

***All of Us* Research Program Tribal Consultation Final Report**

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Executive Summary

March 2021

All of Us Commitments to Tribal Nations

The commitments listed below reflect the foundational promises to Tribal Nations under which *All of Us* will continue to operate. These Tribal commitments were reviewed by the *All of Us* Tribal Collaboration Working Group and the NIH Tribal Advisory Committee.

- The *All of Us* Research Program 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.
- *All of Us* will work to include as much diversity of American Indian and Alaska Native (AI/AN) populations as possible in the cohort by partnering with Tribes and with organizations with urban Indian expertise that want to collaborate.
- *All of Us* will not actively recruit AI/AN members until *All of Us* completes meaningful consultation and, in collaboration with Tribes, develops a set of final rules around recruitment.
- *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 continue to not share data from self-identified AI/AN individuals with the public or researchers until Tribal leaders and AI/AN individuals have been notified of the results of consultation and AI/AN individuals are given time to decide to continue to participate or withdraw.
- *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 with Tribal Nations and urban and rural Tribal communities and will use the information gathered to evaluate the successes and failures before scaling up any collaborations with Tribes.

- *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 a respectful, equitable, ongoing dialogue and conversation 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.

Executive Summary

The *All of Us* Research Program initiated Tribal consultation in 2019 to respectfully engage Tribal Nations about the inclusion of American Indian and Alaska Native (AI/AN) populations in this research program. The comments received during consultation were used to develop specific immediate, short-term, and long-term plans.

Tribal Sovereignty and Research Participation

The *All of Us* Research Program 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 *All of Us* Research Program. In addition, *All of Us* redesigned its public Data Browser prior to release to remove the ability to view data in the aggregate using race/ethnicity or ZIP code. *All of Us* will encourage current and potential AI/AN participants to speak with their Tribal leadership and now has plain language information materials available that summarize the 2019 Tribal consultation for AI/AN participants. Current AI/AN participants will have a 6-month window – from March 29 to September 30, 2021 – to make an informed decision about continuing in the *All of Us* Research Program. After September 30, data from AI/AN participants who do not withdraw and therefore continue with the program will be added to the research platform. The program will seek to engage Tribes to develop Tribally driven participation pilots in the future and is also considering hosting a research priorities workshop to inform research to improve AI/AN health.

Cultural Sensitivity and Awareness

The *All of Us* biobank currently sequesters any biospecimens from AI/AN participants. When an AI/AN participant withdraws from the program or dies, no action is taken until the participant or participant's family specifies their preferences for handling the biospecimens. The program now offers AI/AN participants who withdraw the option of an interTribal ceremony to give a blessing to their samples.

Elders, traditional healers, or other appropriate Tribal community members will perform the ceremony. After the ceremony, the samples are medically destroyed.

Data Access, Use, and Protection

All data and biospecimens provided through the research platform will be de-identified in compliance with the standards of the Common Rule, and no readily identifiable data or biospecimens will be shared. *All of Us* does not seek broad consent for secondary research as defined in the 2018 Common Rule. However, the program's consent protocol does notify potential research participants that data and samples will be made available for other biomedical and health-related research protocols. *All of Us* is eager to work with Tribal Nations to make sure that Tribal leadership and participants understand this part of the consent process. When *All of Us* enters into a specific agreement with a Tribe, the program will work with that Tribe to determine how additional Tribal research review, via an institutional review board (IRB) or another process, will occur.

All of Us has established a research policy to minimize and/or prevent harmful and stigmatizing research. The program has created a Resource Access Board (RAB) to oversee the use of *All of Us* data resources, audit workspaces for potential violations of the Data User Code of Conduct, and review and adjudicate potential violations. The program will develop a list of AI/AN subject matter experts who can be called upon to review a research proposal using AI/AN biospecimens and/or data. The program will draft and implement a policy to notify the National Institutes of Health (NIH) Tribal Advisory Committee (TAC) should any research violations pertaining to AI/AN participants be identified. The program also plans to work with Tribal leaders to implement a specific training module on the use of AI/AN data.

Governance Involvement

All of Us appreciates the need for more AI/AN members within its governance. The program has made its governance structure public and has AI/AN representation on its IRB, RAB, Advisory Panel, and Biospecimen Access Policy Task Force. In addition, the *All of Us* IRB has a process in place to call on subject matter experts in instances that would require additional AI/AN expertise to provide a more appropriate review.

Sensitive Data and Preventing Re-Identification

By understanding the relative contributions of genetic factors, social determinants of health, the environment, and changes over time, researchers can better understand the causes of disease, determine which treatments are most effective, and uncover factors that reinforce resilience and health. However, the program acknowledges that some data, including genomic data, require special considerations, especially with populations where these data may have a disproportionate impact because of underrepresentation in research. Currently, no genomic data from AI/AN participants are being generated or returned by the program, as the program has delayed DNA sequencing for all AI/AN participants. *All of Us* is first providing supplemental communications to participants about Tribal consultation so that participants may decide whether to continue their participation in the program and have their genetic information returned. To protect certain groups at higher risk for re-identification, practices have been put in place to lower the risk of re-identification, and 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. In addition, the *All of Us* Committee on Access, Privacy, and Security will be conducting a risk assessment for re-identifiability within the small sample of AI/AN individuals currently enrolled in the program.

Additional Considerations

The program is considering a request for publication review and a mechanism to notify the NIH TAC when AI/AN-specific scientific findings are published. The program plans to list publications with AI/AN-specific results on its Tribal Engagement website. *All of Us* appreciates and welcomes the opportunity for engagement and alliance with Tribal Epidemiology Centers (TECs) and to support their capacity to advance AI/AN public health. *All of Us* will seek input from TECs and Native American Research Centers for Health for a future researcher training workshop and AI/AN research priorities workshop.

Recommendations for Further Consultation

All of Us is committed to respecting Tribal sovereignty and will continue to work with Tribes on a government-to-government basis to address concerns through dialogue and additional consultation.

Introduction

The National Institutes of Health (NIH) established the *All of Us* Research Program to accelerate health research and medical breakthroughs to enable an era of precision medicine for all. The program seeks to achieve this mission by building relationships with one million or more participant partners; delivering the largest, richest biomedical dataset ever of its kind; and catalyzing a robust ecosystem of researchers eager to use the dataset to potentially advance human health. By gathering health-related information from a large pool of diverse participants, *All of Us* will reach the scale and scope necessary to enable research on a wide range of diseases and health topics.

