

All of Us Research Program 2023 Tribal Consultation Report

Executive Summary	1
Introduction	2
<i>All of Us</i> Tribal Consultation Background.....	3
2023 <i>All of Us</i> Tribal Consultation Process.....	4
Tribal Consultation Comments and Responses.....	5
Management and Sharing of Self-Identified AI/AN Data (Without Tribal Affiliation).....	5
Summary of Comments	7
Response.....	7
Tribal Engagement and Outreach.....	9
Summary of Comments	10
Response.....	10
Planned Program Activities.....	10
Summary of Comments	11
Response.....	11
Additional Considerations	12
Closing.....	12

Executive Summary

The National Institutes of Health’s *All of Us* Research Program strives to partner with at least one million U.S. participants who reflect the diversity of the United States. The program aims to advance biomedical research and personalized medicine. A key focus is the inclusion of populations historically underrepresented in biomedical research, including American Indian and Alaska Native (AI/AN) communities. Through Consultations and ongoing dialogue with Tribal leaders, the program has adapted its strategies to reinforce sensitive and respectful engagement with sovereign Tribal Nations.

The program has held several formal Consultations with Tribal leaders. A primary concern has been incorporating data shared by AI/AN participants with researchers. In response to these concerns, the program paused any work proposing to share data volunteered by participants self-identifying as AI/AN in order to consult on the best path forward. Efforts included both

informal and formal engagement, including virtual information sessions, a Federal Register Notice, two “Dear Tribal Leader Letters,” and additional avenues for providing virtual and written feedback.

Building on prior NIH Consultations, the 2023 Consultation discussed the integration and management of data collected from individuals who identify as AI/AN. The discussion also included plans for inter-Tribal blessing ceremonies to be held at the request of a self-identified AI/AN participant during the disposition of their biosamples. In addition, the program sought feedback on AI/AN-specific considerations for future program phases, such as the inclusion of children in the participant cohort.

An analysis of the comments showed several key themes, including unique considerations for the responsible use of AI/AN data, and the necessity of respecting Tribal sovereignty and ongoing Consultation with Tribal leadership as the program develops. Suggestions included augmenting oversight with more AI/AN representation, ensuring sufficient training for researchers, and transparent dialogue with AI/AN communities.

As expressed by Tribal leaders through the Consultation and in deference to Tribal sovereignty, the program does not recruit participants on Tribal lands and restricts communications and program activities in zip codes that overlap with Tribal lands. Based on the most recent Consultation, the program agrees to continue these practices until it receives explicit permission from Tribes for recruitment and engagement on their land. Future consultations will address how best to begin discussions with individual Tribal Nations to seek this permission and shape efforts around these activities.

The *All of Us* Research Program is committed to a respectful, inclusive approach to engaging with Tribal Nations, ensuring AI/AN representation in biomedical research and honoring Tribal sovereignty. The program will continue to seek feedback and adjust its strategies in collaboration with Tribal leaders and communities, and work to develop new approaches in partnership with Tribes.

Introduction

The [All of Us Research Program](#) is a historic effort, authorized by the U.S. Congress and coordinated by the National Institutes of Health, to collect and study data from at least one million people who reflect the diversity of the United States. The program’s mission is to accelerate biomedical research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us. This mission includes [core values](#), such as: (1) nurturing long-term partnerships with participants (2) building one of the largest, robust biomedical datasets that is broadly accessible and secure; and (3) catalyzing an ecosystem of communities, researchers, and partners who make *All of Us* an indispensable part of biomedical research.

The program recognizes that American Indian and Alaska Native (AI/AN) individuals, communities, and Tribes, are underrepresented in biomedical research. As a result, they may

not have had the opportunity to benefit from medical breakthroughs and have not felt safe or welcome to participate. Although participation in *All of Us* may not benefit individuals directly, the research conducted through *All of Us* data may benefit future generations and provide new insights into factors affecting health and disease, as well as preventative and therapeutic strategies.

In addition, the program also acknowledges that while striving to include AI/AN voices in the design, implementation and oversight of *All of Us*, the program has not always integrated key principles of Tribal sovereignty. *All of Us* and all other research programs that seek to address underrepresentation and form partnerships with AI/AN participants and Tribal Nations must first acknowledge the role of historical trauma, at times perpetuated through research, and actively work with Tribal communities to avoid repeating the mistakes of the past.

