All of Us RESEARCH PROGRAM

Tribal Consultation

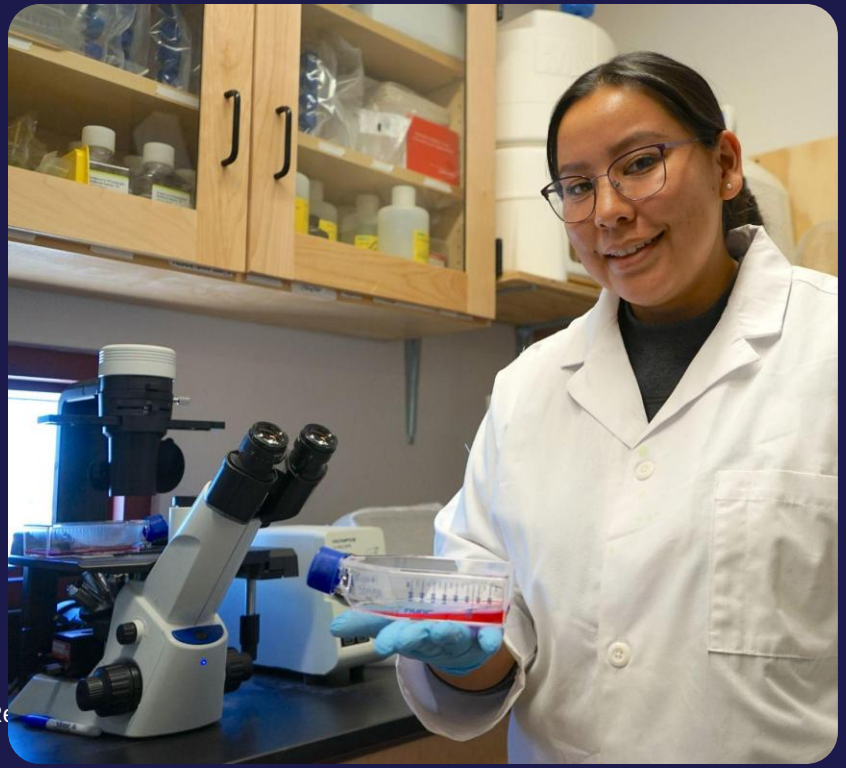
August 17, 2026

Program Speakers

Dr. Minnkyong Lee
Acting Chief Engagement Officer, *All of Us* Research Program

Dr. Jen Adjemian
Senior Advisor for Data Science, *All of Us* Research Program

Dr. Erica Landis
Branch Chief, Innovative Collaborations & Ancillary Studies, *All of Us* Re
Program



"We Are All Scientists"
AISES Campaign

NIH National Institutes of Health

National Institutes of Health (NIH) Speakers



Dr. Karina Walters

NIH Tribal Health Research Office

Director



Dr. Minnkyong Lee

***All of Us* Research Program**

Acting Chief Engagement Officer



Dr. Jennifer Adjemian

***All of Us* Research Program**

Senior Advisor for Data Science



Dr. Erica Landis

***All of Us* Research Program**

Branch Chief, Innovative Collaborations and Ancillary Studies

All of Us Consultation Agenda

- Tribal Consultation Logistics and Purpose
- *All of Us* Research Program Overview
- *All of Us* Controlled Tier Plus
- *All of Us* Partnered Research Studies
- Forum for Tribal leader input

Tribal Consultation Logistics and Purpose

Logistics

- The consultation will be recorded for note-taking but **not** posted online
- Virtual attendance is unavailable
- During discussion, please state your name, title and Tribal Affiliation for the record

Purpose

All of Us is soliciting input to establish robust protections, oversight mechanisms, and collaborative approaches to two new initiatives:

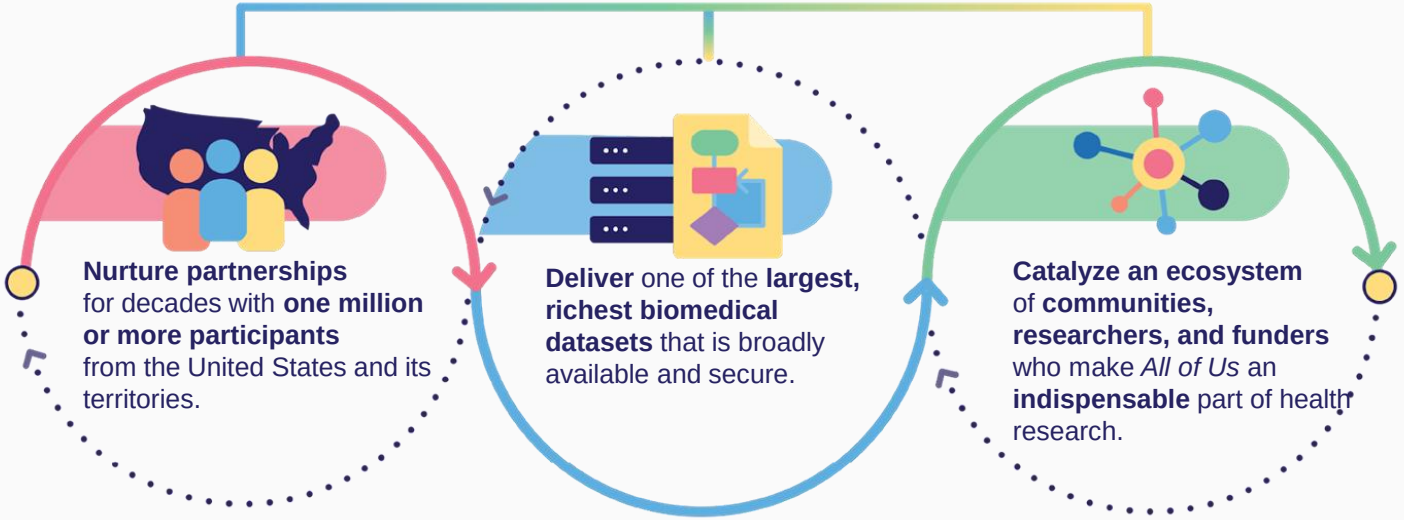
- the inclusion of biospecimens from self-identified AI/AN participants in **Partnered Research Studies** and
- the expansion of the **Controlled Tier Plus** data access model

to rigorously uphold Tribal sovereignty, adhere to ethical standards, and yield meaningful community benefits.

About *All of Us*

Our mission

Accelerate health research, enabling individualized prevention, treatment, and care for all of us.



