

CRSO Regulatory Blog Post

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FDA Announces Proposed Rules to Harmonize with the revised Common Rule

As part of its obligations under the 21st Century Cures Act, the U.S. Food and Drug Administration (FDA) announced, on September 28, 2022, two proposed rules aimed at harmonizing, to the “extent practicable and consistent with statutory provisions,” certain sections of the agency’s regulations on human subject protections and Institutional Review Boards (IRBs) with the “[Federal Policy for the Protection of Human Subjects](#)” (revised Common Rule). Prior to the 2017 revision, the two sets of rules were largely consistent.

“FDA believes that these proposed changes, if finalized, would help ensure clarity and enhance both human subject protection and the IRB review process. In addition, harmonizing with the revised Common Rule would reduce regulatory burden for IRBs, sponsors, and investigators,” the agency wrote.



The proposed rule on [Protection of Human Subjects and Institutional Review Boards](#) would amend [21 CFR part 50](#) and [21 CFR part 56](#) as follows:

- (1) Revise the content, organization, and presentation of information included in the informed consent form and require that key information, most likely to help a potential participant understand the study, be presented first.
- (2) Add new basic and additional elements of informed consent.
- (3) Add a provision that would allow IRBs to eliminate continuing review of research in certain circumstances.
- (4) Revise the IRB recordkeeping requirements for certain determinations related to the need for continuing review.
- (5) Add or modify some definitions (such as legally authorized representative, written or in writing, private information, identifiable private information, and identifiable biospecimen).

It also proposes related changes to the investigational device exemption (IDE) regulations ([21 CFR part 812](#)) to clarify and update the requirements for the submission of progress reports.

The proposed effective date for this rule is 180 days from the final rule date of publication.

In the proposed rule on [Institutional Review Boards; Cooperative Research](#), the FDA intends to replace current requirements for FDA-regulated cooperative research with new requirements that would require any institution located in the United States participating in FDA-regulated cooperative research to rely on review and approval by a single IRB for that portion of the research that is conducted in the United States, with some exceptions. The agency stated:

“FDA believes that, in many situations, mandatory single IRB review for multi-institutional clinical investigations would streamline the review process and increase efficiencies for the oversight of clinical investigations without compromising human subject protections. Increased efficiencies may facilitate faster initiation of clinical investigations supporting the development of new medical products to benefit the public health.”

The proposed exceptions account for situations where, according to the FDA, the burdens of single IRB review are not likely to be outweighed by its benefits but makes it clear that even cooperative research that would qualify for an exception from the single IRB requirement may still use single IRB review. This helps to address the concern that a cooperative research project that is both FDA-regulated and subject to the Common Rule might qualify for an FDA exception but be required to use single IRB review under the Common Rule.

FDA is also proposing an IRB recordkeeping requirement for research that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution.

The proposed effective date for this rule is one year after the final rule is published in the *Federal Register*.

What does it mean for me?

The harmonization efforts between the Common Rule and the FDA regulations are of particular importance for FDA-regulated research that is also federally-funded as both sets of rules would apply. Once the proposed rules are enacted, investigators of FDA-regulated, federally-funded research should be particularly cognizant of how the proposed changes differ from the Common Rule.

The clinical research community is key in enhancing and modernizing clinical research and conduct. If the new proposed rules require further clarification or changes, please share your thoughts with the FDA during the comment period. Detailed instructions for providing comments are provided in the Federal Registry Notice.

More Information to Come

Be on the lookout for additional announcements regarding harmonization efforts in the months to come. The current proposed rules do not address all provisions that may be relevant to FDA regulated research (e.g., posting of consent forms, exempt research, etc.). The FDA is also in the process of finalizing a previously issued proposed rule to harmonize with the revised Common Rule, [Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations](#). Once finalized as proposed, this rule is intended to help enable certain minimal risk clinical investigations for which the informed consent requirement is waived, or certain elements of informed consent are waived or altered.

If you have questions regarding the above notices, please contact the CRSO at crso@med.unc.edu.

