



# Policy

## Respectful Research Involving American Indian and Alaska Native (AI/AN) Populations

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### Background

American Indian and Alaska Native peoples have complex historical and political circumstances that require attention when considering the intersecting paths of these communities and the scientific enterprise. It is important, in the course of these considerations, to recognize that American Indian and Alaska Native (AI/AN) individuals and communities have suffered injustices at the hands of the scientific community, the U.S. government, and society at large. These injustices have resulted in stigma, discrimination, marginalization, disenfranchisement, and other individual and group harms affecting AI/AN populations and Tribal Nations. The *All of Us* Research Program appreciates that these historical injustices do not define the identities of AI/AN individuals, Indigenous communities, and Tribal Nations, nor do they diminish their rich histories and cultures. However, the program acknowledges the role its parent agency and agency antecedents, as well as members of the agency's extended scientific ecosystem, played in such transgressions. In addition, *All of Us* recognizes its missteps in the early phases of the program, and it has committed itself to efforts that promote respectful, equitable, and responsible inclusion of AI/AN individuals and populations in *All of Us* activities.

As a part of these efforts, the program understands that the complex social, cultural, historical, and political factors at play warrant a specific and focused approach to the use of data and other resources where AI/AN populations are concerned. The program's approach must respect Tribal sovereignty and must incorporate relevant norms and values to ensure research conducted with *All of Us* resources is culturally sensitive and conforms to Indigenous customs, cultural and traditional practices, and Tribal laws.

Furthermore, the *All of Us* Research Program's approach to respectful and responsible use of data and other resources must be informed by ongoing dialog and input from AI/AN communities and Tribal Nations to ensure the resulting program practices are conceived of, implemented, and shared appropriately. To these and other ends, the program entered into formal Tribal consultation in 2019 to respectfully engage with Tribal Nations. This consultation resulted in a set of commitments from the program to Tribal Nations, as well as a framework for the appropriate engagement of individuals who self-identify as AI/AN in program activities.

These commitments and framing principles are captured in the [All of Us Research Program Tribal Consultation Final Report](#) and form the basis for this policy.

## Findings and Analysis

The program has established policies that, while intended generally, are of particular relevance for the appropriate use of data and other resources for research that concerns AI/AN populations. These include:

- The [All of Us Policy on the Ethical Conduct of Research](#), which extends the ethical principles of beneficence, justice, and respect for persons to the secondary use of human research data that is not readily identifiable; and
- The [All of Us Policy on Stigmatizing Research](#), which defines and prohibits the conduct of stigmatizing research using resources from the *All of Us* Research Program.

However, during the consultation process, in listening sessions, and via written feedback, Tribal leaders, intertribal organizations, and community members raised important points regarding additional, specific concerns for AI/AN populations, including:

- Respect for Tribal customs and rituals;
- Appropriate and respectful terminology; and
- Re-identification risks that extend beyond individual participants to AI/AN communities and Tribal Nations.

The program has integrated input gathered during the consultation process to further shape policies and program materials to encourage respectful, responsible use of *All of Us* research resources in ways that attempt to address concerns voiced by Tribal leaders and other interested parties. These adjustments include the stand-alone policy included in this document, as well as an additional clause in the *All of Us* Data User Code of Conduct explicitly requiring compliance with this policy. The program has also made changes to the Responsible Conduct of Research Training to reflect these new materials. Over time, as the relationships between Tribal Nations and the *All of Us* Research Program evolve, the program may adapt these policy requirements to respond to emerging concerns, program developments, or other specified needs.

The increased sensitivity of scientific study with AI/AN populations, including secondary use of data, warrants enhanced scrutiny. To help ensure concerns raised during the consultation process are acknowledged and addressed, and the terms of appropriate resource use are followed, the program may subject research that focuses on and/or draws conclusions about such populations to more frequent audits by the program's Resource Access Board (RAB). While RAB membership currently includes AI/AN representation, the board may wish to engage additional subject matter expertise—in the form of informational sources, advisors or ad hoc members—for certain reviews, and it is empowered and encouraged to do so.

