



# *All of Us* Research Program Research Opportunity Announcement - Informational Webinar ROA No. OTA-22-006

Date: June 27, 2022 1:00-2:00 PM ET  
*All of Us* Research Program



# Webinar Agenda

1. Purpose of ROA and overview of the *All of Us* Research Program
2. Research Opportunity Announcement Areas of Interest
  - Area 1
  - Area 2
  - Area 3
  - Area 4
3. Submission requirements and Timelines
4. Questions and Answer

# Purpose of ROA and overview of the *All of Us* Research Program

## Purpose of the ROA

The purpose of this announcement is to fund organizations who can help *All of Us* build its cohort of volunteers who reflect the rich diversity of the United States and are actively engaged as partners. These funded organizations will help design and implement strategies to raise awareness of the program through community and health care provider organizations, drive increased enrollment of participants, foster regular communication with participants, and engage the research community to use the data being gathered.



# All of Us Research Program Overview



Enroll, Consent and Authorize EHR



- Participant Surveys
- Electronic Health Records
- Physical Measurements
- Mobile/Wearable Tech
- Biospecimens

**Research Hub**

Data Access through secure Google-Cloud-based platform

Blank	Outreach	Engagement	Enrollment & Retention	Researcher Engagement
Area 1	✓	✓	✓	blank
Area 2	blank	blank	blank	✓
Area 3	✓	✓	blank	✓
Area 4	✓	✓	✓	blank

# Research Opportunity Announcement Areas of Interest

# Purpose of the ROA

## Area 1: Participant Engagement and Enrollment

**Task 1:** participant outreach and engagement

**Task 2:** enrollment and retention

**Task 3:** pediatric outreach and engagement

**Task 4:** computer access

**Task 5:** healthcare provider outreach and engagement

## Area 2: Researcher Engagement

**Task 1:** Researcher Hub awareness and researcher engagement

**Task 2:** Building research capacity

**Task 3:** Promote team science

## Area 3: Tribal Engagement

**Task 1:** outreach and engagement

**Task 2:** education and resource development

**Task 3:** resource development for outreach and engagement – non-reservation based/urban AI/AN

**Task 4:** development of resources for Tribal partnership agreements

## Area 4: Participant as Partners

**Task 1:** oversight of consortium participant partner related activities

**Task 2:** full integration of participants and advocates

**Task 3:** facilitation of ongoing input from participant representatives

**Task 4:** assess the impact of participant engagement



# Area of Interest 1: Participant Engagement and Enrollment

## Community, Participant, and Provider Engagement, Enrollment and Retention (Section 5.1 )

**Task 1:** Conduct outreach and engagement activities to promote the enrollment of communities who are historically underrepresented in biomedical research, including minority racial and ethnic populations.

- Participant outreach and engagement activities should be meaningful and impactful that promotes enrollment into the *All of Us* Research Program. These activities should not be viewed as **coercive** to individuals.
- Include how these activities will be measured and their impact- unless you are approved to engage in human subject research, you will not have access to participant information.
- Clearly convey the diversity catchment area you are proposing to engage

**Task 2:** Engage, enroll, and retain one million or more participants who reflect the rich diversity of the United States

- The program is interested in reaching out to, engaging, and enrolling a diverse group of participants, using traditional and non-traditional partners. We are interested in recruiting and retaining a truly reflective population of participants living in the U.S., and innovative ideas to engage diverse populations are encouraged.
- Fully convey your infrastructure capabilities to execute Task 2:
  - Plan to approach, engage, and recruit diverse participants.
  - Plan for biospecimen and physical measurement collection.
  - Detailed retention plan.
  - Plan to capture EHR data on participants, and method of capture.
  - Plan to provide defined engagement, enrollment, and retention milestones and measurement metrics.



# Area of Interest 1: Participant Engagement and Enrollment Cont.

## Community, Participant, and Provider Engagement, Enrollment and Retention

**Task 3:** Engage and facilitate pediatric participation in the *All of Us* Research Program

- Pediatric is defined as individuals under the age of 18.
- Looking for strategies/activities to engage current participants with children/guardians under the age of 18 and potential participants whose parents are not currently enrolled in the Program.

