

Overview Information	
Funding Opportunity Title	<i>All of Us Research Program Engagement and Retention Innovators (OT2)</i>
Funding Opportunity Number	OT-PM-19-003
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	OT-PM-16-002 Communication Support for the Precision Medicine Initiative® Research Programs at NIH OT-PM-17-002 <i>All of Us</i> Research Program Engagement Partners
Funding Opportunity Purpose	<p>The <i>All of Us</i> Research Program seeks to create one of the world’s largest and most comprehensive precision medicine research platforms. Its goal is to build a data resource containing multi-layered information on one million or more participants who reflect the rich diversity of the United States.</p> <p>The purpose of this award is to fund engagement innovators who will design strategies and tactics geared toward raising awareness of the <i>All of Us</i> Research Program through community and provider organizations, driving increased enrollment of participants, communicating to existing participants to keep them engaged partners, and engaging the research community to use the data being gathered.</p> <p>These engagement innovators should be expert and experienced organizations that have a proven track record in at least one of the following categories:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Community engagement <input type="checkbox"/> Provider engagement <input type="checkbox"/> Experiential learning <input type="checkbox"/> Multicultural engagement <input type="checkbox"/> Digital engagement <p>Programmatic priority will be given to applicants who have demonstrated experience and success working with and reaching into communities historically underrepresented in biomedical research. <i>All of Us</i> considers the following populations historically underrepresented in biomedical research: racial and ethnic minority groups; children and seniors; sexual and gender minorities; people with disabilities; people with barriers in access to care, low economic status, or low educational attainment; and rural residents.</p>

Overview Information	
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 that applicant direct costs should not exceed \$8M
Anticipated Number of Awards	NIH intends to fund at least one (1) award in FY2019. Other applications may be awarded dependent on applications received and funding availability
Key Dates	
Award Project Period	The total project period is anticipated to be five (5) years.
Post Date	February 11, 2019
Application Due Date	March 29, 2019 (5:00 p.m. local time)
Scientific/Technical Review Date	Review will be conducted in April 2019 after receipt of applications.
Award Timeline	Award(s) will be made upon selection and award negotiation. The estimated timeline is June 2019.
Application Instructions	
Required Application Instructions	<p>This award is meant to address all five categories of desired expertise (community engagement, provider engagement, experiential learning, multicultural engagement, and digital engagement) and awardees with experience in multiple categories are encouraged to apply. However, awardees are not required to have experience in all categories. If a single awardee is not qualified to fulfill all the requirements mentioned in the categories above, multiple awardees may be selected and will be expected to work collaboratively to achieve the intended outcomes. The materials created by all awardees should be replicable and scalable given that they may be utilized by multiple sites in the program.</p> <p>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.</p> <p>Each application submission must clearly state the applicant's qualifications and expertise. Applications shall also include sufficient detail to allow the Government to assess the applicant's capabilities to provide the requested services.</p>

Application Instructions

Applications should include the following within the total application package not exceeding 26 pages:

- Technical Approach: Not to exceed 15 pages
- Organization Description: Not to exceed 1 page. A description of the applicant organization(s), including a summary of their mission statement, a brief history, their projects of note, and lasting impacts, especially with historically underrepresented groups in biomedical research.
- Past Performance (Corporate/Organizational experience related to the funding opportunity): Not to exceed 5 pages. The applicant should indicate which of the five categories (community engagement, provider engagement, experiential learning, multicultural engagement, digital engagement) they have the most proficiency with and provide several examples of previous performance supporting this selection. Responses for individual categories should not exceed 1 page. If an applicant is proficient in multiple categories, the applicant may include responses corresponding to multiple categories. Applicants should describe their track record of performing the specific type of work required in this project, including previous work with the specific community or population (especially communities that are historically underrepresented in biomedical research) they intend to reach, and experience in meeting goals and milestones. In addition, applicants should describe past instances where they incorporated user feedback to change approaches and/or establish best practices.
- Key Personnel Not to exceed 3 pages. The applicant should include a description (biosketches) of key individuals who would work on this project.
- Cost Proposal: Not to exceed 2 pages. Applicants must provide details of how they will use the funds requested. This plan should include quarterly milestones. Proposals can use approaches such as cost-sharing, fixed price, adjustable/cost reimbursable, or a combination of approaches. Budget detail should be specific enough for the reviewers to understand the connection between the funds requested and activity to be conducted.

