Regulatory Brief

21CFR Part 812

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21 CFR Part 812: Investigational Device Exemptions (IDEs)

This document is a summary of the regulation and does include wording taken directly from the regulation itself. The original regulation should be referenced directly, however, for complete information when submitting an IDE request.

What is an investigational device exemption?

An investigational device exemption (IDE) allows a device to be used in a clinical study prior to obtaining market approval to collect safety and effectiveness data. Clinical studies are typically required to support a Premarket Authorization (PMA), but a small percentage of 510(k) applications also require clinical data when a predicate device comparison is inappropriate for the submission.

Before a clinical study is initiated, an investigational device must have an approved IDE, unless it is exempt. Devices may be exempt from IDE requirements if they are noninvasive diagnostic devices, being used for consumer preference testing unrelated to device safety or efficacy, or intended solely for veterinary use or research with laboratory animals. Refer to the full text of 21 CFR 812 for details and additional exemptions.

Part 812 – General Provisions (Subpart A)

Scope

This regulation is applicable to all clinical investigations of devices used to determine safety and effectiveness, except where exempt.

Applicability

Abbreviated Requirements

Investigations are considered automatically approved for IDEs if the device is not considered a significant risk , unless the FDA has specifically notified the sponsor otherwise. In these cases, the sponsor must still obtain IRB approval for the investigation and must comply with other requirements of Part 812, including proper labeling, record keeping, and conformed consent requirements.

Exempted investigations

IDEs are not required for devices that fall into one of the following categories:

- Devices that were in commercial distribution prior to May 28, 1976 that were used or investigated according to requirements in effect at that time. Devices that were introduced after May 28, 1976 but which have been found to be substantially equivalent to devices introduced earlier may also be exempt. This exemption is limited for Class II and III devices from the date an FDA regulation or order calls for the submission of a PMA (in the case of an unapproved Class III device) or establishes a performance standard for a Class II device.
- Diagnostic devices for which the testing is noninvasive and without significant risk, and is not used as a diagnostic procedure without confirmation through another product or procedure.
- Devices undergoing consumer preference testing, or testing of a device modification or combination of already distributed devices, if the testing is not for purposes of determining safety or efficacy and does not put subjects at risk.

- Devices solely for veterinary use.
- Devices intended for research on or with laboratory animals.
- A custom device that is not being used to determine safety or efficacy for commercial distribution.

Definitions

21 CFR Part 812.3 provides definitions for many terms, some of which are listed here.

Institution: A person, other than an individual, who engages in the conduct of research on subjects or in the delivery of medical services to individuals as a primary activity or as an adjunct to providing residential or custodial care to humans. For example, a hospital, retirement home, confinement facility, academic establishment, and device manufacturer. The term has the same meaning as "facility."

Institutional Review Board (IRB): Any board, committee, or other group formally designated by an institution to review biomedical research involving subjects and established, operated, and functioning in conformance with part 56. The term has the same meaning as "institutional review committee."

Investigational device: A device, including a transitional device, that is the object of an investigation.

Investigator: An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

Monitor: When used as a noun, this term means an individual designated by a sponsor or contract research organization to oversee the progress of an investigation. The monitor may be an employee of a sponsor or a consultant to the sponsor, or an employee of or consultant to a contract research organization. Monitor, when used as a verb, means to oversee an investigation.

Significant risk device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Sponsor: A person who initiates, but who does not actually conduct the investigation, that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

Sponsor-investigator: An individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under this part include those of an investigator and those of a sponsor.

Subject: A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.

Labeling of investigational devices

An investigational device or its packaging requires a label with the following information:

- Name and place of business of the manufacturer, packer, or distributor (per 801.1)
- Quantity of contents
- Statement: "CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use."
- Any additional relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.
- If used for animal research, a statement of "CAUTION—Device for investigational use in laboratory animals or other tests that do not involve human subjects" must be on the label

IDE Labeling cannot have any statement that is false or misleading and cannot represent the device as safe nor effective.

