The *All of Us* Research Program Overview and Tribal Engagement

June 6, 2023

Welcome and Introduction

Dr. Karriem Watson

Chief Engagement Officer, *All of Us*

Agenda

- Program Overview (~50 min)
    - About the *All of Us* Research Program
    - Tribal Engagement in All of Us
- Questions and Discussion (~50 min)

Informational Presentation and Discussion Schedule

Session 1: *All of Us* Research Program Overview and Tribal Engagement
Tuesday, June 6, 2023, 1:00 - 3:00 pm ET

Session 2: How Researchers Access and Use *All of Us* Data
Tuesday, June 13, 2023, 1:00 - 3:00 pm ET

Session 3: Describing Self-Identified AI/AN Participants in *All of Us* Data
Tuesday, June 20, 2023, 1:00 - 3:00 pm ET

Session 4: Data and Partnerships in *All of Us*
Tuesday, June 27, 2023, 1:00 - 3:00 pm ET

***All of Us* Tribal Consultation**
Thursday, September 28, 2023, 1:00 - 3:00 pm ET

Logistics

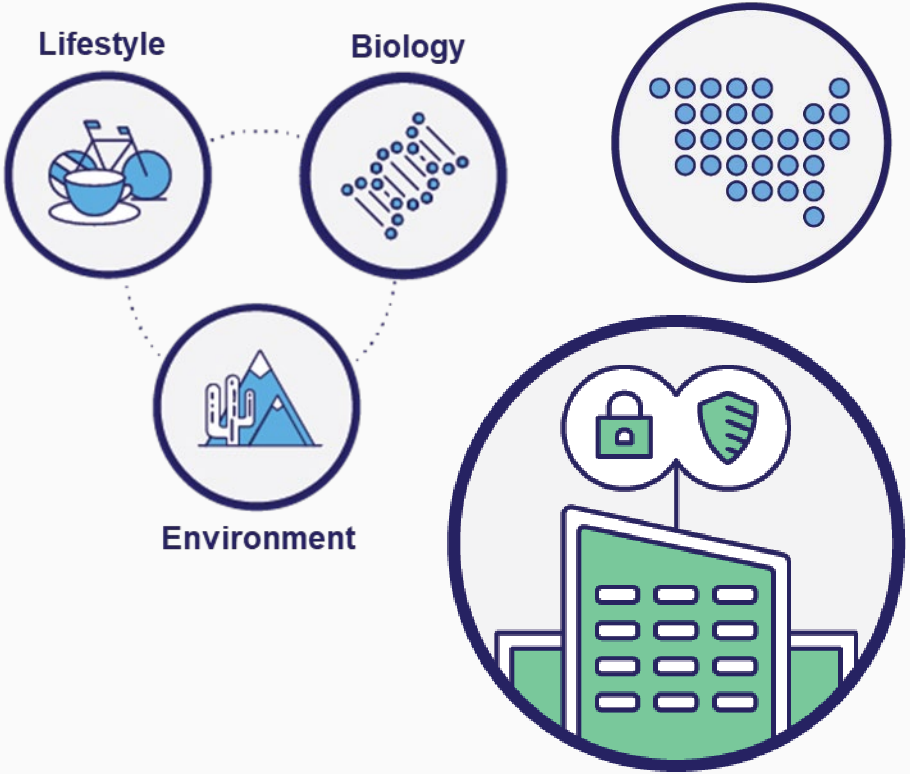
- Links and resources will be posted in the chat
- Please pose questions in the chat
- Please keep yourself on mute - at the end of the program, we’ll address questions in the chat and open up for live questions
- The Questions and Discussion section will be recorded for our notes but not posted online
- Slides and a recording will be posted online afterwards
- Contact the Tribal Engagement team at AOUTribal@nih.gov

What is the *All of Us* Research Program?

What is precision medicine?

Precision medicine is an emerging approach for personalized health care that takes into account individual variability in lifestyle, socioeconomics, 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 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**.

