

Revised Common Rule Key Changes and Transition Plan

On January 19, 2017, the Department of Health and Human Services and fifteen other federal agencies issued revisions to the regulations governing human subjects research (called the Common Rule). Most of these changes go into effect on January 21, 2019.

The key changes that will impact researchers and the implementation and transition plan are outlined below.

A copy of the new Revised Common Rule and related information is available on the [OHRP website](#).

Applicability of the Common Rule

The changes to the Common Rule DO NOT APPLY to research that is regulated by the FDA, Dept. of Justice (DOJ) or Consumer Product Safety Commission (CPSC).

For research regulated by another federal agency and all other research the Revised Common Rule becomes effective for all new research reviewed by the IRB on or after January 21, 2019.

All ongoing research approved before that date will remain under the Current Common rule (pre- 2018 requirements), until such time the study closes or is transitioned to the new rule. See the [Transition section](#) below for more details).

Key Changes

Exempt Research

The Revised Common Rule broadens the types of research that qualify for exemption. Several exempt categories have been revised, and there are new categories of exemptions. The [Exempt Review Guidance](#) shows how the categories have changed. Note that some exemption categories require limited IRB review, which is a new type of review.

Impact of Changes:

- Research Approved before 1/21/2019: No change after 1/21/2019
- Research Approved on or After 1/21/2019: Follows new Common Rule categories, some of which require limited IRB review
- New IRB process/SOP requires notification of closure to the IRB

Continuing Review

The Revised Common Rule removes the requirement for continuing review for research that is minimal risk research OR greater than minimal risk research ("Full Board") research that is in long-term follow-up or data analysis only.

Impact of Changes:

- Research Approved before 1/21/2019:
 - When the IRB conducts continuing review for ongoing research, the IRB will determine whether transition to the Revised Common Rule would be allowed and whether it would be potentially advantageous to the research.
 - This will be considered only on non-regulated research (not federally funded, not FDA regulated).

- Research Approved on or After 1/21/2019:
 - New minimal risk research will not automatically undergo continuing review by the IRB (unless it is FDA-regulated).
 - The IRB may require continuing review for special circumstances such as studies involving conflict of interest, IRB reliance or prior compliance concerns.
 - Even when continuing review is not required, investigators remain responsible for updating the IRB about adverse events and other unanticipated problems, seeking IRB approval for changes to personnel, protocol amendments, recruitment materials, etc., and informing the IRB when the research is complete.

Informed Consent

Additional elements of informed consent are required to be included in consent forms. The [IRB Required Elements of Consent Guidance](#) shows Common Rule revisions.

Consent forms will now require a concise summary of “key information” that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to join the research.

This summary must include:

- Study activities, risks and benefits presented to research participants in the first few pages of the consent document.
- This section must be organized in a way that facilitates understanding.
- Consent forms of previously approved studies will not need to be updated to meet this requirement, unless federally funded and open to enrollment.

Impact of Changes:

The Ascension WI IRB consent templates have already been updated to include these changes format.

The new Common Rule requires certain clinical trial consent forms be posted on a government website. This requirement applies to studies that are conducted or supported by a federal agency and is usually done by the study Sponsor. The posting must occur no more than 60 days after the last study visit by any subject.

Single IRB Review

IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based) starting January 20, 2020. Additional information will be provided later.

Transition from the pre-2018 Common Rule to the Revised Common Rule

The Ascension Wisconsin IRB Office’s transition plan is based on one of the possible transition plans and timelines that OHRP has developed and posted on their [website](#).

Currently approved studies (approved before 1/21/2019) will have the opportunity to transition to the Revised Common Rule requirements if they meet the following criteria:

- Are “non-regulated research” (not federally funded, not FDA regulated)
- One or more of the following are true:
 - Have previously been granted a waiver of informed consent
 - Are closed to enrollment with subjects in long term follow up (only collection of clinical care data)
 - Remains open for data analysis only

At the time of the next continuing review, IRB staff will work with the PI and study team to verify the requirements are met and document the transition. This process may also be done at other times on a limited case-by- case basis.