Prohibition of promotion and other practices

An investigational device is intended for use only within an investigation. Therefore, until a device is approved for commercial distribution by the FDA the sponsor or investigator (or those working on their behalf) cannot:

- Promote or test market the device.
- Charge subjects or investigators a price larger than necessary to cover costs of manufacturer, research, development, and handling.
- Unduly prolong an investigation if data indicates a premarket approval cannot be justified, in the case of Class II devices, or that it will not comply with applicable performance standards, in the case of Class III devices.
- Represent an investigational device as safe or effective for the purposes for which it is being investigated.

Waivers

A sponsor may request a waiver from the FDA for any requirement in Part 812. A waiver may be submitted as part of an application or separately, and the FDA may grant the waiver if it finds that the requirements are unnecessary to protect the rights, safety, or welfare of human subjects. Otherwise, all requirements continue to apply unless waived by the FDA.

Import and export requirements

Any person importing an investigational device is considered the agent of the foreign exporter and acts as the sponsor of the clinical investigation (or they must ensure that another person acts as the agent and sponsor).

Any person exporting an investigational device must obtain the FDA's prior approval, as required by section 801(e) of Part 812 or they must comply with section 802 of Part 812.

Address for IDE correspondence

All correspondence concerning IDEs should include a description of the correspondence (ex: IDE application, supplemental IDE application, or correspondence concerning an IDE) and should be sent to the appropriate agency responsible for regulating the device:

- Center for Devices and Radiological Health
- Center for Biologics Evaluation and Research
- Center for Drug Evaluation and Research

Part 812 – Application and Administrative Action (Subpart B)

This section of the regulation details the submission requirements and process.

Submission

An IDE application is required not only for any investigation involving a device with significant risk, but also for any investigation involving an exception from informed consent. Information regarding exceptions from informed consent requirements for emergency research can be found in 21 CFR Part 50.24.

Contents of an IDE application

An IDE application needs to include, in order, the following:

1. The name and address of the sponsor.
2. A complete report of prior investigations of the device and an accurate summary of appliable sections of the investigational plan or the complete investigational plan and complete report of prior investigations if no IRB has reviewed them (or if requested by the FDA).
3. A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and where appropriate, installation of the device.
4. An example of the investigator's agreement along with a list of all investigators who have signed the agreement.
5. A certification that all participating investigators have signed the agreement.
6. A list of each IRB that has been or will be asked to review the investigation, including the name and contact information for each chairperson.
7. The name and address of any institution at which a part of the investigation may take place, not otherwise listed in the previous paragraph (6).
8. If the device is to be sold, the amount to be charged and an explanation of why sale does not constitute commercialization of the device.
9. A claim for categorical exclusion under § 25.30 or § 25.34, or an environmental assessment under § 25.40.
10. Copies of all labeling for the device.
11. Copies of all forms and informational materials to be provided to subjects to obtain informed consent.
12. Any other relevant information FDA requests for review of the application.

Information previously submitted to the CDRH, CBER, or CDER in accordance with the requirements listed here, need not be resubmitted, but may be incorporated by reference.

Note that additional information requests by the FDA can be treated as a disapproval of the application for purposes of requesting a hearing under part 16.

Investigational Plan

The investigational plan shall include, in the following order:

1. Purpose
2. Protocol
3. Risk analysis
4. Description of the device
5. Monitoring procedures
6. Labeling
7. Consent materials
8. IRB information
9. Other institutions
10. Additional records and reports

Report of prior investigations

This section requires a full listing of all prior clinical, animal, and laboratory testing of the device for the purpose of justifying the proposed investigation. This includes a complete bibliography of all publications relevant to the safety or effectiveness of the device, copies of all adverse information, and a summary of any other applicable, unpublished information. Any relevant information which the sponsor possesses or can reasonably obtain must be included.

Any information on nonclinical laboratory studies must include a statement that the studies were conducted in compliance with applicable requirements in the good laboratory practice regulations in part 58. Otherwise, a statement of the reason for noncompliance must be included.

For data from clinical investigations:

- For those conducted in the United States, a statement that each investigation was conducted in compliance with applicable requirements in part 50 (protection of human subjects) and part 56 (institutional review board regulations). In any instance where an investigation was not in compliance with these regulations, a statement of the reason for noncompliance must be included.
- For those conducted outside of the United States, the requirements of § 812.28 apply (see next section).