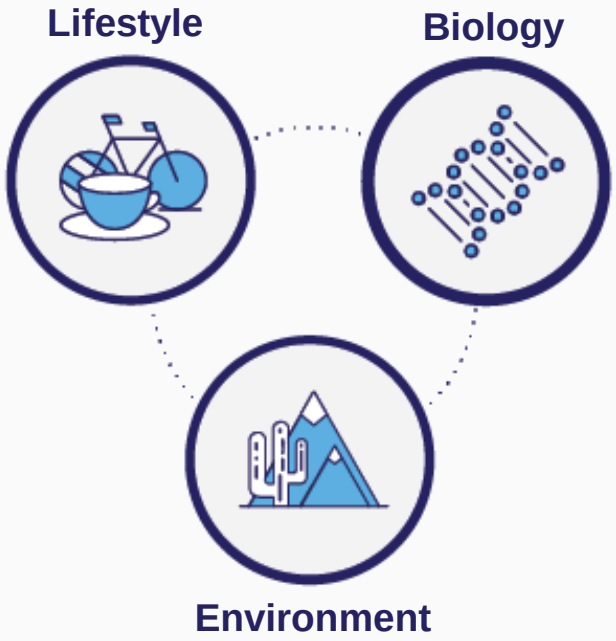
Transforming research and breaking down outdated barriers to discovery at NIH to be a game-changer for precision medicine and deliver real-world impact

What is Precision Medicine?

Precision medicine is an emerging approach for personalized health care. It acknowledges that each person is unique—our genes, our environments, our lifestyles, our behaviors—and that the interaction of these factors greatly impacts our health.

Precision medicine can produce more accurate diagnoses, earlier detection, and better prevention strategies and treatment choices. Precision medicine is a shift from giving everyone the same care to giving the best care possible based on our unique makeup.

To drive discovery and deliver precision medicine, we are building a large, representative dataset for researchers.



Nationwide with Participants from All 50 States

Participant Enrollment

886,000+
Participants

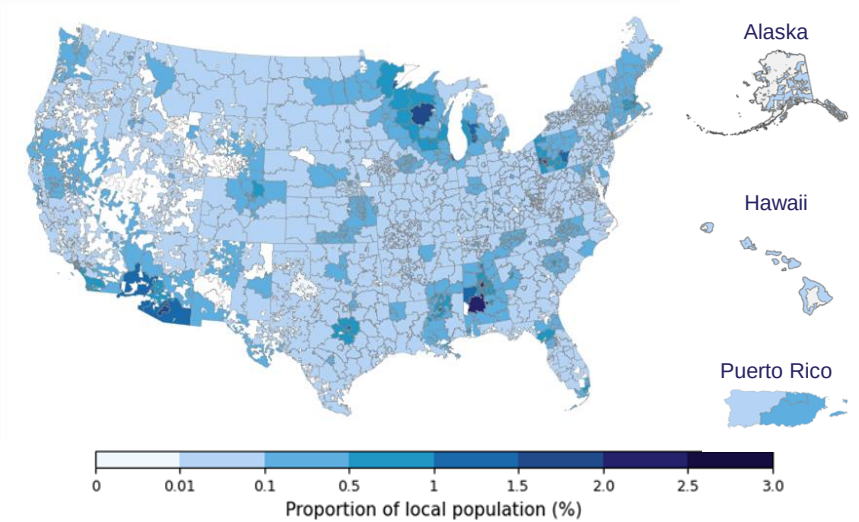
500,000+
Electronic Health Records

598,000+
Participants who have completed initial steps of the program

618,000+
Biosamples

24,000+ Self-Identified AI/AN Biospecimens

Map of Consented Participants



US map of *All of Us* participant density; covers 98.1% of US zip3 codes

Numbers current as of August 9, 2026

How Self-Identified AI/AN Participants Join *All of Us*

Tribal Sovereignty

The program honors Tribal Sovereignty and does not conduct recruitment or enrollment activities within Tribal Jurisdictions.

Enrollment Options

AI/AN individuals living within Tribal Jurisdictions can choose to enroll through enrollment centers outside of Tribal jurisdictions or via the program's online portal.

Tribal Affiliation

The program asks for Tribal Affiliation during enrollment (part of the Basics Survey question, optional) but will never share this information with researchers outside of a Tribal partnership.

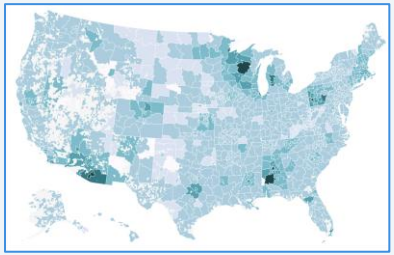
All of Us: From Data to Impact

What Goes in…



Data from **884,000+** Participants from all 50 states including:

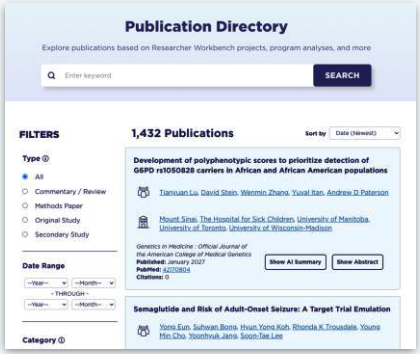
14.7 million Biosample aliquots
598,000+ EHRs
3.4 million Survey Responses



Research is Growing Exponentially…

From **23,830+** Registered Researchers from **1,410+** Organizations

1,420+ Publications (>500 in 2025), now with LLM-based summarization



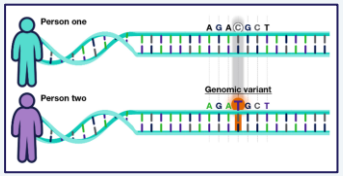
Examples of Health Information Returned to Participants & Translation of Findings into Clinical Care



733,000+ Individual DNA Results Returned to **277,000+** Participants, including:

5,620+ with potentially life-saving genetic variants in 59 genes

158,000+ that could impact how their body processes 50+ medicines



Broad Clinical Labs & Mass General Brigham have developed a **clinical test looking at an individual's risk of 8 cardiovascular conditions** based on *All of Us*

All of Us Research Program, Tribal Engagement and Outreach Team



Naomi Aspaas
(Diné)
Acting Branch Director



Vanessa Castaneda
Engagement Specialist



Vicky Murray
(Bad River Band of Lake Superior Chippewa)
Senior Analyst AI/AN Engagement



Sheila James
Program Officer



Carolina Cerrone
Project Manager



Billy Elliott
(Nottoway)
AI/AN Engagement Specialist

How is the Program Including Indigenous Voices?

