# IDE Preparation


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## IDE Overview

Confused about the need to file an IDE? Think your study may be exempt? Not sure where to start? You are not alone. This website will help faculty navigate the process of developing a Sponsor-Investigator IDE. The information provided pertains to some Class II and all Class III devices that pose risk, have a new intended use, or employ a new, unique technology.

The sponsor of a Significant Risk (SR) device study is required to submit an IDE application to the FDA. The IDE allows the investigational device to be used in a clinical study in order to collect the safety and effectiveness data required to support a marketing application.

Use the IDE Decision Tool to help you determine if an IDE is required. While the first step is a self-assessment of whether an IDE is needed, the IRB serves as a first-level review as designated by FDA. FDA makes the ultimate regulatory decision, if needed.

Please refer to the final guidance "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff."

Need assistance or have regulatory questions? Please contact ResearchGo.

## Mobile Medical Applications

Developing a mobile medical app? The FDA has issued guidance on "Mobile Medical Applications" to clarify the subset of mobile apps to which the FDA intends to apply its authority. You can also contact FDA for a question about your Mobile Medical App.

The Federal Trade Commission (FTC) has created a web-based tool to help developers of health-related mobile apps understand what federal laws and regulations might apply to them.

## Artificial Intelligence and Machine Learning in Software as a Medical Device

Artificial Intelligence (AI) and machine learning (ML) technologies have the potential to transform health care. On March 15, 2024, the FDA published the "Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together," which represents the FDA's coordinated approach to AI. This paper is intended to complement the "AI/ML SaMD Action Plan" published in January 2021.

If you have questions about artificial intelligence, machine learning, or other digital health topics, ask FDA about digital health regulatory policies.

## More Device Guidance

Guidance is available for Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.

In 2022, the FDA issued updated guidance regarding Medical Device Data Systems (MDDS), Medical Image Storage Devices, and Medical Image Communication Devices.

Information for the eCopy Program for Medical Device Submissions can be found here: eCopy Program for Medical Device Submissions.

Please contact FDA Device Advice or ResearchGo for assistance or more information.

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## The Pre-IDE Process

Review the FDA Guidance titled Significant Risk and Nonsignificant Risk Medical Device Studies. The guidance document provides definitions and examples of Significant Risk (SR) and Nonsignificant Risk (NSR) studies. To find information on a specific device or type of device, search the database maintained by CDRH.

The sponsor-investigator makes the initial risk determination for the proposed study and presents it to the IRB. The IRB then reviews the sponsor-investigator's risk determination and agrees or disagrees. FDA is available to help the sponsor-investigator and the IRB in making the determination. If needed, FDA is the final arbiter.

Sponsors of an SR study are encouraged to contact FDA to obtain further guidance prior to the submission of an IDE application. This will be especially beneficial to new sponsors who have not previously had contact with the agency and for sponsors proposing to study new technologies or new uses for existing technologies. The pre-IDE Program is primarily designed to benefit the IDE sponsor. By allowing the sponsor to obtain early FDA input on selected (by the sponsor) sections of the IDE application, FDA hopes that the initiation of clinical trials will be facilitated.

This communication may take the form of telephone conference calls, videoconferences, or face-to-face discussions. The pre-IDE Program is intended as a way for sponsors to obtain preliminary comments on their pre-clinical data (bench/animal testing) or the investigational plan (clinical protocol) in a timely manner. It will also allow FDA personnel to familiarize themselves with the new technologies.

For more information, please refer to the guidance Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.

The sponsor-investigator should contact the Office of Product Evaluation and Quality (OPEQ) reviewing division directly or may contact the FDA CDRH IDE staff for assistance at 301-796-5640.

For comprehensive regulatory education about medical devices and radiation-emitting products, please see Device Advice and CDRH Learn. Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

For questions about devices regulated by the Center for Biologics Evaluation and Research (CBER), contact CBER's Office of Communication, Outreach and Development (OCOD) at either 1-800-835-4709 or Industry.Biologics@fda.hhs.gov.

If you think a pre-IDE meeting with the FDA is warranted, please contact ResearchGo for assistance. Templates for a pre-submission meeting request and briefing package are provided below.

- Pre-submission Meeting Request
- Pre-submission Meeting Briefing Package

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# IDE Preparation

**Develop the IDE Study Protocol**

The IDE Protocol is the basis for both the IRB Application and the initial IDE submission:

- Review the IDE Protocol Template for required content. A completed protocol and cover letter must be included in the IDE application.
- Start with a protocol synopsis (pages 8 to 10 of the protocol template). The protocol synopsis will be valuable if you are planning a pre-IDE meeting.
- Compile a reference list. Include all published articles and unpublished reports or manuscripts cited. Collect a copy of each article or report listed.

**Prepare the Initial IDE Submission**

- The IDE Sponsor-Investigator compiles information in three broad areas:

1. Report of Prior Investigations - published and unpublished reports of all prior clinical, animal, and laboratory testing of the device
2. Investigational Plan - a complete written study protocol
3. Manufacturing Information - a description of the methods, facilities, and controls used for the manufacture, processing, storage, and, where appropriate, installation of the device

- The IDE Sponsor-Investigator writes the IDE Application (including the Investigator's Certification of Financial Interest) and the IDE Cover Letter.