A one-page cover letter is allowed and will not count against the 26-page limit. It will be included with the application material provided to reviewers. Appendices are not allowed.

Application Instructions

	<p>Applicants should familiarize themselves with the report of the PMI Working Group to the Advisory Committee to the Director entitled The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine.</p>
Instructions for Application Submission	<p>Applications must be submitted via the NIH eRA ASSIST System by March 29, 2019. To submit an application via ASSIST, the applicant organization must be registered in eRA Commons (organizations already registered in eRA Commons do not need to reregister).</p> <p>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.</p> <p>Use OTA-19-004 in the field requesting Funding Opportunity Announcement.</p> <p>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.</p>

Eligibility Information

Eligible Applicants	<p>Higher Education Institutions</p> <ul style="list-style-type: none"><input type="checkbox"/> Public/State Controlled Institutions of Higher Education<input type="checkbox"/> Private Institutions of Higher Education <p>The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:</p> <ul style="list-style-type: none">• 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• Indian/Native American Tribal Governments (Federally Recognized)• Indian/Native American Tribal Governments (Other than Federally Recognized)
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Eligibility Information

<p>Eligible Applicants (cont.)</p>	<ul style="list-style-type: none"> • 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"> <input type="checkbox"/> Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education) <input type="checkbox"/> Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education) <p>For-Profit Organizations</p> <ul style="list-style-type: none"> <input type="checkbox"/> Small Businesses <input type="checkbox"/> For-Profit Organizations (Other than Small Businesses)
<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 are not allowed. Foreign components are defined as performance of any significant element or segment of the project outside of the United States either by the award recipient or by an individual employed by a foreign organization whether or not OT2 award funds are expended.</p>

Application Review

<p>Review Process</p>	<p>Applications will be evaluated for responsiveness to the Funding Opportunity requirements and merit by an appropriate review group convened by the NIH.</p> <p>Reviewers will evaluate applications based on the following:</p> <ul style="list-style-type: none"> • Experience • Quality of Submission • Engagement Approach including Measurable Commitments • Proficiency in categories of expertise described in the application: <ul style="list-style-type: none"> <input type="checkbox"/> Community engagement <input type="checkbox"/> Provider Engagement <input type="checkbox"/> Experiential learning <input type="checkbox"/> Multicultural engagement <input type="checkbox"/> Digital engagement • Innovation • Proposed Commitment to the Project • Past Performance • Key Personnel & Experience • Cost Proposal <p>Applicants may receive a brief written summary of the review. Successful applicants will undergo a negotiation process for award determination.</p>
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Application Review

Evaluation Process	<p>Programmatic priority will be given to applicants who have demonstrated experience and success working with and reaching into communities historically underrepresented in biomedical research as defined in the Funding Opportunity Purpose section.</p> <p>Additionally, reviewers will evaluate applications based on the following:</p> <ul style="list-style-type: none">• Demonstrated track record of relevant experience and expertise• Engagement approach including measurable commitments• Past performance and successes• Proven ability to work collaboratively within a large consortium of key stakeholders• Key personnel and experience• Cost proposal
Questions Regarding this Funding Opportunity	<p>Informational Webinar: Wednesday, February 27, 2019, 3:00 pm-4:00 pm EST To register for this webinar and receive instructions, email: AllofUsEngagement@nih.gov.</p> <p>Questions may be submitted via email, to Dr. Dara Richardson-Heron, <i>All of Us</i> Research Program, for programmatic objectives, or to Ms. Irene Haas, <i>All of Us</i> Research Program Agreements Officer, National Center for Advancing Translational Sciences (NCATS), for award mechanism and application submission matters, both at AllofUsEngagement@nih.gov.</p>
Authority	<p>Other Transaction awards will be made pursuant to current authorizing legislation, including the 21st Century Cures Act as specified in Section 402(n) of the Public Health Service Act, 42 U.S.C. 282(n).</p>
<i>All of Us</i> Research Program Other Transaction (OT) Award Policy Guide	<p>Other Transaction awards are subject to the <i>Other Transaction Award Policy Guide for the Precision Medicine Initiative® at NIH</i>. Applicants may review this policy guide, which will be available at: https://allofus.nih.gov/funding.</p>