All of Us Governance Representation

- *All of Us* Advisory Panel
- *All of Us* Institutional Review Board
- Participant Ambassadors
- Resource Access Board (RAB)

All of Us Working Groups

- *All of Us* Indigenous Research Working Group (IRWG)
- *All of Us* Tribal Collaboration Working Group

NIH Colleagues & Tribal Advisory Committee

- Tribal Health Research Office (THRO)
- Tribal Advisory Committee (TAC)
- Tribal Health Research Coordinating Committee

Research Academy Institutional Champions

Supporting institutions driving engagement and researcher training:

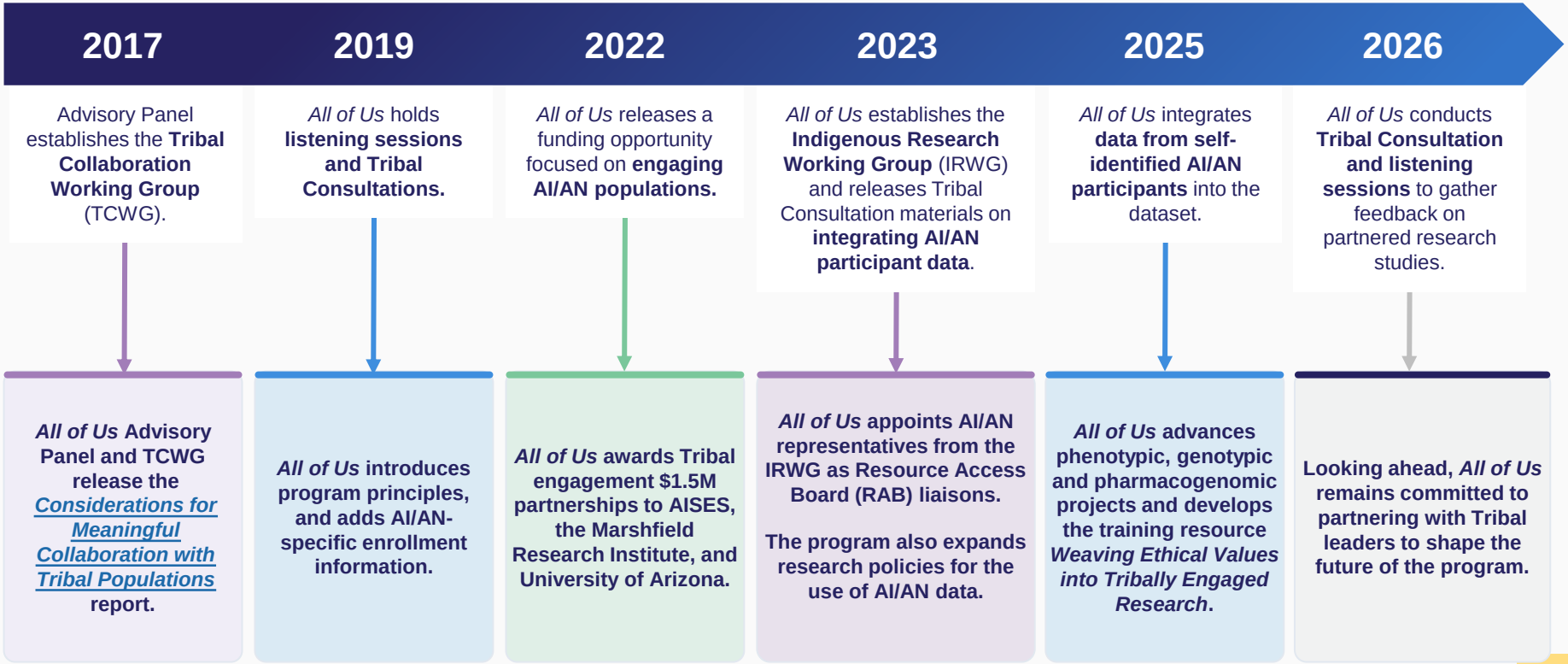
- Diné College
- Lac Courte Oreilles Ojibwe University

Tribal Engagement Award Partners

Collaborate with organizations to develop an Indigenous-focus education and outreach campaign to increase interest and participation in biomedical research:

- Advancing Indigenous Science and Engineering Society
- Marshfield Research Institute

Evolution of Tribal Engagement: From Consultation to Action



Tribal and Researcher Engagement Program Principles

The program is committed to these principles and considers any researcher who will interact with AI/AN data as a partner in this commitment.



Tribal Sovereignty

Researchers will not be able to access participants' Tribal affiliation without an explicit agreement between *All of Us* and the Tribal Nation.



Cultural Practices

The program works with Tribal leaders and communities to help integrate Tribal customs and cultural practices into management and special handling of biospecimens.



Policies & Support

Researchers must agree to a code of conduct, program policies, complete training, and can request that program experts review workspaces to avoid potential stigma or harms.



Data Protection

All of Us removes direct identifiers from data and makes other changes to lower the risk to participant privacy. Researchers are strictly prohibited from re-identifying self-identified AI/AN individuals, Tribal affiliation & the regions from which they come.



Research Transparency

Researchers must provide clear public descriptions of their research in the Researcher Workbench prior to beginning their research. These descriptions inform participants and communities about research underway.



Return of Value

Shared data from participants enables vital health discoveries that improve health for all. New insights that directly benefit Tribal Nations and Tribal communities will continue to emerge as participation in the program grows.

All of Us Data Portfolio & Controlled Tier Plus

Different Levels of Data Access to Enable Discovery

Available to Anyone

PUBLIC TIER

Public resources include:

- **Data Snapshots:** Aggregated, public-facing overviews of participant characteristics and data types
- **Data Browser:** Interactive preview into the *All of Us* dataset through public-facing aggregate data
  - Currently includes participant-provided survey responses, physical measurements, data from EHRs and wearables, and genomic data
- **Survey Explorer:** Details the questions included in each of the surveys
- **Research Projects Directory:** Descriptions of each research project within the Researcher Workbench

Available to Registered Researchers

RESEARCHER WORKBENCH

REGISTERED TIER

Registered researchers can access in-depth data and a variety of research tools to conduct a wide range of studies**.**


Surveys


Electronic Health Records


Physical Measurements



Wearables

Data have been processed to protect participant privacy

CONTROLLED TIER

Registered researchers with amended institutional agreements can access all data in the Registered Tier plus additional and expanded data types, including genomic data, real dates of health events, ICD codes, granular demographic data, and more.


