

Overview Information	
Funding Opportunity Title	<i>All of Us Research Program - National, State, and Local Engagement Partner Funding Opportunity (OT2)</i>
Funding Opportunity Number	OTA-20-009
Participating Organization	National Institutes of Health (NIH)
Components of Participating Organizations	This funding opportunity (FO) is part of the NIH <i>All of Us</i> Research Program. The FO will be administered by the <i>All of Us</i> Research Program.
Opportunity Type	New
Related Notices	OT-PM-17-002 <i>All of Us</i> Research Program Engagement Partners (OT2) OT-PM-19-003 <i>All of Us</i> Research Program Engagement and Retention Innovators (OT2) OT-PM-19-002 <i>All of Us</i> Research Program Communications and Marketing Partners (OT2)
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 multilayered information on one million or more participants who reflect the rich diversity of the United States.</p> <p>This award is designed to fund local, regional, and national engagement partners who will establish strong collaboration with members of the <i>All of Us</i> consortium to design, implement, and evaluate strategies and tactics geared toward the following categories:</p> <ol style="list-style-type: none"> 1. Recruiting and retaining one million or more participants who reflect the rich diversity of the United States. To ensure that the <i>All of Us</i> data reflect the diversity of the country, the program needs to mobilize and collaborate with trusted organizations, intermediaries, and influencers to engage and facilitate enrollment and retention of communities historically underrepresented in biomedical research (UBR). 2. Engaging researchers from diverse backgrounds, including those from underrepresented groups, to utilize the <i>All of Us</i> data resources to advance precision medicine. 3. Collaborating with health care providers who serve UBR communities to promote <i>All of Us</i>. 4. Working with the <i>All of Us</i> consortium and communications team to develop assets that resonate with diverse groups and conduct multiple engagement, enrollment, and retention campaigns based on geography and programmatic scientific priorities.

Overview Information

Funding Opportunity Purpose (continued)	<p>5. Contributing to the science of engaging, enrolling, and retaining UBR communities into research.</p> <p>Each applicant should be an expert and from experienced organizations with a proven track record in some or all tasks and sub-tasks in this FO. Programmatic priority will be given to applicants who have demonstrated experience and success in engaging and recruiting communities historically underrepresented in biomedical research into research. <i>All of Us</i> considers the following populations UBR: racial and ethnic minority groups; children and seniors; sexual and gender minorities; people living with disabilities; people with barriers in access to care; people who have low income or low educational attainment; and rural residents.</p>
Funding Instrument	<p>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. OT provides for the flexibility to adjust the scope of work and milestones during a specific timeframe, based on the requirements of the activity, to respond to the needs of the program and the desire to achieve maximum efficiency. OT will allow the <i>All of Us</i> Research Program to effectively choose activities from among potential awardees to produce a comprehensive set of awardees that can deliver the goals of the program.</p>
Funds Available	<p>Actual amounts will depend on funds available, but the program expects applicant direct costs to not exceed \$1.5 million per year/awardee.</p>
Anticipated Number of Awards	<p>NIH intends to fund at least 6 awards in FY 2021. Applicants may opt to partner with other organizations on a single application submission. Other applications may be awarded dependent on applications received and funding availability.</p>

Key Dates

Award Project Period	<p>The total project period is anticipated to be 5 years.</p>
Post Date	<p>September 25, 2020</p>
Application Due Date	<p>November 23, 2020 (5:00 p.m. of applicant's local time)</p>
Scientific/Technical Review Date	<p>Review will be conducted in December 2020 after receipt of applications.</p>
Award Timeline	<p>Award(s) will be made upon selection and award negotiation. Earliest anticipated start date is May 2021.</p>

Application Instructions

Required Application Instructions	<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>
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Application Instructions