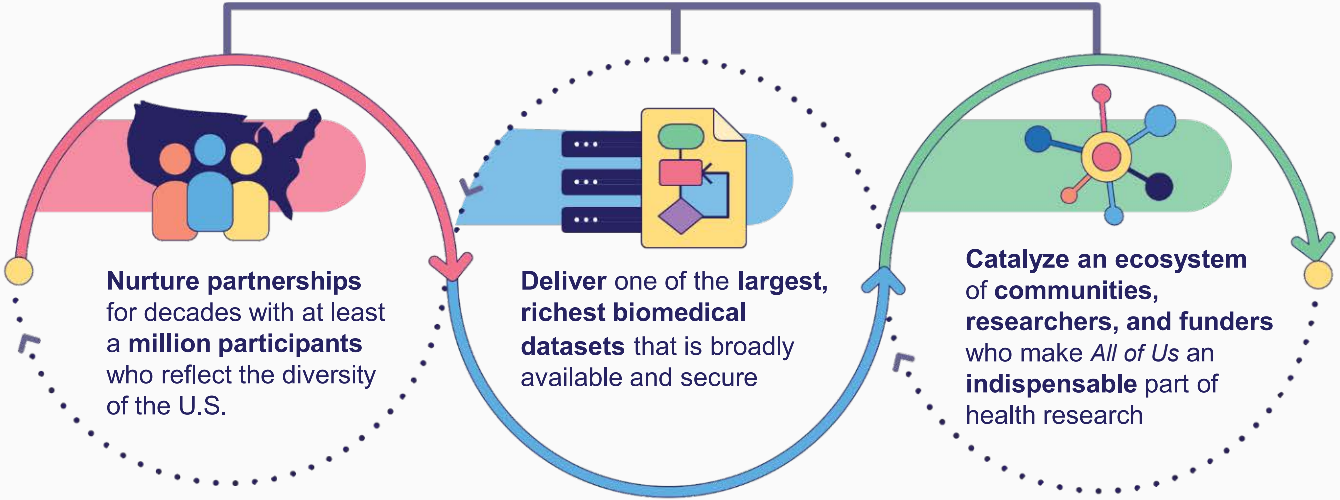
The *All of Us* Research Program is part of the broader Precision Medicine Initiative.

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

Francis Collins, M.D., Ph.D.
Former NIH Director. Science Advisor to the President and Co-Chair of the President's Council of Advisors on Science and Technology (PCAST)

Key Parts of All of Us

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

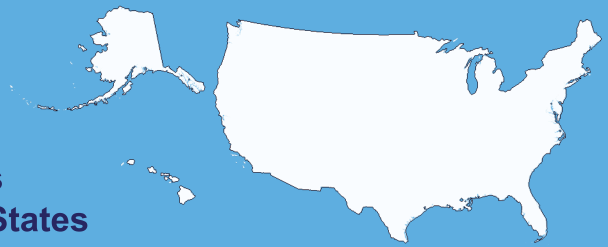
Catalyze an ecosystem of **communities, researchers, and funders** who make *All of Us* an **indispensable** part of health research

Made possible by a team that maintains a culture built around the program's core values

One of the world’s largest, most diverse biomedical datasets of its kind

Inviting at least

1 Million people from across the United States



Data available from **446K+** participants

75% are from communities underrepresented in biomedical research

45% are from racial and ethnic minority groups

Data as of April 2023

Enabling research discoveries that drive more precise approaches to care

Engages **people & communities who have been left out of medical research** in the past

Combines **biological factors and social determinants** on a large, inclusive scale

Easily accessible to any researcher with a secure internet connection and data use agreement

Follows participants as they move, age, and grow

Creating a Standard Way the Program Operates Across the U.S.