Health equity is important to *All of Us*, and the program is committed to building a cohort that is demographically, geographically, and medically diverse, including groups that may not have had the opportunity to benefit from breakthroughs in biomedical research because they were left out of research studies in the past or did not feel welcome to participate. *All of Us* and all other research programs that seek to address underrepresentation must acknowledge the role of historical trauma, at times perpetuated through research, and actively avoid the mistakes of the past. Although participation in *All of Us* may not benefit individuals directly, the research generated may benefit future generations and provide new insights into factors determining health and disease, as well as prevention and therapeutic strategies. Most importantly, a key mission of *All of Us* is to ensure that populations historically underrepresented in biomedical research are included in the research process as partners in research.

All of Us acknowledges that American Indian and Alaska Native (AI/AN) individuals are underrepresented in health research and often are not included in sufficient numbers to arrive at scientifically valid conclusions about this population in national research studies. With the great promise that this program represents for accelerating research on how individual differences in lifestyle, environment, and biology affect health, it is the intent of *All of Us* to respectfully invite collaboration with Tribal Nations about the inclusion of AI/AN populations in this research program.

In preparation for engaging Tribal Nations and Native peoples in the *All of Us* Research Program, *All of Us* staff initially discussed the program with multiple AI/AN groups to better understand the issues related to research involving AI/AN individuals. As a result of these discussions, *All of Us* established the [Tribal Collaboration Working Group](#) (TCWG) in October 2017 to gather more detailed input on the inclusion of AI/AN individuals in *All of Us*. The TCWG includes Tribal leaders, health care providers, researchers, and other community members, as well as NIH staff and *All of Us* consortium representatives.

Program staff also spoke with Tribal leaders and researchers to gather input, discussed the program at numerous NIH Tribal Advisory Committee (TAC) meetings, and presented at events with Tribal leaders and organizations, such as the National Congress of American Indians Policy Research Center's webinar series in January 2018 and the March 2018 TAC meeting. The *All of Us* team also conferred with U.S. Department of Health and Human Services (HHS) and NIH colleagues, who are experienced in working with Tribal Nations. The University of Arizona, an *All of Us* partner, organized a conference to bring together local Tribal Nations to initiate conversations around the *All of Us* Research Program. In April 2018, the TCWG completed its report, "Considerations for Meaningful Collaboration with Tribal Populations," which guided the program in initiating formal Tribal consultation in 2019. Input from TCWG members highlighted the need to keep the NIH TAC updated on the progress and content of this report, to hold informational sessions around key topics, and to clarify program policies on issues such as the handling of biospecimens.

***All of Us* Tribal Consultation Background**

Tribal consultation is part of a government-to-government relationship between the U.S. federal government and Tribal Nations. The importance of consultation with Indian Tribes was affirmed through presidential memoranda in 1994, 2004, 2009, and 2021. HHS established an [HHS Tribal Consultation Policy](#) in 2010, pursuant to [Executive Order 13175](#), which was followed by the NIH Guidance on the Implementation of the HHS Tribal Consultation Policy. The [NIH Tribal Health Research Office](#) (THRO) has provided guidance for how NIH implements this policy, in keeping with the NIH Guidance on the Implementation of the HHS Tribal Consultation Policy. The process is intended to involve Tribes in decision-making, provide Tribal governments with a forum for raising issues or concerns, and identify areas that require additional input and deliberation. Dialogue between Tribes and federal agencies can help to build trust and strengthen communications, resulting in a better relationship and more effective partnership to address important issues.

The consultation process is closely aligned with the core values of *All of Us*, which include openness, partnership, transparency, access, and trust. However, as Tribal leaders have indicated, the program needs to improve its consultation process in order to build a relationship that would enable Tribes to confidently participate. The process by which *All of Us* gathered the Tribal input for this report is described below, and efforts underway to improve consultation are discussed at the end of the report.

To initiate this consultation process, a "[Dear Tribal Leader](#)" letter, distributed in May 2019 by NIH Director Dr. Francis Collins, announced a [series of Tribal consultations and listening sessions](#) on the *All of Us* Research Program to discuss how the program can develop meaningful, culturally appropriate collaborations with AI/AN populations. The program used several established events and venues to

gather broad input from Tribal leadership, interTribal organizations, and AI/AN health experts. The program coordinated with THRO, AI/AN organizations, and Tribal representatives to set up these meetings and invite potential attendees. These events enabled information exchange and provided Tribal leaders and Tribal and urban Indian organization members opportunities to share their input as *All of Us* identified priorities and policies around the inclusion of AI/AN populations in the research program, including the appropriate attention to Tribal research oversight and laws. *All of Us* also developed a [Tribal Engagement website](#) to provide an updated list of consultation events and other relevant resources.

All of Us published a [Request for Information \(RFI\)](#) on September 3, 2019, to invite further comments and suggestions from additional stakeholders on the concerns and challenges communicated by Tribal leaders and participants during the consultations and listening sessions. The program received multiple comments during the comment period, which closed on October 31, 2019. NIH also received seven letters from Tribal Nations and organizations with specific input and requests for *All of Us* to provide additional information and clarify several parts of the program. The consultation period ended on November 30, 2019, at which point *All of Us*, per the TCWG's recommendations, categorized the input received as from consultation, listening sessions, or written feedback (e.g., responses to the RFI). The program then synthesized this information and developed a list of commitments and specific actions *All of Us* will take in response.

Tribal Consultation Themes

The input received by *All of Us* through consultations, listening sessions, and written feedback included a wide spectrum of opinions. This reflects the highly diverse AI/AN population, which currently includes 574 federally recognized Tribes, reservation-based and non-reservation-based urban and rural individuals, and individuals and groups from many different regions of the country. Common themes and shared concerns from this input were compiled by program staff and organized into the following categories:

- Tribal Sovereignty and Research Participation
- Cultural Sensitivity and Awareness
- Data Access, Use, and Protection
- Governance Involvement
- Sensitive Data and Preventing Re-Identification

The points raised during consultation were discussed with *All of Us* leadership to determine appropriate responses and specific short- and long-term plans. *All of Us* also received valuable insight from the TCWG, and the report was shared with the NIH TAC in March 2020.

The following text is a summary of concerns expressed through consultation, listening sessions, and written feedback, accompanied by a description of specific actions the *All of Us* Research Program is currently taking or considering implementing in the future. *All of Us* understands that there are important distinctions between official Tribal consultation and other forms of engagement, as Tribal consultation constitutes the official government-to-government discussions described in the HHS Tribal Consultation Policy. Tribal consultation is a process designed to ensure meaningful and timely input by

Tribal officials in the development of regulations, programs, policies, and projects that have Tribal implications. *All of Us* understands that, while listening sessions and other forms of feedback are useful for framing issues and solutions, Tribal consultation is exclusively between the U.S. federal government and Tribal Nations. Throughout this report, *All of Us* has noted which points of feedback were raised through official consultation versus listening sessions or written comments, like those submitted in response to the RFI. *All of Us* is committed to continuing engagement, building collaborative relationships, and communicating with Tribal Nations, Tribal organizations, and all AI/AN participants with transparency and honesty.

