



NATIONAL CONGRESS OF AMERICAN INDIANS

POLICY RESEARCH CENTER

January 2019



Research Policy Update
Final Rule: Part 1
Human Subjects Research and Protections

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. The 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.

Human Subject Studies and Research – Overview of Regulations

An activity is considered **Human Subjects Research** when it involves human subjects (participants) and the activity has a systematic approach to gather and analyze information and data that can be used to generalize results for a population and advance science.¹ When research falls under this definition, it may be subject to further scrutiny to determine which research regulations apply to the project.

The Belmont Report outlines basic ethical principles and guidelines that structure current policies and regulations for human subject research protections.² The report, published in 1976, heavily informed the initial U.S. Department of Health and Human Services' Common Rule. The Common Rule continues to be updated to protect research participants in studies funded by the federal government in the growing landscape of research studies and new scientific technologies.³

Institutional Review Boards (IRBs) are committees that review research studies to confirm that ethical practices and protections for human subjects (research participants/volunteers) are being followed. The review may also include ensuring that cultural or situational distinctions are being considered and incorporated.⁴ IRBs continue to revisit reviews during the research study to maintain protections for the human subjects/participants in the study.⁵ IRBs additionally verify that the risks to research participants are not outweighed by the benefits they will likely experience.⁶

Depending on the research study, **researchers** need to consider **where** they are required to submit their IRB review request. There are many types of IRBs, including Academic IRBs, Commercial IRBs, Federal IRBs, Medical IRBs, and Tribal IRBs. Usually, a researcher will need to first submit their research to the IRB associated with their place of employment. A research study may also be required to be submitted through multiple IRBs. Changes to the Common Rule may impact where a researcher submits their IRB review request and whether they need to submit to more than one IRB. For more information on these changes and the new **Single IRB (sIRB)** rules, please see the NCAI Policy Research Center's *Research Policy Update – Final Rule: Part 4* brief that discusses the exception to the sIRB rules for tribal IRBs.

Organizations that conduct human subjects research may choose to develop and use their own IRB or designate other external IRBs to review their human subjects research that falls under HHS or FDA regulations. Organizations that conduct human subjects research that falls under the scope of the Common Rule, whether or not they have their own IRB, need to obtain a **Federalwide Assurance (FWA)**. An FWA is an agreement that the organization makes with HHS or FDA to comply with their human subjects research regulations, such as the Common Rule.

During the process of registering for an FWA with the **HHS Office for Human Research Protections (OHRP)**, an organization needs to either register its own IRB or designate an already FWA-registered IRB to serve as their IRB of record for their research studies. If conducting research that falls under a FDA regulated product, a researcher must use an IRB registered through the FDA.⁷ Some IRBs are registered through both HHS and the FDA. If using a different organization's IRB, an external IRB agreement must be documented under the FWA.⁸ Once an organization has a FWA, if the organization engages in federally-funded research that would fall under the federal protections for human research, the organization's IRB or their designated external IRB(s) will need to be used and they need to follow the relevant federal human subjects research regulations.⁹

Organizations that have human subjects research as a part of their activities that are federally funded and fall under the Common Rule (HHS) must have an active FWA, and must renew their FWA every 5 years or face restrictions, suspensions, or termination of their FWA and lose their ability to conduct human subjects research. This applies to tribes, tribal organizations, non-profits, and academic institutions that conduct human subjects research that is under the Common Rule.

To check on the status of your organization's FWA, or to register your organization or IRB with HHS or the FDA, go to: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/index.html>

Research with AI/AN Tribes

Additional steps and protections are often needed when conducting research in collaboration with **American Indian or Alaska Native (AI/AN)** communities and populations. The Common Rule affirms that each tribe may have its own definition of research and its own set of research protections and laws that may have more restrictions than the Common Rule. In addition to the researcher's own organization's IRB process and approval, a researcher must also receive appropriate approvals and review from the tribe throughout the process: when developing the research idea; when applying for funding; while conducting research; and through the publication of research. If the tribe, through its own research review process, does not approve the proposed research, even though the research may have been approved by a separate IRB, the researcher cannot conduct the research with the tribe. This is the tribe's right as a sovereign nation.¹⁰

Tribes have the right to choose how to review research for their community and the right to approve or not approve the research. The process for research review and approval may vary between different tribes and may require additional information and checks on the research being produced beyond federal regulatory requirements. Tribes may have an IRB that reviews for human subject protection, or they may have a research review board or committee that reviews research proposals. They may require tribal council review as the sole review or as an additional review. The tribal review process exists to protect the research participants/volunteers AND to protect the community from harms.

The Indian Health Services (IHS) has an IRB that covers under its FWA research conducted in IHS, tribal, or urban Indian programs and many tribes use the IHS IRB as their external IRB under their FWA. The IHS IRB requires any research being conducted through IHS with AI/AN communities to be done in partnership with the community. This means the researcher must show that the tribe also provided approvals for the research to be done as a part of the IRB application.¹¹ The partnership requirement aims to ensure studies are relevant and beneficial to the community and to make sure the results are clearly explained to and approved by the tribal partners. Any publications resulting from research must be approved by the tribe prior to publication.¹²

An important change to the Common Rule and research with AI/AN communities occurred with the implementation of the Final Rule revisions that go into effect on January 21, 2019. All sections within the Common Rule that "cite [the authority of] state or local law" now must also include "tribal law passed by the official governing body of an AI/AN tribe."¹³ Therefore, all tribes should review their research laws/codes and update them as needed since federally funded researchers must follow them as a result of the Final Rule.

The NCAI Policy Research Center's recent monograph on [The State of Tribal Data Capacity in Indian Country](#) provides more information on tribes and data efforts. The monograph reviews a survey of tribes that found that 28% of tribes have an IRB or committee that approves research conducted with their members or on their lands. For more information, read *Final Rule - Part 5* of this policy research update series.

