

NATIONAL INSTITUTES OF HEALTH

Tribal Consultation Report: Disposition of Biospecimens Collected from Tribal Populations

NIH Office of Science Policy
Office of the Director
National Institutes of Health

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Executive Summary

To respect Tribal sovereignty and the government-to-government relationship between the Federal Government and Indian Tribes, NIH initiated formal Tribal Consultation in October 2024 to identify options for the disposition of biospecimens collected from American Indian and Alaska Native (AI/AN) Tribal members that would be respectful and culturally acceptable for Tribes and that NIH can implement. The Tribal Consultation was initiated on October 30, 2024, with a 'Dear Tribal Leader and Urban Indian Organization Leader Letter' (see Appendix 1) and a 'Framing Letter.' A virtual Consultation was held on December 5, 2024. The biospecimen disposition options presented by NIH at the December 5, 2024 Consultation were developed with input from NIH's Tribal Advisory Committee (TAC). Three of the options covered the return of de-identified biospecimens to Tribes, while two additional options presented alternatives to return, namely NIH stewardship of the biospecimens and NIH disposition of the biospecimens in a culturally sensitive manner. Options were not meant to be mutually exclusive.

At the Consultation, Tribal representatives asked for clarity on: 1) whether the options were meant to apply to new collection of biospecimens from Tribal populations or to already collected biospecimens; 2) whether NIH or Tribe(s) would bear the costs for the selected option(s); 3) how NIH might proceed when Tribal affiliation was unclear or multiple Tribal affiliations were or might be present; and 4) what NIH stewardship might mean. No further questions were submitted to NIH following the Consultation. Responses are below under "Tribal Input and NIH Responses".

Tribal leaders expressed support for the five identified options. NIH appreciated the opportunity to meet with Tribal representatives to discuss these options at the Consultation and looks forward to finalizing these options in partnership with Tribes.

Background

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The NIH invests most of its \$48 billion budget in medical research for the American people. Over 80% of NIH's funding is awarded for extramural research, largely through roughly 65,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state. In addition, approximately 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in NIH laboratories, most of which are on the NIH campus in Bethesda, Maryland.

NIH is a component of the U.S. Department of Health and Human Services (HHS) and is composed of the Office of the Director and 27 Institutes and Centers, many of which have an organ- or disease-specific focus. The Office of the Director is the central office at NIH and is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all NIH components. In the Office of the Director, the Office of Science Policy (OSP) develops, analyzes, and implements policies to promote the responsible conduct of research in partnership with researchers, research participants, and the American public. The Tribal Health Research Office (THRO) ensures meaningful input from, and collaboration with, Tribal Nations on NIH policies, programs, and priorities in line with the United States

government's guidelines for the unique legal and political relationship between the United States and American Indian and Alaska Native (AI/AN) Tribes and the [HHS Tribal Consultation Policy](#).

NIH has a responsibility to be good stewards of public funds, funding high-quality research and protecting study participants. Core to achieving this responsibility is respect for participant preferences regarding their participation in research, ensuring that our work together is meaningful for them, their health, and the health of their communities. NIH recognizes that Tribal Nations have passed Tribal research laws and ordinances pertaining to biospecimens and, in keeping with the intent to honor participant choices, initiated this process of Tribal Consultation to identify respectful and supportable options for the disposition of biospecimens collected from American Indian and Alaska Native (AI/AN) Tribal members.

The NIH OSP and THRO led an effort to develop, review, and refine culturally acceptable and appropriate options for the return of biospecimens collected from Tribal populations. These options were presented to NIH's Tribal Advisory Committee (TAC) at a meeting on August 21, 2024, and again on September 17, 2024, to ensure revised options prepared by NIH were responsive to TAC feedback. NIH then initiated a formal Tribal Consultation process on October 30, 2024, with a 'Dear Tribal Leader and Urban Indian Organization Leader Letter' and a 'Framing Letter' indicating that a virtual Consultation would be held on December 5, 2024.

Consultation Summary

Tribal leaders, AI/AN community members, and NIH staff attended the Consultation. NIH OSP reviewed the potential disposition options for de-identified biospecimens collected from Tribal populations that had been discussed with the TAC and presented in the 'Dear Tribal Leader and Urban Indian Organization Leader Letter' and 'Framing Letter.' NIH stressed that that these options are not necessarily mutually exclusive, and that the intention is to collaboratively identify multiple potential resolutions in partnership with Tribes that NIH can confidently deliver.

