

Overview Information	
Funding Opportunity Title	<i>All of Us Participant Technology Systems Center (OT2)</i>
Funding Opportunity Number	OTA-20-001
Participating Organization	National Institutes of Health (NIH)
Components of Participating Organizations	This funding opportunity is part of the NIH <i>All of Us</i> Research Program. The funding opportunity will be administered by the National Center for Advancing Translational Sciences (NCATS) on behalf of the <i>All of Us</i> Research Program.
Opportunity Type	New
Related Notices	None
Funding Opportunity Purpose	<p>The purpose of this funding opportunity (FO) is to solicit applications for operating the Participant Technology Systems Center (PTSC) for the <i>All of Us</i> Research Program. Applicants should leverage their experience and propose innovative technical solutions to support participation in the <i>All of Us</i> Research Program by individuals reflecting the diversity of the United States, across a broad spectrum of age, cultural background, digital access, educational attainment, health status, socioeconomic status, and technical expertise. The PTSC serves as the <i>All of Us</i> Research Program’s resource for developing and maintaining the technical platforms by which people participate in and engage with the program. The PTSC provides systems, services, user experience design, and development to support account creation and management, informed consent, survey data collection, participant-authorized data sharing from third-party data sources (e.g., consumer apps and devices), return of information (e.g., electronic health records) to participants, and multi-channel participant communications systems and workflows (e.g., email, SMS, direct mail, phone).</p> <p>In addition, the PTSC provides a suite of software tools and services for study teams from more than 50 organizations to facilitate participant engagement and retention. These tools and services include resources for scheduling; communications and case management; cohort, sub-cohort, and individual analytics; and participant account support. The PTSC is responsible for all aspects of development or licensure, operations management, security and privacy, and testing and support for deployed systems. Applicants may propose either to extend and enhance current <i>All of Us</i> PTSC systems or to replace them with alternative systems. Any alternative systems would need to be implemented in collaboration with <i>All of Us</i> consortium award partners, with full security controls, within 6 to 12 months of the award.</p>

Funding Opportunity Purpose (continued)	<p>The PTSC award will provide and/or support the following component systems, functions, and services in close collaboration with NIH and <i>All of Us</i> technical systems partners including (but not limited to) the Data and Research Center and Genetic Counseling Resource awardees:</p> <p>Component 1: Platform Operations and Maintenance Component 2: Systems Integration and Support Component 3: Participant Services Development Component 4: Partner Services Development and Program Support Component 5: Operational Analytics and Reporting</p> <p>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.</p>
Funding Instrument	The funding instrument is the Other Transaction (OT) award mechanism: an OT award is not a grant, cooperative agreement, or contract, and uses Other Transaction Authority.
Funds Available	Actual amounts will depend on funds available, but the program expects applicant direct costs to not exceed \$25 million per year.
Anticipated Number of Awards	NIH intends to fund 1 or more awards in FY 2020.

Key Dates

Award Project Period	The total project period is anticipated to be 5 years.
Post Date	December 6, 2019
Application Due Date	February 14, 2020 (5:00 p.m. local time)
Scientific/Technical Review Date	Review will be conducted in March 2020.
Award Timeline	Award(s) will be made upon selection and award negotiation. Earliest anticipated start date is June 2020.

Application Instructions

Required Application Instructions	<p>This announcement covers five categories of technology innovation and services support:</p> <ol style="list-style-type: none"> 1. Platform operations and maintenance 2. Systems integration and support 3. Participant services development 4. Partner services development and support 5. Operational analytics and reporting <p>Applicants with experience in multiple categories are encouraged to apply. Applicants are not required to have experience in all categories and may choose to apply for some or all categories. Multiple award recipients may be selected; if they are, they will be required to work collaboratively to achieve the intended outcomes.</p>
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Application Instructions

Required Application Instructions (continued)

Eligible organizations may submit only one application. Applicants may opt to partner with other organizations on a single application submission. An organization may be included as a collaborating partner on more than one application. NIH encourages applicants to partner to provide the best response to the FO. Applications must include sufficient detail to allow the Government to assess the applicant's capabilities to provide the requested innovation and services.