Acceptance of data from clinical investigations conducted outside the United States

Well-designed and well-conducted studies outside of the United States will be accepted by the FDA if the following conditions are met:

- A statement is provided that the investigation was conducted in accordance with good clinical practice (GCP).
- In addition to information required elsewhere (in parts 807, 812, and 814), the following information should be submitted for investigations of significant risk devices or others as required by this section:
    1. The names of the investigators and names and addresses of research facilities and sites where investigation records are maintained.
    2. The investigator's qualifications.
    3. A description of the research facilities.
    4. A detailed summary of the protocol and results of the investigation. The FDA may also request case records or additional background data.
    5. For devices used in an investigation outside of the United States, a statement that the device used in the investigation is identical to the device that is the subject of the submission, or details about the device and how it is similar to and/or different from the device that is the subject of the submission.
    6. For investigations intended to support the safety and effectiveness of a device, demonstrate that the data and information constitute valid scientific evidence (per § 860.7).
    7. The name and address of the IEC that reviewed the investigation, along with a statement that the IEC meets the definition in § 812.3(t).
    8. A summary of the IEC's decision to approve the investigation (or modify and approve) or to provide a favorable opinion.
    9. A description of how informed consent was obtained.
    10. A description of what incentives, if any, were provided to subjects to participate in the investigation.
    11. A description of how the investigation was monitored by the sponsor(s) to ensure that the investigation was carried out consistently with the protocol.
    12. A description of how investigators were trained to comply with GCP (as described in paragraph (a)(1)) and to conduct the investigation in accordance with protocol. Include a statement as to whether written commitments by investigators to comply with GCP and the protocol were obtained.

Waivers may be requested by sponsors or applicants for any applicable requirements in paragraphs (a)(1) and (b) of this regulation. Waiver requests may be granted by the FDA if it determines that the waiver is in the best interest of the public health. A waiver request must contain at least one of the following:

- An explanation as to why compliance with the requirement is unnecessary or cannot be achieved.
- A description of an alternative submission or course of action that satisfies the purpose of the requirement.
- Other information justifying a waiver.

A sponsor or applicant must retain all required records for a clinical investigation conducted outside of the United States for 2 years following:

- The termination or completion of an IDE, when the submission is in support of an IDE.
- An agency decision on an applicable marketing application or submission (ex: premarket approval application, premarket notification submission).

The FDA may accept information from a clinical investigation conducted outside of the United States that does not meet the requirements of this section if they believe that the data and results are credible and accurate and that the subjects of the investigation were adequately protected.

FDA action on applications

An IDE application is approved thirty-days after the FDA receives the application unless the FDA notifies the sponsor that the investigation may not begin until there is FDA approval. The investigation may begin sooner upon FDA approval.

An IDE application can be disapproved, or have approval withdrawn, if the FDA determines that:

- There has been a failure to comply with any requirement of this part or the act, any other applicable regulation or statute, or any condition of approval imposed by an IRB or FDA.
- The application or a report contains an untrue statement of a material fact, or omits material information required by this part.
- The sponsor fails to respond to a request for additional information within the time prescribed by FDA.
- There is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective.
- It is otherwise unreasonable to begin or to continue the investigation because of the way in which the device is used or the inadequacy of any of the following:
  - The report of prior investigations or the investigational plan.
  - The methods, facilities, and controls used for the manufacturing, processing, packaging, storage, and, where appropriate, installation of the device.
  - Monitoring and review of the investigation.

The FDA will provide written notification of disapproval or withdrawal, including the reasons for the decision. The sponsor has an opportunity to request a hearing under part 16. A withdrawal of approval does not take effect until the opportunity for a hearing has been provided, unless the FDA determines that there is an unreasonable risk to the public health.

Supplemental applications

Changes in investigational plans

1. **Changes requiring prior approval**

   Except as described in the sections below, approval of a supplemental application must be obtained, along with IRB approval where appropriate (see §§ 56.110 and 56.111), prior to implementing a change to an investigational plan.

2. **Changes effected for emergency use**

   FDA approval of a supplement does not apply in the case of a deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such deviations need to be reported to the FDA within 5 days of the sponsor learning of the event.

