Research Policy Update:
2019 Changes to the Common Rule that Impact Tribal Research

This document includes the entire seven-part series of the National Congress of American Indians (NCAI) Policy Research Center updates that reviewed the 2019 changes to the Common Rule, or the Federal Policy for the Protection of Human Subjects. New amendments were made that directly impact Tribal Nations and research conducted with Tribal Nations.

Each report in the series is outlined below for easy identification of topics of interest.

1. **Final Rule: Part 1 - Human Subjects Research and Protections (January 2019).** This update provides background information on human subjects research protections and information for individuals considering volunteering to participate in research.

2. **Final Rule: Part 2 - Overview of Changes to the Common Rule (January 2019).** This update provides a brief overview of some of the main changes to human subjects research protections in the Final Rule.

3. **Final Rule: Part 3 - Informed and Broad Consent (January 2019).** This update focuses on changes made in the Final Rule to informed consent and the addition of Broad Consent. For Tribal Nations and tribal members, informed consent is particularly important to understand before volunteering for and approving research.

4. **Final Rule: Part 4 - Overview of Single IRB (sIRB) (January 2019).** This update focuses on the new requirement for a single IRB in multi-site studies, and the exception for Tribal Nations to still require tribal review.

5. **Final Rule: Part 5 - Options for Tribal Review and Tribal Research Codes (January 2019).** This update emphasizes the importance of tribal research codes for Tribal Nations. The Final Rule now requires federally funded researchers to follow tribal law.

6. **Final Rule: Part 6 - Exempt Research (June 2019).** This update reviews changes in exempt research categories in the Final Rule.

7. **The Final Rule: Part 7 - Examples of Tribal Research Laws (July 2019).** This update reviews the importance of Tribal Nations to develop their own research laws and provides some examples of existing tribal research laws.
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 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. 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. 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.
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. IRBs continue to revisit reviews during the research study to maintain protections for the human subjects/participants in the study. IRBs additionally verify that the risks to research participants are not outweighed by the benefits they will likely experience.

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. 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. 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) to will need to be used and they need to follow the relevant federal human subjects research regulations.

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
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.  

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.  

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.” 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:

<table>
<thead>
<tr>
<th>More Detailed Information</th>
<th>Where to find the Information?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BELMONT REPORT</strong></td>
<td>☐ The Belmont Report: Basic Ethical Principles and their Application (Video)</td>
</tr>
<tr>
<td></td>
<td>☐ The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research</td>
</tr>
<tr>
<td></td>
<td>☐ HHS Belmont Report Website</td>
</tr>
<tr>
<td><strong>COMMON RULE/ FINAL RULE</strong></td>
<td>☐ Final Rule Material: New and Revised Definitions</td>
</tr>
<tr>
<td></td>
<td>☐ Revised Common Rule (HHS Educational Videos)</td>
</tr>
<tr>
<td></td>
<td>☐ Implementing the Revised Common Rule, 10 Ways to Get Started</td>
</tr>
<tr>
<td><strong>RESEARCH PARTICIPATION</strong></td>
<td>☐ About Research Participation Video Series: Office for Human Research Protections</td>
</tr>
<tr>
<td></td>
<td>☐ Questions to Ask When Deciding to Volunteer for Research</td>
</tr>
<tr>
<td></td>
<td>☐ HHS Protecting Research Volunteers</td>
</tr>
<tr>
<td><strong>CONSENT AND RIGHTS</strong></td>
<td>☐ Human Subject Regulations Decision Charts</td>
</tr>
<tr>
<td></td>
<td>☐ Final Rule Material: Comprehensive Guide to Informed Consent Changes</td>
</tr>
<tr>
<td></td>
<td>☐ Final Rule Material: Understanding Broad Consent</td>
</tr>
<tr>
<td><strong>INSTITUTIONAL REVIEW BOARDS</strong></td>
<td>☐ Indian Health Service Institutional Review Boards</td>
</tr>
<tr>
<td></td>
<td>☐ Human Subject Regulations Decision Charts</td>
</tr>
<tr>
<td></td>
<td>☐ Implementing the Revised Common Rule, Exemptions with Limited IRB Review</td>
</tr>
</tbody>
</table>


Questions: NCAI Policy Research Center – email: research@ncai.org; website: [http://www.ncai.org/prc](http://www.ncai.org/prc)
Endnotes

1[45 CFR 46.102]
6 [45 CFR 46(107)(108), Subpart A]
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.

