

<b>Overview Information</b>	
<b>Funding Opportunity Title</b>	<p><b>All of Us Research Program Engagement Partners (OT2)</b></p> <p><a href="https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/community-partner-fo.pdf">https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/community-partner-fo.pdf</a></p>
<b>Funding Opportunity Number</b>	OT-PM-17-002
<b>Participating Organization</b>	National Institutes of Health (NIH)
<b>Components of Participating Organizations</b>	This funding opportunity is issued by the <i>All of Us</i> Research Program (formerly the Precision Medicine Initiative Cohort Program), part of the NIH Office of the Director. The funding awards will be administered by the National Center for Advancing Translational Sciences (NCATS) on the Program's behalf.
<b>Announcement Type</b>	New
<b>Related Notices</b>	<p><a href="#">NOT-OD-15-159</a> Precision Medicine Initiative Cohort Program Recommendations Issued and Accepted</p> <p><a href="#">RFA-PM-16-001</a> Precision Medicine Initiative Cohort Program Coordinating Center (U2C)</p> <p><a href="#">OT-PM-16-002</a> Communication Support for the Precision Medicine Initiative® Research Programs at NIH</p> <p><a href="#">RFA-PM-16-002</a> Precision Medicine Initiative Cohort Program Healthcare Provider Organization Enrollment Centers (UG3/UH3)</p> <p><a href="#">RFA-PM-16-003</a> Precision Medicine Initiative Cohort Program Participant Technologies Center (U24)</p> <p><a href="#">OT-PM-16-003</a> Precision Medicine Initiative Cohort Program Regional Medical Center Healthcare Provider Organizations (OT2)</p>
<b>Funding Opportunity Purpose</b>	<p>The goal of the <i>All of Us</i> Research Program (“<i>All of Us</i>” or “the Program”) is to build a diverse research cohort of one million or more U.S. volunteers who are engaged as partners in a longitudinal, long-term research effort to transform the understanding of factors contributing to individual health and disease.</p> <p>The purpose of this funding opportunity is to support engagement partners who can:</p> <ul style="list-style-type: none"> <li>Engage, educate, and motivate volunteers to join and remain in the Program, and to facilitate their enrollment where needed, with measurable success;</li> <li>Engage and educate health care professionals (physicians, nurses, physician assistants, etc.) about the <i>All of Us</i> Research Program; and/or enable health care professionals to facilitate</li> </ul>

	<p>enrollment of their patients or patients' family members in the Program, with measurable success.</p> <p>Proposals may have a local, regional, or national scope.</p>
<b>Funding Instrument</b>	The funding instrument is the Other Transaction (OT) award, a mechanism that is not a grant, cooperative agreement or contract, and uses Other Transaction Authority.
<b>Funds Available</b>	Actual amounts will depend on funds available, but is expected to be up to approximately \$5M/year for all awards. Applicants should prepare a budget submission that is compatible with the scope of work to be achieved. We anticipate local community engagement awards may range from \$25-100K/year in direct costs, and regional/national scale community engagement awards may range from \$100-500K/year in direct costs. We anticipate health care professional engagement awards may range from \$25-250K/year in direct costs. The Program aims to make at least one of each type of award in the first round of awards.
<b>Anticipated Number of Awards</b>	NIH intends to fund approximately 3-4 awards in the spring of 2017 and additional awards over the course of FY17.
<b>Key Dates</b>	
<b>Award Project Period</b>	The total project period will be approximately three (3) years.
<b>Post Date</b>	January 31, 2017
<b>Application Due Date</b>	March 24, 2017 (5:00 pm local time)
<b>Scientific/Technical Review Date</b>	Review will be conducted immediately upon receipt of applications.
<b>Award Timeline</b>	Award will be made upon selection and award negotiation. Site visits or visits to NIH may be requested.
<b>Application Instructions</b>	
<b>Required Application Content</b>	<p>Applications should include enough detail to allow the NIH to assess the applicant's ability to provide and measure the requested services.</p> <p>Applications must include the following, with the total application package not exceeding 15 pages:</p> <ul style="list-style-type: none"> <li>• Community Served: Not to exceed 1 page. The applicant should include a description of the community or population that will be engaged, including details about geography, demographics, and languages spoken.</li> <li>• Organization Description: Not to exceed 1 page. A description of the applicant organization(s).</li> <li>• Engagement Approach: Not to exceed 7 pages. The engagement approach should describe the plans and specific activities proposed by the applicant. The applicant should describe how the project will be managed and the anticipated number of people who will be reached.</li> </ul>