All of Us Tribal Consultation Background

Tribal Consultation is an essential part of the government-to-government relationship between the U.S. federal government and sovereign Tribal Nations and is crucial for the participation of Tribal citizens and Nations in *All of Us*. The Consultation process is intended to involve Tribes in program decision-making, provide Tribal governments with a forum to discuss issues or concerns, and identify program areas that require additional input and deliberation.

All of Us held Consultations and listening sessions starting in 2019. In March 2021, the program released a [Consultation report](#) and [report summary](#). The report covers topics that arose throughout the 2019 Consultation period and were distilled from listening sessions, Consultation events, and written feedback. Key outcomes from that Consultation were captured in a set of commitments to Tribal Nations that preface the report. These include an agreement by the program and partners not to recruit participants on Tribal land without the permission of the Tribe. In addition, the Tribal affiliation of self-identified AI/AN participants will not be shared with program researchers without an explicit agreement from the Tribe, and that *All of Us* will work to ensure representation of AI/AN populations throughout all aspects of program governance.

In March 2021, current self-identified AI/AN participants were informed of the report and a summary, and [additional information](#) was added to the enrollment process for all new participants. Following these notifications, AI/AN participants were informed that they could withdraw from the program between March and September 2021, thereby keeping their data from being shared with researchers.

Data from self-identified AI/AN participants has not been included in datasets available to registered researchers through the [All of Us Researcher Workbench](#), which launched in May 2020. Based on the 2019 Consultation, the program had planned to begin incorporating data from AI/AN participants into the *All of Us* dataset but made the decision to delay data integration after feedback from and discussion with the NIH Tribal Advisory Committee and the Secretary of the U.S. Department of Health and Human Services' Tribal Advisory Committee in 2022. These

bodies urged the program to continue to withhold AI/AN data from the Researcher Workbench until a review process responsive to these concerns about AI/AN data was developed and implemented.

2023 *All of Us* Tribal Consultation Process

In order to create an information exchange, mutual understanding, and informed decision-making about the inclusion of data from self-identified AI/AN participants in the Research Workbench and other program activities, the program initiated informational sessions and Consultation in 2023. Consistent with the NIH Tribal Consultation Policy, on May 1, 2023, a [Dear Tribal Leader Letter](#) invited Tribal Leaders to a series of [virtual information sessions](#). The purpose of these sessions was for attendees to learn more about the *All of Us* Research Program and for the program to continue dialogue and engagement with Tribal Nations as well as rural, and urban AI/AN communities. Session topics included an overview of the program, researcher access and use of data, AI/AN self-identification, and program [partnership opportunities](#).

This series was followed by a [Federal Register Notice](#) (FRN) posted on June 28, 2023, inviting Tribal leaders to a Consultation on September 28, 2023. The FRN included specific questions about data management and sharing, Tribal engagement and outreach, and planned program activities. Tribal leaders were invited to submit written testimony until October 28, 2023.

A [second Dear Tribal Leader Letter](#) was posted on July 21, 2023, reminding Tribal leaders of the upcoming Consultation, its topics, and registration details. This final Dear Tribal Leader Letter also provided leaders with links to access recordings of the June 2023 Information Session Series.

Attendees of the Consultation on September 28, 2023, included Tribal officials, public health workers, researchers, AI/AN community members, and representatives from the *All of Us* Research Program leadership team. While Tribal leaders had registered to attend the event, there were no elected Tribal Leaders present during the Consultation. *All of Us* leadership provided updates on the program's approach to Tribal engagement; our secure cloud-based platform, the [All of Us Researcher Workbench](#); and additional program activities. After the presentations, attendees were invited to ask questions, comment, and provide feedback on the topics outlined in the FRN. Commentary, questions and discussion shared during the virtual Consultation were informative, but we recognize that they do not represent the voice of elected/appointed Tribal leaders.