Tribal Sovereignty and Research Participation

Respect for Tribal sovereignty

Respect for Tribal sovereignty is the foundational principle of Tribal engagement within *All of Us*, and the program seeks to uphold the sovereign right of Tribal Nations to govern themselves. During consultation, Tribal leaders emphasized the need to obtain Tribal approval when conducting research with Tribal members and consider the broader impact of the inclusion of self-identified AI/AN participants not living on Tribal lands. As stated by an interTribal organization in response to the draft *All of Us* consultation report, "Whether research occurs on or off Tribal land, if it involves our citizens, it has the potential to impact our Tribal Nations."

In contemplating the different positions of Tribes, individuals, interTribal organizations, and urban/non-reservation-based AI/AN groups, the program seeks to respect the sovereignty of Tribal Nations while also respecting individual rights. Recruitment on Tribal lands or association of a specific Tribal affiliation in the *All of Us* dataset is explicitly prohibited and will never be allowed without approval from Tribal Nations and their respective or designated institutional review boards (IRBs).

In addition, the program will inform all AI/AN individuals currently participating in the program and those who wish to enroll in the future of general concerns held by Tribal Nations and encourage them to talk with their Tribal leadership if they have any questions about those concerns or their participation. *All of Us* has developed informational materials that summarize the 2019 *All of Us* Tribal consultation and describe considerations for AI/AN participants. These materials are available within the participant portal and on the program's website.

Although Native Hawaiians fall outside the formal consultation process established by Executive Order 13175, *All of Us* intends to re-examine how the program engages with Native Hawaiian and other Pacific Islander communities moving forward.

Pilot projects in partnership with Tribal Nations

All of Us believes that the most collaborative and direct way to involve Tribal Nations in the research program while respecting Tribal sovereignty is through pilot projects that are formed in partnership with individual Tribes. *All of Us* will seek to develop collaborative partnerships with Tribes to discuss their priorities for biomedical research. Following consultation, through dialogue, education, and exchange – without obligation – the program will seek to engage Tribes in order to inform a Tribally driven participation pilot in *All of Us*. When the program enters into a partnership with a specific Tribal Nation,

it will work together with them to establish rules and processes to respect Tribal sovereignty, abide by the rules of that Tribe's IRB or other research governing bodies, and address issues important to the Tribe through formal agreements, such as a memorandum of understanding.

Importance of including Tribally guided research in *All of Us*

The program acknowledges the diversity of Tribal Nations and AI/AN individuals and that there is no consensus position or singular source that can represent the differing needs and concerns of all relevant Tribes and individuals. Nevertheless, it is critical for researchers interested in improving AI/AN health to identify and pursue the research questions that are important to Tribes. This is best achieved by researchers engaging directly with interested Tribal communities and maintaining first-hand communication and feedback about priorities and progress. *All of Us* echoes the sentiments of Tribal leaders expressed during consultation: Researchers seeking to work with Tribes must consider community-based participatory research approaches. Community members in listening sessions also emphasized the importance of Tribally guided research.

All of Us continues to engage its stakeholders on a regular basis to gather input on the kinds of research questions that may be answered using this cohort and the types of data that should be collected to answer these questions. This input is helping to expand upon the initial *All of Us* protocol, which will continue to evolve and improve as new tools, technologies, and scientific opportunities emerge.

To ensure the program is gathering data needed to facilitate research into the topics of importance to Tribal Nations, *All of Us* is considering hosting a research priorities workshop to solicit Tribal input. Invited workshop attendees would be asked to identify important data elements related to AI/AN research that the program should incorporate into future versions of its protocol.

All of Us would work closely with Tribal Nations and the AI/AN community to ensure the workshop has proper representation and that all relevant stakeholders have an opportunity to provide input and be included in the discussion. These discussions will ensure that *All of Us* is collecting the right kind of data to provide the greatest benefit toward improving AI/AN health and wellness. *All of Us* acknowledges that Tribal Nations may prefer that the research workshop be held once progress has been made in implementing some of this report's recommendations for ways to address Tribal concerns.

Issues concerning self-identification as AI/AN and Tribal membership

One concern shared by Tribal leaders in consultation, community members during listening sessions, the NIH TAC, and Tribal organizations via written comment, was the need for the program to recognize the difference between self-identified AI/AN participants and members of federally recognized Tribes, sensitivity around displaying Tribal affiliation, and the implications these issues have for Tribal communities and precision research on AI/AN health.

Enrollment, consent, and participant surveys within the program all happen online. Individuals have the option to select AI/AN as a category to describe themselves during the initial demographic surveys. These surveys appear after the consent process, because *All of Us* wants to ensure participants are well informed about what they are participating in before the program asks for personal information.

The "Informed consent for current and future AI/AN participants" section addresses how the program now provides more information before the consent process, to better inform potential AI/AN participants. In the current demographics survey, individuals who choose to select AI/AN – alone or in combination with other racial/ethnic categories – are asked to indicate whether they are American Indian, Alaska Native, or Central or South American or to choose "none of these fully describe me." Finally, they have the option to "provide the name of the Tribe in which you are enrolled or affiliated or your Tribal descent."

As an immediate response to concerns about self-identified AI/AN participants, *All of Us* is currently not including data from individuals who have identified as AI/AN within the dataset available in its research platform. In addition, *All of Us* has redesigned its public Data Browser to remove the ability to view data in aggregate using race/ethnicity or ZIP code. AI/AN data will not be included in the dataset available to researchers until after participants have had the opportunity to review information from consultation.

Furthermore, *All of Us* understands that Tribal affiliation and membership are determined by Tribes themselves and cannot be determined by the program. *All of Us* recognizes that this information is highly sensitive and that verifying Tribal affiliation is currently beyond the capabilities of the program. Tribal affiliation will never be made available to researchers unless the program enters into a partnership with that specific Tribe. Participants currently enrolled in the program will need to re-enroll under that agreement in order to have their Tribal affiliation listed. A communications campaign in late May 2020, which included email, text message, and push and portal notifications, informed AI/AN participants that the program is currently engaged in Tribal consultation and that their data are not being included, as AI/AN participants were generally unaware that their data are not yet being shared. In addition, the *All of Us* Support Center was provided specific information and resources to address questions AI/AN participants might have had after receiving this update. When data from currently enrolled AI/AN individuals are included in the *All of Us* dataset, the program will clearly indicate that all such AI/AN data reflect self-identification, and again, Tribal affiliation will never be displayed without a Tribal agreement in place.