The options presented were as follows:

Option A: Direct return of biospecimens to Tribe(s). The Tribe(s) will arrange the return. NIH is poised to assist with return as needed or requested. When de-identified biospecimens are held by NIH and a decision for disposition has been made, the de-identified biospecimens can be returned directly to Tribe(s) if Tribe(s) is able to receive biospecimens per national, state, and local laws and regulations and per Tribal customary practices and regulations.

Option B: Indirect return of biospecimens to Tribally designated third-party institution or organization, as identified by Tribe(s). The Tribe(s) will arrange the return. NIH is poised to assist with return as needed or requested. When de-identified biospecimens are held by NIH and a decision for disposition has been made, de-identified biospecimens can be returned to a Tribally designated third-party institution or organization if the third-party institution/organization is able to receive biospecimens per national, state, and local laws and regulations and per Tribal customary practices and regulations. The third-party institution or organization will work directly with Tribe(s) to identify and implement culturally appropriate solutions.

Option C: Indirect return of biospecimens to third-party institution or organization identified by NIH in consultation with Tribe(s) and organized by NIH. NIH will arrange the return. When de-identified biospecimens are held by NIH and a decision for disposition has been made, de-identified biospecimens could be returned to a third-party institution or organization identified by NIH in consultation with Tribe(s) that is able to receive biospecimens per national, state, and local laws and regulations. This third-party institution or organization could work directly with Tribe(s) to identify and implement culturally appropriate disposition practices.

Option D: After consultation with Tribe(s), Tribe(s) designates NIH as steward for biospecimens. When de-identified biospecimens are held by NIH, a decision for disposition has been made, and the Tribe(s) elects to have NIH continue stewardship of the de-identified biospecimens, NIH and the Tribe(s) could develop mutually agreed upon terms for continued stewardship and de-identified biospecimen access, in accordance with federal regulations and NIH policies, and in alignment with Tribal research codes, ordinances, and laws.

Option E: After consultation with Tribe(s), Tribe requests NIH dispose of biospecimens in culturally sensitive manner. When de-identified biospecimens are held by NIH and a decision for disposition has been made, but the Tribe(s) does not select any of the options above, Tribe(s) can instead request that NIH dispose of de-identified biospecimens in a culturally sensitive manner identified through Tribal Consultation as a supportable and respectful option for disposition of de-identified biospecimens in these specific cases.

Following the presentation of these options, NIH asked the following questions, that had been posed in advance in the “Dear Tribal Leader and Urban Indian Organization Leader Letter”:

- Do the proposed options adequately respect Tribal sovereignty?
- Do you have particular concerns that need to be addressed for any of these options?
- Are the proposed options sufficient?
- Are there additional options that should be considered?

As noted in the ‘Dear Tribal Leader and Urban Indian Organization Leader Letter,’ written testimony on official Tribal letterhead was welcomed until January 20, 2025 to the THRO mailbox at NIHTribalConsultation@nih.gov. No written testimony was received.

Tribal Input and NIH Responses

At the Consultation, Tribal Leader(s) identified the following questions.

Theme 1: Retroactive versus proactive selection of options

Tribal leader(s) asked whether these options would be presented to Tribes and Tribal populations—including Urban populations—before the collection of biospecimens or whether these options were meant only for biospecimens that have already been collected from Tribal populations.

NIH responded that as part of its efforts to ensure that the sovereignty of Tribes is respected, the current Consultation was meant to address and identify culturally appropriate and acceptable options for the disposition of de-identified biospecimens already collected from Tribal populations. NIH took note of the interest from Tribal leader(s) in proactively addressing the return of biospecimens before future collection. THRO will consider how this might be accomplished in avenues such as the indigenous data sovereignty policy, future consents, and future MOUs.

Theme 2: Costs

Tribal leader(s) asked whether NIH or Tribe(s) would be expected to bear the cost of the different options.

NIH responded that while THRO will work closely with NIH Institutes and Centers to support their ability to bear costs when possible, each Institute and Center will make individual determinations with respect to their budgetary ability in each situation.

Theme 3: Identifying Tribal affiliation(s)

Tribal leader(s) asked whether the de-identified biospecimens currently held by NIH all had associated Tribal affiliation(s), or, if not, whether Tribal affiliation(s) could be determined. Tribal leader(s) additionally asked what might happen in the case where an individual was affiliated with more than one tribe.

