



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

Date: June 8, 2023  
*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 of Interest 1
  - Area of Interest 2
  - Area of Interest 3
  - Area of Interest 4
3. Submission requirements and Timelines

# 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

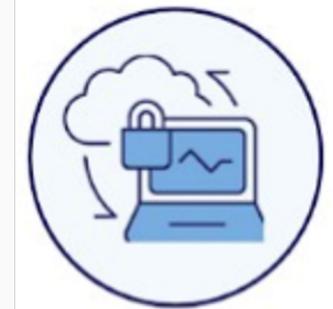


Enroll, Consent and Authorize EHR



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

## Research Hub



Data Access through secure Google-Cloud-based platform

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

# Research Opportunity Announcement Areas of Interest

# Purpose of the ROA

## Area of Interest 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 of Interest 2: Researcher Engagement

- Task 1:** Researcher Hub awareness and researcher engagement
- Task 2:** Building research capacity
- Task 3:** Promote team science

## Area of Interest 3: Tribal Nations, American Indian and Alaska Native populations, and Indigenous Communities

- Task 1:** Outreach and engagement
- Task 2:** Training and career development
- Task 3:** Education and culturally appropriate resource development
- Task 4:** Research infrastructure and capacity building

## Area of Interest 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 (DEO)

## 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 and promote enrollment into and retention in 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. NOTE: Unless you are approved to engage in human subjects research, you will not have access to participant provided information.
- Clearly convey the diversity catchment area you are proposing to engage for your activities.

# Area of Interest 1: Participant Engagement and Enrollment (DCD) *Cont.*

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

**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 (for staff and participants).
  - Plan to capture EHR data on participants, and method of capture.
  - Plan to provide defined engagement, enrollment, and retention milestones and measurement metrics.

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

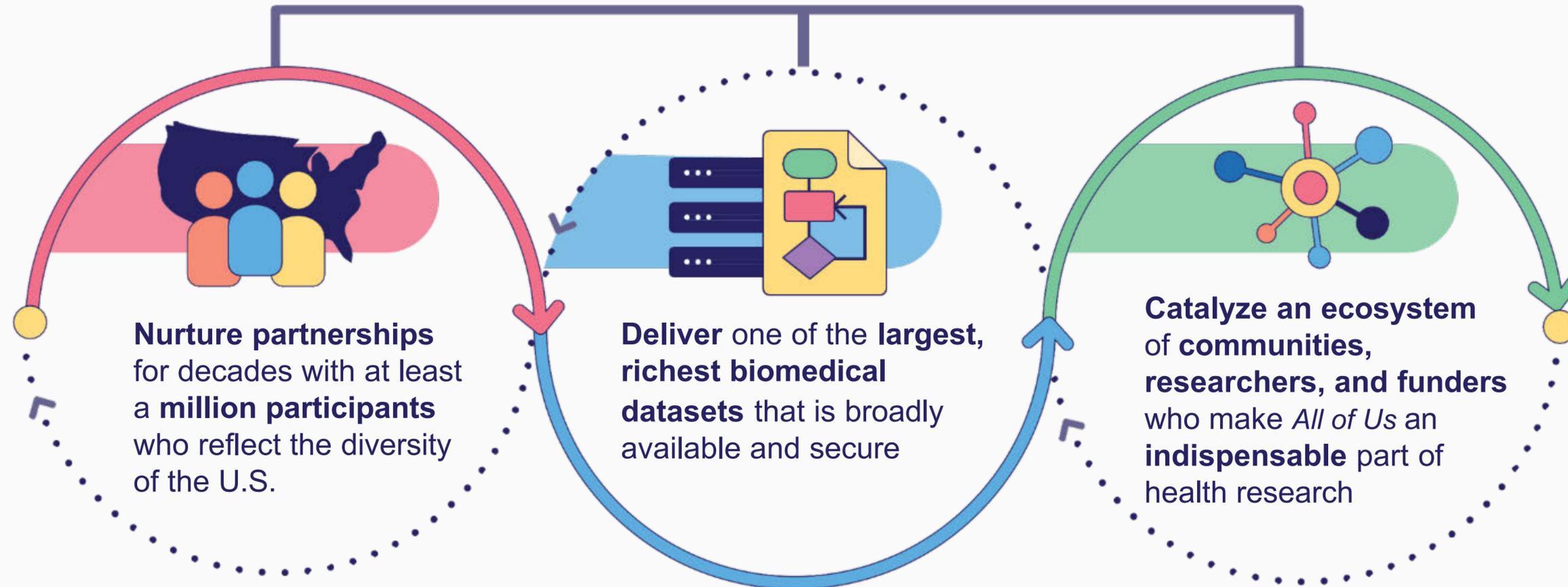
- *Pediatric* is defined as individuals under the age of majority (typically 18 years).
- Engagement activities focused on parents, as well as children of all ages.
- Pediatric enrollment activities for selected sites as protocols and processes developed by program, beginning with youngest age group.