Informed consent for current and future AI/AN participants

Through consultation, listening sessions, and written comments, Tribal leaders, community members, and Tribal organizations expressed concern about AI/AN individuals enrolling in *All of Us* without Tribal consent. As the TCWG noted in its initial report:

"The balance of Tribal sovereignty with individual sovereignty and decision-making ability is an incredibly complex issue. Some Tribal leaders and TCWG members believe that individuals' rights take precedence over Tribal rights when it comes to research participation. Others believe that an individual's participation could impact the Tribe and therefore Tribal consent is required."

Although *All of Us* is not actively recruiting AI/AN participants, individuals who self-identify as AI/AN have enrolled. The program believes it is important to honor the commitment made to currently enrolled participants who have chosen to be part of this research study. However, the program also seeks to respect Tribal sovereignty and to inform AI/AN individuals of the outcomes of Tribal consultation before they decide to enroll or continue participating in the program.

To ensure that currently enrolled AI/AN participants are fully informed regarding the concerns raised by Tribal leaders during the Tribal consultation process and about the program's decisions regarding the use of AI/AN data, the program has developed a robust communications approach to reach out to these participants with the most recent decisions before any of their data are made available to researchers. This approach involves direct emails to current AI/AN participants, webpage announcements, informational materials such as frequently asked questions, and announcements to key stakeholders. In addition, *All of Us* will provide a 6-month window, from March 29 to September 30, 2021, for current AI/AN participants to make an informed decision about continuing in the program. If currently enrolled AI/AN participants wish to avoid having their data used after learning more about the outcomes of consultation, *All of Us* has established a clear path for withdrawing from the program and this 6-month window in which they may seek additional information if needed. This approach will ensure that AI/AN participants' data are never accessed or used by researchers should they no longer wish to participate. After September 30, 2021, data about AI/AN participants who do not withdraw and therefore continue with the program – clearly marked as self-identified and without Tribal affiliation – will be added to the current dataset, and researchers can begin using their data. In addition, like all participants, AI/AN participants may withdraw from the program at any time and for any reason.

For individuals not already enrolled in the program but who want to join, the program has implemented a notification within the online enrollment portal that informs individuals that *All of Us* is responding to feedback received during Tribal consultation and is currently not sharing data from AI/AN participants. In addition, informational modules now offer potential participants more information about AI/AN participation and the results of consultation prior to the consent process (Figure 1). This information is available to all participants; individuals are not required to first identify as AI/AN to get access to this information. These modules discuss concerns raised during Tribal consultation and other important considerations for participation by AI/AN individuals, including information about the risk of group harm. *All of Us* is considering the best options for updating this information for current participants, potential participants, and Tribal leaders going forward.

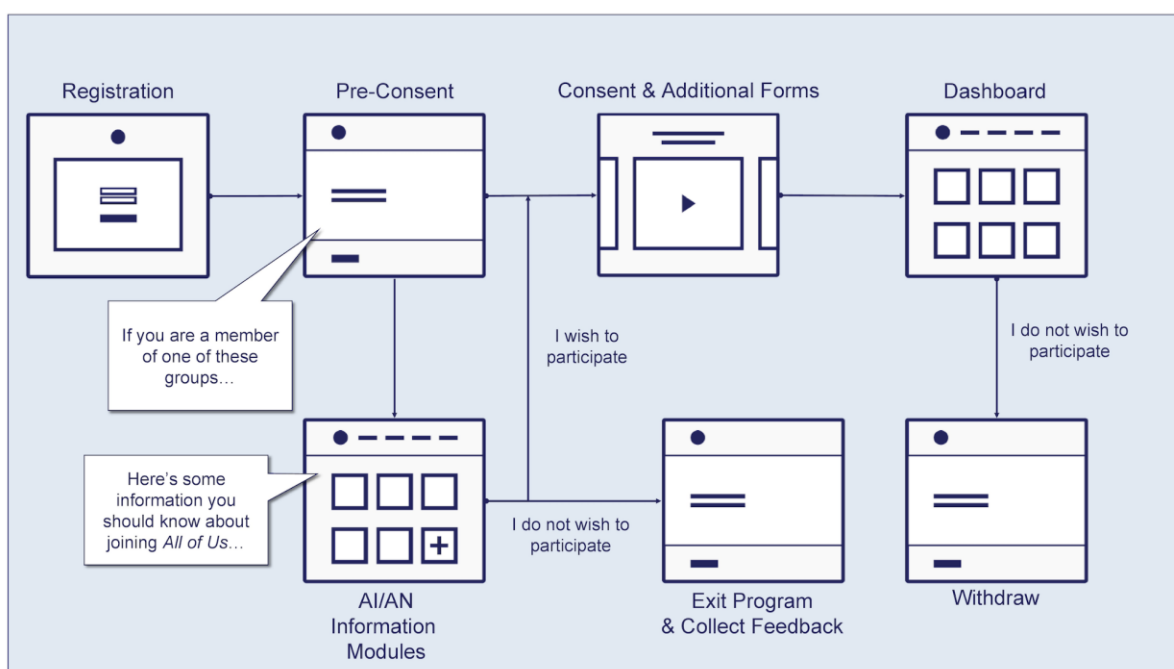


Figure 1: Participant Enrollment Journey, with Proposed Pre-Consent Information Modules for New AI/AN Participants

In addition, *All of Us* is developing a brief overview and frequently asked questions around AI/AN participation and will make information available to researchers, Tribal leaders, participants, and the public.

Community protection and informed consent

InterTribal organizations responding to a draft of this consultation report emphasized the need for an increased focus on community protections and informing participants of the potential for community harm. As one organization stated, "NIH must remember its trust and treaty obligations to Tribal Nations. This includes an obligation to prioritize the protection of our communities (including our citizens who live away from home) as research protocols are developed." *All of Us* emphatically agrees with the need to protect communities as well as individuals from any harms from research, including stigmatization. This applies to all communities, including Tribal Nations, and is a responsibility the program takes very seriously. In addition to addressing the issue of community harm with participants and in researcher training, *All of Us* will work with Tribal leaders and AI/AN research experts to emphasize and strengthen the program's approach to this topic.

When *All of Us* began enrolling participants, the program had not consulted with Tribal Nations and did not emphasize information about community harms, especially as they relate to AI/AN communities. Considering this, a response to the draft of this consultation report has requested that all AI/AN participants be required to re-consent to participation in the program. However, requiring all current AI/AN participants to actively choose to continue participation ("opt in") would place an undue burden on participants and has a substantial risk of excluding participants who have chosen to be part of the program and are not enrolled Tribal members. While the program completed consultation, any participant who selected the AI/AN racial category, either alone or in combination with other categories, was included in the hold on sharing data with researchers and processing biospecimens. Although this definition meant that participants who identified as having AI/AN ancestry but have no formal affiliation with a federally recognized Tribe were included, the broad definition was the best way to ensure that no data that could be considered "AI/AN" were shared with researchers before consultation was completed. Once the consultation report is released and participants have had a chance to deliberate about their continued participation in the program, all participants who have completed the consent process and have not withdrawn will be included in all aspects of the program.

