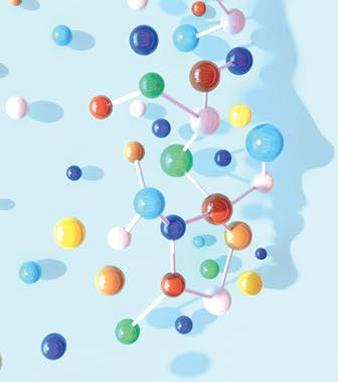




All of Us Research Program

Holly Garriock, PhD
Holly.garriock@nih.gov



Quick Overview

- What is *All of Us*?
- Current status of *All of Us*
- How *All of Us* can be useful to you
- Future plans

All of Us

RESEARCH PROGRAM



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**, 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!”

NIH Director Francis Collins, M.D., Ph.D.

The *All of Us* Research Program is part of the broader Precision Medicine Initiative.

Mission and Objectives

Nurture relationships

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

Catalyze a robust ecosystem

of researchers and funders hungry to use and support it



Deliver the largest, richest biomedical resource ever,

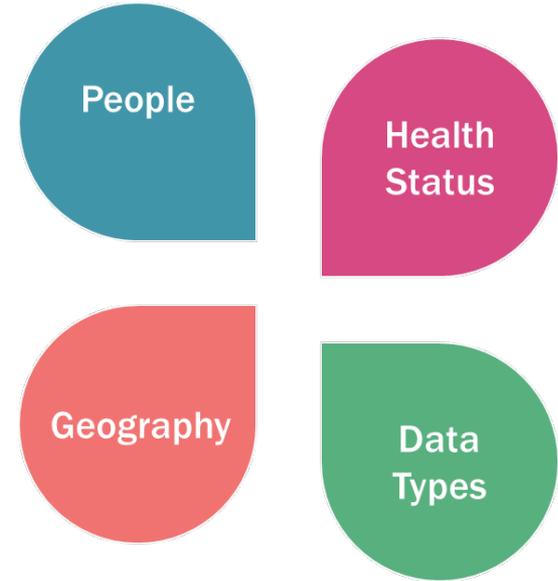
making it as easy, safe, and free to use as possible

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.

Innovative Aspects of *All of Us*

- **Diversity at the scale of 1 million people:** demographically, geographically, medically, and especially those underrepresented in biomedical research
- **Diversity of data types collected longitudinally:** clinical, environmental, genetic, behavioral, socioeconomic
- **Focus on participants as partners:** included in governance, invited to co-invent systems and give input into the science, choice to receive all data and information back
- **National, open resource for all:** open to the public and all researchers, open source software & tools



Launched nationally on May 6th across a range of diverse communities



- Launch was incredibly successful!
- Events in **7 diverse communities** around the country
- **2nd largest media event** for NIH
- **~12,000 participants** from all 50 states signed up during launch week

What are the potential activities asked of participants in the current protocol?



Enroll, Consent and Authorize EHR

- Recruiting 18+ years old initially;
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data



Answering Surveys

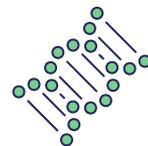
- Six initial surveys: The Basics, Overall Health, Personal Habits, Health Care Access & Utilization, Family Medical History, Personal Health History
- Additional surveys will be released on an ongoing basis.



Physical Measurements*

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

**Based on diverse sampling and capacity*



Provide Biosamples*

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

**Based on diverse sampling and capacity*



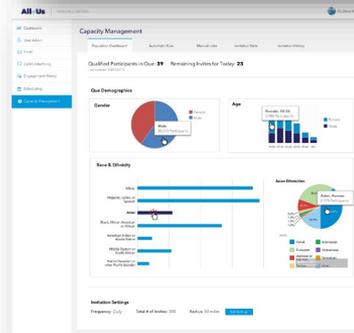
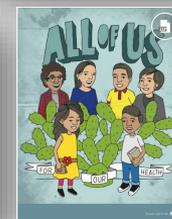
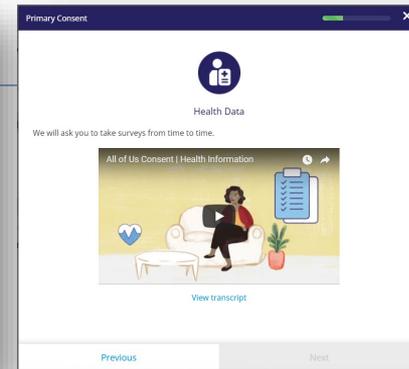
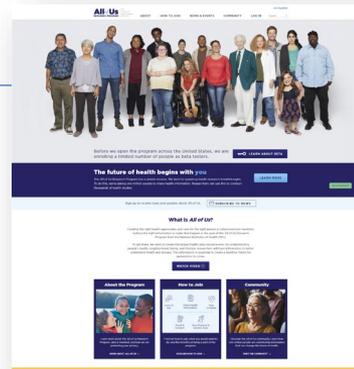
Wearables and Digital Apps