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

Long term goal: Achieve the **All of Us mission** for infants, children, and adolescents

## Our Mission

Accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us.



Made possible by a team that maintains a culture built around the program's core values

# Long term goal: Fulfill **All of Us Core Values** for infants, children, and adolescents

Participation is **open** to all.

Participants reflect the rich **diversity** of the U.S.

Participants are **partners**.

Trust will be earned through **transparency**.

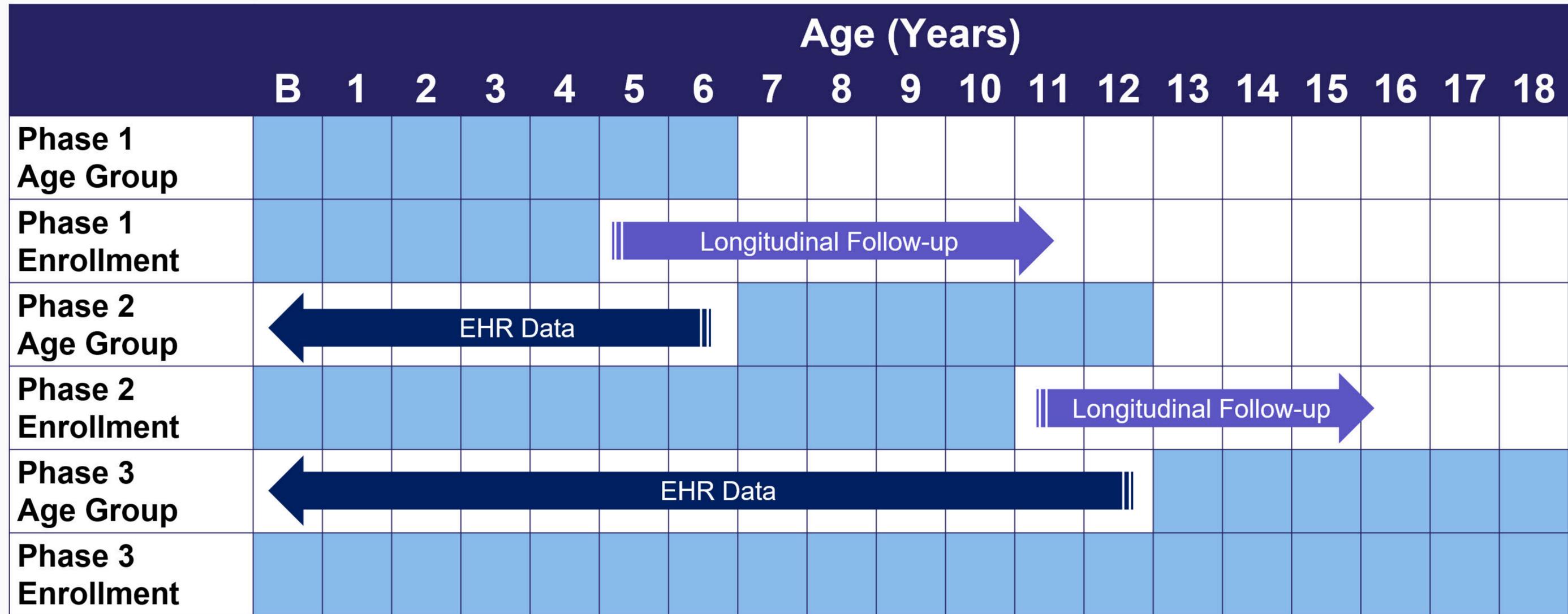
Participants have **access** to their information.