During the written comment period, the program received two letters: one from an elected Tribal leader on behalf of their Tribe, and one from a non-profit, inter-Tribal organization serving federally recognized Tribal Nations. The program recognizes that the input from elected/appointed Tribal leaders is the focus of Consultation, and while input from organizations and individuals such as Tribal citizens is not included in this report, their comments are considered and categorized separately.

In the sections below, this report will briefly describe the background for each topic raised in Consultation, summarize input received on that topic, and describe the program's plans in response.

Tribal Consultation Comments and Responses

Management and Sharing of Self-Identified AI/AN Data (Without Tribal Affiliation)

To date, *All of Us* has not shared data from self-identified AI/AN participants in the program's [Data Browser](#) or the [Researcher Workbench](#). The Data Browser, which displays aggregate data, is a tool that lets the public learn more about the health data participants have shared. The Researcher Workbench is a secure cloud-based platform for biomedical research with individual-level data from participants who consent to sharing their information. Access to the Researcher Workbench is available only to registered researchers affiliated with an organization with a Data Use and Registration Agreement (DURA), a legally binding agreement that outlines organizational responsibilities, as well as permitted and prohibited uses of program data. After a DURA is in place, researchers affiliated with the organization who seek data access must register by verifying their identity, completing the *All of Us* Responsible Conduct of Research (RCR) training, and signing a [Data User Code of Conduct](#).

The *All of Us* [Data User Code of Conduct](#) outlines the rules with which authorized researchers are expected to comply, including the specific program policies that help ensure data are protected and used ethically and responsibly. Those policies include the [Ethical Conduct of Research Policy](#), [Stigmatizing Research Policy](#), [Data and Statistics Dissemination Policy](#), and [Publication and Presentation Policy](#). By signing the Data User Code of Conduct, individual researchers enter into a contract with the program that supplements agreements between the program and the researchers' institutions.

Prior to starting their projects, researchers must provide a workspace description that describes the research project they intend to complete using *All of Us* data. The [Research Projects Directory](#) is accessible to the general public and includes information about all ongoing research projects. This information helps the program better understand the research interests of its user base and provides *All of Us* participants and the public with details about how *All of Us* data are being used.

Research projects can be flagged for review. Review requests are routed to the program's Resource Access Board (RAB), the program governance body charged with ensuring that research projects do not violate the Data User Code of Conduct. The RAB is tasked with reviewing any research proposals that are flagged as concerning or potentially stigmatizing. Proposals can be flagged by staff based on information in the workplace description, but anyone can request that the RAB review a Workbench workspace by filling out an anonymous form on

the public directory. The RAB also reviews random Workspaces and will review proposals at the request of the researcher. The RAB's functions are critical to ensuring responsible use of *All of Us* data resources through oversight of, and assistance provided to, data users. The RAB's duties ensure the program's commitments to stewardship of participant data and maintaining participant trust.

The RAB is composed of various consortium experts in fields such as human subjects research, research ethics, and privacy and security, as well as participant representatives. Current RAB membership includes individuals who self-identify as AI/AN and individuals with experience conducting research with Tribal communities. To help ensure adequate input, the RAB may also bring on additional subject matter experts as ad hoc members for specific reviews.

During the review process, the RAB may contact researchers to request clarifications or ask additional questions. To prevent misuse, the RAB may ask researchers to pause their work while the RAB completes their review, or they may lock the workspace and/or disable users' access to the Researcher Workbench. If the review identifies noncompliance, the RAB may require researchers to adapt their research. In instances of serious or continuing misconduct, the RAB may recommend additional penalties, such as permanent suspension of access to the Workbench, publicly posting violators' names, notifying funding entities, and/or more severe repercussions.

The specific questions provided to Tribal leaders in the 2023 FRN and during the Consultation presentation were:

1. Integrating information from self-identified AI/AN participants in our data platform, the *All of Us* Research Hub at <https://www.researchallofus.org/>
 - (a) How can the program augment the current policies and protections for self-identified AI/AN participant data so that it can be shared with researchers?
 - (b) What additional policies or guidance would you like *All of Us* to consider around the use of data from self-identified AI/AN participants?
2. Honoring Tribal sovereignty when working with self-identified AI/AN individuals who consent to participate.
 - (a) What kinds of protective practices and measures can be implemented to avoid infringing upon Tribal sovereignty when collecting or working with individual participant data?
 - (b) How should the program manage and share data from self-identified AI/AN individuals who choose to participate in the program, including those who are living off Tribal lands and/or who are not affiliated with a federally recognized Tribe?

