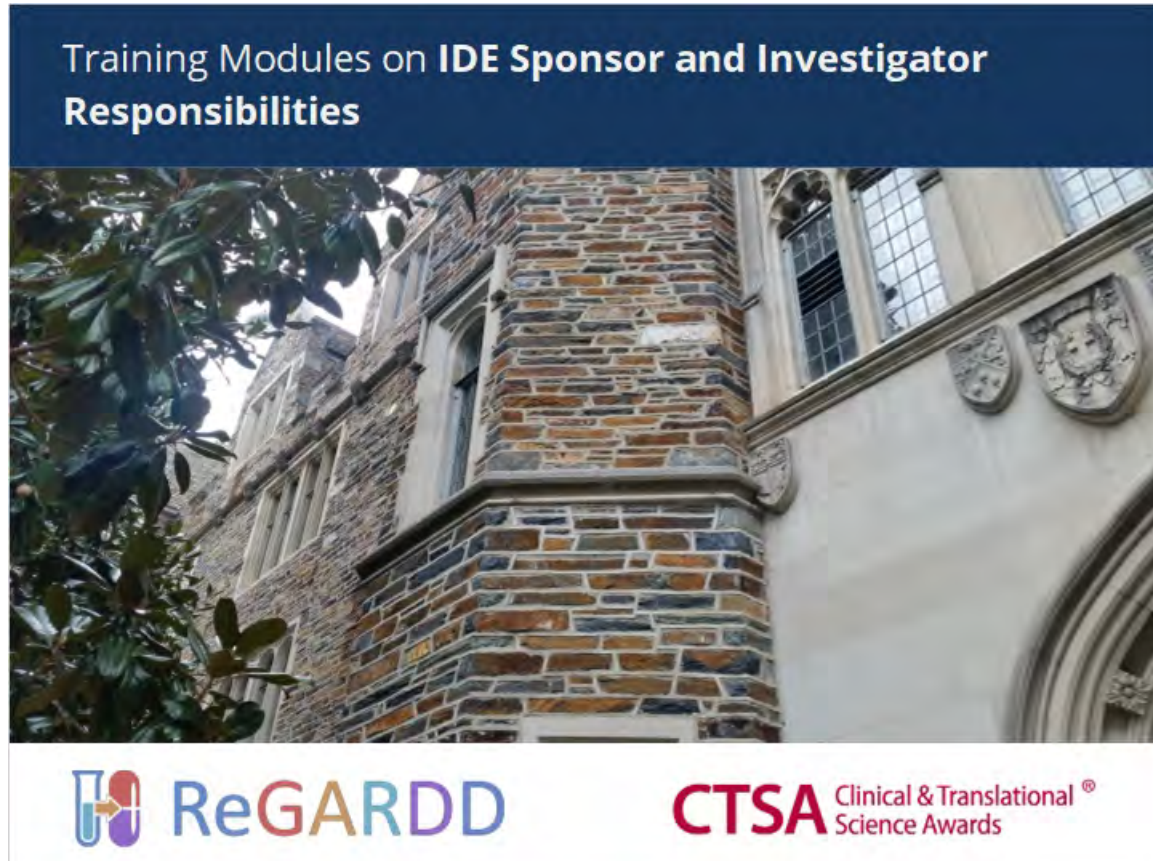


## 1. IDE Sponsor and Investigator Responsibilities

### 1.1 Welcome



#### Notes:

Welcome to the ReGARDDD Training Modules for IDE sponsor-investigator responsibilities. ReGARDDD is an academic collaboration that offers Regulatory Guidance for Academic Research of Drugs and Devices and is supported in part by the Clinical and Translational Science Awards Program from the National Center for Advancing Translational Sciences.

This training consists of ten modules. The first nine modules will cover IDE sponsor responsibilities and the final module will cover responsibilities that must be fulfilled by investigators who conduct a significant risk device study run under an IDE. Investigators fulfilling a dual role as sponsor and investigator, in other words sponsor-investigators, must fulfill the responsibilities of both sponsors and

investigators.

## 1.2 Main Menu



### Notes:

This is your main navigation screen. Please select a module from the Main Menu list. After you have completed a module, you will return to this screen to complete each section of the course. Once all modules have been completed, the menu item "Course Completion" will become available.

## **2. Introduction to IDE Sponsor and Investigator Responsibilities**

### ***2.1 Introduction to IDE Sponsor and Investigator Responsibilities***



**Notes:**



## 2.2 Learning Objectives

### Introduction to IDE Sponsor and Investigator Responsibilities



- ✓ Two Types of IDEs
- ✓ Role of an IDE Sponsor-Investigator
- ✓ Two Sets of Responsibilities for Sponsors and Investigators
- ✓ IDE Acknowledgement Letter and IDE Approval Date
- ✓ FDA Actions on IDEs
- ✓ Maintaining an Approved IDE

### Notes:

After completing this training module, the learner will understand the following:

- The difference between the two types of IDEs;
- The role of an IDE sponsor-investigator;
- That there are two sets of responsibilities (one for sponsors and one for investigators), and that sponsor-investigators are required to comply with both sets of responsibilities;
- What an IDE acknowledgment letter is and how to determine the IDE approval date;
- FDA's possible actions on IDE applications; and
- That the sponsor is responsible for maintaining the IDE once it is approved

## 2.3 What Is an IDE?



Introduction to IDE Sponsor and Investigator Responsibilities

### What Is an IDE?

An IDE is a regulatory submission that permits an investigational device to be used in a clinical study in order to collect safety and effectiveness data.

<u>Significant Risk Device Study</u>	<u>Nonsignificant Risk Device Study</u>
<ul style="list-style-type: none"><li>• FDA and IRB Approval</li><li>• Full IDE application</li></ul>	<ul style="list-style-type: none"><li>• IRB Approval</li><li>• Abbreviated IDE</li></ul>

#### Notes:

An IDE is a regulatory submission that permits an investigational device to be used in a clinical study in order to collect safety and effectiveness data on the device.

There are two types of device studies that require IDEs. Device studies that pose a significant risk to human subjects (known as significant risk device studies) must be reviewed and approved by both the FDA and Institutional Review Board, or IRB, prior to study initiation. FDA approval is obtained by submitting a full IDE application to the Agency.

Device studies that do not pose a significant risk to human subjects (known as nonsignificant risk device studies) do not require a submission to the FDA, but rather are approved and overseen solely by the IRB. The FDA considers a nonsignificant risk device study to have an approved abbreviated IDE when the

IRB concurs with the nonsignificant risk determination and approves the study.

The roles and responsibilities discussed in these training modules are for sponsor-investigators of significant risk device studies overseen by the FDA and IRB. For information on the responsibilities of sponsor-investigators of nonsignificant risk device studies, please visit FDA's website by following the link at the end of this training module.

## ***2.4 Who Is an IDE Sponsor-Investigator?***

The infographic is titled "Introduction to IDE Sponsor and Investigator Responsibilities" and "Who Is an IDE Sponsor-Investigator?". It features a background image of a doctor in a white coat with a stethoscope. Three dark blue boxes are overlaid on the image, each containing a role and its responsibilities:

<u>IDE Sponsor</u>	<u>IDE Investigator</u>	<u>IDE Sponsor-Investigator</u>
<b>Initiates</b> the clinical investigation	<b>Conducts</b> the clinical investigation	<b>Initiates and conducts</b> a clinical investigation

### **Notes:**

The sponsor of an IDE is the individual, company, academic institution, or other organization that takes responsibility for and initiates the clinical investigation. The sponsor submits the IDE to the FDA, but the sponsor does not actually conduct the investigation - unless the sponsor is a sponsor-investigator.



The investigator is the individual who conducts the clinical investigation and under whose immediate direction the device is administered, dispensed, or used. In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. Other individual members of the team are known as subinvestigators.

If the same individual both initiates and conducts the investigation, that person is known as the sponsor-investigator. A sponsor-investigator takes responsibility for the investigation, and the investigational device is administered, dispensed, or used under his or her direction.

## ***2.5 Responsibilities of IDE Sponsors and Investigators***

Introduction to IDE Sponsor and Investigator Responsibilities

### **Responsibilities of IDE Sponsors and Investigators**

- Sponsors and investigators each have specific sets of responsibilities.
- The IDE regulations found in [21 CFR 812](#) describe the responsibilities of sponsors and investigators.
- Sponsor-investigators must fulfill the responsibilities of both the sponsor and the investigator.
- Failure to comply with these responsibilities could result in termination of the IDE.

### **Notes:**

Sponsors and investigators each have specific responsibilities that must be fulfilled when conducting a clinical trial under an IDE. These responsibilities are

## Training Modules on IDE Sponsor and Investigator Responsibilities (No Quiz)

described in the IDE regulations, which are found in Title 21 Part 812 of the Code of Federal Regulations. Click on the provided link to view the IDE regulations.

A sponsor-investigator must fulfill the responsibilities of both the sponsor and the investigator.


It is important for sponsor-investigators to comply with their responsibilities because these responsibilities are in place to protect the rights, safety, and welfare of subjects and also to protect the integrity of the clinical trial.

Additionally, failure to comply with the sponsor and investigator responsibilities could result in termination of the IDE.

This series of training modules will walk through the IDE sponsor and investigator responsibilities.



## 2.6 When Do Sponsor Responsibilities Begin?

Introduction to IDE Sponsor and Investigator Responsibilities 

### When Do Sponsor Responsibilities Begin?

**Sponsor responsibilities begin once the IDE is approved by FDA.**

**IDE Acknowledgement Letter**

- IDE number
- Official FDA date of receipt

Dear John Smith, MD:

The information you have submitted, as required by the Food and Drug Administration (FDA) investigational device exemptions (IDE) regulation, has been assigned the following document control number:

Submission Number: G150123  
Dated: 05/05/2015  
Received: 05/06/2015  
Sponsor: John Smith, MD  
Device: Device System XYZ

FDA will notify you within 30 days when the review of this submission has been completed or if any additional information is required.

### Notes:

Sponsor responsibilities begin once the IDE is approved by FDA.

After an IDE application has been submitted to FDA, an IDE acknowledgement letter will be sent from FDA to the sponsor. The IDE acknowledgement letter contains important information including the IDE number and the official FDA date of receipt.

## 2.7 FDA Action on IDE Applications

Introduction to IDE Sponsor and Investigator Responsibilities

# FDA Action on IDE Applications

- Approval
- Approval with Conditions
- Staged Approval
- Staged Approval with Conditions
- Disapproval



[FDA Decisions for Investigational Device Exemption Clinical Investigations](#)

### Notes:

There are five possible FDA actions following FDA's review of the IDE: approval, approval with conditions, staged approval, staged approval with conditions, or disapproval.

FDA will approve the IDE if there are no outstanding issues that must be addressed to support the clinical investigation.

If FDA has identified issues that must be addressed in a timely manner, but these issues do not prohibit initiation of subject enrollment in the clinical investigation, the IDE will be approved with conditions.

If FDA grants approval or approval with conditions for only a portion of the intended study cohort, this is called staged approval or staged approval with

conditions, respectively.

If an IDE application is disapproved, the sponsor may not initiate enrollment in the clinical investigation until the sponsor amends the IDE to respond to the deficiencies identified by FDA and receives a new letter from FDA granting approval.

For additional information on FDA's actions on IDE applications, please see FDA's Guidance entitled "FDA Decisions for Investigational Device Exemption Clinical Investigations" by clicking on the provided link.

## **2.8 IDE Approval Date**

Introduction to IDE Sponsor and Investigator Responsibilities

### IDE Approval Date

**The official FDA date of receipt starts a 30-day clock for the FDA to review the IDE.**

IDE Approval Date

- 30 days after FDA receives the IDE, unless FDA notifies the sponsor that the IDE has been disapproved
- Or on earlier notification by FDA that the study is approved

### **Notes:**

The official FDA date of receipt starts a 30-day clock for FDA to conduct a

## Training Modules on IDE Sponsor and Investigator Responsibilities (No Quiz)

multidisciplinary review of the IDE and determine the appropriate FDA action as described on the previous slide.

The IDE is considered approved 30 days after FDA receives the IDE, unless FDA notifies the sponsor that the IDE has been disapproved. This date is the IDE approval date. The sponsor may or may not receive an approval letter from the FDA. If the sponsor has not heard anything from FDA by day 30, it is recommended that the sponsor reach out to his or her FDA division contact to confirm that no communications have been lost and the study has been approved.

Occasionally, the FDA will notify a sponsor that the study is approved prior to the end of the 30 day review period. If this occurs, then the date of this notification is the IDE approval date.

The sponsor may not initiate enrollment in the clinical investigation until the IDE is approved and the IRB has reviewed and approved the investigation.



## **2.9 Maintaining an Approved IDE**

Introduction to IDE Sponsor and Investigator Responsibilities

# Maintaining an Approved IDE



The sponsor is responsible for maintaining an approved IDE by submitting IDE modifications, required reports, and responses to any FDA deficiency letters.

### **Notes:**

Once the IDE is approved, the sponsor is responsible for maintaining the IDE by submitting IDE modifications to the investigational plan, required reports to update FDA on study progress or unanticipated events, and responses to any FDA deficiency letters or requests for information. In general, the sponsor needs to ensure that the information in the IDE is accurate and up-to-date.

These IDE reporting requirements will be described in more detail in the following training modules, along with the other IDE sponsor and investigator responsibilities.

## ***2.10 Additional Information***

Introduction to IDE Sponsor and Investigator Responsibilities

### **Additional Information**



For more information on IDE sponsor and investigator responsibilities, please visit [FDA's website](#).

**Return to the Main Menu**

### **Notes:**

For more information on IDE sponsor and investigator responsibilities for both significant risk and nonsignificant risk device studies, please visit FDA's website by clicking on the provided link.