Required Application Instructions (continued)	<p>Applications should include the following within the total application Package, not to exceed 25 pages:</p> <ul style="list-style-type: none">• Technical Approach: Not to exceed 15 pages• Past Performance (corporate/organizational experience related to the solicitation): Not to exceed 5 pages• Key Personnel (Applicants should provide brief biosketches of key personnel): Not to exceed 3 pages. Each application must identify one or multiple Program Directors/Principal Investigators (with a level of effort of at least 10% each). A list of other key investigators must be included. An overall leadership structure and management plan must be included in this section. If there are multiple PDs/PIs, a leadership plan that incorporates a conflict resolution plan must be included.• Cost Proposal: Not to exceed 2 pages. Applicants should build a milestone-driven, cost-allocated plan for proposal. Cost models can be cost-sharing, fixed-price, or adjustable (cost-reimbursable), or have a hybrid approach. A five-year cost proposal including indirect costs should be submitted. Budget details should be specific enough for the reviewers to understand the connection between the funds requested and activity to be conducted. <p>A one-page cover letter is allowed and will not count against the 25-page limit. It will be included with the application material provided to reviewers. Appendices are not allowed.</p> <p>Applicants should familiarize themselves with the report of the PMI Working Group to the Advisory Committee to the Director entitled <i>The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine</i>.</p>
Instructions for Application Submission	<p>Applications must be submitted via the NIH eRA ASSIST System by November 23, 2020. 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.</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-20-009 in the field requesting FO 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

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:

- 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)

Nonprofits Other Than Institutions of Higher Education

- 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)
- Native American Tribal Organizations (Other than Federally Recognized Tribal Governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Independent School Districts
- State or County Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- City or Township Governments
- Special District Governments
- Public Housing Authorities/Indian Housing Authorities

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Eligibility Information

Foreign Institutions

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.

Foreign components are **not** allowed. Foreign components are defined as those responsible for 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.

Application Review

Review Process

Applications will be evaluated for responsiveness to the Funding Opportunity requirements and merit by an appropriate review group convened by the NIH.

Reviewers will evaluate applications based on the following:

- Completeness of technical elements
- Quality of submission
- Past performance and portfolio
- Key personnel, experience, and proposed commitment to the project
- Cost proposal

Successful applicants will undergo a negotiation process for award determination.

Evaluation Process

In addition to technical and scientific merit, applications will be evaluated for programmatic priority.

Programmatic priority will be given to applicants with:

- Demonstrated experience and success in engaging and recruiting communities historically underrepresented in biomedical research into research as defined in the Purpose and Required Application Instructions sections of this FO
- Engagement and outreach strategies including measurable outcomes
- Past performance and successes in the areas in the Purpose and Required Application Instructions sections of this FO.
- Proven ability to work collaboratively within a consortium of diverse stakeholders
- Local, regional, or national network of organizations to help plan, implement, and evaluate engagement and outreach activities
- Key personnel with demonstrated experience, skill, and knowledge to successfully execute the proposed project
- Cost proposal that is commensurate with the proposed project activities

Application Review	
Questions Regarding this Funding Opportunity and Program and Agreements Officer Contact	<p>Informational Webinar: Monday, October 5, 2020, 12PM EDT</p> <p>To register for this webinar and receive instructions, email: AllofUsFOAInquiries@nih.gov.</p> <p>Questions may be submitted via email to Ahmed Elmi, Program Officer, <i>All of Us</i> Research Program, for programmatic objectives; or to Ms. Debra Sowell, <i>All of Us</i> Research Program Agreements Specialist, for award mechanism and application submission matters, both at: AllofUsFOAInquiries@nih.gov.</p>
Authority	Other Transaction awards will be made pursuant to current authorizing legislation, including the 21 st Century Cures Act as specified in Section 402(n) of the Public Health Service Act, 42 U.S.C. 282(n).
<i>All of Us</i> Research Program Other Transaction (OT) Policy Guide	Other Transaction awards are subject to the requirements of the <i>Other Transaction Award Policy Guide for the NIH Precision Medicine Initiative Research Programs</i> . Applicants must review this policy guide, available at: https://allofus.nih.gov/funding .

***All of Us* Research Program Engagement Division**

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 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.

