Supporting Data-Powered Health for Researchers Participants, and Communities

All of Us Research Program

Amanda J. Wilson
Head, National Network Coordinating Office
National Library of Medicine, All of Us Research Program partner
With Thanks
Precision Medicine Initiative
All of Us
RESEARCH PROGRAM

The future of health begins with you

precision medicine:
the right treatment for the right person at the right time
The Cost of Imprecise Medicine

**Patients**
- Health care is often targeted to the average patient, not the individual
- Health problems can take years to unravel, with significant trial and error

**Providers**
- Not enough research to draw on for clinical evidence, especially in diverse populations
- Medical records scattered in different places
- Not enough time to analyze one patient at a time

**Researchers**
- Enormous time and cost spent building IT systems vs. doing research
- Siloed data resources and funding opportunities
- Challenges acquiring large sample sizes
- Slow translation of data into knowledge
what is *All of Us*?

- 2015: White House announced the Precision Medicine Initiative
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- Privacy and Trust Principles
- Data Security Policy Principles
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- 2016: Codified and Statutorily Mandated by the 21st Century Cures Act
21st Century Cures Act

- Provides the Precision Medicine Initiative with $1.455 billion over 10 years
- Language on:
  - Diversity
  - Data sharing
  - Privacy
What is the *All of Us* Research Program?

- **Rich, Longitudinal Resource**: Deliver a national resource of deep clinical, environmental, lifestyle, & genetic data from one million participants who are consented & engaged to provide data on an ongoing, longitudinal basis (60+ years!)

- **Diversity of Participants**: Reflect the broad diversity of the U.S.—all ages, races/ethnicities, gender, SES, geographies, & health status—by over-recruiting those underrepresented in biomedical research

- **Diversity of Researchers**: Build the tools & capabilities that make it easy for researchers from community scientists to premier university labs to make discoveries using the data & biosamples and through ancillary studies w/ the cohort
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
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.
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
An opportunity to fight disease and improve the health of future generations

The opportunity to be part of a movement to make our health care more precise, more personal, and more effective

The opportunity to ensure that your community is included in the studies that may lead to new understanding and new treatments

An opportunity to learn some of your own health indicators and get your own data
What is the Promise for Researchers?

- The opportunity to **save time and resources** and **accelerate your research breakthroughs**
- 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.
Over time, increased scientific evidence and improved guidelines to enable precision medicine opportunities for more people and conditions:

- Better understanding of the impact of environment and lifestyle factors on health.
- Increased knowledge of differences in risk factors and response to treatments among diverse populations.
- More information on the development of conditions that will allow for earlier detection.
- Deeper understanding of different conditions that may allow for better stratification.

Innovations that may make it easier to share electronic health records with other providers and patients.

New knowledge to help address health disparities, increase patient engagement, and understand the usefulness of consumer health devices and apps.
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 identity and data is our most important responsibility.
All of Us Research Program Building Blocks
<table>
<thead>
<tr>
<th>DATA AND RESEARCH CENTER</th>
<th>BIOBANK</th>
<th>PARTICIPANT TECHNOLOGY SYSTEMS CENTER</th>
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</table>
| Big data capture, cleaning, curation, & sharing in secure environment | Repository for processing, storing, and sharing biosamples (35+M vials) 
*Vanderbilt, Verily, Broad Institute* | Web and phone-based platforms for participants 
*Mayo Clinic* |
| PARTICIPANT CENTER / DV NETWORK | HEALTHCARE PROVIDER ORGS NETWORK | COMMUNICATIONS & COMMUNITY NETWORK |
| Direct volunteer participant enrollment, digital engagement innovation, and consumer health technologies 
*Scripps Research Institute* (with multiple partners) | HPOs with clinical & scientific expertise, enrollment & retention of participants 
*30+ regional medical centers, FQHCs, VA, and future awards to grow network* | Communications, marketing, and design expertise; engagement coordination and community partners network 
*Wondros, HCM, community partners, and future awards to grow network* |
# All of Us Consortium Members

## DV Network (Direct Volunteers)
- Scripps Translational Science Institute
- DXC Technology
- Quest Diagnostics
- EMSI Health
- patientslikeme
- WebMD
- BlueCross BlueShield
- Mayo Clinic

## Biobank

## HPO Network (Health Care Provider Organizations)

### RMCs
- California Precision Medicine Consortium
- University of Arizona
- University of Pittsburgh
- Cleveland Clinic
- Mayo Clinic
- University of California, San Diego

### Illinois Precision Medicine Consortium
- Northwestern University
- Keck Medical Center of USC
- NorthShore University Health System
- Rush University Medical Center
- University of Chicago
- Cedars Sinai

### New England Precision Medicine Consortium
- Partners HealthCare
- Boston Children’s Hospital
- Brigham and Women’s Hospital
- Dana-Farber Cancer Institute
- Massachusetts General Hospital
- Massachusetts Eye and Ear Infirmary
- Harvard Medical School

### Trans-American Consortium for the Health Care Systems Research Network
- Stanford Health Care
- Essentia Health
- Baylor Scott & White
- Spectrum Health

