All of Us Research Program

Josh Denny, M.D., M.S.
Chief Executive Officer
What is the NIH 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, we hope that researchers will one day 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!”

NIH Director Francis Collins, M.D., Ph.D.
The *All of Us* Research Program Mission

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

- **Nurture partnerships** for decades with at least a million participants who reflect the diversity of the U.S.
- **Deliver** one of the largest, richest biomedical datasets that is broadly available and secure
- **Catalyze** an ecosystem of communities, researchers, and funders who make *All of Us* an indispensable part of health research.

Made possible by a team that maintains a culture built around the program’s core values
All of Us Research Program Core Values

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.
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All of Us Research Program Core Values
Consented 740K+ Participants With Continued Growth

740,000+ Participants

409,000+ Electronic Health Records

507,000+ Participants who have completed initial steps of the program

525,000+ Biosamples

Map of Consented Participants

Plus >2,800 participants across U.S. territories

Numbers current as of November 29, 2023
Participant Diversity

Race & Ethnicity of Participants

- White: 52.9%
- Black, African American, or African: 17.2%
- Hispanic, Latino, or Spanish: 16.2%
- Asian: 3.2%
- Other: 1.0%
- More than one race/ethnicity: 7.0%
- Native Hawaiian/Pacific Islander: 0.1%
- Middle Eastern/North African: 0.5%
- Prefer not to say/Skip: 1.7%

Over 80% of All of Us participants are underrepresented in biomedical research.

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## All of Us Consortium Members (as of November 2023)

### The Participant Center

- Scripps Research Translational Institute
- BlueCross BlueShield
- South Texas Blood & Tissue Center
- San Diego Blood Bank
- Quest Diagnostics
- Mayo Clinic
- San Antonio Blood Bank
- OhioHealth
- Mary’s Center
- MyFitnessPal
- Nellcor
- MyFitnessPal
- Zocdoc
- Alliance for Health Equity

### Communications & Engagement

- WONDROS
- Precision Medicine
- RTI International
- The University of Utah

### HPO Network (Health Care Provider Organizations)

- All of Us California
  - UC San Diego Health
  - UCI Health
  - Cedars Sinai
  - Keck School of Medicine of USC

- All of Us Wisconsin
  - Marshfield Clinic Health System
  - University of Wisconsin Madison
  - Fondyhealth

- All of Us Pennsylvania
  - University of Pittsburgh

- All of Us Illinois
  - Northwestern Medicine
  - NorthShore
  - Rush University Medical Center
  - UI Health

- All of Us New England
  - Mass General Brigham
  - Harvard Health Hospitals
  - Partners HealthCare
  - New York-Presbyterian

### Trans America Consortium

- Essentia Health
- BayCare Medical Group
- HealthPartners Institute
- Spectrum Health

### New York City Consortium

- New YorkPresbyterian

### All of Us Southern Network

- Columbia University Irving Medical Center
- St. Luke’s University Health Network
- LSU Health New Orleans

### All of Us Southeast Enrollment Center

- UF Health

### Heartland Consortium

- University of Nebraska Medical Center
- University of Missouri Health System
- Nebraska Medical Center

### All of Us Wisconsin

- All of Us Pennsylvania

### All of Us Southern Network

- Tulane University

### All of Us Southeast Enrollment Center

- Trans American Companies
- LVHN
- Florida Hospital

### Participant Technology Systems Center (PTSC)

- Center for Linkages and Acquisition of Data (CLAD)
  - University of Colorado Denver
- Biobank
- Data & Research Center (DRC)

### Genomics Partners

- University of Washington
- Fred Hutchinson Cancer Research Center
- Johns Hopkins University
- UTH Health
- Cincinnati Children’s Hospital Medical Center

### Nutrition for Precision Health (NPH)

- Nutrition for Precision Health (NPH)

### Note:

These are not approved lockups and should not be repurposed on assets.
All of Us Community and Provider Partner Network (as of April 2023)

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Today, the program includes **35 Participant Ambassadors** and **10 Participant Partners** who serve on the Steering Committee, the Executive Committee, and the Advisory Panel.
**All of Us Tribal Engagement**

- **Dec 2017**: Assembled Tribal Collaboration Working Group (TCWG)
- **May-Nov 2019**: 1st Tribal Consultation & Listening Sessions
- **May 2022**: 1st All of Us funding announcement released with focus on Tribal Engagement & Partnership
- **Jun-Sep 2023**: Four virtual listening sessions, Established Tribal Engagement Branch, Tribal Consultation
- **2024 & Beyond**: Report & Implementation, Future Consultations
All of Us Research Program Core Values

- 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.
Data Collected and Return of Value to All of Us Participants

