The *All of Us* Research Program

Engagement Partners Funding Opportunity

National Institutes of Health

Katie Rush and Stacia Fleisher

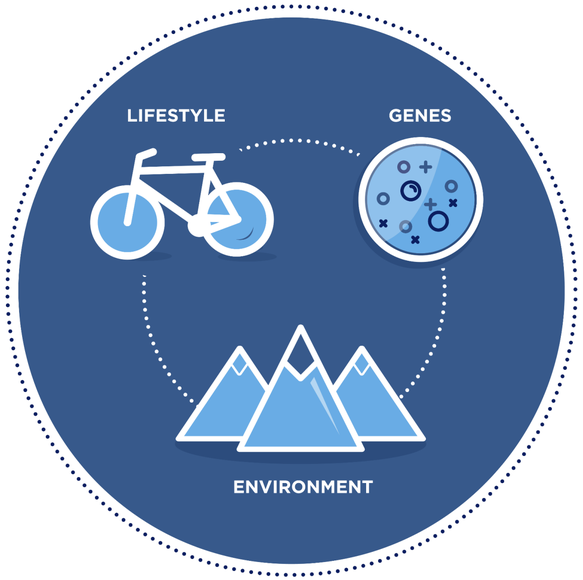
February 10, 2017

The *All of Us* Research Program

The *All of Us* Research Program

- One million or more volunteers nationwide, providing data on an ongoing basis
- Not a study on any one disease, but a huge data resource to inform many research studies on a wide variety of health conditions
- One of the world's largest biomedical databases, to accelerate breakthroughs
- Launching in 2017

All of Us
THE FUTURE OF HEALTH BEGINS WITH YOU
The Precision Medicine Initiative



A Transformational Approach to Diversity

Reflecting the country's rich diversity to produce meaningful health outcomes for historically underrepresented communities

People

Health Status

Geography

Data Types

A Transformational Approach to Participation

Participants in the *All of Us* Research Program will be true partners—not patients, not subjects—in the research process.

Involved in every step of program development

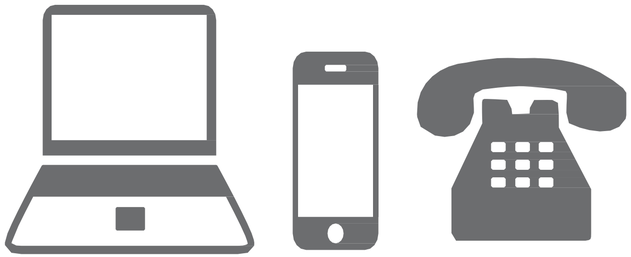
- What data we collect
- What lab analyses we do
- What research is conducted
- How data gets returned

The Power of a Million: How *All of Us* Can Lead to Better Health

- **Provide information** to help researchers and providers to:
    - Determine individuals' risk of developing certain diseases
    - Find biological markers to aid in prevention and diagnosis
    - Find the most effective therapy for different people
    - Identify solutions to health disparities
- **Build a community** of participants interested in joining clinical trials to help research happen faster
- **Empower participants** with data to improve their own health

