

DMB

Display Date	3.5.99
Publication Date	3.8
Certifier	C. W. M. J. D. M.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50 and 812

[Docket No. 96N-0158]

RIN 0910-AA60

Protection of Human Subjects; Informed Consent; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a final rule that appeared in the **Federal Register** of October 2, 1996 (61 FR 51498) on informed consent. The document was published with some inadvertent errors in the codified section. This document corrects those errors to ensure the accuracy and consistency of the agency's regulations.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Bonnie M. Lee, Office of the Executive Secretariat (HF-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301-827-4450.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, October 2, 1996 (61 FR 51498), an amendment for § 50.20 (21 CFR 50.20) was inadvertently omitted. Section 50.20 now provides for two exceptions to obtaining informed consent; one exception is contained in § 50.23 (21 CFR 50.23) and the other is contained § 50.24 (21 CFR 50.24). Accordingly this document conforms § 50.20 to the final regulations. Additionally, an amendment for § 812.47(b) (21 CFR 812.47(b)) inadvertently omitted commas which could cause confusion in understanding the meaning of the last sentence in that paragraph. Accordingly, FDA is amending the last sentence in § 812.47(b) to include two commas so that it will state "The sponsor promptly shall provide

NCR 1

this information in writing to FDA, investigators who are asked to participate in this or a substantially equivalent clinical investigation, and other IRB's that are asked to review this or a substantially equivalent investigation.' Also, the final rule on informed consent amended the Investigational New Drug Application (IND) regulations and the Investigational Device Exemption (IDE) regulations. In the **Federal Register** of June 16, 1997, FDA amended its IND regulations to clarify that, within 30 days after receipt of an IND for any clinical investigation involving an exception from informed consent, FDA will provide a written determination as to whether the investigation may begin. The agency inadvertently omitted a conforming amendment for the IDE regulations in § 812.20 (21 CFR 812.20). Current IDE regulations at § 812.20(a)(4)(i) require sponsors to submit a separate IDE for any clinical investigation involving an exception from informed consent under § 50.24. This requirement is to ensure that FDA has an opportunity to review the protocol and supporting information before the investigation begins. Section 812.20(a)(4)(i) also provides that the clinical investigation may not proceed without prior written authorization from FDA. The statement in § 812.20(a)(4)(i) that 'FDA shall provide such written authorization 30 days after FDA receives the IDE or earlier' might be misread as suggesting that the agency may only grant permission for investigations to begin. To clarify the agency's intent, FDA is amending the last sentence in § 812.20(a)(4)(i) to state that 'FDA shall provide a written determination 30 days after FDA receives the IDE or earlier.'

List of Subjects

21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 50 and 812 are amended as follows:

PART 50—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 21 CFR part 50 is revised to read as follows:

Authority: 21 U.S.C. 321, 346, 346a, 348, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

2. Section 50.20 is amended by revising the first sentence to read as follows:

§ 50.20 General requirements for informed consent.

Except as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

3. The authority citation for 21 CFR part 812 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

4. Section 812.20 is amended by revising the last sentence of paragraph (a)(4)(i) to read as follows:

§ 812.20 Application.

(a) * * *

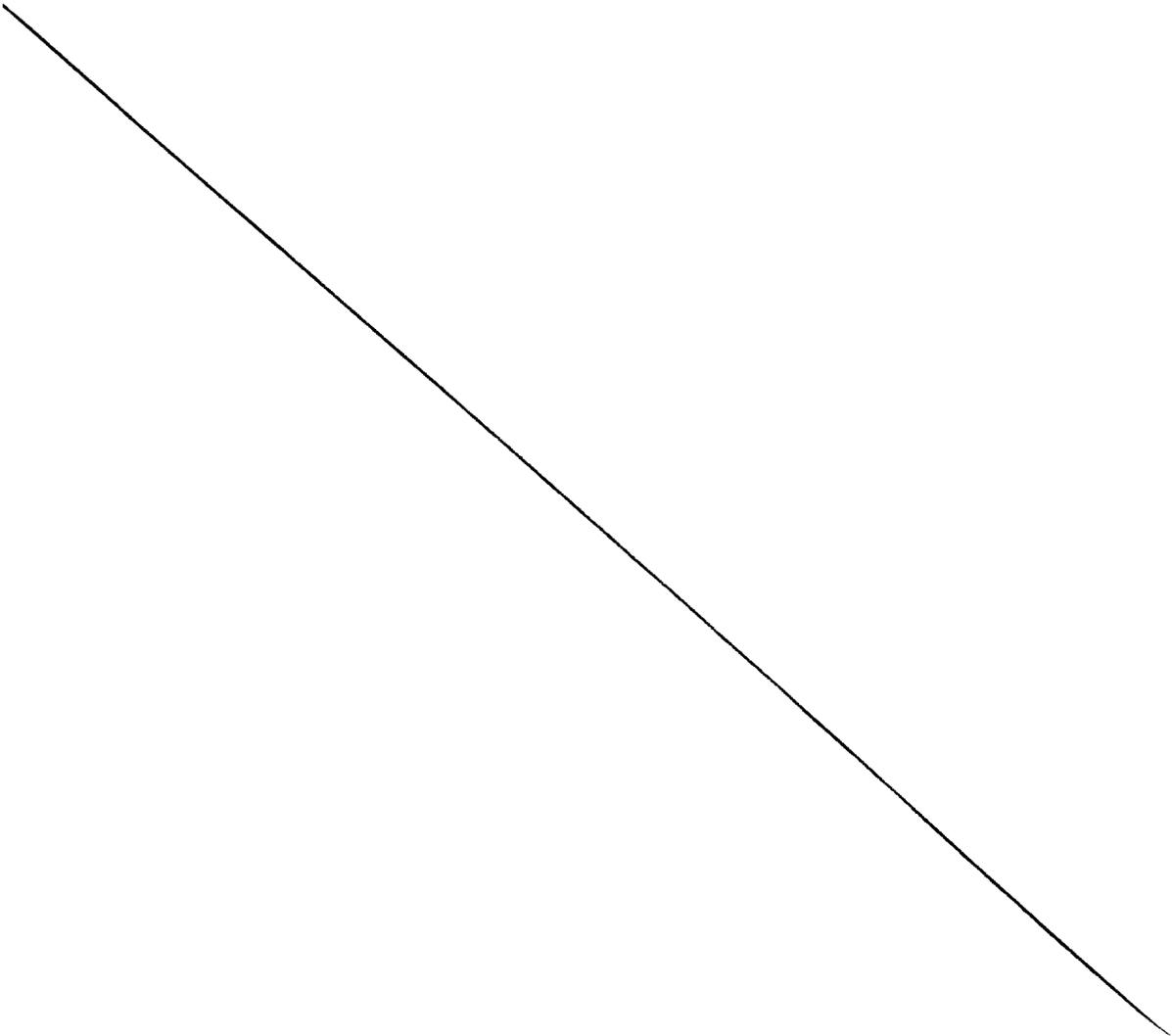
(4)(i) * * * FDA shall provide a written determination 30 days after FDA receives the IDE or earlier.

* * * * *

5. Section 812.47 is amended by revising the last sentence of paragraph (b) to read as follows:

§ 812.47 Emergency research under § 50.24 of this chapter.

* * * * *



(b) * * * The sponsor promptly shall provide this information in writing to FDA, investigators who are asked to participate in this or a substantially equivalent clinical investigation, and other IRB's that are asked to review this or a substantially equivalent investigation.

Dated: March 1, 1999
March 1, 1999



William K. Hubbard
Acting Deputy Commissioner for
Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