Return of Value for Participants

Participants may receive:

- **Genetic information**
- Survey data (comparative)
- EHR and claims data
- Ongoing study updates
- Aggregate results
- Scientific findings
- Opportunities to be contacted for other research opportunities
Participants Can Receive Four Types of Genetic Research Results

Genetic ancestry and traits results
- 7 regions (20 subregions) and 4 traits
  - Sub-Saharan Africa
  - Europe
  - Oceania
  - Southern Asia
  - Eastern and northern Asia
  - The Middle East and North Africa
  - The Americas
  - Ear wax
  - Bitter taste perception
  - Cilantro preference
  - Lactose intolerance

Medicine and your DNA Report
- 7 pharmacogenomics (PGx) genes and 50+ medications
  - CYP2C19
  - DPYD
  - G6PD
  - SLCO1B1
  - NUDT15
  - TPMT
  - UGT1A1

Hereditary Disease Risk (HDR) Report
- 59 genes (SNVs + indels)
  - Breast cancer
  - Ovarian cancer
  - Uterine cancer
  - Colorectal cancer
  - Prostate cancer
  - Melanoma
  - Brain cancer
  - Pancreatic cancer
  - Stomach cancer
  - Familial hypercholesterolemia
  - Cardiomyopathies
  - Arrhythmias
  - Arteriopathies
240,000+ Participants are Currently Eligible to Receive Genetic Results

Data as of 10/19/2023
DNA Results
You'll see all of your DNA results here when they're ready. See options for your DNA results.

Genetic ancestry and trait results

**Genetic ancestry**
Genetic ancestry can be very interesting, but you may also learn information you were not expecting. Learn more.

**Bitter taste perception**
Learn what your genes can tell you about how you taste bitter things.

**Cilantro preference**
Your genes play a role in whether you love cilantro or think it tastes like soap.

**Earwax type**
Flaky or sticky? Earwax type is in your genes.

**Lactose intolerance**
Your genes have a say in how well you digest lactose products like milk.

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**The Americas**
50%
Such as North, Central, and South America

**The Middle East and North Africa**
50%
Such as Morocco, Algeria, and Egypt

**Northern Africa**
10%
Such as Morocco, Algeria, and Egypt

**The Middle East**
40%
Such as the Arabian Peninsula and Egypt

**Western Asia and the Caucasus**
50%
Such as Turkey, Iran, Syria, Iraq, and the Caucasus
Returned 76,000+ Hereditary Disease Risk (HDR) Results; Identified 2,200+ Participants with P/LP Variants

Data as of 10/20/2023
Returned 75,000+ PGx Results, with 68,000+ (>90%) Participants with a Result That Could Impact How the Body Processes Certain Medications

Distributions of two PGx Results in 75,000+ participants

Data as of 10/19/2023
New Surveys on Mental Health and Well-Being Launched July 2023

**Emotional Health History and Well-Being**
- Generalized and lifetime anxiety
- Present and past depression
- Suicidal behavior
- Childhood and adult adversity/trauma
- General well-being

**Behavioral Health and Personality**
- Adult ADHD
- Bipolar disorder
- Psychosis
- Panic disorder
- Obsessive compulsive disorder
- Social phobia and agoraphobia
- Personality

Over 100,000 participants have completed both surveys to date.

Participants receive personality trait report at the end.
### All of Us Research Program Core Values

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Summary statistics of:

- EHR Data (Conditions, Drug Exposures, Lab & Measurements, Procedures)
- Genomic Variants
- Survey Questions (including COVID-19 surveys)
- Physical Measurements
- Open Access (no login required)
All of Us Researcher Workbench: Access to Row-Level Data for Analysis

Researcher Workbench

• Cloud-based central resource for broad data accessibility

• R and Python, soon SAS will be available also

• **Passport access model for approved researchers** - just create, describe your workspace, and get to work! **No separate IRB approval needed.**

• Currently open to academic, health care and not-for-profit organizations

ResearchAllofUs.org/Data-Tools/Workbench/
Nearly 250,000 Whole Genome Sequences Available to Advance Precision Medicine

- **Survey Responses**: 413,350+
- **Physical Measurements**: 337,500+
- **Genotyping Arrays**: 312,900+
- **Electronic Health Records**: 287,000+
- **Whole Genome Sequences**: 245,350+
- **Structural Variants**: 11,350+ (NEW! In 2023)
- **Long-Read Sequences**: 1,000+ (NEW! In 2023)
- **Fitbit Records**: 15,600+ (NEW! Sleep Data)

The whole genome sequence dataset includes variation at more than **1 billion** locations, which is nearly **one-third** of the entire human genome.
All of Us is Enhancing Diversity of Genomic Studies

