



Revised Common Rule 45 CFR 46.114 Cooperative Research Provision

The Office of Human Research Protections (OHRP) has implemented sweeping changes to federal regulations that protect the rights and welfare of human research participants, known as the Common Rule (45 CFR 46). The Common Rule changes are intended to modernize, strengthen and make more effective the federal policies for the protection of human research participants.

The revised Common Rule applies to all new studies submitted after January 21, 2019. The implementation of the Cooperative Research provision in the revised Common Rule has been scheduled to go into effect three years after the initial publication of the Revised Common Rule. 45 CFR 46.114. will be applied to all new studies submitted on or after January 20, 2020 that meet specific criteria set forth in the revised Common Rule 45 CFR 46.114.

What is the Common Rule?

The Common Rule is the Federal policy put in place to protect human participants in research. It is based on the three ethical principles of the Belmont Report: *Beneficence*, *Justice*, and *Respect for Persons*. The Common Rule was first published in 1991, and has remained unchanged since.

Why Change the Common Rule?

With advancements in medicine and technology, and other overlapping Federal policies overseeing research with human participants, the Common Rule failed properly address current issues in the protection of human participants in research, and further complicated the regulatory landscape.

What is the 45 CFR 46.114 Cooperative Research Provision?

This new section adds a requirement for institutions located within the U.S. that are engaged in federal cooperative research (projects involving more than one institution) to rely upon approval by a single IRB (sIRB) for the portion of the research that is conducted in the U.S.

This new provision is a step toward aligning with the National Institute of Health's recently enacted Single IRB Mandate. For studies that must comply with the NIH policy on sIRB review, the effective date was January 25, 2018. See our guidance document on the [NIH Single IRB Mandate for Multi-Site studies](#) for more information.

Related Definitions:

- **Cooperative Research:** Research projects that involve more than one institution.
- **Reviewing IRB:** Also referred to as the IRB of record; is the single IRB chosen to provide regulatory oversight of research conduct at all sites
- **Relying IRB:** The IRB or institution that is engaged in the multicenter cooperative research and ceding the regulatory oversight to the chosen reviewing IRB, or IRB of record.

The following research is not subject to this provision:

- Cooperative research subject approved prior to January 20, 2020
- Cooperative research for which more than single IRB review is required by law (including tribal law)
- Cooperative research when the Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context
- Institutions located outside of the United States
- Research conducted outside of the United States (but, the requirement would apply to any portions of such research conducted inside of the United States)

Choosing a sIRB of Record:

The reviewing sIRB will be specified by the federal department or agency supporting or conducting the research; the “Lead institution” may propose the reviewing IRB, but final federal approval will be required.

Additional Requirements:

A signed agreement between the reviewing IRB and the relying IRB that specifies the responsibilities of each institution engaged in the research.

Resources Available:

- For more information about submission instructions visit our [Reliance Agreements Webpage](#).
- Questions can be sent to relyirb@wayne.edu
- WSU IRB Presentation Video: Policy Updates Human Participant Research Presented May 9, 2019 by Monica Malian & Heather Park-May: <https://youtu.be/0JwZI4rtBoE>
- [OHRP Website resources on the Revised Common Rule’s Cooperative Research Provision](#)

Related WSU IRB Policies:

[4-17 External IRB & Reliance Agreements for Multi-Site Research](#)

[6-3 Collaborating Research](#)