Tribal Consultation on *All of Us* Research Program: Biospecimen Access and Controlled Tier Plus Data Expansion

This document provides an overview of the *All of Us* Research Program topics on Biospecimen Access and Controlled Tier Plus (CT+) Data Expansion initiatives to encourage Tribal Leaders to participate in the upcoming National Institutes of Health (NIH) Tribal Consultation and Urban Confer on August 17, 2026 at the 2026 National Tribal Health Conference in Chandler, AZ.

Purpose of Consultation:
The *All of Us* Research Program is soliciting input to establish robust protections, oversight mechanisms, and collaborative approaches to implementing two new initiatives. This engagement aims to ensure that the inclusion of biospecimens from self-identified American Indian and Alaska Native (AI/AN) participants in Partnered Research Studies and the expansion of the Controlled Tier Plus (CT+) data access model rigorously uphold Tribal sovereignty, adhere to ethical standards, and yield meaningful community benefits.

1. How the program could responsibly approach making biospecimens donated by self-identified American Indian and Alaska Native (AI/AN) participants accessible to external researchers outside of NIH for Partnered Research Studies, and what specific conditions or protections should be in place.

2. Whether the program's expansion of its data access model, through a new tier of data access called Controlled Tier Plus (CT+), which would require Institutional Review Board (IRB) and *All of Us* Resource Access Board (RAB) approval prior to project access to more sensitive participant data, is being approached in a way that reflects Tribal leaders' priorities for protections.

Program Overview
The NIH *All of Us* Research Program aims to advance health research and medical breakthroughs to enable an era of precision medicine for all. *All of Us* is committed to ensuring the program reflects the diversity of the United States, with a specific focus on partnering with AI/AN and Urban Indian communities.

Tribal Consultation is a reflection of the *All of Us* Research Program's commitment to the relationship between the NIH and Tribal Nations and to the principle that decisions affecting AI/AN communities should be informed by AI/AN voices. The program has conducted several Tribal Consultations since 2019 and remains dedicated to upholding Tribal sovereignty through ongoing engagement with Tribal Nations. This Tribal Consultation is the next in a continual series designed to solicit input from Tribal leaders. The feedback during these Tribal consultations are essential to shaping program processes. Tribal community input ensures the future inclusion and responsible use of donated biospecimens and data from consented, self-identified AI/AN participants and that it aligns with ethical standards and cultural considerations.

Tribal Consultation Focus 1: External Partnered Research Studies

This year, *All of Us* is beginning to expand access to participant-donated samples, including blood products (plasma and serum) and extracted DNA, through new partnered research studies. Researchers outside of NIH may apply to use samples for scientific studies. Researchers from eligible institutions, including Tribes, non-profits, universities, and private companies may apply to add new data to the program's existing dataset through mechanisms such as the currently available X01 Notice of Funding Opportunity (NOFO). Each application will be carefully reviewed by NIH through a multi-stage process involving ethical and scientific review, and receive input from *All of Us* participant groups. Currently, samples from self-identified AI/AN participants are excluded from new studies as the program works to complete Tribal consultation.

Discussion 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?

Tribal Consultation Focus 2: Controlled Tier Plus (CT+)

The program is currently expanding its existing data structure (Public, Registered, and Controlled Tiers) by developing a new access level: Controlled Tier Plus (CT+). The CT+ level will build on the existing Controlled Tier base, allowing researchers to request more granular and sensitive participant data to use for specific projects. Initially, researchers will be able to request data such as exact date of birth, 5-digit zip codes, military records retrieved from electronic health records, medical images and pediatric records with the possible addition of other data types in the future.

To access the current data tiers, researchers must be affiliated with an institution that has a valid Data Use and Registration Agreement and must undergo Responsible Conduct of Research Training and agree to the Data User Code of Conduct every year. To enhance data protection commensurate with the increased sensitivity of the data the new tier contains, CT+ access will require mandatory Institutional Review Board (IRB) and *All of Us* Resource Access Board (RAB) 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. We plan to exclude the additional sensitive data types provided by self-identified AI/AN participants

from CT+ until Tribal consultation is held. We are seeking guidance from Tribal leaders on the benefits, risks, and responsible implementation of this new data tier.

Additionally, *All of Us* would like to establish a dedicated partnership pathway for Tribal Nations to conduct their own participatory research studies containing CT+ data from *All of Us* self-identified AI/AN participants.

Discussion Questions for Tribal Leaders: CT+

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 these data?

Use of Tribal Input

The *All of Us* Research Program remains dedicated to collaborating with Tribal Nations to foster inclusivity and ensure direct benefits for AI/AN communities. We honor Tribal sovereignty and prioritize your perspectives on the access, management, and safeguarding of sensitive information. Your feedback will be instrumental in shaping these upcoming initiatives, with a comprehensive summary of the input gathered and shared following the consultation. If you are unable to attend the in-person Tribal Consultation, we encourage you to send written testimony, comments, or questions to NIHTribalConsultation@nih.gov and courtesy copy to AOUTribal@nih.gov by September 17, 2026. For programmatic questions, please contact the *All of Us* Research Program Tribal Engagement and Outreach Branch at AOUTribal@nih.gov.

Consultation Details

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: https://forms.gle/TCyzajvmhiFk3Jj36