Enroll, Consent and Authorize EHR

Recruiting 18+ years old initially; plan to include children in future

Online, interactive consent

Includes authorization to share EHR data

Answer Surveys

- The Basics
- Overall Health
- Lifestyle
- Health Care Access & Utilization
- Personal and Family Medical History
- Social Determinants of Health

Additional surveys will be released on an ongoing basis

Provide Physical Measurements

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

Based on diverse sampling and capacity

Provide Biosamples

Blood (or saliva)

Urine specimen

Biosamples will be stored at the program's biobank

Based on diverse sampling and capacity

Share data from Wearables/Digital Apps

Share data from wearable fitness devices, starting with Fitbit

Fitbit data may include physical activity, step counts, heart rate, and sleep data

Securely collecting a range of different data types

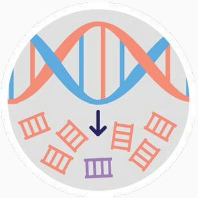
The *All of Us* Research Program's Data and Research Center (DRC) curates a range of different data types as part of the data collection process.

413,350+
Survey Responses

337,500+
Physical Measurements

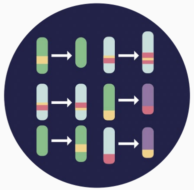
312,900+
Genotyping Arrays

372,000+
Electronic Health Records



245,350+
Whole Genome Sequences (WGS)

15,600+
Fitbit Records
NEW! Sleep Data



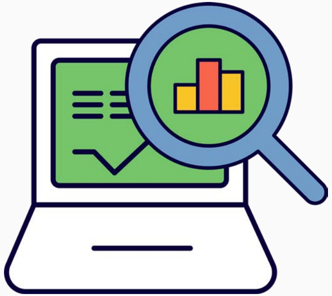
11,350+
Structural Variants
NEW! In 2023

1,000+
Long-Read Sequences
NEW! In 2023

Data as of April 2023

As well as other surveys spanning a variety of topics

1. The Basics
2. Overall Health
3. Lifestyle
4. Health Care Access & Utilization
5. Personal Health History and Family Medical History (Revised)
6. Social Determinants of Health (SDOH)
7. COVID-19 Participant Experience (COPE)
8. COVID-19 Vaccines Minute Surveys



Visit the [Survey Explorer](#) on [ResearchAllofUs.org](#) for more information on survey data

Along with the Social Determinants of Health Survey

By connecting biological and social determinants of health data on a large, inclusive scale and following participants as they move, age, and grow, the *All of Us* dataset is driving new insights into health and disease.

Social Determinants of Health (SDOH) Survey data

from 117,750+ responses

Data as of April 2023

And this is just the beginning

In the coming years, *All of Us* expects to continue adding new data to the dataset, including:

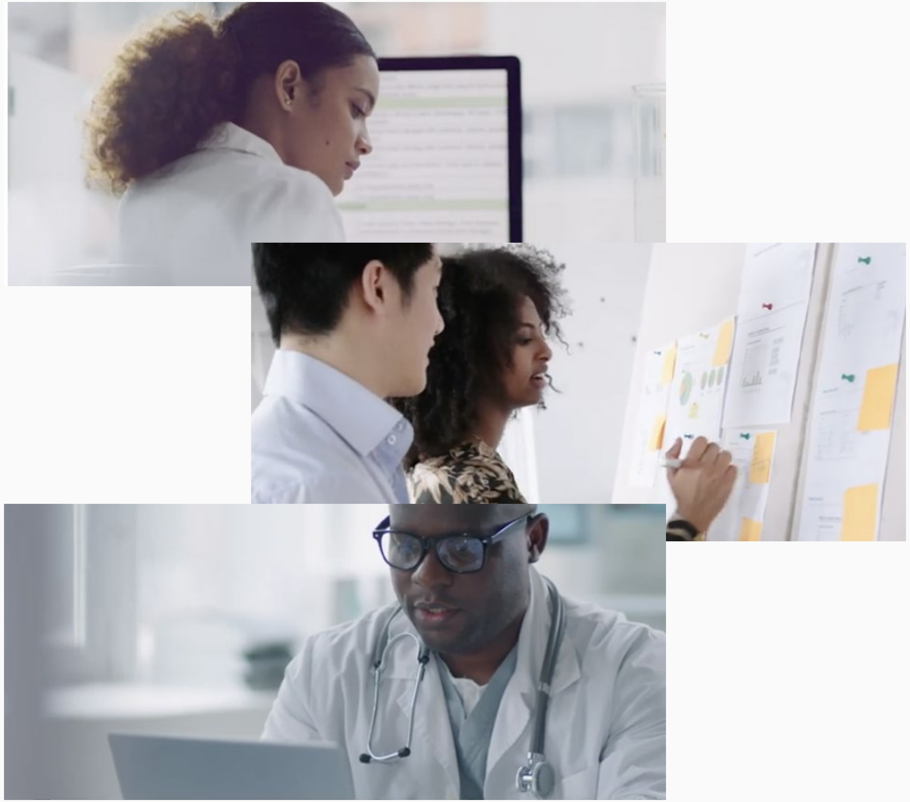
More Wearables Data

More Surveys

New Linkages to External Data Sources

Ancillary Study Data

Building a diverse researcher cohort



- **Encouraging students and early-stage investigators** to bring fresh, creative perspectives & innovative research outcomes.

- **Ensuring access for researchers from various institutions/organizations** to establish a truly equitable resource for all.

- **Supporting a researcher cohort** that promotes responsible and ethical use of data, returns value to participant communities, and accelerates research impact.

And making the data accessible to researchers across stages and settings

Our Researchers

5,520+

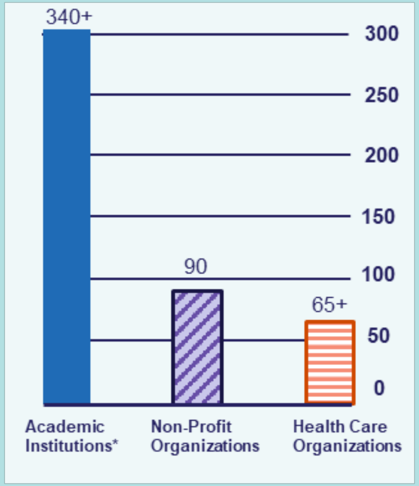
Registered Researchers

across a range of institutional roles and career stages

523+

Institutions

Researchers nationwide are using the Researcher Workbench



*Includes 80+ Historically Black Colleges and Universities and Hispanic-Serving Institutions.

Research Currently Underway

4,990+

Active projects

160

Publications in peer-reviewed journals

Top conditions being studied

In the Researcher Workbench include:

- Cardiovascular disease
- Hypertension
- Mental Health
- Cancer
- Diabetes

Figures accurate as of May 2023

Status of the *All of Us* Research Program (as of May 18, 2023)

Participant Enrollment

638,000+
Participants

372,000+
Electronic Health Records

446,000+
Participants who have completed initial steps of the program

462,000+
Biosamples

Research on the Researcher Workbench

5,520+
Registered Researchers

4,990+
Active Projects

160+
Publications using *All of Us* data

523+
Organizations

Why do we even need the All of Us Research Program?

Participants/Patients

- Patients may not be served well by treatments designed for the “average” patient. We hope in the future that *All of Us* will help advance precision medicine.
- Many people and populations have been left out of biomedical research, and thus, often left out of health care solutions.
- Health problems can take years to unravel and require much trial-and-error.
- Patients may not have access to, or make use of, their own health data.

Health Care Providers

- Precision medicine research is still in the early days, so providers do not have enough information available to provide precision care for many conditions.
- Developing individualized approaches to care often requires time.
- It can be difficult to coordinate care between many different providers, especially with medical records and key data scattered in different silos.

Biomedical Researchers

- Researchers spend a lot of time and resources creating new IT systems, databases, and analytic tools.
- They also face enormous costs and time just to recruit participants.
- Data collection is often not standardized, and data can be siloed and difficult to integrate.
- A single lab’s resources may not be sufficient to answer the research questions that matter.

To help answer many different kinds of questions that can improve health for *All of Us*

How may we prevent the chronic pain that affects more than 100 million people across the U.S. each year?

