

U.S. Department of Health and Human Services National Institutes of Health Tribal Consultation Policy

The National Institutes of Health (NIH), an operating division of the U.S. Department of Health and Human Services (HHS), is committed to supporting the health of American Indians and Alaska Natives (AI/AN). Through enhanced communication and collaboration between NIH and AI/AN communities, NIH strives to build biomedical research capacity, expand research, and enhance cultural competency and community engagement. NIH and Indian Tribes share the goal to establish clear policies that recognize and respect the government-to-government relationship between the Federal Government and Indian Tribes.

1. Purpose

The purpose of the NIH Tribal Consultation Policy (also referred to as “the Policy” in this document) is to establish an effective, meaningful, and transparent process by which the NIH will engage Indian Tribes in Consultation. The Policy is intended to complement the HHS Tribal Consultation Policy by focusing on NIH-specific issues and replace 2014 NIH Guidance on the Implementation of the HHS Tribal Consultation Policy (<https://dpcpsi.nih.gov/thro/policy>). This Policy will ensure a standard process for all NIH Institutes, Centers, and Offices (ICOs) to follow when conducting Consultation with Indian Tribes.

2. Background

In December 2010, HHS issued a Tribal Consultation Policy which states that before any HHS action is taken that will significantly affect Indian Tribes, Consultation with Indian Tribes will occur To The Extent Practicable And Permitted By Law. The HHS Tribal Consultation Policy called on each HHS Operating and Staff Division to have an accountable process for ensuring meaningful and timely input by Indian Tribes in the development of policies that have Tribal implications (see <https://www.hhs.gov/about/agencies/iea/tribal-affairs/consultation/index.html>). In 2014, NIH released the *NIH Guidance on the Implementation of the HHS Tribal Consultation Policy*, which outlines that NIH supports establishing a transparent process, including clear expectations for timelines and deliverables, to ensure meaningful and timely engagement with Indian Tribes on NIH actions that will significantly affect Indian Tribes.

3. Scope and Applicability

- A. This Policy reflects a commitment of NIH and its ICOs to Indian Tribes. This Policy does not create any right, benefit, or trust responsibility, substantive or procedural, enforceable at law by a party against the NIH, or any person.
- B. This Policy does not waive any Tribal governmental rights, including Treaty rights, sovereign immunities, or jurisdiction. Additionally, this Policy does not diminish any rights or protections afforded other AI/AN people or entities under Federal law.
- C. The United States in accordance with treaties, statutes, Executive Orders, and Supreme Court decisions, has long recognized the right of Indian Tribes to self-governance. Indian Tribes exercise inherent sovereign powers over their members and territory. The United States continues to work with Indian Tribes on a government-to-government basis to address issues concerning Tribal Self-Government and Tribal Treaty and other rights.

4. Definitions

This Policy, including capitalized terms, adheres to the definitions provided in the HHS Tribal Consultation Policy. In cases where NIH operationalizes the definitions differently or has additional defined terms, this Policy provides the definitions below.

- A. **Consultation:** An enhanced form of communication that emphasizes trust, respect and shared responsibility. It is an open and free exchange of information and opinion among parties, which leads to mutual understanding and comprehension. Consultation is integral to a deliberative process, which results in effective collaboration and informed decision making with the ultimate goal of reaching consensus on issues.
- B. **Critical Event:** Planned or unplanned event that has or may have a substantial impact on Indian Tribes. This includes, for example, ongoing, proposed, and current NIH policies, programs, and research activities.
- C. **Indian Tribe:** Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.
- D. **Tribal Official:** Elected or duly appointed officials of Indian Tribes or authorized intertribal organizations.
- E. **Tribal Representative:** Elected Tribal Official acting in his/her official capacity or employee who is designated by an elected Tribal Official, and designated to do so in writing, to represent the Tribe in the discussions of issues and concerns between the

Tribe and the Federal Government. A Tribal Representative also includes a Washington representative of an association representing elected Tribal Officials designated by a Tribal Official to act on their behalf.

- F. **Deliberative Process Privilege:** Privilege exempting the Government from the disclosure of Government agency materials containing recommendations, opinions, and other communications that are part of the decision-making process within the NIH.