Genomics


Health and Lifestyle surveys

Growth of Data Available in the Researcher Workbench with Latest Data Release

Total participants with data available **increased** from 633K+ to 747K+



>747,000
With survey responses



>600,000
With physical measurements



>553,000
With genotyping arrays



>535,000
With short-read whole genome sequences (WGS)



>481,000
With electronic health records



>96,000*
With structural variant data



>68,000
With Fitbit records



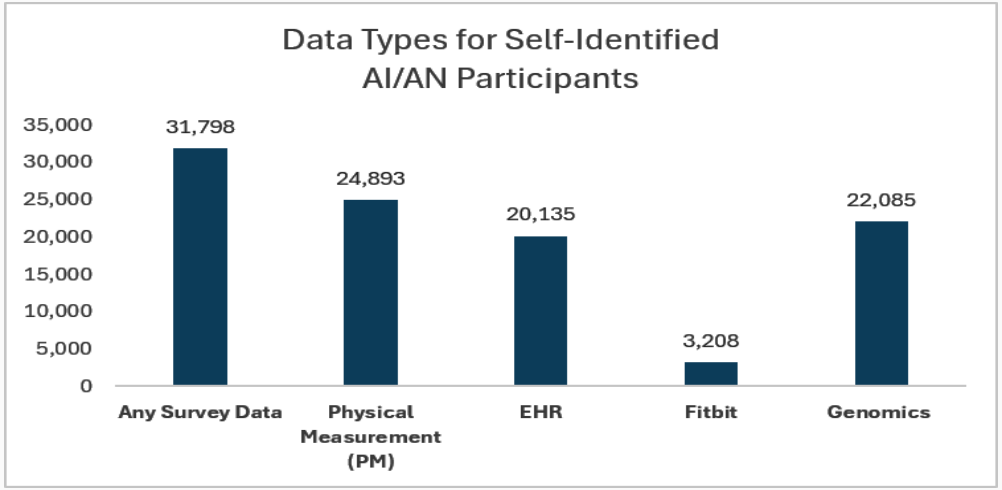
>14,000
With long-read sequences

* Increased counts expected in future upcoming release up to 240K.
Data as of June 2026 Curated Data Repository (CDR) v9 data release.

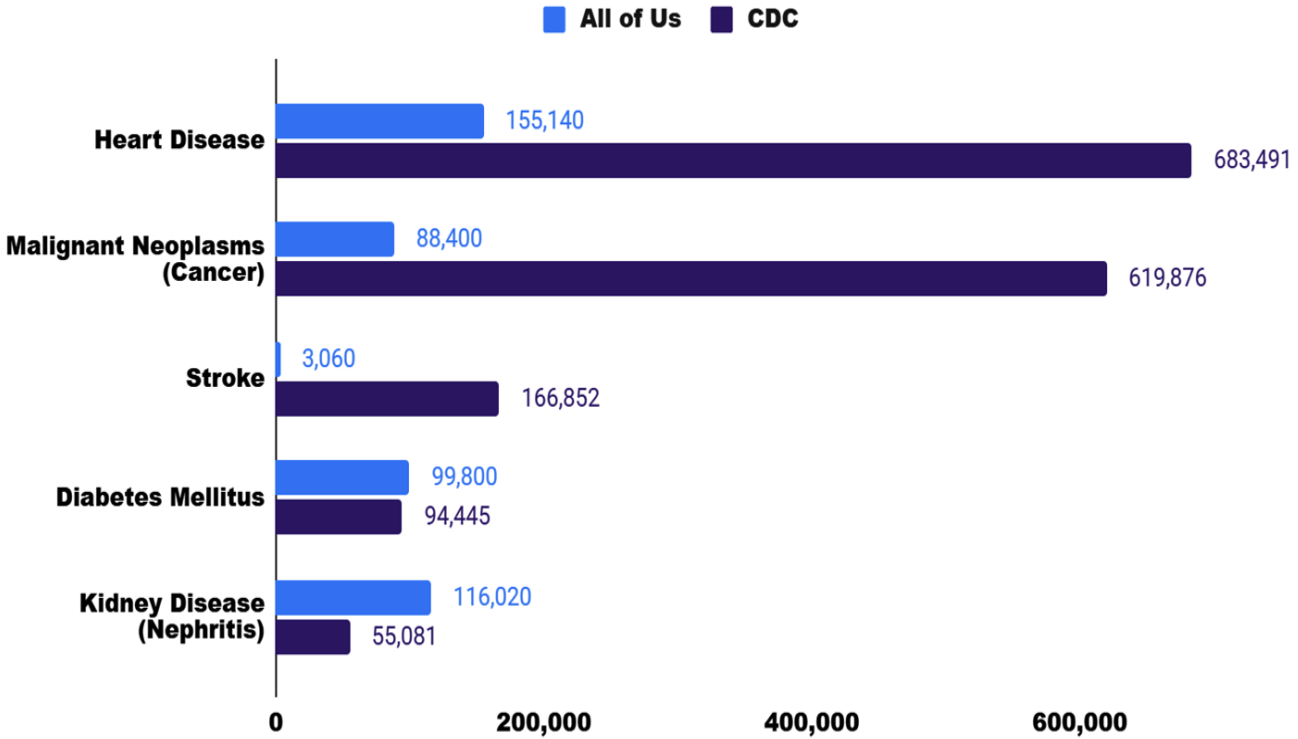
Continued Growth of Self-Identified AI/AN Data Available

- *All of Us* currently has over 31K participants who self-identify as AI/AN for at least one demographic selection and over 7K as AI/AN only

- Includes over 31K with survey data, 24K physical measurements, 22K with genomics, 20K with electronic health records (EHR), and 3K with FitBit data available
    - Over 17K have four or more of these data types available



CDC Top Causes of Mortality and *All of Us* Phenotype Counts (CDR v9)