Or develop pain medicine that potentially may not be addictive?

Or may develop better treatments for diabetes, which affects almost 10% of Americans–or may potentially prevent diabetes altogether?

Or may slow or potentially stop different kinds of dementia?

Or may help researchers develop more cancer cures that will work the first time, so we may skip painful trial-and-error chemotherapy?

Or may drive sustainable interventions that may support health equity?

Tribal Engagement

All of Us Research Program Core Values

Participation is **open** to all.

Participants have **access** to their information.

Participants reflect the rich **diversity** of the U.S.

Data will be accessed **broadly** for research purposes.

Participants are **partners**.

Security and privacy will be of highest importance.

Trust will be earned through **transparency**.

The program will be a catalyst for **positive change** in research.

Responsible Engagement with Tribes & Indigenous Communities

Tribal Sovereignty

Cultural Sensitivity and Awareness

Policies, Training, and Support

Data Protection

Research Transparency

Return of Value

Brief Milestones of *All of Us* Consultation & Tribal Engagement

2017

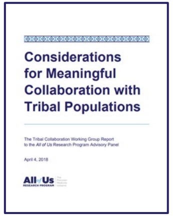
Dec 2017

All of Us Research Program Advisory Panel establishes Tribal Collaboration Working Group (TCWG)

2018

Aug 2018

TCWG releases "Considerations for Meaningful Collaboration with Tribal Populations" report



Considerations for Meaningful Collaboration with Tribal Populations

The Tribal Collaboration Working Group Report
to the *All of Us* Research Program Advisory Panel

April 4, 2018

All of Us RESEARCH PROGRAM

2019

May - Nov 2019

All of Us hosts listening sessions and Tribal Consultation meetings across the country

2020

May 2020

Rapid-response Tribal Consultation convened to discuss the COVID-19 serology study

2021

March 2021

All of Us releases Tribal Consultation Final Report

All of Us Research Program Tribal Consultation Final Report

March 2021

All of Us Commitments to Tribal Nations

In This Report

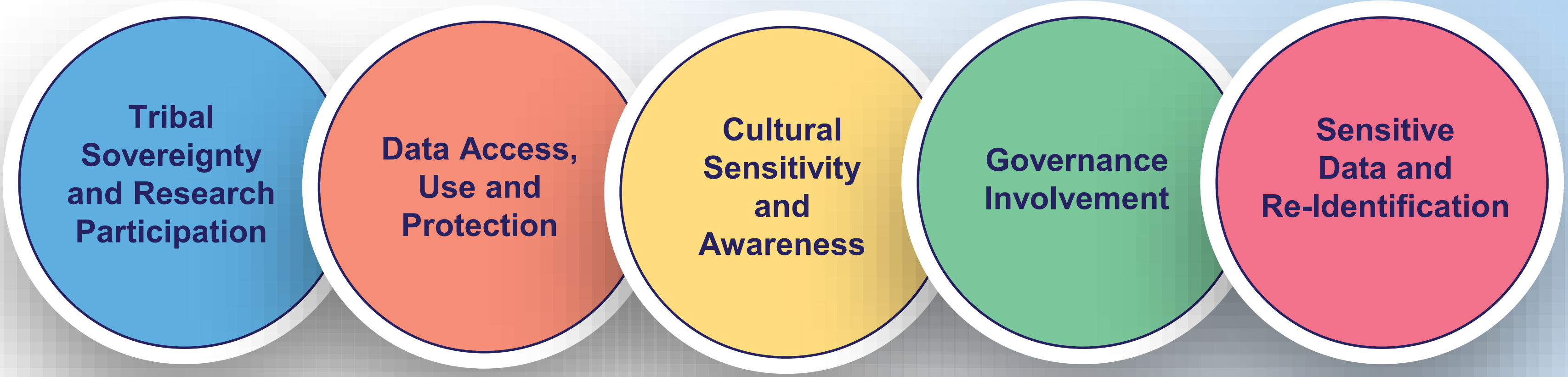
- *All of Us* Commitments to Tribal Nations
- Executive Summary
- Introduction
- *All of Us* Tribal Consultation Background
- Tribal Consultation Themes
- Tribal Sovereignty and Research Participation
- Cultural Sensitivity and Awareness
- Data Access, Use, and Protection
- Governance Involvement
- Sensitive Data and Preventing Re-Identification
- Additional Considerations
- Recommendations for Further Consultation and Informational Sessions about *All of Us*
- Acknowledgements

