plan may also be used to explain the relationship and include signatures from all parties. The multiple PI leadership plan submission via the ASSIST system does not count in the application page limits.

Question 46: Can an individual serve as single PI on an application for an organization in which he/she is not employed?

Response 46 : Yes. Prior to any potential award, NIH would work with the applicant to ensure the proper understanding as well as written assurances are established between the applicant organization and any named PIs that is not employed by that organization. The one-page cover letter may be used to explain the relationship and include signatures from all parties.

Question 47 Can letters of support be provided?

Response 47: The Funding Announcement includes specific page limitations for each section as well as the full application. A one-page cover letter is permitted but no appendices are permitted. Please refer to the key personnel section for details on how to identify individuals that would be key to the project.

Please note that this is an “other transactions” award mechanism meaning it is not a grant, contract, or cooperative agreement. Any concerns or questions regarding the relationship between investigators named in the application and the applicant organization will be discussed, documented and resolved prior to any potential award.

Question 48: Will all patient engagement be handled solely through the current counseling system and portal, etc. for the next 10 years? Please advise on both the follow up testing, test coordination and flow.

Response 48: The All of Us genetic counseling resource will provide a network of genetic counselors to help participants understand what their genomic results mean for their health and their families. For additional information on our award partners please review our program partners page at:

<https://allofus.nih.gov/funding-and-program-partners>

Question 49: Will all of the software that is developed become public/open source?

Response 49: Please refer to the Ownership of Data, Software, and Other Products section of the Funding Opportunity for requirements associated with intellectual property. Ultimately the All of Us Program seeks to develop a research resource that can support the program and align with the broader open science mission of the NIH.

Question 50: Is a fee allowed?

Response 50: The Funding Opportunity nor Policy Guide prohibits the inclusion of a fee in your proposal. If a fee will be included, please clearly describe the amount of the fee and how it was calculated. Documentation confirming the fee is consistently applied across various funding agreements regardless of funding source is also required. Please note the fee amount and calculation will be reviewed carefully and discussed during the negotiation phase of the award.

Question 51: Do you anticipate studies including Human Subject?

Response 51: The current award is coded as being engaged in non-exempt human subject research. Any human subject research requirements will be addressed during the negotiation phase.