### New York City Precision Medicine Consortium
- Columbia University Medical Center
- New York Presbyteriann
- Weill Cornell Medicine

### Southern All of Us Network
- University of Miami
- University of Florida
- Vanderbilt University
- UT Southwestern Medical Center
- University of Alabama at Birmingham
- University of Mississippi Medical Center
- University of South Alabama Health System
- LSU Health Sciences Center

### SouthEast Enrollment Center
- Emory University
- Morehouse School of Medicine
- University of Florida
- University of Miami
- University of South Florida
- University of Central Florida
- University of Kentucky
- University of Kentucky Medical Center
- University of Cincinnati

### All of Us, Wisconsin
- Marshfield Clinic
- University of Wisconsin

### VA Medical Centers
- VA Medical Centers

### FQHCs (Federally Qualified Health Centers)
- Cherokee Health Services
- Community Health Centers, Inc.
- Jackson-Hinds Comprehensive Health Center
- HCMC

### Communication & Engagement
- WONDROS
- Platform Development
- Scripps Translational Science Institute
- Sage
- Vanderbilt University
- WONDROS
- verily
- U.S. Department of Veterans Affairs
Two Methods of Enrollment

DIRECT VOLUNTEERS

HEALTH CARE PROVIDER ORGANIZATIONS
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

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Coming soon
Present

- > 200,000 participants registered
- > 100,000 core participants
- ~ 75% of current participants self-identify as belonging to one or more population that has been historically underrepresented in biomedical research

Future

- **Broaden inclusion** to additional demographics
- **Provider outreach** to engage with and educate clinical stakeholders
- Expand **linguistic support** for non-English or Spanish speakers
- Launch the **researcher portal**
Importance of Historically Underrepresented Populations
1. Participation is **open** to all.
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8. The program will be a catalyst for positive **change** in research.
Persistent Racial and Ethnic Bias in GWA Studies

- Native Peoples: 0.05%
- Pacific Islander: 0.28%
- Mixed: 1%
- Arab/Middle Eastern: 0.08%
- Hispanic/Latino: 0.54%
- African: 3%
- Asian: 14%

Minorities make up 38% of the US population. Minority populations to rise to over 56% of overall population.

Minority enrollment in clinical trials <10% underrepresentation in biomedical research populations includes dimensions of race and ethnicity, as well as age, sex, gender, sexual orientation, income, education, geography, access to care, and disability.
Potential Improvements in Minority Health

Health disparities are well known but NOT well understood.

- Why do African-Americans have a higher mortality rate from chronic diseases, including cancer, Alzheimer’s, diabetes, and heart disease?
- Why is stroke more common among rural communities?
- Why is Hepatitis B more common in the Asian and Pacific Islander population?

Precision medicine asks us to look even beyond racial or ethnic group and into unique biological information to determine likelihood of developing and dying from disease.

But we can only determine these genetic variations if we increase minority participation in research—then, we will be able to speed treatments and cures for the conditions and diseases that afflict minority populations the most.
Disenfranchisement and Historical Abuses
trust will be earned through robust engagement and full transparency.
All of Us Community and Provider Partner Network
All of Us Data Access
All of Us Research Program Core Values

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enrollment and data collection

data transfer and storage

return of results
All of Us Research Program Data

- Participant Surveys
- Electronic Health Records
- Physical Measurements
- Biospecimens and Assays
- Mobile/Wearable Tech
- Geospatial/Environmental Data

Data types will grow and evolve with science, technology, and trust.
Sharing Data with Researchers

- Data ownership and control
- Participant privacy and identifiability
- Rules for appropriate access and use
- Prevention and penalizing misuse

Balancing openness and oversight

Balancing paternalism and autonomy

- Ethical, legal, and regulatory obligations
- Potential benefits and harms
- Content and context of data return
- Feasibility

Sharing Data with Participants
sharing data with researchers
Balancing Openness with Oversight

- What is an appropriate standard of deidentification?
- What privacy and security provisions (should) apply?
- Who should get access to the data, and how much should they be trusted?
- What responsibilities are borne by the data user?
- What are the potential avenues and harms of data misuse?
- What can be done to dissuade and/or punish bad actors?
NIH will invest to level the playing field so diverse researchers can play

- *All of Us* data will be available to *all types of users*
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- *All of Us* data will be available to *all types* of users
- The *All of Us* Data Resource will employ a cloud-based analysis platform
NIH will invest to level the playing field so diverse researchers can play.

- *All of Us* data will be available to all types of users.
- The *All of Us* Data Resource will employ a cloud-based analysis platform.
- Access will be tiered.
The *All of Us* Data Resource Code of Conduct (examples)

**I WILL:**

- know and follow **all applicable federal, state, and local laws** regarding human data access and privacy.
- contact the *All of Us* Research Program Resource Access Board (RAB) within 24 hours if I become aware of **any uses or disclosures of *All of Us* data** that endanger the security or privacy of research participants, including any unintended re-identification of participants through the process of my work.