Cultural Sensitivity and Awareness

Appropriate handling of biospecimens in accordance with Tribal beliefs

During consultation, Tribal leaders expressed the need for better understanding around biospecimens (including handling by *All of Us*), considerations around their return or disposal, and the need to respect religious and cultural beliefs surrounding them. Written comments from Tribal organizations and feedback from listening sessions also touched on this topic. The *All of Us* Research Program recognizes the importance of honoring Tribal beliefs when handling and storing biospecimens. The Mayo Clinic, which has partnered with the program to store blood and urine samples from *All of Us*

participants, has experience working with AI/AN communities and has also affirmed its commitment to respecting Tribal beliefs surrounding biospecimens.

Currently, the Mayo Clinic flags and sequesters any biospecimens from AI/AN participants. When a participant who identifies as AI/AN withdraws from the program or dies, the Mayo Clinic does not destroy their biospecimens; no action is taken until the participant or, in the case of death, participant's family specifies their preferences for handling the biospecimens.

Going forward, the program will continue to develop a plan with the Mayo Clinic that aligns with and respects a participant's or the specific Tribe's beliefs, an issue raised during a listening session. This plan currently includes the option for an interTribal blessing ceremony to be conducted by elders, traditional healers, or other appropriate Tribal community members on samples from participants who request it during withdrawal. After the blessing ceremony, those samples will be appropriately destroyed. Should *All of Us* enter into a partnership with a specific Tribal Nation, agreements about the handling of biospecimens according to that Tribe's preferences can be developed.

Training for researchers

The *All of Us* Research Program recognizes and appreciates that many Tribal Nations and individuals are hesitant to participate in biomedical research, due to historical transgressions by the U.S. federal government and researchers at academic institutions, and recognizes concerns about research that perpetuates stereotypes and creates stigma against AI/AN populations. These concerns were raised during both consultation and listening sessions. *All of Us* is committed to investing in training for researchers that focuses on recognizing past harms, promoting cultural sensitivity, and avoiding stigmatizing research of AI/AN populations. Currently, as noted in the introduction, the program is withholding all AI/AN data from research use. The program will implement a specific training module in the *All of Us* Research Hub about the use of AI/AN data. The content of this training and requirements for researchers will be discussed with Tribal leaders before being implemented. The program also plans to draw on expert guidance to develop a template of appropriate language for researchers that can be used in publications, addressing how to speak to the issues of AI/AN self-identification.

Longer-term plans may include hosting a workshop about preventing stigmatizing research of AI/AN populations, cultural sensitivity, and past harms. Tribal leaders have recommended that the program seek input from programs with existing and meaningful engagement with Tribal Nations, such as the Tribal Epidemiology Centers (TECs) and Native American Research Centers for Health (NARCH), to ensure that appropriate topics and discussions are addressed.

Data Access, Use, and Protection

Through the consultation process, Tribal leaders have expressed deep concern about the use of data for secondary (future) research that might lead to stigmatization of the AI/AN community and concerns about the *All of Us* Research Program's adherence to the requirements in the [Federal Policy for the Protection of Human Subjects \(the Common Rule\)](#). Tribal leaders have asked that Tribal Nations have clear and accurate information on the process and oversight of the secondary uses of their members' data.

Participants attending *All of Us* listening sessions and Tribal organizations (via written comment) expressed similar concerns.

The Common Rule

The *All of Us* Research Program is considered to be human subjects research and thus subject to the requirements of the Common Rule. The *All of Us* Research Program activities that fall under the Common Rule include the operations of the awardee partners and federal personnel for the enrollment and recontact of a one-million-plus person participant cohort, collection and maintenance of data and biospecimen resources, and establishment of an online research platform where data can be analyzed.

Due to the timing of the program's launch, the program is subject to the requirements of the pre-2018 Common Rule. However, the program has taken steps to align its operations as much as possible with the intent of the 2018 update. For example, the *All of Us* Research Program uses a [single program-wide IRB](#) to review all protocol changes and participant-facing materials, including consent documentation and engagement materials.

All data and biospecimens provided through the research platform will be de-identified in compliance with the standards of the Common Rule and related guidance. Currently, for the purposes of the Common Rule, NIH does not consider genomic data, including whole genome sequence data, that is de-identified to the program's standards to be information from which the identity of the subject is or may readily be ascertained. The *All of Us* Research Program does not plan to share any readily identifiable data or biospecimens.

The purpose of the *All of Us* Research Program is to develop a database and auxiliary resources for secondary research. As such, and according to both the mandate of the program and its core values, appropriately de-identified data and specimens will be shared with researchers who are awarded access.

At this point in time, there are no planned uses of identifiable data or biospecimens (according to the standards of the Common Rule) for secondary research. If it determined identifiable data from American Indian or Alaska Native participants would be released to select researchers, the process to determine access pathways and principles would include Tribal consultation.

Broad consent and secondary research

All data and biospecimens provided through the research platform will be de-identified in compliance with the standards of the Common Rule, and *All of Us* does not plan to share any readily identifiable data or biospecimens. *All of Us* currently does not seek broad consent for secondary research as defined in the 2018 Common Rule. That type of broad consent is required only when the secondary use will consist of readily identifiable data and samples. Data types are deemed "identifiable" if there is a significant chance that the data, either alone or in combination with other data, would render the identity of an individual participant readily discoverable. In other words, identifiability is less about an individual data element than about the data in context. Nevertheless, certain information, such as a name or Social Security number, would be inherently identifiable. In addition, certain other data elements, such as narrative fields from electronic health records, where such identifiers are more likely to be featured,

are deemed potentially identifiable and must be heavily altered before becoming eligible to be shared with researchers.

The discussion of identifiability at the individual level, however, does not take into consideration the concern over group identifiability. In most cases, creating definable groups within data is a crucial part of the research process. In some cases, allowing for subpopulations to be singled out can put these subpopulations at risk for stigma and discrimination. The *All of Us* Research Program actively works to prevent, to the extent possible, the conduct of any stigmatizing or discriminatory research with the *All of Us* resources. The program also acknowledges that some groups, communities, and other defined subpopulations, even where stigma or discrimination may be a risk, may wish to make their group, community, or subpopulation discoverable within the dataset in the interests of promoting research that could address health disparities. However, particularly where there are historical reasons contributing to elevated risk of stigmatizing or discriminatory research, *All of Us* will look for guidance from those groups, communities, and subpopulations, including Tribal Nations, for how to approach group identifiability and appropriate harm mitigation strategies.