The application package must not exceed 40 pages in total and should include the following:

- The Technical Approach (not to exceed 25 pages).
- The Past Performance section (not to exceed 5 pages). This section should include corporate or organizational experience related to the solicitation.
- The Key Personnel section (not to exceed 4 pages). Applicants should provide brief biosketches of key personnel and must identify the levels of effort (LoEs) these individuals anticipate committing to this project, if awarded. Minimum LoEs for each level are given below. Each application must identify one Program Director or Principal Investigator (LoE 25%) or multiple Program Directors or Principal Investigators (LoE 20% each). Each application must also identify a Project Manager (LoE 80%). The application must list other key investigators and identify the individual with primary responsibility for information systems security oversight (LoE 50%). An overall leadership structure and management plan must be included in this section. If there are multiple Program Directors or Principal Investigators, the leadership and management plan must include a strategy for resolving any conflicts.
- The Cost Proposal (not to exceed 6 pages). Applicants should build a milestone-driven, cost-allocated plan for the proposal. Cost models can be cost-sharing, fixed-price, adjustable (cost-reimbursable), or a hybrid approach.

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.

Applicants should familiarize themselves with the Precision Medicine Initiative Working Group to the Advisory Committee to the Director's report, [The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine](#), and with the [All of Us Research Program Protocol](#) and associated materials, including consents and surveys.

Application Instructions

Instructions for Application Submission

Applications must be submitted via the NIH eRA ASSIST System by February 14, 2020 (5:00 p.m. local time). To submit an application via ASSIST, the applicant organization must be registered in eRA Commons (see instructions). Organizations already registered in eRA Commons do not need to reregister.

Once the organization is registered, the individual(s) with the role of Signing Official (SO) and Program Director/Principal Investigator (PD/PI) must be affiliated with the organization and have eRA Commons credentials to complete the submission process.

Use OTA-20-001 in the field requesting Funding Opportunity Announcement.

Here [are Instructions for submitting via the NIH eRA ASSIST system](#). In the future, instructions will also be available in the [ASSIST online help \(look for the OTA section\)](#). Technical help is available at the [eRA Service Desk](#)

Eligibility Information

Eligible Applicants

The following entities are eligible to apply as an applicant organization:

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Nonprofits without 501(c)(3) IRS Status
- Faith-based or Community-based Organizations
- Regional Organizations
- Independent School Districts
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)
- State or County Governments
- City or Township Governments
- Special District Governments

Eligibility Information

<p>Eligible Applicants (continued)</p>	<ul style="list-style-type: none"> • Indian/Native American Tribal Governments (Federally Recognized) • Indian/Native American Tribal Governments (Other than Federally Recognized) • Native American Tribal Organizations (Other than Federally Recognized Tribal Governments) • Public Housing Authorities/Indian Housing Authorities <p>Nonprofits Other Than Institutions of Higher Education</p> <ul style="list-style-type: none"> • Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education) • Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education) <p>For-Profit Organizations</p> <ul style="list-style-type: none"> • Small Businesses • For-Profit Organizations (Other than Small Businesses) <p>All applicants under funding consideration will be required to undergo a financial capability assessment.</p>
<p>Foreign Institutions</p>	<p>Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply.</p> <p>Foreign components engaged in research or systems security operations are not allowed. Foreign components shall not be permitted access to participant data, production data systems or environments. Foreign component is defined as the performance of any significant element or segment of the project outside of the United States either by the award recipient or by a researcher employed by a foreign organization, whether or not OT2 or other grant award funds are expended.</p>

