America's Oldest National Monthly IRB Newsletter

Human Research Report

PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

Volume 39, No. 2 ISSN 0885-0615 February, 2024

This newsletter is copyright protected and sold with a limited license. See p. 13 for details.

IRB Waivers for Minimal Risk Investigations (#1)

A final rule on informed consent has been issued by FDA. It became final on January 22 and will affect researchers who wish to conduct "minimal risk" studies and the IRBs that review such experiments.

This rule is not a stand alone guidance or an agency document. Instead, it is comprised of actual changes to the existing federal regulations in the CODE OF FEDERAL REGULATIONS at 21 CFR Part 50 ("Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety"), 21 CFR Part 312 ("Drugs, Exports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety"), and 21 CFR Part 812 ("Health records, Medical devices, Medical research, Reporting and recordkeeping requirements").

> "This final rule allows an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects" (88 Fed. Reg. 88228-88249 at p. 88228, December 21, 2023).

Note that the wording changes to the regulations cited above are quite brief. Not so for the FEDERAL REGISTER's 3-column, small print, 21-page explanation of the research community's reaction to an earlier draft version, or for the FDA's discussions of new implications for IRBs and researchers.

Regulatory Changes Are Brief

Before we focus on key highlights of the new regulations, we present the full text of the brief changes.

The stand out exception to the brevity of most of the final rule is the longer new 21 CFR 50.22.

"PART 50 - PROTECTION OF HUMAN SUBJECTS

• 1. The authority citation for part 50 is revised to read as follows:

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 360, 360c-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262.

• 2. In §50.20 revise the first sentence to read as follows:

§50.20 General requirements for informed consent.

Except as provided in §§50.22, 50.23, and 50.24, no investigator may involve a human being as a subject in research covered by these regulations

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.

unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative ***" (supra at p. 88248).

IRBs Have Authority to Waive Requirements

"• 3. Add §50.22 to subpart B to read as follows:

§50.22 Exception from informed consent requirements for minimal risk clinical investigations.

The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent set forth in §50.25(a) and (b), or may waive the requirement to obtain informed consent, provided the IRB finds and documents the following:

(a) The clinical investigation involves no more than minimal risk to the subjects;

(b) The clinical investigation could not practicably be carried out without the requested waiver or alteration;

(c) If the clinical investigation involves using identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;

(d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation" (ibid).

Researchers Have Protection Responsibilities Too

"PART 312 - INVESTIGATIONAL NEW DRUG APPLICATION

• 4. The authority citation for part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360(bbb), 371; 42 U.S.C. 262.

• 5. Revise §312.60 to read as follows:

§312.60 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation.

An investigator shall obtain the informed consent of each human subject to whom the drug is administered, in accordance with part 50 of this chapter. Additional specific responsibilities of clinical investigators are set forth in this part and in parts 50 and 56 of this chapter" (ibid).

Medical Device Regs Are Also Changed

"PART 812 - INVESTIGATIONAL DEVICE EXEMPTIONS

• 6. The authority citation for part 812 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 360hh-360pp, 360rr-360ss, 360bbb-8b, 371, 372, 374, 379e, 381, 382; 42 U.S.C. 216, 241, 262.

• 7. Revise §812.2(b)(1)(iii) to read as follows:

§812.2 Applicability

* * * * *

(b) * * *

(1) * * *

(iii) Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent in accordance with part 50 of this chapter.

* * * * *

Dated December 1, 2023 (Note that each asterisk (*) listed above represents FEDERAL REGISTER language explicitly deleted from the cited material by the FEDERAL REGISTER itself) (see supra at page 88249).

We now do something that we do not often do; namely, we present a summary of the costs of these new widely applicable IRB regulations. Not surprisingly, it is expected that these costs will be borne primarily by IRBs themselves and their host institutions. Institutions that subcontract their IRB responsibilities with third parties may have different arrangements.

D. Costs and Benefits

… We expect costs in the form of affected IRBs, as well as investigators and sponsors of clinical investigations, reading and learning the rule. We