



## OVERVIEW

This document is a guideline for researchers on how to conduct respectful and beneficial research in American Indian and Alaska Native (AI/AN) communities, including tribes, pueblos, nations and urban.

These guidelines cover a variety of topics, including recognizing AI/AN tribes as sovereign nations and what documentation is needed to perform research, and where to search for additional resources (see resources below).

There are approximately 110 federally recognized Indian tribes in California, some of these tribes have lines that cross state boundaries. In addition, there are about 81 groups seeking federal recognition.

Many tribal communities have created IRBs and have generated guidelines for researchers. The method and detail of research requirements vary among tribes according to their resources and experience with researchers. Even if a tribe has not created research guidelines or an IRB, investigators are required to talk directly to the tribal leadership and secure permission through tribal decision-making processes (e.g., via tribal council meetings and securing tribal resolutions). Approval can take time. Even then, recruiting and securing cooperation from eligible tribal members can be challenging.

## Background

The Revised Common Rule ([45CFR46](#)) includes provisions for specific populations under the various [sub-parts](#). Protected populations include pregnant women, human fetuses, and neonates (subpart B); prisoners (subpart C) and children (subpart D). While certain populations are protected under the various subparts, IRBs also consider specific populations to be vulnerable to coercion or undue influence, including American Indian and Alaskan Natives, adult students, Department of Defense Personnel, and/or employees who are targeted participants in a research study. Anyone who could be perceived as being unduly influenced by a higher authority could be considered vulnerable. Section 22.1 of the iStar application lists populations identified as protected or vulnerable—note AI/AN populations are not currently listed.

Tribes are sovereign nations. They establish their own rules, policies, and procedures with respect to research conducted in and on their communities. Research conducted with tribes must be respectful of tribal sovereignty and tribal culture and traditions (described in more detail below, under “Conducting Research with AI & AN Populations”).

Sovereignty means that each tribe has the authority to govern itself and includes the ultimate decision-making power to enforce research regulations within their territories. Researchers need to be familiar with and be sensitive to culture, traditions, and wishes and/or expectations of a given AI/AN community. **No decisions about a tribe’s lands and citizens shall be made without the explicit participation and consent of the tribe/government(s)/governing council/appropriate organization identified as representing the interests of the tribe(s)/communities (herein known as tribal leadership).**

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The Revised Common Rule specifically gives tribal nations sovereignty over research that takes place on tribal lands and/or with tribal citizens. Tribes have the right to choose how to review research for their community, as well as the right to approve (or disapprove) research for their community (described in more detail under “Tribal Governments and the Revised Common Rule”). In addition, the Revised Rule allows exemptions to DHHS regulations, including the regulations related to data ownership and data sharing. The study protocol and informed consent form must be consistent with the requirements made by the tribal leadership.

While the “carve-out” in the regulations is limited to AI/AN communities on tribal land, USC’s IRB requires the same considerations for all distinct social and cultural groups that share collective ancestral ties to the lands and natural resources where they live, occupy and/or from which they have been displaced. The land and natural resources on which they depend are inextricably linked to their identities, cultures, livelihoods, as well as their physical and spiritual well-being. They often subscribe to their customary leaders and organizations for representation that are distinct or separate from those of the mainstream society or culture. These communities may also be known as Indigenous.

### History of Conducting Research with AI & AN Populations

The history of human subjects research is rife in harms and exploitation of research participants. These harms and exploitations have resulted in implementation of legislation, oversight, and protections for human subjects, as well as additional protections for specific populations. Most instances of unethical research conducted on AI/AN populations have resulted in physical, psychological, social, and/or economic harms to the whole community rather than to an individual participant.

The two most known instances where AI/AN communities were harmed by either research activities or by stereotyping are “The Diabetes Project with the Havasupai Tribe” and the “Hantavirus Outbreak.” These instances underscore the importance of respectful interactions with AI/AN communities.

The Diabetes Project with the Havasupai Tribe was conducted in 1989 by the Arizona State University (ASU). The aim of the study was to provide health education. Researchers collected and tested blood samples and conducted genetic testing to search for links between genes and diabetes risk for the tribe. When researchers were not able to find a genetic link, they changed their research without obtaining consent from either the tribe or the participants. Data and samples continued to be collected, but for purposes other than what those communicated to participants in the informed consent process. The purposes included schizophrenia, inbreeding, and migration all of which are highly charged topics that are taboo in the Havasupai culture. The tribe only found out about the revised aims when a tribe member attended a lecture about the study at ASU. A lawsuit was filed against the Arizona Board of Regents and ASU. The settlement included monetary compensation as well as the return of the DNA samples to the Havasupai.

