FDA
Investigational Device Exemption (IDE) Toolkit

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Step 1

Start Up Checklists

Do you need an IDE?

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IDE Applicability Checklist

Mark “Yes” or “No” for each of the below:

Yes	No	
☐	☐	1. Is the investigation within the categories exempt from the IDE regulation under 812.2?

If YES: IDE Application is not required
IRB clearance & informed consent is recommended
Check with institutional policies

☐	☐	2. Is this a nonsignificant risk device investigation?

If YES: Submission to and approval from FDA is not required for nonsignificant risk devices
Follow abbreviated requirements, including IRB approval and informed consent

If both of the above rows are checked “No”: An IND application must be submitted to FDA and approval must be obtained from both IRB and FDA before the study may begin.

KZT 05 Dec 2019 https://www.fda.gov/medical-devices/device-advice-investigational-device-exemption-ide/ide-application

FDA IDE Applications: Required Elements (Short Checklist)

1. Name & Address of Sponsor
2. Report of Prior Investigations (clinical, laboratory, animal testing of device)
3. Investigational Plan
4. Methods, facilities and controls used for manufacture
5. Sample Investigator Agreement
6. Names & Addresses and IRB chairpersons to review
7. Name & Addresses of institutions conducting investigation
8. Device cost and explanation
9. Device labeling
10. Informed consent forms
11. Relevant information requested by FDA

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FDA IDE Applications: Required Elements (Detailed)

Significant Risk Devices require complete IDE application including 3 copies of a signed IDE application

1. Name and Address of Sponsor

2. Report of Prior Investigations

   Must include report of all prior clinical, animal, and laboratory testing of the device.

   - Bibliography of all publications that are relevant to the safety & effectiveness of the device
   - Copies of all published & unpublished adverse information
   - Copies of other significant publications if requested by an IRB or FDA
   - Summary of all other unpublished information (adverse & supportive)
   - Nonclinical laboratory data: a statement that such studies have been conducted in compliance with Good Laboratory Practice (21 CFR Part 58). If not conducted in compliance, include a brief statement with reason

3. Investigational Plan

   Must include the following items in this order

   A. Purpose (name & intended use of the device and the objectives and duration of the investigation)
   B. Protocol (describing the methodology to be used and an analysis of the protocol demonstrating scientific soundness)
   C. Risk Analysis (description & analysis of all increased risks to subjects and how these risks will be minimized; a justification for the investigation; and a description of the patient population incl. number, age, sex, and condition)
   D. Description of the device (each important component, ingredient, property, and principle of operation of the device, any anticipated changes in the device during the investigation)
   E. Monitoring Procedures (sponsor's written procedures for monitoring the investigation & name/address of each monitor)
   F. Additional Records & Reports (a description of any records or reports of the investigation other than those required in Subpart G of the IDE Regulations)

4. Description of methods, facilities, and controls used for manufacture, processing, packing, storage, and installation of the device

5. Example of the agreement to be signed by the investigators and a list of the names/addresses of all investigators.

6. Certification that all investigators have signed the agreement, that the list of investigators includes all investigators participating in the study, and that new investigators will sign the agreement before being added to the study

7. List of the names, addresses, and chairpersons of all IRBs that have or will be asked to review the investigation & a certification of IRB action concerning the investigation (when available)
8. Name/address of any institution (other than those above) where a part of the investigation may be conducted
9. The amount, if any, charged for the device and an explanation of why sale does not constitute commercialization
10. Copies of all labeling for the device
11. Copies of all informed consent forms and all related information materials to be provide to subjects
12. Any other relevant information that FDA requests for review.

IDE Application: Detailed Checklist

Elements	Included
Format for submission: Table of contents (recommended) Paginated pages (recommended)	Yes/No
Report of Prior Investigations: Are the following items provided and are they comprehensive and adequate to justify the proposed investigation?	
• Report of all prior clinical, animal and laboratory testing	Yes/No
• Bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety and effectiveness of the device	Yes/No
• Copies of all published and unpublished adverse information	Yes/No
• Summary of all other unpublished information, whether adverse or supportive, that is relevant to an evaluation of safety and effectiveness of the device	Yes/No
• Statement whether nonclinical tests comply with the good laboratory practice (GLP) regulations in Part 58 If any studies were not conducted in compliance with the GLP regulation, a brief statement of the reason for the noncompliance must be provided. Failure or inability to comply with this requirement does not justify failure to provide information on a relevant nonclinical test study.	Yes/No
If any item is not provided, a justification for its omission must be provided.	
Investigational Plan: Are the following items included, preferably in the following order:	
Purpose: Are the following clearly defined? • name and intended use of the device • objectives of the investigation • duration of the investigation (specify in months and years)	Yes/No