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Human Subject Studies and Research – Overview and Definitions

What is the difference between the Common Rule, Revised Common Rule, and Final Rule? The terms Common Rule, Revised Common Rule, and the Final Rule are often used interchangeably or as separate distinct rules depending on the organization. For this series, these terms are defined below:

- **The Common Rule** or the U.S. Department of Health and Human Services (HHS) Federal Policy for the Protection of Human Subjects is a comprehensive set of regulations to guide ethical research practices and protect human subjects from harm.1

- **The Revised Common Rule** has been used at times interchangeably with the Final Rule. For the purposes of this series of briefs, the Revised Common Rule refers only to the changes
announced by HHS in 2017 and revisions during the January 22, 2018 to January 20, 2019 transition to Final Rule. The Revised Common Rule included many but not all elements of the Final Rule and continued to be updated through 2018. Implementation was delayed to 2019.

- The **Final Rule** went into effect on January 21, 2019. The Final Rule is the result of continued work on strengthening revisions to the Common Rule since before 2011. These final changes to the HHS 45 CFR 46, Subpart A (Common Rule) that went into effect on January 21, 2019 are what will be discussed in this brief as the **Final Rule**, and key changes will be reviewed.

**Federal Policy for the Protections of Human Subjects Revisions Timeline**

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<tbody>
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<td><strong>2015 NPRM Comment Period</strong></td>
<td>HHS issued updates to the “Federal Policy for the Protection of Human Subjects” (45 CFR 46, Subparts A). These were published on the Federal Register and open to comment.</td>
<td>IRBs transitioned in preparation for the Final Rule. Revisions to the Common Rule were made during the transition and implementation was delayed until January 21, 2019. During the transition, not all parts of the Final Rule were allowed to be implemented.</td>
<td>The Final Rule went into effect for studies and IRBs funded or certified through HHS.</td>
<td>The U.S. Food and Drug Administration (FDA) plans on updating the FDA “Protection of Human Subjects” (21 CFR 50) and “Institutional Review Boards” (21 CFR 56) policies to match HHS</td>
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As of January 2019, 20 federal departments and agencies plan on following the Final Rule, and 17 of the 20 are official signatories. The U.S. Department of Justice intends to become an official signatory of the Final Rule. The U.S. Food and Drug Administration is not a Common Rule agency but it will be updating its Federal Policy for Protection of Human Subjects to coordinate with the HHS Final Rule changes.

**Research Studies Started Before the Final Rule (January 21, 2019)**

The **Final Rule** introduced many changes to human subject research protection definitions and terminology, consent processes, and IRB requirements. All research studies determined by an IRB review to be approved, waived, or exempt before January 21, 2019 are not subject to the Final Rule. The Final Rule can be applied to new research studies; however if a study or IRB wants to apply a section of the Final Rule changes to a research activity approved prior to January 21, 2019, all changes from the Final Rule must be applied to that research activity. IRBs and researchers cannot pick and
choose what new regulations to use; either they use all or none of them. As of January 21, 2019, new research studies must comply with the Final Rule provisions that went into effect on that date.

**Final Rule Definitions and Terminology Changes**

The Final Rule amended several definitions and examples are included below.

**Research** is the systematic collection and analysis of data to answer a specific question that can “develop or contribute to generalizable knowledge.”

The Final Rule identified four activities that are now **NOT considered to be research** under the Federal Policy for the Protection of Human Subjects:

- “Scholarly and Journalistic activities” that are focused on gathering information about a specific person. This includes oral histories and biographies.
- Any activity deemed part of certain “public health surveillance activities.”
- Collection of information (can include biospecimens, records, other information) for a criminal justice agency. The activity will be approved through the law or a court order prior to collection and can only be used for a criminal investigation.
- Collection of information for the purposes of U.S. “intelligence, homeland security, defense, or other national security.”

**Written or In Writing** was expanded to include electronic mediums. This means that for any place within the Final Rule that requires something written or in writing, this could be provided through an electronic version.

An important change to the Final Rule terminology was the inclusion that all provisions 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.” As a result, it is very important that tribes establish or update their tribal research laws or codes since researchers working on studies supported by federal funding from agencies under the Common Rule are required to follow those laws per the Final Rule.

**Changes to IRBs and Federal Wide Assurance**

The Revised Common Rule proposed removing the option (known as the “checkbox”) for organizations with Federalwide Assurances to voluntarily extend federal human subject research protections to research activities not funded through federal agencies signed on to the Common Rule. This means that the Office for Human Research Protections (OHRP) in HHS would no longer have the ability to regulate studies not funded or supported by a federal signatory of the Common Rule. Due to concern about a gap in research oversight and regulations, the OHRP in HHS may delay implementing this provision. Therefore, IRBs can continue to review non-federally funded research under the requirements of the Common rule or establish and/or comply with other rules for non-federally funded research.
The Final Rule changed the regulations for IRBs reviewing human subjects research studies that are funded, supported, or conducted by federal agencies. If an IRB is reviewing such research, the IRB must comply with the Final Rule. This change allows the federal agencies to enforce human subject protections directly, even when the IRB is not operated by a FWA institution or registered with HHS.12