The program recognizes that there is a concept of broad consent that is not fully accounted for by broad consent as defined by regulation. The program acknowledges that it is requesting broad consent from participants according to the conceptual interpretation, rather than the specific regulatory provision in the 2018 Common Rule. However, the *All of Us* consent does notify potential research participants that their data and samples will be made available for all types of other biomedical and health-related research protocols in such a way that these data and samples are not readily identifiable. Such secondary use of de-identified data and samples is not considered human subjects research. The program is eager to work with Tribal Nations to make sure that Tribal leadership and potential participants understand this part of the consent process.

Data access

Participant data is stored in the [All of Us Research Hub](#). *All of Us* data is hosted on a secure platform where the activity of researchers is tracked and subject to audits. Access to the data is divided into three tiers:

- **Public:** Anonymized, aggregate-level data that poses negligible risks to the privacy of research participants. The [Data Browser](#), available to the general public, displays aggregate (i.e., compiled) de-identified participant data. Only this aggregate-level data is available, and it can be accessed without logging in to the *All of Us* Research Hub.
- **Registered:** Data that pose a minimal risk to the privacy of research participants. This tier provides access to de-identified individual-level data that can only be accessed in the [All of Us Researcher Workbench](#) by authorized users, who are provided a unique login and password. All access is logged and may be audited for compliance with the [Data User Code of Conduct](#). This tier is available only to authorized users who sign the *All of Us* Research Program Data User Code of Conduct and complete research ethics training. This policy helps the program further protect participant privacy and ensures that only approved researchers can access the Researcher Workbench data for research purposes.
- **Controlled:** De-identified data that pose some risks to the privacy of research participants. This tier provides authorized users access to more sensitive data. *All of Us* will define a path to user

authorization that appropriately establishes user trustworthiness, with requirements that build on those for the registered tier.

Registered Tier data can be accessed by any individual who has completed the steps to become an authorized user. Initially, access to any nonpublic *All of Us* data will be available only to authorized users with an eRA Commons ID and an Institutional Data Use and Registration Agreement Code of Conduct signed by their institution. This requirement will ensure institutional engagement in any research using nonpublic *All of Us* resources. After an initial "beta" period, access to Registered Tier data will be broadened to include researchers without an institutional affiliation, as well as community scientists. The Controlled Tier data, once available, will include more stringent access requirements to ensure appropriate protection for the release of more granular – and hence more sensitive – data.

All of Us values transparency and will require all studies that propose to use *All of Us* Research Workbench data to develop a clear and accurate description of the research's purpose and submit it prior to beginning the research. The descriptions of an applicant's research project will be posted publicly, as required by the [21st Century Cures Act](#). This will allow anyone, including participants and members of the public, to request that the program review a specific workspace for potential violations of the Data User Code of Conduct or flag a study as potentially stigmatizing. *All of Us* acknowledges the potential that resources collected in good faith could be used to the detriment of some groups. The program has established a [Stigmatizing Research Policy](#) to prevent or minimize resource use with the potential to stigmatize. The *All of Us* Resource Access Board (RAB) will not review all research uses but will oversee the use of the *All of Us* data resources, monitor workspaces for potential violations of the Data User Code of Conduct, and review and adjudicate potential violations flagged by the public or other authorized users. The RAB includes *All of Us* participant ambassadors and members from a diverse and broad background with ethical, legal, and social implications and/or bioethics expertise, as well as experience working with or advocating for underrepresented groups. The RAB is empowered to engage additional subject matter experts if it does not have appropriate expertise for a given research project review. The RAB also includes an AI/AN representative.

The program is considering developing a small task force with five to seven AI/AN subject matter experts who can be called upon to review a research proposal focused on AI/AN data. If a particular research proposal is not deemed consistent with the values of the program, the applicant will not be able to proceed with the research.

Disciplinary actions for violations of the Data User Code of Conduct

Community members indicated that there is a need for disciplinary action by the program if a researcher violates the terms for using *All of Us* data. *All of Us* takes the privacy and respect of all its participants very seriously and has developed policies and procedures to ensure that participant data are accessed and used in accordance with the *All of Us* consent, policies, and protocol. Before a user may access and/or work with the data in the Researcher Workbench, he or she must sign the Data User Code of Conduct and complete research ethics training, to be renewed annually. Failure to comply with the terms of the Data User Code of Conduct may result in termination of the user's Researcher Workbench account, as well as other sanctions, such as having the violator's name and affiliation posted on a public *All of Us* Research Program webpage. The program is also considering

implementing a policy to notify the NIH TAC whenever research violations pertaining to AI/AN data are identified.

Emphasis on data protection, security, and privacy

During consultation, Tribal members indicated that data privacy is of critical importance to Tribal communities. Tribal leaders, Tribal organizations, and community members in listening sessions expressed concerns about the security of participant-provided data, participants' right to privacy, and potential misuse and exploitation of the data. Security and privacy are of highest importance to the *All of Us* Research Program and are part of its [eight core values](#). Extensive policies, governance, and technical safeguards have been developed and implemented by the program, with systems closely monitored by a dedicated data security team, to ensure that participant data are appropriately protected. Specifically, *All of Us* and/or its awardees:

- Follow all applicable federal, state, and local laws and rules for keeping data safe;
- Have strict policies and procedures to prevent misuse of data; (see the [Privacy and Trust Principles](#) and [Data Security Policy Principles and Framework](#))
- Have a [Certificate of Confidentiality](#) from the U.S. federal government, to help the program fight legal demands (e.g., subpoenas) to give out information that could identify a participant;
- Continuously monitor and test the security of its databases;
- Will alert participants immediately if there is a risk to their privacy because of a known data breach;
- Store data on a secure, encrypted platform that is routinely updated;
- Require researchers to agree to follow data use rules, specifically stating they will not try to identify participants;
- Do not allow researchers to download data.

Interaction with Tribal IRBs or designees

Tribal Nations have asked that the *All of Us* Research Program implement steps for Tribal oversight of any research conducted with Tribal citizens or on Tribal lands. Currently, *All of Us* awardees are prohibited from focusing specifically on AI/AN individuals for recruitment or conducting any human subjects research on Tribal lands for the program. *All of Us* will recruit on Tribal lands only in cases where it has a partnership agreement in place with that specific Tribe. *All of Us* acknowledges that the program is unable to verify Tribal citizenship, which is determined by Tribes themselves, as emphasized by Tribal leaders during consultation. The program acknowledges and agrees with the need for special considerations regarding AI/AN communities, respects Tribal sovereignty, and seeks to honor applicable Tribal laws and processes with approval from Tribal Nations and their respective IRBs. The *All of Us* IRB follows the regulations and guidance of the [HHS Office for Human Research Protections](#) for all studies, ensuring that the rights and welfare of research participants are overseen and protected uniformly. In addition, the *All of Us* IRB operates under the [NIH Single IRB Policy for Multi-site Research](#), which generally requires a single IRB of record for multi-site studies that are conducting the same protocol to enhance and streamline the IRB review process so that research can proceed efficiently without compromising ethical principles and protections for research participants.