In 1983-1985 epidemiologists studied an outbreak of congenital syphilis in a southwestern American Indian Tribe (Gerber et al., 1989). The State Health Department publicly named the Tribe, local media included this information in their reporting of the research, leading to stigmatism for the children who attended off-reservation schools.

In 1993 there was a severe (and fatal) pulmonary illness in the Four Corners region of the southwestern United States (Arizona, Colorado, New Mexico, and Utah). The source was unknown and predominately affected the Navajo nation. The illness became known in the media by many derogatory names, such as the “Navajo Flu” and “Navajo disease,” which resulted in stereotyping of the Navajo community and causing discrimination against the nation. After an investigation by the CDC, in collaboration with the Indian Health Service, the Navajo Nation, and state health departments in the affected states, it was determined that the pulmonary illness was caused by sweeping dried droppings from deer mice carrying the previously unknown species of hantavirus, in enclosed spaces.

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## Conducting Research with AI & AN Populations

Research with AI/AN communities is *not* the same as working with other underserved, minority, or rural populations. As previously stated, tribal sovereignty gives the tribes the inherent right to make their own laws, enact regulations, and determine what research can take place on, or near their lands. If research, including the use of self-identifiers, involves multiple tribes or tribal governments, approval from all tribes and/or tribal governments must be obtained. Just as having a local context review is required for studies that require review by a single IRB, Tribal Nations are required to retain oversight of research occurring on tribal land, with tribal communities, and/or using tribal resources, including environmental, animal, plant, and cultural resources. Constant engagement with the AI/AN community in all facets of the research process increases the likelihood of a successful research project.

Tribes and/or tribal governments have the right to:

- Approve or deny requests for research
- Decide how research is reviewed and conducted
- Require research activities to stop
- Review research reports, press releases, or publications before they are publicly shared
- Negotiate exclusive or shared ownership of all data and how research results are presented
- Decide if, how, and what cultural knowledge or practices are shared

Additional considerations:

- Consent occurs *throughout* the research project, not just at the outset
- Research activities taking place on tribal land needs tribal approval
  - Research conducted off tribal land does not negate the requirement for AI/AN community engagement, meaningful discussions with the relevant urban/suburban AI/AN leadership should take place with persons who are not affiliated with the research in any way including advisory. For example, utilizing Urban Indian Programs (UIP) for research conducted in an urban setting
  - Tribal clearance is required when tribal identifiers are used, including the use of self-identifiers. Thereby respecting tribal sovereignty, tribal culture, and traditions.
- Some ceremonies that take place on public should not be recorded
- Protecting the identifiers of AI/AN communities (name of tribe or geographical area) is just as important as protecting participant identifiers. Some tribes/villages are very small and can be easily identified by their geographic location
- Data Use or Data Sharing Agreements may be required by the tribe
- An exempt or NHR determination may not be accepted by the tribal leadership

*All systematic research related activities involving AI/AN populations, which requests tribal affiliation must obtain approval from the relevant tribes/tribal government/governing council prior to submitting an application to the USC IRB, including research that does not meet the definition of human subjects research, such as quality assurance, quality improvement and secondary data analysis studies. Tribal leadership will determine the review required for any research activity conducted on and/or within their community.*

Researchers are required to justify conducting research with AI/AN populations, including how the research is intended to improve the community as well as how the research will impact the community.

In general, research data collected from participants belongs to the institution; in the case of data collected from AI/AN populations, the data may belong to the tribe/government. Most tribes require researchers to present their findings to the tribal community, including tribal leadership, and require approval from

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leadership regarding dissemination of the results as well as future use of the data. Data Use Agreements and Memorandum of Understanding are described in more detail under “Data Use Agreements” further down in this document.

In addition to community harms, researchers must be aware that benefits of conducting research activities on Tribal communities should be applicable to the community, as well as the individual.

### Tribal Governments and the Revised Common Rule

Effective January 19, 2018, all human subjects related research activities submitted to USC’s IRB must adhere to the [Revised Common Rule](#), which explicitly recognizes tribal sovereignty and requires tribal consultation for research and provides provisions for their sovereignty. The Revised Common Rule includes five provisions for AI/AN participants:

- State and local laws providing additional protections 45CFR46.101(f)
  - This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.
- Provision of emergency care 45CFR46.102(j)
  - (j) *Emergency medical care*. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).
- Public Health Authority 45CFR46.102(k)
  - *Public health authority* means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.
- Single IRB for cooperative research 45CFR46.114(b) (2)
  - (b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
- (2) The following research is not subject to this provision:
  - (i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
  - (ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
- Additional Information disclosed in informed consent 45CFR46.116(i)

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- (i) *Preemption*. The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

The Revised Common Rule allows each tribal government to develop laws related to the protection of human subjects that are more protective than the Common Rule. These laws must be followed by researchers when conducting research related activities involving AI/AN populations. Ultimately, the tribal IRB or government is responsible for overseeing investigators conducting research activities with their tribe.