- Share data from wearable fitness devices, starting with FitBit
- Share data, such as cardio-respiratory fitness, through integrated apps (coming soon)
- More integrations under development

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

What's the current status of the program?

- ~250 clinic sites now up and running
- ~197k participants from all 50 states with ~118k completed whole V1 protocol; program goal is 1M core participants by end of 2023!
- Doing very well on Underrepresented in Biomedical Research (UBR): 79% of participants UBR, 50% racial/ethnic diversity
- EHR data coming in for tens of thousands of participants; quality evaluations and cleaning of EHR data now underway
- Biobank at Mayo already received >2M biosample tubes of blood & urine; saliva pilot underway soon



NIH leaders say: "already the largest diverse cohort in NIH history"

Genomics plans & aspirations: genotyping, WGS, and “RROI” to participants

- **Genotyping & whole genome sequencing for all 1M participants** as fast as funding/capacity build out allow
- Made awards in October 2018 for **three genome centers**
 - Will start genotyping and whole genome sequencing in 2019
- **Genetic Counseling Resource** funding opportunity—released in fall 2018; award in 2019
- Plan to launch **pilot of Genetic return of information and consent** in 2019 with 40k diverse participants
 - Scope: 1) Pathogenic/Likely pathogenic ACMG variants; 2) Report of no pathogenic ACMG variant observed; 3) PGx report;



We are working to build out our genomic capabilities as quickly as possible, but this will not happen overnight.

Researcher Portal Plans & Aspirations

- Completed needs-finding for researchers
- Developed research access policies & committee
 - Approved 3 tier approach for data (public, registered, controlled)
 - Developing policies on access to samples & cohort
 - Developing procedures for allowing citizen scientist access to controlled tier
- Basic model of the Research Portal is
 - Entry page with description of program, policies & procedures, values, data, and tools
 - Public data browser
 - Research workspace, with cohort builder, Jupyter notebooks, & common analytic tools
- Initial research website launched in August 2018
- Alpha and beta testing our data cleaning, curation processes
- On track to launch **1st curated dataset in 2019**; access to cohort and samples to come later

The screenshot shows the homepage of the All of Us Research Hub. At the top, there are logos for All of Us Research Hub and the National Institutes of Health (NIH). The main heading is "Welcome All of Us Researchers". Below this, there is a paragraph describing the program as one of the largest biomedical resources, aimed at exploring how lifestyle, environment, and biological makeup affect health and disease. To the right of the text is a graphic of colorful geometric shapes (pentagons, circles, triangles) surrounding photos of diverse people. A dark blue banner below the main text contains the text "Sign up to get updates on the All of Us Research Hub." and a "SEE EMAIL UPDATES" button. The next section is titled "What makes us unique?" and includes a video player with a play button. The video description states that enrolling one million or more volunteers will have the scale and scope to enable research for most common and many rare conditions. Below the video is a graphic of a DNA double helix with a play button. The final section is titled "We're building a community of researchers" and describes the program as a diverse community of traditional and non-traditional researchers. It includes a graphic of three people in circular frames connected by lines.

Challenges: complex security & beta testing; balance of recruit vs. release; managing expectations

There are thousands of research questions. Let's find some answers.

The *All of Us* Research Program is building one of the largest biomedical resources of its kind to explore how lifestyle, environment, and biological makeup affect health and disease. When it's available, researchers will be able to use the diverse data here to explore a wide range of biomedical and scientific hypotheses.

