

<b>Overview Information</b>	
<b>Funding Opportunity Title</b>	<b><i>All of Us Research Program Communications and Marketing Partners (OT2)</i></b>
<b>Funding Opportunity Number</b>	OT-PM-19-002
<b>Participating Organization</b>	National Institutes of Health (NIH)
<b>Components of Participating Organizations</b>	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.
<b>Opportunity Type</b>	New
<b>Related Notices</b>	<a href="#">OT-PM-16-002</a> Communication Support for the Precision Medicine Initiative Research Program at NIH
<b>Funding Opportunity Purpose</b>	<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>This award is designed to fund Communications and Marketing partners who will design strategies and tactics geared toward raising awareness of the <i>All of Us</i> Research Program, 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>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.</p> <p>Using the OT mechanism will also allow the NIH to engage more than one partner if a combination of partners will provide a fuller breadth and depth of capabilities.</p>
<b>Funding Instrument</b>	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.
<b>Funds Available</b>	Actual amounts will depend on funds available, but the program expects applicant direct costs to not exceed \$15 million per year.
<b>Anticipated Number of Awards</b>	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

<b>Award Project Period</b>	The total project period is anticipated to be five (5) years.
<b>Post Date</b>	February 11, 2019
<b>Application Due Date</b>	March 29, 2019 (5:00 p.m. local time)
<b>Scientific/Technical Review Date</b>	Review will be conducted in April 2019 after receipt of applications.
<b>Award Timeline</b>	Award(s) will be made upon selection and award negotiation. The estimated timeline is June 2019.

## Application Instructions

<b>Required Application Instructions</b>	<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>Applications should include the following within the total application package not exceeding 30 pages:</p> <ul style="list-style-type: none"><li>• Technical Approach: Not to exceed 20 pages</li><li>• Past Performance (Corporate/Organizational experience related to the solicitation): Not to exceed 5 pages</li><li>• Key Personnel (Applicants should provide brief biosketches of key personnel): Not to exceed 3 pages. Each application must identify a Program Director/Principal Investigator.</li><li>• Cost Proposal: Applicants should build a milestone driven, cost allocated plan for proposal. Cost models can be cost-sharing, fixed price, adjustable (cost reimbursable), or a hybrid approach: Not to exceed 2 pages.</li></ul> <p>A one-page cover letter is allowed and will not count against the 30-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 <a href="#"><u>The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine</u></a> .</p>
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## Application Instructions

### Instructions for Application Submission

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

Use OTA-19-003 in the field requesting Funding Opportunity Announcement.

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

## Eligibility Information

### Eligible Applicants

Higher Education Institutions

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

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

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

## Eligibility Information

<b>Eligible Applicants (cont.)</b>	<p>Nonprofits Other Than Institutions of Higher Education</p> <ul style="list-style-type: none"><li><input type="checkbox"/> Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)</li><li><input type="checkbox"/> Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)</li></ul> <p>For-Profit Organizations</p> <ul style="list-style-type: none"><li><input type="checkbox"/> Small Businesses</li><li><input type="checkbox"/> For-Profit Organizations (Other than Small Businesses)</li></ul>
<b>Foreign Institutions</b>	<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

<b>Review Process</b>	<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"><li>• Completeness of technical and cost elements</li><li>• Quality of submission</li><li>• Past performance and portfolio</li><li>• Key personnel experience and proposed commitment to the project</li><li>• Cost proposal</li></ul> <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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<b>Application Review</b>	
<b>Evaluation Process</b>	<p>In addition to technical merit, applications will be evaluated for programmatic priority.</p> <p>Programmatic priority will be given to applicants with:</p> <ul style="list-style-type: none"> <li>• Demonstrated success in developing and executing effective national multicultural communications campaigns.</li> <li>• Proven ability to work cooperatively within a large consortium of stakeholders</li> <li>• Deep expertise/experience with health communications activities, preferably with experience in medical research recruitment.</li> <li>• Exceptional creative and Web design capabilities</li> <li>• National network of consultants to plan, strategize, and execute regional campaigns.</li> </ul>
<b>Questions Regarding this Funding Opportunity and Program and Agreements Officer Contact</b>	<p>Informational Webinar: Tuesday, February 26, 2019, 1:00 pm-2:00 pm EST</p> <p>To register for this webinar and receive instructions, email: <a href="mailto:PMICPFOAInquiries@mail.nih.gov">PMICPFOAInquiries@mail.nih.gov</a>.</p> <p>Questions may be submitted via email, to Ms. Alyssa Cotler, <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 <a href="mailto:PMICPFOAInquiries@mail.nih.gov">PMICPFOAInquiries@mail.nih.gov</a>.</p>
<b>Authority</b>	<p>Other Transaction awards will be made pursuant to current authorizing legislation, including the 21<sup>st</sup> Century Cures Act as specified in Section 402(n) of the Public Health Service Act, 42 U.S.C. 282(n).</p>
<b>All of Us Research Program Other Transaction (OT) Award Policy Guide</b>	<p>Other Transaction awards are subject to the requirements of the Other Transaction Award Policy Guide for the NIH Precision Medicine Initiative. Applicants must review this policy guide, which is available by accessing: <a href="https://allofus.nih.gov/funding">https://allofus.nih.gov/funding</a>.</p>

## ***All of Us* Research Program Communications and Marketing Program**

### **Background**

The mission of the *All of Us* Research Program (<https://allofus.nih.gov/>) is to accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for *All of Us*. To accomplish this, the program will partner with one million or more people across the United States to build the most diverse biomedical data resource of its kind, to help researchers gain better insights into the biological, environmental, and behavioral factors that influence health. Our core values of participant-centeredness and transparency are at the heart of everything we do.