Updated genomic data set
~45% diverse by race/ethnicity
77% underrepresented in biomedical research

All Global GWAS values from www.gwasdiversitymonitor.com. Values current as of November 2023
Researcher Workbench Usage and Diversity (data as of November 29, 2023)

Our Researchers

8,120+ Registered Researchers
620+ Institutions

Over 74% of our researchers are underrepresented in the biomedical workforce — including over 33% diverse by race and ethnicity (other than Non-Hispanic White or Asian)

620+ Organizations:
- 40 Historically Black Colleges & Universities
- 61 Hispanic Serving Institutions

Research Currently Underway
8,100+ Active projects

Top conditions being studied
- Cardiovascular disease
- Hypertension
- Mental Health
- Cancer
- Diabetes
Publications are Growing
One example of GWAS in *All of Us*

### The Genetic Basis of Primary Hypothyroidism

2011 - eMERGE Network analysis
- 5 sites worked together to find autoimmune hypothyroidism in EHRs
- Discovered one genetic loci in European ancestry individuals
- Took ~2.5 years and ~40 people

2023
- *All of Us* Researcher Workbench
- >10 genetic loci in diverse population
- Took one postbaccalaureate student about 6 weeks for initial analysis

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![Graph showing genetic loci and associated p-values](image)

**eMERGE**
- 1,317 Cases
- 5,053 Controls

**All of Us Trans-ancestry**
- 9,575 Cases
- 56,585 Controls
Ancillary Studies Will Have a Positive Impact on Increasing Access to a Research-Ready, Diverse National Cohort

Example Ancillary Studies:
- Randomized controlled trials
- Observational trials
- Devices
- New biospecimen collection
- Deploying questionnaires/tasks in portal
- Biospecimen access

Core All of Us participant data
Broad Data use through the Researcher Workbench
Goal: To develop algorithms to predict individual responses to foods and dietary patterns

1. Examine baseline diet and physiological responses to meal challenges
   - 10,000 All of Us participants

2. Examine responses to 3 short-term intervention diets in free-living controlled feeding studies
   - 1,500-2,000 Module 1 participants

3. Examine responses to 3 short-term intervention diets in domiciled controlled feeding studies
   - 500-1,000 Module 1 participants
Ancillary Studies: Nutrition for Precision Health

New Data from Nutrition for Precision Health

- Lifestyle/Behavioral Data
- Physiometabolic Data
- Physical Measurements
- Diet
- Microbiome
- Environmental Data

NPH Enrollment Over Time

- Consented to NPH Module 1
- Completed NPH Module 1

5/1/2023 7/1/2023 9/1/2023 11/1/2023

0 250 500 750 1000 1250
Recent *All of Us* Funding Announcements

**NIH Awards $9.7 Million to Advance the Use of All of Us Research Program Dataset**

- *All of Us* and 10 partner ICOs are funding 26 research projects using *All of Us* data.
- Funding for awards provided by *All of Us*, NEI, NHLBI, NHGRI, NIAMS, NIDA, NIMH, NIMHD, NLM, OBSSR, and ODSS

**All of Us Awards $1.5 Million to Institutions Collaborating with Tribal Communities**

- Funding will support outreach and engagement with Tribal and Indigenous communities, strengthen the research infrastructure supporting AI/AN researchers, and broaden the base of researchers conducting cultural and ethical research with Tribal communities
- Awardees are the University of Arizona, Marshfield Clinic, American Indian Science and Engineering Society

**All of Us Establishes New Center for Linkage and Acquisition of Data (CLAD)**

- Awarded $30 million to the University of Colorado Anschutz Medical Campus and its partners.
- CLAD will connect new types of information to *All of Us* participant data to help researchers better understand the drivers of health and disease (e.g., health care claims, mortality data, environmental data).
“By Participating in the All of Us Research Program, I am helping to shape health research. By providing my health information to All of Us, I am learning things about myself, like how my body responds to certain medications. This information empowers me to work with my doctor to find the right dose. Health research hasn’t always included people like me, but All of Us is changing that. I’m ready for it.”

— Michelle Anderson, Former All of Us Participant Ambassador

Learn More: USA Today Article
Supporting Health Research Across the Lifespan

**Age at Enrollment: Current State**

**Age at Enrollment: Future State**

**Phased Approach**

- **Phase 1**: Participation from birth to 6
  - Enroll: Birth to age 4

- **Phase 2**: Participation from birth to 12
  - Enroll: Birth to age 10

- **Phase 3**: Participation from birth to age of majority
  - Enroll: All ages

Thank you to our 740,000+ participants!