### **3. Overview of IDE Maintenance and Tracking**

#### ***3.1 Overview of IDE Maintenance and Tracking***



**Notes:**

### 3.2 Learning Objectives

#### Overview of IDE Maintenance and Tracking



- ✓ Maintain an Approved IDE
- ✓ Categorize IDE Submissions
- ✓ IDE Tracking System
- ✓ Submission Process
- ✓ Compliance with FDA's eCopy Program

#### Notes:

After completing this training module, the learner will understand the following:

- How to maintain an approved IDE through the submission of supplements, reports, and amendments;
- How to categorize IDE submissions as supplements, reports, and amendments;
- How to implement the IDE tracking system for any submissions sent to the IDE;
- The submission process; and
- How to be compliant with FDA's eCopy Program for medical device submissions



### ***3.3 Maintaining an Approved IDE***

Overview of IDE Maintenance and Tracking

## **Maintaining an Approved IDE**

The sponsor is responsible for maintaining the IDE by submitting IDE modifications, required reports, and responses to any FDA deficiency letters.

All submissions that are sent to the IDE are tracked by the FDA as supplements, reports, or amendments.

**Notes:**

Once the IDE is approved, the sponsor is responsible for maintaining the IDE by submitting IDE modifications to the investigational plan, required reports to update FDA on study progress or unanticipated events, and responses to any FDA deficiency letters or requests for information. In general, the sponsor needs to ensure that the information in the IDE is accurate and up-to-date.

After submission of the original IDE application, all subsequent submissions that are sent to the IDE are tracked by the FDA as either supplements, reports, or amendments.

### 3.4 Categorizing IDE Submissions

Overview of IDE Maintenance and Tracking

## Categorizing IDE Submissions

- Supplements:** Requests for new protocols, changes to the approved protocol, or changes to the device
- Reports:** Updates on study progress and unanticipated events
- Amendments:** Response to deficiencies communicated in an FDA disapproval, approval with conditions, or deficiency letter

**Notes:**

We have summarized on this slide the types of IDE submissions that would be categorized as supplements, reports, and amendments for tracking purposes. These IDE submissions are used to update information in the IDE, and the following training modules will provide specific information on these types of submissions. Importantly, sponsors are responsible for keeping FDA apprised of all essential information in the IDE.

The FDA tracks requests for new protocols, changes to the approved protocol, or changes to the device, such as device design or manufacturing changes, as supplements. Supplements can be submitted when an application is under review or once the IDE is approved. Supplements are intended to seek FDA's approval for something new or different and thus, the FDA usually issues a reply. The reply will be similar to the original IDE application (for example, approved, approved with conditions, staged approval, or disapproval).

## Training Modules on IDE Sponsor and Investigator Responsibilities (No Quiz)

The FDA tracks updates on study progress and unanticipated events as reports. Reports are intended to provide notification or updates for FDA's routine monitoring of a clinical investigation and include reports on adverse device effects, annual progress of the investigation, semiannual investigator lists, and any failures to obtain informed consent. Generally, the FDA will not reply to a report unless issues are identified.

The FDA tracks any response to deficiencies communicated in an FDA disapproval, approval with conditions, or deficiency letter as an IDE amendment.

It is important to note that while supplements and reports are submitted to the original IDE application, amendments may be submitted to a supplement, a report, or the original IDE.

Keep in mind that any information that could affect the safe use of the investigational device, the rights, safety, or welfare of study subjects, or the integrity of the clinical trial should be submitted to the IDE, even if it does not fall within the scope of the submission categories listed here.

### 3.5 IDE Tracking System – Supplements and Reports

Overview of IDE Maintenance and Tracking

## IDE Tracking System – Supplements and Reports

IDE Supplements and Reports are tracked independently and are numbered consecutively in the order in which they are submitted.

Example IDE Tracking

- Submission 1: Original IDE Submission
- Submission 2: Supplement 001
- Submission 3: Report 001
- Submission 4: Supplement 002

#### Notes:

The FDA tracks submissions to the IDE based on the category of the submission. IDE supplements and reports are tracked independently and are numbered consecutively in the order in which they are submitted.

To illustrate the IDE tracking system, we provide the following example:

- Submission 1 is the original IDE submission.
- The next submission, submission 2, is a request to amend the clinical protocol. This would be tracked as a supplement and would be numbered as Supplement 001.
- The next submission, submission 3, is a report of an adverse device effect. This would be tracked as a report and would be numbered as Report 001.
- The next submission, submission 4, is a request for a change in manufacturing of the device. This is another example of a supplement and would be numbered



as Supplement 002.

It is important to note that since supplements and reports are tracked independently, it is possible for a sponsor to be on Report 003 but on Supplement 001.

### 3.6 IDE Tracking System – Amendments

Overview of IDE Maintenance and Tracking

## IDE Tracking System – Amendments

**Amendments may be submitted to the original IDE, an IDE supplement, or an IDE report.**

Each amendment should reference the number of the submission that is being amended.

**Example IDE Tracking**

• Submission 1: Original IDE Submission	• FDA Deficiency Letter Received
• Submission 2: Supplement 001	• Submission 5: Amendment 001 to Supplement 002
• Submission 3: Report 001	• FDA Deficiency Letter Received
• Submission 4: Supplement 002	• Submission 6: Amendment 002 to Supplement 002

#### Notes:

As discussed previously, an amendment is any response to an FDA deficiency letter. Amendments may be submitted to the original IDE, an IDE supplement, or an IDE report. Thus, it is important for each amendment to reference the number of the original IDE, supplement, or report submission that is being amended.

Let's return to the IDE tracking example from the previous slide. Supplement 002 was submitted to request a change in manufacturing of the device. If after submission of this supplement, the sponsor receives an FDA deficiency letter noting issues with the request, then the sponsor should amend the supplement to address the deficiencies identified in FDA's letter. To do this, the sponsor would submit Amendment 001 to Supplement 002. FDA will review the amendment, and if additional deficiencies are identified, they will communicate these to the IDE sponsor.

Amendments submitted to the same IDE submission should be numbered consecutively. Thus, if an additional deficiency letter were received in the example above, Amendment 002 to Supplement 002 should be submitted. The sponsor should continue to amend the supplement until all deficiencies have been addressed.

### **3.7 IDE Tracking System**

Overview of IDE Maintenance and Tracking

## IDE Tracking System

**Each IDE submission should be limited to one submission category.**

Sponsors should not submit information that should be submitted separately as a supplement, report and/or amendment together in one submission.

FDA will work interactively with IDE sponsors to address any submissions that mistakenly contain multiple categories of IDE submissions.

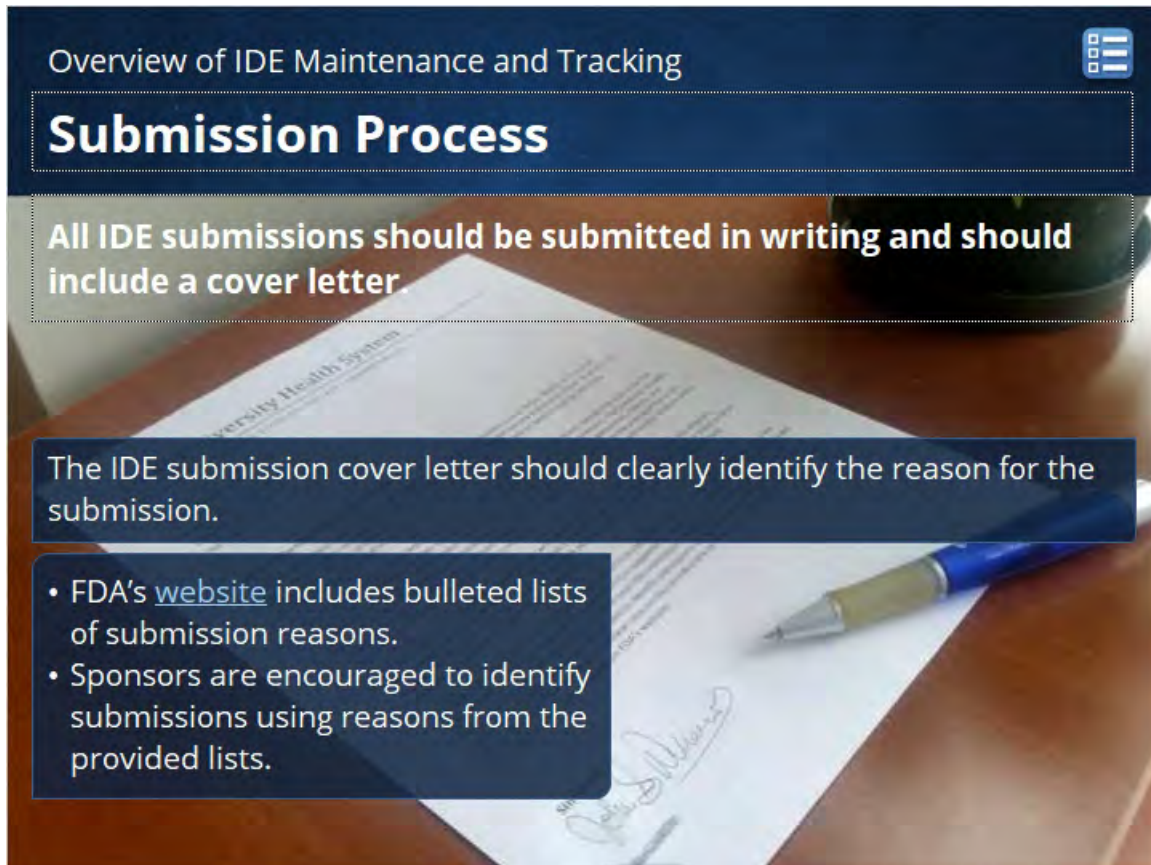
**Notes:**

Each IDE submission should be limited to one submission category.

Because FDA makes only one decision per submission, the sponsor of an IDE application is discouraged from submitting information that should be submitted separately as a supplement, report and/or amendment together in one submission. For example, if a sponsor submits an annual progress report in combination with a request to change the study protocol, the FDA will prioritize review of the protocol change over review of the report since they need to reply to the protocol change within 30 days. FDA will categorize the submission a supplement and the reporting requirement will not have been met and a separate report will be required. To avoid challenges and facilitate timely review of IDE submissions, sponsors are advised to separate submissions falling into more than one IDE submission category.

When possible, FDA will work interactively with IDE sponsors to address any submissions that mistakenly contain multiple categories of IDE submissions.

### 3.8 Submission Process



Overview of IDE Maintenance and Tracking

## Submission Process

All IDE submissions should be submitted in writing and should include a cover letter.

The IDE submission cover letter should clearly identify the reason for the submission.

- FDA's [website](#) includes bulleted lists of submission reasons.
- Sponsors are encouraged to identify submissions using reasons from the provided lists.

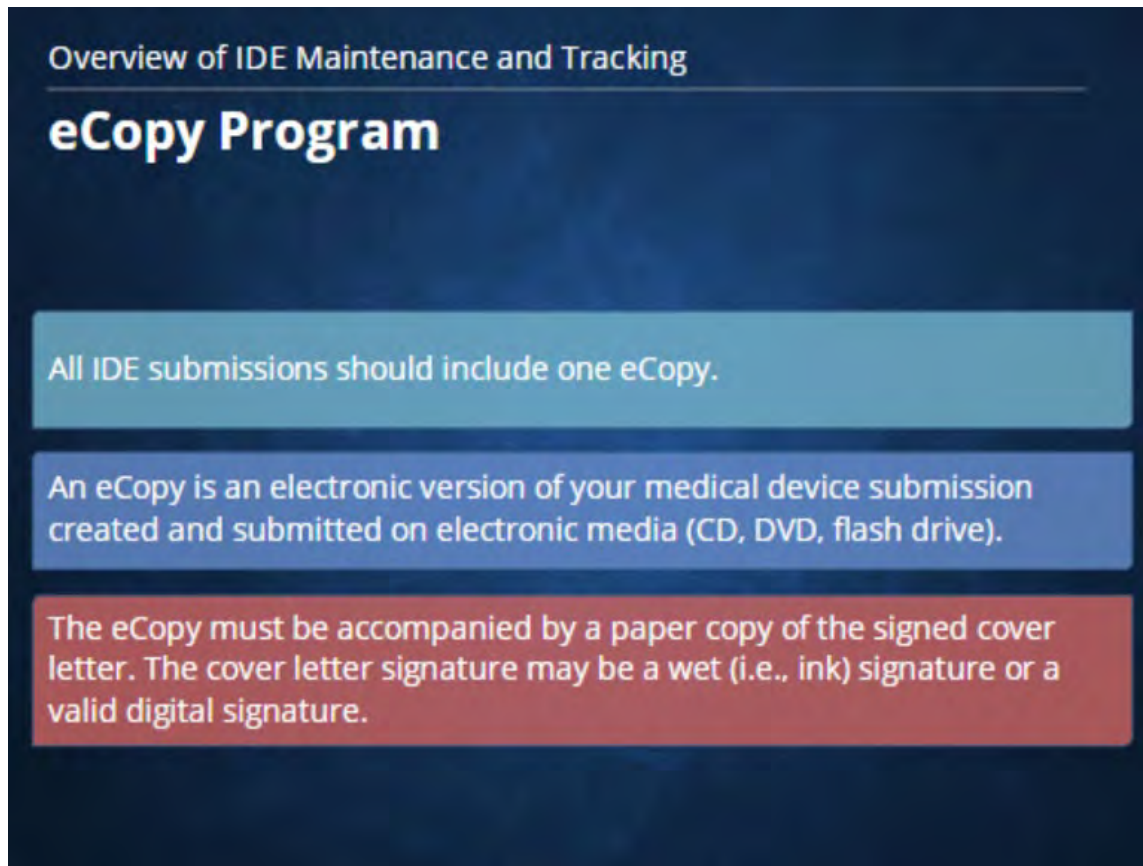
#### Notes:

All IDE submissions should be submitted in writing and should include a cover letter. While not required, sponsors can also include with their submission the CDRH Premarket Review Submission Cover Sheet or Form FDA 3514. The use of this form is optional, but it may allow the sponsor to better organize and track information contained within each submission.

The IDE submission cover letter, and Form FDA 3514 as applicable, should clearly identify the reason for the submission, including whether the submission is a supplement, report, or amendment. FDA's website includes bulleted lists of submission reasons within each IDE submission category (i.e., supplements, reports, and amendments). Sponsors are encouraged to identify submissions using reasons from the provided lists in the cover letter of their submission. Please click on the provided link to view the lists of submission reasons within each IDE submission category on FDA's website.