Application Review

<p>Review Process</p>	<p>A review group convened by NIH will evaluate applications for responsiveness to the funding opportunity requirements and merit.</p> <p>Reviewers will evaluate applications based on the following:</p> <ul style="list-style-type: none"> • Completeness of technical and cost elements • Alignment with <i>All of Us</i> Research Program objectives • Quality of submission • Past performance and portfolio • Key personnel experience and proposed commitment to the project • Cost proposal
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Application Review	
Review Process (continued)	Applicants may receive a brief written summary of the review. Successful applicants will undergo a negotiation process for award determination.
Evaluation Process	<p>Applications will be evaluated for programmatic priority as well as technical and scientific merit.</p> <p>Programmatic priority will be given to applicants with:</p> <ul style="list-style-type: none"> • Demonstrated evidence of successful support of complex multi-stakeholder collaborations associated with software development and services delivery. • Demonstrated expertise in supporting scalable software solutions supporting 100,000 to 1 million users or more. • Demonstrated expertise in cloud systems security and privacy implementation and compliance with NIST standards to a Federal Information Security Management Act (FISMA) Moderate requirement. • Demonstrated expertise in implementation and maintenance of multiple third-party systems integrations. • Demonstrated expertise in management of multi-channel communications platforms for multi-centered organizations and/or tiered communications audiences. • Experience working collaboratively to deliver and support software services for multiple organizations. • Experience in research data collection using web-based and native mobile clients. • Expertise in user experience design and user interface/user experience (UI/UX) design research methods. • Expertise in user data analytics, including integration of technology, to assess the effectiveness of marketing campaigns and overall user experience. • Ability to support multiple PTSC components within a single proposal.
Questions Regarding this Funding Opportunity and Program and Agreements Officer Contact	<p>Informational Webinar: Monday, December 16, 2019, 3:00–4:00 p.m. ET.</p> <p>To register for this webinar, receive instructions, or submit questions about this funding opportunity, email AllofUsFOAInquiries@nih.gov.</p> <p>Questions about scientific/programmatic objectives should be addressed to James McClain, Ph.D., M.P.H., <i>All of Us</i> Research Program; questions about award mechanism and application submission matters should be addressed to Ms. Irene Haas, <i>All of Us</i> Research Program Agreements Officer, National Center for Advancing Translational Sciences (NCATS).</p>
Authority	Other Transaction awards will be made pursuant to current authorizing legislation, including Section 402(n) of the Public Health Service Act, 42 U.S.C. 282(n), as amended.

Application Review

All of Us Research Program Other Transaction (OT) Policy Guide

Other Transaction awards are subject to the requirements of the *Other Transaction Award Policy Guide for the NIH Precision Medicine Initiative Research Programs*. Applicants must review this policy guide, available at <https://allofus.nih.gov/funding>.

All of Us Research Program Participant Technologies System Center

Background

The *All of Us* Research Program is a historic effort to gather data over many years from one million or more people living in the United States, with the ultimate goal of accelerating research and improving health. Unlike research studies that are focused on a specific disease or population, the *All of Us* Research Program will serve as a national research resource to inform thousands of studies, covering a wide variety of health conditions. Researchers will use data from the program to learn more about how individual differences in lifestyle, environment, and biological makeup can influence health and disease. Participants may be able to learn more about their own health and can contribute to an effort that may advance the health of generations to come.

The partnership between the *All of Us* Research Program and the participants enrolled in the program will involve everything from participant involvement in program governance to communication of research findings with participants and participant communities. One of the program's core values is that "participants have access to their information." Such information may include participants' physical measurements, electronic health records obtained from health care providers, and results from biological samples donated by participants. The PTSC supports technologies and user experience that both operationalize the research protocol and return value to the participants. (Value includes responsible return of health- and non-health-related information, health education, and engaging activities as part of participant-centered design.)

The PTSC, initially funded in March 2017 (see [RFA-PM-16-003](#)), serves as the *All of Us* Research Program's resource for protocol delivery and digital interactions with program participants; it has provided systems and services to support the enrollment of participants in the program, communications with participants, and various user interfaces to allow for ongoing data collection. The PTSC has also provided a suite of software tools and services for study teams from more than 50 organizations to facilitate participant engagement and retention. The PTSC has been responsible for all aspects of development or licensure, security and privacy, operations management, testing and support for deployed participant systems, and associated staff tools for participant support and engagement used in the *All of Us* Research Program.

Key All of Us Systems Partners and Integration Points

Funding for the *All of Us* Data and Research Center (DRC) was awarded in July 2016 (see [RFA-PM-16-001](#)) to acquire, organize, and provide secure access to datasets and to provide research support for the scientific data and analysis tools of the *All of Us* Research Program. Research data collected by the PTSC are transferred to the DRC, and information or results will be transferred from the DRC to the PTSC (and/or partner systems) for access by participants.

Funding for the *All of Us* Genetic Counseling Resource (GCR) was awarded in August 2019 (see [OT-PM-19-001](#)) to support the responsible return of genomic results to participants. The PTSC will coordinate

participant communications, authorization, and user experience (UX) workflows with the GCR to deliver information and results related to genomics.