Data will be accessed **broadly** for research purposes.

**Security and privacy** will be of highest importance.

The program will be a catalyst for **positive change** in research.

# Expected design approach: Phased launch, beginning with the youngest age group, enrolling children of current participants



LINKAGE of data from parent of participant will extend exposure data to prenatal and preconception time frames

# Design principle: Carefully examine the entire current protocol and adapt to support pediatric and family participation

Area	Matches Current	Planned Peds Adaptation
Participant Portal	Each participants has an account	Peds accounts are linked to adult accounts
Participant Provided Information	Survey format (for now)	Revised questions
EHR Data	Requested for each participant	Parent provides authorization
Biospecimens	Blood preferred; saliva optional	Smaller volume for blood
Physical Measurements	Height & weight/length required with additional measurements	Revisions based on age

# Area of Interest 1: Participant Engagement and Enrollment (DEO) *Cont.*

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

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

- Include where these centers will be located and specify the target audience for adult and/or pediatric populations
- 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.

- Can include health care providers for adult and/or pediatric populations
- Include any foreseen barriers to engage healthcare providers and how you propose to overcome these barriers

**Note:** For Task 4 and Task 5, pediatric-related activities will be dependent on the development of pediatric protocols by *All of Us*.

# 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
  - Note: there is a current programmatic focus on Hispanic Serving Institutions in addition to other MSIs
- 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 develop educational tools, curricula, and other resources to support researchers utilizing the *All of Us* dataset
  - Note: there is a current programmatic focus on:
    - Development of curriculum teaching R and Python coding skills
- Must propose a mentorship program to connect students, trainees, and fellows with researchers on the *All of Us* Research Hub
  - Note: there is a current programmatic focus on Hispanic Serving Institutions in addition to other MSIs
- 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: Engagement with Tribal Nations, American Indian and Alaska Native Populations, and Indigenous Communities

The *All of Us* Research Program initiated **tribal consultation in 2019** to engage Tribal Nations about the inclusion of American Indian/Alaska Native (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***

- **Outreach and engagement** to AI/AN and Indigenous communities
- **Training and career development** in research as it relates to precision medicine
- **Education and culturally appropriate resource development** for AI/AN populations and partners
- **Research infrastructure and capacity building** within AI/AN and Indigenous communities ensuring sustainability of precision medicine research

# Area of Interest 3: Engagement with Tribal Nations, American Indian and Alaska Native Populations, and Indigenous Communities

## ***Technical Approach***

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

- Task 1: Outreach and engagement to AI/AN and Indigenous communities
  - **Development of resources for Tribal partnership agreements with Tribal Nations**
- Task 2: Training and career development in research as it relates to precision medicine
  - **Create career enhancement projects across all career stages to improve the research skills of investigators involved with AI/AN and Indigenous communities**
- Task 3: Education and culturally appropriate resource development for AI/AN populations and partners
  - **Development of a suite of *All of Us* educational and resource materials**
- Task 4: Research infrastructure and capacity building within AI/AN and Indigenous communities ensuring sustainability of precision medicine research
  - **Develop tools to support research from within the communities, as well as the long-term maintenance and evolution of their research agenda**

# Area of Interest 3: Engagement with Tribal Nations, American Indian and Alaska Native Populations, and Indigenous Communities, continued

## *Requirements - Letter of Support*

Letters of Support: If the Proposer(s) is working with Tribal Nations/Tribal governments then an appropriate letter of support must accompany the proposal. Letters of support are **not required for the white paper submission, but will be required for the full proposal**, if invited.