Elements	Included
Protocol: Are the following items provided and adequate? • a written protocol describing the methodology to be used including: • objectives, hypothesis to be tested, or question to be answered • description of the type of trial (i.e., controlled/open, double-blind/single-blind, etc.) • detailed description of the conduct of the trial • description of statistical methods • case report forms • an analysis of the protocol demonstrating its scientific soundness	Yes/No
Risk Analysis: Are the following items provided and adequate to determine that the benefit and knowledge to be gained from the investigation outweigh the risks to the subjects? • a description and analysis of all increased risks to the research subjects • the manner in which risks will be minimized • a justification for the investigation • a description of patient population, including number, age, sex and condition	Yes/No
Description of the Device: Are the following items provided and adequate? • a description of each important component, ingredient and property • the principle of operation of the device • a description of any anticipated changes in the device during the investigation	Yes/No
Monitoring Procedures: Are the following items present? • the written procedure for monitoring the investigation • the name and address of the individual(s) who will monitor the study	Yes/No
Manufacturing Information: Is adequate manufacturing information provided to allow a judgement about the quality control of the device (e.g., that the device will meet the intended specifications) based on the description of methods, facilities and controls used for: a. manufacturing b. processing c. packing d. storage e. installation	Yes/No
Investigator Information: Are the following items included?	[redacted]

Elements	Included
Example of investigator agreement which should include: 1. the investigator's curriculum vitae; 2. where applicable, a statement of the investigator's relevant experience (including the dates, location, extent and type of experience); 3. if the investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination; and 4. a statement of the investigator's commitment to: • conduct the investigation in accordance with the agreement, the investigational plan, Part 812 and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB and FDA; • supervise all testing of the device involving human subjects; and • ensure that the requirements for obtaining informed consent are met • Investigator's commitment to provide sufficient and accurate financial disclosure information and update information if any relevant changes occur during the investigation and for one year following the completion of the study.	Yes/No
Certification that all participating investigators have signed the agreement and that no investigator will be added until the agreement is signed.	Yes/No
Name and address of investigators who have signed the agreement.	Yes/No
IRB Information: Are the following items included?	
Name, address, and chairperson of each IRB	Yes/No
Certification of the action taken by each IRB, (i.e., approval letter) • How many IRBs have approved the investigation? • How many IRBs are currently reviewing the investigation or will review it in the future?	Yes/No
Names and addresses of any institutions (other than those identified above) where a part of the investigation may be conducted	Yes/No
Sales Information: [812.7(b)] Is the following information provided?	
Is the device to be sold?	Yes/No
If yes, is the amount to be charged provided?	Yes/No

Elements	Included
Explanation of why sale does not constitute commercialization	Yes/No
§ 812.7(b) prohibits the commercialization of an investigational device by charging subjects or investigators for a device a price larger than necessary to recover costs of manufacture, research, development, and handling.	
Environmental Impact Assessment: An environmental impact assessment or a claim for categorical exclusion is no longer required.	
Labeling: Are copies of all labeling for the device provided and include the following?	
Does the labeling contain the statement "CAUTION-Investigational Device. Limited by Federal (or United States) Law to Investigational Use."	Yes/No
Does the labeling contain adequate information for the purposes of the investigation, in accordance with § 812.5(a), including the name and place of business of the manufacturer, packer, or distributor, the quantity of contents, and a description of all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions? If any item is not addressed, a justification for its omission must be provided.	Yes/No
Note: The device may not be promoted as safe and effective for the use for which it is being investigated.	
Informed Consent Materials	
Are all forms and informational materials to be presented to the subject included?	Yes/No
Does the informed consent form seek consent from the subject or a legally authorized representative, when appropriate (e.g., when the subject is a minor)?	Yes/No
Does the informed consent form contain the basic required elements? Required Elements: • a statement that the study involves research • an explanation of the purposes of the research • the expected duration of the subject's participation • a description of the procedures to be followed • identification of any procedures which are experimental • a description of any reasonably foreseeable risks or discomforts to the subject • a description of any benefits to the subject or others • a disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject	Yes/No