All of Us participant enrollment and retention is supported by multiple awards. Health care provider organizations (HPOs), including regional medical centers (see [OT-PM-16-003](#)), Federally Qualified Health Centers, and the Department of Veterans Affairs, engage local communities and participants in the *All of Us* Research Program. Funding was awarded in July 2016 for The Participant Center (TPC) (see [RFA-PM-16-003](#)), which aims to enroll individuals who do not have access to participating HPOs; TPC manages overall operations for direct volunteer enrollment across the country. Collectively, the HPOs and TPC help build the research protocols; enroll interested individuals; collect essential health data, biological specimens, and shared health records data authorized by participants; develop and refine approaches for bringing underserved individuals and communities into the *All of Us* Research Program; and design and implement strategies to keep diverse populations of participants engaged over the long term.

Purpose and Objectives of the *All of Us* Research Program PTSC

NIH solicits proposals from organizations to serve as the PTSC for the *All of Us* Research Program and to provide innovative solutions to meet the technology and services needs of the program, as described below. NIH is using the Other Transactions (OT) mechanism to enable maximum innovation and flexibility. Enrolling and retaining one million or more people from all walks of life into a longitudinal research program is unprecedented; there is no established playbook for success. Using the OT mechanism will enable organizations beyond frequent NIH applicants to propose innovative strategies and technology solutions to communicate and engage with potential participants, increase efficiency of recruitment, return information and value to participants, and maintain enrollees' participation in the program for 10 or more years.

The PTSC has multiple areas of responsibility for the *All of Us* Research Program, including platform operations and maintenance, systems integration and support, participant services development, partner services development and support, and operational analytics and reporting. Applicants should leverage their experience and propose innovative solutions to meet the challenges of providing technology systems to support program participation from individuals across a broad spectrum of age, cultural background, digital access, educational attainment, health status, socioeconomic status, and technical expertise.

The specific research and support objectives for this funding opportunity are described below. Applicants may submit proposals for some or all components, based on their capabilities. Programmatic priority will be given to proposals and teams capable of supporting multiple components. Applicants are encouraged to partner with other organizations on application submissions to provide the best response to this funding opportunity. Components included in submissions should be addressed in the application's Technical Approach section.

Component 1: Platform Operations and Maintenance

Applicants should demonstrate awareness of and capabilities to operate, maintain, monitor, and assess a cost-efficient, privacy- and security-compliant cloud environment for *All of Us* systems development and operations. Deliverables and services may include:

- Supporting platform operations and maintenance (O&M,) including security operations, privacy and security compliance (see Data Security and Privacy Management);
- Supporting development operations and managing commercial cloud platform and software; and

- Implementing quality assurance systems and processes to manage the software development life cycle.

Applicants should consider staffing requirements to support separation of duties for security and privacy operations and compliance. Applicants should also budget to support an accredited third-party assessment organization to perform the initial and periodic assessments of cloud systems to ensure they meet FISMA security requirements, as well as third-party penetration testing services as part of a continuous security monitoring program. The awardee will support O&M services for partners, to leverage shared resources among integrated systems.

Component 2: Systems Integration and Support

Applicants should demonstrate awareness of and capabilities to support system integrations and accelerate assessment, onboarding, and operational integration for technology or research service partners for the *All of Us* Research Program. Potential deliverables and milestones include maintaining open source and documented resources including documented API/SDK components for systems integration within key program or third-party services or systems. The PTSC will either develop and maintain new or leverage existing open source libraries, services, and documentation, using standards-based approaches. Applicants should consider opportunities to reduce cost or improve quality of program implementation via integration of robust, widely used, and/or highly innovative system components or services.

The vision of the *All of Us* Research Program is to ultimately open application development opportunities to broader research and software development communities by leveraging an innovation ecosystem to expand research data collection methods, enhance engagement and return of information to participants, and support customized user experiences for specific populations or research protocols over time. The PTSC awardee(s) and systems will work to enable and support this vision in collaboration with the *All of Us* Research Program and consortium partners. Over the award period, activities may include contributing to data standards and interoperability initiatives, supporting open competitions, collaborating with developers outside of the program, and integrating, hardening, and/or extending existing open source tools either independently or in collaboration with new partners. The awardee(s) will support sub-contracting with technology or services vendors that support specific program needs for *All of Us* participants or study staff, in line with the program vision and protocol.