NIH is committed to returning de-identified specimens collected from Tribal populations according to Tribal preferences. Some of these de-identified biospecimens will have known Tribal affiliation(s). Where Tribal affiliation is not clear, NIH will work flexibly with Tribes to ensure acceptable and culturally appropriate solutions are identified. For example, if NIH is aware a de-identified biospecimen was collected from a specific area, NIH could work with all local Tribes to develop an MOU and/or process agreeable to all parties for the appropriate, culturally acceptable return of these biospecimens. In the case where all that is known is that a specimen is Tribally associated, NIH might work with larger Tribal associations to understand preferences. Similarly, when a specimen is affiliated with more than one Tribe, NIH will work with all involved Tribes to identify a culturally appropriate and acceptable solution.

Theme 4: Clarifying Option D

Tribal leader(s) asked whether Option D (Tribe(s) designates NIH as steward for biospecimens) meant that biospecimens would be used for other research projects or just stored.

NIH responded that Options D and E were created after feedback from the TAC that return might not be the only option requested by Tribes. In every situation, NIH looks forward to working with Tribe(s) to determine what stewardship means to them and how Tribal wishes would be respected regarding research conducted using Tribal specimens. These wishes might be formalized using data access plans that would spell out issues such as whether the Tribe wanted to be notified when the biospecimens were used or whether the biospecimens would be available only via restricted access.

Additional Input from Tribal-Serving Organizations

No input was received from Tribal-Serving Organizations.

Closing

NIH thanks Tribal leaders for their time and invaluable input on these options for the appropriate and culturally acceptable return of de-identified biospecimens collected from Tribal populations. NIH will take the input received and move towards finalizing and posting the policy on the THRO website. NIH is committed to building strong relationships with Tribal Nations and is grateful for the opportunity for this engagement.

Appendix 1: Dear Tribal Leader Letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

October 30, 2024

Dear Tribal Leader and Urban Indian Organization Leader:

I am writing from the Office of Science Policy (OSP), part of the National Institutes of Health (NIH) under the United States Department of Health and Human Services (HHS), to initiate a Tribal Consultation on *"NIH Disposition of Biospecimens Collected from Tribal Populations."* After discussion with our Tribal Advisory Committee, NIH has developed a set of options for the disposition of de-identified biospecimens collected from Tribal and International Indigenous population members, including return to Tribes. The goal of this Consultation is to finalize options for disposition of de-identified biospecimens that fully respect Tribal sovereignty and cultural sensitivities, including when transfer/return has been requested by a Tribe.

The virtual Consultation will be held on December 5, 2024 from 11am-1pm EST. Please register at <https://osp.od.nih.gov/events/registration-for-tribal-consultation-on-nih-disposition-of-biospecimens-collected-from-tribal-populations/>. I hope you will be able to participate in this discussion on December 5 and/or provide written testimony (recognized by the use of official Tribal letterhead) by January 20, 2025 to the THRO mailbox at NIHTribalConsultation@nih.gov.

NIH is asking for Tribal input regarding options for the disposition of these de-identified biospecimens, to ensure the options finalized for use by Tribes fully respect Tribal sovereignty and cultural sensitivities. The options under consideration, detailed further in the accompanying framing letter, include:

- **Direct transfer/return of de-identified biospecimens to Tribe.** The Tribe will arrange the transfer/return. NIH is poised to assist with transfer/return as needed or requested.
- **Indirect transfer/return of de-identified biospecimens to Tribally designated third-party institution or organization, as identified by Tribe.** The Tribe will arrange the transfer/return. NIH is poised to assist with transfer/return as needed or requested.

- **Indirect transfer/return of de-identified biospecimens to third-party institution or organization identified by NIH in consultation with Tribe and organized by NIH.** NIH will arrange the transfer/return.
- **After consultation with the Tribe, Tribe designates the NIH as the steward for de-identified biospecimens.**
- **After consultation with the Tribe, Tribe requests NIH dispose of de-identified biospecimens in culturally sensitive manner.**

Thank you for your continued partnership and your assistance in helping NIH develop approaches for advancing health in meaningful and respectful ways.

Regards,

Lyric Jorgenson
Associate Director for Science Policy and
Director of the Office of Science Policy
National Institutes of Health