



NATIONAL CONGRESS OF AMERICAN INDIANS

POLICY RESEARCH CENTER

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Research Policy Update ***Tribal Implications of the Revised Common Rule & NIH sIRB Policy***

MAIN POINTS

- *Two revised policies specify that federally funded researchers are required to follow tribal research laws.*
- *Tribes can develop laws to ensure research benefits and protections beyond individual protections required in federal research policies.*
- *New federal requirements for single IRB review in multi-site studies allow for exemptions when tribal law requires local review.*
- *Tribes should review their current laws related to research and consider updates.*

Two federal policies – Subpart A of 45 Code of Federal Regulations part 46 (the Common Rule) and the National Institutes of Health (NIH) Single Institutional Review Board (sIRB) Policy – have implications for research with tribal populations. The National Congress of American Indians (NCAI) Policy Research Center (PRC), along with several tribes and tribal organizations, have been tracking these revisions and advocated for respect for tribal sovereignty within the research process. Overall, ***our collective efforts have contributed to positive progress concerning recognition of tribal authority over research activities on tribal lands and with tribal citizens.***

However, given the diversity of existing tribal research oversight processes, we encourage tribal leaders and researchers engaged in research activities with tribal populations to ***be informed and stay involved as implementation of the final Common Rule and NIH sIRB policies unfolds.*** Updates and additional resources related to each policy are provided below.

THE COMMON RULE

In September 2015 the Department of Health and Human Service and 15 other federal departments and agencies released a Notice of Proposed Rulemaking (NPRM) proposing revisions to the Common Rule, which is the main federal policy governing research with human subjects. While the NCAI PRC commended the effort to revise the policy, several of the proposed changes in the NPRM elicited concern, including those that promoted broad consent, use of a single Institutional Review Board (sIRB) in multi-site studies, and processes that seemed to transfer the responsibility of ethical determinations to individual researchers. The PRC saw the revision process as an opportunity to explicitly recognize tribal sovereignty in research and submitted formal comments (available at: <http://www.ncai.org/policy-research-center/research-data/priorities/fed-res-priorities>).

Updates

- The Final Rule was posted on 1/19/2017 (<https://www.federalregister.gov/d/2017-01058>).
- Research funded on or after 1/19/2018 by federal agencies that follow the Common Rule must comply with the Final Rule.
- The Final Rule incorporated tribal comments by stating that tribes have the authority to develop research laws and federally funded researchers are required to abide by them. It refers to **“tribal law passed by the official governing body of an American Indian or Alaska Native tribe.”**

- A Tribal Consultation Statement in the Final Rule summarized comments and clarified revisions as follows:

*"The final rule includes a modification to the provision requiring single IRB review, and several clarifications specifying that regulatory references to state and local law are **intended to include tribal law**, in response to concerns raised during the tribal consultation and in the NPRM public comments....the final rule clarifies in §__.101(f) that **tribal governments can develop laws related to the protection of human subjects that are more protective than the Common Rule**, and that these laws must be followed by federally funded researchers in activities involving these populations. Section __.114 now provides that if a tribal government requires review by more than one IRB by law in multi-institutional research, the single IRB review requirement in §__.114 does not apply. Additional clarification has also been made to §__.116(i) that **tribal governments can develop their own informed consent standards** that provide additional protections to subjects and that investigators conducting research involving populations under the jurisdiction of the tribal governments would have to follow these rules. Finally, additional language has been added to §__.116(j) noting that nothing in §__.116 is intended to limit the authority of a treating physician to the extent the authority is granted by tribal law."*

Additional Resources

- Public Responsibility in Medicine and Research (PRIM&R) developed a webpage on understanding the revised Common Rule (<http://www.primr.org/commonrule/>).
- The Collaborative Research Center for American Indian Health (CRCAIH) held a workshop on the new policy with the Office of Human Research Protection (OHRP). Slides and videos are posted at: <http://crcaih.org/summit/501-summit-workshops>.
- OHRP is developing resources to explain the Final Rule, which will be posted to www.hhs.gov/ohrp. Questions can be submitted to OHRP@hhs.gov.

NIH SINGLE IRB POLICY

In 2014 and 2015, the National Institutes of Health (NIH) requested comments on a draft policy that proposed single Institutional Review Board (sIRB) review for NIH-funded multi-site research studies. After input from tribes, the NCAI PRC, the NIH Tribal Advisory Committee (TAC), and others, the final policy included an automatic exception when local IRB review is required.

Updates

- The final NIH sIRB Policy was released on 6/21/16 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>) and will take effect on 9/25/17.
- A list of Frequently Asked Questions (FAQs) about implementation from the NIH Office of Science Policy (http://osp.od.nih.gov/sites/default/files/sIRB_Extramural_FAQs_o.pdf) notes:
 - Exceptions to the NIH sIRB Policy are allowed and "**...automatic when local IRB review is required by federal, tribal, and /or state law/regulation/policy**".
 - "Research involving Tribal Nations have an automatic exception...However **if a Tribal Nation wishes to use the designated single IRB, they may do so.**"

Additional Resources

- Public comments, NIH notices, Federal Register Notices, and additional resources on the NIH sIRB Policy can be found on the NIH Office of Science Policy website at: <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review>.

The NCAI PRC advises tribes to review their current research laws in light of these revisions and consider updates as necessary to ensure federally funded researchers required to follow the Common Rule and NIH sIRB policies also follow any additional requirements of tribal law. Questions can be sent to the PRC (research@ncai.org) and additional resources are available at: www.ncai.org/policy-research-center/initiatives/research-regulation.