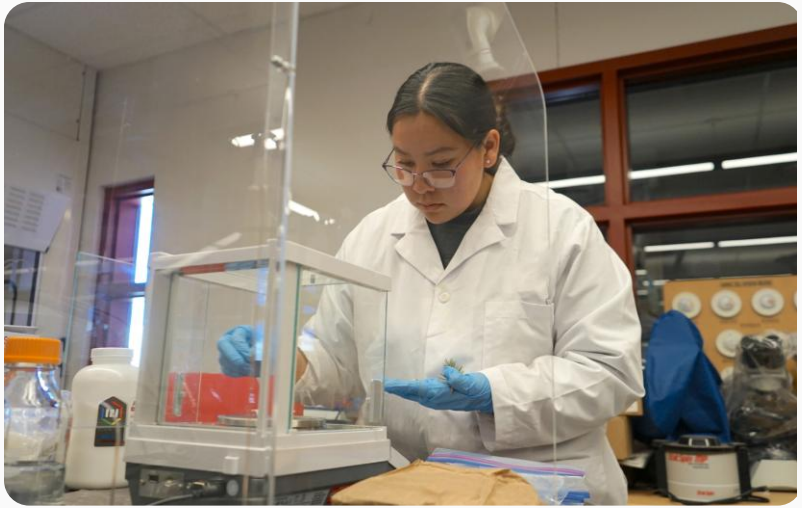


Key Insight

The *All of Us* cohort enables research that aligns with the top causes of mortality in the United States according to CDC data reports.

Source: CDC Data Brief, Mortality in the United States, 2024 (https://www.cdc.gov/nchs/products/databriefs/db548.htm#fig4) and All of Us Researcher Workbench, CDR v9

Indigenous-led Research Projects for In-Depth First Look at AI/AN Data



"*We Are All Scientists*"
AISES Campaign

Phenotypic/Survey Project

To analyze and compare non-genomic data to findings from the NHLBI Strong Heart Study.

Genotypic Project

To compare genomic data to reference populations and associations with elevated disease risk and prevalence factors.

Pharmacogenomics Project

To evaluate pharmacogenomic data availability to support future gene-drug analyses, while highlighting limitations that must inform study design.

Goal: To address any concerns identified and publish findings, along with a manuscript describing the program's Tribal engagement and outreach efforts

Data Access Tiers Available in “Passport Model”



Public Tier

Available to anyone

Visit DataBrowser.ResearchAllofUs.org to explore:

- **Aggregated overviews** (participant identifiers removed)
- **Interactive data previews** (participant identifiers removed)

Registration is not required.

Researcher Workbench

Available to registered researchers



Registered Tier

Includes individual-level data from:

- **Electronic health records (EHR)**
- **Wearables**
- **Surveys**
- **Physical measurements**

Registration + Responsible Conduct of Research training required for access.



Controlled Tier

Includes data available on the Registered Tier, as well as:

- **Genomic data** (short-read whole genome sequences (WGS), long-read WGS, genotyping arrays, and structural variant data)
- **Expanded demographic, survey, and EHR data**

Registration + Responsible Conduct of Research training + additional training required for access.

Counts between all three data tiers and Data Snapshots may vary because of the lag time associated with the data curation process.

Need for New Tier to Support Future Research Opportunities

- Researchers can access available data with the passport model.
- There is **scientific value** in releasing different types of data that could increase re-identification risk and are therefore not well-suited for the passport model, such as:
  - More granular geospatial data to determine environmental risk factors.
  - Familial linkage data to understand genetic risks for disease.
  - Evaluation of sensitive imaging data to better characterize disease phenotypes.
- A **new access pathway and research tier** will support this research while introducing additional important protections, such as project-specific IRB review and increased program oversight.

Summary of the New Research Data Tier: Controlled Tier Plus (CT+)

CT+ will enable secure access to additional and more sensitive research data while ensuring that participant privacy is highly protected

Secure Access to Data

CT+ will provide secure access to additional, more sensitive data, with the initial version including:

- Expanded electronic health record concepts
- 5-digit Zip Code (adjusted for small populations)
- Date of Birth
- Initial Pediatric Cohort

Review Boards & Technical Controls

- IRB and Resource Access Board (RAB) review of each project proposals
  - RAB includes members of the Indigenous Research Working Group
- Restricted CT+ access (not permitted to use other research tiers while in CT+)
- Protections in place to reduce re-identification risk such as unique research IDs and controls restricting ability to upload or download data

- **Tribal affiliation never shared and no recruitment or engagement** allowed on Tribal lands
- **AI/AN data will remain the same** as is currently available in the existing Controlled Tier for the initial version of CT+ while *All of Us* seeks Tribal leader input through this consultation

Stronger Protections through IRB Review for CT+

- IRB review for CT+ is a *program requirement* to offset the increased re-identification risk and better protect program participants.
  - Although federal regulation does not require IRB review for the types of data currently planned for CT+, *All of Us* is requiring this step to protect our participants.

- CT+ Data Framework unlikely to meet regulatory definition of “human subjects” (no direct identifiers), but **there is increased risk of re-identification**.
  - Requiring IRB review holds researchers to higher standards for research ethics and ensures that risks are appropriately considered and mitigated where possible.

CT+ Initial Data Plans

CT+ Data Plan: The Controlled Tier (CT) dataset serves as the researcher's base data layer which will be augmented with specific data elements according to their project plan as approved by the IRB and RAB.

- **Note:** *Self-identified AI/AN participant data **will remain as-is** in the CT level that is currently available; additional data will not be available for AI/AN participants until additional requirements are developed in partnership with Tribal leaders.*

Expanded EHR Concept Data (Requested by Project)	Linked Sets (Requested by Project)
• Assault/Homicide • Diagnosis codes subject to public knowledge • Drowning • Emergent Disease Codes • Family Dynamics (Billing codes about family dynamics such as family social history, family disruption; not pediatric linkage data) • Motor Vehicle Accidents • Legal Intervention • Military Operations / Operations of War • Multiparity / Multiples • Non-Motor Vehicle Accidents • Prolonged stay in weightlessness • Suffocation • Suicide • Terrorism • Unemployment	• Pediatrics • Zip5 • Date of Birth and Indicators of Birth (will NOT be provisioned jointly with geolocation data less granular than zip3)

Integrating AI/AN Feedback & Expertise into CT+ Planning & Development

- Incorporating AI/AN Data Science subject matter experts (SMEs) into CT+ planning process to think through unique needs for Tribal communities.
- Interested in understanding potential scientific value for AI/AN communities and options to support using additional data in CT+ given additional protections with project-specific review and approval.
- Seeking input and feedback on the CT+ plan and future AI/AN research options, including what types of data would best serve Tribal communities.

