America's Oldest National Monthly IRB Newsletter

Human Research Report™

PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

Volume 38, No. 3 ISSN 0885-0615 March, 2023

IRBs and Major Changes To Federal Regulations (#4)

We continue this month with more of the many changes that FDA has proposed for its regulations on protecting human research subjects.

A large number of those proposed changes are to achieve "harmonization" with the requirements of the Common Rule on informed consent, IRB reviews, data confidentiality, etc. However, FDA is also proposing to not make some changes, as can be seen in the following excerpts.

> "The revised Common Rule contains two other provisions identifying circumstances in which continuing review would not be necessary at 45 CFR 46.109(f)(1)(i) and (ii).
>
> We are not proposing to adopt the revised Common Rule provision at 45 CFR 46.109 (f)(1)(i), which eliminates the requirement for an IRB to conduct continuing review of research that is eligible for expedited review in accordance with 45 CFR 46.110 unless the IRB determines otherwise" (87 Fed. Reg. 58733-58752 at p. 58741, September 28, 22).

What FDA Plans to Not Do

Before proceeding further with this update, note that FDA is currently reviewing comments that it received from the compliance community when these proposals were first issued.

Nevertheless, pending major arguments to the contrary, many of the FDA proposals (in our opinion) are likely to become final.

Hence, IRBs should be prepared to implement the changes in the future. These updates should help IRBs with the required implementation.

We now resume with this portion of their proposals where FDA states what it plans to not do:

> "As described below, OHRP [i.e., federal Office for Human Research Protections] has clarified that, in order for research to qualify for expedited review under the current list of research eligible for expedited review referenced in 45 CFR 46.110(a), a determination must still be made by an IRB that the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
>
> It is not practicable for FDA to adopt this provision because continuing review for minimal risk FDA-regulated clinical investigations would provide meaningful protections

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, or missing words. However, we will on occasion insert words or edit text and/or formating in brackets [ ] to make the material easier to read.

NOTE #2: Emphases are added to articles by HRR by underlining or adding ***bold/italics*** to selected text, unless stated otherwise.

NOTE #3: Articles **T**o **B**e **C**ontinued in subsequent issues are marked at the end of the article with **{TBC}**.

Also In This Issue

Published monthly by The Deem Corporation, P.O. Box 451117, Omaha, NE 68145. Editor and Publisher: Dennis M. Maloney, Ph.D.

to human subjects participating in such investigations.

For example, as a study progresses, the analysis of risks to subjects receiving a[n] FDA-regulated product may change based on adverse events that occur during the course of the study and that do not rise to the level of unanticipated problems involving risks to human subjects or otherwise require reporting to the IRB" (ibid).

FDA Not Interested in "Limited IRB Review"

"Continued IRB oversight of such studies would offer added human subject protection to those participating in such investigations by enabling the IRB to assess whether there are any additional risks that present more than minimal risk to participants and require discussion and/or action.

Furthermore, for clinical investigations that are subject to both FDA's human subject regulations and the revised Common Rule, the Common Rule provision at 45 CFR 46.109(f)(1)(i) allows an IRB to determine that continuing review of research eligible for expedited review is required.

Finally, we are not proposing to adopt provisions from the revised Common Rule related to limited IRB review at this time, including 45 CFR 46.109(f)(1)(ii).

As we continue to consider how other provisions of the revised Common Rule could be applied to FDA-regulated research, including the revised Common Rule's exemptions, we may take additional steps to harmonize with such provisions at a later time" (ibid).

FDA Keeping "Expedited IRB Reviews"

"In addition, as described below, we are proposing changes to the IDE regulations at §812.150(a)(3) and (b)(5) to align the IRB progress reporting requirements with these proposed changes to IRB continuing review requirements under part 56.

We propose reordering and redesignating the remaining language in §56.109(f), and current §56.109(g) and (h) as §56.109(g), (h), and (i), respectively.

6. Expedited Review

FDA's current regulations under §56.110(a) state that FDA has established, and published in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure ('expedited review list').[15]

[FN #15: See 'Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure,' 63 FR 60353, November 9, 1998.]" (ibid).

"Expedited IRB Review" List Can Change

"FDA is not proposing any changes to §56.110(a) at this time, and the categories of research included on the expedited review list referenced in §56.110(a) are identical to the categories of research included on the expedited review list referenced in 45 CFR 46.110(a) ('HHS Expedited Review List').[16]

[FN #16: See 'Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure,' 63 FR 60364, Nov. 9, 1998.]

The revised Common Rule requires that the Secretary evaluate the HHS expedited review list at least every 8 years and amend it, as appropriate, after consultation with other Federal Departments and Agencies and after publication in the FEDERAL REGISTER for public comment.

We intend to participate in this process and will update our own expedited review list, as appropriate for FDA-regulated studies.

As described in the revised Common Rule, an IRB may use the expedited review procedure to review studies that involve activities appearing on the expedited review list, unless the IRB reviewer determines that the studies involve more than minimal risk (see 45 CFR 46.110(b)(1)(i)).

OHRP has clarified that until a new list is finalized, the entire 1998 HHS Expedited Review List, including the 'Applicability' section, remains in effect for studies subject to the revised Common Rule" (ibid). © **{TBC}**