**Task 4:** Provide access to computers and internet to individuals with limited access to facilitate enrollment

- Include where these centers will be located and the target audience
- Include how these centers can assist in other program activities

**Task 5:** Engage and collaborate with health care providers serving communities that are historically underrepresented in biomedical research (UBR) to facilitate enrollment and retention.

- Include any foreseen barriers to engage healthcare providers and how you propose to overcome these barriers

**Note:** Offers must include Task 1 community/participant engagement when responding to Task 2

# Area of Interest 2: Researcher Engagement

**Engage researchers from diverse backgrounds, including those from underrepresented groups, to utilize the *All of Us* data resources to advance precision medicine (Section 5.2)**

**Task 1:** Create a network of trusted voices (e.g., universities, scientific organizations, and/or other professional societies) to raise awareness of the Research Hub and engage with diverse researchers on a nationwide scale.

- Must develop a plan to establish a network of organizations
- Must coordinate a series of network activities as part of a high-touch and high tech outreach campaign to raise awareness about the *All of Us* Research Hub
  - Network activities should aim to strengthen the diversity of the *All of Us* researcher cohort

**Task 2:** Build research capacity for students, trainees, and fellows from diverse backgrounds to utilize the *All of Us* dataset.

- Must propose a mentorship program to connect students, trainees, and fellows with researchers on the *All of Us* Research Hub
- Must develop educational tools, curricula and other resources to support researchers utilizing the *All of Us* dataset
- Must propose ways to augment professional development and training opportunities

**Task 3:** Promote team science by encouraging researchers from different disciplines and levels of formal training (including potentially citizen/community scientists) to work together to utilize the Research Hub for community-based research and health equity work.

- Must promote opportunities to incentivize collaborative research on the *All of Us* Researcher Workbench.
  - Examples: mini-grant programs or networking opportunities for researchers to share resources

**Note:** Do not include any activities that will require infrastructure/platform changes to the Research Hub or Researcher Workbench

## Area of Interest 3: Tribal Engagement

### **Engage with Tribal Nations and Urban and Non-Tribal Land Based AI/AN Populations (Section 5.3)**

The *All of Us* Research Program initiated **tribal consultation in 2019** to engage Tribal Nations about the inclusion of AI/AN populations in this research program. The information received during consultation has been used to guide our work with AI/AN communities and Tribes.

### ***Technical Objectives***

- **Strengthen partnerships and AI/AN community engagement in research** related to precision medicine
- **Promote training and career enhancement of student and/or faculty research scientists** interested in addressing health research issues within this AI/AN population
- **Encourage research infrastructure and capacity building** within AI/AN populations, ensuring sustainability of precision medicine research

## Area of Interest 3: Tribal Engagement Cont.

### Engage with Tribal Nations and Urban and Non-Tribal Land Based AI/AN Populations

#### *Technical Approach*

Offeror(s) have the option to address one or more task areas in their Technical Approach:

- Task 1: **Outreach and engagement** to Tribal Nations and urban and non-Tribal land based AI/AN populations
  - Develop and implement strategies for engaging populations through ongoing, mutually beneficial interactions
- Task 2: **Education and resource development** for AI/AN populations and partners
- Task 3: Development of resources for outreach and engagement of **non-reservation based and urban AI/AN communities**
  - Includes urban Indians and urban Indian organizations
  - Outreach & engagement or educational activities must be focused on education and engagement, not recruitment
- Task 4: Development of **resources for Tribal partnership agreements** with Tribal Nations



## Area of Interest 3: Tribal Engagement Cont.

### Engage with Tribal Nations and Urban and Non-Tribal Land Based AI/AN Populations

#### *Requirements - Letter of Support*

Letters of Support: If the offeror(s) is working with Tribal Nations/Tribal governments then Tribal/community resolutions of support, or equivalent documents, must accompany the proposal.

Letters of Support should explicitly stipulate an agreed-upon timeframe for response from the Tribal Nations to inquiries or requests for approval from the offeror.