Controlled Tier Plus Questions for Tribal Leaders

1. Considering the sensitivity of the new data types in CT+, what protections should *All of Us* implement to ensure Tribal Nations will benefit from the research conducted using CT+ data, while mitigating potential harm?

1. For researchers applying to access CT+ data from self-identified AI/AN participants, what safeguards are necessary to ensure the data are being used ethically and responsibly?

1. Sensitive participant data stemming from a Tribal partnership could be separately and securely stored within CT+. What can we do to honor Tribal data sovereignty for data emerging from Tribal partnerships that are held and managed by *All of Us*? Are there additional protections needed specifically for these data?

Note: These questions will be displayed again during the discussion.

Accelerating Discovery Through Partnered Research Studies with *All of Us* to Analyze Participant Samples

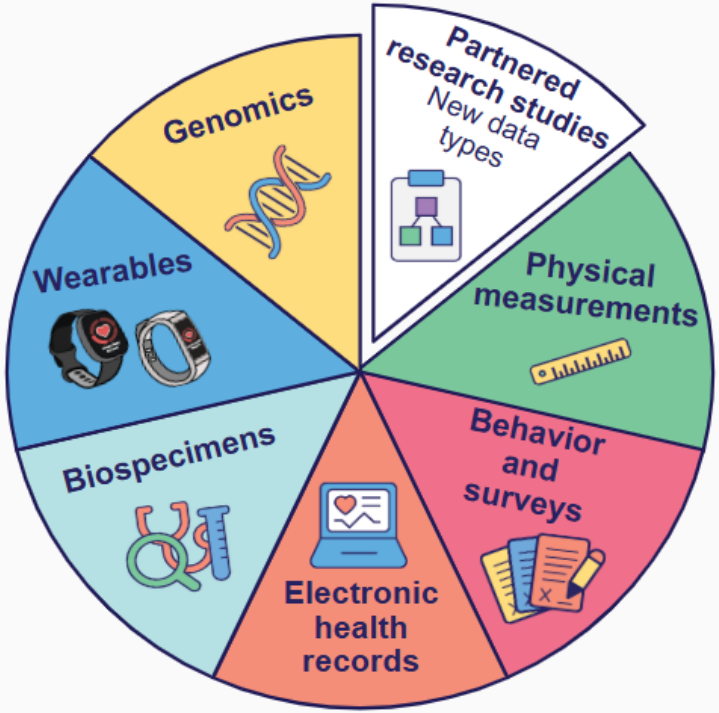
Today's Agenda

1. Introduce Partnered Research Studies (PRS)
2. Provide examples of PRS
3. Discuss program's first external PRS
4. Gather feedback

What is a Partnered Research Study?

All of Us partnered research studies (PRSs) are collaborative research projects funded by a study sponsor that add new data to the Researcher Workbench.

- **Offer engagement opportunities** for our participants
- **Address important scientific questions** and deliver insights into health and disease
- **Expand the *All of Us* dataset** by adding new data and/or engaging unique participant communities
- **Enable research across boundaries** with novel analyses of lifestyle, environmental, and biologic data



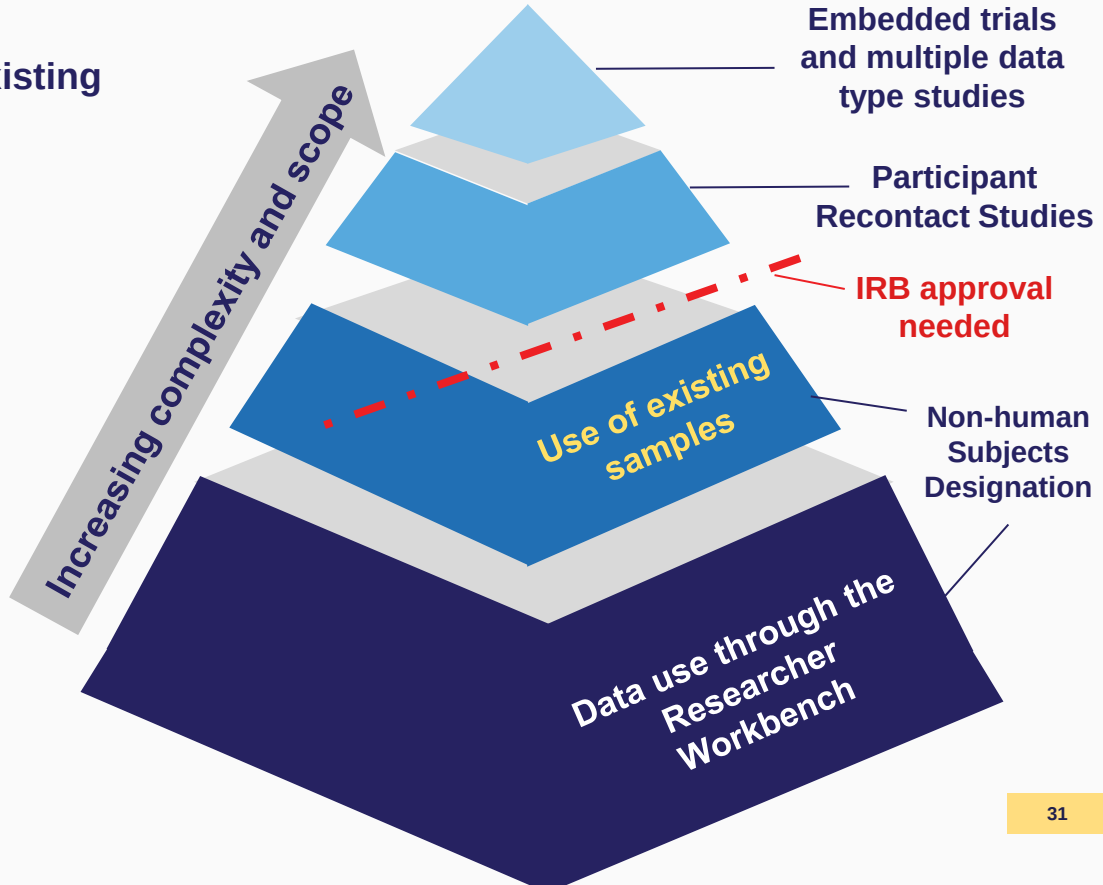
***All of Us* is now opening PRS opportunities to partners outside of the NIH.**

Partnered Research Studies: Then, Now and in the Future

Partnered research studies build on the existing data in the Researcher Workbench

All of Us supports many partnered research study designs and methodologies including:

- New assays of previously collected samples
- Surveys
- Digital health technology and wearable data collection methods
- Multi-data type, trial-like studies which test interventions and collect multiple new data types



Timeline of PRS Governance, Oversight, and Accountability

2020 2021 2022 2023 2024 2025 2026

Building infrastructure, governance boards, and transparent review criteria to allow researchers to submit proposals

Launching research studies in partnership with NIH institutes, centers, and offices.