### 3.9 eCopy Program



Overview of IDE Maintenance and Tracking

## eCopy Program

- All IDE submissions should include one eCopy.
- An eCopy is an electronic version of your medical device submission created and submitted on electronic media (CD, DVD, flash drive).
- The eCopy must be accompanied by a paper copy of the signed cover letter. The cover letter signature may be a wet (i.e., ink) signature or a valid digital signature.

**Notes:**

All IDE submissions should include one electronic copy or eCopy.

An eCopy is an electronic version of your medical device submission created and submitted on electronic media (e.g., CD, DVD, or flash drive).

The eCopy must be accompanied by a paper copy of the signed cover letter. The cover letter signature may be a wet (i.e., ink) signature or a valid digital signature.

### 3.10 eCopy Program



Overview of IDE Maintenance and Tracking

## eCopy Program

There are additional technical standards that must be followed for eCopies.

To ensure full eCopy compliance, IDE sponsors are encouraged to review FDA's Guidance entitled "[eCopy Program for Medical Device Submissions](#)" prior to any IDE submission.

**Notes:**

In addition to the aforementioned requirements, there are additional technical standards that must be followed for eCopies, including specific files types, sizes, and naming conventions.

To ensure full eCopy compliance, IDE sponsors are encouraged to review FDA's Guidance entitled "[eCopy Program for Medical Device Submissions](#)" prior to any IDE submission.

### ***3.11 Additional Information***

Overview of IDE Maintenance and Tracking

## **Additional Information**



For more information on IDE maintenance and tracking, please visit [FDA's website](#).

**Return to the Main Menu**

**Notes:**

For more information on IDE maintenance and tracking, please visit FDA's website by clicking on the provided link.

## 4. IDE Progress and Final Reports

### 4.1 IDE Progress Reports and Final Reports




# IDE Progress Reports and Final Reports

Notes:



## 4.2 Learning Objectives

IDE Progress Reports and Final Reports



- ✓ When an IDE Progress Report Is Due
- ✓ When an IDE Final Report Is Due
- ✓ Content for Progress and Final Reports

### Notes:

After completing this training module, the learner will understand the following:

- When an IDE progress report is due;
- When an IDE final report is due; and
- The content required for progress and final reports

### 4.3 Progress Report Due Date

IDE Progress Reports and Final Reports

## Progress Report Due Date


Provide progress reports to all IRBs and the FDA at regular intervals but no less than yearly.



**Notes:**

The IDE sponsor must provide progress reports to all reviewing Institutional Review Boards, or IRBs, and the FDA at regular intervals but no less than on a yearly basis.

#### **4.4 Final Report Due Date**

A presentation slide titled "IDE Progress Reports and Final Reports" with a sub-header "Final Report Due Date". The slide features a background image of a calendar. Two text boxes provide key information: "Notify FDA and all IRBs within 30 working days of the completion or termination of the investigation." and a bullet point: "• Submit a final report to FDA, all IRBs, and investigators within 6 months after the completion or termination." A small icon of a calendar is in the top right corner.

IDE Progress Reports and Final Reports

### Final Report Due Date

Notify FDA and all IRBs within 30 working days of the completion or termination of the investigation.

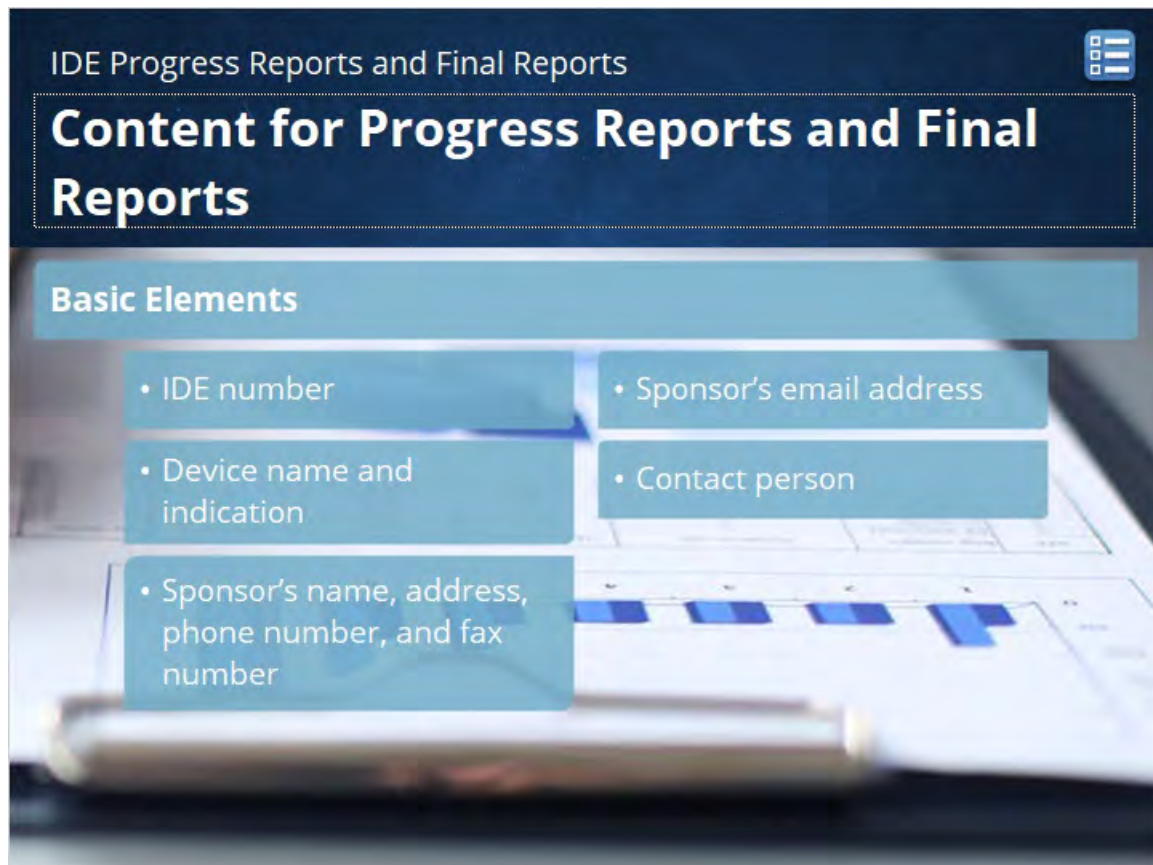
- Submit a final report to FDA, all IRBs, and investigators within 6 months after the completion or termination.

**Notes:**

Upon completion or termination of an investigation, the sponsor must notify FDA and all reviewing IRBs within 30 working days of the completion or termination date.

A final report must also be submitted to FDA, all reviewing IRBs, and all participating investigators within 6 months after the completion or termination of the investigation.

#### ***4.5 Content for Progress Reports and Final Reports***



**Notes:**

The next several slides will describe the content required for an IDE progress report and final report. While the content contained in progress reports and the final report is similar, differences between these two reports will be highlighted. If any of the described sections are not applicable, we recommend stating "Not Applicable" in the report rather than deleting those sections.

The report should begin with basic elements. This section is required to contain the following information:

- The IDE number;
- The device name and indication(s) for use;
- The sponsor's name, address, phone number, and fax number;
- The sponsor's email address; and
- A contact person.



#### ***4.6 Content for Progress Reports and Final Reports***



**Notes:**

The next section of the report should discuss study progress and include data from the beginning of each clinical investigation being run under the IDE. The following information should be included in this section:

- A brief summary of the study progress in relation to the investigational plan;
- The number of investigators and investigational sites, including a list of all investigators;
- The number of subjects enrolled by indication or model;
- The number of devices shipped;
- A brief summary of results;
- A summary of anticipated and unanticipated adverse effects; and

- A description of any deviations from the investigational plan by investigators since the last progress report.

#### ***4.7 Content for Progress Reports and Final Reports***



**Notes:**

For final reports, information on the disposition of the devices must also be included in this section of the report.

#### ***4.8 Content for Progress Reports and Final Reports***

IDE Progress Reports and Final Reports

## Content for Progress Reports and Final Reports

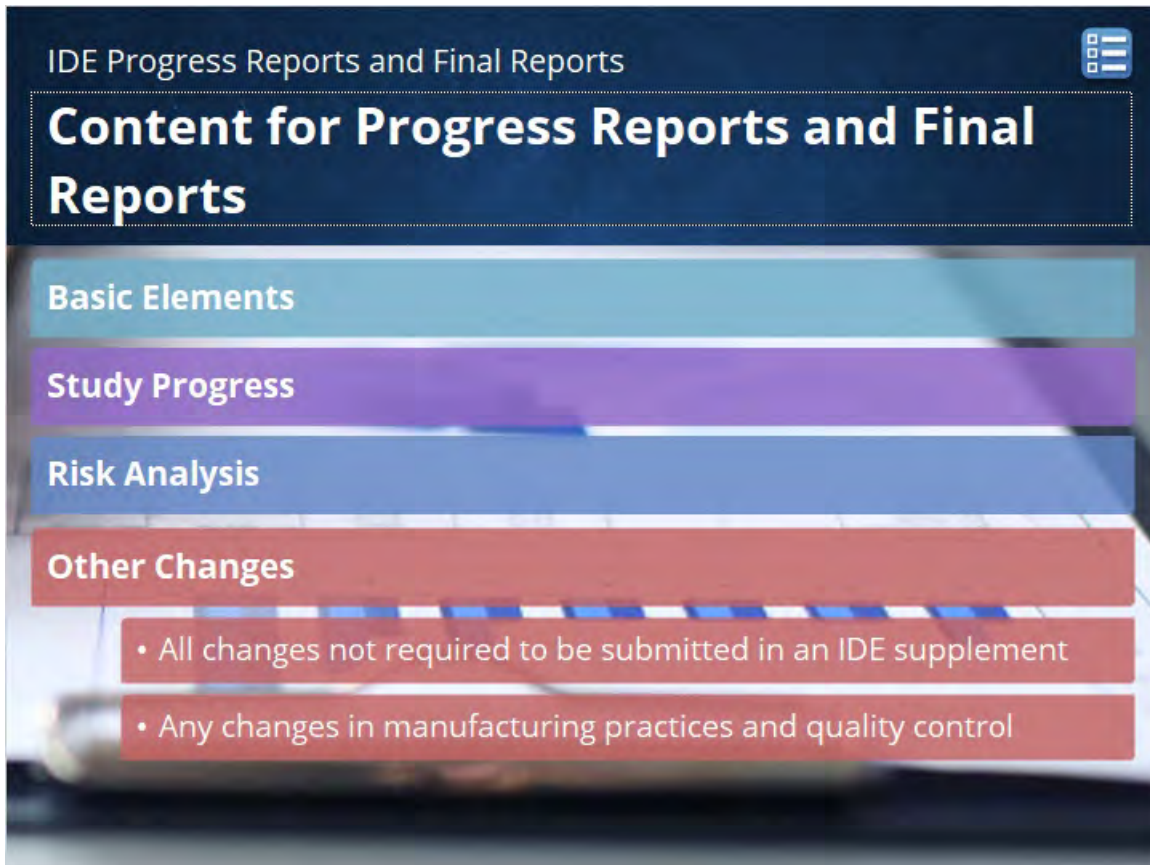
- Basic Elements
- Study Progress
- Risk Analysis
  - Summary of new adverse information that may affect the risk analysis
  - Reprints of any articles published from data collected under the IDE
  - If there is new information, include a new risk analysis

**Notes:**

The next section of the report should include any updates to the risk analysis. Specifically, this section should contain a summary of any new adverse information that may affect the risk analysis, including data from preclinical and clinical studies. The sponsor should also include reprints of any articles published from data collected under the IDE in this section of the report.

If conduct of the study results in new information that significantly affects the risk analysis, a new risk analysis should be provided.

#### ***4.9 Content for Progress Reports and Final Reports***



**Notes:**

The next section of the report should summarize any other changes to the IDE. This should include changes in the investigational plan that were not required to be submitted in an IDE supplement. Any changes in manufacturing practices and quality control should also be discussed.

For more information on changes that should be reported in the IDE progress report, please see the IDE modifications training module.



#### ***4.10 Content for Progress Reports and Final Reports***



**Notes:**

Finally, future plans for the IDE must be provided, and should discuss progress toward a product marketing application or indicate that marketing is not planned. The sponsor should also discuss any plans to change the investigation, for example, to expand the study size or indications, to discontinue portions of the investigation, or to change manufacturing practices.

Please note that a separate IDE supplement should be submitted to request implementation of the change. For more information on implementing changes under an IDE, please see the IDE modifications training module.

#### ***4.11 Content for Progress Reports and Final Reports***

IDE Progress Reports and Final Reports

## Content for Progress Reports and Final Reports

- Basic Elements
- Study Progress
- Risk Analysis
- Other Changes
- Future Plans
  - Progress toward a marketing application or indicate that marketing is not planned
  - Any plans to submit another IDE application for the device

**Notes:**

For the final report, this section must also include any plans to submit another IDE application for the same device or a modified version of the device.

#### **4.12 Additional Information**

IDE Progress Reports and Final Reports

## **Additional Information**



For more information on IDE progress reports and final reports, please visit [FDA's website](#).

**Return to the Main Menu**

**Notes:**

For more information on IDE progress reports and final reports, please visit FDA's website by clicking on the provided link.

## 5. IDE Modifications

### 5.1 IDE Modifications




Notes:



## 5.2 Learning Objectives

### IDE Modifications



- ✓ Requirements for IDE Modifications
- ✓ Reporting Timelines
- ✓ How to Submit an IDE Modification

### Notes:

After completing this training module, the learner will understand the following:

- The requirements for IDE modifications to the investigational plan,
- The reporting timelines for notifying FDA of such modifications, and
- How to submit an IDE modification

### 5.3 Requirements for IDE Modifications

IDE Modifications

## Requirements for IDE Modifications

A sponsor can make modifications to the investigational plan of an IDE, including changes to the device or clinical protocol.

