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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 Class III devices, that is, devices with the greatest risk or those that 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 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 the [CTSI Office of FDA Affairs](#).

### Mobile Apps

Developing a mobile health 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. The FTC developed the tool in conjunction with OCR, the HHS Office of National Coordinator for Health Information Technology (ONC), and the Food and Drug Administration (FDA).

### More Device Guidance

Guidance is also now available for "[Investigational Device Exemptions \(IDEs\) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human \(FIH\) Studies.](#)"

On June 20, 2014 the FDA issued draft guidance regarding [Medical Device Data Systems \(MDDS\), Medical Image Storage Devices, and Medical Image Communication Devices](#). The draft guidance also contains some edits to the 2013 Mobile Medical Applications Guidance to conform to its draft guidance here.

Required as of January 2013 - [eCopy Program for Medical Device Submissions](#)

Please contact [FDA Device Advice](#) or the [CTSI Office of FDA Affairs](#) for assistance or more information.

Last updated: 18 Jul 2018

## 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.

The sponsor should contact the Office of Device Evaluation (ODE) reviewing division directly or may contact the IDE staff for assistance:

IDE Staff  
Investigational Device Exemptions Program  
Office of Device Evaluation  
Center for Devices and Radiological Health  
10903 New Hampshire Avenue  
WO66-1648  
Silver Spring, MD 20993-0002  
Telephone 301-796-5640

Please review the latest [FDA guidance for IRBs, Clinical Investigators, and Sponsors](#). For additional information on submitting IDEs, review of your IDE submission, or need assistance, please contact the [CTSI Office of FDA Affairs](#).

Last updated: 26 Sep 2016

## 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 attached [IDE Protocol Template](#) for required content. A completed protocol and [cover letter](#) must be included in the IDE application.
- Start with a protocol synopsis (page 7 and 8 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:

- Report of Prior Investigations. Published and unpublished reports of all prior clinical, animal, and laboratory testing of the device
- Investigational Plan. A complete written study protocol
- 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
- Coming soon - the IDE Investigator Handbook for more information

Need assistance or have regulatory questions? Please contact the [CTSI Office of FDA Affairs](#).

Last updated: 12 Jan 2017

## File the IDE

Now Required - [eCopy Program for Medical Device Submissions](#)

An electronic copy (eCopy) is an electronic version of your medical device submission stored on a compact disc (CD), digital video disc (DVD), or a flash drive. Including an eCopy with your submission has been required since January 1, 2013. A submission with an eCopy that does not meet the technical standards outlined in the [eCopy guidance](#) will be placed on eCopy hold until a valid eCopy is received.

For most devices, mail the cover page and accompanying materials, including a valid eCopy, to the following address:

### Devices regulated by the Center for Devices and Radiological Health:

Food and Drug Administration  
Center for Devices and Radiological Health

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Document Mail Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

All correspondence relating to IDEs regulated by CDRH should also be sent to this address. The IDE correspondence should be submitted in triplicate and reference the IDE number. The outside wrapper of each submission should identify the contents, for example, "Original IDE Application," "IDE Supplement," "IDE Report," etc.

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

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  
Email: [industry.biologics@fda.gov](mailto:industry.biologics@fda.gov)

Keep a copy of the courier Airbill. Track the shipment on the courier website for confirmation of delivery.

File a PDF copy of the delivery confirmation with the PDF copy of the signed submission.

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 otherwise. An IDE may be approved, approved with conditions, or disapproved. It is advised that you obtain written confirmation (email or fax) that the FDA review has been completed and that the Study May Proceed. Please upload FDA Study May Proceed confirmation in webIRB. 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](#).

Last updated: 26 Sep 2016

## 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](#)
- [IDE Safety Reporting Information \(Dartmouth-Hitchcock\)](#)

Need assistance or have regulatory questions? Please contact the [CTSI Office of FDA Affairs](#).

Last updated: 13 Dec 2016

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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 \(TOC\)](#)
- [Sample IRB Checklist: Non-Significant Risk Device](#)

## Useful Links

- [FDA Device Advice](#)
- [Email Mobile Medical Device Questions to FDA](#)
- [IDE Pre-Submission Process \(Q-Sub\)](#)
- [Amendments, Safety Reports & Annual Reports \(FDA Guidance\)](#)
- [Center for Devices & Radiological Health Documents](#)
- [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](#)

Need assistance or have regulatory questions? Please contact the [CTSI Office of FDA Affairs](#).

Last updated: 10 Jul 2019

Last updated: 14 Aug 2019

- Group 1
  - [Clinical Research Information Systems](#)
  - [Clinical Research Business Partners](#)
- Group 2
  - [Office of Research Administration](#)
  - [Jonsson Comprehensive Cancer Center](#)
- Group 3
  - [Office of Human Subjects Protection](#)
  - [CareConnect Website](#)

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