



NATIONAL CONGRESS OF AMERICAN INDIANS

POLICY RESEARCH CENTER

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Research Policy Update

Final Rule – Part 5:

Tribal Research Codes

In 1991, the Federal Policy for the Protection of Human Subjects, also known as the **Common Rule**, was published. The Common Rule is a regulation that guides research protections for studies with human subjects funded by certain federal agencies. U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) have separate but complimentary regulations for ethical research with human subjects.

On January 21, 2019, recent revisions to the Common Rule (known as the Final Rule) went into effect for studies and IRBs under HHS regulations. The U.S. Food and Drug Administration will be updating their Protections for Human Subjects to match with HHS regulations in the future. A comprehensive list of federal departments and agencies signed on to follow the Common Rule can be found at <http://bit.ly/2Fqbvhr>.

The NCAI Policy Research Center created this series of Research Policy Updates on the Final Rule. These updates provide a brief overview of only some recent changes to the Common Rule. Please visit the [HHS Office for Human Research Protections](http://www.hhs.gov/ohrt/) website or read the regulation: <http://bit.ly/2CqTH1l>

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Tribal Research Laws/Codes – Questions to ask

As sovereign nations, tribes have the right to decide how to engage with research conducted in their community. The Federal Policy for the Protections of Human Subjects, the Common Rule, does not include specific procedures for tribal review but does **require federally-funded researchers to obey state, local, and tribal laws.**³ With the January 21, 2019 Common Rule revisions in effect, it is more important than ever for tribes to review, update or adopt tribal research laws and codes that put in place the protections they want for their tribal citizens, lands, and resources.

However tribes decide to approach the research review and approval process, **updating tribal laws** to include research codes and specific procedures will help protect the tribe from unwanted and unethical research.

Tribes can protect their rights to approve or disapprove of research conducted on their lands by updating tribal laws to include their own research requirements. When structuring tribal research review procedures, tribes may want to consider some of the following questions:

- **What does the tribe want to gain from participating in research in general, and for each proposed project? How does the tribe measure or ensure benefit to the community from research?**
- **How does the tribe measure and consider any risks in the research? Are there any research practices that are unacceptable in any circumstance?**
- **How much oversight does the tribe want over research, and at what stages of the process?**
- **How does the tribe want to ensure that human subjects protections are in place for all research studies conducted with their tribe? Do they want to establish their own IRB or use an external IRB?**
- **How much review of publications and presentations does the tribe want to require?**
- **How does the tribe want to deal with the new single IRB requirement?² See the NCAI Policy Research Center *Research Policy Update – Final Rule Part 4, Single IRBs*.**
- **Who owns and controls the data and specimens gathered in a research project? How long will the data be used and maintained?**
- **What are the most important protections the tribe wants to require for any research conducted on their lands or with their citizens?**

Options for Research Review and Approvals – Tribal Options

Each tribe must determine their own answers to these questions in order to establish the right tribal laws and codes. In the 2019 updates, the Common Rule honors tribal laws on research.³ Tribes must act now to ensure that their tribal research laws are updated or enacted and their sovereign right to govern research is not lost by inaction. We encourage tribes to consult with other tribes that have tribal IRBs or research review processes already in place for examples of tribal research laws or codes.

Tribes have the right to shape their own tribal review process. There are two aspects to research review and approval that tribes should consider: 1) human subjects protection review of proposed and ongoing research projects to comply with federal regulations; and 2) tribal review and approval of research that protects and benefits the tribe.

Review of human subjects protections is what IRBs normally do, but while necessary, they are not fully sufficient for tribes. Tribes must also incorporate some form of a review and approval process to ensure the tribe approves of the research being conducted. Tribes that rely on external IRBs for human subjects review will also need some type of tribal review process in place. An external IRB cannot decide whether a research project benefits the tribe. Below are a few options for conducting tribal research

review. Each option could be used on its own or in combination with other options. Tribes can also create entirely new research procedures not listed below to fit their desired research protections. Tribes are not limited to the examples provided in this brief. Tribes do need to ensure though that both human subjects review and tribal review/approval are included in their local process.