- Prior approval
- Notification within 5 days
- Submission in a progress report



#### Notes:

During the course of a clinical investigation, the sponsor of a study can make modifications to the investigational plan of an IDE, including changes to the device or clinical protocol.

These changes may be simple modifications, such as clarifying the instructions for use, or they may be significant changes, such as modifications to the study design or the device materials.

This module will describe the types of IDE modifications and associated reporting timelines, including changes for which prior approval should be obtained versus those that require notification within 5 days of implementing the change or those that only require submission in an IDE progress report.

Keep in mind that modifications to the IDE may also require approval from the Institutional Review Board, or IRB, prior to implementation.

### ***5.4 Changes that Require Prior Approval***

The infographic features a dark blue header with the text 'IDE Modifications' and a small icon of three vertical bars. Below the header, the title 'Changes that Require Prior Approval' is displayed in a white box. The background of the infographic shows a close-up of a doctor in a white coat with a blue stethoscope. A dark blue text box in the center states: 'An IDE supplement requiring prior approval must be submitted for any change that may affect:'. Below this, there are two columns of dark blue boxes, each containing a white bullet point. The left column lists: '• Validity of the data', '• Risk to benefit relationship', and '• Scientific soundness'. The right column lists: '• Rights, safety, or welfare of subjects' and '• Operation of the device or design'.

IDE Modifications

## Changes that Require Prior Approval

An IDE supplement requiring prior approval must be submitted for any change that may affect:

- Validity of the data
- Risk to benefit relationship
- Scientific soundness
- Rights, safety, or welfare of subjects
- Operation of the device or design

**Notes:**

Certain changes to the investigational plan require submission of an IDE supplement and approval by FDA before implementation.

An IDE supplement requiring prior approval must be submitted for any change that may affect the following:

- The validity of the data resulting from the study,
- The risk to benefit relationship for subjects enrolled in the study,
- The scientific soundness of the investigational plan,



- The rights, safety, or welfare of subjects involved in the investigation, or
- The basic principles of device operation or design that would constitute a significant change unless those changes are made in response to information gathered during the course of the investigation.

Examples of IDE modifications requiring prior approval include changes in the indication, type of study control, primary end point, or expansion of the study.

•

### ***5.5 Submitting Changes that Require Prior Approval***

IDE Modifications

## Submitting Changes that Require Prior Approval

IDE supplement should include:

- Detailed description of the change
- Rationale for the change
- Impact of the change
- Documentation supporting the change

Cross-reference sections of the original submission that are being modified.

FDA will review within 30 days and issue a response.

#### **Notes:**

Modifications that require prior approval should be submitted to the FDA in an IDE supplement, which should include a detailed description of the change, rationale for the change being requested, an assessment of the impact of the



change on the study, and documentation supporting the change. The type of supporting documentation that should be included in the supplement depends on the change being requested. This documentation may include preclinical bench or animal testing, peer-reviewed published literature, a risk analysis of the change, or a statistical analysis of the impact on the study.

The supplement should also cross-reference sections of the original submission that are being modified.

FDA will review the IDE supplement within 30 days and issue an approval, approval with conditions, or disapproval letter.

### ***5.6 Emergency Changes***

The slide features a dark blue header with the text 'IDE Modifications' and a menu icon. Below this, the title 'Emergency Changes' is displayed in a large, white, bold font. The main content area has a background image of a modern building at night with a sign that reads 'EMERGENCY'. Overlaid on this image are two dark blue text boxes. The first box contains the text 'Emergency changes do not require prior approval when:'. The second box contains a bulleted list of two conditions.

IDE Modifications

## Emergency Changes

Emergency changes do not require prior approval when:

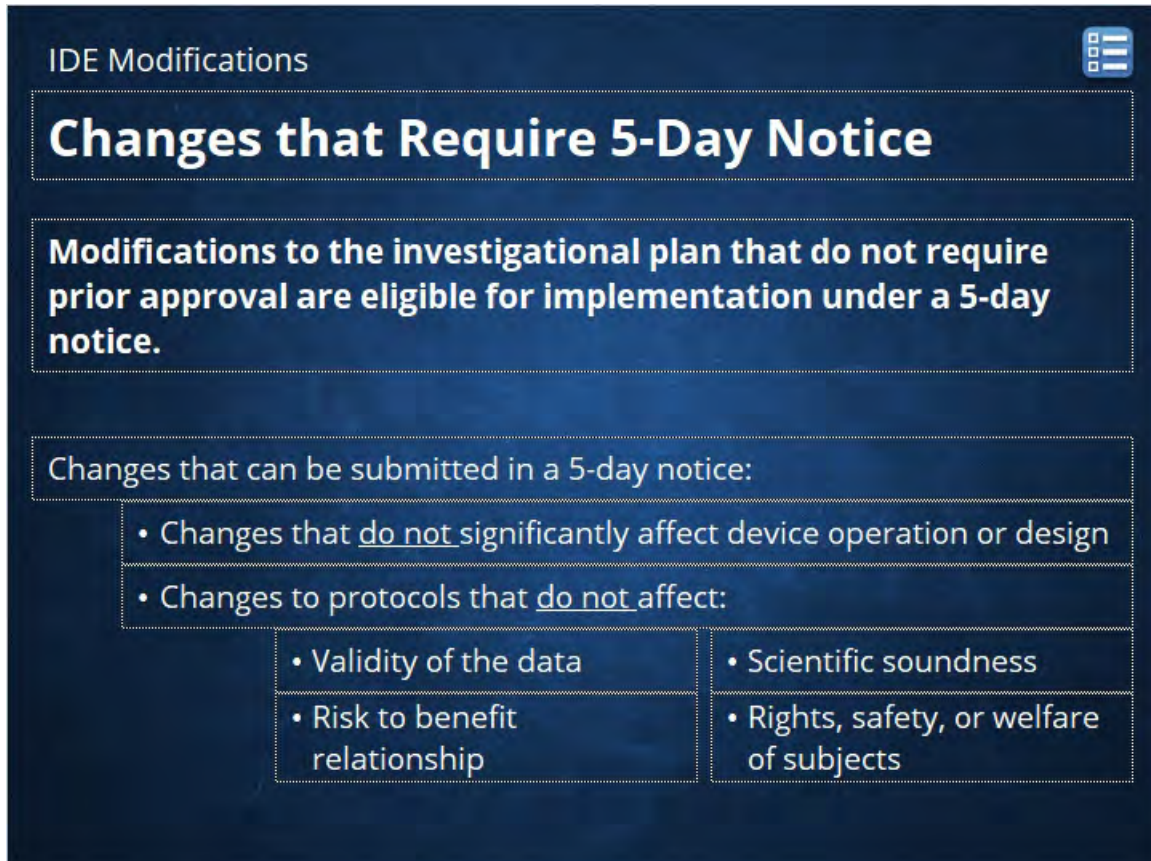
- A deviation is made to protect the life or physical well-being of a subject in an emergency
- Reported to FDA within 5 working days after the sponsor learns of it

**Notes:**

---

The requirements regarding FDA approval of a supplement do not apply in the case of emergency changes during a clinical investigation as long as the deviation from the investigational plan is to protect the life or physical well-being of a subject in an emergency and such deviation is reported to FDA within 5 working days after the sponsor learns of it.

### ***5.7 Changes that Require 5-Day Notice***

A presentation slide titled "IDE Modifications" with a sub-header "Changes that Require 5-Day Notice". The slide contains a summary statement, a list of eligible changes, and a detailed table of factors that do not affect eligibility. A small icon of three horizontal bars is in the top right corner.

IDE Modifications

## Changes that Require 5-Day Notice

**Modifications to the investigational plan that do not require prior approval are eligible for implementation under a 5-day notice.**

Changes that can be submitted in a 5-day notice:

- Changes that do not significantly affect device operation or design
- Changes to protocols that do not affect:

• Validity of the data	• Scientific soundness
• Risk to benefit relationship	• Rights, safety, or welfare of subjects

#### **Notes:**

Modifications to the investigational plan that do not require prior approval and are not implemented under an emergency change are eligible for implementation under a 5-day notice. The following changes may be implemented immediately provided FDA is notified within 5 working days through the submission of an IDE supplement:

- Changes that do not significantly affect device operation or design and that are

made in response to information gathered during the course of the investigation, or

- Changes to the clinical protocol that do not affect:
  - The validity of the data resulting from the study,
  - The risk to benefit relationship for subjects enrolled in the study,
  - The scientific soundness of the investigational plan, or
  - The rights, safety, or welfare of subjects involved in the investigation.

The sponsor should determine if the proposed change meets the criteria for submission in a 5-day notice based on credible information, such as results of preclinical testing, clinical studies, peer-reviewed published literature, or other reliable information.

### ***5.8 Submitting Changes in a 5-Day Notice***

IDE Modifications

## Submitting Changes in a 5-Day Notice

Include a description of the change and a summary of the information upon which the change was based.

FDA will review within 30 days and typically will not issue a response.



**Notes:**

A 5-day notice must include a description of the change and a summary of the relevant information gathered during the course of the investigation upon which the change was based.

FDA will review the 5-day notice within 30 days and, typically, there will be no response from FDA to the sponsor. However, if clarification or additional information is needed, the Agency will contact the sponsor.

While it is the sponsor's responsibility to determine if a device, manufacturing, or protocol change meet the criteria for implementation under a 5-day notice and do not require prior Agency approval, FDA has reserved the right to question the sponsor's determination.

### ***5.9 Changes Included in a Progress Report***

The slide features a dark blue header with the text 'IDE Modifications' and a hamburger menu icon. The main title 'Changes Included in a Progress Report' is in a white box. The background image shows a hand holding a pen over a document. A text box states: 'Minor changes to the investigational plan may be submitted in an IDE progress report.' Below this is a table of items.

• Purpose of the study	• Labeling
• Risk analysis	• Informed consent
• Monitoring	• IRB information



**Notes:**

Changes to the investigational plan that do not meet the criteria for submission in an IDE supplement for prior approval or as a 5-day notice may be submitted to FDA in an IDE progress report. Minor changes eligible for reporting in a progress report are those that would not affect the validity of the data, the risk to benefit relationship for study subjects, the scientific soundness of the investigational plan, or the rights, safety, or welfare of study subjects. These could include minor changes to the purpose of the study, risk analysis, monitoring procedures, labeling, informed consent materials, and IRB information.

***5.10 Submitting Changes in a Progress Report***

The image is a screenshot of a training module titled "IDE Modifications" with a sub-header "Submitting Changes in a Progress Report". The background shows a blurred office scene with people working at a desk. In the foreground, there is a document with a bar chart. A dark blue text box is overlaid on the image, containing the instruction: "Include a description of the change and a summary of the information upon which the change was based."

**Notes:**

If a modification to the investigational plan is included in a progress report, the sponsor should include a description of the change and a summary of the

information upon which the change was based.

Typically, there will be no response from FDA to the sponsor for these types of changes. However, if clarification or additional information is needed, the Agency will contact the sponsor.

For more information on submitting an IDE progress report, please see the IDE progress reports and final reports training module.

### **5.11 Additional Information**

IDE Modifications

## Additional Information

For more information on IDE modifications, please see FDA's Guidance entitled ["Changes or Modifications During the Conduct of a Clinical Investigation."](#)

**Return to the Main Menu**

#### **Notes:**

For more information on IDE modifications, please see FDA's Guidance entitled "Changes or Modifications During the Conduct of a Clinical Investigation" by clicking on the provided link.

## **6. Unanticipated Adverse Device Effects**

### ***6.1 Unanticipated Adverse Device Effects***



# **Unanticipated Adverse Device Effects**

**Notes:**

## 6.2 Learning Objectives

### Unanticipated Adverse Device Effects



- ✓ Definition of an Unanticipated Adverse Device Effect
- ✓ Timeline for Reporting Unanticipated Adverse Device Effects to FDA
- ✓ Termination of an Investigation

### Notes:

After completing this training module, the learner will understand the following:

- The definition of an unanticipated adverse device effect;
- The timeline for reporting unanticipated adverse device effects to FDA; and
- The responsibility of the IDE sponsor to terminate an investigation if the unanticipated adverse device effect presents an unreasonable risk to subjects



### 6.3 Unanticipated Adverse Device Effects



The infographic has a dark blue background. At the top left, the title 'Unanticipated Adverse Device Effects' is written in white. To the right of the title is a small icon of a document with three vertical bars. Below the title, the main heading 'Unanticipated Adverse Device Effects' is displayed in a large, bold, white font. Underneath this, a white-bordered box contains the text 'Report all unanticipated adverse device effects to FDA, all reviewing IRBs, and all participating investigators.' in bold. Below this box, the text 'Unanticipated Adverse Device Effect:' is followed by a list of two bullet points, each in a separate white-bordered box. The first bullet point describes a serious adverse effect on health or safety, any life-threatening problem, or death associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the current IDE application. The second bullet point describes any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Unanticipated Adverse Device Effects

**Report all unanticipated adverse device effects to FDA, all reviewing IRBs, and all participating investigators.**

Unanticipated Adverse Device Effect:

- Any serious adverse effect on health or safety, any life-threatening problem, or death associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the current IDE application
- Any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects

#### Notes:

The IDE sponsor is required to report all unanticipated adverse device effects to FDA, all reviewing Institutional Review Boards, or IRBs, and to all participating investigators.

An unanticipated adverse device effect is:

- Any serious adverse effect on health or safety, any life-threatening problem, or death associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the current IDE application; or
- Any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

## 6.4 Reporting Responsibilities

Unanticipated Adverse Device Effects

### Reporting Responsibilities

Immediately conduct an evaluation of the unanticipated adverse device effect.

Submit results of the evaluation to FDA in an IDE report within 10 working days after the sponsor is notified of the effect.

Additional reports concerning the device effect must be submitted if requested by FDA.

#### Notes:

Once the IDE sponsor has been notified of an unanticipated adverse device effect, he or she must immediately conduct an evaluation.

The sponsor must submit the results of the evaluation to FDA in an IDE report as soon as possible but no later than 10 working days after the sponsor is notified of the effect. All reviewing IRBs and participating investigators must also be notified of the unanticipated adverse device effect within 10 working days.

