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Karen Wall, Ed.D., M.A.
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Our 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
Our Five Year Goals

**By end of 2026, we will:**

- Enroll 1 million participants who reflect the diversity of the U.S., cover the lifespan, and have shared all baseline elements. Of these participants, 500,000 are actively engaged in the program.
- Expand data available for 1 million participants to include survey, health data streams, a whole genome sequence, environmental data, and physical measures.
- Launch ancillary studies as a core and scalable capability, expanding the cohort and delivering phenotypic, lifestyle, environmental, and biologic data.
- Establish a diverse global community of 10,000 researchers productively using All of Us data.
- Incorporate participant return of value into data collections and assess its impact, including return of information to participants on genomics and EHR.
All of Us in the News

The Atlanta Journal-Constitution
‘All of Us’ program diversifies medical research, health care

To boost diversity in clinical trials, NIH takes to the road to collect DNA from underrepresented groups
Blake Farmer | Aug 9, 2022

How Digital Technology Can Increase Diversity, Equity And Inclusion In Medical Research

NIH study suggests coronavirus may have been in U.S. as early as December 2019

MEDPAGE TODAY
NIH Project Aims to Boost Diversity in Precision Medicine Research
― "We have vastly underrepresented anyone who wasn’t European in ancestry"

What's the 'lived experience' of diverse Americans? A large-scale NIH survey is seeking the answer.

Los Angeles Times
NIH delves into COVID-19 racial disparities with ‘All of Us’

POLITICO
Van Driest has been named the first director of pediatrics at NIH’s All of Us research program. She previously was an associate professor of pediatrics and medicine at Vanderbilt University Medical Center.

CPR News
Medical research doesn’t serve everyone. This effort hopes to build one of the most diverse health databases ever
By John Dildy | Sep. 15, 2022, 4:00 am
All of Us will Enhance Diversity of Genomic Studies

First genomic data set

~50% diverse by race/ethnicity

80% underrepresented in biomedical research

All Global GWAS values from www.gwasdiversitymonitor.com. Values current as of February 17, 2022
Some slides from one talk at American Society of Human Genetics: Diverse genetic ancestries in *All of Us* & replication associations.
June 2022: Surpassed CY2022 goal of 2,500 new researchers, 6 months early!
October 12-13, 2022: Our First All of Us Face-to-Face Consortium Meeting in 2.5 years
Sara Van Driest, M.D., Ph.D. tapped to set the foundation for pediatric enrollment in *All of Us*

Dr. Van Driest joined the program’s Division for Cohort Development to support future enrollment and retention of pediatric and adolescent participants who reflect the diversity of the United States. This will entail developing the program’s model for pediatric recruitment and family-based participation with a focus on engaging those who are from communities historically underrepresented in biomedical research.

Prior to joining the program, Dr. Van Driest served as an associate professor of pediatrics and medicine at Vanderbilt University Medical Center.
Genomic Health-Related Return of Results in Pilot Testing

**DNA Results**
You will see all of your DNA results here when they are ready. See options for your DNA results.

Filter by: All Health-related Genetic ancestry and traits

**Health-related results**

- **Hereditary disease risk results**
  Please review the benefits and risks to getting your DNA results about hereditary disease risk.
  
- **Medicine and your DNA results**
  Please review the benefits and risks to getting your DNA results about medicine and your DNA.

**Genetic ancestry and trait results**

- **Genetic ancestry**
  Where in the world did your genes come from?
  