NIH developed [supplemental information](#) to the NIH Policy for Data Management and Sharing in collaboration with Tribal Consultation, public comments from AI/AN organizations, as well as community members and researchers.

### Tribal Governments and the Single IRB Mandate

In addition to creating additional laws/guidance, tribal governments can determine whether the single IRB review requirement is applicable for multi-institutional research studies, it allows tribal governments to develop their own informed consent standards that provide additional protections to research participants; investigators conducting research involving populations under the jurisdiction of the tribal governments are required to follow the rules and requirements of the tribe/government and the IRB is required to accept these requirements. For example, this might include separating the Parental Permission Form and Child Assent Form for research activities conducted with minors, the tribe may require a consent document specific to each tribe/nation.

If a single IRB review is agreed upon, the tribal IRB would serve as the reviewing IRB, or IRB of record, with USC serving as the relying IRB.

### Indian Health Services (IHS) and/or Tribal Review

The Indian Health Services (IHS) has a responsibility to provide health care services to AI/AN people, including Urban Indians. Many tribes have taken over their health care delivery system, which may require tribal review of research related activities; however, if the research involves IHS staff, facilities, data or programs, IHS review and approval is required. For research focused on health, the partners should include the local community health department and, as applicable the Health Board and/or the Indian Health Service.

All proposed research must have obtained the formal, written approval of the appropriate tribal government(s) prior to submitting an application to the IHS IRB. Evidence of support from the facility's Chief Executive Officer (CEO) must also be provided, to document that the project will not use IHS resources in a manner that would adversely impact the health care provided at the facility.

All proposed research must have obtained the formal, written approval of the appropriate Tribal government(s) prior to submitting an application to the IHS IRB. Evidence of support from the facility's Chief Executive Officer (CEO) must also be provided, to document that the project will not use IHS resources in a manner that would adversely impact the health care provided at the facility.

### Working with Tribal Nations and Community Advisory Boards/Committees

Access to research and data allows tribal leaders to make informed decisions, be proactive about shaping the future of their communities, secure funding for programs to benefit the community, and refine the programs currently offered to tribal citizens. However, many native people are wary of research and do not trust

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researchers. This is largely because “research” generally reminds native people of the myriad projects conducted by outsiders that did not benefit Native communities and that have resulted in harm to native peoples.

As policy and planning increasingly rely on research-based evidence, native communities are engaging more with research and program evaluation activities. However, the research process requires specific approaches and methods that are necessary to gauge the impact (positive or negative) and benefit of projects.

Researchers and tribal entities should work together, while the use of a Community Advisory Board or Community Advisory Committees are not required, they are recommended. The CAB/CAC are advisory groups made up of community members who may act as a liaison between the nation, their community, and the researchers. Having a CAB/CAC does not negate the need for review by the nation or by an IRB.

### IRB Submission Requirements

The following information is required to be included in the iStar application, study protocol, recruitment tools, and/or Informed Consent Form, as applicable:

- The protocol must list all tribes and/or tribal nations. If research is conducted on tribal land or with a tribal nation, section 6d should include the location and/or tribal nation
- Where applicable, review and approval documents, from the tribal IRB/Ethics Committee/governing body must be submitted with the iStar application
- The study protocol must list all tribal nations and indicate the native language spoken
- The protocol and consent documents must clearly indicate how the data will be used
- The protocol and consent document must clearly state that data/information collected will not be shared with outside researchers, members of the researchers’ other communities, academic researchers, outside agencies (e.g., private, federal or state) without explicit permission from research participants and/or tribal communities
- All participant facing materials should be translated into the language of the relevant tribe, when required by tribal leadership

**No research related activities can begin until there is tribal leadership approval (where applicable) and USC IRB approval.**

USCs risk/review determination, and expiration date will be consistent with tribal leadership’s determination, unless tribal leadership has otherwise documented in their approval/permission/determination notice.

### Data Use Agreements/Memorandum of Understanding/Material Transfer Agreements

The USC IRB require that all research related activities conducted under IHS or tribal leadership include written agreements delineating the roles and responsibilities of each party, to whom the data/sample belongs, who has access to the data/samples, data security, data confidentiality, under what circumstances the data/sample can be used for secondary purposes, publishing or presentation requirements, etc. As previously stated, the IHS or tribe may own the data, may limit secondary data use, and/or may require review/approval of abstracts, prior to publication and/or presentation.