However, there are exceptions, such as if the supporting federal department or agency were to decide and document that the use of a single IRB would not be appropriate for a particular context, or where review by the proposed single IRB would be prohibited by a federal, Tribal, or state law, regulation, or policy. In cases where the program determines, documents, and enters into a contractual agreement with a Tribe, the Tribe will work with *All of Us* to determine how additional Tribal IRB review will occur.

Some Tribal leaders have requested that *All of Us* work with the Indian Health Service (IHS) IRBs when overseeing AI/AN research. In any partnership with a Tribal Nation, the Tribe will determine which IRB is appropriate, and the *All of Us* IRB will seek to work collaboratively with their designee (such as the IHS IRB) regarding oversight of any research conducted with Tribal citizens or on Tribal lands in the future. Within a partnership with a Tribe, the Tribal IRB or its designee may have more restrictive policies, and the program would work to abide by such rules and processes. *All of Us* is open to providing resources for partnering Tribes that may not have their own IRBs, a concern brought up during a listening session.

Governance Involvement

During consultation, Tribal leaders and members repeatedly emphasized the importance of including AI/AN individuals as governance members to ensure Tribal representation within the groups charged with overseeing the program. Tribal leaders and Tribal organizations reiterated the importance of Tribally guided research and called for Tribal representation in *All of Us* governance to better promote the interests of AI/AN communities and safeguard against stigmatizing research.

Inclusion of AI/AN members in *All of Us* governance bodies and IRB

All of Us strives to ensure its governance bodies reflect the diversity of its participants and appreciates the need for more AI/AN representation. As part of its emphasis on transparency, *All of Us* has made its [governance structure](#) public. Currently, the program has AI/AN members on its RAB, Advisory Panel, and Biospecimen Access Policy Task Force.

The program acknowledged Tribal leaders' concerns that the IRB did not have an AI/AN member and has added an AI/AN member to its IRB. In addition, the *All of Us* IRB has a process in place to call on subject matter experts in instances that would require additional AI/AN expertise and perspective in order to provide an appropriate and thorough review.

Desire for *All of Us* to engage and include AI/AN researchers

Tribal leaders and members called for *All of Us* to especially support and promote AI/AN researchers. The program strongly encourages AI/AN researcher participation and will aim to collaborate with Tribal leaders to hold presentations on how to use the *All of Us* Research Hub at Tribal events, AI/AN-focused scientific conferences and workshops, and webinars.

Sensitive Data and Preventing Re-Identification

Genomic sequencing and research

The inclusion of genomic research is an important part of the *All of Us* Research Program. By understanding the relative contributions of genetic factors, social determinants of health, the environment, and changes over time, researchers can better understand the causes of disease, determine which treatments are most effective, and uncover factors that reinforce resilience and health. However, *All of Us* has heard and understands the concerns Tribal leaders expressed during consultation and that AI/AN communities raised outside of consultation. Tribal leaders also stressed the importance of ensuring AI/AN communities have an appropriate understanding of the potential benefits and risks of genomic research before deciding to participate. Related issues, such as the handling of biospecimens, are also important areas of concern and are discussed earlier in the report.

Currently, no genomic data from any AI/AN participants are being generated or returned by the *All of Us* Research program. *All of Us* wants anyone who is part of the program to be fully informed on the risks and potential benefits of genomic sequence analyses before agreeing to participate or receiving back genomic information. For AI/AN participants, *All of Us* understands that harm to the group and not just the individual is an important consideration. Tribal leaders also expressed specific concerns about Tribal affiliation possibly being identifiable using genetic data (although it is important to note that identifying Tribal affiliation in that way would be a violation of the Data User Code of Conduct). It was important for the program to hear these concerns through official Tribal consultation and listening sessions, and *All of Us* is committed to providing more information to current AI/AN participants prior to proceeding in the program and to potential participants prior to enrollment in the program.

Given these concerns, the program has temporarily delayed sequencing the DNA of current participants who identified as AI/AN and who have already consented to be part of *All of Us*. Instead, *All of Us* will first release this report and provide supplemental communications to current participants about Tribal consultation and general concerns and beliefs about genomics research that have been expressed by some Tribes, so that participants can decide whether to continue their participation in the program.

All of Us has developed a new genomic consent module that will help participants better understand DNA sequencing and determine what (if any) genetic information about themselves, such as ancestry- or health-related reports, they want to receive. However, the program seeks to respect Tribal sovereignty and so, as described in the section "Genomic sequencing and research", will inform AI/AN individuals of the outcomes of Tribal consultation prior to sequencing the DNA of any AI/AN participants. Information about the results of consultation will also be available to potential participants before they make a decision about enrolling in the program or participating in specific activities such as contributing a sample for genomic sequencing.

Should AI/AN participants wish to continue participating in the program and have their genomic results returned to them, the program will provide genetic counseling resources, as offered for all participants, to help them interpret their genomic results.

All of Us will include this process and the kind of information that Tribal members could receive in any discussions with Tribes considering partnership in the program prior to signing agreements. Also, any genomic or other data generated, as well as how that data are accessed and used, would be part of an agreement with that Tribe.

Past abuses have made genomic data an especially sensitive issue for Tribal communities. It is the intention of *All of Us* to work with Tribal representatives to make sure that the risks and benefits – for the individual and the community – of using this kind of data to improve human health are understood by AI/AN participants who consent to participate. Such dialogue will help individual participants make thoughtful, informed decisions.

Sample sizes and re-identification

During the consultation sessions, Tribal leaders raised concerns regarding the risks associated with small sample sizes and the potential re-identification of AI/AN members and communities. Community members participating in listening sessions also emphasized this issue, particularly with the small populations found in certain ZIP codes. The program has policies in place to help mitigate that risk and a dedicated data science team that constantly tests the risk of re-identification as new data become available. Practices were also put in place to lower the risk of re-identification for groups that were deemed to be potentially at higher risk for re-identification. The Data User Code of Conduct also explicitly prohibits any attempt to re-identify individuals and prohibits linking *All of Us* data with external data at the individual participant level. To further reduce any remaining risk of re-identification, *All of Us* is exploring technological solutions to alert for any large external dataset uploads that may warrant further monitoring.