Component 3: Participant Services Development

Applicants should propose innovative technology solutions to support *All of Us* participation from diverse populations and settings. *All of Us* participants have widely variable levels of digital literacy and access, self-motivation, and available time. By leveraging an appropriate combination of customized solutions and/or off-the-shelf technologies, the PTSC will support an open source technical infrastructure that will include a microservices server architecture and associated responsive web and iOS and Android client applications that deliver a self-guided user experience. The infrastructure should also support user-friendly account/user management, authorizations and permissions management, communications system and services, configuration and rendering of forms data, and analytics data collection. The infrastructure should allow implementation and development of standards-based APIs for interaction with *All of Us* (e.g., DRC) and third-party systems. Using these components and others as necessary, the awardee(s) will:

- Implement current and future protocols for the *All of Us* Research Program, including informed consent materials, surveys, educational content, return/visualization of participant information, customization of content or experience based on participant profile or preferences, and user authorizations management for data sharing.

- Consider UX optimization and innovation for both facilitated and unassisted participant interactions in order to improve efficiency and effectiveness of enrollment, engagement, and long-term retention of participants.
- Support rapid implementation and ensure compliance of protocol elements and participant experience, consistent with protocol approvals and associated regulatory requirements.
- Provide tools to support access to program components (e.g., consent materials and surveys) for purposes of review, user testing, staff training, or demonstration.
- Support a testbed for rapid user testing and piloting of tools not yet deployed but in development or consideration for use.
- Ensure that all digital products and platforms meet or exceed the requirement for Section 508 compliance.
- Review the current [Scientific Protocol and materials](#) and consider the future needs of the program to support additional user populations (e.g., children and adolescents), protocol-based substudies, and ancillary studies.

Component 4: Partner Services Development and Program Support

Applicants should propose innovative technology solutions to support engagement, enrollment, and retention of diverse participants within a variety of settings. The PTSC will provide appropriate solutions through customized open source and/or off-the-shelf technologies. Tools should support protocol implementation, facilitation, and management, including:

- Appointment scheduling and management.
- Multi-channel (e.g., email, SMS, push notifications, direct mail, phone) participant communications and communications workflows.
- Case management, including cohort, sub-cohort, and individual analytics data access associated with participant status/demographics/region/et cetera.
- Participant account management and user support.

PTSC tools should support the ability for study staff—based on roles and permissions—to segment audiences for participant communications/management within a tiered, multi-organization model of participant engagement (i.e., with national program and local partners). PTSC tools must support needs for:

- Centralized programmatic communications defined by *All of Us* research protocol(s) and communications strategies.
- Local communications by partner organizations to specific audience segments (groups or individuals) of the cohort.

Additionally, the PTSC will provide support for or coordinate implementation of essential services necessary for PTSC or partner/integrated systems. Deliverables and services will include:

- UI/UX testing for iOS, Android, and web applications.
- Training and support resources for all PTSC-managed software/services.
- Section 508 compliance auditing and mitigation for PTSC-provided tools.

The PTSC may also support custom application development for digital modes of community engagement (e.g., interactive or educational kiosk or displays), as requested by the *All of Us* Research Program, using web-based or native applications.

Component 5: Operational Analytics and Reporting

Applicants should propose innovative approaches and technology solutions to support and enhance capability for the *All of Us* Research Program to leverage rapid and iterative data science methods to

increase the performance and efficiency of program components, including strategies for awareness, education, and recruitment, and participant communications for engagement and retention. Potential services and deliverables include:

- 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).
- Curated web and/or mobile platform analytics (e.g., Google Analytics) to optimize the program's ability to monitor and iteratively enhance content and experience to improve enrollment, engagement, progression, and retention of participants.
- Implementation of technology and analytics dashboards to inform the effectiveness of participant recruitment activities and participant experience.

Data Security and Privacy Management

The awardee will work closely with the *All of Us* Data and Research Center, Genetic Counseling Resource, and our enrollment partners to support data transfer, participant interactions across systems, and tools for study and participant management.

Applicants should describe their organization's information technology (IT) platform, approach to data security, and prior experience with the general security requirements listed below. Technical details that will enable data exchange with the Data and Research Center (which uses a secure enclave on the Google Cloud Platform) should be provided. Awardees will be required to maintain standards and practices for data security to *All of Us* requirements.