Elements	Included
• a statement describing the extent to which confidentiality of the subject's records will be maintained and that FDA may inspect the records • an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of or sources of further information • an explanation of whom to contact for answers to questions about the study and the subject's rights and whom to contact in the event of a research-related injury • a statement that participation is voluntary and that subjects may refuse to participate or discontinue participation at any time without penalty or loss of benefits	
Additional Elements Required When Justified: • A statement that the procedure or treatment may involve unforeseeable risks to subject, or to the embryo or fetus if the subject were to become pregnant • Anticipated circumstances under which the investigator may terminate the subject's participation without regard to the subject's consent • Any additional costs to subject as a result of participation • Consequences of a subject's decision to withdraw and procedures for withdrawal • A statement that significant new findings which may relate to the subject's willingness to participate will be provided to the subjects • The approximate number of subjects involved in the study • Does the consent process involve a "short form" written consent [21 CFR Part 50.27(b)(2))]. If yes, a copy of the "short form" and a written summary of what is to be said to the subject or representative should be provided.	Yes/No/NA
The informed consent form may not contain exculpatory language	
Elements: Informed Consent and Clinical Trials.gov	Included
Title VIII of the Food and Drug Administration Amendment Act of 2007 (FDAAA) expanded the ClinicalTrials.gov database to include mandatory registration and reporting of results for applicable clinical trials of human drugs and devices. You should review 42 U.S.C. 282(j) to determine whether the requirements of FDAAA apply to this application/submission. Additional information on registering your clinical trials is available at the Protocol Registration System (PRS) Information Site at http://prsinfo.clinicaltrials.gov. If this is an “applicable clinical trial” (https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf), does the informed consent form contain the following statement?: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you.	Yes/No/NA

Elements	Included
At most, the Web site will include a summary of the results. You can search this Web site at any time.”	
Other Information: Provide additional information supportive of the investigation and any information FDA has identified (through previous contact with the agency or through guidance documents) as required. If any item is not provided, a justification for its omission must be provided.	[redacted]

Step 2

Submission Procedures

Guidance Documents

- FDA Decisions for Investigational Device Exemption Clinical Investigations- Guidance for Sponsors, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff.

- Investigator Responsibilities- Protecting the Rights, Safety and Welfare of Human Subjects

- Investigator's Responsibilities for Significant Risk Device Investigations (Nov. 1995)

- Guidance for Sponsors, Investigators, and Institutional Review Boards- Questions and Answers on Informed Consent Elements 21 CFR 50.25(c)

- FDA Acceptance of Clinical Data to Support Medical Device Applications and Submissions- Frequently Asked Questions

- eCopy Program for Medical Device Submissions- Guidance for Industry and Food and Drug Administration Staff

- Oversight of Clinical Investigations- a Risk-Based Approach to Monitoring

IDE Cover Letter: Checklist

Element	Included
Statement that submission is an original IDE application.	Yes/No
Device Information: • Device Name • Intended Use	Yes/No
Sponsor – (must be located in United States) [§812.18(a)]: • Name • Address • Contact Person • Telephone Number • Fax • Email address	Yes/No
Manufacturer Information • Name • Address • Contact Person • Telephone Number • Fax	Yes/No
Correspondent Information (Note: IDE application will not be approved without a U.S. sponsor) [§812.18(a)] • Name • Address • Contact Person • Telephone Number • Fax	Yes/No
If applicable, provide the following information: • Q-Submission/Pre-Submission Number • Significant Risk Determination Q-Submission Number • Waiver Requests/Justification • Referenced Files	Yes/No

Original IDE Application: Cover Letter

Application Statement	Information provided is an original IDE submission
Device Information	Device Name Intended Use
Sponsor Contact Information	*Must be in the U.S.A. Name Address Contact Person Telephone Number & Fax Email address
Manufacturer Information	Name Address Contact Person Telephone Number & Fax
Correspondent Information	If organization submitting is not the sponsor (i.e. consultant, lawyer) include contact information for correspondent
Q-Submissions/Pre-Submissions (if applicable)	Describe any discussions with the FDA about the device State the Pre-sub number and provide a copy of the written feedback provided by the FDA If Pre-Sub meeting occurred, provide name of the FDA contact person and a copy of meeting minutes
Study Risk Determination (SRD) Q-Submission (if applicable)	If a SRD Q-Sub was submitted, provide the Q-Sub number and a copy of the FDA determination letter
Waiver Requests	Identify any requests for waivers and include a justification for the waiver
Referenced Files	Identify any files that are referenced in the IDE application (i.e. premarket approval, premarket notification 510(k), IDE or master files. If files not submitted by the sponsor, include a letter from the owner of the files that grants FDA permission to reference files in its review of the current application