Two Ways for Participants to Enroll

Direct Volunteers



Health Care Provider Organizations

Regional Medical Centers
Health Centers
VA Medical Centers

What a Participant Will Be Asked to Do

1. Enroll & Consent

2. Surveys

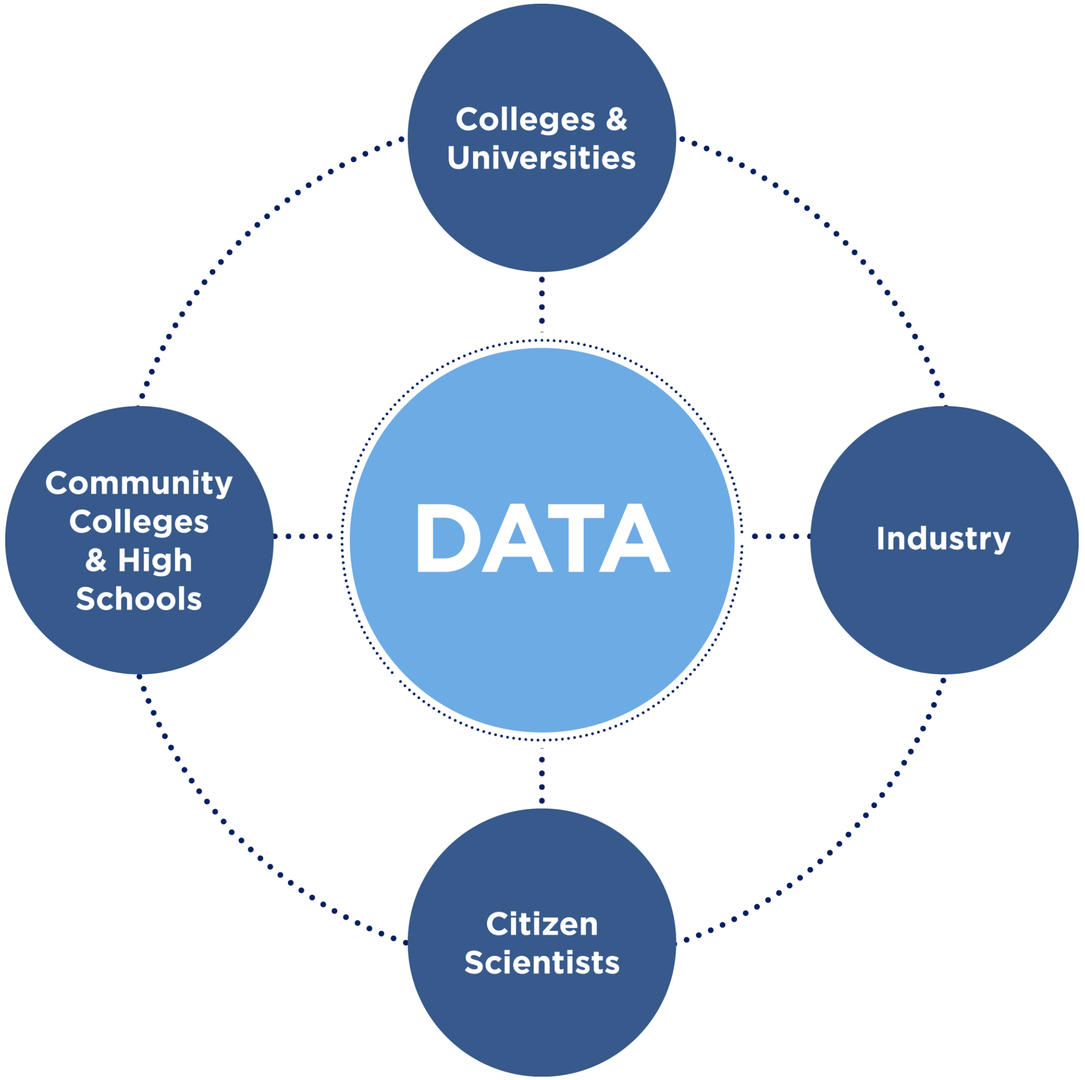
3. Baseline Measurements

4. Biosamples

5. Wearables/ mobile tech

Data Access

- Data sharing will be a priority to both researchers and participants
  - Participants will have access to study information and data about themselves
- Privacy and security will adhere to the highest standards
- Program will level the playing field so diverse researchers can benefit, including citizen scientists



The Value of Participating in *All of Us*

- An opportunity to **fight disease** and improve the health of future generations
- An opportunity to **ensure that your community is included** in studies that lead to new understanding and new treatments
- **A chance to learn** more about your own health
- The chance to **be part of a movement**, to make our health care more precise, more personal, and more effective

For More Information, Visit

https://www.nih.gov/precisionmedicine

Engagement Partners Funding Opportunity

Funding Opportunity

- The purpose of this funding opportunity is to support engagement partners who can:

  - Engage, educate, and motivate **volunteers** to join and remain in *All of Us*, and to facilitate their enrollment where needed, with measurable success

  - Engage and educate **health care professionals** about the program and/or enable health care professionals to facilitate enrollment of their patients or patients' family members, with measurable success

The “Other Transactions” (OT) Award Mechanism

- Not a grant, contract, or cooperative agreement
- Gives NIH flexibility to alter the course of projects in real time to meet program goals. Projects may be expanded, modified, partnered, not supported, or later discontinued based on program needs, emerging methods, technologies, or approaches, and availability of funds.
- *All of Us* awardees are expected to collaborate with one another, NIH staff, and other designated consultants. There will be significant NIH staff involvement.
- Funding for these awards will be distributed incrementally, in segments ranging from 1 to 12 months. Future award segments are not guaranteed and depend on milestone progress and scientific directions.
- Awardees must adhere to the *All of Us* Other Transactions Policy Guide; please review prior to submitting an application: https://www.nih.gov/research-training/allofus-research-program/funding