Letters of Support:

- Should specifically reference the **proposal** and approval of specific **activities**.
- Proposals that include more than one Tribe or community, or a consortium of Tribal Nations or communities, must provide proof of support from **each Tribe or community** where activities will occur.

# 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 strengthen the national participant program by building upon:

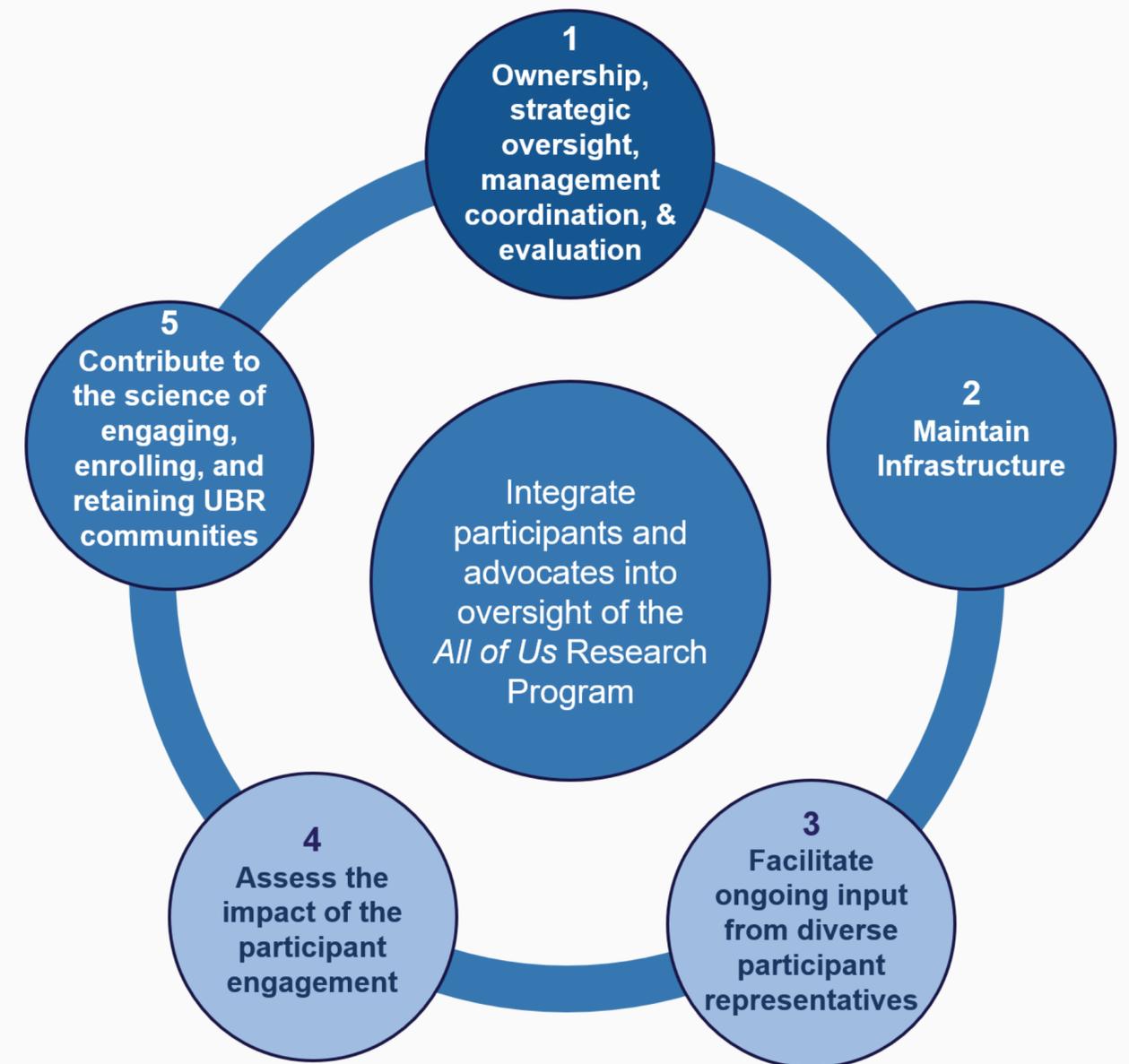
1. The program's core values, participation is open to all, and participants reflect the rich diversity of the United States.
2. The program's core value, participants have access to their information.
3. The program's core value of participants as partners.