USC policies and/or larger tribes may require fully executed Data Use Agreements (DUA), Material Transfer Agreements (MTAs) or Memorandum of Understanding (MOU), depending upon whether data and/or samples will be shared with colleagues or private entities. [USC’s Stevens Center for Innovation](#) (SCI) are responsible for the execution of DUAs and MTA.MOUs will require review by General Council.

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## Exempt Determinations with AI/AN Populations

Some sovereignties/tribal governments will not allow anything other than an expedited or full board review of research applications, this means they would not accept an exempt or NHSR determination on research activities which enroll AI/AN participants. In addition, Continuing Review may be required, based on the requirements of the sovereign nation. USC will support their determination.

## Research Involving Biospecimen Collection

Consent must be obtained for all biospecimen collection. The USC IRB recommends that consent for biospecimens be obtained both at the tribal and individual level. Researchers must consider community, cultural values and/or benefits when biospecimen collections are obtained for research related purposes.

## Changes to the Research Study

Investigators must adhere to USC's policies with regards to changes to all studies. As part of the investigator's discussion with tribal leadership, investigators must clarify when/how tribal leadership will be informed of minor changes to the study. Changes to the study procedures (including questions asked of participants), protocol and Informed Consent require approval by tribal leadership and USC's IRB prior to implementing.

## Credits

[American Indian and Alaska Native Research in the Health Sciences – Critical Considerations for the Review of Research Applications](#)

[California Tribal Epidemiology Center](#)

[California Indian Culture and Sovereignty Center \(CICSC\)](#)

[Choctaw Nation of Oklahoma Institutional Review Board](#)

[DoD Environment, Safety and Occupational Health Network and Information Exchange \(DENIX\)](#)

Heather Miller (Stanford University)

[HHS](#)

[Indian Health Service](#)

[Institutional Review Board – Management and Function \(Chapter 9-10 – pp. 563–579\)](#)

[National Congress of American Indians](#)

[National Congress of American Indians – Research Regulation](#)

[National Library of Medicine](#)

[Pacific Northwest IRB Conference](#)

[Revised Common Rule FAQs](#)

[Sault Ste. Marie Tribe of Chippewa Indians](#)

[Sisseton Wahpeton Oyate](#)

[Turtle Mountain Band of Chippewa Indians](#)

[Tribal Self Governance Advisory Committee](#)

[United South and Eastern Tribes](#)

[University of Arizona Indigenous Governance](#)

[University of Arizona Office of Native American Advancement & Tribal Engagement \(NAATE\)](#)

[University of Washington Indigenous Wellness Research Institute](#)

William Freeman

## Government & Tribal Resources

[American Indian Law Center](#)

[Collaborative Research Center for American Indian Health \(CRCAIH\)](#)

[Indian Health Service](#)

[Indian Health Service Institutional Review Boards](#)

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[National Congress of American Indians](#)  
[National Congress of American Indians – Consultation Support Center](#)  
[National Institutes of Health – Tribal Health Research Office](#)  
[Native American Heritage Commission](#)  
[Office of Minority Health](#)  
[Revised Common Rule FAQs](#)  
[Tribal Self-Governance](#)  
[Urban Indian Health Institute](#)  
[Urban Indian Health Service Organizations](#)

#### **Institutions with AI/AN Resources**

[Cal State University San Bernadino](#)  
[Cal State University San Marcos - California Indian Culture and Sovereignty Center \(CICSC\)](#)  
[Center for American Indian Resilience \(CAIR\)](#)  
[Indian Health Service](#)  
[Indigenous Wellness Research Institute](#)  
[Indigenous Wellness Research Institute National Center of Excellence \(IWRINCoE\)](#)  
[University of Alaska Fairbanks](#)  
[University of Arizona Indigenous Governance Database](#)  
[University of Arizona Native Peoples Technical Assistance Office](#)  
[University of Washington Indigenous Wellness Research Institute](#)

#### **Urban Indian Programs**

[Los Angeles City/County Native American & Indian Commission](#)  
[Native American Organization in the City and County of Los Angeles](#)  
[United American Indian Involvement](#)  
[Urban Indian Health Programs – California Area](#)

#### **Workshops & Education Materials**

[CRCAIH Summit Workshop](#)  
[OHRP Virtual Workshop – Supporting Ethical Research Involving American Indian/Alaskan Native \(AI/AN Populations\)](#)

#### **Additional Resources**

[Institutional Review Board – Management and Function \(Chapter 9-10 – pp. 563–579\)](#)  
[University of Arizona Guidance AIAN Checklist](#)

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