Changes to the IRB functions in the Final Rule were made to match HHS regulations with FDA regulations.53

Exempt Research and Expedited Review

Exempt Research
Exempt research is research that is not required to go through the full IRB review and approval process because it falls outside the realm of the Common Rule federal protections for human subject research. For the full list of exemptions, the definitions, revisions and restrictions, see 45 CFR 46.104.14

The prior exemptions include certain research conducted in certain educational settings, educational tests, observations of public behavior, certain types of de-identified secondary research, federally conducted research, and taste/food quality and consumer acceptance studies. The Final Rule lists all the categories of exempt research and there are several updates within the categories.

Among the new exemptions, benign behavioral interventions was added as one of the new categories of exempt research. This category allows for research that is “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.”15

The two other new exemptions added to the list are discussed in the NCAI Policy Research Center Research Policy Update - Final Rule Part 3: Informed and Broad Consent and are listed below. Even though they are considered exempt, they actually have to follow the Final Rule requirements for Limited IRB review since Broad Consent was used:

- Research may be exempt from full IRB review if solely for the purpose of storage and maintenance of biospecimens prior to secondary analysis. The IRB must conduct a limited IRB review (usually just by the IRB chair) to ensure adequate privacy and confidentiality protections and documentation of Broad Consent in the original research study; 16
- Secondary research may be exempt from full IRB review when Broad Consent was obtained in the original research study and was applied to the storage and maintenance of identifiable biospecimens and information.17 The IRB must conduct a limited IRB review to ensure adequate privacy and confidentiality protections, and that the use of the identifiable data is within the scope of the Broad Consent.18

Who determines research is exempt or does not need IRB review?
Institutions must identify who is responsible within their organization for making decisions about whether research is exempt from IRB review. Researchers are not allowed to determine that their own research is exempt from IRB review; this must be done by the institution’s identified person.59
Limited IRB review is a newly introduced concept within the Final Rule. The limited IRB review, usually by the IRB chair, must determine that enough human protections and sensitive data protections are in place for studies that involve identifiable information and otherwise qualify as exempt from full IRB review under one of the new exceptions. Certain studies that previously required IRB review may now qualify as exempt from full IRB review but require a limited IRB review. The limited IRB review uses the same process as the expedited IRB review and does not require continuing review.20

Continuing review. The Final Rule eliminates the requirement that the IRBs conduct continuing review of a research project if it is no more than minimal risk and it meets certain conditions, such as being exempt research requiring limited IRB review, research eligible for expedited review, or for research studies under full IRB review that are at the stage where data is only being analyzed.21 However, research that underwent IRB review and approval prior to the new Final Rule still requires continuing review.

Policy Research Center: Final Rule Update Series

To help tribes, researchers, and research volunteers understand some key changes to the Common Rule in the 2019 Final Rule, the NCAI Policy Research Center has written a series of Research Policy Updates. This is the second brief in the series. This brief series provides an overview of some changes, but there may be other changes from the Final Rule that may have different impacts. The NCAI Policy Research Center recommends using the HHS code when making official research or research review changes based on the Final Rule. The code can be found at http://bit.ly/2CqTHa1. Many academic institutions and centers have training materials, many of which are available online, for researchers on these updates.

The NCAI Policy Research Center’s 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 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 tribes and tribal members, this will be particularly important to understand before volunteering for research.
- **Final Rule: Part 4** introduces the new Single IRB (sIRB) and its effect on tribal communities.
- **Final Rule: Part 5** overviews options for tribal review and tribal research codes.


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


7 [45 CFR 46.102(ll), Subpart A] “

8 [45 CFR 46.102(ll), Subpart A]


14 [45 CFR 46.104, Subpart A]


Informed Consent. Before conducting human subject research, researchers must receive explicit permission from research volunteers to participate in their research study. This explicit permission is called “informed consent.” Potential research volunteers must be provided enough and complete information to make an informed decision to participate in the study or to refuse to participate in the study. For participants to have a full and accurate understanding, language, cultural, and education factors need to be incorporated for valid consent.¹ IRBs and researchers must make sure that informed consent includes the appropriate languages and translations available, included cultural distinctions, and can be accessible by all education levels.² Consent must be given free from pressure or coercion.³ The required elements for informed consent, including the updated elements from the 2019 Final Rule that must be included on consent forms, are listed on the next page.
## Informed Consent Checklist for Studies Beginning After January 21, 2019

- A statement that clearly explains:
  - the study or activity is research;
  - the purpose of the research and how the information will be used;
  - the anticipated time and any financial commitment a research volunteer can expect from participating in the study;
  - what the research volunteer will be doing during the study.

