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PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

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IRBs and New Changes For Informed Consent (#1)

OHRP and FDA have jointly announced an important new draft guidance titled "Key Information and Facilitating Understanding in Informed Consent." As a draft, of course, it is not immediately required that IRBs and others heed its recommendations.

However, the draft will inevitably become final and, based on past such agency proposals, much of its recommendations will indeed become required. Hence, this is an opportune time to influence the content of the proposals. It's also the best time to begin preparing IRB members for relevant updates.

> "In this draft guidance, FDA and OHRP provide recommendations for developing a key information section for clinical trials or studies, including strategies to make consent information as a whole more understandable for prospective research participants" (89 Fed. Reg. 15094-15096 at p. 15095, March 1).

Note that we devote much of this initial introductory HRR article on this guidance to describing which entities are most affected by it.

Federal Agencies Request IRB Input

> "We [i.e., OHRP and FDA] also provide a sample approach to the key information section that is based, in part, on research regarding patient understanding of information found in labeling for prescription drugs.
>
> By using simple phrases and plain language principles, as well as formatting and organizational tools, researchers found that presenting information in a discrete bubble format with topics organized or grouped together can facilitate consumer understanding [see Boudewyns et al., 'Influence of Patient Medication Format on Comprehension …,' in *Patient Education and Counseling*, Vol. 98(12)].
>
> In the appendix of the draft guidance, we provide an example of a key information section using the bubble format.
>
> We encourage interested parties, with input from IRBs, to develop innovative ways to provide key information that will help prospective subjects better understand the reasons why one might or might not want to participate in research" (ibid).

The 16-page guidance addresses a number of consent areas that apply to most human subjects studies.

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

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"Specifically, this guidance addresses the presentation of key information and includes recommendations for the content, organization, and presentation of informed consent information in FDA-regulated clinical investigations of drugs, devices, and biologics … and in HHS-supported or -conducted nonexempt human subjects research[4,5]" (guidance, pp. 1-2; on the Web at https://www.fda.gov/media/176663/download).

Applicable Regulations Cited for OHRP and FDA

"[FN #4: This guidance applies to FDA-regulated clinical investigations of drugs, biologics, or devices that are subject to 21 CFR parts 50 and 56, including investigations under 21 CFR parts 312 and 812.

This guidance also applies to HHS-supported or -conducted nonexempt human subjects research that is subject to 45 CFR part 46.

As used in this guidance, an investigational medical product is an investigational drug or biological product as defined in 21 CFR part 312 or an investigational device as defined in 21 CFR part 812.]

[FN #5: In this guidance, the terms *investigation*, *trial*, *study*, and *research* are used interchangeably, and refer to clinical investigations regulated by FDA under 21 CFR parts 50 and 56, and to human subjects research subject to regulation by HHS under 45 CFR part 46, as applicable, unless otherwise noted.]" (ibid).

IRBs Are Major Focus of New Consent Changes

"The recommendations in this guidance should inform the communication of consent information to subjects, including prospective subjects or their legally authorized representatives, and may be conveyed by written, oral, or electronic means.

This guidance is intended to assist institutional review boards (IRBs), investigators, and sponsors engaged in or responsible for oversight of human subject research subject to FDA and HHS regulations with the development of consent information that would comply with 45 CFR 46.116(a)(5) and FDA's proposed revisions to 21 CFR 50.20(e), if finalized as proposed.[6]

[FN #6: See FDA's notice of proposed rulemaking 'Protection of Human Subjects and Institutional Review Boards' (87 FR 58733, September 28, 2022), available at https://www.federalregister.gov/documents/2022/09/28/2022-21088/protection-of-human-subjects-and-institutional-review-boards.

As stated in the preamble, FDA intends to exercise enforcement discretion with respect to the proposed revisions to 21 CFR 50.20(d) through (e), 50.25(a)(9) and (b)(7) through (9), and 50.27(b)(2) for FDA-regulated studies that are ongoing when the proposed new requirements would become effective.

In the event that the proposed rule is not finalized as proposed, FDA intends to address any differences in future guidance.]" (p. 2).

Agencies Advise That "Key Information" Should Be Brief

"The revised Common Rule [see 82 Fed. Reg. 7149, January 19, 2017] requires consent information to 'begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research' (45 CFR 46.116(a)(5)(i)). FDA's proposed regulations would add identical language to 21 CFR 50.20(e)(1) ….

We recommend that the key information section of a consent document be relatively short (e.g., generally no more than a few pages). A sample key information section of a consent form for a hypothetical clinical trial is included in the appendix of this guidance ….

Interested parties could consider developing alternate ways to present key information that would facilitate understanding by prospective subjects by, for example, consulting in advance with patient advocacy groups or prospective subjects about their views on key information" (pp. 3-4).

Both FDA and OHRP are accepting public comments about these new recommendations on informed consent until April 30.

For more information about the guidance and/or the comment process, contact: for FDA -- FDA's Office of Clinical Policy at 301-796-8340; and/or for OHRP -- OHRP's Division of Policy and Assurances at 240-453-6900 or 866-447-4777. © **{TBC}**

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