FDA Regulatory Update

USC Research and Innovation
Human Research Protection Program

Institutional Review Board
Waiver or Alteration of Informed Consent
for
Minimal Risk Clinical Investigations

January 2024

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Objective:

Update IRB Staff and Members to FDA's regulatory change

New Rule issued by FDA on 12/21/2023

In alignment with 2016 Cures Act for FDA to “harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations,” to the extent practicable and consistent with other statutory provisions

Rule harmonizes with the Common Rule’s requirement under 45 CFR 46.116(f)(3)

FDA will withdraw previous guidance document from 2017 that allowed waiver/alterations until the final rule was issued

Rule effective on 1/22/2024

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The New 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

- Permits an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations.

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Resultant changes to

- 21 CFR 50.20 – General requirements for informed consent
- 21 CFR 312.60 – (Drugs) General responsibilities of investigators
- 21 CFR 812.2 – (Devices) Applicability

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21 CFR 312.60 – (Drugs) 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~~, in accordance with the provisions of part 50 of this chapter,~~ obtain the informed consent of each human subject to whom the drug is administered, ~~except as provided~~ in §§accordance with part 50~~.23 or 50.24~~ of this chapter. Additional specific responsibilities of clinical investigators are set forth in this part and in parts 50 and 56 of this chapter.

21 CFR 812.2(b)(1)(iii) – (Devices) Applicability

Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent ~~under part 50 and documents it, unless documentation is waived by an IRB under § 56.109(c).~~in accordance with part 50 of this chapter.

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Title 21 / Chapter I / Subchapter A / Part 50

	Part / Section
Title 21 Food and Drugs	
Chapter I Food and Drug Administration, Department of Health and Human Services	1 – 1299
Subchapter A General	1 – 99
Part 50 Protection of Human Subjects	50.1 – 50.56
Subpart A General Provisions	50.1 – 50.3
§ 50.1 Scope.	
§ 50.3 Definitions.	
Subpart B Informed Consent of Human Subjects	50.20 – 50.27
§ 50.20 General requirements for informed consent.	
§ 50.22 Exception from informed consent requirements for minimal risk clinical investigations.	
§ 50.23 Exception from general requirements.	
§ 50.24 Exception from informed consent requirements for emergency research.	
§ 50.25 Elements of informed consent.	
§ 50.27 Documentation of informed consent.	
Subpart C [Reserved]	
Subpart D Additional Safeguards for Children in Clinical Investigations	50.50 – 50.56
§ 50.50 IRB duties.	
§ 50.51 Clinical investigations not involving greater than minimal risk.	
§ 50.52 Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects.	
§ 50.53 Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition.	
§ 50.54 Clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.	
§ 50.55 Requirements for permission by parents or guardians and for assent by children.	
§ 50.56 Wards.	

NATIONAL ARCHIVES

Code of Federal Regulations

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Title 21

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21 CFR 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 private information or 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.

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Resources:

Federal Register, Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations, FDA, HHS, Final Rule

FDA eases informed consent requirements for minimal risk trials, Regulatory Focus, Mary Ellen Schneider, 21 December 2023

21 CFR 50, Subpart B, Informed Consent of Human Subjects

21 CFR 812.2(b)(1)(iii) – (Devices) Applicability

21 CFR 312.60 – (Drugs) General responsibilities of investigators