- Explanation of any experimental procedures.

- Statement free of pressure or coercion that participation in the research is voluntary.
  Researchers need to make clear that there will be no penalty or loss of benefits to an individual if he/she chooses not to participate or to stop participating in a study.
  - Reasons for why an individual may be asked to stop participating in a study, regardless of consent, need to be outlined.
  - Procedures on how to stop participating in a study, and what the consequences of ending participation may be, should be discussed during the consent process.

- A list of potential risks or discomforts.
  - If consequences to pregnancy or to research volunteers who become pregnant during the study are unknown, this must be discussed during the informed consent process.

- A list of potential benefits.

- Appropriate alternatives to study participation.

- The privacy and security measures taken to protect a volunteer's identifiable.

- If any identifiable data will be collected, including biological/DNA samples, researchers must disclose which of the following applies to the study*:
  - The data collected may be used in future studies by other researchers and consent will not need to be obtained again. Identifiable information will be removed for any future secondary use but, informed consent to use that de-identified data in future studies will not be required. By participating and providing consent in the first study, research volunteers are providing consent for his/her data to be used in all future studies.*
  - The data collected will only be used for the initial study and will not be shared beyond the research team or for any additional research. If additional research is conducted, the researcher must obtain consent from the volunteer again.*

- For research collecting genetic/DNA samples:
  - If biological samples or data are being or may be sold for commercial use, researchers need to disclose and discuss whether the research volunteer will receive a portion of the initial sale or any future profits.*
  - A disclosure if the samples may or will be used for whole genome sequencing. Whole genome sequencing identifies the entire DNA sequence of an individual. A debate regarding the ethics and privacy of whole genome sequencing is currently ongoing.*
  - Under what conditions an individual's research results will be disclosed.*

- Approximate number of study participants.

- Contact information for someone that participants can ask questions regarding the study or study process, learn more about his/her rights as a study participant, or to receive information and assistance for study related injuries.

* This symbol indicates these requirements for informed consent were added and implemented by the Final Rule for Human Research Protections on January 21, 2019. See HHS 45 CFR 46.116 (b)(c), Subpart A
Understanding Primary vs. Secondary Research. Primary research is when Researcher A conducts new research, collects new data, and uses the research collected for a pre-approved and identified research question/purpose. Researcher A will have received informed consent from the research volunteers who participated in the study. The research may or may not be collecting data that is identifiable (i.e. is clearly data from a specific research volunteer).

Secondary research is when a new researcher, Researcher B, uses the data collected by Researcher A to answer a new research question for a new research study. Researcher A may also want to use the data for a new research study. Depending on the research question, the type of data collected, whether the data is identifiable, and what was included in the original consent, Researcher B may or may not have to obtain consent from the research volunteers again. For example, the Final Rule allows in certain circumstances use of secondary data that is not identifiable. The research volunteers from Researcher A's study may have no idea how their data is being used by Researcher B in the new study. Before the Final Rule, if the data was identifiable, Researcher B would have to obtain consent from the volunteers to use their data again for the new research study.

Broad Consent. Under the new provisions in the Final Rule, Researcher A could ask the research volunteer before the primary research study for Broad Consent in the Informed Consent process for permission to use their identifiable data in future research studies without obtaining informed consent again. This would allow ANY future researcher to be able to use the identifiable personal data from Volunteer A collected by Researcher A for a completely different secondary research study B without informed consent for the new secondary research study. If a research volunteer agrees to Broad Consent, they may not know how their identifiable data will be used or what generalizations about their community will be made in future research studies. Researcher A's consent form must be clear about how long the research volunteer's data will be stored for future research, and information about the types of research that might occur, including genetic research or research for commercial profit. These requirements are included in the Informed Consent Checklist on the previous page. Researcher A must provide one of two options on the study consent form: informed consent for this study only; or Broad Consent for any future study.
As mentioned above, the January 21, 2019 Final Rule included a new type of consent called Broad Consent, which only applies to the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Biospecimens are “samples of material, such as urine, blood, tissue, cells, DNA, RNA, and protein from humans...” Broad Consent means that future research studies not discussed during the initial consent process can use the same identifiable private information and biospecimens collected during the original research study without the new researchers needing to obtain consent from the original research volunteers. Research volunteers providing Broad Consent may not know how their identifiable information and data will be used in future research.

This discussion of Broad Consent does not apply to certain types of de-identified data, which may be exempt from IRB review and does not require informed consent to analyze. Please refer to the list of exempt research in the Final Rule for more information. However, tribes or tribal IRBs may decide that all research requires tribal review, even though it might be exempt from IRB review based on the Common Rule, especially since the Common Rule allows tribes to implement more restrictive informed consent requirements. Check with the individual tribe for their research review requirements.