***All of Us* Research Program Engagement and Retention Innovators**

Background:

The *All of Us* Research Program is an 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, *All of Us* 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 contribute to an effort that may advance the health of generations to come.

Purpose and Objectives of *All of Us* Research Program Engagement and Retention Innovators

Funding opportunity

The *All of Us* Research Program is defined by impactful engagement. Impactful engagement means a bidirectional, co-equal relationship between the program and its participants. Relationships are a reward in the *All of Us* Research program, and to build these relationships, the program will create a library of digital and analogue inclusive engagements that are made with – not just for – all communities living in the US. These engagements will delight, educate, inspire, and establish a long-lasting connection with the communities they have been designed with. These engagements are meant to be scalable, used by the entire *All of Us* consortium, and should be designed to be easily uploaded to a digital repository that will be a common resource for different members of the Consortium to download and cost-effectively fabricate using their vendor of choice. These engagements should also be customizable for many different communities as the *All of Us* is reflective of the rich diversity of those living in the US, including communities historically underrepresented in biomedical research. *All of Us* considers the following populations historically underrepresented in biomedical research: racial and ethnic minority groups; children and seniors; sexual and gender minorities; people with disabilities; people with barriers in access to care, low economic status, or low educational attainment; and rural residents.

To design these engagements, the program will work with world-class organizations to design innovative experiences based on the principles of community based participatory design, community co-creation, informal science-based experiential learning, inclusivity, and user-centric design. What makes *All of Us* different from other research programs is its focus on engagement and inclusivity. Interested organizations must have unparalleled expertise in these two areas. The awardee must be innovative, collaborative, flexible, creative, responsive to many different stakeholders, and comfortable with being self-directed where appropriate.

Awardees should have the capacity to develop ideas that will be iteratively refined and responsive to user feedback when these experiences are deployed. These experiences will be living artifacts, constantly evolving to be responsive to their target audiences over the life of the program. These experiences shall also be created with core metrics that will be used to evaluate their effectiveness. Metrics may include-but are not limited to-the number of people engaging with these experiences at public events, the number of times consortium members download specific materials, user ratings, the amount of time users engage with experiences, etc. The awardee shall outline evaluation metrics to be used, analyze these metrics on an ongoing basis, and offer recommendations for modifications to experiences as needed.

NIH is using the OT mechanism to enable maximum innovation and flexibility. Enrolling and retaining 1 million or more people from all walks of life into a longitudinal research program are unprecedented tasks. There is no established playbook for success. Using the OT mechanism will enable organizations beyond frequent NIH applicants to propose innovative strategies to communicate with potential participants and increase participant recruitment and retention.

Requirements

We are looking for expert and experienced organizations that have a proven track record in at least one of the following categories:

- Community engagement
- Provider Engagement
- Experiential learning
- Multicultural engagement
- Digital engagement

These organizations will serve two principle audiences:

- Participants and potential *All of Us* participants, especially those from populations historically underrepresented in biomedical research
- All of Us* Research Program Consortium partners who are recruiting, engaging and retaining *All of Us* program participants

As there is limited literature regarding best practices for designing inclusive and effective engagement experiences for a program of this scale and scope, materials and the process of material production created as part of this award will serve as a roadmap for future cohorts.