Summary of Comments

In a written response, one Tribe noted that *All of Us* provides a unique opportunity for Tribal citizens to help define what precision medicine would look like in their community going forward. Additionally, they recognized that research has yielded many individual and community-based benefits for Tribes.

All of Us was advised that there is a need for continued Consultation and dialogue between Tribes and the NIH, in order to protect Tribal citizens and Tribal sovereignty. The inter-Tribal organization recommended additional oversight on research proposals planning on utilizing AI/AN data. They suggested the creation of a designated oversight task force of experts with experience in research in Indian Country who do not have existing conflicts of interest. Further, the recommendations stated that all researchers should undergo annual training created in consultation with Tribes with an emphasis on Tribal sovereignty, community protections, and the Nation-to-Nation relationships between Tribes and the U.S. government.

During the Consultation, an attendee raised concern about self-identification, reiterating that self-identified AI/AN individuals may not be citizens of federally or state-recognized Tribes. Another attendee recommended that any data produced should be shared back to communities and participants.

Response

All of Us initiated the current Consultation process after concerns about the oversight of research with AI/AN data, once it is made available to researchers. In response to these concerns, the program has increased the governance committees with additional AI/AN representation and expertise. In addition, the program developed new policy tools to help protect AI/AN research materials. With these measures in place, *All of Us* plans to incorporate data from self-identified AI/AN participants into the Researcher Workbench with the next data release, currently planned for late 2024.

All of Us will continue to work together with Tribes to ensure the policies and protections for self-identified AI/AN participant data are reflective of the input we have received through Consultation. This includes ensuring that [governing bodies](#) of the *All of Us* Research Program have representation from AI/AN and Indigenous voices and access to AI/AN subject matter experts. *All of Us* has added AI/AN representation to oversight boards such as the Advisory Panel, Steering Committee, Institutional Review Board, Resource Access Board, and Participant Ambassadors.

Consultation feedback advised that *All of Us* create a task force for reviewing AI/AN-related research proposals. *All of Us* will provide the RAB with ad-hoc support from AI/AN and Indigenous voices for review of projects focusing on AI/AN individuals, groups, or communities. The RAB will therefore have involvement by more AI/AN individuals in their oversight of any AI/AN-related research proposals that are flagged for review. Existing and newly formed bodies

such as the Advisory Panel's Tribal Collaboration Working Group (TCWG) or the program's Indigenous Research Working Group (IRWG) may be called upon to add expertise in these cases.

As part of the registration process for the *All of Us* Researcher Workbench, researchers are required to complete the Responsible Conduct of Research (RCR) Training before gaining data access. This training educates researchers on conducting responsible and ethical research with data from *All of Us* participants, taking care to respond to the needs of researchers with diverse scientific backgrounds and variable exposure to research ethics concepts. The training covers basic principles of research ethics, as well as more complex topics like cultural humility and the prevention of stigmatizing research and includes specific examples relevant to research with AI/AN and Indigenous communities. The RCR training takes approximately 45-60 minutes for researchers to complete and is followed by a quiz that researchers must pass to gain data access. In order to maintain their data access, users are required to retake the Responsible Conduct of Research training and quiz each year.

Envisioning the eventual integration of data from AI/AN individuals into the Researcher Workbench, *All of Us* added a clause to the Data User Code of Conduct. Researchers are required to comply with any *All of Us* policies pertaining to the respectful use of data from AI/AN individuals. The program will have the opportunity to outline specific expectations and enhanced oversight for projects focusing on AI/AN individuals, groups, and communities. The program has since drafted a policy regarding the use of research materials—including data, biospecimens, and other future donations—from American Indian and Alaska Native individuals that:

- Reinforces existing rules that are especially important in the context of using data from AI/AN individuals, including the policy against stigmatizing research;
- Prohibits re-identification of AI/AN individuals, the regions that they are from, or the Tribes to which they belong; and
- Requires researchers to use respectful and appropriate language and preferred terminology, as dictated by guidance from the program.