	<ul style="list-style-type: none"> <li>• Past Performance (Organizational experience related to the funding opportunity): Not to exceed 2 pages. Applicants should describe their track record of performing the type of work required in this project, including previous work with the specific community or population they intend to reach, and experience in meeting goals and milestones.</li> <li>• Key Personnel &amp; Experience: Not to exceed 2 pages. The applicant should include a description (bios) of key individuals who would work on this project. Note the level of effort (% time) of the key personnel. At least one individual should devote significant effort to the proposed engagement activity.</li> <li>• Funding 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.</li> </ul> <p>A one-page cover letter is allowed and will not count against the 15-page limit. Appendices are not allowed.</p>
<b>Instructions for Application Submission</b>	<p>Applications must be submitted in a single email attachment in PDF (Adobe) format to Ms. Irene Haas, <i>All of Us</i> Research Program Agreements Officer, at <a href="mailto:PMICPFOAInquiries@mail.nih.gov">PMICPFOAInquiries@mail.nih.gov</a>. Applications must be submitted by an authorized individual from your organization. Paper applications will not be accepted.</p>
<h2 style="color: #800040;">Eligibility Information</h2>	
<b>Eligible Applicants</b>	<p>Organizations, including subaward partners, currently receiving funding support through the <i>All of Us</i> Research Program are NOT eligible to apply.</p> <p>The following entities are eligible to apply as an applicant organization:</p> <ul style="list-style-type: none"> <li>• Nonprofits with 501(c)(3) IRS Status</li> <li>• Nonprofits without 501(c)(3) IRS Status</li> <li>• Faith-based or Community-based Organizations</li> <li>• Regional Organizations</li> <li>• Independent School Districts</li> <li>• Hispanic-serving Institutions</li> <li>• Historically Black Colleges and Universities (HBCUs)</li> <li>• Tribally Controlled Colleges and Universities (TCCUs)</li> <li>• Alaska Native and Native Hawaiian Serving Institutions</li> <li>• Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)</li> <li>• State or County Governments</li> <li>• City or Township Governments</li> <li>• Special District Governments</li> </ul>