5. Policy

- A. Before any action is taken that will significantly affect Indian Tribes, NIH will, To The Extent Practicable And Permitted By Law, undertake Consultation with Indian Tribes. Such actions refer to Critical Events, as defined in this Policy, and may be perceived as either having positive or negative implications for Indian Tribes.
- B. Any time an Indian Tribe(s) or NIH identifies a Critical Event meeting the stated requirements above, NIH will determine whether to initiate Consultation in accordance with this Policy. The extent and duration of Consultation will depend on the magnitude and significance of the identified action. In general, NIH will not initiate a separate Consultation on NIH's budget or related general issues and will instead continue to address these through the HHS regional Tribal Consultation sessions and the Annual HHS Tribal Budget and Policy Consultation.
- C. Consultation is an official government-to-government interaction, initiated by NIH, which emphasizes trust, respect, and shared responsibility. It is a free exchange of information and opinions among NIH and Indian Tribes that leads to mutual understanding and comprehension.
- D. Tribal Consultation does not bind NIH to accept Tribal recommendations and nothing in this Policy waives the Federal Government's Deliberative Process Privilege.

6. Objectives

- A. To standardize the NIH process for initiating Consultation and seeking participation by Tribal Representatives in ongoing, proposed, and current policies, programs, and research activities that impact Indian Tribes.
- B. To establish a minimum set of requirements and expectations with respect to Consultation and participation for NIH and its ICOs .

- C. To establish a process for identifying Critical Events and initiating Consultation by the NIH.
- D. To identify Critical Events where partnerships and the inclusion of Indian Organizations would complement Consultation with Indian Tribes.
- E. To promote and develop innovative Consultation methods with Indian Tribes in the development of NIH policy.
- F. To coordinate with the HHS Divisions/Regional Offices, State agencies, and others as needed to assist Indian Tribes to communicate their priorities through biomedical research.
- G. To charge and hold responsible all levels of management within the NIH for the implementation of this Policy.

7. Consultation Process

- A. **Initiating Tribal Consultation.** A Critical Event may be identified by the NIH and/or an Indian Tribe. Indian Tribe requests for NIH to consider undertaking a Consultation must come from an elected or appointed Tribal Official, or their Tribal Representative(s).
- B. **Consultation Requests.** A Consultation request should be addressed to the Tribal Health Research Office (THRO) in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), Office of the Director, NIH. THRO serves as the central point of contact for Indian Tribes at the NIH. NIH may also request a Consultation with a single Indian Tribe or multiple Indian Tribes.
 - 1. Within two weeks of a request for Consultation from an Indian Tribe(s), the NIH Director, NIH Principal Deputy Director, or their designee will determine whether to initiate Consultation by evaluating and determining whether the action meets the definition of Critical Event as described within this Policy.
 - 2. Within 30 days of NIH's determination to initiate Consultation, the NIH Director, NIH Principal Deputy Director, Institute Director, or their designee will notify the affected or potentially affected Indian Tribe(s) that NIH is initiating Consultation on the Critical Event through a "Dear Tribal Leader Letter" (DTLL). The DTLL shall include:
 - a. An acknowledgement, if the Consultation was requested by an Indian Tribe(s), of the request that initiated the Consultation.
 - b. A description of the Critical Event on which Consultation is sought.

- c. The anticipated mechanism(s) by which Consultation will be achieved (e.g., specially convened teleconferences, face-to-face meetings, HHS regional Tribal Consultation sessions).
 - d. The anticipated timeline and schedule for Consultation.
 - e. Information provided in the DTLL will also be made publicly available on the NIH website and circulated through other mechanisms as appropriate, such as the Federal Register, email notification, and other targeted mechanisms as needed.
- C. **Meetings.** Within 60 days of issuing official notification, NIH may convene a meeting with the affected or potentially affected Indian Tribe(s) to discuss the Critical Event on which Consultation is sought, To The Extent Practicable And Permitted By Law. The date and location of this meeting will be provided in the DTLL and circulated through other mechanisms as appropriate.
- 1. Consultation mechanisms may include, but are not limited to, one or more of the following activities:
 - a. Face-to-Face Meetings
 - b. Virtual Meetings
 - c. Teleconferences
 - d. Webinars
 - e. Correspondence
 - 2. NIH is committed to coordinating with HHS to maximize Tribal Representatives' time and avoid duplications or conflicts with other national Tribal events. Thus, NIH will strive to utilize regularly scheduled meetings such as the HHS Annual Regional Tribal Consultations to engage in Consultation. NIH may choose to engage in a single meeting or multiple meetings to meet the expectations for Consultation, depending on the complexity of the issue, time constraints, and the number of affected or potentially affected Indian Tribes. When possible, the anticipated events for Consultation will be outlined in the DTLL initiating Consultation.
- D. **Input.** NIH welcomes input specific to the Critical Event for which Consultation has been initiated throughout the Consultation period and may request feedback through a DTLL and/or the Federal Register and through the THRO. During the Consultation period NIH may suspend further decisions on the Critical Event and thus no pre-decisional information will be shared with Indian Tribes before the conclusion of Consultation. If NIH receives official correspondence from an Indian Tribe related to the Critical Event during the Consultation period, NIH will acknowledge receipt within 15 business days and provide updates, when possible, on the Consultation process.