Three Types of Applications Expected for this Opportunity

- Local Community Engagement
  - $25-100K direct costs, <20,000 people engaged, in one geographically contiguous area
- Regional/National Community Engagement
  - $100-500K direct costs, >20,000 people engaged, in one or more geographical areas
- Health Care Professional Engagement (Regional/National)
  - $25-250K direct costs, focused on education of health care professionals; possibly to include the facilitation of enrollment of patients or patient family members

Eligible Organizations

- Nonprofits with 501(c)(3) IRS Status
- 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)
- 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)
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally Recognized tribal governments)

All Nonprofit Organizations are Eligible

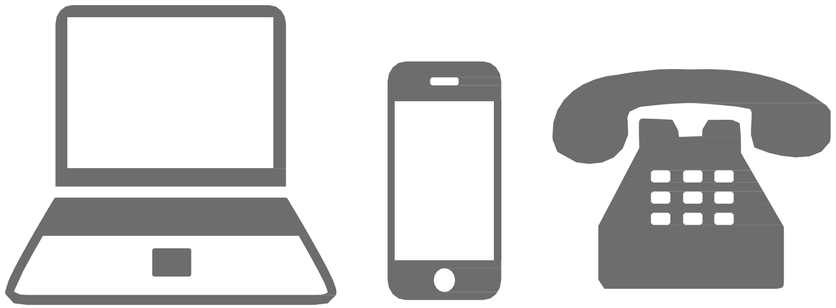
Review Criteria

- Community Served
- Engagement Approach, including Measureable Commitments
- Past Performance
- Key Personnel & Experience
- Cost Proposal

- Additionally, Programmatic Priorities:
  - Reaches communities historically underrepresented in biomedical research
  - Reaches priority geographic regions

Geography

Direct Volunteers



- Digital enrollment eventually available nationwide
- Rollout to begin in select states, cities in year 1
- **Geographic priority: Year 1 DV rollout areas**

Health Care Provider Organizations

- 14 awardees, listed online
- Coverage in 18 states in year 1
- Coverage expected in 28 states in years 2-5
- **Geographic priority: States with no HPO coverage**

Example Activities (Selected)

- *All of Us*-specific education events (in person or online)
- Sustained communication programs including media outreach, social media activities, and/or member outreach
- Train-the-trainer programs (across multiple chapters and/or networks) or continuing education modules
- Support for an *All of Us* community ambassador
- “Enrollment facilitation night” in community

Applicants are required to make measureable commitments, e.g., to educate x community members, to facilitate the enrollment of y individuals, to train z trainers, etc.

Timing

- Proposals Due: **March 24**
- Reviews Complete: April 6
- Awards Made: May 15 (estimate)

- 3-4 grants anticipated in round one
- Additional awards to be made from the pool of applications throughout the fiscal year (through September 2017)
- Project period: approximately 3 years

Program Infrastructure

Program Website: joinallofus.org

Materials

- Design files for branded communications materials will be available for awardees' use.
- Printing expenses will be incurred by the awardee and *should be included in the funding proposal.*
- Any additional materials awardees develop must be reviewed and approved by NIH and potentially also by the *All of Us* Institutional Review Board (IRB) to ensure consistency and accuracy in messaging.
  - Materials must follow the *All of Us* branding and co-branding guidelines.
  - Organizations may add their own logos, if desired, within co-branding guidelines.

Examples

All of Us
THE FUTURE OF HEALTH BEGINS WITH YOU
The Precision Medicine Initiative

What is precision medicine?

Precision medicine is health care that is based on you as an individual. It takes into account factors like where you live, what you do, and your family health history. Precision medicine's goal is to be able to tell you the best ways to maintain your health. And, if you get sick, the treatment that will work for you.

What is the All of Us Research Program?

The *All of Us* Research Program is part of the Precision Medicine Initiative. We hope that more than a million people living in the United States will join. People who join will give us information about their health. By looking for patterns, scientists may learn more about what affects people's health. *All of Us* will last for many years. This will allow us to study health over time. If you decide to join *All of Us*, you will be contributing to an effort to improve the health of generations to come.

How do I join All of Us?

All of Us starts in 2017. To join, visit our website or call

Why should I join All of Us?