What does Broad Consent look like?
The Final Rule does not provide a template or guidance as to the format of how Broad Consent needs to look. The Final Rule does specify that Broad Consent needs to include all elements of the normal informed consent process, in addition to an explanation of Broad Consent and any boundaries on research for future research conducted under that consent. When secondary research is planned, an IRB needs to confirm that the research planned is within whatever boundaries were set by the researcher during the initial consent process in the primary research project.

Refusing Broad Consent
Research volunteers can refuse Broad Consent and request to provide only informed consent for a specific research study. This means that the researcher has consent to ONLY use the volunteer’s information for the current specified study. If the researcher or another research wishes to conduct more or different research with the volunteer’s identifiable information, the researcher must obtain a new informed consent specifically for the new research study.

If a research volunteer refuses Broad Consent, “an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens [genetic samples].” Researchers will not be legally able to use a research volunteer’s information after the initial study is completed and cannot override the research volunteer’s decision.

In addition to individuals refusing Broad Consent, entities, such as IRBs, or even tribes, can also refuse to implement Broad Consent. An IRB can refuse a consent form for a study that includes Broad Consent, and refuse to approve that study. Similarly, a tribal IRB or tribe can decide not to implement Broad Consent and refuse to approve research studies that involve Broad Consent. Broad Consent is an alternative to the regular informed consent process. Therefore, entities can choose not to implement it under the Final Rule. Tribes may consider amending their research laws to incorporate their decisions on whether to implement Broad Consent since according to the Final Rule, researchers conducting research with federal funding under the Common Rule must follow tribal law.

Broad Consent
An example of language used by an entity that has decided to not implement Broad Consent is included below:

“Broad consent is a new term introduced by the Final Rule that allows an investigator to seek prospective consent to unspecified future research. It’s intended for “secondary research use” of private identifiable information and identifiable biospecimens. Broad consent is required for exempt categories 7 and 8. Harvard University has decided not to implement Broad Consent.”

### Individual Rights and Amending Consent

Research volunteers have **the right to refuse consent to any human subjects research study**.
- Under the Federal Policy for the Protections of Human Subjects, research participation is *voluntary* and free of “pressure or undue influence”.*5
- Potential research volunteers cannot be punished or denied any benefits he/she would have been previously received, regardless whether asked to participate in the study. *6

Research volunteers **can withdraw consent** from study participation at **any time**.
- The volunteers cannot be punished or denied any benefits he/she would have normally received. *7

Potential reasons for **why research volunteers may be removed from a study** by a researcher need to be discussed during the initial informed consent process. *8

Research volunteers have the right to contact a designated study official at any time to ask questions about the study process, the individual’s rights and protections as a volunteer, and how to access help for study related injuries or complications. *9

### Contact for Questions on Consent and Protections

The U.S. Department of Health and Human Services, Office for Human Research Protections created a printable document of “Questions to Ask When Deciding Whether to Volunteer for Research.” The document helps potential research participants ask the questions for greater understanding of the research.

**Research is voluntary**, and individuals should make sure they understand what they are volunteering for and their rights and protections as a volunteer. Even though a researcher might be pressuring someone to sign a form in a hurry or without reading it, they have the right to read it, consider it, and make sure they understand it. See the below chart for contact information where research volunteers can receive help with their protections and rights.
<table>
<thead>
<tr>
<th>ORGANIZATION NAME</th>
<th>ROLE/QUESTION</th>
<th>CONTACT AND RESOURCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office for Human Research Protections</td>
<td>For general questions about regulations, the IRB review process, and protections for human research subjects.</td>
<td>Phone Numbers: (240) 453-6900 (866) 447-4777 (Toll-Free within the United States) Email: <a href="mailto:OHRP@HHS.gov">OHRP@HHS.gov</a></td>
</tr>
</tbody>
</table>
| Office for Human Research Protections: Division of Compliance Oversight | If an individual needs to report an incident of non-ethical research practices, the Division of Compliance Oversight can answer questions and investigate violation reports. | • Resources on Compliance: Common Rule and Rights  
• Guide on How to Report Violations  
• OHRP Determination Letters (Results of Reported Non-compliance) |
| Office of Human Research Protections: Division of Policy and Assurances | For questions related to IRBs or Federalwide Assurances and registration.  | Email: IRBorFWA@hhs.gov                                                                                                                                 |
| U.S. Food and Drug Administration                      | For questions on human subjects research protections with studies under FDA regulations.            | • Reporting Complaints Related to FDA-Regulated Clinical Trials  
• IRB Reporting: FDA Contacts                                                                                                                                 |
| Specific Study                                         | For every Human Subjects Research Study, a point of contact should be provided to all research volunteers to ask questions about the study, the participants’ rights, and assistance for study related injury. | • Check the signed copy of the research volunteer informed consent form. If there is no contact information, request this from the Investigator. If the Investigator cannot provide this information, contact OHRP at OHRP@HHS.gov |