- E. **Concluding Tribal Consultation.** The date for concluding Consultation shall be defined in the initial DTLL unless an extension has been explicitly communicated through a subsequent DTLL. Any recommendations adopted by NIH as a result of the Consultation will be tracked by NIH and reported to HHS for inclusion in the HHS Annual Tribal Consultation Report. NIH will publish a Consultation Report described in Section F.
- F. **Annual Reporting.** Within 90 days of the conclusion of Consultation, NIH will publish a Consultation Report describing themes and recommendations heard throughout the Consultation and any NIH plans in response. The Consultation Report shall be provided to the affected or potentially affected Indian Tribe(s) through a DTLL and will be made available publicly on the NIH website. The Consultation Report will include, at a minimum:
1. A description of the Critical Event and the steps taken to initiate a Consultation
 2. A summary of the Consultation process
 3. A summary of the concerns and perspectives raised, or recommendations provided by Indian Tribes during the Consultation process
 4. NIH's responses to stated concerns and/or recommendations; and
 5. A description of any steps to adopt measures or changes recommended by Indian Tribes
 6. Proposed timelines for addressing input provided by Indian Tribes during the Consultation process
- G. **Conflict Resolution.** One goal of this Policy is to enhance NIH-Indian Tribal collaborations in future research. At the request of a Tribal Representative or an NIH representative, unresolved issues or concerns will be addressed, To The Extent Practicable And Permitted By Law, by the NIH. Nothing in the Policy creates a right of action against NIH for failure to comply with this Policy.
- H. **Waivers.** Tribal Representatives should also submit a written communication to the NIH ICO point of contact, with a copy to the THRO, to apply for any waivers from statutory and regulatory requirements that are discretionary and subject to waiver by NIH.

8. Evaluation, Recording of Meetings, and Reporting

- A. NIH will maintain a record of each Consultation, including official correspondences, recordings of relevant meetings (if available), and meeting materials. Consultation Reports will be publicly available on the NIH website. All national and regional consultation meetings and recommended activities shall be formally recorded, and summaries made available to Indian Tribes through the NIH website and upon request.

- B. NIH will assess, on an ongoing basis, whether the intended purpose of Consultations was achieved and will take steps to solicit recommendations to improve the Consultation process. At a minimum, NIH will conduct an Annual Consultation to consult with Indian Tribes on the Consultation process. Every Consultation session will also include evaluation components for receipt of verbal and written comments from participating Indian Tribes to obtain immediate feedback on the consultation process for the consultation session conducted.
- C. NIH will also seek Tribal feedback to assist in evaluating the implementation and effectiveness of the NIH Tribal Consultation Policy and utilize comments to determine whether amendment to the Policy may be required.

9. Roles in the NIH Tribal Consultation Process

- A. The NIH [Institutes, Centers, and Offices \(ICOs\)](#): The ICOs work with the Office of the Director, particularly the Tribal Health Research Office, to assist in identifying Critical Events that may result in NIH initiating Tribal Consultation, and are responsible for implementing this Policy.
- B. NIH [Tribal Health Research Office \(THRO\)](#): Within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the NIH Office of the Director, THRO acts as the central coordinating office on Tribal health research issues and works with the ICOs to gather meaningful and timely input from Indian Tribes on NIH policies, programs, and activities.
- C. [Tribal Advisory Committee \(TAC\)](#): TAC is an external advisory group that provides recommendations to the NIH and may assist NIH in planning and coordinating Tribal Consultation sessions. TAC comprises representatives of the 12 geographic areas served by the Indian Health Service (IHS) and one representative for each of five National at-large Tribal member positions.

10. Effective Date

This Policy is effective as of March 1, 2022 and applies to Consultations initiated after this date.

Contact

For questions regarding this Policy, please contact:

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