Opening to external investigators



First *All of Us* Participant Listening Session



Participant and Community Advisors



Biospecimen Access Board



Participant Contact for Ancillary Studies Board



Partnered Research Advisory Board

Launched call for applications for biospecimen access

joinallofus.org/learn-more-prs

Building Together: How Partnered Research Studies Begin

PHASE 1

Proposal and Review

Study ideas are developed with partners and reviewed for scientific merit, program alignment, and values.

PHASE 2

Planning

Resources and study needs are identified. The protocol and timeline are developed, and approvals are initiated.

PHASE 3

Launch

Study plans, including participant communication, governance, and evaluation, are finalized.

All Registered Researchers

Standard Requirements for Researcher Workbench Access and Data Dissemination

- **Data User Code of Conduct (DUCC):** Mandatory alignment with core values, compliance with laws and regulations, and respect for participant privacy.
- **Responsible Conduct of Research:** Yearly mandatory training.
- **Research Workspace Description:** Public and searchable project summaries.
- **Resource Access Board (RAB):** Continuous monitoring and oversight of Workspace Descriptions.
- **Strict Policy Enforcement:** Ethical and non-stigmatizing research policies for respectful and responsible use of *All of Us* research resources. Data dissemination policies for publishing and presentation of results.
- **Guidance for using AI/AN data**: Educational materials to avoid stigmatizing and unethical research using AI/AN data.

Partnered Research Studies

Standard Requirements + Advanced Requirements for Partnered Research Study Sponsors and Teams

- **IRB Approval:** May require Institutional Review Board authorization prior to study launch.
- **Research Compliance:** Continuous evaluation of study activities by *All of Us* regulatory body.
- **Partnered Research Access Board:** Rigorous evaluation to ensure responsible stewardship of participants' trust and time.
- **Community and Participant Advisors for Ancillary Studies:** Advisory panel to ensure ethical and respectful partnered research that is relevant and responsive to the needs of *All of Us* participants.
- **Stringent Policy Framework:** Compliance guidelines for human biological sample handling and guidance framework for ethical access to participants.
- **Biospecimen Code of Conduct:** Specialized ethical framework for sample utilization.

Timeline of Partnered Research Studies

2020 2021 2022 2023 2024 2025 2026

Building and testing systems to launch new studies, communicate with participants, and steward samples.

Launching research studies in partnership with NIH institutes, centers, and offices.

Opening to external investigators



COVID-19 Serology Study



Nutrition for Precision Health Study



Exploring the Mind Study



Environmental Health & Exposomics Study



Eyes on Health Study

Four more studies will launch in 2026

joinallofus.org/learn-more-prs

Nutrition for Precision Health

Nutrition for Precision Health (NPH) is the first large *All of Us* partnered research study. It will develop algorithms to **predict individual responses to food and dietary patterns** of participants by analyzing new and existing *All of Us* data.



Over 6,100 participants now enrolled!

Data from Nutrition for Precision Health

- Lifestyle/Behavioral Data
- Diet
- Physiometabolic Data
- Microbiome
- Physical Measurements
- Environmental Data



- Analytic Centers
- Research Infrastructure Centers
- Study Locations
  1. University of Alabama
  2. University of California, Los Angeles
  3. University of California, Davis
  4. Cedars Sinai Medical Center
  5. Northwestern University
  6. Illinois Institute of Technology
  7. University of Chicago
  8. Louisiana State University Pennington Biomedical Research Center
  9. Louisiana State University Health Sciences Center
  10. Tufts University
  11. Massachusetts General Hospital
  12. University of North Carolina at Chapel Hill Chapel Hill North Clinic
  13. University of North Carolina at Chapel Hill Nutrition Research Institute Clinic

Environmental Health and Exposomics

A partnership with the National Institute of Environmental Health Sciences (NIEHS), this study **measures environmental exposures**, also known as the exposome using participant blood samples**.**

The exposome is defined as all an individual's exposures in a lifetime and how those exposures relate to health. (CDC)

Exposures may come from:


Our homes


Our lifestyles


Pollution


Social behaviors

Environmental exposures can inform research on a number of health conditions:

- Neurological disorders
- Metabolic and digestive disorders
- Cancer
- Aging
- Reproductive health
- Child development
- Asthma and allergies

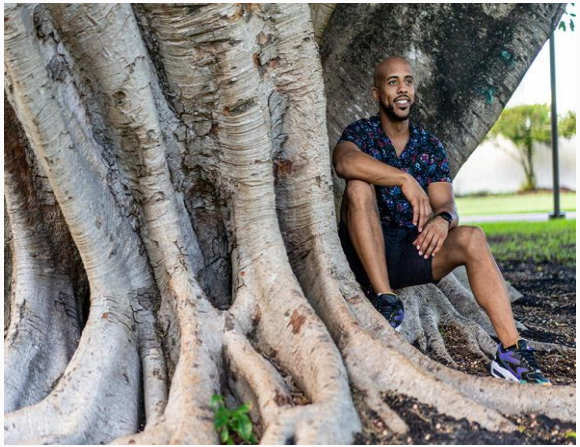
Environmental Health and Exposomics

>5,600 samples shared by *All of Us* participants will be used for this study.

Researchers will conduct an investigation of the environmental exposures of participants with type 2 diabetes.

Data on **environmental, pharmaceutical, dietary, and endogenous metabolites** are anticipated to be available as part of the *All of Us* dataset in the future.

