



NATIONAL CONGRESS OF AMERICAN INDIANS

POLICY RESEARCH CENTER

January 2019



## Research Policy Update

### *Final Rule: Part 2*

### *Overview of Changes to the Common Rule*

In 1991, the Federal Policy for the Protection of Human Subjects, also known as the **Common Rule**, was published. The Common Rule is a regulation that guides research protections for studies with human subjects funded by certain federal agencies. U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) have separate but complimentary regulations for ethical research with human subjects.

On January 21, 2019, recent revisions to the Common Rule (known as the Final Rule) went into effect for studies and IRBs under HHS regulations. The U.S. Food and Drug Administration will be updating their Protections for Human Subjects to match with HHS regulations in the future. A comprehensive list of federal departments and agencies signed on to follow the Common Rule can be found at <http://bit.ly/2Fqbvhr>.

The NCAI Policy Research Center created this series of Research Policy Updates on the Final Rule. These updates provide a brief overview of only some recent changes to the Common Rule. Please visit the [HHS Office for Human Research Protections](http://www.hhs.gov/ohrt/) website or read the regulation: <http://bit.ly/2CqTH11>

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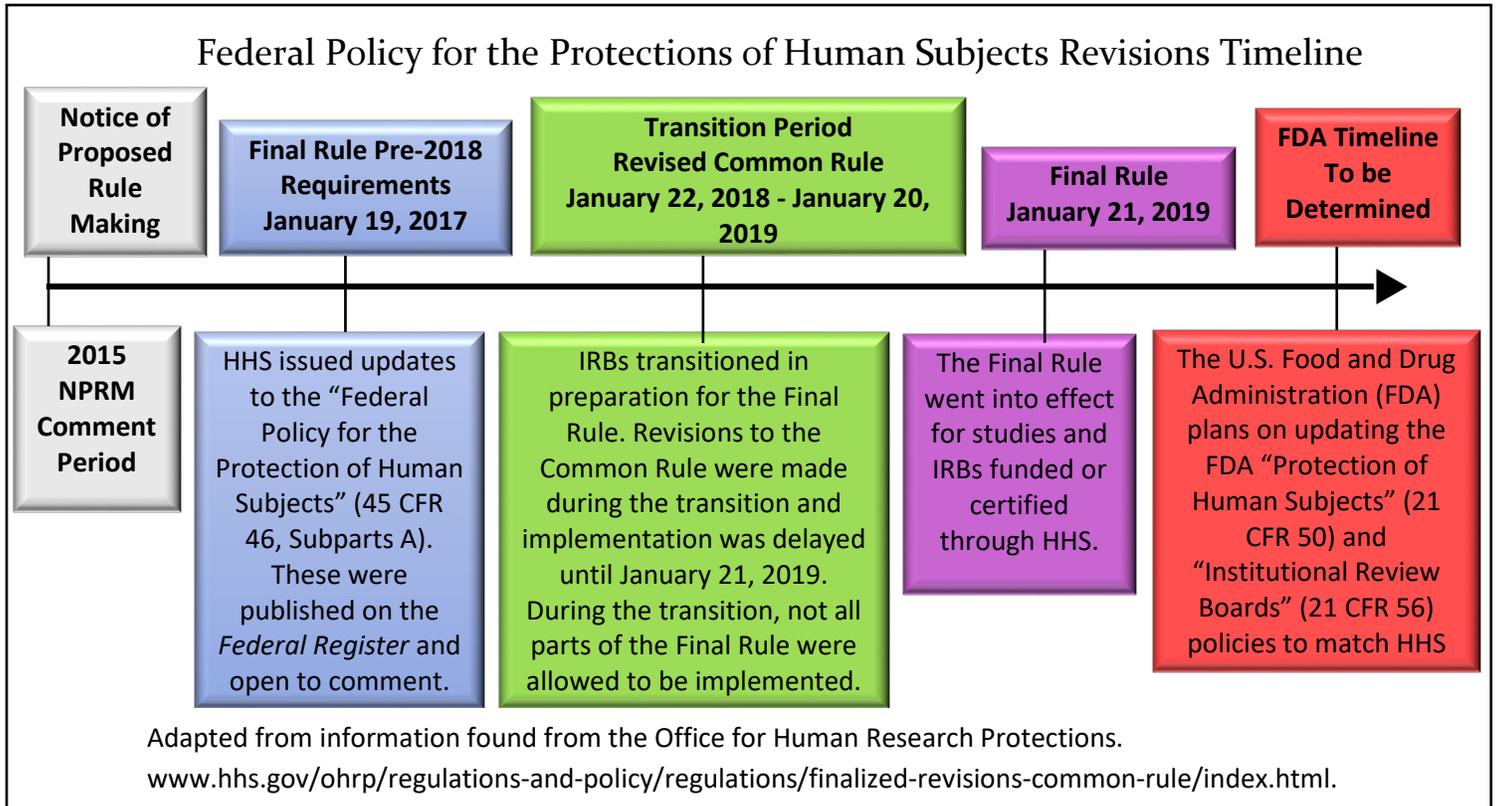
## **Human Subject Studies and Research – Overview and Definitions**

**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.<sup>1</sup>
- 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.



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.<sup>2</sup>

### 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.<sup>3</sup> 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.<sup>4 5</sup> 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.”<sup>6</sup>

The Final Rule identified four activities that are now **NOT considered to be research** under the Federal Policy for the Protection of Human Subjects.<sup>7</sup>

- “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.”<sup>8</sup>

**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<sup>9</sup>

**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.”**<sup>10</sup> 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**.<sup>11</sup> 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.<sup>12</sup>

Changes to the IRB functions in the Final Rule were made to match HHS regulations with FDA regulations.<sup>13</sup>

## 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.<sup>14</sup>

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.”<sup>15</sup>

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;<sup>16</sup>
- 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.<sup>17</sup> 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.<sup>18</sup>

### 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.<sup>19</sup>

**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.<sup>20</sup>

**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.<sup>21</sup> 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/2CqTH1l>. 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.