To learn more, please visit the following three websites:

- Program overview: <https://allofus.nih.gov/>
- Enrollment site: <https://www.joinallofus.org/>
- Research Hub: <https://www.researchallofus.org/>

Further Background Information About Relevant Previous OT and Program Awardees

[OT-PM-17-002](#) *All of Us* Research Program Engagement Partners (OT2)

[OT-PM-19-003](#) *All of Us* Research Program Engagement and Retention Innovators (OT2)

[OT-PM-19-002](#) *All of Us* Research Program Communications and Marketing Partners (OT2)

To learn more about the *All of Us* partners, please visit <https://allofus.nih.gov/funding-and-program-partners>.

Purpose and Objectives of the *All of Us* Research Program National, State, and Local Engagement Partner FO

The NIH solicits proposals from organizations to serve as engagement partners for the *All of Us* Research Program. To ensure that the *All of Us* data reflect the diversity of the country, the program needs to mobilize and collaborate with trusted organizations, intermediaries, and influencers to engage and facilitate enrollment and retention of UBR communities. The engagement of these communities is essential for the program to meet the 21st Century Cures Act requirement to “consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities.”

The *All of Us* Research Program is defined by impactful engagement – a bidirectional, co-equal relationship between the program and its participants. According to the [Principles of Community Engagement \(2nd Edition\), NIH Publications No. 11-7782](#), community engagement is “the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people.” Community engagement requires integrating many theories, concepts, models, and principles from various disciplines, including sociology, cultural anthropology, psychology, health behavior, intersectionality, community-based participatory research, and communications. A well-planned community engagement has the potential to improve research quality and increase the relevance of research results to intended communities. Through authentic community engagement, the program has the opportunity to develop trust with communities, create messages, mediums, and methods that will resonate with diverse communities, which could be applied to promote enrollment, retention, and return of information to participants.

The engagement partners will collaborate with other program awardees and divisions to involve UBR communities using engagement, outreach, enrollment, and retention strategies and tactics. These partners will share the concerns of their communities with the program, which will help us develop ways to overcome communities’ distrust of the research enterprise, and to assist people in making informed decisions about participation. To help deliver on the promise of *All of Us*, the program will build a national network of trusted community organizations to motivate diverse communities to enroll and remain. The program is committed to ensuring that participant perspectives are considered throughout every aspect of the program and giving a voice to those who are historically underrepresented in medical research.

The program plans to implement several goals over the next five years which will require partnering with national, state, tribal, and local organizations who are trusted and considered influencers by their respective UBR communities. These goals include the refinement and the national implementation of the direct volunteer pathway (an enrollment pathway for people who want to join *All of Us* but do not have access to a participating health care provider organization); strengthening retention strategies for all participants; launching the return of results to participants, including genomics information; and conducting multiple engagement, enrollment and retention campaigns based on geography and programmatic scientific priorities.

As the program reimagines its direct volunteer pathway, partners could be asked to assist in strengthening this enrollment path. They could be asked to pilot community-based enrollment sites to help make the enrollment process seamless for their UBR communities. As the program grows, community partners could be asked to activate their existing partners or new partners who serve these communities in cities and states the program is not active in yet.

The program is also committed to enrolling children under 18 years old. The inclusion of children in the program will require trusted partners who can engage children and their parents and/or guardians. The addition of children will require new strategies, and there will be a need to adapt to different requirements in each community and state.

Partnership with national and community engagement organizations positions the program for understanding the necessary engagement and outreach strategies for increasing involvement of UBR communities over many years. Through these engagements, we will aim to co-develop promising strategies to engage and manage relationships with a diverse set of participants. The program expects this will improve the quality and relevance of the data resources, and support the development of more customized prevention, diagnosis, and treatment strategies that may help alleviate health disparities.

By continuing to engage, enroll, and retain participants from UBR communities, the program will be well-positioned to contribute to the body of knowledge supporting the science of community engagement. This includes identifying evidence-based, promising practices, and guidance for developing a bidirectional, co-equal relationship between the program and its participants to improve research quality and increase the relevance of research results to intended communities. This body of knowledge could also lead to a better understanding of engaging diverse community stakeholders who are not often involved in NIH biomedical research and how to form bidirectional relationships and trust that are critical to sustaining participation in biomedical research among UBR communities. This could serve as a roadmap for future cohorts.