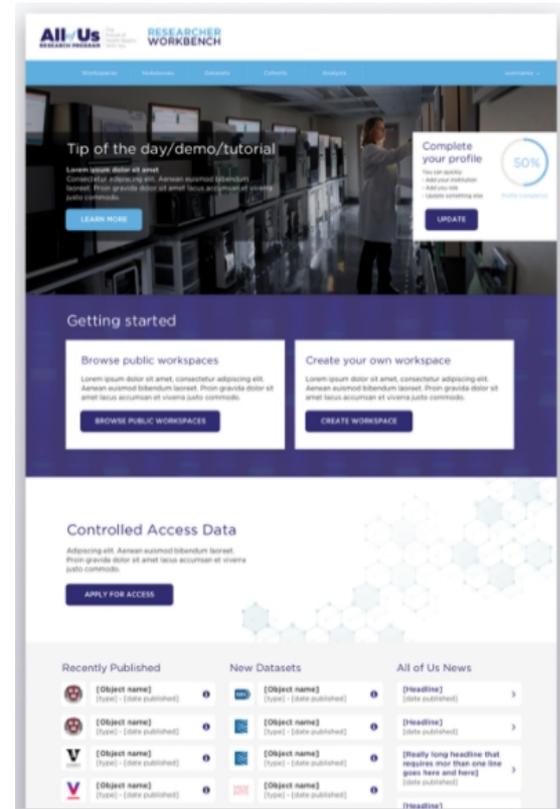


Sign up to get updates on the *All of Us* Research Hub.

GET EMAIL UPDATES

What is the promise for researchers?

- The opportunity to **save time and resources** and **accelerate your research breakthroughs** by leveraging:
 - A **rich resource of data**, including biospecimens and increasingly robust electronic health records.
 - A **longitudinal dataset** that will follow participants as they move, age, develop relationships, get sick, and try treatments.
 - A **diverse cohort of participants**, including people both healthy and sick, from all walks of life and all parts of the country.
 - Both raw data and data that is already **cleaned and curated**.
 - **Robust computing and analytic tools** to support complex data analyses in a **secure data environment**.
 - A group of **engaged participants** who may be eager to participate in ancillary studies.
- The ability to easily **share workspaces and analyses** with research partners and reviewers.
- The chance to learn from the program's pilots and experiments and **leverage innovations** for other studies and cohorts.



As with most studies, we are collecting, evaluating, and curating initial datasets; availability in 2019.

How will *All of Us* lead to discoveries?

Participants Share Data

Participants share health data online. This data includes health surveys and electronic health records. Participants also may be asked to share physical measurements and blood and urine samples.

Researchers Study Data

In the future, approved researchers will use this data to conduct studies. By finding patterns in the data, they may make the next big medical breakthroughs.

Researchers Share Discoveries

Research may help in many ways. It may help find the best ways for people to stay healthy. It may also help create better tests and find the treatments that will work best for different people.



Data Is Protected

Personal information, like your name, address, and other things that easily identify participants will be removed from all data. Samples—also without any names on them—are stored in a secure biobank.

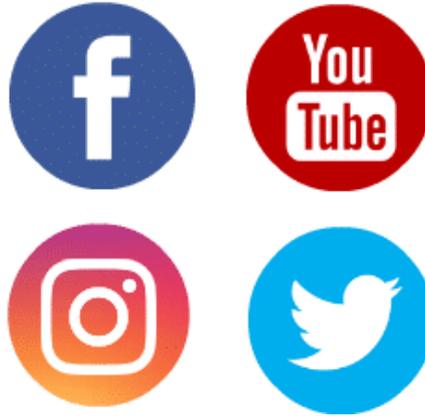
Participants Get Information

Participants will get information back about the data they provide, which may help them learn more about their health.

Thank you!