Unlike research studies focused on a single disease or set of conditions, the *All of Us* Research Program aims to support thousands of studies examining many different questions about health and disease. The program will engage a diverse cohort of participant partners, with a special focus on those from communities that have been historically underrepresented in research. Participants will share data over many years in a variety of ways, including through surveys, electronic health records, biosamples, physical measurements, and information from health trackers and other digital technologies. These data will be broadly accessible to a broad range of researchers, from students and citizen scientists to investigators in academia and industry.

The program [launched national enrollment in May 2018](#) following a two-year period of program development and beta testing. To date, more than 175,000 people have registered to take part at <https://www.joinallofus.org>, and more than 100,000 have completed all of the steps in the core protocol (see <https://allofus.nih.gov/about/all-us-research-program-protocol>).

In coming months and years, enrollment will remain a top priority, along with other major program activities, such as improvements to the participant experience, the enrollment of pediatric populations, the return of information to participants (including genetic information), the release of data to registered researchers through the *All of Us* Research Hub (<https://www.researchallofus.org/>), and the rollout of new data collection methods.

The *All of Us* Research Program Office at NIH provides strategic vision and serves as the coordinating center for a consortium of more than 100 funded and non-funded partner organizations around the country that work collaboratively to implement the program:

- Health care provider organizations (HPOs) are responsible for local outreach, recruitment, enrollment, and retention.
- The Participant Center and its partners are responsible for recruitment, enrollment, and retention of “direct volunteers,” participants not associated with HPOs.
- Community engagement partners are responsible for additional outreach, education, and engagement activities targeted to their diverse communities.
- The Participant Technology Systems Center is responsible for building and maintaining the technology platforms through which participants enroll and provide data to the program.
- The Data and Research Center is responsible for securely housing and providing controlled access to the data.
- The biobank is responsible for shipping and storage of participant biosamples.
- The Genome Centers generate and analyze genomic data from participant biosamples.

Communications and marketing are fundamental to the success of the program, and all of the program’s partners rely on its communications partners for communications strategies, messages, and assets that are both scientifically sound and engaging for diverse audiences to raise awareness of the program and facilitate enrollment. Communications and assets will need to be tailored to resonate with various audiences across the country and will be informed by other awardees’ input.

### **Purpose and Objectives of the *All of Us* Research Program Communications and Marketing Partner**

The NIH solicits proposals from organizations to serve as Communications and Marketing Partners for the *All of Us* Research Program, focusing four major tasks to be planned and implemented both nationally and regionally in collaboration with a variety of partners. Through novel and unique strategies and methods, the goals of these four tasks will be to raise awareness and enthusiasm of the program, enable recruitment activities, and keep the public and research community informed of key events, milestones, and activities.

As more people enroll in the program, our focus may need to shift from recruitment to retention and participant-focused communications. We may also need to develop multiple, innovative strategies to recruit and/or retain specific populations, communities, and demographics. As the program looks to begin enrollment of special populations, including children, novel strategies and communications products will need to be developed and deployed to reach those populations, including pregnant women, families, and to educate and engage the children themselves. New communications needs may arise as precision medicine science evolves and new elements of the program are introduced to participants and researchers. Enhanced and unique communications to the research community will be necessary to encourage them to leverage the data resource being built. At this time, it's impossible to forecast all of the communications and marketing needs of the program or the scope of those needs. In addition, NIH is unsure if one partner or multiple partners will be needed to meet the ever-evolving needs of the program.

#### ***Task 1. Communications, public relations, and marketing strategies to support national program***

This is a large, high-profile, and complex program with many partners, stakeholders, and key audiences. Applications should describe the process of developing a comprehensive and integrated strategy for communications and marketing that will achieve the program's broad objectives of enrolling and retaining 1 million people from every walk of life throughout the country. Applications should address how they will engage our participants to have an active and authentic voice in the evolution of the program while also engaging a diverse research community hungry to use the data. They should also address the types of communications channels and products they would employ to support the strategy. Applicants should have a proven track record of creating compelling messages and communications products and of utilizing unique communication and marketing methods and strategies to reach different populations, and a track record of adjusting strategies and methods to changing circumstances in a fast-paced environment.

#### ***Task 2. Integrated campaign strategies within regions or demographic segments***

The program works with partners across the country, including health care provider organizations, corporate enrollment and marketing partners, and community organizations. In addition, we have two mobile engagement assets that serve to educate and engage diverse audiences. Applications should address how they will develop and implement locally-relevant and integrated campaign strategies within local regions and tailored to audiences who have been underrepresented in biomedical research. Applicants should have a proven track record of establishing multiple campaigns that use unique and robust strategies to effectively reach diverse populations in different geographic regions.

### **Task 3. Consortium-wide communications support**

With a consortium of over 100 organizations, all serving slightly different audiences in different regions, consortium-wide communications activities must remain consistent, brand-compliant, yet also flexible enough to meet varying local needs. Applications should have a proven track record and suggest novel and flexible ways to provide excellent and timely customer service to our partners to ensure they are well-equipped to deliver local communications activities to recruit and retain participants.

### **Task 4. Evaluation**

Evaluation of communication and marketing strategies and methods is key to the evolution of the program and its ability to communicate effectively with participants, researchers, and the general public. Applications should outline methods to gather and analyze key metrics across the program to evaluate effectiveness and impact of communications messages activities. Applicants should also provide examples of using metrics to make positive change to effectiveness of communications and marketing activities.

### **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, 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. The IRB has regulatory oversight over all recruitment-related communications materials. 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 \$15M 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 intellectual property (*e.g.*, data, software, or other products), whether owned by the awardee or a third party except those specifically referenced in the application, will be utilized without express prior permission of NIH.

### **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.