2022

May 2022

Research Opportunity Announcement released by *All of Us* with an area of interest specific to engaging with Tribal Nations and Urban AI/AN Populations

Themes from *All of Us* Research Program Consultation with Tribal Nations



Tribal Sovereignty and Research Participation

Data Access, Use and Protection

Cultural Sensitivity and Awareness

Governance Involvement

Sensitive Data and Re-Identification

https://allofus.nih.gov/tribalengagement

Shaping the Program for Responsible Research with Tribal Nations

Pre-Consent Screens

No Tribal Affiliation

Biospecimen Handling After Withdrawal

Tribal Partnerships

Return of Results

Five Considerations for Research with Tribal Nations and AI/AN Populations

Consultation Is Critical to Engagement

Consultation Alone Is Not Engagement

Transparency and Trust Are Tied

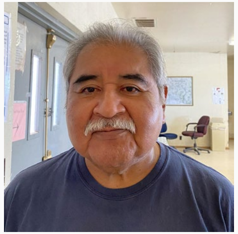
Governance > Promises

Investments Should Match Intentions

Increased AI/AN Representation in *All of Us* Governance

John Molina, M.D., J.D., L.H.D.
(*Pascua Yaqui and Yavapai Apache*)
Advisory Panel

Chester Antone
(*Tohono O'odham Nation*)
Institutional Review Board (IRB)



Miguel Flores Jr.
(*Pascua Yaqui Tribe and Tohono O'odham Nation*)
Steering Committee; Biospecimen Access Policy Task Force

Teshia Solomon, PhD
(Choctaw Nation)
Science Committee;
Ethical, Legal, and Social Implications (ELSI) Brain Trust;
Biospecimen Access Policy Task Force

Christina C. Bell Andrews, J.D., M.P.H., M.B.A, M.A.
(*Tohono O'odham Nation*)
Participant Ambassador

Investing in Tribal Partners and Capacity

- Research Opportunity Announcement (ROA): NIH *All of Us* Engagement, Communications, and Enrollment Partnerships (SAM.gov)
- Continue to build relationships with tribal leadership and intertribal organizations
- Seeking to collaborate with Urban Indian Health Centers and Tribal Epidemiology Centers
- Engaging AI/AN Researchers and Institutions
- June 8, 2023: ROA Pre-Submission Webinar (Registration Link)

2022

May 2022

Research Opportunity Announcement released by *All of Us* with an area of interest specific to engaging with Tribal Nations and Urban AI/AN Populations

2023 Information Session & Consultation Timeline

May

- 5/3: Announced listening sessions to Tribal leaders (30 day notice)

June

- Hold 4 listening sessions & make recordings available

September

- Hold virtual Tribal Consultation
- 30-day period for written comments opens

October

- 10/30: Period for written comments closes

November

- Draft consultation report

December

- Finalize report & post on website

Informational Presentation and Discussion Schedule

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Community Voices Informing the Next Steps of the Program

Tribal Sovereignty

Cultural Sensitivity and Awareness

Policies, Training, and Support

Data Protection

Research Transparency

Return of Value

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Questions and Discussion

Vicky Murray
Tribal Engagement Specialist
Dr. Karriem Watson
Chief Engagement Officer, All of Us

Thank You!

All of Us RESEARCH PROGRAM

NIH National Institutes of Health

AllofUs.nih.gov/TribalEngagement

AllofUs.nih.gov

@AllofUsResearch
#JoinAllofUs