Maintaining the trust of *All of Us* participants and ensuring the security of their data are essential elements of the program. Applicants should comment on policies and procedures to maintain compliance with the following *All of Us* Research Program principles:

- [Precision Medicine Initiative: Data Security Policy Principles and Framework](#)
- [Precision Medicine Initiative: Privacy and Trust Principles](#)

Security Requirements for Awardees

Upon award, the NIH *All of Us* requires the awardee to describe how it will design and implement technical and policy safeguards necessary to ensure data security, including compliance with NIST standards to a Federal Information Security Management Act (FISMA) Moderate requirement. Prior to system use in *All of Us*, an Authority to Operate (ATO) from NIH will be required along with documentation describing the current security monitoring/practices in place in accordance with FISMA review standards. Multiple ATOs may be necessary as the *All of Us* evolves.

The NIH *All of Us*, through the program Information System Security Officer (ISSO) in coordination with the Award Program Officer, may require additional security measures not included in the FISMA moderate standards. *All of Us* and the awardee will establish data security implementation plans and timelines collaboratively. *All of Us* will regularly monitor compliance with ongoing and new security requirements as specified by the program and agreed upon by the awardee.

A Plan of Action and Milestones (POAM) document will be maintained by the awardee and reviewed at least monthly with the *All of Us* ISSO. The awardee will use an NIH designated site to share documents as directed by the *All of Us* ISSO. Status of all milestones will be included in quarterly reporting. The NIH *All of Us* ISSO will request an annual independent review of security controls, in addition to continual review and testing, to ensure overall effectiveness against evolving threats and consistent implementation as a requirement of renewal of the ATO. The Awardee will be required to use a document repository, provided by *All of Us* ISSO (currently OMB Max) for the sharing of all

documents. Additionally, the Awardee should be prepared for the implementation of a third-party Security Operations Center in the ATO environment (e.g., a 24x7 SOC monitoring intrusion detection alerts and responding to threats in concert with the awardee). The intent of the SOC is to respond to threats in a near-real time manner to reduce adversary dwell time.

All of Us Research Program Organization and Governance Structure

The *All of Us* Research Program functions as a Consortium, with all awardees considered members. Under the present structure, committees, task forces, and boards are established by the *All of Us* Research Program to oversee the development and implementation of Consortium activities. The governance structure may change periodically to meet the evolving needs of the program. Awardee personnel may hold specific roles in program governance structure based on their role in their institution's program activities. For example, the *All of Us* Research Program Steering Committee currently consists of the contact Program Directors/Principal Investigators (PDs/PIs) from all awards. The *All of Us* Research Program Consortium includes participant representatives throughout its governance structure. In addition, as a Technology Partner in the *All of Us* Research Program, the PTSC Awardee will have regular interactions with the program's Chief Technology Officer and Chief Experience Officer on strategy, direction, and priority.

The *All of Us* Research Program has a single Institutional Review Board (IRB) charged with reviewing the protocol, informed consent, and other participant-facing materials for the *All of Us* Research Program. The IRB follows the regulations and guidance of the [Office for Human Research Protections](#) for all studies, ensuring that the rights and welfare of research participants are overseen and protected uniformly. The single IRB includes representatives from the participant community. Each awardee will be required to either agree to an existing IRB reliance agreement with the program or establish a new IRB reliance agreement, depending on program requirements.

Budget

Funds requested for salary support for all personnel must comply with the [NIH Salary Cap](#) in effect at the time of award.

Application PI/PDs and key personnel should plan for several weekly calls and team meetings as needed over the course of the award. In addition, three members from the awardee should plan and budget for up to four trips annually to Bethesda, MD, for *All of Us* Research Program Steering Committee and other strategic meetings.

The estimated budget should be based on the milestones proposed. Budget detail should be specific enough for the reviewers to understand the connection between the funds requested and activity to be conducted.

The total budget will be based on funds available, but is not expected to exceed \$25M per year in direct costs.

Inventions and Patents

To promote the broad sharing of information and inventions in the *All of Us* Research Program, awardee inventions will be governed by FAR clause 52.227-13, which provides title to the Government in any invention made under this award, subject to a revocable, nonexclusive, paid-up license in each patent application filed in any country on a subject invention and any resulting patent in which the Government obtains title. This is to assure that patents directed to inventions made under this award cannot be used to block access by the research public to this important resource and associated technology.