	<ul style="list-style-type: none"> <li>• Indian/Native American Tribal Governments (Federally Recognized)</li> <li>• Indian/Native American Tribal Governments (Other than Federally Recognized)</li> <li>• Native American Tribal Organizations (Other than Federally Recognized Tribal Governments)</li> <li>• Public Housing Authorities/Indian Housing Authorities</li> </ul>
<b>Foreign Institutions</b>	<p>Non-domestic (non-U.S.) Entities (Foreign Institutions) <b>are not</b> eligible to apply.</p> <p>Non-domestic (non-U.S.) components of U.S. Organizations <b>are not</b> eligible to apply.</p> <p>Foreign components are <b>not</b> 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>
<b>Application Review</b>	
<b>Objective Review Process</b>	<p>Applications will be evaluated for merit by an appropriate review group convened by the NIH. The review group will include expert community and federal reviewers.</p> <p>Reviewers will evaluate applications based on the following:</p> <ul style="list-style-type: none"> <li>• Community/population to be served</li> <li>• Engagement Approach including Measureable Commitments</li> <li>• Past Performance</li> <li>• Key Personnel &amp; Experience</li> <li>• Cost Proposal</li> </ul>
<b>Evaluation Process</b>	<p>In addition, applications will be evaluated for programmatic priority. Programmatic priority will be given to applicants with:</p> <ul style="list-style-type: none"> <li>• Reach into <a href="#">priority geographic regions</a>.</li> <li>• Reach into communities historically underrepresented in biomedical research including clinical trials (including but not limited to individuals with physical disabilities, racial or ethnic minorities, women, individuals from geographically isolated communities, economically disadvantaged individuals, and sexual and gender minorities).</li> </ul>
<b>Questions Regarding this Funding Opportunity</b>	<p>Questions may be submitted via email to  Ms. Katie Rush  <i>All of Us</i> Research Program  Email: <a href="mailto:PMICPFOInquiries@mail.nih.gov">PMICPFOInquiries@mail.nih.gov</a></p>
<b>All of Us Research Program Contact</b>	<p>Ms. Katie Rush  <i>All of Us</i> Research Program  Email: <a href="mailto:PMICPFOInquiries@mail.nih.gov">PMICPFOInquiries@mail.nih.gov</a></p>
<b>Authority</b>	<p>Other Transaction awards will be made pursuant to current authorizing legislation.</p>

<b>All of Us Research Program Other Transaction (OT) Policy Guide</b>	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 <a href="http://www.nih.gov/sites/default/files/research-training/initiatives/pmi/20151118-ot-award-policy-guide.pdf">http://www.nih.gov/sites/default/files/research-training/initiatives/pmi/20151118-ot-award-policy-guide.pdf</a> .
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## All of Us Research Program Background

The [All of Us Research Program](#) is a historic effort to gather health-related data from 1 million or more people living in the United States, over many decades, to accelerate research and improve health. The program will be open to people both healthy and sick, from all communities, to reflect the rich diversity of the country.

Unlike a single research study focused on one 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 that affect many different people.

Participants will have opportunities over many years to provide data about themselves that will help researchers learn more about how individual differences in lifestyle, environment, and biological make-up can influence health and disease. By taking part, participants can learn more about their own health and contribute to an effort that will advance the health of generations to come.

Over the past year, the NIH has issued awards to build the foundational partnerships and infrastructure needed to launch the Program. The [awards](#) support a Data and Research Support Center, Participant Technologies Center, a network of Health Care Provider Organizations (HPOs), and a Biobank. NIH has also issued awards to external communications firms to support *All of Us* Research Program branding, communications, and public relations.

The *All of Us* Research Program values a highly interactive participation model, which is unique for a project of this scale. Participants will be providers of information about their health and experiences, sources of proposed research studies, mediators of access to their health care data, contributors to overall data quality control, donors of data from mobile and wearable devices, and recipients of their own data as well as aggregate data and scientific results, according to their preferences.

Data provided by participants will make up the core dataset and will be stored in a secure computing environment under rigorous standards to protect individual privacy. The Program will utilize a variety of data collection methods throughout its duration, including research questionnaires, collection of baseline and longitudinal data from electronic health records, physical measurement, collection and analyses of blood or other samples, and, over time, data from mobile technologies.

## Enrolling in All of Us

Enrollment in the *All of Us* Research Program is expected to begin in 2017. Individuals will be able to enroll in the *All of Us* Research Program in one of two ways: through an [All of Us Research Program Health Provider Organization \(HPO\)](#) or through a Direct Volunteer (DV) path. There are currently three types of HPOs within the *All of Us* Research Program: regional medical centers, community health centers, and U.S. Department of Veterans Affairs Medical Centers. These HPOs have committed to sharing the *All of Us* Research Program opportunity with their members or patients and/or their

families. Individuals who enroll through an HPO are likely to do so in conjunction with a scheduled visit to a health care provider. The Program currently has HPOs in 18 states for year 1 with 28 states anticipated in years 2-5.

