



INVESTIGATOR RESPONSIBILITIES FOR DEVICE STUDIES

Federal Research Regulations

The FDA is responsible for regulating devices for human use. Investigators conducting clinical trials involving devices have specific responsibilities outlined in 21 CFR 812.

The University of Utah applies the principles of the International Conference on Harmonization's Good Clinical Practices (ICH-GCP) to clinical investigations, as adopted by the FDA and insofar as the standards and requirements are consistent with 21 CFR. This document describes the ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects.

Description

Investigators are 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 devices under investigation. Additional responsibilities are found in the FDA regulations (see [Appendix A](#) of this document) and Good Clinical Practice.

Except when an exemption is granted, investigators must obtain the informed consent of each human subject to whom the device is administered. *Exceptions to the informed consent requirements found in 21 CFR 50 are not described in this document. For more information regarding exceptions please refer to the IRB website or contact the IRB office.*

Points to Address

Application:

1. **HIPAA and the Covered Entity Page:** A question will ask whether your study will involve the investigational use of a medical device. Mark "yes". Marking "yes" will prompt additional pages to complete in the ERICA system.
2. **Investigational Use of a Device Page:** The investigator must make an initial declaration of the risk determination of the device (e.g., non-significant risk, significant risk, or exempt from IDE requirements).
 - a. ~~Continue to the next page if~~ the study is a non-significant risk (NSR) device study, continue to the next page. Read and agree to the declaration of the Non-Significant Risk Device.
 - b. ~~Continue to the next page if~~ the study is exempt from IDE requirements, continue to the next page. Select the category of exemption from IDE requirements.
 - c. If the study is a significant risk (SR) device study complete the rest of the page. A plan to control for the investigational device proposed in the research study (i.e., how it will be stored, controlled, and dispensed to ensure that only qualified investigators and the participants use the investigational device) will be required as well as the IDE number.

Consent Document:

1. **Background:** State that the device used in the study is or is not investigational and whether ~~or not~~ it has been approved by the FDA.
2. **Confidentiality:** If the research is subject to FDA regulation, a statement must be included that notes the possibility that the FDA may inspect the records.
3. **Authorization for Use of Protected Health Information:** If the research is subject to FDA regulation, the FDA should be listed as an agency that will have access to protected health information.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



Documents and Attachments:

4. **Signature Block:** Signature and date of the participant and the person obtaining consent must be included.

If the medical device requires an IDE: Attach a document which verifies the IDE number (e.g., FDA letter providing the IDE, IDE number printed in protocol, letter from the sponsor, other sponsor-generated document).

References & Links

*IRB SOP 502: Clinical Research
Involving Investigational
Drugs and Devices*

<https://irb.utah.edu/guidelines/irb-sops.php>

*ICH E6: Good Clinical Practice:
Consolidated Guidance*

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1>

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Appendix A: Selections from [21 CFR §812](#) regarding the responsibilities of investigators

An investigator is responsible for the following: [\[21 CFR §812\]](#)

1. Ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations. [21 CFR §812.100]
2. Protecting the rights, safety, and welfare of those under the investigator's care. [21 CFR §812.100]
3. The control of devices under investigation.
4. An investigator may determine whether potential participants would be interested in participating in an investigation, but shall not request written informed consent of any participant to participate, and shall not allow any participant to participate before obtaining IRB and FDA approval. [21 CFR §812.110]
5. An investigator shall conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, this part and applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA. [21 CFR §812.110]
6. An investigator shall permit an investigational device to be used only with participants under the investigator's supervision. An investigator shall not supply an investigational device to any person not authorized under this part to receive it. [21 CFR §812.110]
7. A clinical investigator shall disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required under part 54 of this chapter. The investigator shall promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study. [21 CFR §812.110]
8. Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator shall return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs. [21 CFR §812.110]
9. A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation: [21 CFR §812.140(a)]
 - a. All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.
 - b. Record of receipt, use or disposition of a device that relate to:
 - i. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
 - ii. The names of all persons who received, used, or disposed of each device.
 - iii. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
 - c. Records of each participant's case history and exposure to the device. Case histories include case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include:
 - i. Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study.
 - ii. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each participant upon entering, and during the course of, the investigation, including information about relevant previous medical history and the result of all diagnostic tests.
 - iii. A record of exposure of each participant to the investigational device, including date and time of each use, and any other therapy.

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- iv. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.
 - v. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.
 - d. An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol. [21 CFR §812.140(d)]
 - e. An investigator or sponsor may withdraw from the responsibility to maintain records for the period required in 21 CFR §140(d) and transfer custody of the records to any other person who will accept responsibility for them under 21 CFR §812.140, including the requirements of 21 CFR §812.145. [21 CFR §812.140(e)]
 - i. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs.
- 10. An investigator will allow the following inspections by the FDA: [21 CFR §812.145]
 - a. Any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).
 - b. All records relating to an investigation.
 - c. Records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.
- 11. An investigator shall prepare and submit the following complete, accurate, and timely reports: [21 CFR §812.150(a)]
 - a. An investigator shall submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.
 - b. An investigator shall report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.
 - c. An investigator shall submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less than yearly.
 - d. An investigator shall notify the sponsor and the reviewing IRB (see 21 CFR §56.108(a) (3) and (4)) of any deviation from the investigational plan to protect the life or physical well-being of a participant in an emergency. Such notice shall be given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human participants, FDA and IRB in accordance §812.35(a) also is required.
 - e. If an investigator uses a device without obtaining informed consent, the investigator shall report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.
 - f. An investigator shall, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and reviewing IRB.
 - g. An investigator shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

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