Citation: NCAI Policy Research Center (2019). *Research Policy Update: Final Rule Part 2 – Overview of Changes to the Common Rule*. National Congress of American Indians, January 2019

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

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## Endnotes

<sup>1</sup> Office for Human Research Protections. “Federal Policy for the Protection of Human Subjects (‘Common Rule).” HHS.gov, US Department of Health and Human Services, 18 Mar. 2016, [www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html).

<sup>2</sup> Office for Human Research Protections. “Federal Policy for the Protection of Human Subjects (‘Common Rule).” HHS.gov, US Department of Health and Human Services, 18 Mar. 2016, [www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html).

<sup>3</sup> Office for Human Research Protections, and OHRP. “The Revised Common Rule Compliance Dates and Transition Provision.” HHS.gov, US Department of Health and Human Services, 10 Jan. 2019, <http://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-revised-common-rule-compliance-dates-transition-provision-45-cfr-46-1011/index.html>.

<sup>4</sup> “Implementing the Revised Common Rule – 10 Ways to Get Started.” Research Ethics and Compliance Management Solutions, HRP Consulting Group, <https://thehrpconsultinggroup.com/wp-content/uploads/2018/11/10-Ways-to-Get-Started-with-Appendicies-A-Applying-the-CR-B-Broad-Consent-C-Existing-Studies-version-10.22.18.pdf>.

<sup>5</sup> Final Rule Material: Overview of the Final Rule Revisions. CITI Program, [about.citiprogram.org/wp-content/uploads/2019/01/Final-Rule-Material-Overview-of-the-Final-Rule-Revisions.pdf](http://about.citiprogram.org/wp-content/uploads/2019/01/Final-Rule-Material-Overview-of-the-Final-Rule-Revisions.pdf).

<sup>6</sup> Final Rule Material: New and Revised Definitions. CITI Program, [about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-New-and-Revised-Definitions.pdf](http://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-New-and-Revised-Definitions.pdf).

<sup>7</sup> [45 CFR 46.102(l), Subpart A] ”

<sup>8</sup> [45 CFR 46.102(l), Subpart A]

<sup>9</sup> Final Rule Material: New and Revised Definitions. CITI Program, [about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-New-and-Revised-Definitions.pdf](http://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-New-and-Revised-Definitions.pdf).

<sup>10</sup> “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](http://thehrpconsultinggroup.com/wp-content/uploads/2018/11/Recent-Common-Rule-Changes-Summary-Table-with-Notes-Section-Final-version-10.22.18-1-1.pdf).

<sup>11</sup> “Implementing the Revised Common Rule – 10 Ways to Get Started.” Research Ethics and Compliance Management Solutions, HRP Consulting Group, <https://thehrpconsultinggroup.com/wp-content/uploads/2018/11/10-Ways-to-Get-Started-with-Appendicies-A-Applying-the-CR-B-Broad-Consent-C-Existing-Studies-version-10.22.18.pdf>.

<sup>12</sup> Final Rule Material: Overview of the Final Rule Revisions. CITI Program, [about.citiprogram.org/wp-content/uploads/2019/01/Final-Rule-Material-Overview-of-the-Final-Rule-Revisions.pdf](http://about.citiprogram.org/wp-content/uploads/2019/01/Final-Rule-Material-Overview-of-the-Final-Rule-Revisions.pdf).

<sup>13</sup> Final Rule Material: Overview of the Final Rule Revisions. CITI Program, [about.citiprogram.org/wp-content/uploads/2019/01/Final-Rule-Material-Overview-of-the-Final-Rule-Revisions.pdf](http://about.citiprogram.org/wp-content/uploads/2019/01/Final-Rule-Material-Overview-of-the-Final-Rule-Revisions.pdf).

<sup>14</sup> [45 CFR 46.104, Subpart A]

<sup>15</sup> Final Rule Material: Changes to the Exempt Determination Process. CITI Program, [about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf](http://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf).

<sup>16</sup> Final Rule Material: Changes to the Exempt Determination Process. CITI Program, [about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf](http://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf).

<sup>17</sup> U.S. Department of Health and Human Services. YouTube, HHS, 9 Oct. 2018, [www.youtube.com/watch?v=APRVsvKsPrM&feature=youtu.be](http://www.youtube.com/watch?v=APRVsvKsPrM&feature=youtu.be).

<sup>18</sup> Final Rule Material: Changes to the Exempt Determination Process. CITI Program, [about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf](http://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf).

<sup>19</sup> “Exempt Research Determination FAQs.” HHS.gov, US Department of Health and Human Services, [www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/index.html#4109](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/index.html#4109) .

<sup>20</sup> U.S. Department of Health and Human Services. YouTube, HHS, 9 Oct. 2018, [www.youtube.com/watch?v=APRVsvKsPrM&feature=youtu.be](http://www.youtube.com/watch?v=APRVsvKsPrM&feature=youtu.be).

<sup>21</sup> What's New with Continuing Review for Expedited Research? CITI Program, [about.citiprogram.org/wp-content/uploads/2018/07/Handout-3-Whats-New-With-Continuing-Review-for-Expedited-Research.pdf](http://about.citiprogram.org/wp-content/uploads/2018/07/Handout-3-Whats-New-With-Continuing-Review-for-Expedited-Research.pdf).