

NIH Tribal Advisory Committee (TAC) Meeting Accelerating Discovery Through Partnered Research Studies with *All of Us* to Analyze Participant Biospecimens

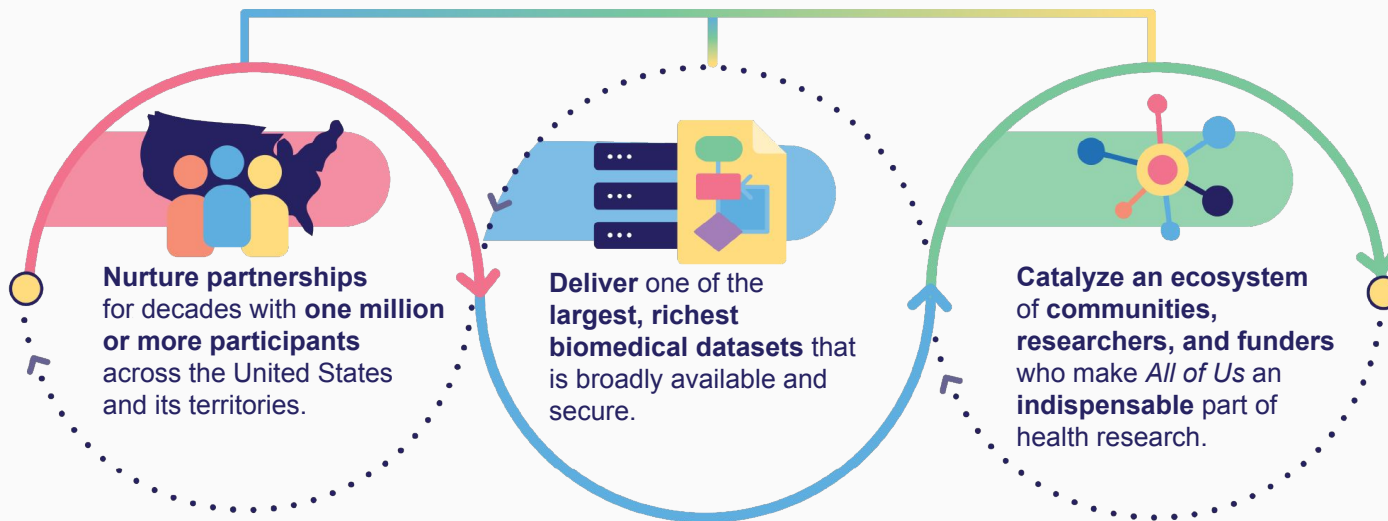
August 28, 2025



Dr. Joshua Denny, MD, MS, Chief Executive Officer, *All of Us* Research Program
Dr. Sheri Schully, Deputy Chief Medical and Scientific Officer, *All of Us* Research Program