3. **Changes effected with notice to FDA within 5 days**

   Certain changes can be made without prior approval of a supplemental application, but do require notification to the FDA within 5 days of making these changes. These notifications are identified as "notice of IDE change," (see 812.35(A) for information on the contents of a notice of IDE change). Changes that apply in this section are:

   - Developmental changes that do not constitute a significant change in design or basic principles of operation and that are made in response to information gathered during the course of an investigation.

     Credible information must be provided to support developmental changes and includes data generated under the design control procedures, preclinical/animal testing, peer reviewed published literature, or other reliable information such as clinical information gathered during a trial or marketing of the device.

   - Changes to clinical protocol that do not affect the validity of the data, the patient risk to benefit, the scientific soundness of the investigational plan, or the rights, safety, or welfare of the human subjects.

     Credible information must be provided to support changes to clinical protocols. Credible information for this purpose is defined as documentation supporting the conclusion that a change does not have a significant impact on the study design or planned statistical analysis, and that the rights, safety, or welfare of subjects are not affected. Documentation can include peer reviewed published literature, recommendations of the clinical investigator(s), and/or the data gathered during the clinical trial or marketing.

4. **Changes submitted in annual report**

   Prior approval and 5-day notification requirements do not apply to minor changes to the purpose of the study, risk analysis, monitoring procedures, labeling, informed consent materials, and IRB information that do not affect:

   - The validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol.
   - The scientific soundness of the investigational plan.
   - The rights, safety, or welfare of the human subjects in the investigation.

IRB approval for new facilities

A sponsor shall submit to the FDA certification of any IRB approval of an investigation or part of an investigation not included in the IDE application. If there are no other changes to the investigation, the supplemental application shall consist of the information required in 812.20(b) (see Contents of an IDE application), along with a description of any modifications to the investigational plan required by the IRB as a condition of approval. While IRB approval is not required in the initial submission of the supplemental application, a sponsor may not begin part of an investigation at the facility until approval of the IRB has been obtained and the FDA has received the certification of the approval and approved the application.

Treatment use of an investigational device

a. General

Devices under clinical investigation or awaiting market approval may be used to treat serious or immediately life-threatening diseases or conditions in patients for whom no satisfactory alternative device or therapy is available. A treatment investigational device exemption (IDE) is used to facilitate the availability of promising new devices to desperately ill patients as early as possible.

b. Criteria

The FDA shall consider the use of an investigational device under a treatment IDE if all of the following conditions exist:

- The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition.
- There is no comparable or satisfactory alternative device or other therapy available to treat or diagnose that stage of the disease or condition in the intended patient population.
- The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or such clinical trials have been completed.
- The sponsor of the investigation is actively pursuing marketing approval/clearance of the investigational device with due diligence.

c. Applications for treatment of use

A treatment IDE application shall include, in order:

- The name, address, and telephone number of the sponsor of the treatment IDE.
- The intended use of the device, the criteria for patient selection, and a written protocol describing the treatment use.
- An explanation of the rationale for use of the device, including, as appropriate, either a list of the available regimens that ordinarily should be tried before using the investigational device or an explanation of why the use of the investigational device is preferable to the use of available marketed treatments.
- A description of clinical procedures, laboratory tests, or other measures that will be used to evaluate the effects of the device and to minimize risk.
- Written procedures for monitoring the treatment use and the name and address of the monitor.
- Instructions for use for the device and all other labeling as required under § 812.5(a) and (b).
- Information that is relevant to the safety and effectiveness of the device for the intended treatment use. Information from other IDE's may be incorporated by reference to support the treatment use.
- A statement of the sponsor's commitment to meet all applicable responsibilities under this part and part 56 of this chapter and to ensure compliance of all participating investigators with the informed consent requirements of part 50 of this chapter.
- An example of the agreement to be signed by all investigators participating in the treatment IDE and certification that no investigator will be added to the treatment IDE before the agreement is signed; and if the device is to be sold, the price to be charged and a statement indicating that the price is based on manufacturing and handling costs only.

