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?
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

Follows participants as they move, age, and grow

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

- **Survey Responses**: 413,350+
- **Physical Measurements**: 337,500+
- **Genotyping Arrays**: 312,900+
- **Electronic Health Records**: 372,000+
- **Whole Genome Sequences (WGS)**: 245,350+
- **Fitbit Records**: 15,600+
- **Structural Variants**: 11,350+
- **Whole Genome Sequences (WGS)**: 1,000+

*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**

- Neighborhood Safety
- Neighborhood Environment
- Social Support
- Discrimination
- Loneliness
- Health Care Discrimination
- Housing
- Food Security
- Stress
- Spiritual Experiences
- Religious Attendance
- English Proficiency

*from 117,750+ responses*
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
523+ Institutions

Researchers nationwide are using the Researcher Workbench

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

**Or may slow or potentially stop different kinds of dementia?**

**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 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.
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

**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

**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

**Miguel Flores Jr.**
*(Pascua Yaqui Tribe and Tohono O’odham Nation)*
Steering Committee;
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

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

**Teshia Solomon,** PhD
*(Choctaw Nation)*
Science Committee;
Ethical, Legal, and Social Implications (ELSI) Brain Trust;
Biospecimen Access Policy Task Force
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)
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
- Hold virtual Tribal Consultation
- 30-day period for written comments opens

September
- 10/30: Period for written comments closes

October
- Draft consultation report

November
- Finalize report & post on website

December
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Community Voices Informing the Next Steps of the Program

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- Cultural Sensitivity and Awareness
- Policies, Training, and Support
- Data Protection
- Research Transparency
- Return of Value
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Thank You!

AllofUs.nih.gov/TribalEngagement

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@AllofUsResearch
#JoinAllofUs