Additionally, within the policy, the program reserves the right to additional review and scrutiny when the research is focused on American Indian or Alaska Native populations. This means that these projects may be subject to more frequent audits by the program's oversight body and that violations can be escalated to the NIH Tribal Advisory Committee. The draft AI/AN Research Materials Use Policy will be finalized prior to any release of data from self-identified American Indian or Alaska Native individuals. These programmatic policies and policy changes augment existing laws and NIH policies that inform scientific data governance strategies. These include [Certificates of Confidentiality](#), discussed during previous Tribal Consultations, and the recent [NIH Policy for Data Management and Sharing](#), which includes supplemental guidance for the [Responsible Management and Sharing of American Indian/Alaska Native Participant Data](#) and [Protecting Privacy When Sharing Human Research Participant Data](#).

All of Us is working with the NIH Tribal Health Research Office (THRO) to notify the NIH Tribal Advisory Committee (TAC) when AI/AN-specific scientific findings are published from research

using the *All of Us* dataset. The program will list publications with AI/AN-specific results on its [Tribal Engagement website](#). Additional requirements for using Tribe-specific data (e.g., prior approval of research questions, presentations, or publications) could be included in partnership agreements with Tribes and the ability of the program to provide that oversight has been reserved in the draft AI/AN research materials use policy.

In response to concerns that participants in the program are self-identified as AI/AN and may not maintain tribal affiliation or community attachment, the program is considering adding language within the surveys that participants complete explaining how AI/AN status within the *All of Us* data is self-identified and does not indicate enrollment in any Tribe. The program also is committed to working with the NIH THRO on options for better clarifying AI/AN and enrollment status in any future Tribal partnerships.

All of Us will continue to coordinate with Tribes and seek input on resources related to the collection, use, and oversight of AI/AN data.

Tribal Engagement and Outreach

All of Us does not allow anyone associated with the program to recruit program participants on Tribal land without a Tribe's permission. We also will only release a participant's voluntary, self-disclosed Tribal affiliation under a formal partnership with that specific Tribe.

All of Us currently limits geographic information to state or territory in its public Data Browser, and the program includes only limited geographic information in the data that researchers use in the Researcher Workbench.

Currently, the program restricts some communications and other program activities within zip codes that overlap with Tribal boundaries. This includes mailing of program materials such as brochures. It also can apply to participants who request program materials or home visits, when it is unclear if their address is on Tribal lands. This rule applies to anyone residing within shared zip codes, not just self-identified AI/AN individuals. *All of Us* brought this topic to Consultation in hopes that Tribal leaders could provide strategies or best practices for engagement within shared or overlapping zip codes without infringing on Tribal lands.

The specific questions provided to Tribal leaders in the 2023 FRN and during the Consultation presentation were:

1. Possible future marketing efforts in zip codes that overlap on Tribal land and areas bordering Tribal land.
 - (a) How should the program guide engagement and outreach efforts where zip codes overlap with Tribal land?
2. Program activities for individual participants on Tribal land.

(a) What protocol should be followed when individual participants request program materials to be mailed to them or request home visits on Tribal lands?

Summary of Comments

It was advised that the program continue these policies as is, at a minimum. Guidance from Tribal leaders stated that NIH should consult with a Tribe's Institutional Review Board or Research Review Board whenever they want to conduct research and/or program engagement on or near Tribal lands or Tribal communities.

Written input from the inter-Tribal organization asserts that in any situation where zip codes overlap with Tribal lands, outreach must be conducted through a community consent lens with all materials created and approved in Consultation, following the development of agreements with each individual Tribal Nation.

Response

The program will continue its restrictions on engagement and outreach activities in zip codes that overlap Tribal boundaries. We will work to form agreements with Tribes in areas where the program is seeking to do recruitment and engagement activities and will coordinate with a Tribe's Institutional Review Board or Research Review Board whenever present.

Planned Program Activities

As the program continues to expand, in pursuit of its inclusivity goals, one expanded plan has begun - the inclusion of children in the *All of Us* Research Program. The program sought Tribal leader input for unique considerations and specific factors that should be considered when planning for the participation of AI/AN parents and their children.