JoinAllofUs.org



[@AllofUsResearch](https://twitter.com/AllofUsResearch)
[#JoinAllofUs](https://twitter.com/AllofUsResearch)



National Institutes
of Health

AllofUs.nih.gov

All of Us
RESEARCH PROGRAM

**The future
of health
begins
with you**



National Institutes
of Health

Extra Slides



Major building blocks of the *All of Us* Research Program consortium

DATA AND RESEARCH CENTER

Big data capture, cleaning, curation, & sharing in secure environment

Vanderbilt, Verily, Broad Institute

BIOBANK

Repository for processing, storing, and sharing biosamples (35+M vials)

Mayo Clinic

PARTICIPANT TECHNOLOGY SYSTEMS CENTER

Web and phone-based platforms for participants

Vibrent Health

GENOMICS INFRASTRUCTURE

Genotyping and whole genome sequencing of biosamples; counseling and educational resources for participants

Baylor College of Medicine, Broad Institute, University of Washington (with multiple partners), and future awards to grow infrastructure

PARTICIPANT CENTER / DV NETWORK

Direct volunteer participant enrollment, digital engagement innovation, and consumer health technologies

Scripps Research Institute (with multiple partners)

HEALTH CARE PROVIDER ORGS NETWORK

HPOs with clinical & scientific expertise, enrollment & retention of participants

30+ regional medical centers, FQHCs, VA, and future awards to grow network

COMMUNICATIONS & COMMUNITY NETWORK

Communications, marketing, and design expertise; engagement coordination and community partners network

Wondros, HCM, 36 community partner orgs, and future awards to grow network

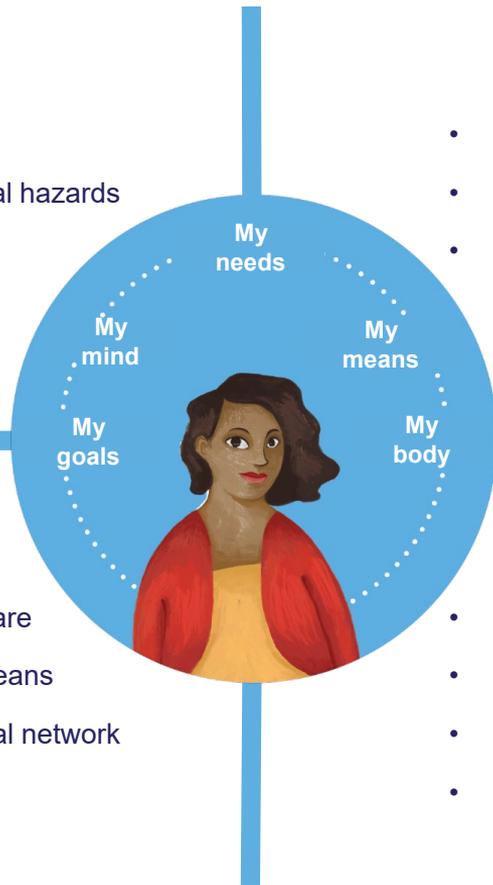
Understand the whole person: Example data types that *All of Us RP* may collect

Environmental

- Highway proximity
- Weather
- Chemical exposures
- Occupational hazards
- Air pollution
- Zip code
- Water quality

Biological/Clinical

- Metabolomics
- Electronic health records
- Mental health
- Proteomics
- Medications
- Genomics
- Microbiomics



Social

- Upbringing
- Access to care
- Education level
- Financial means
- Family structure
- Size of social network
- Stress
- Religion
- Literacy level

Behavioral

- Exercise
- Drug usage
- Eating
- ADLS
- Drinking
- Smoking history
- Self-report
- Routines

Genomics plans & aspirations: genotyping, WGS, and “RROI” to participants

- **Genotyping & whole genome sequencing for all 1M participants** as fast as funding/capacity build out allow
- Made awards in October 2018 for **three genome centers**
 - Baylor College of Medicine with Johns Hopkins University and The University of Texas Health Science Center at Houston; The Broad Institute with Color and the Laboratory for Molecular Medicine at Partners HealthCare; Northwest Genomics Center at the University of Washington
 - Will start genotyping and whole genome sequencing in early 2019
- **Genetic Counseling Resource** funding opportunity—released in fall 2018; award in 2019
- Plan to launch **pilot of Genetic return of information and consent** in 2019 with 40k diverse participants
 - Compare approaches (from preference engine to messaging)
 - Scope: 1) Pathogenic/Likely pathogenic ACMG variants; 2) Report of no pathogenic ACMG variant observed; 3) PGx report; 4) Access to data file
- Three **big challenges**:
 - Lowering the costs & increasing the U.S. capacity for sequencing and analysis
 - Accessing large enough genetic counseling capacity
 - Streamlining the cleaning, curation, & sharing of genomic data to make it available to a wide range of researchers



We are working to build out our genomic capabilities as quickly as possible, but this will not happen overnight.