**I will NOT:**

- use *All of Us* Research Program data for research that is discriminatory or stigmatizing of individuals, families, or communities.
- attempt to re-identify research participants or their relatives.
- use or disclose the information other than as permitted by this DUA.
- make copies of or download **individual-level data** resources outside of the *All of Us* research environment without approval from RAB.
The *All of Us* Approach to Data Access

NIH will invest to level the playing field so diverse researchers can play

- *All of Us* data will be available to all types of users
- The *All of Us* Data Resource will employ a cloud-based analysis platform
- Access will be tiered
- Users will be granted data passports
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- Access will be tiered.
- Users will be granted data passports.
- Project information will be made public and auditable.
All of Us Research Hub

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.

Learn more about becoming a participant at joinallofus.org
Learn about the program at AllofUs.nih.gov

www.ResearchAllofUs.org
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.
sharing data with participants
Research Participants Want Information Back

PLOS ONE published a public opinion survey conducted by the Foundation for the NIH.

2,601 responses were analyzed.

79% supported the program after reading a short description.

54% said they would definitely or probably participate if asked—not predictive of enrollment numbers, but encouraging.

- Little variability among demographic groups
- Most important incentive for participation: learning about one’s health information

Balancing Paternalism with Autonomy

- What information should participants receive? What information do participants have a right to receive?
- What are the potential benefits and harms to the receipt of that information?
- Are there means of mitigating negative outcomes resulting from the return of information?
- Where is the apposite limen between research and clinical care?
- Is there an obligation to provide participants with a choice to receive some or all of the information?
WORKSHOP GOALS:

• Assess the state-of-the-field for the return of genomic information.

• Establish guidelines for return of genetic results considering the distinctive features and core principles of the All of Us Research Program.
Key Insights

- Ask participants if they want data about themselves, and how they want it
- Develop multiple means of communication
- Challenges of the digital divide and low literacy/health literacy
- Start small, test, and then build
- Be realistic and clearly communicate with participants
- Build upon best practices
National Academies Report

- Support decision making regarding the return of results on a study-by-study basis

- Promote high-quality individual research results

- Foster participant understanding of individual research results

- Revise and harmonize current regulations
All of Us ELSI Priorities: The Four Buckets

- Policy Implications
- Value to Stakeholders
- Research Practice
- Convenings Support
The *All of Us* Approach to Return of Results

- Opportunities for participant education will be provided to promote informed decision making.
- Participants must opt in to receive information carrying more than minimal risk.
- Medically actionable pathological genetic variant positivity will be returned in a way to maximize participant safety and understanding.
- Support services will be available to anyone, regardless of results.
Return of Information

- **Individual and Comparative Information**
  - Survey data
  - EHR data, claims data
  - Assays, including genomics

- **Study Results**
  - Aggregated results
  - Scientific findings

- **Program and Research Information**
  - Ongoing study updates
  - Opportunities to be contacted for other research opportunities
All of Us + NLM
Goals of the NLM Strategic Plan 2017-2027

- Accelerate discovery and advance health through data-driven research
- Reach more people in more ways through enhanced dissemination and engagement
- Build a workforce for data-driven research and health
National Network of Libraries of Medicine (NNLM)

7100+ organizational members
NNLM All of Us Community Engagement Network

MidContinental Region
George Strawley

Greater Midwest Region
Darlene Kaskie

Middle Atlantic Region
Veronica Leigh Milliner

Southeastern/Atlantic Region
April Wright

New England Region
Catherine Martin

Pacific Northwest Region
Michele Spatz

Pacific Southwest Region
Kelli Ham

South Central Region
Rachel Tims

Contact your Engagement Coordinator at LIB-nnlmallofus@uiowa.edu
NNLM All of Us Training and Education Center

AoU Learning Platform

U.S. National Library of Medicine
National Network of Libraries of Medicine
Community Engagement through NNLM + *All of Us*

**Education Topics**
- All of Us Training
- Digital Literacy
- Evaluating Health Information
- Genetics
- Health Literacy
- Health Numeracy
- Researcher Ethics
- Return of Genomic Results

**Engagement Activities**
- Book Mobiles/Book Bikes
- Citizen Science Projects
- Community Conversations
- Health/Science Fairs
- Health and Wellness
- Programming
- Online Games
- Summer Reading
NNLM + *All of Us*: Community Engagement Examples

**TRAINING**
opportunities and consultations

**FUNDING**
for projects to “blanket the nation”

**CONNECTING**
communities via libraries

U.S. National Library of Medicine
National Network of Libraries of Medicine
NNLM + All of Us: Community Engagement Examples

TRAINING opportunities and consultations
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NNLM + *All of Us*: Community Engagement Examples

**TRAINING**
opportunities and consultations

**FUNDING**
for projects to “blanket the nation”

**CONNECTING**
communities via libraries
NNLM All of Us Partnership Leadership Team

**Amanda J. Wilson**
Head, National Network Coordinating Office
National Library of Medicine
amanda.wilson@nih.gov

**Jennifer R. Jones**
Executive Director, NLM Training and Education Center for the All of Us Research Program
NNLM Middle Atlantic Region
jrq25@pitt.edu

**Brittney Thomas**
Manager, NNLM All of Us Community Engagement Center
NNLM Greater Midwest Region
brittney-thomas@uiowa.edu