



NATIONAL CONGRESS OF AMERICAN INDIANS

POLICY RESEARCH CENTER

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Research Policy Update
Final Rule - Part 7:
Examples of Tribal Research Laws

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) go 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/2Fqbyhr>.

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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Why Have Tribal Research Laws?

The Federal Policy for the Protection 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.**¹ The Common Rule update requires researchers to follow tribal laws in addition to the usual federal protections. This update gives tribal nations the flexibility and added protections to define what kind of research and what level of review is necessary for their nation.

Why are research laws important? In the absence of tribal research laws, researchers may only be required by their institution to follow institutional research review policies. Depending on the institution, policies may or may not include additional requirements when tribal nations are a part of the research study. By passing tribal research laws, tribal nations are able to define what research is

appropriate for their community, regulate research that can benefit their community, and prevent research that may negatively impact them.

What exactly do the Common Rule updates say and where is tribal law referenced? The Common Rule update includes references to tribal law in the two following sections:

*"This policy [the Common Rule] 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."* [45 CFR 46.101(f), Subpart A]

And

*"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)."* [45 CFR 45.114(b)(2)(i), Subpart A]

In both sections, the Common Rule addresses "tribal law passed by the official governing body." Tribal nations should document the approval process for their research laws, codes, or policies to ensure that they meet this requirement.

What goes into designing the research review process and requirements? Tribes have the flexibility to choose and design what they would like to have in their research laws. Tribes can expand definitions of what classifies as identifiable data. Biospecimens (blood, saliva, tissue, etc.) and zip codes are not currently classified under federal regulations as individually identifiable information, but these types of data and information potentially could be used by researchers to easily identify different tribes and tribal communities. Tribal nations have the flexibility to define identifiable information beyond being just about the individual to any information or data that can identify the tribal nation and its citizens.

Tribal nations can place additional requirements on researchers conducting research through tribal laws. This could include a requirement that the researchers share grant funding with the tribal nation or pay a fee for tribal research review, required tribal ownership of the data and any potential inventions, patent rights, and/or profits from the research outcomes, requirements for tribal pre-approval of publications, and requirements to conduct the research according to principles of community based participatory research. Tribal nations can also require research studies with broad consent and single IRB review to undergo additional tribal review for each new study, or can prohibit these types of consent and review processes. This list of requirements that a tribal nation can set in their research codes is just a list of examples and tribal nations may develop other requirements that are not listed here. Tribal nations are sovereign and they have the ability to enact tribal research laws that govern research that occurs on their lands and with their citizens.

Additional Resources – Creating Tribal Research Review & Laws

Many free resources are available online for creating and designing tribal research review that is guided by tribal research laws. Below are listed some available resources.

- Collaborative Research Center for American Indian Health Tribal IRB Toolkit:
<https://www.crcaih.org/irb-toolkit.html>

- CRCAIH Research Data Management Toolkit Version 2:
<https://www.crcaih.org/training-and-resources/data-management-toolkit.html>
- Model Tribal Research Code by the American Indian Law Center, Inc.:
<https://ccph.memberclicks.net/assets/Documents/CBPRCurriculum/AppendixF/mdl-code.pdf>

Examples of Existing Tribal Research Laws

The following table shows examples of different tribal research laws for tribal nations interested in creating or amending their own research laws.

Tribal Nation	Review Board/Committee/Council Website	Tribal Research Laws
Colorado River Indian Tribes	CRIT Ethics Review Board	http://bit.ly/2GFeyRx
The Confederated Tribes of the Colville Reservation	Colville Business Council	http://bit.ly/314DWRV
Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians	Tribal Council Review	https://ctclusi.org/tribalcode Title 1 – Chapter 1-10
Eastern Band of Cherokee Indians	Eastern Band of Cherokee Indians Medical Institutional Review Board	http://bit.ly/2GDcbPB
Ho-Chunk Nation	Ho-Chunk Nation Institutional Review Board (IRB)	http://bit.ly/2YB2OG2
Karuk Tribe	Karuk Resources Advisory Board and Karuk Tribal Council	http://bit.ly/2SWI2Qa
Oglala Sioux Tribe	Oglala Sioux Tribal Research Review Board	Oglala Sioux Tribe Ordinance #07-053
Pascua Yaqui Tribe	Research Review Committee	http://bit.ly/2Kd5cOa
Sisseton Wahpeton Oyate	Sisseton Wahpeton Oyate Local Research Review Board	http://bit.ly/3312gN6
Tohono O’odham Nation	Tohono O’odham Nation Institutional Review Board	http://www.tolcnsn.org/docs/Title17Ch8.pdf
Turtle Mountain Band of Chippewa Indians	Tribal Nations Research Group	http://bit.ly/2K39oRA

Of note, this is not a full list of all existing tribal research laws. NCAI has not reviewed the research laws of each tribal nation and this list does not endorse any tribal laws over any others. These examples are solely for educational purposes and to show a variety of options. Tribal nations hold an inherent authority to create laws in their own format and it is up to each respective tribal nation to define what qualifies as tribal law.

NCAI Policy Research Center: Final Rule Update Series

The NCAI Policy Research Center has written a series of Research Policy Updates to help tribal nations, researchers, and research volunteers understand some key changes to the Common Rule in the 2019 Final Rule. This is the seventh brief in the series. This series provides an overview of some changes related to tribal research, but there may be other changes from the Final Rule that may have different impacts. The NCAI Policy Research Center recommends using the Common Rule text when making official research or research review changes based on the Final Rule. The Common Rule (regulation) can be found at <http://bit.ly/2CqTH1l>.

The NCAI Policy Research Center Research Policy Updates on the Final Rule include the following:

- **Final Rule: Part 1** provides background information on current human research protections and information for individuals considering volunteering to participate in research
- **Final Rule: Part 2** gives a brief overview of some of the main changes to human research subject protections from the Final Rule
- **Final Rule: Part 3** focuses on changes made from the Final Rule to informed consent and the addition of broad consent. For tribal nations and tribal members, this will be particularly important to understand before volunteering for research
- **Final Rule: Part 4** introduces the new Single IRB (sIRB) requirement and its effect on tribal communities
- **Final Rule: Part 5** overviews options for tribal review and tribal research codes
- **Final Rule: Part 6** explains the eight types of exempt research that do not need to go through full IRB review, although a couple do need to undergo Limited IRB Review
- **Final Rule: Part 7** provides additional information on and examples of tribal research laws

More information about tribal research laws or codes is included in *Final Rule – Part 5: Tribal Research Codes*.

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

¹ [45 CFR 46.101(f), Subpart A]