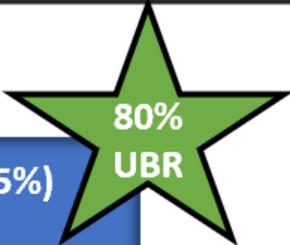
Approach to Privacy and Security

- Guided by privacy, trust, and data security principles developed by experts with input from the public.
- Data warehouse is built with the most advanced security available.
- Experts have done and will continue to do rigorous security testing.
- Data is encrypted and direct identifiers are removed.
- Researchers must agree to a code of conduct before accessing the data.
- Participants' preferences will be respected.
- Protected by a Certificate of Confidentiality.
- Committed to transparency in the event of a data breach.



Safeguarding your identity and data to the best of anyone's abilities is our most important responsibility.

All of Us RP UBR Data (3/11/19)



80%
UBR

****UBR Count: 94,321 of 118,270 Core participants qualify as UBR (79.75%)**

Note: The data includes Women/Females as RBR

Rank	UBR Diversity Category*	Category Count	Category %
1	Ancestry (R/E)	59,774	50.54%
2	Income	36,106	30.53%
3	Age	28,498	24.1%
4	Educational Attainment	12,791	10.82%
5	Sexual and Gender Minorities	12,105	10.24%
6	Geography	5,988	5.06%
7	Sex	81	0.07%
---	Access to Care	In development	---
---	Disability	In development	---

***Note:** Categories overlap. Many participants qualify in more than one category.

****Note:** Each person counts only once in the overall UBR count, no matter how many UBR categories they qualify in.



Current consortium members (beyond community partners)

DV Network (Direct Volunteers)



Biobank



Communication & Engagement

WONDROS



patientslikeme®



HPO Network (Health Care Provider Organizations)

RMCS

California Precision Medicine Consortium

UC San Diego Health



Keck Medical Center of USC



UC Irvine Health

UC HEALTH

UCSF



Illinois Precision Medicine Consortium



THE UNIVERSITY OF CHICAGO



RUSH

THE UNIVERSITY OF ILLINOIS AT CHICAGO

New England Precision Medicine Consortium



MASSACHUSETTS GENERAL HOSPITAL

BRIGHAM HEALTH BRIGLEE AND WOMEN'S HOSPITAL

BU

BOSTON MEDICAL CENTER

UNIVERSITY OF MASSACHUSETTS UNASS Medical School

Trans-American Consortium for the Health Care Systems Research Network



Essentia Health

BaylorScott&White HEALTH

SPECTRUM HEALTH

New York City Precision Medicine Consortium



NYC HEALTH+HOSPITALS

NewYork-Presbyterian

Weill Cornell Medicine

Southern All of Us Network



The University of Mississippi MEDICAL CENTER

UAB MEDICINE UAB HOSPITAL

Tulane University

TUSKEGEE UNIVERSITY

HUNTSVILLE HOSPITAL

University Medical Center

UNIVERSITY OF SOUTH ALABAMA HEALTH SYSTEM

LSU Health NEW ORLEANS

SouthEast Enrollment Center



EMORY UNIVERSITY

MOREHOUSE SCHOOL OF MEDICINE

OneFlorida Clinical Research Consortium

All of Us, Wisconsin

Marshfield Clinic



University of Wisconsin SCHOOL OF MEDICINE AND PUBLIC HEALTH



BLOODCENTER of WISCONSIN PART OF VERSITI

University of Arizona

THE UNIVERSITY OF ARIZONA

Banner Health

University of Pittsburgh

University of Pittsburgh

FQHCs (Federally Qualified Health Centers)

Cherokee HEALTH SYSTEM

JACKSON-HINDS COMPREHENSIVE HEALTH CARE

Community Health Center, Inc.

EmCare



VA Medical Centers



Platform Development



WONDROS

Genomics Infrastructure



UTHealth The University of Texas Health Science Center at Houston



verily

color



UNIVERSITY OF WASHINGTON

Community Partners Network