If you join, you will be contributing to research that may improve health. Our goal is to understand what makes people sick and develop new treatments. Here are some examples:

- Better tests to see if you are sick or are at risk of getting sick.
- Better mobile apps to encourage healthy habits.

mation about how
ght for you.
l of Us information.
you. You may also
choose, can share
lth care provider.

t my privacy?

and we will take great
ere are a few of the

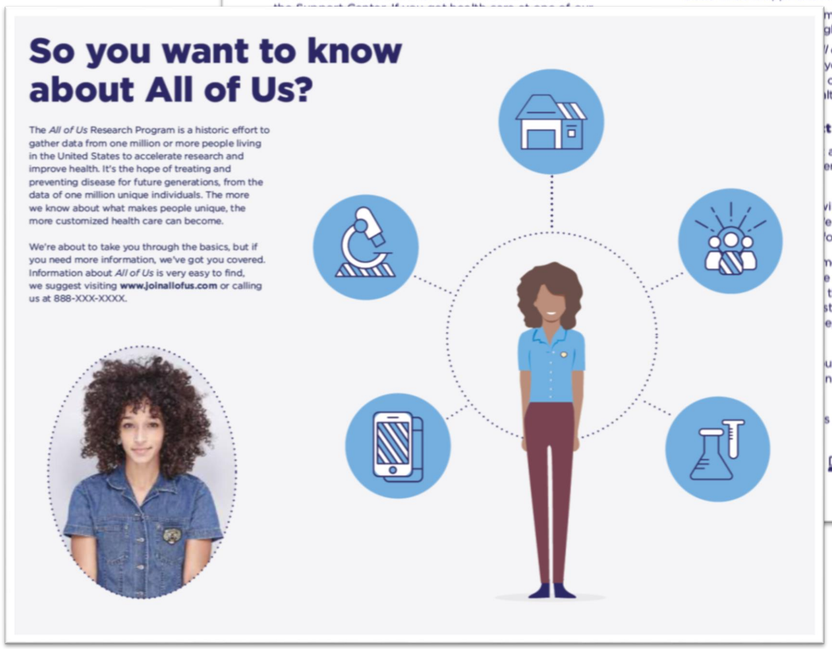
vill be stored on
e will limit and keep
formation.

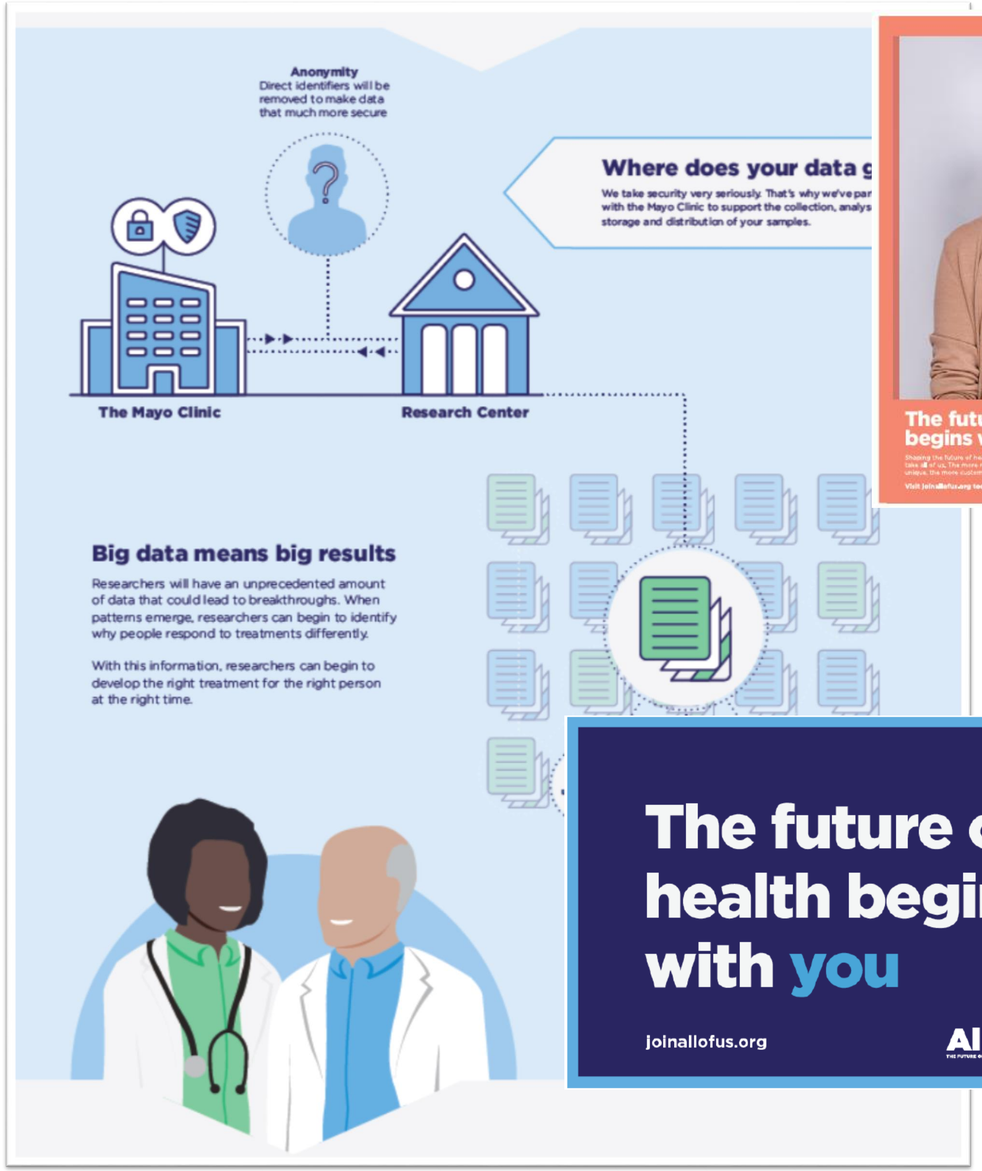
ne and other direct
e of birth) from your
them with a code.
st linking the codes
ep it separate