Additional reports concerning the device effect must be submitted if requested by FDA.

## 6.5 Termination of an Investigation

Unanticipated Adverse Device Effects

### Termination of an Investigation

If an unanticipated adverse device effect presents an unreasonable risk to subjects, all investigations or parts of investigations presenting that risk must be terminated as soon as possible.

- No later than 5 working days after the sponsor makes this determination
- No later than 15 working days after the sponsor first received notice of the effect

The terminated study may not resume without FDA and IRB approval.

### Notes:

If a sponsor determines that an unanticipated adverse device effect presents an unreasonable risk to subjects, all investigations or parts of investigations presenting that risk must be terminated as soon as possible. Termination must occur no later than 5 working days after the sponsor makes this determination and no later than 15 working days after the sponsor first received notice of the effect.

The terminated study may not resume without FDA and IRB approval.



## 6.6 Additional Information

Unanticipated Adverse Device Effects

### Additional Information



For more information on reporting unanticipated adverse device effects, please see federal regulations found in 21 CFR 812.

- [812.46 – Monitoring Investigations](#)
- [812.150 – Reports](#)

[Return to the Main Menu](#)

#### Notes:

For more information on reporting unanticipated adverse device effects, please see federal regulations found in 21 CFR 812 by clicking on the provided links.



## 7. IDE Reports


### 7.1 IDE Reports



**Notes:**

## 7.2 Learning Objectives

### IDE Reports



- ✓ IDE Reports Required to Be Submitted by the Sponsor
- ✓ Reporting Obligations for Each IDE Report
- ✓ Timelines for Report Submissions

### Notes:

After completing this training module, the learner will understand the following:

- The IDE reports that are required to be submitted by the sponsor;
- The specific reporting obligations for each IDE report; and
- The timelines for submission of each report.

### 7.3 Sponsor Reports for IDEs



**Notes:**

The reports listed here are required to be submitted by the regulatory sponsor of an IDE application per regulation. As discussed in the Overview of IDE Maintenance and Tracking Module, these submissions should be clearly identified as IDE reports when submitted to the FDA.

## 7.4 Sponsor Reports for IDEs



### Notes:

This training module will go into detail about the specific reporting obligations for each IDE report, with the exception of unanticipated adverse device effects, progress reports, and final reports. These reports will be covered in detail in separate training modules.



## ***7.5 Withdrawal of IRB Approval***

A graphic titled "IDE Reports" with a sub-header "Withdrawal of IRB Approval". The background is a blurred image of a document with a pen. Two text boxes are overlaid on the image. The first box contains the text: "The sponsor must notify FDA, all reviewing IRBs, and all participating investigators of the withdrawal of IRB approval of an investigation or any part of an investigation." The second box contains the text: "Timeline: Send report within 5 working days after receipt of the withdrawal of IRB approval."

IDE Reports

### Withdrawal of IRB Approval

The sponsor must notify FDA, all reviewing IRBs, and all participating investigators of the withdrawal of IRB approval of an investigation or any part of an investigation.

**Timeline:** Send report within **5 working days** after receipt of the withdrawal of IRB approval.

#### **Notes:**

The IDE sponsor has a reporting obligation anytime there is a withdrawal of Institutional Review Board, or IRB, approval. The sponsor must notify FDA, all reviewing IRBs, and all participating investigators of the withdrawal of IRB approval of an investigation or any part of an investigation.

This report should be sent to the FDA, all reviewing IRBs, and all participating investigators within 5 working days after receipt of the withdrawal of IRB approval.

## 7.6 Withdrawal of FDA Approval

A presentation slide with a dark blue background. At the top left, it says 'IDE Reports' in white. At the top right is a small icon of a document with three lines. Below this is a white-bordered box containing the title 'Withdrawal of FDA Approval' in bold white text. The background features a large, stylized, 3D 'FDA' logo in light blue and white. Overlaid on the logo are two semi-transparent dark blue boxes with white text. The first box contains the text: 'The sponsor must notify all reviewing IRBs and participating investigators of any withdrawal of FDA approval of the investigation.' The second box, below the first, contains the text: 'Timeline: Send report within 5 working days after the sponsor is notified.'

IDE Reports

### Withdrawal of FDA Approval

The sponsor must notify all reviewing IRBs and participating investigators of any withdrawal of FDA approval of the investigation.

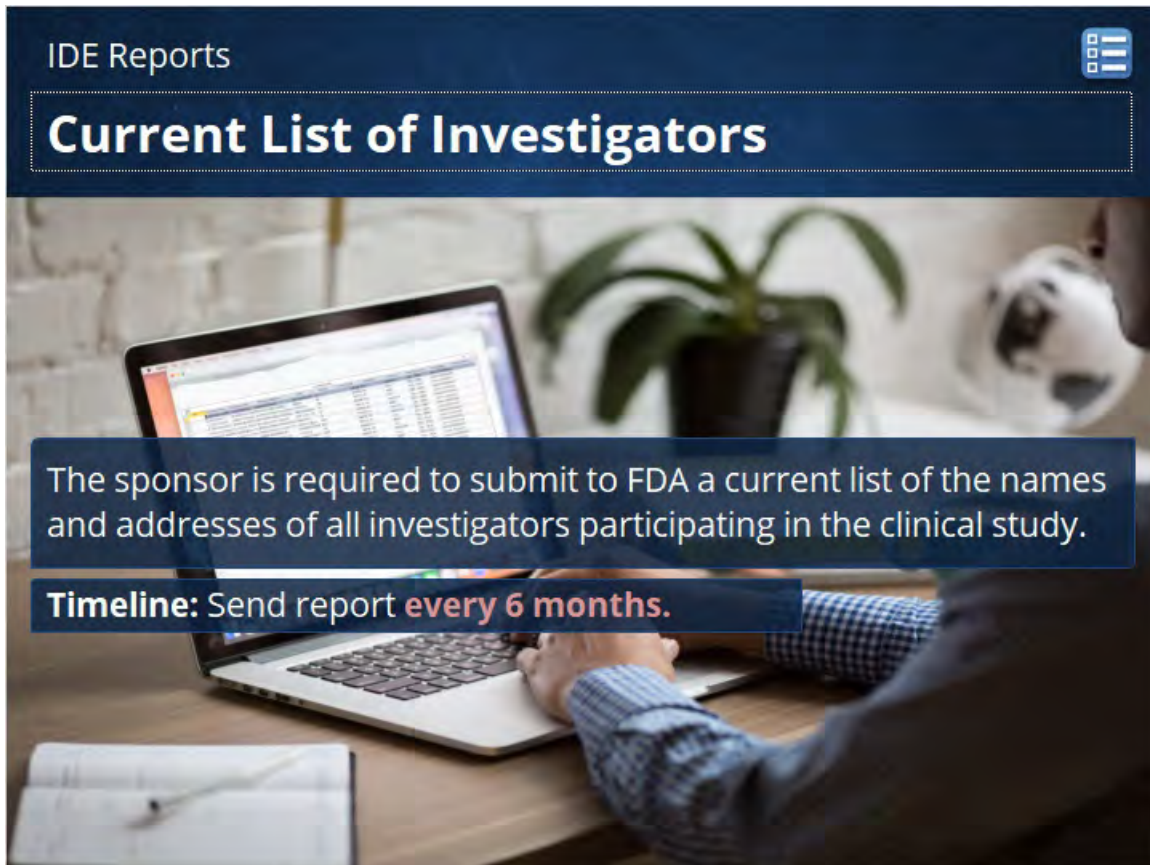
**Timeline:** Send report within **5 working days** after the sponsor is notified.

#### Notes:

The sponsor must also notify all reviewing IRBs and participating investigators of any withdrawal of FDA approval of the investigation.

This report should be sent to all reviewing IRBs and participating investigators within 5 working days after the sponsor is notified of the withdrawal of FDA approval.

## 7.7 Current List of Investigators



IDE Reports

### Current List of Investigators

The sponsor is required to submit to FDA a current list of the names and addresses of all investigators participating in the clinical study.

**Timeline:** Send report **every 6 months.**

#### Notes:

The sponsor is required to submit to FDA a current list of the names and addresses of all investigators participating in the clinical study.

This report should be submitted to FDA every 6 months regardless of whether there have been any changes to the investigator list. The first report should be submitted 6 months after IDE approval and then every 6 months thereafter.

## 7.8 Recalls and Device Disposition

A presentation slide titled "IDE Reports" with a sub-header "Recalls and Device Disposition". The background is a blurred image of hands holding a small electronic device. Two text boxes are overlaid on the image. The first box contains the text: "The sponsor must notify FDA and all reviewing IRBs of any request that an investigator return, repair, or dispose of any unit of an investigational device." The second box contains the text: "Timeline: Send report within 30 working days after the request is made and state why the request was made." The slide also features a small icon in the top right corner.

IDE Reports

### Recalls and Device Disposition

The sponsor must notify FDA and all reviewing IRBs of any request that an investigator return, repair, or dispose of any unit of an investigational device.

**Timeline:** Send report within **30 working days** after the request is made and state why the request was made.

### Notes:

The sponsor is also required to report any recalls or device dispositions. The sponsor must notify FDA and all reviewing IRBs of any request that an investigator return, repair, or dispose of any unit of an investigational device.

This report should be submitted to FDA and all reviewing IRBs within 30 working days after the sponsor requests a recall or device disposition. An explanation of why the request was made must be included in the report.



## 7.9 Failure to Obtain Informed Consent



IDE Reports

### Failure to Obtain Informed Consent

The sponsor must also submit a report to FDA if a device is used without first obtaining informed consent from a participant in the clinical investigation.

**Timeline:** Send report within **5 working days** after the sponsor is notified of the failure to obtain informed consent.

#### Notes:

The sponsor must also submit a report to FDA if a device is used without first obtaining informed consent from a participant in the clinical investigation. To fulfill this reporting requirement, the sponsor can submit a copy of the report received from the investigator that describes the event. This report should be submitted to FDA within 5 working days after the sponsor is notified of the failure to obtain informed consent.

### ***7.10 Significant Risk Device Determination***



IDE Reports

## Significant Risk Device Determination

If the sponsor had proposed that a device is nonsignificant risk and an IRB later determines the device to be significant risk, the sponsor is required to report this determination to the FDA.

**Timeline:** Send report within **5 working days** after the sponsor learns of the IRB's determination.

**Notes:**

Lastly, if the sponsor had proposed that a device is nonsignificant risk and an IRB later determines the device to be significant risk, the sponsor is required to report this determination to the FDA.

This report should be submitted to FDA within 5 working days after the sponsor learns of the IRB's determination.

### **7.11 Additional Information**

IDE Reports

## **Additional Information**



For more information on IDE reports, please visit [FDA's website](#).

**Return to the Main Menu**

**Notes:**

For more information on IDE reports, please visit FDA's website by clicking on the provided link.

## **8. Maintaining Accountability Records for IDEs**

### ***8.1 Maintaining Accountability Records for IDEs***



# **Maintaining Accountability Records for IDEs**

**Notes:**



## 8.2 Learning Objectives

### Maintaining Accountability Records for IDEs



- ✓ Records That Need to Be Maintained and Accounted for by the IDE Sponsor
- ✓ Controlling Distribution and Disposition of Devices
- ✓ Length of Time IDE Records Need to Be Retained

### Notes:

After completing this training module, the learner will understand the following:

- The records that need to be maintained and accounted for by the IDE sponsor;
- The requirements for controlling the distribution and disposition of devices; and
- The length of time that IDE records need to be retained.

The sponsor responsibilities discussed in this training module are for significant risk device studies overseen by the FDA and IRB. For information on the sponsor responsibilities for nonsignificant risk device studies, please visit FDA's website by following the link at the end of this training module.

### ***8.3 Records That Must Be Maintained***

Maintaining Accountability Records for IDEs

## **Records That Must Be Maintained**

**The sponsor is responsible for collecting and maintaining the following records relating to an investigation conducted under an IDE:**

- All correspondence
  - Another sponsor
  - Monitor
  - Investigator
  - IRB
  - FDA

**Notes:**

The sponsor is responsible for collecting and maintaining the following records relating to an investigation conducted under an IDE:

- All correspondence, including any required IDE reports, that may be exchanged with another sponsor, a monitor, an investigator, an IRB or the FDA


## ***8.4 Records That Must Be Maintained***

Maintaining Accountability Records for IDEs

### Records That Must Be Maintained

**The sponsor is responsible for collecting and maintaining the following records relating to an investigation conducted under an IDE:**

- All correspondence
- Records of shipment
  - Name and address of consignee
  - Type and quantity of devices
  - Date of shipment
  - Batch numbers or code marks



**Notes:**

- Records of device shipment, including name and address of consignee, the type and quantity of devices, the date of shipment, and batch numbers or code marks

### ***8.5 Records That Must Be Maintained***

Maintaining Accountability Records for IDEs

## Records That Must Be Maintained

**The sponsor is responsible for collecting and maintaining the following records relating to an investigation conducted under an IDE:**

- All correspondence
- Records of shipment
- Records of disposition
  - Batch number or code mark of devices returned, repaired, or disposed of
  - Reasons for and method of disposal

**Notes:**

- Records of disposition of the device describing batch number or code mark of devices returned, repaired, or disposed of by the investigator or other persons and reasons for and method of disposal



## ***8.6 Records That Must Be Maintained***

Maintaining Accountability Records for IDEs

### **Records That Must Be Maintained**

**The sponsor is responsible for collecting and maintaining the following records relating to an investigation conducted under an IDE:**

- All correspondence
- Records of shipment
- Records of disposition
- Signed investigator agreements, including financial disclosure information



**Notes:**

- Signed investigator agreements, including financial disclosure information


## ***8.7 Records That Must Be Maintained***

Maintaining Accountability Records for IDEs

### Records That Must Be Maintained

**The sponsor is responsible for collecting and maintaining the following records relating to an investigation conducted under an IDE:**

- All correspondence
- Records of shipment
- Records of disposition
- Signed investigator agreements, including financial disclosure information
- Complaints and adverse device effects



**Notes:**

- Records concerning complaints and adverse device effects (whether anticipated or unanticipated)


## ***8.8 Records That Must Be Maintained***

Maintaining Accountability Records for IDEs

**Records That Must Be Maintained**

**The sponsor is responsible for collecting and maintaining the following records relating to an investigation conducted under an IDE:**

- All correspondence
- Records of shipment
- Records of disposition
- Signed investigator agreements, including financial disclosure information
- Complaints and adverse device effects
- Any other records that FDA requires by regulation



**Notes:**

- Lastly, any other records that FDA requires by regulation or by specific requirement for a category of investigation or a particular investigation should be collected and maintained.