Tribal Council Approval or Resolution is a formal agreement of support by the Tribal Council or a Tribal Council designated official for proposed research. Tribal Council approval may be the only requirement for tribal research approvals or one of many requirements.⁴ The tribal council may require a full research review by the council before providing formal support.

Designated External IRBs. Tribes may decide not to establish their own IRB for human subjects protection review. Instead, tribes can designate other IRBs to review the research proposals through an agreement. These designated external IRBs could be commercially run IRBs, tribal college IRBs, other academic IRBs, or even the Indian Health Services IRB.⁵ Designating an outside IRB to conduct a research review can be helpful, but the tribal and community perspective may be lost. Tribes may want to consider potential benefits and drawbacks to using external IRBs (i.e. less resources required by the tribe but less control over the research requirements and review) when considering this or any option.⁶ Tribes generally should also have some sort of internal tribal review of research proposals when they designate an external IRB to review their research for human subjects review.

Tribal Research Review Committees or Boards conduct review and approvals for all proposed research for the tribe, but may not meet the formal requirements to be an IRB set by the Common Rule.⁷

Tribal Institutional Review Boards (IRBs) are IRBs run by the tribe to protect tribal sovereignty, participating community members, and protect the community as a whole AND review research for human subjects protections required in the Common Rule. Tribal IRBs may differ in process from other IRBs but will still must meet the general requirements to be an IRB under the Common Rule.⁸ The review process could introduce new requirements, extra requirements, and/or culturally specific requirements.⁹ For example, the Final Rule now allows tribes to enact more stringent consent procedures in research. With a Tribal IRB, the tribe decides what requirements are necessary for researchers to conduct studies in their communities in addition to federal requirements and conducts the review and approval for both.

Inter-tribal IRB Groups or Consortiums are intertribal groups that conduct the research review process and provide research oversight for multiple tribes.¹⁰⁻¹¹ Participating in an inter-tribal research review group means member tribes share the burden of resources to conduct appropriate review.¹² This option allows tribes to pool resources and maintain control over research conducted in their communities.

Indian Health Services (IHS) IRB. Any research conducted through IHS, with IHS staff, facilities, and/or resources must receive IRB approval through the IHS IRB. Many tribes use the IHS IRB as their designated external IRB. Before submitting research proposals to the IHS IRB, researchers must already have “formal, written approval of the appropriate Tribal government(s).”¹³ IHS requires researchers to engage tribes in the review process even if tribes do not have formal processes in place. If a tribe does have extra tribal approval requirements in place, the researchers will need to obtain those approvals before submitting IRB review proposals to IHS. An extra review requirement could be as simple as obtaining final approval by the tribe. This means that researchers would need tribal approval before submitting to the IHS IRB, and tribal approval again after the IHS IRB review. Indian Health Services has

a Federalwide Assurance (FWA) and can serve as the IRB of record for studies relating to health. Tribes that approve or conduct research that is federally-funded should have a FWA for their tribe. For more information on FWAs see NCAI Policy Research Center *Research Policy Update – Final Rule Part 1, Human Subjects Research and Protections*.

Community Advisory Boards (CABs) or Tribal Advisory Committees (TAC) are advisory groups made up of community members “who share a common identity, history, symbols and language, and culture.”¹⁴ These advisory groups help both their communities and researchers understand the research impact on the community, the consent process, and the research being conducted. Rather than conducting research review, CABs and TACs only serve as advisors to both the community and the researchers.¹⁵ CABs and TACs may be more involved in designing a research study than IRBs, but will not have authority to approve or disapprove of the research request.¹⁶ A CAB or TAC may be useful as an extra requirement to tribal research review.

Final Rule updates to the Common Rule on January 21, 2019 made significant changes to the consent process for human subjects research, the use of secondary data, and the introduction of the single IRB requirement.¹⁷ The introduction of Broad Consent means that unspecified research can be conducted with data and biospecimens and not be disclosed during the initial research study’s consent process and data collection. To read more about the changes to the consent process and how the changes impact tribes, read NCAI Policy Research Center *Research Policy Update – Final Rule Part 3, Informed and Broad Consent*.