- (1) The Awardee shall include the substance of this patent rights clause in all third-party agreements for experimental, developmental, or research work. This patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the third parties (subcontractor, sub-awardees, and vendors) have all rights and obligations of the Awardee in the clause. The Awardee shall not, as part of the consideration for awarding the third-party agreement, obtain rights in the third party's subject inventions.
- (2) In the event of a refusal by a prospective third party to accept the clause, the Awardee—
 - a. Shall promptly submit a written notice to the *All of Us* Research Program Agreements Officer setting forth the third party's reasons for such refusal and other pertinent information that may expedite disposition of the matter; and
 - b. Shall not proceed with such third-party agreement without the written authorization of the *All of Us* Research Program Agreements Officer.
- (3) In third party agreements at any tier, the agency, the third party, and the Awardee agree that the mutual obligations of the parties created by the patent rights clause constitute a contract between the third party and the agency with respect to those matters covered by this clause.
- (4) The Awardee shall promptly notify the *All of Us* Research Program Agreements Officer in writing upon the award of any third party at any tier containing a patent rights clause by identifying the third party, the applicable patent rights clause, the work to be performed under the third-party agreements, and the dates of award and estimated completion. Upon request of the *All of Us* Research Program Agreements Officer, the Awardee shall furnish a copy of such third-party agreement, and, no more frequently than annually, a listing of the third-party activities that have been awarded.

Ownership of Data, Software, and Other Products

NIH will own all rights in data, software, and other products (collectively "Works") made or developed under this award, subject to a paid-up, nonexclusive, irrevocable worldwide license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the awardee. The parties further agree that these Works are "works made for hire" as defined by the Copyright Act. The Awardee may not use *All of Us* data or content/images for any non-*All of Us* Research Program activities.

Award recipients agree that no commercial intellectual property (*e.g.*, data, software, or other products), whether owned by the awardee or a third party except those specifically referenced in the application, will be utilized without express prior permission of NIH.

Data Policies

All research data generated by the *All of Us* Research Program, including the Participant Technologies Systems Center, are intended for use through the *All of Us* Data and Research Center. Awardees must restrict their use of the data only to activities stipulated and characterized in the program.

All activities between the prime awardee, any sub-awardees, or other third parties will be required to conform to the *All of Us* Research Program approved protocols.

Awardees, and some partnering organizations, will be required to execute an Interconnection Security Agreement with the DRC to ensure the secure transfer of data. In addition, awardees are subject to security breach reporting requirements involving *All of Us* data.

Material Transfer Agreement

All awardees and partnering organizations will be required to comply with the established material transfer agreement below.

Any and all Material delivered pursuant to the award is understood to be experimental in nature and may have hazardous properties. The recipients of funds under this award, and any sub-awardees, may not make any representations and extend no warranties of any kind, either expressed or implied, with regards to such Materials. Unless prohibited by law, neither the recipients of funds under this award, nor any of their respective officers, directors, employees or agents shall be liable to the *All of Us* Research Program Biobank, for any direct, indirect, or consequential loss or damages arising out of the transfer, use, storage, or disposal of any such Material.

Institutions who receive Data and/or Materials under these awards are required to use Data and/or Materials only as outlined in the *All of Us* Research Program protocols, in a manner that is consistent with applicable state and federal laws and regulations, including any informed consent requirements and the terms of the institution's NIH funding, if any. Failure to adhere with this criterion may result in enforcement activities, including termination of award.

Human Subjects Requirements

The institution and personnel involved in the conduct of the research are required to comply with 45 CFR Part 46 and establish a reliance agreement with the *All of Us* Research Program central IRB. The NIH will issue all awardees a Certificate of Confidentiality to protect against the compelled disclosure of *All of Us* identifiable, sensitive information and to support and defend the authority of the Certificate against legal challenges, per this [Notice](#).

Termination/Expiration Requirement

A fundamental objective of this Other Transaction award announcement is to ensure that all specimens and data remain available without interruption to the research public, even in the event that awardees withdraw, are terminated, or can otherwise no longer manage the project. Upon termination or expiration of this OT award, NIH may take exclusive ownership, custody, and control of the resources generated by the *All of Us* Research Program, including specimens, data, and software, at its reasonable discretion. For purposes of this solicitation, "exclusive custody and control" means that upon termination or expiration of this award, the departing awardee and its partners may not retain or disclose a copy of any data and may not use any specimen (or portions thereof), acquired or generated under the award.

If the NIH decides to terminate this award, the termination of the award will be considered a unilateral change and the recipient will not have the right to appeal. Although a decision is made to terminate an award, the recipient must continue to comply with the Record Retention and Access, and Final Reporting requirements, and may need to sign a non-disclosure agreement to complete the termination process.