In addition, the *All of Us* Committee on Access, Privacy, and Security is charged with ensuring that the program's core values of protecting participant privacy, securing participant data, and building trust are extended to the establishment and maintenance of its scientific resources. This committee will be conducting a risk assessment for re-identifiability within the small sample of AI/AN individuals currently enrolled in the program. Should a participant withdraw from the program before their data are ever released to researchers on the Researcher Workbench platform, *All of Us* will retain only the minimal amount of data required by law and regulation. These data will not be released to researchers for use in studies.

Should a participant withdraw from the program after their data are already released on the platform, that data will remain part of existing workspaces but will be deleted from all new datasets in the future. No new studies on that data will be allowed. However, the data must be maintained within an archive to validate studies already done on that dataset. Participants also have the option to allow their data and samples to be kept by the program so that they can continue to be shared with researchers. Tribal affiliation will never be released to researchers unless *All of Us* has an explicit agreement with a specific Tribe, in current or archived datasets.

Additional Considerations

Publications and stigmatizing research

Tribal leaders and community members raised concerns regarding the potential for stigmatizing research, both within AI/AN communities generally and with specific Tribes through access to Tribal affiliation. Tribal members expressed a desire for safeguards and oversight of publications to protect against such research.

The *All of Us* Data User Code of Conduct, which all registered data users must sign, has specific requirements for publications using *All of Us* data. Specifically, users must acknowledge the program in the publication and agree to deposit an electronic version of the final, peer-reviewed manuscript on the National Library of Medicine's PubMed Central, in accordance with the provisions stipulated in the *All of Us* [Publication and Presentation Policy](#).

The program does not currently have a process in place to review manuscripts before publication but is considering enacting a request for publication review. While *All of Us* works through internal discussion, the program is considering a mechanism to notify the NIH TAC when AI/AN-specific scientific findings are published from research using the *All of Us* dataset. The program also plans to 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) may be included in partnership agreements with Tribes.

Collaboration with Tribal Epidemiology Centers and Native American Research Centers for Health for engagement strategies

Tribal leaders during consultation and community members at listening sessions suggested that *All of Us* leverage the experience and knowledge of TECs and NARCH. *All of Us* appreciates and welcomes the opportunity for engagement and alliance with these entities. *All of Us* will explore options for collaborating with TECs and supporting their capacity to advance AI/AN public health. In addition, *All of Us* could collaborate with the TECs and NARCH program office and recipients to develop training workshops on using the *All of Us* Researcher Workbench for AI/AN researchers and on AI/AN research priorities for interested researchers.

Need to ensure plain language and terminology

The program heard concerns from Tribal leaders regarding the need for plain language and terminology for *All of Us* communications with participants and the AI/AN community at large. The program agrees with this sentiment and has already written all outreach and enrollment materials at the middle-school reading level, generally at the seventh-grade level. This practice aligns with the program's core values and ensures that these materials are easily understood by the greatest number of U.S. residents.

Need to accommodate limited computer access

All of Us acknowledges that members of many communities, including AI/AN communities, may not have access to a computer, tablet, or smartphone. Currently, all individuals must sign up electronically, which can limit participation by some communities. If the program were to enter into a partnership with a specific Tribal Nation, the program would consider implementing some of the following strategies that have proven successful with current partners:

- *All of Us* has kiosks available at participating health clinics where individuals can enroll.
- Individuals can access tablets at the program's many Health Care Provider Organization (HPO) sites around the country. Individuals must create their own accounts themselves, but trained program staff at HPO sites can assist them.
- The [All of Us Journey Exhibit](#) and the [All of Us Mobile Education and Enrollment Center](#) visits communities nationwide to raise awareness of the *All of Us* Research Program. Both exhibits

feature hands-on activities for visitors to learn about research, precision medicine, and the opportunity to enroll in *All of Us*. The *All of Us* Mobile Education and Enrollment Center is also equipped for visitors who join the program to provide physical measurements and blood and urine samples on board.

Recommendations for Further Consultation and Informational Sessions about *All of Us*

All of Us is committed to respecting Tribal sovereignty and will continue to work with Tribes on a government-to-government basis to address concerns through dialogue and additional consultation. The program has heard from Tribal leaders and acknowledges that it did not pursue consultation with Tribes early enough. The program needed to provide more detailed and clear information about the policies for which it was seeking input, as well as more time for Tribal leaders to discuss relevant issues with their technical advisors and community members. The program acknowledges that asking for input about a large and complex program like *All of Us* during a consultation that included multiple other complicated topics did not give Tribal leaders enough time to consider the issues and provide meaningful input. *All of Us* also heard from Tribal leaders and Tribal organizations via written comment that all parts of NIH need to be clearer about the timeline for consultation and Tribal input and provide clear deadlines for Tribal input so that Tribes can expect timely responses to critical issues.

The NIH Tribal Health Research Office is located in the Division of Program Coordination, Planning, and Strategic Initiatives in the NIH Office of the Director. THRO was created in recognition of the importance of ensuring meaningful input from and collaboration with Tribal Nations on NIH programs and policies. THRO is currently developing an NIH Tribal Consultation Policy with the NIH TAC, to align with the HHS Tribal Consultation Policy and provide guidance specific to NIH's activities and configuration. During the *All of Us* Tribal consultation, the importance of having dedicated liaisons with Tribal Nations was raised, especially in implementing effective consultation. *All of Us* has recently established a Tribal engagement team in order to better and more efficiently work to address Tribal concerns.

Honesty and transparency are key values of the *All of Us* Research Program and are critical to building a trusting and respectful relationship with Tribal Nations. *All of Us* is committed to these principles. *All of Us* also acknowledges Tribal leader feedback regarding the need to conduct more in-depth informational sessions about the program and is exploring these events for the future. The *All of Us* [Tribal Engagement website](#) will be updated with any additional informational sessions for sharing details on the program once they become available. This report is intended to reflect the decisions and policies of the program at the current time, and *All of Us* will provide updates to this report via the [Tribal Engagement website](#). In addition, as noted previously in this report, the program is exploring options for an AI/AN research priorities workshop and demonstrations of the Data Browser and Researcher Workbench at Tribal events.

The *All of Us* Research Program greatly appreciates the feedback and concerns raised by Tribal leaders about the program and looks forward to continuing to work with Tribes on a government-to-government basis to address these concerns.

Acknowledgements

The *All of Us* Research Program would like to extend its sincere gratitude to the many groups and individuals who participated in this Tribal consultation. *All of Us* appreciates the invaluable feedback given by Tribal leaders and members who attended the *All of Us* consultation and listening sessions or provided written comments. The program would also like to acknowledge the assistance and support of partners and organizations who provided *All of Us* with a forum at which to receive feedback. *All of Us* also benefited from the contract support of Kendra King Bowes and the rest of the team at Miami Environmental & Energy Solutions.

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