  2 results

  5 results
Genomic Health-Related Return of Results in Pilot Testing (continued)

• Hereditary disease risk (starting with ACMG59) and medicine and your DNA (pharmacogenomics)
• Participants can choose results they want
• Interpretation begins at Clinical Validation Laboratories
• All results supported by Genetic Counselors
• Participants can obtain clinical results available for ACMG59 at no cost
Participant notifications do not reveal results. Results can only be accessed by participants through the portal online and/or genetic counseling.
# All of Us Genetics Return Strategy

## Engagement

Genetic ancestry and traits results

- **7 regions (21 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

## Health Information

Hereditary Disease Risk Report

- **59 genes (SNVs + indels)**
  - Breast cancer
  - Ovarian cancer
  - Brain cancer
  - Uterine cancer
  - Colorectal cancer
  - Prostate cancer
  - Melanoma
  - Pancreatic cancer
  - Stomach cancer
  - Familial
  - Hypercholesterolemia
  - Cardiomyopathies
  - Arrhythmias
  - Arteriopathies

## Medicine and your DNA Report

- **7 genes**
  - CYP2C19
  - DPYD
  - G6PD
  - SLCO1B1
  - NUDT15
  - TPMT
  - UGT1A1
Enrollment Update as of November 1, 2022

546,000+ Participants
328,000+ Electronic Health Records
384,000+ Participants who have completed initial steps of the program
402,000+ Biosamples

Diversity
Includes racial and ethnic minorities as well as sexual and gender minorities, people with low income or limited education and other groups.

50%+ Racial and Ethnic Minorities
80%+ Underrepresented in Biomedical Research
All of Us Ancillary Studies

- Exploring the Mind
  - Embedded studies
    - Recontact of participants for custom surveys, wearables, etc
  - Biospecimen use to generate new data
- COVID Serology Study
- Broad Data use through the Researcher Workbench

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

Access Policies/IRB Approvals/etc
Mental Health Projects Coming Soon to All of Us

New Mental Health & Wellbeing Module

Exploring the Mind Ancillary Study

Goals:
- Encourage and enable research projects relevant to mental health through self-reported data
- Engage participants on topic of mental health in meaningful and innovative ways

Survey Content spans over 17 mental health-related domains, combining over 10 validated instruments:
- Domain: Depression, Anxiety, Trauma, Personality, General Well-being, Phobias
- Instrument: PHQ-9, GAD-7, UK Biobank, ACE Questionnaire

Planning Return of Information including relevant resources
Researcher Data Access

**Individual Biospecimen and Participant Data**
(Available in the Future)

**Controlled Tier**
(Available Now)
No obvious PII. Genomics, real dates, eventually Clinical Narrative data, and more

**Registered Tier**
(Available Now)
Surveys, EHRs, Physical Measurements, shifted dates Exceeds HIPAA Safe Harbor Standards

**Public Tier**
(Available Now)
Summary Statistics Aggregate Counts

**Future Ancillary Studies**
Could recontact participants, use biospecimens, issue new surveys or DHT, enroll in clinical trials

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**Data Curation**

- Raw Data Repository
  - Data Harmonization
  - Privacy
  - Methodology
  - QA/QC

**Researcher Workbench**
[ResearchAllOfUs.org/Apply/](http://ResearchAllOfUs.org/Apply/)

**Data Browser**
[databrowser.researchallofus.org](http://databrowser.researchallofus.org)
(public, no login required)
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 Beta

- Cloud based central resource
- Passport access model - just create, describe your workspace, and get to work! No separate IRB approval needed.
- Currently open to US nonprofits, academic institutions, and healthcare organizations

ResearchAllofUs.org/Data-Tools/Workbench/
Recent Scientific Publications Utilizing All of Us

Migraine among adults with atopic dermatitis: A cross-sectional study in the All of Us research program

Ryan Fan, Audrey C Leasure, William Damsky, Jeffrey M Cohen

Clinical and Experimental Dermatology, llac004, https://doi.org/10.1093/ced/llac004
Published: 20 October 2022

Association of step counts over time with the risk of chronic disease in the All of Us Research Program

Hiral Master, Jeffrey Annis, Shi Huang, Joshua A. Beckman, Francis Ratsimbazafy, Kayla Marginean

Published in final edited form as:

Novel Association between Opioid Use and Increased Risk of Retinal Vein Occlusion Using the National Institutes of Health All of Us Research Program

Caitlin Dreisbach PhD, RN-1,2, Susan Grayson BSN, RN-3, Katelyn Leggio MSN, RN-4, Alex Conway MS-1, Theresa Kolecik PhD, RN-1,2, R.88
Researcher Workbench: By the Numbers *(Since Launch in May 2020)*

Research on the Researcher Workbench

- **3,374** Registered Researchers
- **2,836** Active Projects
- **65+ Publications** using *All of Us*

>400 organizations, including:
- non-profit healthcare and federal agencies
- >20 Historically Black Colleges and Universities
- >30 Hispanic Serving Institutions

(Data as of 10/28/22)
**Historical Data Access Path**

**Enrolling 1 Million: Building the cohort**

### 2019
- **Data Browser**
  - *(launched May 2019)*
  - Interactive tool available to public to summary data to understand characteristics of our participant population, explore data types available and plan research questions
  - **Access:** fully open, no login needed for aggregate data

### 2020
- **Researcher Workbench**
  - *(launched May 2020)*
  - Released first version of *All of Us* dataset and first set of researcher tools for beta testing;
    - *Survey* data
    - *Physical measurements*
    - *EHR* data
  - **Access:** Registered tier (individual-level data) available to registered researchers with institutional sign-off. U.S.-based academic, nonprofit, or health care institutions may enter into Data Use and Registration Agreement.

### 2021
- **Expansion of data and tools**
  - *(throughout 2021)*
  - Expanded *All of Us* dataset with additional survey, measurement, and EHR data
    - *Start of genotyping* and WGS
    - *Initial return of results* to participants
    - >1K researchers registered
  - **Access:** Expanded by proactively working to establish agreements with wide range of organizations (e.g. HBCUs, HSIs, RM1s)

### 2022
- **Controlled Tier & Genomics**
  - *(ongoing)*
  - Launch Controlled tier:
    - *Genomics* data
    - *Individual & granular-level* information
    - Available in Registered and Controlled tier with basic information available via our public data browser:
      - *ACS data linkage*
      - *New surveys*
  - **Access:** Available to registered researchers who have taken additional steps and training to access these data.

### 2023 and beyond
- **Additional data types and tools**
  - *(ongoing)*
  - Continue to expand the *All of Us* dataset with new data releases, over time:
    - *Assay* data
    - *Additional wearables* data
      - Fitbit sleep data
      - Apple Healthkit
    - *New surveys* (e.g., Mental Health & Wellbeing)
    - New linkages to *external data sources*
    - Ancillary study data
  - **Access:** continued expansion of researcher access
Program was built on the promise that data will be broadly accessible for research, including researchers from all sectors and within and outside the United States. We continue to expand our researcher audience from its first release.

Program designed with this in mind: our cloud environment, data standards, access policies, policy framework, and importantly our consent with participants.

Developing plans with input from participant communities and other stakeholders. This includes consideration of regulatory, legal, and policy requirements, options for identity verification, and potential partnerships to promote equitable access.

Accelerating & Democratizing Science: A Genome Wide Association Study (GWAS) of Type 2 Diabetes in All of Us

- ~23M SNPs
- ~20k participants
- GWAS runtime of ~20 minutes
- Cost $37
Incident Diagnoses after 6 months

- Analysis uses average of daily steps prior to diagnosis.
- Effect size per 1000 steps, adjusted for age, sex, race

Adjusted for age, sex, race, CAD, cancer, BMI, systolic blood pressure, education level, smoking, alcohol use, and monthly daily steps (time varying)

Master et al. (2022) Nat Med, 10.1038/s41591-022-02012-w.
Thank You!

A big thank you to our 546,000+ participants!

AllofUs.NIH.gov
JoinAllofUs.org
ResearchAllofUs.org

@AllofUsResearch
@AllofUsCEO
#JoinAllofUs