An Introduction to the

All of Us

Research Program

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All of Us Research Program
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Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in lifestyle, socioeconomic, environment, and biology.

It is a radical shift in how each of us can receive the best care possible based on our unique makeup.
What is the *All of Us* Research Program?

The *All of Us* Research Program is a historic, longitudinal effort to **gather data from one million or more people** living in the United States to **accelerate research and improve health**. By taking into account individual differences in **lifestyle, socioeconomics, environment, and biology**, researchers will uncover paths toward delivering **precision medicine** – or **individualized prevention, treatment, and care** – for all of us.

“All of Us is among the most ambitious research efforts that our nation has undertaken!”

*NIIH Director Francis Collins, M.D., Ph.D.*
All of Us Mission and Objectives

Nurture relationships
with one million or more participant partners, from all walks of life, for decades

Our mission
To accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us

Catalyze a robust ecosystem
of researchers and funders hungry to use and support it

Deliver the largest, richest biomedical dataset ever
that is easy, safe, and free to access
Sample Scientific Opportunities

- Develop quantitative **estimates of risk** for a range of diseases by integrating environmental exposures and biological factors
- Identify the causes of individual variation in response to commonly used therapeutics = pharmacogenomics
- Discover **biological markers** that signal increased or decreased risk of developing common diseases
- Use **mobile health technologies** to correlate activity, physiological measures, and environmental exposures with health outcomes
- Develop **solutions to health disparities**
- Create a platform to enable **trials of targeted therapies**
- Empower study participants with information to improve their own health
Transformational Approaches
All of Us Research Program Core Values

1. Participation is open to all.
2. Participants reflect the rich diversity of the U.S.
3. Participants are partners.
4. Trust will be earned through transparency.
5. Participants will have access to their information.
6. Data will be accessed broadly for research purposes.
7. Security and privacy will be of highest importance.
8. The program will be a catalyst for positive change in research.
A Transformational Approach to Diversity

Reflect the country’s rich diversity to produce meaningful health outcomes for communities historically underrepresented in biomedical research.
A Transformational Approach to Participation

Participants are true partners - not patients, not subjects - in the research process.

They are involved in helping us think through:

- What data we collect
- What lab analyses we do
- What research is conducted
- How data gets returned
All of Us will invest to level the playing field so diverse researchers can play

- *All of Us* data will be available to all types of users
- Data collection will start small and grow over time
- The program will adhere to the highest privacy and security standards
- The data resources will be centralized, tiered, and operate on a passport system of access
- Project information will be made public and auditable
Program Building Blocks & Enrolling in *All of Us*
**All of Us Research Program Building Blocks**

### GENOME CENTERS
Genotyping and WGS, clinical validation, return of results
HGSC/CIDR; Genome Sciences UW; Broad, Partners, Color

### GENETIC COUNSELING RESOURCE
Facilitating return of genomic information to participants
TBD

### COMMUNICATIONS & COMMUNITY NETWORK
Communications, marketing, and design expertise; engagement coordination and community partners network
Wondros, HCM, 34 community partner orgs, and future awards to grow network

### BIOBANK
Repository for processing, storing, and sharing biosamples (35+M vials)
Mayo Clinic

### HEALTHCARE PROVIDER ORGS (HPOs) NETWORK
HPOs with clinical & scientific expertise, enrollment & retention of participants
10 regional medical centers, 6 FQHCs, VA, totaling 165 enrollment sites

### DATA AND RESEARCH CENTER
Big data capture, cleaning, curation, & sharing in secure environment
Vanderbilt, Verily, Broad Institute

### PARTICIPANT TECHNOLOGY SYSTEMS CENTER
Web and phone-based platforms for participants
Vibrent Health

### THE PARTICIPANT CENTER (DIRECT VOLUNTEER)
Direct volunteer participant enrollment, digital engagement innovation, and consumer health technologies
Scripps Research Institute (with multiple partners)
All of Us Community and Provider Partner Network (Updated April 2019)
The future of health begins with you.

The All of Us Research Program has a simple mission. We want to speed up health research breakthroughs. To do this, we’re asking one million people to share health information. In the future, researchers can use this to conduct thousands of health studies.
Potential Activities Asked of Participants

**Enroll, Consent and Authorize EHR**
- Recruiting 18+ years old initially; plan to include children in 2019
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data

**Answering Surveys**
- Surveys: The Basics, Overall Health, Lifestyle, Family History, Health Care Access and Utilization
- Additional surveys will be released on an ongoing basis.

**Physical Measurements***
- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

**Provide Biosamples***
- Blood (or saliva, if blood draw is unsuccessful)
- Urine specimen
- Biosamples will be stored at the program’s biobank

**Wearables and Digital Apps**
- Share data from wearable fitness devices, starting with FitBit
- Share data about mood & cardio-respiratory fitness through integrated apps
- More integrations to come

*Based on diverse sampling and capacity

**Pilots under development:** richer EHR data, health apps, fitness wearables, and return of genetic info
Present

- **209,295** registered participants
- **126,764** participants completed the protocol
- **More than 75%** of current participants self-identify as belonging to one or more UBR communities
- **More than 500,000** surveys completed
- Active enrollment at **300+** clinics across the U.S.

Future

- **Broaden inclusion** to additional demographics
- Conduct direct **provider outreach** to engage with and educate clinical stakeholders
- Expand **linguistic support** for non-English or Spanish speakers
- Launch the **research hub**

*All of Us Today and into the Future*
Learn More

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