DEPARTMENT OF HEALTH & HUMAN SERVICES National Institutes of Health

All of Us Research Program
NIH DPCPSI, Office of the Director (OD)
Bethesda, Maryland 20817

July 7, 2026

Dear Tribal Leader and Urban Indian Organization Leader:

The National Institutes of Health's (NIH) *All of Us* Research Program will initiate an in-person Tribal Consultation to seek feedback on two upcoming program initiatives: Partnered Research Studies, and Controlled Tier Plus (CT+). The Tribal Consultation will be held August 17th, 2026 at the 2026 National Tribal Health Conference in Chandler, AZ. We encourage your participation in this discussion. The feedback during these Tribal consultations is essential to shaping program processes. Your input ensures the future inclusion and responsible use of donated biospecimens and data from consented, self-identified American Indian and Alaska Native (AI/AN) participants aligns with ethical standards and cultural considerations.

The *All of Us* Research Program was established to accelerate health research and medical breakthroughs to enable precision medicine for all. Precision medicine is an approach to treating and preventing disease that aims to be more effective by considering each person's unique environment, lifestyle, and genetics.

All of Us has conducted several Tribal Consultations since 2019 and remains dedicated to upholding its commitment to Tribal sovereignty through ongoing engagement with Tribal Nations. The program understands decisions affecting AI/AN communities should be informed by AI/AN voices. This Tribal Consultation is the next in a continual series designed to solicit input from Tribal leaders.

The **Partnered Research Studies** (PRS), for the first time, will provide researchers external to the NIH with access to participant samples—including blood, urine, and saliva—to advance new medical research discoveries. Researchers from a broad range of institutions, such as universities, non-profits, private industry, Tribal Nations, and government agencies may apply to use *All of Us* biospecimens for broad research purposes. Each proposal will undergo a rigorous multi-stage process encompassing scientific and ethical review by NIH and input from *All of Us* participants. Access will be restricted to approved researchers only. Currently, biospecimens from self-identified AI/AN participants are excluded from new studies as the program works to complete Tribal consultation.

We seek your feedback for these PRS questions at Tribal consultation:

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?

The *All of Us* Research Program is currently expanding its existing data structure (Public, Registered, and Controlled tiers) by developing a new access level, **Controlled Tier Plus (CT+)**. This level will contain sensitive participant data, including 5-digit zip codes, electronic health records, medical images and possible other data types in the future. We are seeking Tribal guidance on the benefits, risks, and responsible implementation of this new data tier. To enhance protection commensurate with the increased sensitivity of the data, access to the new CT+ will require mandatory Institutional Review Board (IRB) and *All of Us* Resource Access Board approval for every project. Importantly, *All of Us* maintains our commitment of not sharing any participant's self-identified Tribal affiliation with researchers without an explicit agreement from the respective Tribe. For the first iteration, we plan to exclude the additional sensitive data types provided by self-identified AI/AN participants from CT+ until Tribal consultation is held.

We seek your feedback for these Controlled Tier Plus questions at Tribal consultation:

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?

Please send written testimony, comments, or questions to NIHTribalConsultation@nih.gov with a courtesy copy to AOUTribal@nih.gov by September 17, 2026. For programmatic questions, please contact the *All of Us* Research Program at AOUTribal@nih.gov.

We hope that you will join us at the 2026 National Tribal Health Conference in August. The *All of Us* Research Program will continue engagement efforts with Tribal communities to advance health for American Indian and Alaska Native peoples through research, now and in the years to come.

Participant information:

What: NIH Tribal Consultation on two new *All of Us* Research Program initiatives: Partnered Research Studies, and Controlled Tier Plus (CT+)

Date: Monday, August 17, 2026
Time: 10:15a - 11:45a MST
Location: In-person only, National Indian Health Board Conference, Sheraton Grand at Wild Horse Pass, 5594 W Wild Horse Pass Blvd, Chandler, Arizona
Registration link: https://forms.gle/TCyzajvmhiFk3Jj36

Sincerely,

Joshua Denny, MD, MS
Chief Executive Officer
All of Us Research Program
National Institutes of Health