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

1 [45 CFR 46.116, Subpart A]
2 [45 CFR 46.107, Subpart A]
3 [45 CFR 46.116(a), Subpart A]
4 [45 CFR 46.116(e), Subpart A]
7 [45 CFR 46.104, Subpart A]
11 [45 CFR 46.116(e), Subpart A]
15 [45 CFR 46.116(a),(b)8, Subpart A]
16 [45 CFR 46.116(b)8, Subpart A]
17 [45 CFR 46.116(b)8, Subpart A]
18 [45 CFR 46.116(c)2, Subpart A]
19 [45 CFR 46.116(b)7, Subpart A]
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.

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. 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.

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

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.
The National Institutes of Health included a policy for the use of single IRBs for multi-site research on January 25, 2018. 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.

- 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. 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. 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.

- 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. 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**. 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. 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**.

**sIRB Eligibility and Exceptions – Research with Tribes**

The single IRB requirement only applies to U.S. institutions and research conducted within the United States. Additional IRB approvals and additional human research protections may be needed for research conducted on foreign soil and with foreign institutions. 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.

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.”

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. 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.

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**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.

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.

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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.

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

Endnotes

10 [45 CFR 46.114(b)(1), Subpart A]
12 [45 CFR 46.114(a), Subpart A]
15 [45 CFR 46.114(b), Subpart A]
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]
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 website or read the regulation: http://bit.ly/2CqTH1I

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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. 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? 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. 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. 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. 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. 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.

**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. The review process could introduce new requirements, extra requirements, and/or culturally specific requirements. 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. Participating in an inter-tribal research review group means member tribes share the burden of resources to conduct appropriate review. 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).” 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
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.” 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. 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. 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. 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.” 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. 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.


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]
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]
Research Policy Update

Final Rule: Exempt Research

Exempt Research – What is exempt research? Who can determine?

Exempt research is research that, due to its low level of risk, is not required to go through the full Institutional Review Board (IRB process). However, some categories of exempt research do need to go through a limited IRB review. The 2019 Common Rule updates revised, removed, and added to the list of exempt research categories. There are currently eight categories for exempt research.

The U.S. Department of Health and Human Services (HHS) does not specify who at an institution determines exempt research. Researchers are not prohibited by HHS from determining if his/her own research is exempt from IRB review. However, due to potential conflicts of interest, the Office for Human Research Protections (OHRP) recommends against researchers determining the exempt status of his/her own study. Instead, OHRP recommends that institutions define a specific individual or individuals to determine if research studies qualify as exempt. In addition, some of the new exempt categories require limited review by the IRB chair to ensure privacy safeguards are adequate.
IRBs and/or researchers must first determine if the proposed activity is research, which is defined as a “systemic investigation designed to develop or contribute to generalizable knowledge.” OHRP has a number of decision charts to help make these determinations. If the activity is determined to be research and it involves human subjects, then there needs to be a determination if it is “exempt” from IRB review, or whether it must go through an expedited or full IRB review. The following sections review the eight separate categories for exempt research. Each category will be identified as new, replaced, or revised category based on the recent updates to the Common Rule. A summary of the changes is included below.

<table>
<thead>
<tr>
<th>Updates to Exempt Research Categories – Final Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1 REVISED  Educational Settings – new conditions</td>
</tr>
<tr>
<td>Category 2 REVISED  Public Behavior – clarifications, must meet one of three criteria which could include limited IRB review</td>
</tr>
<tr>
<td>Category 3 REPLACED  Benign Behavioral Interventions – defined conditions, must meet one of three criteria with possible limited IRB review required</td>
</tr>
<tr>
<td>Category 4 REVISED  Secondary Research with No Required Consent – now includes biospecimens, must meet one of four criteria, new HIPAA requirements, federal data requirements</td>
</tr>
<tr>
<td>Category 5 REVISED  Research and Demonstration Projects – added research supported by federal agency, not just conducted by federal agency</td>
</tr>
<tr>
<td>Category 6 UNCHANGED  Taste and Food Quality</td>
</tr>
<tr>
<td>Category 7 NEW  Storage &amp; Maintenance of Secondary Data under Broad Consent – requires limited IRB review</td>
</tr>
<tr>
<td>Category 8 NEW  Secondary Research with Required Broad Consent – requires limited IRB review</td>
</tr>
</tbody>
</table>
Exempt Category 1 – Educational Settings

Exempt category one (1), research “conducted in established or commonly accepted educational settings,” was revised in the 2019 Common Rule updates. The 2019 changes to this exemption added the requirement that the research cannot negatively impact students’ ability to learn required course content or the normal assessment of teachers. Research can only include testing on normal teaching strategies, assessments, curriculum, and classroom management.

