



Introduction to the Revised Common Rule: 45 CFR 46

The Office of Human Research Protections (OHRP) has announced changes to federal regulations that protect the rights and welfare of human research participants, known as the Common Rule. The Common Rule changes seek to modernize, strengthen and make more effective the federal policies for the protection of human research participants. The Common Rule changes are set to be effective January 19, 2018 and are expected to be applied to any study approved on or after January 19, 2018.

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 are the changes?

This guidance will take you through an overview of significant changes made to each section the Common Rule. You can find additional guidance documents that provide more specific information pertaining to some of the sections listed below. New guidance will be posted to the website as it becomes available.

46.102: Definitions:

New Definitions: Clinical Trial, Federal Department or Agency, Identifiable Specimen, Public Health Authority, Written or In Writing

Revised Definitions: Department or Agency Head, Human Subject (Participant), Intervention, Identifiable Private Information, Legally Authorized Representative, Private Information, Research

46.104: Exempt Research: Overview of changes

(See Exempt Review of Research Guidance document for more detailed information.)

- Revisions to Exempt Categories 1, 2, 4 and 5.
- New Category 3 for Social Behavioral Research: Benign Behavioral Interventions
- Limited IRB Review option for research meeting certain conditions within Exempt categories 2 and 3
- Annual Status Update Reports for all minimal risk research including Exemptions.

The revised common rule includes optional new exempt categories #7 and #8. The WSU IRB has elected to opt out of the optional categories #7 and #8 as described in 45 CFR 46.104. These categories involve research with bio specimens in which broad consent is obtained. Any study with broad consent will not be eligible for exempt review under the WSU Exempt Policy.

46.109: IRB Review of Research: Continuing Review/Renewals

Continuing review is no longer required in the following circumstances:

- i. Research eligible for expedited review in accordance with 46.110
- ii. Research reviewed by the irb in accordance with the limited IRB review described in 46.104
- iii. Research that has progressed to the point that it involves one or both of the following which are part of the IRB-approved study:
 - a. Data analysis, including analysis of identifiable private information or identifiable biospecimens
 - b. Accessing follow-up clinical data from procedures that are performed as a part of the standard clinical care.

Example of expedited Studies that must maintain Continuing Review:

- Projects regulated by the FDA or by sponsor that require continuing review
- Study involves additional oversight (i.e. conflict of interest, corrective action plans due to serious non-compliance)
- Research conducted at international research sites
- Investigator with research with a determination of serious non-compliance or a pattern of non-compliance
- Determination made by the convened IRB or expedited reviewer that continuing review is required.

WSU Status Checks for Minimal Risk Research

In order to provide an appropriate level of oversight and adjust to the changes in the Common Rule, the WSU IRB is implementing a new process for the ongoing review of minimal risk research. For minimal risk research in which the continuing review is waived by the Common Rule in accordance with 45 CFR 46.104, 46.109 & 46.110. Status check instructions will be provided on the initial approval memorandum.

Current approved minimal risk studies will be evaluated at the point of continuation to determine whether continuing review is required.

In addition to the routine status updates, investigators are also responsible for submitting an amendment to the IRB for any proposed changes to the study. This can be done by completing and submitting the Medical/Behavioral Amendment Form. The amendment must have IRB approval prior to implementing any proposed changes.

46.110 Expedited Review of Research:

The Secretary of HHS stated in the preamble of the final Common Rule that they will be publishing a revised list of categories of research that may be reviewed by the IRB through an expedited review procedure. This list is not yet available. We will update this guidance when that information becomes available.

46.114 Cooperative Research (Single IRB Review for multicenter research)

Any institution located in the U.S that is engaged in cooperative research must rely on approval by a single IRB for that portion of the research that is conducted in the U.S.

The Reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

The **Reviewing IRB** or **IRB of record** is the single IRB chosen to provide regulatory oversight of research conduct at all sites.

The **Relying IRB** or **Relying Institution** is 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.

46.117: Informed Consent

(See Informed Consent Guidance documents for more detailed information)

- New Required Basic and Additional Elements
- Electronic Consent is permitted when a written copy is provided
- Changes to waiver and alteration criteria (See Waiver and Alteration of Consent Guidance for more details)
- New consent provision that describes screening, recruiting and determining eligibility without informed consent.
- New requirement to post the consent form to a Federal website.

Key Information: A new term that is used in this section of the common rule to describe important information that must be provided in the beginning of the informed consent form.

- Key information is described in the Common Rule as: Information that a reasonable person would want to have in order to make an informed decision about whether to participate.
- The Key Information element mandates that “Informed consent must begin concise and focused presentation of the key information that is most likely to assist a prospective subject (participant) or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.” (45CFR46.116(a)(5)(i))

***Note:** A new element of informed consent in the common rule is the element of Broad Consent. This is an optional element that WSU has chosen to opt out of for many reasons. Any information regarding changes to the Common Rule which involve Broad Consent have been omitted from our policies and guidance.