The Newsletter for IRBs & Research Ethics Committees

Human Research Report™

PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

Volume 36, No. 6 ISSN 0885-0615 June, 2021

IRBs and Signature Waivers for Researchers in Human Studies (#1)

The FDA has released a revised guidance for IRB members and others that is partially titled "Frequently Asked Questions -- Statement of Investigator (Form FDA 1572) (Revision 1)."

"This draft guidance partially revises the final information sheet guidance for sponsors, clinical investigators, and institutional review boards (IRBs) entitled 'Frequently Asked Questions -- Statement of Investigator (Form FDA 1572)' (May *2010*) (the Form FDA 1572 FAQ Guidance) to explain FDA's current thinking regarding waivers of the signature requirement for Form FDA 1572.

This draft guidance proposes to revise responses to frequently asked questions 10, 11, and 13 from the Form FDA 1572 FAQ Guidance by including information regarding the waiver of the Form FDA 1572 signature requirement and proposes a new section regarding signature waivers" (86 Fed. Reg. 27449-27450 at p. 27449, May 20).

Researchers Have Questions for FDA

As a brief reminder, we note that Form FDA 1572 is not an especially long form. It is, however, a vital component of human subjects research involving products regulated by FDA.

"This guidance is intended to assist sponsors, clinical investigators, and institutional review boards (IRBs) involved in clinical investigations of investigational drugs and biological products.

This guidance applies to clinical investigations conducted under 21 CFR part 312 (investigational new drug application (IND) regulations) and describes how to complete the Statement of Investigator (Form FDA 1572).

FDA has received questions about Form 1572 …. This guidance has been developed in response to multiple inquiries regarding waivers of the signature requirement on Form FDA 1572 and, when finalized, will explain FDA's current thinking regarding signature waivers.

Specifically, this draft guidance revises general questions 10, 11, and 13 from the Form FDA 1572 FAQ Guidance and in-

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

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

NOTE #3: Articles **To Be Continued {TBC}** in subsequent issues are marked at the end 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.

cludes a new section (see questions 39 through 46) about waivers of the Form FDA 1572 signature requirement" ("Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs -- Frequently Asked Questions, Statement of Investigator (Form FDA 1572) (Revision 1)," May, p. 1; on the Web at https://www.fda.gov/media/148810/download).

Conducting a Human Subjects Study Without Researcher's Signature

To understand just how important a document FDA Form 1572 is, and how crucial it is to conducting applicable human subject studies, we refer to the actual regulation, as follows.

"No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c))."

In general, Form FDA 1572 constitutes a promise by researchers that they will protect the rights and welfare of human research subjects, along with an assurance that all relevant federal regulations will be followed. This promise is by researchers to sponsors.

However, it is also possible to seek and receive a waiver wherein the researcher need not sign such an agreement. As one might expect, waivers come with many questions and requirements. Answers to such questions form the primary focus of the FDA FAQ document.

We begin our coverage of the highlights of this FDA guidance with the agency's revisions of previous recommendations.

"**III. General Questions (10, 11, and 13)**

10. Must investigators who conduct studies outside of the United States sign a 1572? (Revised 2021)

If a clinical study is conducted at a foreign site under an IND, all FDA IND regulations, including the requirement to obtain a signed 1572 (21 CFR 312.53(c)(1), must be met unless the sponsor requests and is granted a waiver that provides for specific exceptions.

In the case where a foreign investigator cannot or will not sign Form FDA 1572 (e.g., because regional, national, or local laws or regulations prohibit its signing), the sponsor may submit a request for a waiver of the 1572 signature requirement under 21 CFR 312.10 (see section (IV) of this guidance); alternatively, the site may operate as a non-IND site, in which case the study would be conducted as a non-IND study" (guidance, page 2).

Only FDA Has Authority to Waive Signature

"If a clinical study is conducted outside of the United States and the study is not under an IND, then the investigator need not sign a 1572.

If the study data from a non-IND site is to be submitted to support a marketing application (e.g., a new drug application (NDA)), the study at the non-IND site must be conducted in compliance with 21 CFR 312.120. (Also, see question 14 in the Form FDA 1572 FAQ Guidance.)

11. If a foreign clinical study is being conducted under an IND, what are the investigator's responsibilities with respect to regional, national, or local laws and regulations? (Revised 2021).

Investigators are responsible for complying with the applicable laws and regulations of the country in which the study is being conducted, regardless of whether the study is being conducted under an IND.

We recommend that sponsors obtain signed, written statements from investigators acknowledging their commitment to comply with regional, national, or local laws and requirements.

In addition, if a foreign clinical study is being conducted under an IND, the investigator must sign Form FDA 1572 (investigator statement) (21 CFR 312.53(c)(1)) and ensure that the study is conducted in accordance with the investigator statement and all other applicable regulations under 21 CFR part 312 unless the sponsor has requested, and FDA has granted, a waiver of the signature requirement" (ibid). © {TBC}