The time required for approving each of these:

1. Should be proposed and stated within the resolution of support (or equivalent document),
2. May differ for each of these activities,
3. May be modified only in consultation with the Tribal/community leadership, and
4. Should identify an individual or entity within the Tribe or community to whom a request for waiver of the time requirement can be directed if circumstances arise.



# Area of Interest 4: Participants as Partners

## **Integrate participants and advocates into oversight of the *All of Us* Research Program (Section 5.4)**

**A central principle of the *All of Us* Research Program is to include participants as partners in all aspects of the program – from research design through governance.**

- 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 biomedical research.
- Program participants are our partners, not subjects.
- Participants are co-designers for the program, and the collaborative design process is a relationship-building experience vital to trust and transparency

We are looking for those who can help the program build upon:

1. The program's core values, participation is open to all and participants reflect the rich diversity of the United States.
2. The program's core value, participants have access to their information.
3. The core value of participants as partners

# Area of Interest 4: Participants as Partners Cont.

Offerors to Outline Plan and must:

1. Provide detailed approaches for partnering with research participants and their advocates
2. Establish standardized participant engagement and recruitment evaluation approaches and data collection
3. Identify and/or develop instruments designed to assess participant engagement
4. Develop novel and innovative quantitative approaches to assess impact of effective and meaningful engagement within the *All of Us* consortium.
5. Develop and implement a participant retention program

\*\*\***Note:** Additionally, identify and address any other topics or forward-looking approaches needed for skillful and successful implementation of the Consortium Participant Partner Program



# Submission Requirements and Timeline

## *White Paper (section 8.2)*

- CY2022 Deadline dates are: August 31, 2022 and November 30, 2022
- Email to [AOU-ROA@nih.gov](mailto:AOU-ROA@nih.gov)
- One white paper per Area of Interest
- Page limit: 5 pages (excluding cover page, resumes, bibliographies, and table of contents)
- White paper review and decision window: up to 120 calendar days

## *Content (section 8.2.4)*

- Provide enough information to clearly convey the proposed concept and high level activities
- Include estimated direct and indirect costs (a brief rationale describing how the estimate was calculated)
- A single page summary resume for each Principal Investigator

**Note:** You may be asked to provide expanded oral presentation if the white paper is selected.

# Submission Requirements and Timeline Cont.

## *Full Proposal (section 8.3)*

- Offerors will be notified via email, from [AOU-ROA@nih.gov](mailto:AOU-ROA@nih.gov), if the Government is interested in receiving a full proposal
- The offeror will be given **at least 45 days** from notification to submit a full proposal
- The full proposal must be submitted via the NIH eRA ASSIST System (eRA Commons registration required)
- Page limit: 27 pgs. (see section 8.3.1 for details)
- Submission must be in Adobe PDF file

## *Content (section 8.3.2)*

- **Organization Description:** include if the organization has local, regional, or national resources or network of organizations
- **Technical Approach:** if you are responding to multiple Areas of Interest, technical approach should be clearly labeled for each Area of Interest
- **Planned Milestones:** present milestones in SMARTIE format (Specific, Measurable, Reasonable, Timed and emphasizing Inclusivity, and Equity)
- **Cost Proposal:**
  - base year and options
  - breakdown by labor category, salary, % of effort

# Questions & Answers



# Questions & Answers ( Pre-submitted)

1. Is the approximate funding amount per award, per year Total Costs or is that direct costs only?

The approximate funding amount per award, per year is the Total Costs (direct & indirect costs).

2. The White paper process for AOI 4, per ROA OTA-22-006 section 8.3 Full proposal submission instructions: The white paper submission and evaluation (within 120 days) proceeds the full technical proposal with associated documents. Conceivably, white papers submitted on August 31, 2022 will be notified by email by December 29, 2022 if they are advanced to full proposal.

Yes, that is correct.

3. Per ROA OTA-22-006 section 8.2.5 Oral presentation: Will this occur within the 120 day period noted above and how much advance notice will PIs get to present their white paper?