Individuals enrolling through the Direct Volunteer path will enroll through an app, a website, or a toll-free call center. The digital portals will be in English and Spanish, and the call center will also have English and Spanish language capability, with the expectation that additional languages will be added after the Program's initial launch. The call center will be able to answer questions about the *All of Us* program as well as to facilitate enrollment.

Participants will be asked to consent to participate, complete brief survey modules, and provide data from their electronic health records, if they have them. In addition, they may be asked to undergo a baseline physical measurement and provide blood, urine, and/or saliva samples (biospecimens). Individuals who join the program through the DV path will have their baseline physical measurement and their biospecimen collections facilitated by the Program and conducted at participating Walgreens stores or designated commercial laboratories, or, in some cases, during a home visit.

If more than one million participants enroll in the *All of Us* Research Program, the Program may not have sufficient funding to collect biospecimens and physical measurements from all participants. In the initial phase of the Program, only volunteers 18 years or older will be eligible to participate; children will be included in the future.

Volunteers are expected to participate in the study over many years. They may also choose to be re-contacted about future research studies. Participation in any future study is entirely optional. Participants who complete the baseline physical measurement and supply biospecimens will be provided a one-time payment of \$25 to help defray the cost of their participation.

## **Value to Participants**

Individuals who participate in the *All of Us* Research Program will have access to information and data collected from them. A million participants will have their genomes sequenced, several years from now. Participants will be informed of any studies that use their data and the results of those studies.

Initial Program research suggests that the following factors motivate potential participants:

- An opportunity to fight disease and improve the health of future generations.
- An opportunity to ensure that one's community is included in the studies that lead to new understanding and new treatments.
- A chance to learn some of one's own health indicators.
- The chance to be part of a movement designed to make our health care more precise, more tailored, and more effective.

The *All of Us* Research Program is not medical treatment. Participants will not get direct medical benefit from taking part. However, participants may indirectly benefit from taking part by learning about their own health and contributing information that helps scientists and doctors understand more about what keeps people healthy or makes them sick.

## **Purpose and Objectives of *All of Us* Research Program Engagement Partners**

The purpose of this Funding Opportunity is to enable Partners to educate, motivate, and facilitate enrollment in the *All of Us* Research Program. The *All of Us* Research Program seeks to enroll volunteers that reflect the diversity of the United States, including those historically underrepresented in biomedical research. The HPOs have a diversity commitment in their recruitment plans, as well as their own partnerships with local organizations. We seek additional partners to complement these efforts, especially in [priority geographic areas](#).

Awardees under this Funding Opportunity as well as from the HPOs and DV will be expected to share best practices and lessons learned through collaboration and, more formally, through the *All of Us* governance structure.

Engagement partners are needed to:

- Educate and inspire community leaders and members about the *All of Us* Research Program, its value, and the opportunity to participate.
- Serve as a community-specific resource for potential participants.
- Facilitate the enrollment of individuals into the *All of Us* Research Program.
- 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.

These activities could be conducted in a variety of ways. Applicants should recommend approaches that are the best fit with the community of interest, the applicant's abilities, and any partners involved.

Example engagement activities include:

- *All of Us* Research Program-specific education events (in person or online).
- Sustained communications programs inclusive of media outreach, social media implementation, and/or member communication.
- Train-the-trainer programs (across multiple chapters and/or networks).
- Presentations at major conferences.
- Creating an *All of Us* Research Program booth or other presence at existing events (i.e., community health fair, walk for a cure, or reading night).
- Developing and implementing an *All of Us* Research Program communications effort using existing organization tools (e.g., existing newsletters, website, or educational programs).
- Training and supporting an *All of Us* Research Program community ambassador.
- Hosting "enrollment facilitation night" in the community.
- Funding of dedicated staff time or employment of community members to support outreach activities.
- In-language support for developing tools, media outreach, participant enrollment, and/or train-the-trainer programs.
- Developing and offering of Continuing Medical Education, Continuing Nursing Education, or Continuing Education Units.

