

2021 Tribal Consultation Report: Summary of Themes and Commitments

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Executive Summary

The *All of Us* Research Program initiated Tribal consultation in 2019 to engage Tribal Nations about the inclusion of American Indian and Alaska Native (AI/AN) populations in the program. Consultation sessions were held from May to October 2019, including four in-person sessions, multiple listening sessions, and written testimony. The resulting Final Report, released in March 2021, documents the comments received and the specific commitments *All of Us* made in response. This summary provides an overview of the five consultation themes and the key program commitments under each.

Full report: [All of Us Research Program Tribal Consultation Final Report \(March 2021\)](#)

Theme 1: Tribal Sovereignty and Research Participation

Tribal leaders and community members emphasized that the United States government has a nation-to-nation relationship with sovereign Tribal Nations, and that *All of Us* must engage Tribes formally and respectfully before any recruitment or use of AI/AN data. Tribes requested that participation be Tribally driven and that the program not proceed without explicit Tribal authorization.

Program commitments: *All of Us* will respect Tribal sovereignty by engaging Tribal Nations to ensure that research using the program's biospecimens and data from Tribal members is conducted in a manner that is respectful of applicable Tribal customs, culture, and laws. Recruitment on Tribal lands or researchers' use of Tribal affiliation in the *All of Us* dataset is prohibited and will never be allowed without approval from Tribal Nations. All data from self-identified AI/AN individuals is being withheld from the public and from researchers, and data will not be released until AI/AN participants have had time to learn more about the results of this consultation and make an informed decision about continuing in the program. *All of Us* will seek to engage Tribes to develop Tribally driven participation pilots in the future.

Theme 2: Cultural Sensitivity and Awareness

Tribal leaders raised concerns about how the program would handle biospecimens from AI/AN participants in culturally appropriate ways, including after participant withdrawal or death. They requested that the program recognize Tribal customs and spiritual practices related to the handling of biological materials.

Program commitments: The *All of Us* biobank sequesters biospecimens from AI/AN participants. When an AI/AN participant withdraws from the program or dies, no action is taken until the participant or their family specifies their preferences for handling the biospecimens. *All of Us* offers AI/AN participants who withdraw the option of an interTribal ceremony to give a blessing to their samples, performed by elders, traditional healers, or other appropriate Tribal community members. After the ceremony, the samples are medically destroyed.

Theme 3: Data Access, Use, and Protection

Tribes expressed concerns about how participant data would be de-identified, who could access it, how consent was structured, and what safeguards existed to prevent harmful or stigmatizing research using AI/AN data.

Program commitments: All data and biospecimens will be de-identified in compliance with the standards of the Common Rule. *All of Us* has established a research policy to minimize and prevent harmful and stigmatizing research. The program created a Resource Access Board (RAB) to oversee data use, audit workspaces, and adjudicate violations. *All of Us* will develop a list of AI/AN subject matter experts to review research proposals using AI/AN biospecimens or data. The program will implement a policy to notify the NIH Tribal Advisory Committee (TAC) if any research violations pertaining to AI/AN participants are identified, and will work with Tribal leaders to implement a training module on the use of AI/AN data.

Theme 4: Governance Involvement

Tribal leaders called for meaningful AI/AN representation within *All of Us* governance structures, not just advisory roles, so that Tribal perspectives are embedded in program decisions from the start.

Program commitments: *All of Us* has made its governance structure public and has AI/AN representation on its Institutional Review Board (IRB), Resource Access Board (RAB), Advisory Panel, and Biospecimen Access Policy Task Force. The IRB has a process in place to call on AI/AN subject matter experts when additional expertise is required. *All of Us* will work to ensure representation of AI/AN populations throughout all aspects of program governance.

Theme 5: Sensitive Data and Preventing Re-Identification

Tribal leaders raised concerns about genomic data in particular, noting that genetic information from a small, underrepresented AI/AN sample carries heightened risk of re-identification and community harm if misused.

Program commitments: No genomic data from AI/AN participants are being generated or returned by the program; *All of Us* has delayed DNA sequencing for all AI/AN participants until after Tribal consultation is complete and participants have had the opportunity to make an informed decision about their continued participation. Practices have been put in place to lower re-identification risk. The Data User Code of Conduct explicitly prohibits linking *All of Us* data with external data at the individual participant level and any attempt to re-identify individuals. The Committee on Access, Privacy, and Security will conduct a risk assessment for re-identifiability within the enrolled AI/AN sample.

Foundational Program Commitments to Tribal Nations

The following commitments reflect the foundational promises under which *All of Us* commits to operate. These were reviewed by the *All of Us* Tribal Collaboration Working Group and the NIH Tribal Advisory Committee.

- *All of Us* will respect Tribal sovereignty by engaging Tribal Nations to ensure research is conducted in a manner respectful of applicable Tribal customs, culture, and laws.
- *All of Us* will work to include as much diversity of AI/AN populations as possible by partnering with Tribes and with organizations with urban Indian health expertise.
- *All of Us* will not actively recruit AI/AN members until consultation is complete and, in collaboration with Tribes, a set of final rules around recruitment has been developed.
- *All of Us* will not recruit or allow its awardees to recruit AI/AN members on Tribal lands or focus on specific AI/AN populations without first obtaining approval from the Tribe.
- *All of Us* will not allow researchers to access participants' Tribal affiliation without an explicit agreement between *All of Us* and the Tribe in question.
- *All of Us* will support the development of educational materials, working with AI/AN researchers in partnership with AI/AN communities, and promote community-based participatory research.
- *All of Us* will first engage with Tribal communities through smaller pilot projects and will use information gathered to evaluate successes and failures before scaling up any collaborations.
- *All of Us* will work to ensure representation of AI/AN populations throughout all aspects of program governance.
- *All of Us* pledges to engage in respectful, equitable, ongoing dialogue with Tribes and Tribal organizations and conduct formal government-to-government consultation when indicated.
- *All of Us* acknowledges the transgressions against Tribal Nations and will aim to maximize benefits and minimize harm for AI/AN participants in the program.
- *All of Us* will work with Tribal Nations and organizations with urban Indian health expertise to address Tribal health research priorities and to encourage AI/AN researchers to conduct such research.