The date and time of the oral presentation can be determined between the offeror and the government.

4. Will NIH be developing the informed consent process and materials for pediatric participants to provide to awardees for use during engagement and enrollment?

Yes, NIH in coordination with the *All of Us* Consortium members will be developing the consent, collaterals and materials for use during engagement and enrollment.

## Questions & Answers ( Pre-submitted) Cont.

5. If an offeror is responding to multiple tasks for Area of Interest (AOI) 1, including Task 2, should only one white paper be submitted? Or should one white paper be submitted for AOI 1, tasks 1 and 2, and a second white paper for AOI 1, tasks 3, 4, and 5?

When responding to multiple Tasks for Area of Interest, Offerors should only submit one white paper. For example, If an offeror is responding to AOI 1 Task 1 and Task 2, they should only submit one white paper.

6. Does NIH expect each offeror to “engage, enroll, and retain one million or more participants” or does NIH expect each offeror to engage, enroll, and retain participants that contribute to the overall goal of one million program participants?

The expectation is that each offeror engage, enroll, and retain participants that contribute to the overall goal of enrolling one million or more participants.

7. Does a proposal for AOI 1 need to include a plan to capture all the diversity metrics outlined in Section 10.1.2.1 on page 41?

The proposal should include a plan to capture one or more diversity metrics outlined in Section 10.1.2.1.

8. What age range does NIH consider “pediatric” for the *All of Us* program?

Pediatric is defined as individuals under the age of 18.

## Questions & Answers ( Pre-submitted) Cont.

9. Does NIH anticipate that contractors will enroll pediatric patients for the *All of Us* program under this ROA? If not, what does NIH consider “facilitate” pediatric participation in the program?

At the present time, we do not expect awardees to enroll in the pediatric population. Facilitating enrollment involves activities intended to drive enrollment, such as mitigating the digital divide by providing sites with computers or tablets with secure internet access, connecting prospects with local enrollment sites, and hosting community-based enrollment events.

10. We are a small business with HUBZone certification along with WBENC and NMSDC certifications, can you clarify is this classification fits what you are looking for? We ask because we are not an academic or university, etc.?

Yes, small business are eligible to apply (see section 6.3 For-Profits).

11. Can you clarify the importance of collecting lifestyle and motivation data as part of the *All of Us* database?

Most lifestyle and motivation data are collected through the Lifestyle, Social Determinants of Health Survey and the COVID-19 Participant Experience (COPE) survey. By readily connecting biological and social determinants of health data (i.e., neighborhood safety, social support, discrimination, food security, etc.) on a large, inclusive scale and following participants as they move, age, and grow, the *All of Us* dataset is driving new insights into health and disease. The integration of lifestyle and motivation data allows registered researchers to explore potential associations across a variety of lifestyle factors and how these factors impact the physical and mental health of the participants. ([link to additional resource](#)).

# **Q&A session from Chat**

# Closing

1. ROA Informational Webinar slides and Questions and Answers will be posted as an amendment on [Sam.gov](https://sam.gov)
2. Follow this opportunity on Sam.gov to get notifications to amendments.
3. Email any inquires to [AOU-ROA@nih.gov](mailto:AOU-ROA@nih.gov)



# Thank You!

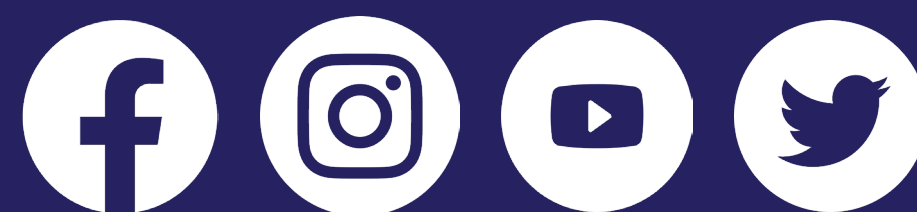


<https://www.joinallofus.org/>



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# **Additional Slides for Area of Interest 3: Tribal Engagement (section 5.3)**