Expectations

Task 1. Create experiences focused around community engagement

Community engagement is community involvement based around community based participatory design throughout the life cycle of the experience. An example might be convening community members for brainstorming sessions, designing experiences based on community preferences identified from these sessions, creating prototypes of these experiences and then refining experiences through multiple iterations with community members. Awardees shall understand that participant partners and communities are co-designers for the program and that the collaborative design process is a relationship building experience vital to trust and transparency, two of the [core values](#) of the *All of Us*. Awardees shall keep detailed records of community interactions and note community input to specifically identify how community involvement optimized experience design. Community involvement may take multiple formats: town halls, presentations to [Participant Ambassadors](#), engagement studio workshops, surveys, focus groups, etc.

Task 2. Create experiences focused around experiential learning

Experiential learning means learning by doing. Awardees should design multimodal experiences that can be adapted to be applicable to a wide variety of audiences, require interactivity and hands-on activities based around the *All of Us* and [precision medicine](#), are relevant to specific individuals and communities, and are suitable for any age range and physical ability requirement. Experiences should nurture skill development, wonder, delight, play, comfortability with the *All of Us*, as well as inspire internal motivation through memorable, fun activities that apply to the daily lives of a million people or more. Experiential learning might take the form of games, problem solving activities, immersive presentations, creating artistic items, etc. and may be utilized for broad audiences.

Task 3. Create experiences focused around multicultural engagement

The goal of the *All of Us* is to create a diverse cohort and among its target audiences are groups historically underrepresented in biomedical research, as defined in the purpose and objectives section above. Awardees shall have expertise in how best to make experiences accessible for many cultures and regardless of barriers in language, physical ability, technological comprehension, etc. Awardees shall make special effort to tailor experience images to be reflective of the experience's intended community, keep experience reading level at a fifth-grade level or lower, be easily translated to multiple languages, and be reflective of the cultural norms of specific communities. An example of multi-cultural engagement might be making game instruction cards bilingual, collaborating with community partners to identify relevant experience topics, etc.

Task 4. Create experiences focused around digital engagement

The scale and scope of the *All of Us* dictates that much of the program is digitally based. Awardees shall be experts in cyberlearning and game-based design to not only create materials and activities that are easily scalable and deployable but are also deeply immersive. Awardees shall create innovative digital materials that will have the capacity to be used by individuals of different technological experience levels and access. Awardees shall have the capability to be able to translate analog experiences to digital ones. Digital engagements might include app development, virtual reality (VR) and augmented reality (AR) experiences, creating web-based experiences etc. Finally, awardees shall have the capacity to capture digital engagement using metrics to determine engagement effectiveness. Metrics may include—but are not limited to—the amount of time using digital engagements, website metrics, usability testing data, etc. Applicants must work collaboratively with other award partners to create appropriate interfaces and connections to existing IT infrastructure where appropriate.

Task 5. Create experiences focused around provider engagement

As a trusted individual consulted by many potential participants and participants about their health, health care providers are a crucial component of *All of Us*'s engagement strategy. Awardees shall create materials that can serve to two (2) purposes:

1. Serve as teaching aids to educate health care providers (physicians, nurses, physician assistants, etc.) about the *All of Us* Research Program, its implications for their patients and providers, and the means by which patients and patient's family members can enroll.
2. Serve as education aids that health care providers may use in their discussions with their patients to help initiate conversations about the program and program components and support health care providers' on-going efforts in engaging with potential participants in one-on-one or group settings (e.g. town halls, panel discussions, etc.).

Awardees shall have the capacity to iteratively design materials in collaboration with health care providers and be able to record and analyze metrics specific to health care providers' needs. Some examples of these metrics might be creating and analyzing surveys regarding specific engagement materials generated for health care providers, recording how many health care providers are using materials and in what capacity, recording how the patients of health care providers respond to these materials, etc.

Other Program Requirements:

Data Security and Management

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](#)

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, including 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 aspects of the awards. The *All of Us* Research Program consortium includes participant representatives throughout its governance structure.

The *All of Us* Research Program has a single Institutional Review Board (IRB) that ensures prompt and thoughtful consideration of the evolving protocols and the central importance of participants as research partners in the *All of Us* Research Program. 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 total budget will be based on funds available, but not expected to exceed \$8M 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. Award recipients agree that no commercial IP (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.

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.