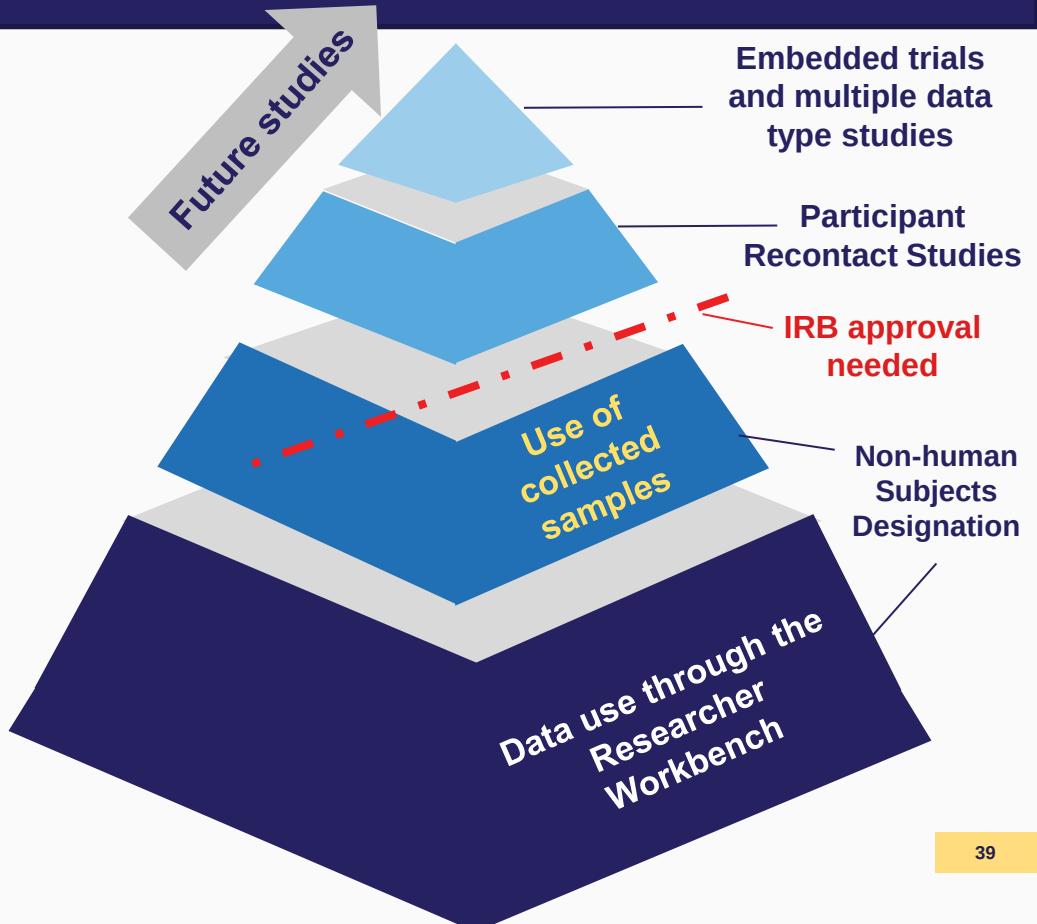
New research on environment, gene, and behavior interactions will **drive discovery across health conditions**.



86% of participants in this study self-identify as members of communities underrepresented in biomedical research, and **62%** self-identify as members of racial and ethnic minority groups.

Partnered Research Studies: Now and in the Future

- **What is happening now?**
  - *All of Us* is expanding partnered research studies to partners outside of the NIH
  - The number of samples that are studied may be large
- **What does the future hold?**
  - In the future, partnered research studies will become more complex and need *All of Us* IRB approval



Turning Participant Samples Into New Discoveries for Everyone

Currently, participants choose to contribute samples, like blood and saliva, for future research

- Samples are de-identified and stored in the *All of Us* Biobank without identifying information
- *All of Us* generates data from samples and shares it with registered researchers

Starting in 2026, external researchers can apply to study samples donated by *All of Us* participants

- All applications will be carefully reviewed by *All of Us* governing bodies and only registered researchers will be able use *All of Us* samples for their studies
- Researchers will begin to study samples to better understand health and disease

The *All of Us* Biobank stores samples from 617,000+ participants

Data from samples have already powered 25,000+ studies

In 2027 and beyond, researchers will share information and resources that benefit both participants and researchers

- At this time, researchers will not return personal results to participants
- Researchers will share summaries of their findings with participants
- Data will be added to the Researcher Workbench so other registered researchers can study and learn from the findings

Timeline of *All of Us* Engagement Activities on Partnered Research Studies



July 2025

Met with NIH Tribal Health Research Office (THRO)

Discussed engagement strategy and information dissemination.

Aug 2025

Presentation to NIH Tribal Advisory Committee (TAC)

Informational presentation and feedback on consultation questions.

Sep 2025

Presentation to *All of Us* Indigenous Research Working Group (IRWG)

Presented to IRWG to gather feedback on Tribal Consultation plans.

Jan/June 2026

Invited back to have deeper discussions with TAC

Discussed biospecimen analysis partnered research study with TAC.

TODAY

Aug 2026

NIHB Tribal Consultation

All of Us is holding a Tribal consultation on AI/AN sample inclusion.

Fiscal Year 2027

Additional Tribal consultations and listening sessions

More consultations on AI/AN sample inclusion at future events

DISCUSSION

Protocol Order: Comments & Questions

1. Tribal President Chairperson/Governor
2. Tribal Vice-President/ Vice-Chairperson/Lt. Governor
3. Elected or Appointed Tribal Official
4. Designated Tribal Official

All Consultation Questions for Tribal Leaders

Partnered Research Studies

1. *All of Us* de-identifies all samples donated by participants and never shares participants' self-identified Tribal affiliation with researchers. Are there additional protections or measures we should put in place for *All of Us* to share samples from self-identified AI/AN participants with research entities outside the NIH?

2. If data and samples from *All of Us* self-identified AI/AN participants were authorized for use in partnered research studies, what types of research would be beneficial to Tribal Nations? What strategic partnerships should the Program explore to ensure this research is conducted in a respectful and impactful way for AI/AN communities?

3. How can *All of Us* best partner and communicate with Tribal communities and *All of Us* AI/AN participants to ensure your voices and input are incorporated with the use of samples in future partnered research studies?

Controlled Tier Plus

1. Considering the sensitivity of the new data types in CT+, what protections should *All of Us* implement to ensure Tribal Nations will benefit from the research conducted using CT+ data, while mitigating potential harm?

2. For researchers applying to access CT+ data from self-identified AI/AN participants, what safeguards are necessary to ensure the data is being used ethically and responsibly?

3. Sensitive participant data stemming from a Tribal partnership could be separately and securely stored within CT+. What can we do to honor Tribal data sovereignty for data emerging from Tribal partnerships that are held and managed by *All of Us*? Are there additional protections needed specifically for this data?

All of Us RESEARCH PROGRAM

Thank You!

We invite you to send written testimony, comments, or questions to **NIHTribalConsultation@nih.gov** with a courtesy copy to **AOUTribal@nih.gov** by September 17, 2026.