FDA Submissions: eCTD Requirement

Required for the following types of submissions to CDER/CBER:

- New Drug Applications (NDAs)
- Abbreviated New Drug Applications (ANDAs)
- Biologics License Applications (BLAs)
- Commercial IND Applications (for products that are intended to be distributed commercially)
- All subsequent submissions to these types of applications (amendments, supplements, reports)
- Master files, such as DMFs, which are considered to be submissions to an IND, NDA, ANDA, or BLA

Optional but encouraged for:

- Noncommercial INDs (investigator-sponsored IND and expanded access INDs)
- Submissions for blood and blood components, including source plasms
- Submissions for promotional materials for human prescription drug

Steps:

1. Before making the 1st electronic submission to an application, must obtain a pre-assigned application number by contacting the appropriate Center.
2. FDA Forms:
   Must include fillable forms and electronic signatures (scanned images of FDA forms will not be accepted)
3. Receipt date: determined only after submission has passed a technical validation check to ensure it can be opened, processed & archived

Transmitting Electronic Submissions

FDA Electronic Submissions Gateway (ESG) for all submissions 10 GB or smaller
For submissions greater than 10 GB, refer to Specification for Transmitting Submissions using eCTD Specifications

Common Formats

Narrative: Portable Document Format (PDF)
Structured: Extensible Markup Language (XML)
Graphic: whenever possible use PDF. When appropriate, or PDF is not possible, use JPEG, PNG, SVG, GIF

Reference Documents:

Electronic Common Technical Document Specification (Section III.D)
Specifications for File Format Types Using eCTD Specifications

Specification for Transmitting Submissions using eCTD Specifications
Specifications for eCTD validation criteria

Template folders may be available through ICH

Forms available at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

Need Help? Contact:

CDER Electronic Submission Support Team esub@fda.hhs.gov
CBER ESUB Support Team esubprep@fda.hhs.gov

IDE Application: Submission Details

Three copies of a signed "Application for Investigational Device Exemption."

Cover page should identify submission as an application for investigational device exemption – should be signed by the sponsor

Should reference the IDE number

Outside wrapper of each submission should identify the contents (ex: “Original IDE Application”, “IDE supplement”, “IDE Report”)

Mail the cover page & accompanying materials to CDRH’s Document Control Center.

Should include a valid eCopy- See guidance “eCopy Program for Medical Device Submissions”

Center for Devices & Radiological Health Mailing Address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC)- WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Center for Biologics Evaluation & Research Mailing Address:

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

*For Couriers: Room G112, Ground Floor, Building 71

For devices regulated by the Center for Biologics Evaluation and Research (CBER) please contact them for further assistance at either 1-800-835-4709 or Industry.Biologics@fda.hhs.gov

IDE Submissions: Suggested Format

- Use paper with nominal dimensions of 8 1/2" by 11".
- Use at least a 1 1/2" wide left margin to allow for binding into jackets.
- Use 3-hole punched paper to allow for binding into jackets.
- If the submission exceeds 2" in thickness, separate into volumes and identify volume number.
- Clearly and prominently identify submission as original IDE application or, for additional submissions to an IDE application, clearly identify the FDA assigned document number (e.g., G960000) and the reason for the submission (e.g., amendment, supplement, or report) and the type of submission (e.g., Response to FDA letter; Addition of New Institution, etc.).
- All copies of each submission must be identical.
- Include an eCopy per the guidance document, " eCopy Program for Medical Device Submissions"
- Do not combine IDEs, PMAs and 510(k)s together; they must be separate submissions.
- Unless the IDE sponsor has provided authorization in writing for another person to submit information on the sponsor's behalf, only the IDE sponsor may amend, supplement, or submit reports to the IDE.
- Sequentially number the pages, providing a detailed table of contents, and use tabs to identify each section. This will help to facilitate the review of your submission.

Step 3

Modifications

IDE Modifications

Sponsor must obtain approval of a supplemental application & IRB-approval prior to implementing a change to an investigational plan.