The specific tasks for this FO are described below. Each applicant should be expert and experienced organizations with a proven track record in similar work that can assist us in some or all tasks and sub-tasks in this FO. Programmatic priority will be given to proposals and teams capable of supporting multiple components.

We are looking for expert and experienced organizations that have a proven track record enabling them to excel at the following tasks:

Task 1: Recruit and retain one million or more participants who reflect the rich diversity of the United States

Engagement partners will help develop, implement, and evaluate engagement, enrollment, and retention strategies and tactics and should have the experience and expertise in the following areas:

- Engaging and building relationships and trust with communities historically underrepresented in biomedical research, including communities that have historically experienced unethical research
- Utilizing distinct and tailored engagement practices and tactics for diverse and multicultural communities, and incorporating the dynamic nature of social perspectives and networks, intersectionality, and cultural influences
- Utilizing an effective digital engagement and outreach strategy with partners that demonstrates digital maturity and capabilities for creating a digital drumbeat and campaigns to promote *All of Us* engagement, enrollment, and retention
- Facilitating the enrollment of communities that have been historically underrepresented in biomedical research into research using promotion, enrollment, and retention strategies and tactics
- Engaging and facilitating pediatric participation in the *All of Us* Research Program

Task 2: Engage researchers from diverse backgrounds, including those from underrepresented groups, to utilize the All of Us data resources to advance precision medicine

We believe a diverse and broadly accessible data resource can help us build a healthier future. The program has partnered with prominent institutions and organizations to build a research protocol that respects participants and the needs of the research community. Engagement partners are expected to engage researchers from diverse backgrounds, including early-stage investigators, graduate students, and post-doctoral candidates and trainees, as well as citizen scientists from underrepresented groups, to utilize *All of Us* data and resources to advance precision medicine.

Task 3: Engage and collaborate with health care providers serving UBR communities to learn about and connect with All of Us

Health care providers are well positioned to speak with their patients and their peers about *All of Us*. Engagement partners could collaborate with these providers to develop, deploy, and evaluate strategies and tactics to educate their patients and peers.

Task 4: Collaborate with the All of Us consortium to develop assets that resonate with diverse groups

Engagement partners are expected to collaborate with the *All of Us* consortium, the program's engagement and communications teams, and diverse stakeholders to develop assets, messaging, and strategies for engaging diverse audiences about biomedical research. This could be achieved by the formation of an active and engaged Community Advisory Board (CAB) consisting of key individuals who are attuned to and responsive to the needs of the communities being recruited to participate in the *All of Us* Research Program.

Task 5: Contribute to the science of engaging, enrolling, and retaining UBR communities in research

Engagement partners will contribute to the collection of evidence-based and promising practices for engaging, inviting, and retaining UBR communities. The partners will help develop, test, and deploy messages, mediums, and methods that will resonate with diverse communities, which could be applied to enrollment, retention, and return of information to participants.

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, the program establishes committees, task forces, and boards to help 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 **\$1.5 million** per year in direct costs, per awardee.

Inventions and Patents

To promote the broad sharing of information and inventions in the *All of Us* Research Program, awardee inventions will be deemed subject to the terms of FAR clause 52.227-13, which provides title to the Government in any subject invention made under this award, subject to a revocable, nonexclusive, paid-up license to the awardee 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 prevent an awardee from denying access to 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 Government, 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 Government 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

The Government will own all rights in data, software, and other copyrightable works (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. For this purpose, “data” means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.

Awardee agrees that no intellectual property (*e.g.*, data, software, or other copyrightable works), whether owned by the awardee or a third party, except those specifically referenced in the application, will be utilized without express prior permission of *All of Us* Research Program Agreements Officer .

Human Subjects Requirements

The institution and personnel involved in the conduct of the research must comply with all applicable requirements of 45 CFR Part 46 and establish a reliance agreement with the *All of Us* Research Program central IRB unless otherwise excepted. The NIH will issue all awardees a Certificate of Confidentiality to allow the awardees to protect against the compelled disclosure of *All of Us* participant data 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.