

NIH Intramural Policy on Research Involving AI/AN Persons, Their Data and Biological Materials

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August 27, 2025



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Who am I

- Physician-scientist that now lives in the research oversight world
- Director of the Office of Human Subjects Research Protections, within the Office of Intramural Research at NIH



Why develop a policy?

- Sovereign nations within the US
- Laws and culture should be respected
- History of exploitation in research
- NIH has not always done this well

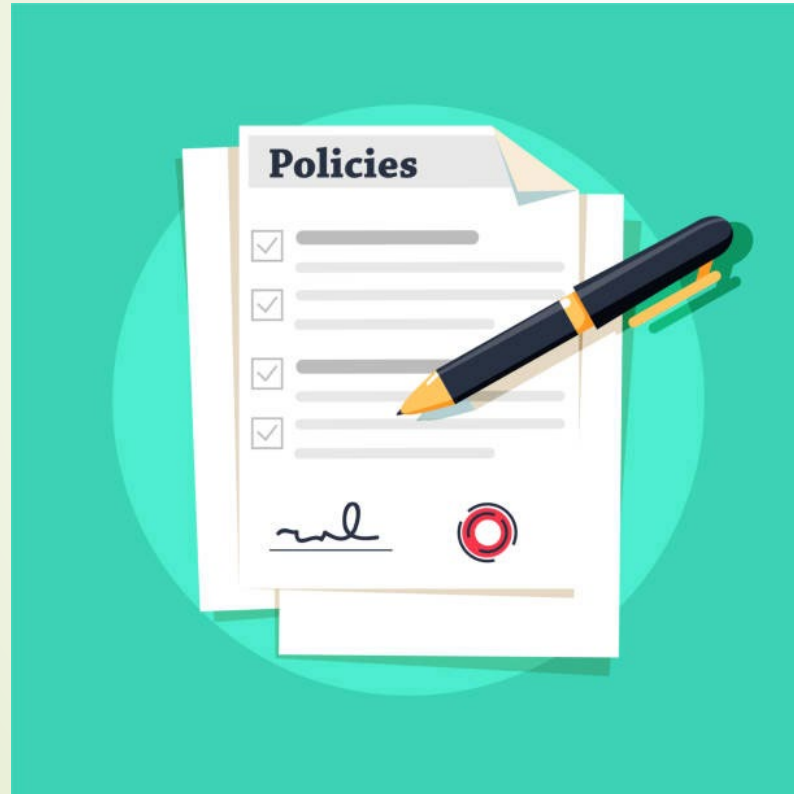


Policy Workgroup

- Office of Human Subjects Research Protections (OHSRP)
- Tribal Health Research Office (THRO)
- Investigators/study teams
- Institute leadership
- Office of Science Policy
- Other interested persons



Hot off the press!



- Published in the NIH Manual on July 9, 2025



Purpose of the policy

- To describe the additional protections and considerations that apply when conducting or reviewing NIH IRP research that enrolls AI/AN persons or uses samples/data collected from AI/AN persons.
- To ensure that Tribal sovereignty is respected, and measures are taken in the design, implementation, and review of the research to promote community-based protections and to mitigate the potential for group harm, while also recognizing the autonomy of individuals who choose to enroll in research, including that expected by the Common Rule (45 CFR 46).
- These measures are in addition to the protections afforded by the Common Rule (45 CFR 46), other applicable laws and NIH policies.



Scope/Applicability

- Exempt, non-exempt and some NHR if:
 - the research is likely to include AI/AN communities and/or persons and make inferences about AI/AN populations or communities
 - or will use data and/or biospecimens in secondary research that are known to have been collected from AI/AN persons and the secondary research will make inferences about AI/AN populations or communities.
- For example
 - a. Any aspect of the research, including recruitment, takes place entirely or in part on tribal land.
 - b. The research will intentionally recruit AI/AN persons as participants and/or AI/AN populations are the focus of the research.
 - c. Secondary research using data and/or biospecimens known to have been collected from AI/AN persons that were originally collected for other purposes and will make inferences about AI/AN populations or communities.
 - d. Secondary research using data and/or biospecimens that were originally collected on Tribal land is subject to this policy, regardless of the aims of the secondary research.



Individual and Community

- This does not include research that may incidentally include AI/AN persons as part of the research, if not intentionally recruited as participants, and the research will not make inferences about tribal communities or populations.
- Nothing in this policy is intended to prevent AI/AN persons from being considered for enrollment in NIH Intramural research for which they are otherwise eligible.



Draft policy in a nutshell

- Any protocol subject to the policy needs to be looked at by THRO.
- THRO will provide written recommendations as to whether tribal engagement is needed and will facilitate that process. THRO may also make recommendations about the protocol. These will be provided to the investigator and the NIH IRB.
- When Tribal authority approval is required by the tribe, this must be obtained and submitted to the NIH IRB. This could be Tribal government approval or a designated research review board.
 - NIH IRB will not approve without this.
- If not subject to the single IRB policy, and Tribal IRB review is required, this must be obtained and approval submitted to the NIH IRB.
 - NIH IRB will not approve without this.
- If subject to the single IRB policy, and the tribe requests Tribal IRB review, this must be obtained and submitted to the NIH IRB, which will incorporate the review into its local context determinations.
- NIH review will be by an IRB panel with a majority of AI/AN members.



IRB review implementation



- When reviewing research subject to the policy, we will put together a special panel with a majority of the members being AI/AN.
- Some research that would usually be reviewed by expedited procedures may go to FB for review.
- Opportunity to learn
- New things for FB members to think about in applying the regulations.

Goal

- Engage with Tribal communities throughout the research lifecycle.
- Plan, review and conduct research in an ethical and culturally sensitive manner.