## ***8.9 Controlling Distribution and Disposition of Devices***



Maintaining Accountability Records for IDEs

### **Controlling Distribution and Disposition of Devices**

Sponsors should only ship investigational devices to qualified investigators participating in the clinical investigation.

Sponsors should take appropriate measures to instruct investigators regarding their responsibilities with respect to recordkeeping and device disposition.

#### **Notes:**

Although investigators are responsible for ensuring that investigational devices are made available only to persons who are legally authorized to receive them, sponsors also bear responsibility for taking proper measures to ensure that devices are not diverted outside of legally authorized channels.

Sponsors should only ship investigational devices to qualified investigators participating in the clinical investigation.

To further ensure compliance with these requirements, sponsors should take appropriate measures to instruct investigators regarding their responsibilities with respect to recordkeeping and device disposition. Upon completion or termination of a clinical investigation or at the sponsor's request, an investigator is required to return to the sponsor any remaining supply of the device or otherwise to dispose of the device as the sponsor directs.



## 8.10 Financial Disclosure Records

Maintaining Accountability Records for IDEs

### Financial Disclosure Records

**Maintain complete and accurate records concerning investigator financial interests:**

- Any financial arrangement where the value of the compensation could be influenced by the outcome of the study
- Any significant payments of other sorts
- Any proprietary interest in the tested product
- Any significant equity interest in any sponsor

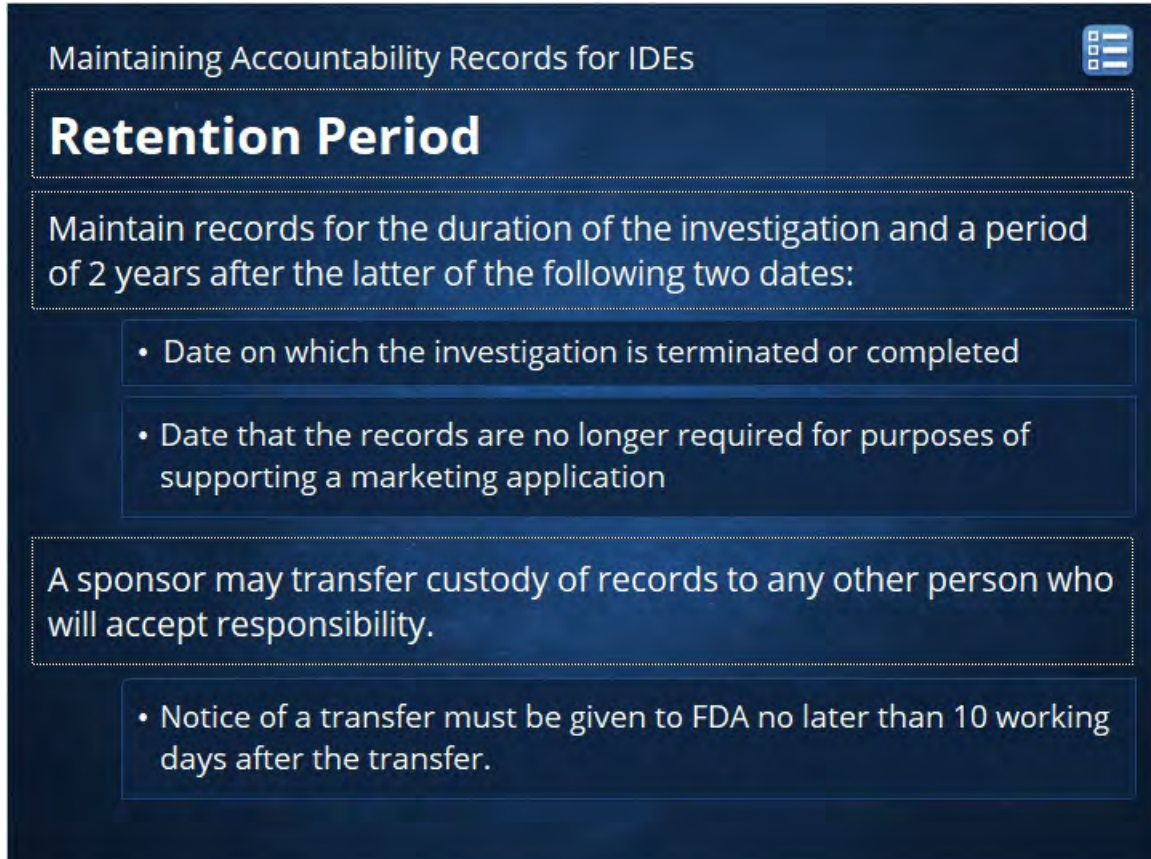
### Notes:

The sponsor must maintain complete and accurate records of financial interests for all investigators directly involved in the conduct of a clinical study that may support a marketing application. Financial interests that should be captured and maintained by the sponsor include the following:

- Any financial arrangement where the value of the compensation to the investigator could be influenced by the outcome of the study;
- Any significant payments of other sorts from any sponsor, such as a grant to fund ongoing research or compensation in the form of equipment;
- Any proprietary interest in the tested product held by an investigator; and
- Any significant equity interest in any sponsor held by an investigator.

Financial disclosure forms are only required to be submitted to the FDA in a marketing application and are often not applicable to sponsor-investigator initiated studies. Please see the training module on financial disclosure to learn more.

### **8.11 Retention Period**



Maintaining Accountability Records for IDEs

## Retention Period

Maintain records for the duration of the investigation and a period of 2 years after the latter of the following two dates:

- Date on which the investigation is terminated or completed
- Date that the records are no longer required for purposes of supporting a marketing application

A sponsor may transfer custody of records to any other person who will accept responsibility.

- Notice of a transfer must be given to FDA no later than 10 working days after the transfer.

#### **Notes:**

A sponsor must maintain the required IDE records for the duration of the investigation and a period of two years after the latter of the following two dates:

- The date on which the investigation is terminated or completed;
- Or the date that the records are no longer required for purposes of supporting a marketing application.

A sponsor may withdraw from the responsibility to maintain records for the period required and transfer custody of the records to any other person who will accept responsibility. Notice of a transfer must be given to FDA no later than 10 working days after the transfer.

### **8.12 Records Inspection**

The slide features a dark blue background with a large, 3D, light blue FDA logo in the center. At the top left, the text 'Maintaining Accountability Records for IDEs' is displayed in a light blue font. To the right of this text is a small icon of a document with three horizontal lines. Below the top text, the title 'Records Inspection' is written in a bold, white font, enclosed in a white dashed rectangular border. At the bottom of the slide, there are two white rectangular boxes containing text. The first box contains the text 'Sponsors are required to permit FDA to enter and inspect any establishment where devices are held.' and the second box contains the text 'FDA may inspect and copy all records relating to an investigation.'

Maintaining Accountability Records for IDEs

## Records Inspection

Sponsors are required to permit FDA to enter and inspect any establishment where devices are held.

FDA may inspect and copy all records relating to an investigation.

#### **Notes:**

Sponsors are required to permit FDA to enter and inspect any establishment where devices are held, including any establishment where devices are manufactured, processed, packaged, installed, used, or implanted or where records or results from use of devices are kept.

FDA may also inspect and copy all records relating to an investigation including, in certain situations, records which identify subjects.



### **8.13 Additional Information**

Maintaining Accountability Records for IDEs

## **Additional Information**



For more information on maintaining accountability records, please visit [FDA's website](#).

**Return to the Main Menu**

**Notes:**

For more information on maintaining accountability records, please visit FDA's website by clicking on the provided link.



## 9. IDE Monitoring and Multi-Center Trials

### *9.1 IDE Monitoring and Multi-Center Trials*



# IDE Monitoring and Multi-Center Trials

Notes:

## 9.2 Learning Objectives

### IDE Monitoring & Multi-Center Trials



- ✓ Purpose of Monitoring a Clinical Investigation
- ✓ Sponsor Is Responsible For Monitoring the Investigation
- ✓ Risk-Based Approach to Monitoring
- ✓ Sponsor Requirements For Conducting a Multi-Center Trial

### Notes:

After completing this training module, the learner will understand the following:

- The purpose of monitoring a clinical investigation;
- That the sponsor is responsible for monitoring the investigation;
- That FDA recommends a risk-based approach to monitoring; and
- Sponsor requirements for conducting a multi-center trial

### 9.3 Monitoring

A graphic titled "IDE Monitoring & Multi-Center Trials" with a sub-header "Monitoring". The background features a blurred image of a person in a white lab coat. Overlaid on this are several digital elements: a blue heart icon with a white ECG line, a hand pointing at the heart, and a list of health metrics (Calories, Heart rate, Blood sugar, Blood pressure) next to a circular progress indicator showing 90% and 93%.

IDE Monitoring & Multi-Center Trials

## Monitoring

Monitoring is a quality control tool for determining whether study activities are being carried out as planned so that deficiencies can be identified and corrected.

Effective monitoring is critical for the protection of human subjects and the conduct of high quality investigations.

**Notes:**

All clinical investigations conducted under an IDE should be monitored, including multi-center trials, single-center trials, and those conducted by sponsor-investigators.

Monitoring is a quality control tool for determining whether study activities are being carried out as planned so that deficiencies can be identified and corrected.

Effective monitoring is critical for the protection of human subjects and the conduct of high quality investigations.

## 9.4 Sponsor Responsibility for Monitoring



IDE Monitoring & Multi-Center Trials

### Sponsor Responsibility for Monitoring

The sponsor is responsible for monitoring the progress of all clinical investigations being conducted under the IDE.

Submission of written monitoring procedures is not required for studies conducted by a sponsor-investigator.

If a sponsor-investigator chooses not to personally monitor the investigation, he or she should select individuals qualified by training and experience to monitor the progress of the investigation.

#### Notes:

The sponsor is responsible for monitoring the progress of all clinical investigations being conducted under the IDE. Written monitoring procedures are required for all studies involving more than one investigator and must be included in the original IDE application along with the name and address of the study monitor.

Submission of written monitoring procedures is not required for studies conducted by a sponsor-investigator, where only one investigator is involved in the study. It is assumed, unless otherwise specified, that the sole investigator will serve as the study monitor and ensure that the study is being carried out as planned.

If a sponsor-investigator chooses not to personally monitor the investigation, he or she should select individuals qualified by training and experience to monitor



the progress of the investigation and include their names and addresses in the original IDE application.

### ***9.5 Risk-Based Approach to Monitoring***

IDE Monitoring & Multi-Center Trials

## **Risk-Based Approach to Monitoring**

Develop a monitoring plan that is tailored to the specific data integrity and human subject protection risks of the investigation.

Prospectively identify critical data and processes that if inaccurate, not performed, or performed incorrectly, would threaten the protection of human subjects or the integrity of the study results.



#### **Notes:**

Since the regulations are not specific about how sponsors are to conduct monitoring, FDA recommends a risk-based approach that focuses on preventing or mitigating important and likely risks to data quality and to processes critical to ensure human subject protection. Thus, the sponsor should develop a monitoring plan that is tailored to the specific data integrity and human subject protection risks of the investigation.

While developing a monitoring plan, sponsors should prospectively identify critical data and processes that if inaccurate, not performed, or performed incorrectly, would threaten the protection of human subjects or the integrity of

the study results. Examples of critical data and processes that could be included in a monitoring plan include verification that informed consent was properly obtained and that administration of the investigational product was completed in accordance with the protocol.

## 9.6 Monitoring Methods



### Notes:

Monitoring can take place either at the site of the clinical investigation or at a remote centralized location. The sponsor should prospectively determine which method is appropriate for their study based on a risk assessment.

On-site monitoring is an in-person evaluation of the clinical investigation and is useful for identifying data entry errors and missing data in source records. On-site monitoring can also be used to assess investigator supervision, compliance with the protocol, and control of the investigational device. On-site monitoring

can therefore be particularly helpful early in a study, especially if the protocol is complex and includes novel procedures with which investigators may be unfamiliar.

Centralized monitoring is a remote evaluation of the clinical investigation and relies on electronic systems for review of records and communication. Centralized monitoring allows for review of data in real time, and it also identifies higher risks sites that the sponsor may wish to target with on-site monitoring. FDA encourages use of centralized monitoring practices, where appropriate.

A combination of on-site and centralized monitoring can also be used. If sponsors intend to rely heavily on centralized monitoring practices, they are encouraged to include one or more on-site monitoring visits as part of the monitoring plan.

### **9.7 Monitoring Activities**

IDE Monitoring & Multi-Center Trials

## Monitoring Activities



- Communication with the investigator and study site staff
- Review of the study site's processes, procedures, and records
- Verification of the accuracy of data submitted to the sponsor



**Notes:**

Once the monitoring plan is developed, the sponsor is responsible for ensuring that monitoring activities are conducted according to the plan. Monitoring activities include:

- Communication with the investigator and study site staff;
- Review of the study site's processes, procedures, and records; and
- Verification of the accuracy of data submitted to the sponsor.

If the monitor identifies any non-compliance, these findings should be evaluated to determine whether additional actions, such as training of the clinical investigator or site staff, are necessary to ensure human subject protection and data quality. If non-compliance is discovered at any site, the sponsor should promptly secure compliance or discontinue the study at that site.

### ***9.8 Additional Information***

IDE Monitoring & Multi-Center Trials

**Additional Information**



For more information on monitoring, please see FDA's Guidance entitled ["Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring."](#)



**Notes:**

For more information on monitoring, please see FDA's Guidance entitled "Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring" by clicking on the provided link.