Whatever the approach, applicants are required to make measureable commitments, such as: to train x trainers, to educate x community members, to facilitate the enrollment of x community members, to plan x community events, to generate x website visits, to educate x nurses, etc., and to include a timetable for meeting these commitments through specific activities.

Applicant organizations are encouraged to partner with other eligible groups as needed to engage the community of interest. For all applications, one organization must serve as the lead applicant and fiscal sponsor. All participating organizations must be identified along with an explanation for why the partner(s) were chosen.

## Existing Communications Tools & Requirements for New Materials

NIH leads overall communications efforts for the *All of Us* Research Program and will provide support to awardees through technical assistance, standard language and branding guidelines, and design files for communications materials (including, but not limited to, fact sheets, brochures, videos, and infographics). Printing expenses will be incurred by the awardees; applicants should include these estimates in their cost proposal.

NIH may also provide awardees access to the *All of Us* Research Program Mobile Asset—i.e., a traveling exhibit on wheels—for limited periods of time, depending on schedule and availability.

Any new communications products developed by the awardee will require advance approval by the *All of Us* Research Program communications team at NIH and potentially also the Program’s Institutional Review Board (IRB) to ensure consistency and accuracy in messaging. Engagement partner communications products will be required to follow the Program’s branding and co-branding guidelines.

## Funding Mechanism Details & Key Dates

The Other Transaction award mechanism allows significant ongoing involvement from NIH staff and provides the NIH the flexibility to alter the course of the project in real time to meet the overarching goal. This may mean that awarded activity could be expanded, modified, partnered, not supported, or discontinued based on program needs, emerging methods or approaches, and availability of funds. Performance during the award period will be reviewed on an ongoing basis, and course corrections will be made as necessary.

Key Events	Dates	Action needed by applicants
Funding announcement posted	January 31, 2017	Initiate teaming conversations and/or application preparation.
Funding Opportunity Webinar	February 10, 2017, 12-1pm Eastern Time. (tentative)	Check <a href="http://www.nih.gov/precisionmedicine">www.nih.gov/precisionmedicine</a> for webinar details and participate.
SAM and DUNS number registration	March 1, 2017	Begin registration process if needed.
Proposal due	March 24, 2017	Email completed application by 5pm local time.
Review of written applications completed	April 6, 2017	None.
Possible site visit or reverse site visit	April 11-12, 2017	Hold dates for possible site visit by NIH or reverse site visit to NIH.
SAM and DUNS number registrations	April 15, 2017	Potential award recipients must provide confirmation of SAM and DUNS number registration.

Estimated award date	May 15 , 2017	
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\*\*[DUNS](#) and [SAM](#) number [registration](#) can take several weeks. Please see the registration link for helpful instructions. Awards require a DUNS or SAM registration. The registration link is specific to grants: however, the process for DUNS and SAM registration for this OT award is the same. Candidates should begin the registration process several weeks prior to this deadline to ensure completion in time to provide this information to NIH.

### Key Elements to Include in the Application

	Community Engagement Local Scale*	Community Engagement Regional/National Scale*	Health Care Professional Engagement Regional/National Scale
Community to be addressed. No more than 1 page.	A description of the community to be engaged using a set of tangible and explicit criteria. The criteria can include, for example, a common interest, characteristic, and/or geographic area. The description should include demographic information and languages spoken.		A tangible and explicit description of the professional community to be engaged, including geographical locations and languages spoken.
Organization description. No more than 1 page.	A description of the applicant organization or applicant consortium, including a description of the applicant’s connection to the community to be engaged, and the organization’s annual operating budget. If the application includes multiple organizations, one organization must serve as the lead applicant and fiscal sponsor.		
Engagement Plan. No more than 7 pages.	The engagement methods, materials, and activities the applicant proposes to use to educate and inspire the community about the <i>All of Us</i> Research Program, including a timeline of key activities by quarter.		
	When and how the applicant plans to assist volunteers in enrolling in the Program (e.g., by providing language or technical support, access to a computer or tablet and the internet, transportation to sites for physical measurements, etc.)		The engagement methods and activities the applicant proposes to use to educate and inspire health care professionals about the <i>All of Us</i> Research Program.
	The retention approach the applicant will take to encourage volunteers to remain active in the Program after initial enrollment and throughout the period of award.		The methods, materials, and activities the applicant intends to use, if any, to enable health care professionals to facilitate the enrollment of patients or patients’ family members in the <i>All of Us</i> Research Program.
	The number of people who will be educated, trained to educate others, and/or enrolled in the <i>All of Us</i> Research Program as the result of the applicant’s efforts.		If the applicant proposes to facilitate enrollment of volunteers, the applicant should also describe the retention strategy to be used to encourage volunteers to remain active