Our mission

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



Enrolled 865K+ Participants With Continued Growth

Participant Enrollment

865,000+
Participants

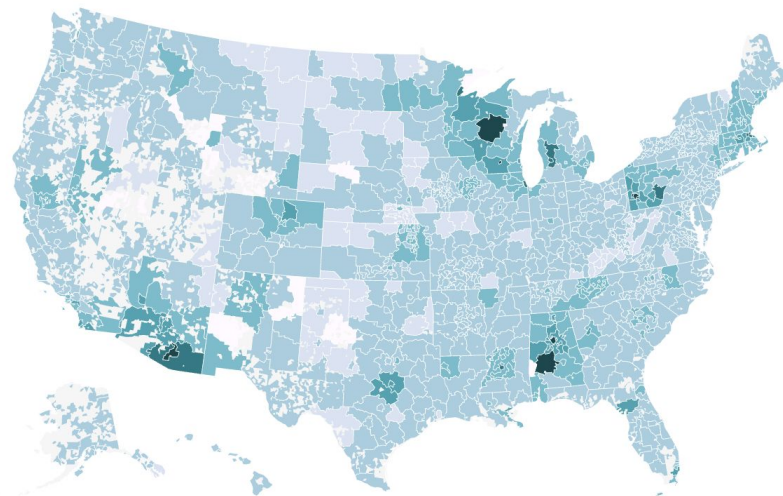
470,000+
Electronic Health
Records

594,000+
Participants who
have completed initial
steps of the program

609,000+
Biospecimens

**23,000+ AI/AN
Biospecimens**

Map of Consented Participants



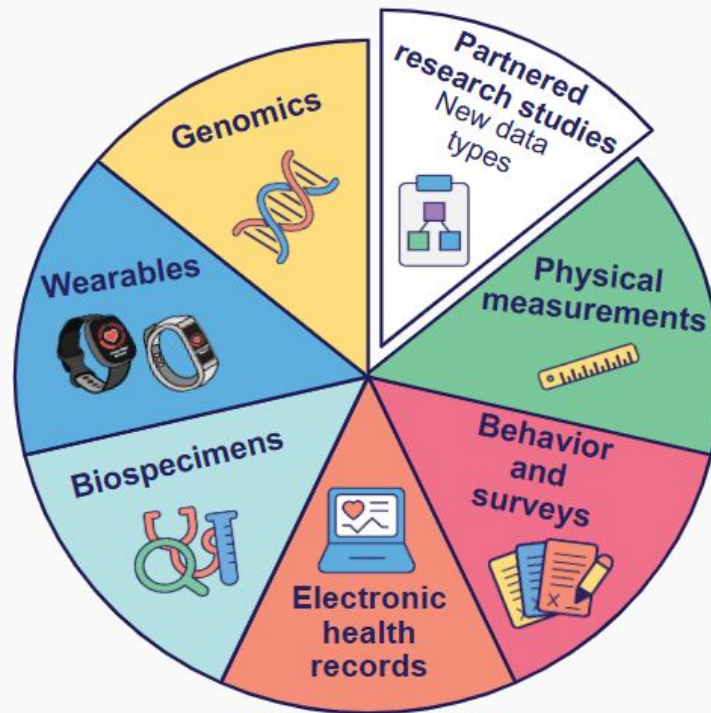
US map of *All of Us* participant density; covers
98.1% of US zip3 codes

Numbers current as of July 31, 2025

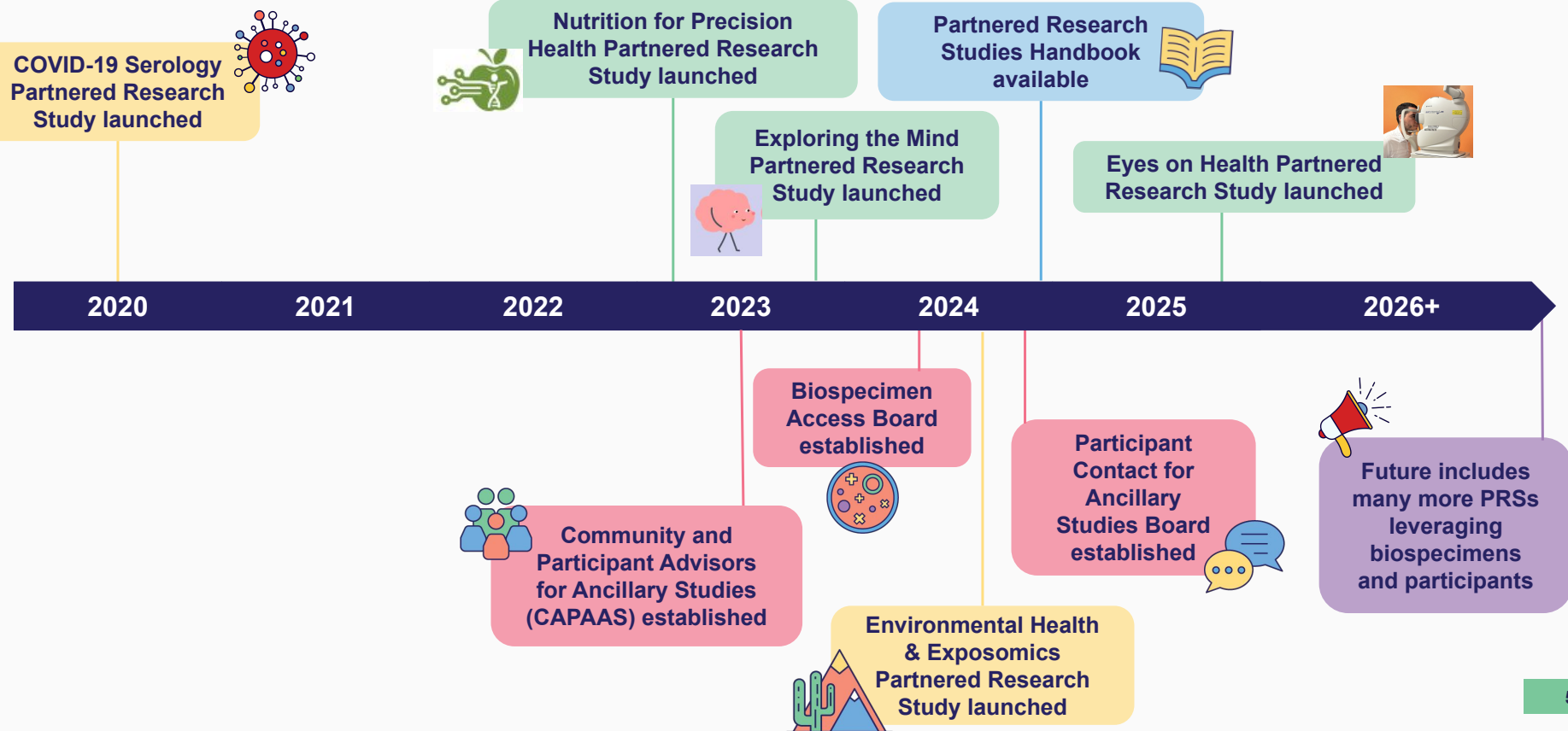
What is a Partnered Research Study?