If a sponsor intends to conduct an investigation that involves an exception to informed consent, the sponsor must submit a separate IDE application.

Submission Guidelines: IDE number on cover sheet
Submitted in duplicate with a valid eCopy
Outside wrapper to state "IDE Supplement

Changes that <u>do not</u> require prior FDA approval:

Category	*Description*	*FDA Reporting Requirement*
Emergency Use	In the case of a deviation to protect the life or physical well-being of a subject in an emergency.	Must be reported to the FDA within 5 working days
Certain Developmental Changes	Developmental or marketing changes that do not constitute a significant change in design or basic principles of operation (per Sponsor) and that are made in response to information gathered during the investigation.[1]	Must provide notice to FDA within 5 working days *"Notice of IDE Change":* Changes to device are deemed to occur on the date the device, manufactured incorporating the design or manufacturing change, is distributed to investigators.
Certain Changes to the Clinical Protocol	Per Sponsor, changes that do not affect: 1. The validity of the data or information in the approved protocol, or the patient risk/benefit relationship relied upon to approve the protocol 2. The scientific soundness of the investigational plan 3. The rights, safety, or welfare of the human subjects involved in the investigation. [2]	Must provide notice to FDA within 5 working days of change "Notice of IDE Change" Changes to a clinical protocol are deemed to occur when a clinical investigator is notified by the sponsor that the change should be implemented or when a sponsor-investigator incorporates the change.

[1] Generic types of device and manufacturing changes include changes to the control mechan^{2}m, principle of operation, energy type, environmental specifications, performance specifications, ergonomics of patient-user interface, dimensional specifications, software or firmware, packaging or expiration dating, sterilization, and manufacturing process (including manufacturing site). Any specific change of these types may not be appropriate under the 5-day notice provision due to the range in significance.

[2] Examples: modification of inclusion/exclusion criteria to better define the target patient population; increasing the frequency at which data or information is gathered; inclusion of additional patient observations or measurements; modifying the secondary endpoints

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Changes to be Submitted in the Annual Report

Must be reported if changes do not affect:

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

Include minor changes in the following areas:

Purpose of the study	Labeling
Risk analysis	Informed Consent Materials
Monitoring procedures	IRB information

IDE Supplements for New Facilities

If initial IDE application does not contain a certification of IRB approval for each investigational site, FDA may approve the investigational sites without IRB approval.

Sponsor is required to submit the certification in an IDE supplement when IRB approval is obtained.

If sponsor has determined the number of investigational sites but not identified them, the FDA may grant a waiver at the time of IDE approval

Allows sponsor to enroll the sites, obtain IRB approvals and then submit the certifications of IRB approval to FDA as part of the IDE annual progress report

Once the IDE is approved, the sponsor may submit an IDE supplement to request approval of additional clinical study sites.

FDA will respond in writing to the supplement approving or denying the request.

<u>Sponsor is required to submit:</u>

- Identification of the investigational site
- Certification of IRB approval
- Information updating the initial IDE application (if investigation is changed)
- A description of any modifications required by the IRB as conditions of approval

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Step 4

Ongoing Reporting Requirements

Sponsor Reports

Investigator Reports

IDE Progress Report: Suggested Format

IDE Final Report: Suggested Format

Investigator Annual Progress Reports and Final Progress Reports

Sponsor Reporting (Quick Reference)

Reporting Requirement	Reporting Timeframe
Unanticipated Adverse Device Effects	Reporting to FDA, IRBs and investigators **within 10 working days** after first notified of event
Withdrawal of IRB Approval	Reporting to FDA, IRBs, and investigators **within 5 working days** of receipt of the withdrawal of approval.
Current List of Investigators	**Every 6 months** in a significant risk device investigation
Progress Reports (or Annual Reports)	At regular intervals, **at least yearly** to IRBs. For significant risk, must also submit to FDA.
Recalls and Device Disposition	Notify FDA and IRBs **within 30 working days** after the request is made.
Final Report	*Significant Risk Device*: Notify FDA and IRBs **within 30 working days** of the completion or termination of the investigation. Submit report to FDA, IRBs and investigators **within 6 months** after completion or termination of the investigation. *Nonsignificant Risk Device*: sponsor must submit final report to all IRBs **within 6 months** after completion or termination.
Failure to Obtain Informed Consent	Report to FDA **within 5 working days** after notice of such use.
Significant Risk Device Determination	If IRB determines the device is significant risk a report must be to submitted to FDA **within 5 working days**
Other Reports	If requested, must report in a timely manner upon request of IRB or FDA.