# Area of Interest 3: Tribal Engagement

## Engage with Tribal Nations and Urban and Non-Tribal Land Based AI/AN Populations

### *Introduction*

#### Tribal Engagement Team

- **Serve as contacts** for *All of Us* Research Program partners interested in working with Tribal Nations and American Indian and Alaska Native (AI/AN) populations
- Provides **guidance and technical assistance** to *All of Us* partners on culturally relevant and appropriate Tribal engagement and outreach to AI/AN populations
- Develop *All of Us* Research Program **policies, communications, messaging, training curriculums and Tribal engagement education and information materials in partnership** with subject matter experts and AI/AN advisors

# Area of Interest 3: Tribal Engagement

## Engage with Tribal Nations and Urban and Non-Tribal Land Based AI/AN Populations

### *Background*

- *All of Us* Research Program is committed to health equity and building a cohort that is demographically, geographically, and medically diverse
- Seeks to include groups that may not have had the opportunity to benefit from breakthroughs in biomedical research
- Is working to accelerate health research in a non-stigmatizing way and ensure that populations historically underrepresented in biomedical research are included in the research process as partners
- Acknowledges the health disparities faced by AI/AN populations and the underrepresentation in health research

The *All of Us* Research Program initiated **tribal consultation in 2019** to engage Tribal Nations about the inclusion of AI/AN populations in this research program. The information received during consultation has been used to guide our work with AI/AN communities and Tribes.

## Area of Interest 3: Tribal Engagement

### Engage with Tribal Nations and Urban and Non-Tribal Land Based AI/AN Populations

#### *Excluded Activities*

The following activities are excluded and not funded under the anticipated award(s):

1. Political campaigning or partisan activities
2. Providing monetary incentives for attending outreach, engagement and enrollment activities
3. Purchasing meals and refreshments for people attending events
4. Health care providers are not expected to enroll their patients into the *All of Us* Research Program



## Area of Interest 3: Tribal Engagement

### Engage with Tribal Nations and Urban and Non-Tribal Land Based AI/AN Populations

#### *Requirements - Letters of Support cont.*

- Tribal letter of support from each of the Tribal governments to be served by proposed activities should reference that particular project.
- The Tribal resolution or letter should specifically reference the proposal and approval of specific activities.
- If the current Tribal resolution under which a Tribal organization operates would encompass the specific proposed activities, then a copy of the current resolution submitted with the discrete project would be sufficient.
- Proposals that include more than one Tribe or community should include a resolution of support, or equivalent document from each participating Tribe and community. If the proposal includes a consortium of Tribal Nations or communities, the offeror should provide a resolution of support from each Tribe or community of the consortium.

# Area of Interest 3: Tribal Engagement

## Engage with Tribal Nations and Urban and Non-Tribal Land Based AI/AN Populations

### *Requirements - Letters of Support cont.*

- Offerors including participants from an extant study must submit, prior to the review, a letter from the Program Directors/Principal Investigators (PD/PI) or steering committee of the parent study approving their participation.
- If the offeror is a Tribally sanctioned non-profit Tribal organization, specific Tribal resolution(s) of support will not be required if the current Tribal resolution(s) under which the organization operates encompasses activities proposed in the proposal. A copy of the current operational resolution(s) must be submitted with the proposal.
- Each AI/AN organization that participates in the project should also submit an individual, or sign onto, a common letter of support.

## Area of Interest 3: Tribal Engagement

### Engage with Tribal Nations and Urban and Non-Tribal Land Based AI/AN Populations

#### *Technical Objectives cont.*

- **Encourage research infrastructure and capacity building** within AI/AN populations, ensuring sustainability of precision medicine research
  - To support research infrastructure developments, ensuring sustainability
  - Provide tools to support research from within the communities, long term maintenance and evolution of their research agenda.

*By involving the community in precision medicine research and integrating the training of researchers, the pool of investigators and the scientific knowledge of the communities can be increased. This approach benefits the communities in terms of research design and sustainability, by involving Tribal Nations and urban and non-Tribal land based AI/AN communities in the research agenda for the proposed application.*