Exempt Category 2 – Public Behavior

Exempt category two (2), “Research that only includes interactions involving educational test, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)” was revised in the 2019 Common Rule updates with changes related to visual and auditory recordings, identifiable or sensitive information, and limited IRB review. The changes made to this category made the requirements clear that research qualifying for this exemption only includes certain interactions or observations, and any research with an intervention or an alteration of the environment does not qualify under this category. Visual and auditory recordings were added as a research method in this category.

To qualify under this category, research must meet at least one of the following requirements:

i. Information collected must be recorded in such a way that individuals are not identifiable. Research falling under this requirement cannot survey or interview children. Children can only be included in research if the researcher does not participate in the activities being observed.

ii. Disclosure of individuals’ identities or responses outside the research space does not place the research subjects at a risk for harm, including criminal or civil liability, or financial, employment, educational, or reputational disadvantage or damage. Again, children can only be included in research if the researcher does not participate in the activities being observed.

iii. If identifiable information is collected with the potential for harm, limited IRB review is required to determine that research contains appropriate protections for research subjects’ privacy, maintains confidentiality, and the information is gathered and recorded in a way in which individuals are not identifiable. Children cannot be included under an exemption in this category.

Exempt Category 3 – Benign Behavioral Interventions

Exempt category three (3), “Research that involves [both] benign behavioral interventions and the collection of information from adults through verbal answers, written answers, and/or audiovisual recordings. The participant must agree to the intervention and collection of information,” is a new exempt category in the 2019 Common Rule updates that previously required expedited IRB review.
Benign behavioral interventions in this category should be “brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects and…. [there also should be] no reason to think the subjects will find the interventions offensive or embarrassing.”

No research involving children, adults with limited decision making abilities, or any medical interventions are allowed under any section of this exemption. The use of deception is not allowed unless the research subjects agree to be misled or unaware of the purpose of the research.

Exempt research under this category needs to fit into at least one of the three requirements below:

i. Information must gathered from the intervention in such a way that the study participants cannot be easily identified or linked to his/her responses.

ii. If study participants can be linked to his/her own answers, the release of the participants’ responses will not reasonably put participants at risk for criminal or civil liberty violations, nor damage the participants’ financial, educational, employment, or reputational standing.

iii. If information is available that can easily link a participant to his/her answers and disclosure is a potential for harm to the participant, a limited IRB review must be conducted for privacy and confidentiality protections.

Exempt Category 4 – Secondary Research with No Required Consent

Exempt category four (4), “Secondary research for which consent is not required: secondary research uses of identifiable private information or identifiable biospecimens” was revised in the 2019 Common Rule updates to include biospecimens, data under HIPPA authority, federally conducted research, and federally generated data. No primary data collection can occur under this exemption. Data and biospecimens from pregnant women, children, prisoners, and adults with impaired judgement are not allowed under this exemption.

Research is exempt and does not require informed consent if at least one of the following four requirements are met:

i. Publicly available data, including identifiable private information or identifiable biospecimens, is being used.

ii. Information is recorded in a way in which study participants cannot be readily identified, and the researchers do not have contact with participants and will not re-identify them.

iii. The research uses health information regulated by HIPPA and is specifically for “health care operations” and “public health activities or purposes.” HIPPA regulations still apply and HIPPA authorizations and waivers are still required and must be obtained.

iv. The research is done by, or on behalf of, a federal agency and uses federally collected data that was collected initially for non-research activities. If the research uses identifiable data, the research project may fall under the scope of the E-Government Act of 2002 or the Paperwork Reduction Act of 1995.
Exempt Category 5 – Research and Demonstration Projects

Exempt category five (5), “Research and demonstration projects that are conducted or supported by a Federal department or agency, or [are] otherwise subject to the approval of department or agency heads…, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs,” was revised in the 2019 Common Rule updates to include research supported by a Federal agency in addition to research conducted by a Federal agency.39

If research falls under this category, researchers must define the public benefit and service program that is being researched. Exempt research must be listed on a publicly available Federal website operated by or maintained for the department or agency conducting or supporting the research. “The research or demonstration project must be published on this list prior to [the beginning of the] research involving human subjects.”40

Exempt Category 6 – Taste and Food Quality

Exempt category six (6), “Taste and food quality evaluation and consumer acceptance studies,” is the only category that was unchanged in the 2019 Common Rule updates.42