FDA Website: Sponsor Reports

IDE Sponsor Reporting (Detailed)

Unanticipated Adverse Device Effects

The sponsor must report the results of an evaluation of an unanticipated adverse device effect to FDA and all reviewing IRBs and investigators within 10 working days after the sponsor first receives notice of the adverse effect.

Withdrawal of IRB Approval

The sponsor must notify FDA and all reviewing IRBs and participating investigators of the withdrawal of IRB approval of an investigation (or any part of an investigation) within 5 working days of receipt of the withdrawal of approval.

Withdrawal of FDA Approval

The sponsor must notify all reviewing IRBs and participating investigators of any withdrawal of FDA approval within 5 working days after receipt of the notice.

Current List of Investigators

Every six months the sponsor must submit to FDA a current list of the names and addresses of all investigators participating in a significant risk device investigation. [21 CFR 812.150(b)(4)] FDA may grant a waiver allowing the sponsor to submit a current list to FDA annually as part of the annual progress report, in lieu of every six months.

Progress Reports (or Annual Reports)

At regular intervals and at least yearly, the sponsor must provide progress reports to all reviewing IRBs. For a significant risk device, the sponsor must also submit the progress report to FDA. A suggested format is provided below.

Recalls and Device Disposition

The sponsor must notify FDA and all reviewing IRB's of any request that an investigator return, repair, or dispose of any unit of an investigational device. The notice must be made within 30 working days after the request is made and must state why the request was made.

Final Report

For a significant risk device, the sponsor must notify FDA and all reviewing IRBs within 30 working days of the completion or termination of the investigation. The sponsor must also submit a final report to FDA and all reviewing IRBs and participating investigators within 6 months after the completion or termination of the investigation. For a nonsignificant risk device, the sponsor must submit a final report to all reviewing IRBs within 6 months after completion or termination.

FDA Website: Sponsor Reports

Failure to Obtain Informed Consent

Sponsors must submit a copy of any report by an investigator of the use of a device without first obtaining informed consent. The report must be made to FDA within 5 working days after receipt of the notice of such use.

Significant Risk Device Determination

If an IRB determines that the device is a significant risk device and not a nonsignificant risk device as the sponsor had proposed to the IRB, a report must be submitted to FDA within 5 working days after the sponsor learns of the IRB's determination.

Other Reports: The sponsor must provide accurate, complete, and current information about any aspect of the investigation upon request from the reviewing IRB or FDA.

FDA Website: Sponsor Reports

Investigator Reports (Quick Reference)

The investigator must provide the following reports to the sponsor in a timely manner under §812.150.

Reporting Requirement	Reporting Timeframe
Unanticipated Adverse Device Effects	**No later than 10 working days** after the investigator first learns of the effect
Withdrawal of IRB Approval	**Within 5 working days**
Progress Reports	**No less than on a yearly basis**
Deviations from the Investigational Plan	In an emergency: **no later than 5 working days** after the event occurred If it is not an emergency, prior approval from the sponsor is required for changes in or deviations from the investigational plan.
Informed Consent	Use of device without obtaining informed consent- **within 5 working days** after the use.
Final Report	**Within 3 months** after completion or termination of the investigation.
Other Reports	**In a timely manner once requested**

FDA Webpage: Investigator Reports

Investigator Reports (Detailed)

Unanticipated Adverse Device Effects

The investigator must submit to the sponsor and the reviewing IRB a report of any unanticipated adverse device effect as soon as possible but no later than 10 working days after the investigator first learns of the effect.

Withdrawal of IRB Approval

The investigator must report to the sponsor a withdrawal of approval of the reviewing IRB within 5 working days.

Progress Reports

The investigator must submit progress reports to the sponsor, the monitor, and the reviewing IRB at regular intervals but no less than on a yearly basis.

Deviations from the Investigational Plan

The investigator must notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. The notice must be provided as soon as possible but no later than 5 working days after the emergency occurred.

If it is not an emergency, prior approval from the sponsor is required for changes in or deviations from the investigational plan. If the change or deviation may affect the scientific soundness of the investigational plan or the rights, safety or welfare of the subject, the sponsor is required to obtain prior IRB approval and also to obtain FDA approval for a significant risk device investigation by submitting an IDE supplement.

