

2018 Revised Common Rule:

Revisions to the Common Rule

The Department of Health and Human Services and fifteen other federal agencies issued revisions to the regulations governing human subject's research. This federal regulation governing the protections of human subject's is referred to as the Common Rule. These changes are effective January 19, 2018 with the exception of the Single IRB (sIRB) requirement.

The federal Office of Human Research Protections (OHRP) indicates the purpose of the regulatory changes as: 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.

Visit OHRP to obtain a copy of the new rule / related information at: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

The Office of Research Compliance and Assurance is offering informational sessions highlighting these new requirements. For session dates/times, please visit the Research Education Learning Portal at: <http://www.southalabama.edu/departments/research/research-training-resources/index.html>

SUMMARY OF 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 exemption comparison chart shows how the categories have changed. Note that some exemption categories require limited IRB review, which is a new type of review.

- [KUMC Overview of Exempt Research Beginning January 19, 2018](#)

Continuing Review

The Revised Common Rule removes the requirement for continuing review for minimal risk research and for full-board research that is in long-term follow-up or data analysis only. This new requirement does not unless the research is FDA-regulated.

- Research Approved After January 19, 2018: New minimal risk research will not automatically undergo continuing review by the IRB unless it is FDA-regulated. However, the IRB has the authority to require continuing review for special circumstances (i.e., conflict of interest, compliance concerns).
- Ongoing research: Currently, all ongoing research will adhere to pre-2018 regulations. In the future, the IRB will determine when to transition to the Revised Common Rule and whether it would be potentially advantageous to the research.

NOTE: The Investigator is still responsible for the following activities, even though continuing review is not required. These activities include: (i) submitting adverse events and other

unanticipated problems, (ii) seeking IRB approval for Investigator changes, (iii) protocol amendments, (iv) recruitment materials, etc., and (v) notifying the IRB when the research is complete.

Informed Consent

Effective January 19, 2018, new changes will be required to the informed consent. Specifically, the organization and content of 'key information' be presented at the beginning of the informed consent. Consent forms must begin with 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. The purpose of this change is to facilitate comprehension. See [KEY INFORMATION](#) template for guidance.

Additionally, there are new requirements for additional consent elements for use of de-identified information, use of bio-specimens, potential for commercial profit and return of clinically-relevant results. The USA IRB informed consent checklist and consent form templates will be updated to facilitate compliance. USA IRB will apply these changes to all research projects, regardless of funding.

Additionally, the 2018 regulations mandate that specified clinical trial consent forms be posted on a government website, not yet identified. The post must take place no greater than 60 days after the last study visit by any subject.

Single IRB Review

Effective January 25, 2018, all multi-center NIH-funded studies are required to use single IRB review for the domestic sites. Additional information is posted at: <https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>

NOTE: Single IRB review, as required by the Common Rule, will be effective January 2020.

Ongoing Research and Impact of Changes

Currently, ongoing research will continue to adhere to the pre-2018 regulations. Investigators are not required to make any changes to ongoing research.

IRB application and templates

IRB applications, checklists, and templates are being updated to reflect changes regarding the revised regulations.

Additional Information

Please visit this site for updates about the 2018 revised Common Rule. Updated application forms, standard operating procedures, templates and guidance are under development. On October 7, 2018, the Department of Health and Human Services requested a one year delay in the implementation date, but to-date, a final rule making to grant the delay has not been published. Therefore, unless a delay is approved and published in the Federal Register, the new 2018 revised Common Rule will apply to human subjects research approved post January 19, 2018.