## **9.9 Multi-Center Trials**

IDE Monitoring & Multi-Center Trials

### Multi-Center Trials

IDE sponsors of multi-center trials are required to:

- Select qualified investigators and provide them with information to conduct the study.
- Obtain the investigator's qualifications and a signed investigator statement.
  - The investigator's curriculum vitae
  - A statement of the investigator's relevant experience
  - An explanation of the circumstances surrounding termination
  - Sufficient financial disclosure information
  - A statement of the investigator's commitment to (1) conduct the investigation in accordance with the agreement, the investigational plan, and federal regulations; (2) supervise all testing; and (3) obtain informed consent

**Notes:**

A multi-center trial is a clinical investigation that is conducted at more than one site. Under the IDE regulations, sponsors of multi-center trials are required to:

- Select qualified investigators and provide them with information required to conduct the study properly. This includes supplying all investigators with a copy of the investigational plan and any reports of prior investigations of the device.
- The sponsor must also obtain from each investigator a signed agreement that

contains:

- The investigator's curriculum vitae
- A statement of the investigator's relevant experience
- If the investigator was involved in an investigation that was terminated, an explanation of the circumstances surrounding that termination
- Sufficient financial disclosure information
- And a statement of the investigator's commitment to (1) conduct the investigation in accordance with the agreement, the investigational plan, and federal regulations; (2) supervise all testing of the device involving human subjects; and (3) ensure that the requirements for obtaining informed consent are met.

### **9.10 Multi-Center Trials**



IDE Monitoring & Multi-Center Trials

## Multi-Center Trials

IDE sponsors of multi-center trials are required to:

- Select qualified investigators and provide them with information to conduct the study.
- Obtain the investigator's qualifications and a signed investigator statement.
- Obtain certification of IRB approval from each site and submit certifications to the IDE.
- Only ship the investigational product to participating investigators.

Notes:

IDE sponsors of multi-center trials should also:

- Obtain certification of Institutional Review Board, or IRB, approval from each site and submit certifications to the IDE.
- And only ship the investigational product to participating investigators.

### **9.11 Multi-Center Trials**

IDE Monitoring & Multi-Center Trials

## Multi-Center Trials

IDE sponsors of multi-center trials are required to:

- Review and evaluate unanticipated adverse device effects reported by investigators.
- Report unanticipated adverse device effects to the IDE and to each site.
- Keep each participating investigator informed of new observations on the device.
- Maintain current, complete, and accurate records.
- Monitor the investigation to ensure compliance.

#### **Notes:**

IDE sponsors of multi-center trials are responsible for oversight of all investigations and ensuring that all investigators, IRBs, and FDA are updated with information necessary to safely conduct the clinical investigation. The sponsor should promptly review and evaluate unanticipated adverse device effects provided by investigators.

The sponsor should report unanticipated adverse device effects to the IDE and to

## Training Modules on IDE Sponsor and Investigator Responsibilities (No Quiz)

each site participating in the investigation. Each investigator must also submit such reports to their IRB.

The sponsor should keep each participating investigator informed of new observations on the device, particularly with respect to adverse device effects and safe use. Such information may be distributed to investigators by means of periodically revised instructions for use, reprints or published studies, reports or letters to clinical investigators, or other appropriate means.

It is also the sponsor's responsibility to maintain current, complete, and accurate records that pertain to each site. This includes up-to-date information on investigator qualifications and financial disclosure information, when applicable.

Lastly, the sponsor is responsible for continued oversight of all investigators to ensure that the study is conducted correctly and that all sites are following the protocol. The sponsor should monitor the investigation to ensure compliance with the protocol and signed investigator agreement. If the sponsor discovers non-compliance at any site, they should promptly secure compliance or discontinue the study at that site.



### ***9.12 Additional Information***

IDE Monitoring & Multi-Center Trials

**Additional Information**



For more information on sponsor responsibilities when conducting multi-center trials, please see federal regulations found in [21 CFR 812 Subpart C-Responsibilities of Sponsors](#).

**Return to the Main Menu**

**Notes:**

For more information on sponsor responsibilities when conducting multi-center trials, please see federal regulations found in 21 CFR 812 Subpart C-Responsibilities of Sponsors by clicking on the provided link.

## 10. Financial Disclosure

### *10.1 Financial Disclosure*




# Financial Disclosure

**Notes:**

## 10.2 Learning Objectives

### Financial Disclosure



- ✓ Purpose of Financial Disclosure
- ✓ Definitions Pertaining to Financial Disclosure
- ✓ When Financial Disclosure Is Required
- ✓ Interests That Must Be Disclosed
- ✓ Responsible Parties

### Notes:

After completing this training module, the learner will understand the following:

- The purpose of financial disclosure;
- The definitions pertaining to financial disclosure;
- When financial disclosure is required;
- The interests that must be disclosed; and
- The responsible parties for financial disclosure.

### ***10.3 Purpose of Financial Disclosure***

A presentation slide titled "Financial Disclosure" with a sub-header "Purpose of Financial Disclosure". The slide features a background image of a calculator, a stethoscope, and a document with financial data. Two text boxes are overlaid on the image. The first box states: "Intended to eliminate bias and preserve the integrity of the data submitted in a marketing application". The second box states: "Information is used in the Agency's assessment of the reliability of the data." The slide also includes a small icon in the top right corner.

Financial Disclosure

## Purpose of Financial Disclosure

Intended to eliminate bias and preserve the integrity of the data submitted in a marketing application

Information is used in the Agency's assessment of the reliability of the data.

**Notes:**

Financial disclosure is intended to eliminate bias and preserve the integrity of the data submitted in a marketing application for a drug, biologic or device.

The FDA may consider clinical studies inadequate, and the data inadequate, if appropriate steps have not been taken to minimize the risk of financial bias.

Financial disclosure information is submitted in a marketing application and is used in the Agency's assessment of the reliability of the data.



## **10.4 Financial Disclosure Definitions Per 21 CFR 54**

Financial Disclosure

### **Financial Disclosure Definitions Per 21 CFR 54**

**Clinical Investigator** – Individual directly involved with treatment or evaluation of research subjects, including spouse and each dependent child

**Covered Clinical Study** – Any study relied upon to establish that the product is effective, or where a single investigator makes a significant contribution to the demonstration of safety, for a marketing application

**Sponsor** - Any party supporting a particular study at the time it was carried out

**Applicant** - The party who submits a marketing application to FDA for approval and is responsible for submitting financial disclosure statements

#### **Notes:**

The definitions pertaining to financial disclosure are found in Title 21 of the Code of Federal Regulations Part 54.

For the purpose of financial disclosure:

- A clinical investigator is an individual directly involved with treatment or evaluation of research subjects. The term clinical investigator also includes the spouse and each dependent child of the investigator, but it does not include those who provide ancillary or intermittent care that do not make direct and significant contributions to the data.
- A covered clinical study is any study relied upon to establish that the product is effective, or where a single investigator makes a significant contribution to the

demonstration of safety, for a marketing application.

- The sponsor of a covered clinical study is any party supporting a particular study at the time it was carried out. For example, if one party designed and conducted the covered clinical study, a second party provided funding, and a third party provided the test product, there would be three sponsors of the covered clinical study.
- An applicant is the party who submits a marketing application to FDA for approval and is responsible for submitting financial disclosure statements.

Please note that the financial disclosure definitions of clinical investigator and sponsor are broader than those found in the IND and IDE regulations.

### ***10.5 When Is Financial Disclosure Required?***



Financial Disclosure

## When Is Financial Disclosure Required?

Applicants who submit a marketing application are required to submit information concerning the compensation to, and financial interests and arrangements of, any clinical investigator conducting a covered clinical study.

- Any study relied upon to establish effectiveness
- Any study in which a single investigator makes a significant contribution to the demonstration of safety

## Training Modules on IDE Sponsor and Investigator Responsibilities (No Quiz)

### Notes:

Applicants who submit a marketing application are required to submit information concerning the compensation to, and financial interests and arrangements of, any clinical investigator conducting a covered clinical study.

As a reminder, a covered clinical study is any study submitted in a marketing application that is relied upon to establish effectiveness of the product or any study in which a single investigator makes a significant contribution to the demonstration of safety.

Covered clinical studies, in general, do not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies, large open safety studies conducted at multiple sites, and expanded access protocols. Non-commercial studies that are conducted for the purpose of publication and will not be submitted as part of a marketing application are also generally not considered covered clinical studies.

Please note that the definition of covered clinical studies does not distinguish between foreign and domestic clinical sites.

## 10.6 Financial Disclosure Responsibilities

A presentation slide titled "Financial Disclosure Responsibilities" with a dark blue header. The slide content is organized into three dark blue boxes with white text. The first box states the sponsor's responsibility to collect financial disclosure information. The second box states that each clinical investigator must provide sufficient and accurate financial information to the sponsor, with a bullet point requiring updates during the study and for one year after completion. The third box states the applicant's responsibility to report financial information to the FDA. The background of the slide shows a blurred image of a financial spreadsheet.

Financial Disclosure

### Financial Disclosure Responsibilities

Sponsor's responsibility to collect financial disclosure information

Each clinical investigator must provide sufficient and accurate financial information to the sponsor.

- Commit to promptly update this information if any relevant changes occur during the course of the study and for one year following the completion of the study.

Applicant's responsibility to report financial information to the FDA

### Notes:

It is the sponsor's responsibility to collect financial disclosure information from investigators for covered clinical studies that will be used for a marketing application.

Each clinical investigator must provide sufficient and accurate financial information to the sponsor and must commit to promptly update this information if any relevant changes occur during the course of the study and for one year following the completion of the study.

It is the applicant's responsibility to report financial information to the FDA when a marketing application is submitted. The applicant must submit certification that no clinical investigators of covered clinical studies had financial interests with the sponsor, or the applicant must submit a disclosure statement that describes the nature of the investigator's financial interests and the steps taken to minimize



bias.

### ***10.7 Financial Interests That Must Be Disclosed***

Financial Disclosure



## **Financial Interests That Must Be Disclosed**

- Any compensation by any sponsor in which the value of compensation is affected by study outcome
- Any proprietary interest in the tested product
- Any equity interest in any sponsor of the covered clinical study whose value cannot be readily determined through reference to public prices
- Any equity interest in any sponsor of the covered clinical study if that sponsor is a publicly held company and the interest exceeds \$50,000
- Significant payments of other sorts that have a cumulative monetary value of \$25,000 or more made to the investigator or the investigator's institution

#### **Notes:**

The financial interests and arrangements that must be disclosed by each clinical investigator of a covered clinical study are as follows:

- Any compensation by any sponsor in which the value of compensation is affected by study outcome,
- Any proprietary interest in the tested product,
- Any equity interest in any sponsor of the covered clinical study whose value cannot be readily determined through reference to public prices,
- Any equity interest in any sponsor of the covered clinical study if that sponsor is a publicly held company and the interest exceeds \$50,000, and
- Significant payments of other sorts that have a cumulative monetary value of

\$25,000 or more made to the investigator or the investigator's institution.

If a clinical investigator or their spouse or dependent child is a full or part-time employee of a sponsor of the covered clinical study, financial disclosure is not required.

### ***10.8 Additional Information***

Financial Disclosure

## Additional Information



For more information on financial disclosure, please see FDA's Guidance entitled ["Financial Disclosure by Clinical Investigators."](#)

[Return to the Main Menu](#)

**Notes:**

For more information on financial disclosure, please see FDA's Guidance entitled "Financial Disclosure by Clinical Investigators" by clicking on the provided link.

## 11. IDE Investigator Responsibilities

### *11.1 IDE Investigator Responsibilities*



**Notes:**

## 11.2 Learning Objectives

### IDE Investigator Responsibilities



- ✓ Role of an IDE Investigator
- ✓ General and Specific Responsibilities of an IDE Investigator
- ✓ Reports Required to Be Submitted by the Investigator
- ✓ Records That Must Be Maintained by the Investigator

### Notes:

After completing this training module, the learner will understand the following:

- The role of an IDE investigator;
- The general and specific responsibilities of an IDE investigator;
- The reports required to be submitted by the investigator; and
- The records that must be maintained by the investigator



### 11.3 Who Is an IDE Investigator?

The infographic features a dark blue header with the title 'IDE Investigator Responsibilities' and a sub-header 'Who Is an IDE Investigator?'. Below the header is a background image of a doctor in a white coat with a stethoscope. Overlaid on this image are three dark blue boxes, each representing a role and its responsibilities:

<u>IND Sponsor</u>	<u>IND Investigator</u>	<u>IND Sponsor-Investigator</u>
<b>Initiates</b> the clinical investigation	<b>Conducts</b> the clinical investigation	<b>Initiates and conducts</b> a clinical investigation

#### Notes:

The sponsor of an IDE is the individual, company, academic institution, or other organization that takes responsibility for and initiates the clinical investigation. The sponsor submits the IDE to the FDA, but the sponsor does not actually conduct the investigation - unless the sponsor is a sponsor-investigator.

The investigator is the individual who conducts the clinical investigation and under whose immediate direction the device is administered, dispensed, or used. In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. Other individual members of the team are known as subinvestigators.

If the same individual both initiates and conducts the investigation, that person is known as the sponsor-investigator. A sponsor-investigator takes responsibility for the investigation, and the investigational device is administered, dispensed, or

used under his or her direction.

### ***11.4 General Responsibilities of IND Investigators***

IDE Investigator Responsibilities

## General Responsibilities of Investigators

- Ensure that the investigation is conducted according to the signed investigator agreement, the investigational plan, and applicable FDA regulations.
- Protect the rights, safety, and welfare of subjects.
- Maintain control of the devices under investigation.
- Obtain informed consent.

#### **Notes:**

Investigators have general responsibilities that must be fulfilled when conducting a significant risk device study under an IDE. Investigators must ensure that the clinical investigation is conducted according to the signed investigator agreement, the investigational plan, and applicable FDA regulations. It is also the investigator's responsibility to protect the rights, safety and welfare of their subjects, maintain control of the devices under investigation, and obtain informed consent for each subject. Note that there may be exceptions to the requirement to obtain informed consent in emergency situations.