All of Us partnered research studies (PRs) are funded by a study sponsor external to *All of Us* to collect new biospecimens, or 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



We have learned from Partnered Research Studies and laid groundwork for a sustainable, scalable future



Biospecimen Analysis Partnered Research Study



- *All of Us* plans to release a call for applications in late 2025/early 2026
- NIH researchers, U.S. academic institutions, non-profit organizations, and for-profit organizations, like commercial and/or private entities are eligible to apply



- Applications will be rigorously reviewed by *All of Us* governing bodies and staff including Community and Participant Advisors for Ancillary Studies (CAPAAS) and the Biospecimen Access Board (BAB)
- All applications must include a Return of Value (ROV) plan for participants
- Applicants must fund their own projects – *All of Us* will not allocate funding



- After MOUs and MTAs are in place, de-identified samples will be batched and shipped by the *All of Us* Biobank to the awarded researcher(s)
- Once analyses are done, the researchers must share the data/results with *All of Us*
- The program will share linked participant-level data on the Researcher Workbench

Engagement Strategy to include AI/AN Specimens in Future PRS'

- The program plans to **exclude** AI/AN blood samples in the first iteration of the biospecimen analysis PRS until appropriate feedback is provided by Tribal leaders, Urban Indian, and Tribal communities
- Planned tribal engagement efforts to **include** AI/AN specimen in future PRS:
 - Host a **Tribal Consultation and Urban Indian Listening Sessions** in collaboration with THRO in **Winter 2025/2026**
 - Gather feedback, comments and suggestions to plan for a programmatic response, and incorporate feedback into future PRS initiatives

Privacy and Protection Measures for future use of these samples

- Samples will be de-identified and no identifying information will be shared
- Indigenous voices have been added to the program's governance
- All researchers must follow *All of Us* policies and guidance:
 - New Policy on research involving AI/AN data: Forbids researchers from attempting to re-identify AI/AN individuals and the region from which individuals come
 - New Guidance for researchers using AI/AN data: Educates researchers on ways to avoid stigmatizing and unethical research using AI/AN data
 - Additional policies: Data User Code of Conduct, Policy on Stigmatizing Research, Policy on Ethical Conduct of Research, and Responsible Conduct of Research training
- Applications will undergo review for scientific merit and alignment with *All of Us* Core Values
- Proposed research will undergo workspace review conducted by the Resource Access Board (RAB)

Addressing Key Concerns and Implementing Mitigation Strategies

Erosion of Trust

Past research created distrust



Mitigate by transparent, ongoing dialogue and culturally appropriate, Tribe-governed consent processes. Encourage Tribes to conduct own Tribal PRS').

Blood Sample Sharing

Potential misuse and commercialization concerns



Mitigate by co-developing strict data/biospecimen governance with Tribes, prioritizing "Return of Results," and considering Tribal-controlled analyses.

Biospecimen Utilization

Balance scientific potential with cultural considerations



Mitigate by investing in Tribal research capacity, supporting Tribal IRBs, & focusing on Tribe-identified research priorities. Educate researchers in working with AI/AN data.

Lack of Tribal Support

Without Tribal endorsement, program legitimacy suffers



Mitigate by comprehensive engagement, formal agreements & utilizing advisory panels / committees with decision-making authority to guide program AI/AN inclusion.

Discussion Questions

- What concerns will Tribes and Urban Indian communities have about external researchers having access to de-identified, self-identified AI/AN participant blood samples?
- What types of materials or outlets/opportunities are best for communicating about upcoming PRS opportunities?
 - How much information to share, when, where, etc.?
- What types of value from these partnered research studies would be most beneficial to Tribes, Urban Indian communities, and current participants?

Send written feedback to AOUTribal@nih.gov

Making Health Discoveries Possible

The *All of Us* Research Program wouldn't be possible without the generosity of our participants and the dedication of our researchers.



Thank You!



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