Research in this category must already have satisfied requirements and regulations for food safety and consumption by the U.S. Food Safety and Inspection Service in the U.S. Department of Agriculture and/or the U.S. Environmental Protection Agency.43 This category relates only to testing already defined safe foods for taste and quality. Including children and pregnant women in research under this exemption is allowed.44

Exempt Category 7 – Storage and Maintenance of Secondary Data under Broad Consent

Exempt category seven (7), “Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review,” is one of two new categories from the 2019 Common Rule updates.46

This new category only applies to the storage and maintenance of identifiable biospecimens or private information gathered under broad consent and prior to any secondary data analysis, not the act of using the data for research. Storage and maintenance for data under this category will need to undergo a limited IRB review to establish that procedures and policies are in place to protect the privacy and confidentiality of the data.47

The limited IRB review will need to confirm that all requirements for broad consent were met and the consent was received for the data storage and secondary use. IRBs may not waive consent in this exemption for any individual who refused consent.48
Exempt Category 8 – Secondary Research with Required Broad Consent

Exempt category eight (8), “Secondary research for which broad consent is required. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use,” is the second new exempt category from the 2019 Common Rule updates. While the seventh category for exempt research relates only to the storage and maintenance of data, the eighth category specifically relates to the use of the stored identifiable private data or identifiable biospecimens. A limited IRB review is required prior to secondary analysis for this exemption. The review will ensure that proper privacy and confidentiality procedures are in place, proper broad consent was received, no plans to return research results to participants exist, and the proposed research falls under the scope of the initial broad consent. IRBs may not waive any refused consent under this exemption. To learn more on secondary research and broad consent, read the NCAI Policy Research Center Research Policy Update – Final Rule Part 3, Informed and Broad Consent brief.

Considering Changes to Exempt Research

The U.S. Department of Health and Human Services has the overall authority to define when research qualifies as exempt. To prevent inaccurate decisions and conflicts of interest, OHRP recommends researchers do NOT determine if his/her own research is exempt and to also have institutionally identified individuals and policies on how to determine projects’ exempt status.

When considering making changes to exempt research projects, OHRP recommends first contacting the individual who initially granted the exempt status. Each institution will need to make their own policies on how to make changes to exempt research. Making these policies can help ensure research projects maintain the correct exempt or non-exempt status.


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

Endnotes
1 [45 CFR 46.104(a), Subpart A]
3 [45 CFR 46.102(l), Subpart A]
5 [45 CFR 46.104(d)(1), Subpart A]


[45 CFR 46.104(d)(4), Subpart A]

[45 CFR 46.104(d)(5), Subpart A]

[45 CFR 46.104(d)(6), Subpart A]

[45 CFR 46.104(d)(7), Subpart A]


[45 CFR 46.104(d)(8), Subpart A]


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/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 website or read the regulation: http://bit.ly/2CqTH1I

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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. 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](https://www.crcaih.org/irb-toolkit.html)
The following table shows examples of different tribal research laws for tribal nations interested in creating or amending their own research laws.

<table>
<thead>
<tr>
<th>Tribal Nation</th>
<th>Review Board/Committee/Council Website</th>
<th>Tribal Research Laws</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Colorado River Indian Tribes</strong></td>
<td>CRIT Ethics Review Board</td>
<td><a href="http://bit.ly/2GFeYrx">http://bit.ly/2GFeYrx</a></td>
</tr>
<tr>
<td><strong>Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians</strong></td>
<td>Tribal Council Review</td>
<td><a href="https://ctclusi.org/tribalcode">https://ctclusi.org/tribalcode</a> Title 1 – Chapter 1-10</td>
</tr>
<tr>
<td><strong>Karuk Tribe</strong></td>
<td>Karuk Resources Advisory Board and Karuk Tribal Council</td>
<td><a href="http://bit.ly/2SWI2Qa">http://bit.ly/2SWI2Qa</a></td>
</tr>
<tr>
<td><strong>Oglala Sioux Tribe</strong></td>
<td>Oglala Sioux Tribal Research Review Board</td>
<td>Oglala Sioux Tribe Ordinance #07-053</td>
</tr>
<tr>
<td><strong>Pascua Yaqui Tribe</strong></td>
<td>Research Review Committee</td>
<td><a href="http://bit.ly/2Kd5cOa">http://bit.ly/2Kd5cOa</a></td>
</tr>
<tr>
<td><strong>Tohono O’odham Nation</strong></td>
<td>Tohono O’odham Nation Institutional Review Board</td>
<td><a href="http://www.tolc-nsn.org/docs/Title17Ch8.pdf">http://www.tolc-nsn.org/docs/Title17Ch8.pdf</a></td>
</tr>
</tbody>
</table>

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.
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/2CqTH11.

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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\[45\text{ CFR} 46.101(f), \text{ Subpart A}\]