A licensed practitioner who uses a device under a treatment IDE is an "investigator" and is responsible for meeting all applicable responsibilities.

d. FDA action on treatment IDE applications

- Treatment use may begin 30 days after the FDA receives the treatment IDE submission, unless the FDA notifies the sponsor sooner that the treatment may or may not begin. Approval may be given as proposed or with modifications.
- The FDA may disapprove or withdraw approval if the criteria specified in § 812.36(b) are not met or the treatment IDE does not contain the information required in § 812.36(c), or if the FDA determines that any of the grounds for disapproval or withdrawal of approval listed in § 812.30(b)(1) through (b)(5) apply. Additional reasons for disapproval are listed in 21 CFR 812.36(d)(2).

e. Safeguards

Treatment use of an investigational device is conditioned upon the sponsor and investigators complying with the safeguards of the IDE process and the regulations governing informed consent and institutional review boards.

f. Reporting requirements

The sponsor of a treatment IDE shall submit progress reports on a semi-annual basis to all reviewing IRB's and FDA until the filing of a marketing application.

Confidentiality of data and information

The FDA will not disclose the existence of an IDE if its existence has not previously been publicly disclosed, until the FDA approves the application for premarket approval, or a notice of completion of a product development protocol for the device has become effective. They may, however:

- Make publicly available a detailed summary of information concerning the safety and effectiveness of the device used as the basis or an approval, disapproval or withdrawal of approval order.
- Honor Freedom of Information Act requests for investigations involving exceptions from informed consent.
- Disclose a copy of applicable adverse device effects reports to persons on whom an investigational device was used.

Otherwise, the FDA will make publicly available, upon request, a detailed summary of information concerning the safety and effectiveness of the device.

Part 812 – Responsibilities of Sponsors (Subpart C)

General responsibilities of sponsors

Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, submitting an IDE application to FDA, and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation.

FDA and IRB approval

A sponsor shall not begin an investigation or part of an investigation until an IRB and FDA have both approved the application or supplemental application relating to the investigation or part of an investigation.

Selecting investigators and monitors

a. Selecting investigators – A sponsor shall select qualified investigators.
b. Control of device – A sponsor is responsible for shipping investigational devices only to qualified investigators participating in the investigation.
c. Obtaining agreements – A sponsor is responsible for obtaining a signed agreement from each participating investigator.
d. Selecting monitors – A sponsor is responsible for selecting qualified monitors to monitor the investigation in accordance with all applicable FDA regulations.

Informing investigators

A sponsor shall supply all investigators participating in the investigation with copies of the investigational plan and the report of prior investigations of the device.

Monitoring investigations

If a sponsor discovers that an investigator is not complying with the signed agreement, investigational plan, or any application regulations or conditions imposed by the FDA or IRB, they must promptly secure compliance or discontinue shipping the device to the investigator and terminate their participation in the investigation. In this case, the sponsor should also ensure that the investigator either disposes of or returns the device, unless this action would jeopardize the rights, safety, or welfare of a subject.

A sponsor shall also immediately evaluate any unanticipated adverse effects and terminate all applicable investigations, or parts of investigations, if it is determined that the device presents an unreasonable risk to subjects. Termination of the investigation needs to occur within 15 days of the sponsor receiving notice of the adverse effect and within 5 days of the sponsor making a determination of unreasonable risk. A sponsor may not resume a terminated study for a significant risk device without IRB and FDA approval.

Emergency research under 50.24

e. The sponsor shall monitor the progress of all investigations involving an exception from informed consent under § 50.24 of this chapter. When the sponsor receives from the IRB information concerning the public disclosures under § 50.24(a)(7)(ii) and (iii) of this chapter, the sponsor shall promptly submit to the IDE file and to Docket Number FDA–1995–S–0036 in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, copies of the information that was disclosed, identified by the IDE number.
f. The sponsor also shall monitor such investigations to determine when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception in § 50.24(a) of this chapter or because of other relevant ethical concerns. The sponsor shall promptly 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.

IRB Review and Approval (Subpart D)

IRB composition, duties, and functions

An IRB reviewing and approving investigations under this part shall comply with the requirements of part 56 in all respects, including its composition, duties, and functions. IRB's are responsible for:

1. Reviewing all investigations covered in this part, with the authority to approve, require modifications (to secure approval), or disapproving the investigation. If no IRB exists, a sponsor may submit an application to the FDA.
2. Conducting reviews of an investigation in accordance with part 56.
3. Making significant risk determinations.