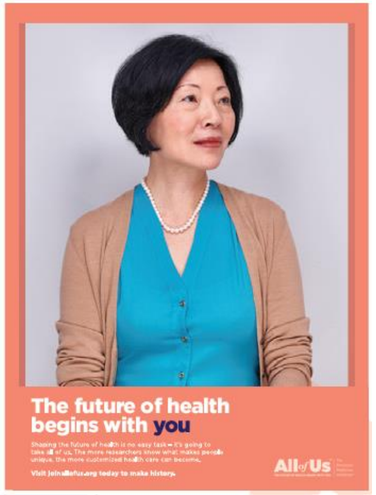
ur health information,
not to try to

s a data breach.

joinallofus.org







DRAFT

Mobile Engagement Asset

- A traveling exhibit to build awareness about *All of Us*
- 37-week national tour starting later this year
- May be hosted at various community outreach events, pending availability
- Organizations may request the MEA at no cost

DRAFT

Frequently Asked Questions

Frequently Asked Questions

My type of organization is not included on the eligible applicant list. May I still apply?

No. Only organizations that are on the eligible applicant list will be considered for this funding opportunity. However, please note that some of the categories are quite broad. It is possible that while your specific organization type is not listed, you are eligible under a broader category that is listed.

Frequently Asked Questions

I see that current awardees are not eligible to apply for this funding opportunity. If my organization applies and is awarded under this funding opportunity, will we become ineligible for future *All of Us* funding opportunities?

Not necessarily. Each funding opportunity has its own eligibility requirements. In this specific case, NIH is interested in expanding outreach in communities beyond the ones already covered by existing awardees, which is why we've structured the eligibility as we did. Future funding opportunities may have different goals and different eligibility requirements.

Frequently Asked Questions

I am affiliated with a health care provider organization (HPO) that is one of your awardees. However, my department or office is not part of the HPO's *All of Us* team. Are we eligible for funding?

No. Awards are made to institutions, not individuals. No existing *All of Us* awardee institution is eligible for this funding opportunity.

Frequently Asked Questions

I am an employee with an HPO that is an *All of Us* awardee. I am also affiliated (i.e., as a volunteer board member, part-time staff member, etc.) with another organization that is interested in applying for funding. Are we eligible for funding?

Awards are made to organizations, rather than individuals. As long as the applicant organization is not a recognized awardee or sub-awardee with *All of Us*, they can apply and you can be part of the application.

Frequently Asked Questions

May funds be used for:

- **Hiring staff?** Yes. However, the applicant organization should understand the OT award program and know that NIH will not be responsible for continued support of hired staff once the award period is completed.

- **Purchasing equipment (ex. computers)?** If well justified and necessary for the scope of the project to be completed, equipment may be purchased.

- **Providing food at awareness events?** No meals; other food expenses may be considered on a case-by-case basis and must be well justified.

- **Offering health screenings at awareness events?** No.

Frequently Asked Questions

How many individuals should we seek to reach with our engagement activities?

All applications will be evaluated on a variety of metrics, and the number of individuals reached is only one of them, so we do not have specific numerical targets to recommend. The community or geographic region being reached, engagement approach, past performance, and other factors will also be carefully evaluated.

Note: Applications in one category (i.e., local community engagement, regional/national community engagement, or regional/national health care professional engagement) will be considered in comparison to other applications in the same category.

Your Questions?

PMICPFOAInquiries@nih.gov

All of Us, the *All of Us* logo, and The Future of Health Begins with You are service marks of the U.S. Department of Health and Human Services.