Please review the IDE Required Elements for additional information

Need assistance or have regulatory questions? Please contact ResearchGo.
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# IDE Submission

## eCopy Program

On October 3, 2022, the FDA announced that you may now send electronic copy (eCopy) submissions online through the CDRH Customer Collaboration Portal ("CDRH Portal"). For more details, refer to eCopy Medical Device Submissions.

An electronic copy (eCopy) is a duplicate device submission in electronic format of the previously required paper copy submission sent to the FDA. An electronic copy is not considered an electronic submission.

For details on the eCopy program, including the technical standards for eCopies, refer to the eCopy guidance: eCopy Program for Medical Device Submissions.

An eCopy is required for IDE submissions. For additional details, review Section III. "For what submission types is an eCopy required?" in the eCopy guidance.

## Contact for Questions about eCopy

**Devices Regulated by the Center for Devices and Radiological Health (CDRH):**

If you have questions about the **CDRH** eCopy Program, contact the CDRH eCopy Program Coordinators at CDRH-eCopyinfo@fda.hhs.gov.

Mailing Address:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

**Devices Regulated by the Center for Biologics Evaluation and Research (CBER):**

For information on sending regulatory submissions to **CBER**, such as the current mailing address for CBER's Document Control Center (DCC), refer to CBER's Regulatory Submissions in Electronic and Paper Format for CBER-Regulated Products. Regulatory submissions may be submitted via email to CBER's DCC at CBERDCC_eMailSub@fda.hhs.gov.

If you have questions about such regulatory submissions, contact CBER at 1-800-835-4709 or Industry.Biologics@fda.hhs.gov.

Mailing Address:
Center for Biologics Evaluation and Research
Office of Communication, Outreach and Development
10903 New Hampshire Avenue
Building 71, Room 3103
Silver Spring, MD 20993-0002
Telephone Number: 240-402-8010 or 1-800-835-4709

## FDA Response

FDA will reply to the submission with an acknowledgement letter containing:

- the date of receipt of the IDE application
- the IDE number assigned to your application
- the name of the project manager to address in future submissions under the IDE

An IDE application is considered approved 30 days after it has been received, unless FDA informs the sponsor-investigator otherwise. An IDE may be approved, approved with conditions, or disapproved. It is advised that you obtain written confirmation (e.g. email) that the FDA review has been completed and that the Study May Proceed. Please upload FDA Study May Proceed confirmation in webIRB/BruinIRB. In cases of disapproval, a sponsor has the opportunity to respond to the deficiencies and/or to request a regulatory hearing under 21 CFR Part 16.

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## Maintain the IDE

Amendments, Safety Reports & Annual Reports **(FDA Guidance)**

IDE sponsor-investigators are required under 21 CFR 812.150 to submit the following reports:

**Unanticipated adverse device effects (UADE)**
A UADE is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

A UADE Report consists of a completed Form FDA 3500A and an analysis of the event in a cover letter, submitted 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**
Submitted to FDA and all reviewing IRBs and participating investigators within 5 working days after receipt of notice of the withdrawal of IRB approval of an investigation (or any part of an investigation)

**Withdrawal of FDA approval**
Submitted to all reviewing IRBs and participating investigators within 5 working days after receipt of notice of any withdrawal of FDA approval

**Current list of investigators with addresses**
Submitted to FDA every six months

**Progress reports**
Submitted to FDA and all reviewing IRBs at regular intervals and at least yearly. A suggested format for the **Progress Report** can be found on the CDRH website.

**Recalls and device disposition**
Submitted to FDA and all reviewing IRBs within 30 working days after receipt of a request to return, repair, or dispose of any unit of an investigational device. The report must state why the request was made.

**A final report**
For a significant risk device, the sponsor must submit a **final report** notifying 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.

**Use of a device without informed consent**
Submitted to FDA within 5 working days after receipt of notice of such use

**SR device determination**
Submitted to FDA within 5 working days after determination by an IRB that the device is a SR device and not an NSR device as the sponsor had proposed

**Other reports**
Accurate, complete, and current information about any aspect of the investigation upon request from FDA or the reviewing IRB

**Recommended Links:**

- IDE Definitions & Acronyms
- FDA.gov IDE Reports

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## IDE Templates, Education & Useful Links

**Templates & Forms**

- IDE Decision Worksheet
- IDE Protocol Template
- IDE Application Cover Letter
- IDE Application Template
- IDE Certification of Financial Interest of Clinical Investigators
- IDE Informal Progress Report
- IDE Formal Progress Report (TOC)
- IDE Annual Progress Report
- IDE Annual Progress Report Cover Letter
- Pre-submission Meeting Request
- Pre-submission Meeting Briefing Package
- Sample IRB Checklist: Non-Significant Risk Device

**Useful Links**

- FDA Device Advice
- FDA Division of Industry and Consumer Education
- Email Mobile Medical Device Questions to FDA
- IDE Pre-Submission Process (Q-Sub)
- Amendments, Safety Reports & Annual Reports (FDA Guidance)
- Center for Devices and Radiological Health
- CDRH Learn
- Center for Biologics Evaluation and Research
- Device Classification
- FAQs about IDEs
- IDE Policy
- IDE Required Elements
- General Requirement for the Submission of IDE Applications for Clinical Research Studies
- Marketing Your Medical Device
- Sponsor's Responsibilities for Significant Risk Device Investigations

- FDA Guidance: Significant Risk and Nonsignificant Risk Medical Device Studies
- FDA Guidance: Frequently Asked Questions About Medical Devices

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