Informed Consent

If an investigator uses a device without obtaining informed consent, the investigator must report the used to the sponsor and to the reviewing IRB within 5 working days after the use occurs.

Final Report

The investigator must submit a final report to the sponsor and to the reviewing IRB within 3 months after termination or completion of the investigation.

Other Reports

The investigator must provide accurate, complete, and current information about any aspect of the investigation upon request from the reviewing IRB or FDA.

FDA Webpage: Investigator Reports

IDE Progress Report: Suggested Format

1. **Basic Elements**
    - IDE Number
    - Device name and indication(s) for use
    - Sponsor's name, address, phone number, and fax
    - Sponsor's email address
    - Contact person
2. **Study Progress** (Data from beginning of the study should be reported, unless otherwise indicated.)
    - Brief summary of the study progress in relation to the investigational plan
    - Number of investigators/investigational sites (attach list of investigators)
    - Number of subjects enrolled (by indication or model)
    - Number of devices shipped
    - Brief summary of results
    - Summary of anticipated and unanticipated adverse effects
    - Description of any deviations from the investigational plan by investigators (since last progress report)
3. **Risk Analysis**
    - Summary of any new adverse information (since the last progress report) that may affect the risk analysis; this includes preclinical data, animal studies, foreign data, clinical studies, etc.
    - Reprints of any articles published from data collected from this study
    - New risk analysis, if necessary, based on new information and on study progress
4. **Other Changes**
    - Summary of any changes in manufacturing practices and quality control (including changes not reported in an IDE supplement)
    - Summary of all changes in the investigational plan not required to be submitted in an IDE supplement
5. **Future Plans**
    - Progress toward product approval/clearance, with projected date of PMA or 510(k) submission
    - Any plans to change the investigation, e.g., to expand the study size or indications, to discontinue portions of the investigation or to change manufacturing practices (NOTE: Actual proposals for these changes should be made in a separate IDE supplement).

FDA Webpage: Suggested Format for IDE Progress Report

IDE Final Report: Suggested Format

1. **Basic Elements**
    - IDE Number
    - Device name and indication for use
    - Sponsor's name, address, phone number, and fax number
    - Sponsor's email address
    - Contact person
2. **Study Progress.** Data from beginning of the study should be reported, unless otherwise indicated.
    - Brief summary of study progress in relation to investigational plan
    - Number of investigators/investigational sites (attach list of investigators)
    - Number of subjects enrolled (by indication or model)
    - Number of devices shipped
    - Disposition of all devices shipped
    - Brief summary of results
    - Summary of anticipated and unanticipated adverse effects
    - Description of any deviations from the investigational plan by investigators (since last progress report)
3. **Risk Analysis**
    - Summary of any new adverse information (since last progress report) that may affect the risk analysis; this includes preclinical data, animal studies, foreign data, clinical studies, etc.
    - Reprints of any articles published from data collected from this study
4. **Other Changes**
    - Summary of any changes in manufacturing practices and quality control (including changes not reported in an IDE supplement)
    - Summary of all changes in investigational plan not required to be submitted in an IDE supplement
5. **Marketing Application or Future Plans**
    - Progress toward product approval/clearance, with date (or projected date) of PMA or 510(k) submission; or indication that marketing of device is not planned.
    - Any plans to submit another IDE application for this device or a modification of this device.

FDA Webpage: Suggested Format for IDE Final Report

Investigator Annual Progress Reports and Final Reports

The IDE regulations do not specify the content of the annual progress or final reports. Therefore, the contents of these reports may largely be dictated by the sponsor.

Reports to the IRB: The IRB itself may specify what information it wishes to be included in these reports. Because FDA does require the information listed below, it is suggested that, at a minimum, the annual progress and final reports to the sponsor and the IRB include the following items:

1. IDE number
2. Device name
3. Indications for use
4. Brief summary of study progress in relation to investigational plan
5. Number of subjects enrolled
6. Number of devices received, used, and, in the final report, the final disposition of unused devices
7. Brief summary of results and, in the final report, conclusions
8. Summary of anticipated and unanticipated adverse device effects
9. Description of any deviations from investigational plan
10. Reprints of any articles published by the investigator in relation to the study

FDA Webpage: Investigator Annual Progress Reports and Final Reports