



NATIONAL CONGRESS OF AMERICAN INDIANS

POLICY RESEARCH CENTER

January 2019



Research Policy Update *Final Rule – Part 4: Single IRBs*

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>

This publication was supported by the National Institute on Minority Health and Health Disparities of the National Institutes of Health under Award Number U54MD008164. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Single Institutional Review Board (sIRB) – Overview and Definitions

Recent updates to the Common Rule, or the Federal Policy for the Protection of Human Subjects, aimed to increase protections for human research participants and decrease administrative burdens on the review process.¹ The Final Rule introduced the **single Institutional Review Board (sIRB)** requirement for multi-site cooperative research studies as one of their measures to decrease the administrative burden on researchers and IRBs.²

- **Cooperative Research Projects** are projects with more than one institution involved in conducting the research/study.³ **Multi-site studies** include sites or individuals not associated with the same IRB or institution.⁴

On **January 20, 2020**, all cooperative research projects supported or conducted by federal departments and agencies following the Common Rule must use a single IRB for review of research involving human

subjects.⁵ The National Institutes of Health included a policy for the use of single IRBs for multi-site research on January 25, 2018.⁶ The U.S. Food and Drug Administration (FDA) has separate protections from the HHS Common Rule for human research subjects. The FDA does not yet require using sIRBs for multi-site research regulated by the FDA.⁷

- The **IRB of Record or the single IRB** is the IRB identified to be the responsible IRB for reviewing research for human subjects protections for all participating sites and institutions in a cooperative research study.⁸ The IRB of Record/ single IRB is the IRB held accountable to the supporting or partnered federal agency following the requirements of the Common Rule.⁹ The lead institution on a research project proposes which IRB to use as the IRB of record. The federal agency supporting the research makes the final decision on which IRB will be the IRB of record.¹⁰
- The **Relying IRB** is the IRB that designates a different IRB to serve as the single IRB for review of a specific multi-site study.¹¹ This means the relying IRB will not be responsible to conduct IRB review for the specific study and will leave the official review to the designated sIRB.

Under the 2019 changes to the Common Rule, **cooperative (multi-site) research projects must designate one IRB, the IRB of Record, to conduct IRB review for all institutions participating in the specific research project.**¹² Before the introduction of the sIRB, many multi-site studies needed each site or institution to submit the project for review to all of the participating institutions' IRBs.¹³ All partnered institutions may still conduct their own IRB review for projects required to follow single IRB review, however the **IRB of Record will be the only review with "regulatory status" for Common Rule compliance.**¹⁴

sIRB Eligibility and Exceptions – Research with Tribes

The single IRB requirement only applies to U.S. institutions and research conducted within the United States.¹⁵ Additional IRB approvals and additional human research protections may be needed for research conducted on foreign soil and with foreign institutions.¹⁶ Institutions conducting multi-site research not supported by Common Rule departments or agencies can still engage in the single IRB process or a joint review arrangement, although those studies are not required to do so under the Common Rule.¹⁷

The Final Rule revisions included **two exceptions to the single IRB requirement:**

Exception 1: Research that is not part of the single IRB requirement is any cooperative research where local law specifically requires additional review. The Common rule clarifies that this exception includes any tribal laws passed by American Indian or Alaska Native "official governing bodies."¹⁸

If a tribe is a part of a multi-site research project and does not want to be subject to single IRB review requirements that do not officially include the tribal IRB, updating tribal research codes and laws are important to be able to use this exception. To ensure tribal review for all research conducted on tribal lands and about the tribal community, updating official tribal governing laws to include provisions on required research approvals by the tribe will be necessary.

Some tribes, especially those that do not have IRBs may agree with the use of a single IRB outside the tribe as they participate in multi-site research studies, but tribes may also require additional tribal reviews and approvals beyond IRB (human subjects review) to ensure that the research both protects and benefits the tribe.

The key point here is that **tribes have the opportunity to choose** whether or not they participate in a single IRB review in a multi-site research study. In order to preserve their option to require all research be reviewed by the tribe, even if there is an external single IRB involved with the research study in which they are participating, they **must have tribal law** enacted.

Exception 2: A supporting Common Rule federal agency or department can decide if the single IRB approval process is not appropriate for a specific research project and can require the project partners to use additional IRBs and processes.¹⁹ Tribes may consider encouraging federal agencies and departments under the Common Rule to establish policies that require consideration of tribal choice around whether they want to participate in a single IRB process or whether they want to require tribal IRB approval in addition to a single IRB for the multi-site research study in which they are a participant.