Volunteering as a Research Subject

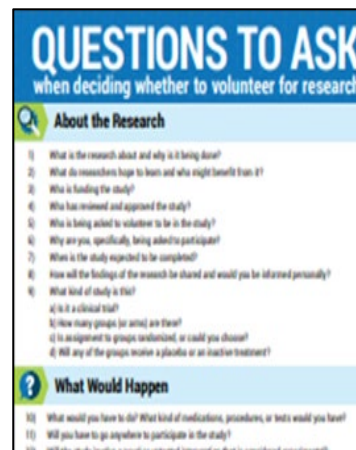
When deciding to participate as a research volunteer (subject) for a research study, an individual should understand what the study is about, the approvals the researchers received for the study, the protections in place to make sure the risk of harm is minimized, their rights as a volunteer, and whom to contact should they have questions or require assistance with their rights. Informed consent is the way in which individuals who volunteer to participate in a research study understand their rights and can make an informed decision to participate.

On January 21, 2019, the Federal Policy for the Protection of Human Subjects, the HHS Common Rule, was implemented to reflect the changing research landscape. These updates to the Common Rule, known as the Final Rule, impact the requirements for receiving informed consent. A more detailed explanation of the changes and how they affect researchers and research participants is provided in the NCAI Policy Research Center *Research Policy Update – Final Rule Part 3, Informed and Broad Consent* brief.

For more information on the requirements for informed consent, view these resources:



Visit the OHRP *Protecting Research Volunteers* webpage to learn about the rights and protections for Research Volunteers:
<http://bit.ly/2QWgmlq>



Before agreeing to participate in research, understand the study with the OHRP “Questions to Ask” document:
<http://bit.ly/2FFamBT>

Resources to Learn More about Human Subject Research Protections

Here are links to some resources on the topics raised in this document:

More Detailed Information	Where to find the Information?
BELMONT REPORT	<ul style="list-style-type: none"> <input type="checkbox"/> The Belmont Report: Basic Ethical Principles and their Application (Video) <input type="checkbox"/> The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research <input type="checkbox"/> HHS Belmont Report Website
COMMON RULE/ FINAL RULE	<ul style="list-style-type: none"> <input type="checkbox"/> Final Rule Material: New and Revised Definitions <input type="checkbox"/> Final Rule Material: Overview of Final Rule Provisions <input type="checkbox"/> Revised Common Rule (HHS Educational Videos) <input type="checkbox"/> Implementing the Revised Common Rule, 10 Ways to Get Started
RESEARCH PARTICIPATION	<ul style="list-style-type: none"> <input type="checkbox"/> About Research Participation Video Series: Office for Human Research Protections <input type="checkbox"/> Questions to Ask When Deciding to Volunteer for Research <input type="checkbox"/> HHS Protecting Research Volunteers
CONSENT AND RIGHTS	<ul style="list-style-type: none"> <input type="checkbox"/> Human Subject Regulations Decision Charts <input type="checkbox"/> Final Rule Material: Comprehensive Guide to Informed Consent Changes <input type="checkbox"/> Final Rule Material: Understanding Broad Consent
INSTITUTIONAL REVIEW BOARDS	<ul style="list-style-type: none"> <input type="checkbox"/> Indian Health Service Institutional Review Boards <input type="checkbox"/> Human Subject Regulations Decision Charts <input type="checkbox"/> Implementing the Revised Common Rule, Exemptions with Limited IRB Review

Citation: NCAI Policy Research Center (2019). *Research Policy Update: Final Rule Part 1 – Human Subjects Research and Protections*. National Congress of American Indians, January 2019

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

Endnotes

¹[45 CFR 46.102]

² National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. [Bethesda, Md.]: The Commission, 1978.

³ Office for Human Research Protections. "The Belmont Report." HHS.gov, US Department of Health and Human Services, 15 Mar. 2016, www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

⁴ "IRB Registration Process FAQs." HHS.gov, US Department of Health and Human Services, www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/irb-registration-process/index.html.

⁵ Office of the Commissioner. "Search for FDA Guidance Documents - Institutional Review Boards Frequently Asked Questions - Information Sheet." U S Food and Drug Administration Home Page, Center for Drug Evaluation and Research, www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm.

⁶ [45 CFR 46(107)(108), Subpart A]

⁷ Office of the Commissioner. "Search for FDA Guidance Documents - Institutional Review Boards Frequently Asked Questions - Information Sheet." *U S Food and Drug Administration Home Page*, Center for Drug Evaluation and Research, www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm.

⁸ Office for Human Research Protections. "IRBs and Assurances." HHS.gov, US Department of Health and Human Services, 18 Mar. 2016, www.hhs.gov/ohrp/irbs-and-assurances.html.

⁹ Office for Human Research Protections. "FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS." HHS.gov, US Department of Health and Human Services, 31 July 2017, www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjectt/index.html.

¹⁰ Kelley, Allyson et al. "Research ethics and indigenous communities" *American journal of public health* vol. 103,12 (2013): 2146-52.

¹¹ "Human Subjects Research Protections - Research." Phoenix Area, Indian Health Services, www.ihs.gov/dper/research/hsrp/.

¹² "Research - The Division of Planning, Evaluation, and Research." Phoenix Area, Indian Health Services, www.ihs.gov/dper/research/.

¹³ "Summary of Changes - Revised Common Rule." Research Ethics and Compliance Management Solutions, HRP Consulting Group, thehrpconsultinggroup.com/wp-content/uploads/2018/11/Recent-Common-Rule-Changes-Summary-Table-with-Notes-Section-Final-version-10.22.18-1-1.pdf.