# 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:** This opportunity is to further enhance and strengthen the current National Participant Partner Program. This does not include the development of local/regional participant governance structures. Additionally, identify and address any other topics or forward-looking approaches needed for skillful and successful implementation of the Consortium Participant Partner Program.



# White Paper Submission Requirements & Format

## *White Paper Submission Instructions (Section 8.2)*

- CY2023 Submission Deadline: August 31, 2023
- CY2024 Submission Deadline: February 28, 2024
- Submit via Email to [AOU-ROA@nih.gov](mailto:AOU-ROA@nih.gov)
- 1 white paper per each Area of Interest proposed
- **White paper review and decision window is up to 120 calendar days from ROA submission.**

## *White Paper Format (Section 8.2.3)*

- Paper Size: 8.5 x 11-inch paper
- Margins: 1 inch
- Spacing: single-spaced
- Font: Times New Roman, 12 point
- Page limit: 5 pages (excluding cover page, resumes, bibliographies, and table of contents)
- MS Office or Adobe PDF formats



Review [SAM.gov](https://sam.gov) for full Submission Requirements

# White Paper Selection

## *White Paper Selection (Section 9.1.1)*

- **Tier I:** Demonstrates an overall approach that appears to be adequate and is expected to meet or exceed program goals and objectives.
- The estimated costs are considered appropriate or are lower than what is considered appropriate to complete the proposed tasks.
- The Government may request a full proposal based on Government need and funding.
- Tier I rated White Papers will remain valid for a period of one year from the ROA submission date.

## *White Paper Selection Cont. (Section 9.1.1)*

- **Tier II:** The overall approach lacks completeness, contains deficiencies, and/or does not appear to be a feasible solution that could meet program goals and objectives.
- The estimated costs are higher than what is considered appropriate to successfully complete the tasks or exceeds available funding limits.
- The Government will not pursue a full proposal.

# Full Proposal Submission Requirements

## *Full Proposal (Section 8.3)*

- Proposers will be notified via email, from [AOU-ROA@nih.gov](mailto:AOU-ROA@nih.gov), if a full proposal is requested
- The proposer 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: 33 pgs. (See section 8.3.1 for details)
- Submission must be in Adobe PDF file

## *Full Proposal Content (section 8.3.2)*

- **Organization Description:** Include if the organization has local, regional, or national resources or network of organizations
- **Technical Approach:** If 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

# Full Proposal Evaluation and Ratings

## ***Full Proposal Evaluation (Section 9.2)***

The basis for selecting proposals based on the evaluation criteria, importance to the *All of Us* Research Program, and funds availability.

## ***Full Proposal Evaluation Criteria (Section 9.2.1)***

Criterion 1: Technical Merit

Criterion 2: Planned Milestone

Criterion 3: Technical Experience

Criterion 4: Key Personnel

## ***Full Proposal Evaluation Rating (Section 9.2.2)***

**Acceptable:** The proposal deemed appropriate for additional consideration and discussion. Generally considered well-conceived, scientifically and technically sound, and important to program goals and objectives.

**Unacceptable:** The proposal deemed inappropriate for additional consideration and discussion at this time. Proposals given this designation are not technically sound and/or do not meet program priorities and will not proceed to negotiations.

## ***Cost/Price Evaluation (Section 9.2.3)***

No evaluation rating, evaluated for reasonableness and overall best value to the Government.



**Full Proposals rated Acceptable remain valid for a period of one year from submission date.**

# 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!



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