A second topic was the incorporation of a blessing ceremony prior to the disposal of biosamples from AI/AN participants, following their withdrawal from the program. During the 2019 Tribal Consultation, Tribal leaders expressed the need for better understanding around biospecimen handling, considerations around their return or disposal, and the need to respect religious and cultural beliefs. The program then instituted an option for AI/AN participants who chose to withdraw from the program to indicate if they would like to have their biosamples included in a "intertribal blessing ceremony" prior to their disposal. The program sought advice through Consultation on how to proceed with implementing this option.

The specific questions provided to Tribal leaders in the 2023 FRN and during the Consultation presentation were:

"1. Future inclusion of children in the *All of Us* Research Program

(a) What unique considerations are there for the future inclusion of AI/AN infants, children, and adolescents as participants in the program, given that a child's parent or legal guardian must be a current participant?

(b) What unique considerations are there for family-based enrollment in the research program (e.g., parent or legal guardian participating with their child)?

(c) What specific factors should be taken into account when enrolling families in the research program, considering the possibility of kinship caregivers or non-traditional child care arrangements for the child?

2. AI/AN traditional blessing ceremony for biosamples of participants who withdraw from the program.

(a) How should the program proceed in conducting a traditional blessing ceremony for the participants who self-identify as AI/AN and request a blessing ceremony prior to biosample disposition?"

Summary of Comments

Guidance received around traditional blessing ceremonies stressed the need to recognize Tribes as diverse, noting that ceremonial practices vary across Tribes. That input indicated that any blessing ceremonies needs to be determined in consultation with each individual Tribal Nation. Another commenter noted that the program must be very thoughtful about what it is willing to do regarding a blessing ceremony, given the diversity of traditions across Tribal communities.

No input was received in regard to the future inclusion of children in the program.

Response

When children participate in *All of Us*, they can help researchers understand why some children get sick or stay healthy. Researchers can learn how children change and develop over time. This will help researchers understand how health may change across a person's whole life. The knowledge gained by researchers may help improve the care of children and adults in the future.

All of Us continues to plan for enrolling children of current participants. It will be several years until children of all ages can join *All of Us*. This approach to enrollment will help us consider the unique needs of each age group carefully. We will continue to raise this topic with Tribal leaders and communities as this part of the program progresses.

The program is reviewing the feasibility of various options for blessing ceremonies, including offering ceremonies that are specific to participants' Tribal or cultural affiliations.

Additional Considerations

The *All of Us* Research Program is committed to continuing to deepen its relationship with Tribes. *All of Us* will continue to coordinate with the NIH Tribal Health Research Office (THRO) to bring more frequent opportunities for Tribal Consultations. Additionally, *All of Us* is exploring the feasibility of in-person and regional Consultations, rather than relying solely on virtual fora.

Some feedback received during the Consultation applies to the NIH at large and can be summarized as follows: Appointing more elected Tribal leaders to the NIH Tribal Advisory Committee (TAC), working in collaboration with Indian Health Services (IHS) to ensure IHS patients can participate in and benefit from *All of Us*, establishing an NIH Tribal - designated Institutional Review Board, and holding further Consultations. *All of Us* has shared these comments with THRO and look forward to collaborating with them on addressing this feedback.

All of Us would like to encourage Tribal leaders to reach out at any time to AOUTribal@nih.gov to raise concerns, seek information on the program, or request programmatic support. The program hopes to bring future award and partnership opportunities directly to Tribes and AI/AN serving institutions.

Closing

The *All of Us* Research Program extends sincere gratitude to Tribal leaders, TAC members, researchers, policy advocates and community members for their valuable contributions and insights regarding the program's direction and initiatives. The program and the NIH are devoted to fostering robust partnerships with Tribal Nations that honor Tribal sovereignty and the nation-to-nation relationship between Tribes and the federal government. These efforts are crucial in shaping biomedical research that serves the interests of Tribal communities and reflects community-driven research priorities. *All of Us* remains committed to ongoing dialogue and a respectful, inclusive approach to engaging with Tribal Nations, ensuring AI/AN representation in biomedical research and honoring Tribal sovereignty.