Responsibilities of Investigators (Subpart E)

An investigator is responsible for ensuring that:

1. An investigation is conducted according to the signed agreement, investigational plan, and application FDA regulations, and does not supply the device to any unauthorized party.
2. The rights, safety, and welfare of subjects are protected.
3. Informed consent is obtained.

Specific responsibilities are detailed in § 812.110.

An investigator can be disqualified if the FDA has reason to believe that an investigator has repeatedly or deliberately failed to comply with the requirements of part 812, part 50, or part 56 of the CFR. The FDA will notify the investigator, IRB, and sponsor when this occurs. Disqualified investigators will be ineligible to receive FDA-regulated test articles and an evaluation will be made as to whether the investigator has submitted unreliable data that is essential to the continuation of an investigation, the clearance or approval of a marketing application, or the continued marketing of an FDA-regulated product.

Records and Reports (Subpart F)

Records

Investigator records

An investigator is required to maintain accurate, complete, and current records relating to their participation in the investigation, including:

1. All correspondence with another investigator, an IRB, the sponsor, monitor, or the FDA.
2. Records of receipt, use, or disposition of a device.
3. Records of each subject's case history and exposure to the device, including evidence of informed consent.
4. The investigation protocol, including dates and reasons for any deviation.
5. Any additional records required by the FDA.

Sponsor records

1. All correspondence with another sponsor, a monitor, an investigator, an IRB or the FDA.
2. Records of shipment and disposition.
3. Signed investigator agreements, including financial disclosure information.
4. For each investigation subject to § 812.2(b)(1) of a device other than a significant risk device, the records described in paragraph (b)(5) of this section and the following records, consolidated in one location and available for FDA:
    e. The name and intended use of the device and the objectives of the investigation.
    f. A brief explanation of why the device is not a significant risk device.
    g. The name and address of each investigator.
    h. The name and address of each IRB that has reviewed the investigation.
    i. A statement of the extent to which the good manufacturing practice regulation in part 820 will be followed in manufacturing the device.
    j. Any other information required by FDA.
5. Records concerning adverse device effects (whether anticipated or unanticipated) and complaints.
6. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation.

IRB records

An IRB shall maintain records in accordance with part 56 of this chapter.

Retention period

Records required in this section of the regulation shall be maintained for a period of 2 years after the latter of either:

1. The date on which the investigation is terminated or completed; or
2. The date that the records are no longer required for purposes of supporting any market submission application.

Records custody

An investigator or sponsor may transfer custody of the records to any other person who will accept responsibility for them under the requirements of this regulation. Notice of such a transfer will be given to the FDA no later than 10 working days after the transfer occurs.

Inspections

A sponsor, IRB, or investigator shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to:

1. Enter and inspect any establishment where devices are held.
2. Inspect and copy all records relating to an investigation.
3. Inspect and copy records that identify subjects, upon notice that the FDA has reason to suspect that adequate informed consent was not obtained, or that required reports were not submitted, are incomplete, inaccurate, false, or misleading.

Reports

Investigator reports

Investigators are responsible for submitting the following complete, accurate, and timely reports:

1. Unanticipated adverse device effects
2. Withdrawal of IRB approval
3. Progress reports
4. Deviations from the investigational plan
5. Informed consent
6. Final report – submitted within 3 months of the termination or completion of an investigation, or the investigator's part of the investigation
7. Other reports as requested by a reviewing IRB or FDA

Sponsor reports

Sponsors are responsible for submitting the following complete, accurate, and timely reports:

1. Unanticipated adverse device effects
2. Withdrawal of IRB approval
3. Withdrawal of FDA approval
4. Current investigator list
5. Progress reports
6. Recall and device disposition
7. Final report – submitted within 6 months of the completion or termination of the investigation (FDA shall be notified within 30 working days)
8. Informed consent
9. Significant risk device determinations
10. Other reports as requested by a reviewing IRB or FDA

For additional information, see the FDA's Investigational Device Exemption (IDE).


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