These updates in the Final Rule may compromise the level of tribal oversight for certain research projects. However, the Common Rule updates also include wording to protect tribal sovereignty and laws. The updated wording states that all provisions which “cite [the authority of] state of local law” now must also include “tribal law passed by the official governing body of an AI/AN tribe.”¹⁸ Tribal sovereignty is recognized in the Common Rule, but tribal laws need to be updated to include research procedures and oversight to ensure tribes maintain whatever level of tribal review and control is desired.

On January 20, 2020, the requirement for all multi-site collaborative research projects to undergo a single IRB review goes into effect. Unless otherwise specified by an official tribal code or law, or the supporting federal Common Rule agency, no other IRBs will be required or used.¹⁹ To understand more on the single IRB requirement and the impact to tribes, read NCAI Policy Research Center *Research Policy Update – Final Rule Part 4, Single IRBs*.

All the NCAI Policy Research Center publications are available at: <http://www.ncai.org/policy-research-center/research-data/prc-publications>.

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Questions: NCAI Policy Research Center – email: research@ncai.org; website: <http://www.ncai.org/prc>

Endnotes

¹ [45 CFR 46.101(f), Subpart A]

² [45 CFR 46.114, Subpart A]

³ [45 CFR 46.101(f), Subpart A]

⁴ Ketchum, Scott, and Richard Meyers. 2018. "Recognizing and Respecting Tribal IRBs." *Anthropology News* website, July 11, 2018. DOI: 10.1111/AN.908

⁵ Hernandez, Juan A. Avila. Blood, Lies, and Indian Rights: TCUs Becoming Gatekeepers for Research. *Tribal College Journal*, 2004. 16(2).

⁶ Sahota, Puneet Chawla. *Research Regulation in American Indian/ Alaska Native Communities: Policy and Practice Considerations*. NCAI Policy Research Center, [depts.washington.edu/ccph/pdf_files/Research Regulation in AI AN Communities - Policy and Practice.pdf](https://depts.washington.edu/ccph/pdf_files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf).

⁷ "Institutional Review Boards - Human Subjects Research Protections." Phoenix Area, Indian Health Services, www.ihs.gov/dper/research/hsrp/instreviewboards/.

⁸ "Institutional Review Boards - Human Subjects Research Protections." Phoenix Area, Indian Health Services, www.ihs.gov/dper/research/hsrp/instreviewboards/.

⁹ Ketchum, Scott, and Richard Meyers. 2018. "Recognizing and Respecting Tribal IRBs." *Anthropology News* website, July 11, 2018. DOI: 10.1111/AN.908

¹⁰ "Institutional Review Boards - Human Subjects Research Protections." Phoenix Area, Indian Health Services, www.ihs.gov/dper/research/hsrp/instreviewboards/.

¹¹ "Research Review Board." *Tribal Nations Research Group*, www.tnrg.org/research-protection.html.

¹² Sahota, Puneet Chawla. *Research Regulation in American Indian/ Alaska Native Communities: Policy and Practice Considerations*. NCAI Policy Research Center, [depts.washington.edu/ccph/pdf_files/Research Regulation in AI AN Communities - Policy and Practice.pdf](https://depts.washington.edu/ccph/pdf_files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf).

¹³ *Human Subjects Research Protections*. Indian Health Services, www.ihs.gov/dper/research/hsrp/.

¹⁴ Strauss, R P et al. "The role of community advisory boards: involving communities in the informed consent process" *American journal of public health* vol. 91, 12 (2001): 1938-43.

¹⁵ "Tribal Advisory Committee - CDC." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, www.cdc.gov/tribal/consultation-support/tac/index.html?CDC_AA_refVal=https://www.cdc.gov/tribal/tac/index.html.

¹⁶ Sahota, Puneet Chawla. *Research Regulation in American Indian/ Alaska Native Communities: Policy and Practice Considerations*. NCAI Policy Research Center, [depts.washington.edu/ccph/pdf_files/Research Regulation in AI AN Communities - Policy and Practice.pdf](https://depts.washington.edu/ccph/pdf_files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf).

¹⁷ [45 CFR 46.104(d)(7)(8), Subpart A]; [45 CFR 46.114, Subpart A]

¹⁸ [45 CFR 46.101(f), Subpart A]

¹⁹ [45 CFR 46.114(b)(2), Subpart A]