Tribes should ensure that any research proposals to federal agencies under the Common Rule have clear reference to the tribe's right to require tribal IRB review in addition to single IRB review in multi-site research studies. We recommend tribes quote the Common Rule provision and provide the language in their tribal laws that requires tribal review.

sIRB and Tribal Law/Codes - Sample Language

The single IRB requirement for all multi-site cooperative research will go into effect on **January 20, 2020**. We encourage tribes to update their research laws and codes before then to indicate their requirements around the sIRB requirement. A tribe may include language in their tribal laws or codes such as the following to show their requirement for tribal IRB review regardless of whether an external single IRB is required:

All proposed research projects must be reviewed and approved by the tribe's designated review body regardless of review required by any other external research review entity.¹

This language intends to require tribal review and approval even when there is a designated single IRB for a multi-site research project, since the single IRB would be considered "any other external research review entity" as stated in the above example.

We encourage tribes to share language in their tribal laws or codes and their experience under the new sIRB provision with other tribes.

¹ Please note that this language is intended as an example and tribes should consult their legal representatives to develop their own language, which would address their own specific needs and concerns.

Citation: NCAI Policy Research Center (2019). *Research Policy Update: Final Rule Part 4 – Single IRBs*. National Congress of American Indians, January 2019

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Endnotes

¹ “Final Rule.” The Nutrition Source, Harvard T.H. Chan School of Public Health, 18 Jan. 2019, www.hsph.harvard.edu/ohra/final-rule/.

² “Single IRB Policy for Multi-Site Research.” National Institutes of Health, U.S. Department of Health and Human Services, 14 Jan. 2019, grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm.

³ “Final Rule.” The Nutrition Source, Harvard T.H. Chan School of Public Health, 18 Jan. 2019, www.hsph.harvard.edu/ohra/final-rule/.

⁴ “Overview of IRB Requirements for Multisite and Collaborative Research.” University of Wisconsin Knowledgebase, Health Sciences Institutional Review Boards, Dec. 2017, <https://kb.wisc.edu/hsirbs/page.php?id=17731>.

⁵ Office for Human Research Protections, and Ohrp. “The Revised Common Rule Compliance Dates and Transition Provision.” HHS.gov, US Department of Health and Human Services, 10 Jan. 2019, www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-revised-common-rule-compliance-dates-transition-provision-45-cfr-46-1011/index.html.

⁶ “Single IRB Policy for Multi-Site Research.” National Institutes of Health, U.S. Department of Health and Human Services, grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm.

⁷ Hhs.gov. “Attachment D - Granting Exceptions Requirements for Single IRB.” HHS.gov, US Department of Health and Human Services, 17 Apr. 2018, www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-d-points-to-consider-granting-exceptions-to-requirements-for-single-institutional-review-board-review-for-multi-site-research/index.html.

⁸ Final Rule Material: New and Revised Definitions. CITI Program, about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-New-and-Revised-Definitions.pdf.

⁹ Final Rule Material: Impact on IRB and Institutional Operations. CITI Program, about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Final-Rule-Impact-on-IRB-and-Institutional-Operations.pdf.

¹⁰ [45 CFR 46.114(b)(1), Subpart A]

¹¹ “Single IRB.” IRB Institutional Review Board Office, Office for Research, Northwestern University, irb.northwestern.edu/single-irb.

¹² [45 CFR 46.114(a), Subpart A]

¹³ “Single IRB Policy for Multi-Site Research.” National Institutes of Health, U.S. Department of Health and Human Services, grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm.

¹⁴ Final Rule Material: Impact on IRB and Institutional Operations. CITI Program, about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Final-Rule-Impact-on-IRB-and-Institutional-Operations.pdf.

“Single IRB.” IRB Institutional Review Board Office, Office for Research, Northwestern University, irb.northwestern.edu/single-irb.

¹⁵ [45 CFR 46.114(b), Subpart A]

¹⁶ “Single IRB.” Office of Minority Affairs Diversity, University of Washington, www.washington.edu/research/hsd/single-irb/.

¹⁷ [45 CFR 46.114(c), Subpart A]

¹⁸ [45 CFR 46.114(b)(2)(i), Subpart A]

¹⁹ [45 CFR 46.114(b)(2)(ii), Subpart A]