

Revised Common Rule January 2019

The federal policies mandating the protection of human subjects are known as the “Common Rule”. On January 19, 2018, the Department of Health & Human Services (DHHS) announced that the much-anticipated substantial revision to the Common Rule would be delayed.

After an additional comment period, the revisions to the Common Rule, referred to as the Revised Common Rule, was approved on July 19, 2018, along with a 6-month period to allow institutions to comply with these changes.

Effective January 21, 2019, institutions which review federally-funded research must adopt the Revised Common Rule changes and apply these regulations to all new human subject research reviewed and approved on or after January 21, 2019.

Office of Human Research Protections (OHRP), a component of DHHS, describes the purpose of the regulatory changes:

- The new rule **strengthens protections** for people who volunteer to participate in research, while ensuring that the oversight system does not add **inappropriate administrative burdens**, particularly to low-risk research. It also allows **more flexibility** in keeping with today's dynamic research environment.

Additional information can be found on OHRP's website. [A copy of the new Revised Common Rule and related information has been posted there.](#)

Key Changes of the Revised Common Rule

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. These changes to exemption will apply to research that is federally funded or supported.

For other low and minimal risk research, investigators are encouraged to consult the [MCW HRPP webpage for Registration Projects](#) and the [MCW Policy: Registration Projects: HSR Projects which qualify for Flex Review](#) to learn more about MCW's streamlined options.

Continuing Review

The Revised Common Rule removes the requirement for continuing review for minimal risk research and for greater than minimal risk research that is in long-term follow-up or data analysis only, unless the research is FDA-regulated.

When the new rules go into effect, 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.

For greater than minimal risk projects which are in long-term follow up or data analysis only, this change will not go into effect on January 21st. MCW IRB Office is continuing to work on how to implement this new change for applicable projects to ensure full compliance with the federal regulations.

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

With the Revised Common Rule, changes will be required to the structure and content of informed consent documents. [These changes were announced by the MCW IRB Office in January 2018.](#)

MCW IRB Office has incorporated all these changes into MCW consent form templates, and these forms have been available for use since early 2018. [Teams have been strongly encouraged to use these templates all throughout 2018 to ensure compliance when the Revised Common Rule goes into effect.](#)

Research teams will be required to use the most current MCW consent form template for all new projects effective January 21, 2019 to ensure compliance with the Revised Common Rule.

Currently approved projects under the oversight of MCW IRB which are using a consent template older than January 26, 2018 must update their approved consent documents to the current template under the MCW IRB Office Revised Common Rule transition plan.

[Information has been posted to the HRPP website regarding MCW IRB Office's Revised Common Rule transition plan for currently approved research.](#)

Finally, the Revised Common Rule requires that 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. The posting must occur no more than 60 days after the last study visit by any subject. As of this time, the specific government website has not yet been named.

Single IRB Review

A component of the Revised Common Rule required Single IRB review for studies conducted or supported by other federal agencies. This change aligns with NIH's policy

changes requiring all multi-center NIH-funded studies to use single IRB review for domestic sites, which went into effect on January 25, 2018. [More information can be accessed from NIH's policies and procedures on single IRB review for multi-site research.](#)

This component of the Revised Common Rule is slated to go into effect January 2020, and MCW IRB Office will keep researchers informed on the implementation of this component of the Revised Common Rule as we approach January 2020.