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FDA's Response to HHS' Revised Common Rule: Four Things to Know

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In a final rule published on January 19, 2017, HHS and several federal departments and agencies made revisions to the Common Rule, the federal policy for the protection of human subjects applicable to human subject research conducted or supported by participating federal departments and agencies.[1] Compliance with the revised Common Rule is expected on January 21, 2019.[2]

In response, on October 12, 2018, the FDA published guidance directed toward sponsors, investigators, and Institutional Review Boards (IRBs) entitled, "Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations", which provides FDA's current thinking regarding clinical research subject to the revised Common Rule and FDA's human research protection regulations.[3] Clinical investigations conducted or supported by HHS that involve an FDA-regulated product are subject to both 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56, which contain certain differences between HHS' human subject regulations and FDA's human subject regulations.

While FDA has stated that the agency intends to undertake notice and comment rulemaking to harmonize the FDA's regulations with the revised Common Rule, FDA's guidance attempts to quell confusion in the interim. The guidance specifically addressed informed consent requirements, expedited review procedures, and IRB continuing review.

1. Informed Consent

FDA clarified that, despite inclusion of new informed consent requirements in the revised Common Rule, which include content, organization, and presentation changes to the consent form and process of consenting human subjects and changes to the basic elements of consent, the provisions of revised Common Rule are not inconsistent with FDA's current policies and guidances. In so doing, FDA noted that sponsors and investigators may not have to develop two informed consent forms for research subject to HHS and FDA human subject regulations.

2. Expedited Review Procedures and List

FDA regulations set forth expedited IRB review procedures for research involving no more than minimal risk as established through a Federal Register Notice.[4] FDA established and published a

list of categories of such research in the Federal Register.[5] Under Section 56.110(b), IRB reviewers must find that the research on the list involves no more than minimal risk for the IRB to use the expedited review procedure. Despite the revised Common Rule providing for limited IRB review proceeding via the expedited review mechanism, FDA stated that IRBs must continue to use the list in the Federal Register when reviewing research subject to HHS and FDA human subject regulations.

3. IRB Continuing Review

FDA's recent guidance clarifies that, where the regulations differ, the regulations that offer the greater protection to human subjects should be followed, as has been the historical position of FDA.[6] For example, the revised Common Rule eliminated the requirement that research involving no more than minimal risk undergo an annual, continuing review.[7] However, FDA maintains its requirement under 21 C.F,R . § 56.109(f) regarding studies required to undergo an annual, continuing review.

4. Future Rulemaking

FDA intends to issue three more guidances aimed at harmonizing the agency's regulations with HHS' Common Rule. On October 17, 2018, the White House's 2018 fall regulatory agenda indicated that the FDA will engage in the formal rulemaking process, including accepting and considering public comments, in advance of issuing the guidances: Part 50 Protection of Human Subjects and Part 56 Institutional Review Boards, which would add definitions, conform wording, and other changes to FDA regulations to harmonize with the revised Common Rule;[8] Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations, which would permit an IRB to waive or alter the informed consent requirements under certain conditions for minimal risk clinical investigations;[9] and Institutional Review Boards; Cooperative Research, which would replace current FDA requirements for cooperative research so that any U.S. institution participating in multisite cooperative research could rely on approval by a single IRB for the portion of the research that is conducted in the U.S., with some exceptions.[10]

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[1] 82 Fed. Reg. 7149 (January 19, 2017); https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf.

[2] 83 Fed. Reg. 28497 (June 19, 2018); https://www.gpo.gov/fdsys/pkg/FR-2018-06-19/pdf/2018-13187.pdf.

[3] *See* 45 C.F.R .part 46; 21 C.F.R. parts 50 and 56.

[4] *See* 21 C.F.R. § 56.110(a).

[5] 63 Fed. Reg. 60353 (November 9, 1998;) http://www.gpo.gov/fdsys/granule/FR-1998-11-09/98-29748.

[6] *See, e.g.*, "Use of Electronic Informed Consent Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors," (December 2016), https://www.fda.gov/downloads/drugs/guidances/ucm436811.pdf.

[7] *See* 45 C.F.R. § 4§6.109(f)(1).

[8] RIN:
0910-AI07, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=0910-AI07.

[9] RIN:
0910-AH52, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=0910-AH52.

[10] RIN:
0910-AI08, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=0910-AI08.

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