		in the Program after initial enrollment and throughout the period of award.
Past Performance. No more than 2 pages.	Applicants should describe their past experience in health- or research-related engagement efforts in the proposed community and experience in meeting goals and milestones.	
Key Personnel. No more than 2 pages.	The applicant should include a description (bios) of key individuals working on this project and the percentage of time they would devote to this project if awarded.	Applicants should describe their past experience in health care professional education efforts, research recruitment, and experience in meeting goals and milestones.
Funding Proposal. No more than 2 pages.	Applicants must provide details of how they will use the funds requested. This cost plan should include quarterly quantitative milestones of the number of people educated, trained, and/or enrolled over the three-year period. In event of an award, NIH staff will evaluate and negotiate a list of milestones to be met for each interval of support.	

\*Local applications are those that address a community of fewer than 20,000 in one geographically contiguous area. Regional/national scale applications address a community of greater than 20,000 or more than one geographic area.

**Milestones & Timetables**

Applicants are required to submit an engagement plan with measureable commitments and a quarterly timetable for meeting these commitments through specific activities. Each plan should be specifically designed to best engage the community of interest, but these elements must be included in all proposals:

- An initial communications plan should be completed and approved by the *All of Us* Research Program by the end of the first quarter of the award. This plan should include a list of the communications materials needed to execute the engagement plan as well as any desired use of the Mobile Asset.
- Education activities should commence no later than the second quarter of effort.

**Reporting**

Awardees will be asked to provide regular progress reports to the *All of Us* Research Program.

**Privacy & Security**

Among other important aspects of participant engagement are privacy, trust, and security. To this end, applicants should be familiar with these principles:

- Precision Medicine Initiative: Privacy and Trust Principles:  
<https://obamawhitehouse.archives.gov/sites/default/files/microsites/finalpmiprivacyandtrustprinciples.pdf>

- Precision Medicine Initiative: Data Security Policy Principles and Framework:

[https://obamawhitehouse.archives.gov/sites/obamawhitehouse.archives.gov/files/documents/PMI\\_Security\\_Principles\\_Framework\\_v2.pdf](https://obamawhitehouse.archives.gov/sites/obamawhitehouse.archives.gov/files/documents/PMI_Security_Principles_Framework_v2.pdf)

The purpose of this Funding Opportunity is to enable Partners to educate, motivate, and facilitate enrollment in the *All of Us* Research Program. Partners awarded under this announcement should not collect or retain health-related information as part of this effort. If awardees collect or retain non health-related personal information of *All of Us* volunteers, they may be subject to privacy and security requirements designed to protect that information.

## **Program Organization and Governance Structure**

The *All of Us* Research Program functions as a Consortium, with all awardees as members with specific roles in its governance structure. For example, the Program Steering Committee consists of the Program Directors/Principal Investigators (PDs/Pis) from each of the major awards. Committees are established by the *All of Us* Research Program Consortium Steering Committee to oversee the development and implementation of specific Consortium activities. Successful applicants to this funding opportunity will be expected to serve in the governance structure of the Consortium.

## **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.

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