In addition to RAB review, Tribal leaders and community members involved in the consultation process urged the program to leverage additional oversight bodies to facilitate a more unified, agency-wide response to appropriate use. As such, the program may escalate issues to the NIH Tribal Advisory Committee, where direct input from Tribal officials (or their designated representatives) and ready access to agency leadership may galvanize concerted action.

## Policy Statement

In the interests of ensuring responsible and respectful use of *All of Us* resources<sup>1</sup> when focusing on, producing findings specific to, or otherwise singling out AI/AN participants or populations, authorized users of *All of Us* resources agree to abide by the following terms:

**Acknowledgement:** Authorized users acknowledge the scientific community's past transgressions against AI/AN populations and promise to conduct research that recognizes Tribal sovereignty and is respectful of Tribal cultures, knowledge, and values. Encompassed in this promise is the pledge, on the part of authorized users, to take appropriate measures to avoid further harms, including stigmatization. As such, authorized users:

- Must review and abide by the terms of the [All of Us Data User Code of Conduct](#), the [All of Us Policy on Stigmatizing Research](#), the [All of Us Policy on the Ethical Conduct of Research](#), and all other relevant program policies and agreements.
- Must be up-to-date on their Responsible Conduct of Research (RCR) Training, including any additional training modules required for specific use cases.
- Must agree to use respectful and appropriate language and preferred terminology when discussing AI/AN individuals, groups, and communities and all information related thereto.
- Must **NOT** conflate political, social, and biological concepts, particularly when evaluating participants' genetic similarity to populations with inferred Indigenous American genetic ancestry and drawing conclusions based on such evaluation.
- Must **NOT** use *All of Us* resources, either alone or in combination with other data or resources, for political or Tribal enrollment purposes.
- Must **NOT** attempt to re-identify AI/AN individuals or groups or attempt to re-identify the Tribe(s) to which such individuals or groups belong or the region from which they come.
- Must **NOT** use external data or materials that contain personally identifiable information (PII),<sup>2</sup> protected health information (PHI),<sup>3</sup> or identifiable private information (IPI),<sup>4</sup> including information about Tribal affiliation, in conjunction with *All of Us* resources.

**Legal and Regulatory Compliance:** Authorized users must abide by all relevant federal, state, and local laws and regulations applicable to the research.

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<sup>1</sup> Such as research, operational, and other program resources, including, but not limited to, *All of Us* data, biospecimens, and program-mediated participant recontact

<sup>2</sup> Personally Identifiable Information: Information that can be used to distinguish or trace the identity of an individual (e.g., name, social security number, biometric records, etc.), either alone or when combined with other personal or identifying information, that is linked or linkable to a specific individual. (adapted from 2 CFR § 200.1)

<sup>3</sup> Protected Health Information: Individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. (adapted from 45 CFR § 160.103)

<sup>4</sup> Identifiable Private Information: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (adapted from 45 CFR § 46.102)

**Enhanced Oversight:** Authorized users agree to additional scrutiny when research focuses on or draws conclusions regarding AI/AN populations.

- Workspaces associated with such research may be subjected to additional audits by the *All of Us* Resource Access Board, which may engage ad hoc members who are subject matter experts and/or Tribal officials for the purposes of such reviews.
- Violations of *All of Us* policies where the outcome of the violation may have bearing on AI/AN individuals, Indigenous communities, and/or Tribal Nations, may be reported to the NIH Tribal Advisory Committee or other relevant oversight bodies and, as a consequence, may incur additional penalties.

**Additional Questions:** Authorized users should contact the *All of Us* Resource Access Board by emailing [support@ResearchAllofUs.org](mailto:support@ResearchAllofUs.org) with requests for any clarifications and guidance to aid in their compliance with this and other program policies.