National Institutes of Health (NIH) Tribal Consultation on *All of Us* Research Program: Biospecimen Access and Controlled Tier Plus Data Expansion

This document provides an overview for Tribal leaders and their designees to participate in the upcoming in-person NIH Tribal Consultation on the *All of Us* Research Program's Biospecimen Access and expansion of the existing data access model to take place on Monday, October 19, 2026, from 12:00 p.m. - 2:00 p.m. PST at the National Congress of American Indians' 83rd Annual Convention & Marketplace in Palm Springs, CA.

National Institutes of Health

The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The *All of Us* Research Program, part of the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), 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 American Indian and Alaska Native (AI/AN) and Urban Indian communities. To explore the *All of Us* Research Program's ongoing research initiatives, please see the active and public research underway on the Research Project Directory.

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 AI/AN participants in Partnered Research Studies and the expansion of the existing data access model rigorously uphold Tribal sovereignty, adhere to ethical standards, and yield benefits to Tribal communities through future Tribal partnerships. *All of Us* collaborated with the NIH Tribal Health Research Office to release a joint Federal Register Notice.

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 is essential to shaping program processes. Consultation feedback will guide future inclusion and responsible use of donated biospecimens and data from self-identified AI/AN participants.

Initiative 1: External Partnered Research Studies (PRS)
This year, *All of Us* is expanding access to participant-donated samples, including blood, urine, and saliva, to advance new medical research discoveries. Researchers from a broad range of eligible institutions, including Tribes, non-profits, universities, government agencies and private companies may apply to use *All of Us* samples for broad research purposes through funding mechanisms such as the X01 Notice of Funding Opportunity (NOFO). The data resulting from these projects will add to the program's existing dataset. Each application will be carefully reviewed by NIH through a multi-stage process involving ethical and scientific review and receive input from the *All of Us* participant groups. Access will be restricted to approved researchers only. 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

Question	Why This Matters
How should *All of Us* responsibly share self-identified AI/AN participant samples in PRS with researchers external to the NIH while protecting participants' data and ensuring meaningful Tribal input?	Informs program governance, policies and processes, helps create pathways to reduce the risks of stigmatization and data misuse, and supports research that incorporates Tribal priorities.

Initiative 2: Controlled Tier Plus (CT+)
The program is 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 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 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. 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 to not share 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 the new data access tier until Tribal consultation is complete. 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. We are seeking input on best approaches to establish these partnership pathways.

Discussion Questions for Tribal Leaders: CT+

Questions	Why This Matters
1. What safeguards should be considered as *All of Us* builds out this new tier with controlled access that contains sensitive data?	Protects Tribal communities, helps evaluate risks/benefits, and aims to prevent misuse and stigmatization.
2. What requirements should researchers follow in order to access and analyze sensitive data from self-identified AI/AN participants?	Establishes ethical standards, institutional oversight, and accountability mechanisms prior to participant data access.
3. How can we incorporate Indigenous data sovereignty principles within this new tier?	Aligns with program commitments to honor Tribal sovereignty and partner with Tribes.

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. The program honors Tribal sovereignty and prioritizes Tribal perspectives on the access, management, and safeguarding of sensitive information. A summary of feedback will be shared following the consultation. If Tribal leaders are unable to attend the in-person Tribal consultation, we invite them to attend virtually through the registration link provided below. Written testimony, comments, or questions can be sent to NIHTribalConsultation@nih.gov and courtesy copy AOUTribal@nih.gov until November 20, 2026. For programmatic questions specific to the *All of Us* Research Program, please contact the *All of Us* Research Program Tribal Engagement and Outreach Branch at AOUTribal@nih.gov.

Logistics and Participation:

Who should attend: Tribal leaders or their designees
Date: Monday, October 19th, 2026
Time: 12:00p.m. - 2:00p.m. PST
Location: In-person at the Palm Springs Convention Center, 277 N Avenida Caballeros, Palm Springs, CA 92262.
Registration link: Please visit https://rtiorg.zoom.us/webinar/register/WN_5xnSi6mhTAeOS3ial_GORw#/registration to register for virtual participation and the THRO website https://dpcpsi.nih.gov/thro/tribal-consultations for more information.