### ***11.5 Specific Responsibilities of Investigators***



The image is a presentation slide titled "IDE Investigator Responsibilities" with a subtitle "Specific Responsibilities of Investigators". The slide features a dark blue background with a medical-themed graphic on the right side, including a heart rate monitor, a stethoscope, and various medical icons. Four white text boxes are overlaid on the left side of the slide, each containing a specific responsibility. The text is as follows:

- Obtain IRB and FDA approval prior to initiating enrollment.
- Only allow an investigational device to be used with subjects under the investigator's supervision.
- Provide sufficient financial information as required by the sponsor.
- Return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.

#### **Notes:**

The regulations also require that investigators fulfill a number of specific responsibilities. An investigator must not initiate enrollment until the clinical investigation has been approved by both the Institutional Review Board, or IRB, and FDA.

The investigator must also only allow an investigational device to be used with subjects under the investigator's supervision and must not supply an investigational device to any person not authorized to receive it.

The investigator must provide sufficient financial information as required by the sponsor and promptly update this information if any relevant changes occur during the course of the investigation and for one year following the completion of the study. Please see the training module on financial disclosure to learn more. Upon completion or termination of a clinical investigation or at the sponsor's request, the investigator must return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.



## 11.6 Investigator Reports



The slide features a dark blue header with the text 'IDE Investigator Responsibilities' and a small icon of three vertical bars. Below the header, the title 'Investigator Reports' is displayed in a large, bold, white font. A list of six report types is shown in white text on dark blue rectangular backgrounds. The background of the slide is a close-up image of a blue stethoscope resting on a white medical chart with numerical data.

- Unanticipated Adverse Device Effects
- Withdrawal of IRB Approval
- Progress Reports (or Annual Reports)
- Deviations from the Investigation Plan
- Failure to Obtain Informed Consent
- Final Report

### Notes:

In addition to the responsibilities described on the previous slides, investigators are also responsible for preparing and submitting each report listed here to the IDE sponsor. The following slides will go into detail about the specific reporting obligations for each report.



## 11.7 Unanticipated Adverse Device Effects

IDE Investigator Responsibilities



### Unanticipated Adverse Device Effects

**The investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect.**

Unanticipated Adverse Device Effect:

- Any serious adverse effect on health or safety, any life-threatening problem, or death associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the current IDE application
- Any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects

**Timeline:** Send report as soon as possible, but in no event later than **10 working days** after the investigator first learns of the effect.

### Notes:

The investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation. An unanticipated adverse device effect is:

- Any serious adverse effect on health or safety, any life-threatening problem, or death associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the current IDE application; or
- Any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

This report should be submitted to the sponsor and to the reviewing IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

### ***11.8 Withdrawal of IRB Approval***

A presentation slide with a dark blue header. The header contains the text 'IDE Investigator Responsibilities' on the left and a small icon of three vertical bars on the right. Below the header, the title 'Withdrawal of IRB Approval' is displayed in large white font. The background of the slide is a photograph of a doctor in a white coat with a stethoscope, sitting at a desk and writing on a piece of paper. Two text boxes are overlaid on the image: a larger one in the middle and a smaller one below it, both with dark blue backgrounds and white text.

IDE Investigator Responsibilities

## Withdrawal of IRB Approval

The investigator must notify the sponsor of a withdrawal of IRB approval of the investigator's part of the clinical study.

**Timeline:** Send report within **5 working days** after receipt of the withdrawal of IRB approval.

**Notes:**

The investigator must also notify the sponsor of a withdrawal of IRB approval of the investigator's part of the clinical study.

This report should be sent to the sponsor within 5 working days after receipt of the withdrawal of IRB approval.

### ***11.9 Progress Reports (or Annual Reports)***

A presentation slide titled "IDE Investigator Responsibilities" with a sub-header "Progress Reports (or Annual Reports)". The background is a blurred image of a document with a pie chart. Two text boxes are overlaid on the slide. The first box states: "The investigator must submit progress reports to the sponsor, the monitor, and the reviewing IRB." The second box, labeled "Timeline:", states: "Send report at regular intervals but no less than yearly."

IDE Investigator Responsibilities

## Progress Reports (or Annual Reports)

The investigator must submit progress reports to the sponsor, the monitor, and the reviewing IRB.

**Timeline:** Send report at **regular intervals** but no less than **yearly**.

**Notes:**

The investigator must keep the sponsor, the monitor, and the reviewing IRB updated on the progress of the investigation through the submission of progress reports.

These reports should be submitted at regular intervals but no less than yearly.



### ***11.10 Deviations from the Investigational Plan***



IDE Investigator Responsibilities

## **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.

**Timeline:** Send report as soon as possible, but in no event later than **5 working days** after the emergency occurred.

#### **Notes:**

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.

This notice must be given as soon as possible, but in no event later than 5 working days after the emergency occurred.

Prior approval by the sponsor and IRB is required for any non-emergency changes or deviations from the investigational plan. If these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, the sponsor will also need to communicate these changes with FDA.



### ***11.11 Failure to Obtain Informed Consent***

IDE Investigator Responsibilities

## **Failure to Obtain Informed Consent**

The investigator must report any failure to obtain informed consent to the sponsor and the reviewing IRB.

**Timeline:** Send report within **5 working days** after the use occurred.

**Notes:**

If an investigator uses a device without first obtaining informed consent, the investigator must report this use to the sponsor and the reviewing IRB.

This report should be sent within 5 working days after the use occurred.

### **11.12 Final Report**

A presentation slide titled "IDE Investigator Responsibilities" with a sub-header "Final Report". The background is a blurred image of a document with a pie chart. Two text boxes are overlaid on the image. The first box states: "The investigator must submit a final report to the sponsor and the reviewing IRB." The second box, labeled "Timeline:", states: "Send report within 3 months after termination or completion."

IDE Investigator Responsibilities

## Final Report

The investigator must submit a final report to the sponsor and the reviewing IRB.

**Timeline:** Send report within **3 months** after termination or completion.

**Notes:**

When the clinical study is terminated or completed or when the investigator's part of the clinical study is terminated or completed, the investigator is required to submit a final report to the sponsor and the reviewing IRB.

This report should be sent within 3 months after termination or completion.

### ***11.13 Investigator Recordkeeping***

A graphic titled "IDE Investigator Responsibilities" with a sub-header "Investigator Recordkeeping". It states "Investigators must maintain the following records:" and lists five items: "All correspondence", "• Another investigator", "• Monitor", "• IDE sponsor", "• IRB", and "• FDA". The background shows a stack of colorful folders.

IDE Investigator Responsibilities

## Investigator Recordkeeping

Investigators must maintain the following records:

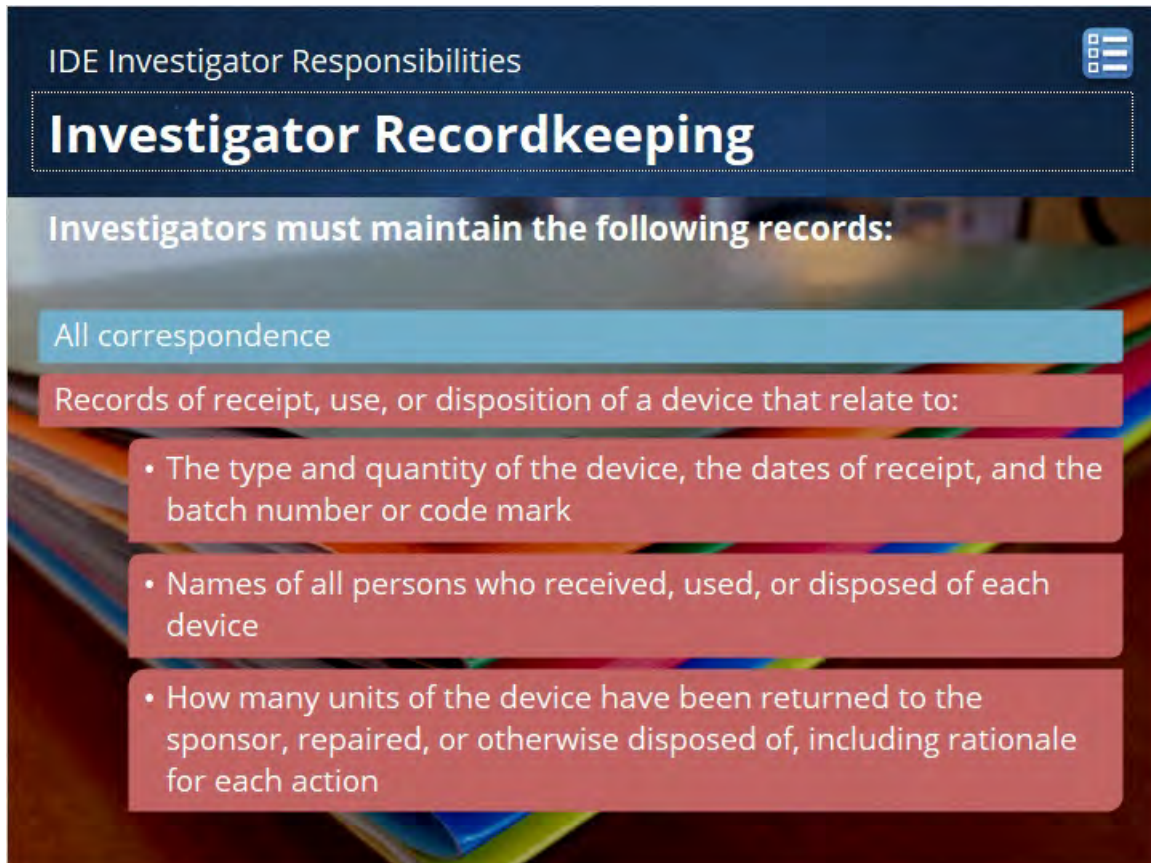
- All correspondence
  - Another investigator
  - Monitor
  - IDE sponsor
  - IRB
  - FDA

**Notes:**

The final responsibility of investigators is that of recordkeeping. Investigators are responsible for maintaining records relating to their participation in clinical studies conducted under an IDE. All investigators must maintain the following accurate, complete, and current records:

- All correspondence, including any required reports, with another investigator, a monitor, the IDE sponsor, an IRB, or FDA

### ***11.14 Investigator Recordkeeping***

A presentation slide titled "IDE Investigator Responsibilities" with a sub-header "Investigator Recordkeeping". The slide lists the records investigators must maintain. The background is a dark blue gradient with a faint image of a stack of colorful folders. A small icon of a document with three lines is in the top right corner.

IDE Investigator Responsibilities

## Investigator Recordkeeping

Investigators must maintain the following records:

- All correspondence
- Records of receipt, use, or disposition of a device that relate to:
  - The type and quantity of the device, the dates of receipt, and the batch number or code mark
  - Names of all persons who received, used, or disposed of each device
  - How many units of the device have been returned to the sponsor, repaired, or otherwise disposed of, including rationale for each action

**Notes:**

- Records of receipt, use, or disposition of a device that relate to (1) the type and quantity of the device, the dates of receipt, and the batch number or code mark; (2) the names of all persons who received, used, or disposed of each device; and (3) how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of, including rationale for each action.



### 11.15 Investigator Recordkeeping

A graphic titled "IDE Investigator Responsibilities" with a sub-header "Investigator Recordkeeping". It lists the records investigators must maintain. The background shows a stack of colorful folders.

IDE Investigator Responsibilities

## Investigator Recordkeeping

Investigators must maintain the following records:

- All correspondence
- Records of receipt, use, or disposition of a device
- Records of each subject's case history and exposure to the device
  - Documents verifying informed consent
  - All relevant observations, information, and data on the condition of each subject
  - Record of the exposure of each subject to the investigational device

#### Notes:

- Records of each subject's case history and exposure to the device, including the case report forms and supporting data. Examples of supporting data that should be maintained are progress notes of the physician, the individual's hospital charts, and the nurses' notes. These records should include:
  - Documents verifying that informed consent was obtained prior to participation in the study and, for any use of a device without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent;
  - All relevant observations, information, and data on the condition of each subject upon entering and during the investigation, including previous medical history and results of relevant diagnostic tests;
  - And a record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.

### ***11.16 Investigator Recordkeeping***

A presentation slide titled "IDE Investigator Responsibilities" with a sub-header "Investigator Recordkeeping". The slide lists four recordkeeping requirements: "All correspondence", "Records of receipt, use, or disposition of a device", "Records of each subject's case history and exposure to the device", and "Protocol with documents showing the dates of and reasons for each deviation". The background of the slide shows a stack of colorful folders.

IDE Investigator Responsibilities

## Investigator Recordkeeping


Investigators must maintain the following records:

- All correspondence
- Records of receipt, use, or disposition of a device
- Records of each subject's case history and exposure to the device
- Protocol with documents showing the dates of and reasons for each deviation

**Notes:**

- The protocol with documents showing the dates of and reasons for each deviation from the protocol

### ***11.17 Investigator Recordkeeping***

A presentation slide titled "IDE Investigator Responsibilities" with a sub-header "Investigator Recordkeeping". The slide lists five types of records that investigators must maintain. The background features a stack of colorful folders. A small icon of three vertical bars is in the top right corner.

IDE Investigator Responsibilities

## Investigator Recordkeeping

Investigators must maintain the following records:

- All correspondence
- Records of receipt, use, or disposition of a device
- Records of each subject's case history and exposure to the device
- Protocol with documents showing the dates of and reasons for each deviation
- Any other records that FDA requires by regulation

**Notes:**

- Lastly, any other records that FDA requires by regulation or by specific requirement for a category of investigations or a particular investigation should be maintained by all investigators.



### ***11.18 Additional Information***

IDE Investigator Responsibilities

## **Additional Information**



For more information on investigator responsibilities, please see FDA's Guidance entitled "[Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects.](#)"

**Return to the Main Menu**

**Notes:**

For more information on investigator responsibilities, please see FDA's Guidance entitled "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" by clicking on the provided link.



## 12. Course Completion

### 12.1 Course Completion



#### Notes:

Congratulations!

You have completed the Training Modules on IDE Sponsor and Investigator Responsibilities!

Click the Close Course button to close this course.

Click the Return to Main Menu button to return to the main menu and review any sections of this course.