IDE Development Process

Maintain the IDE

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

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

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

A UADE Report consists of a completed Form FDA 3500A and an analysis of the event in a cover letter, submitted to FDA and all reviewing IRBs and investigators within 10 working days after the sponsor first receives notice of the adverse effect.

Withdrawal of IRB approval
Submitted to FDA and all reviewing IRBs and participating investigators within 5 working days after receipt of notice of the withdrawal of IRB approval of an investigation (or any part of an investigation)

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

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

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

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

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

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

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

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

Recommended Links:

- IDE Definitions & Acronyms
- FDA.Gov IDE Reports

Last updated: 20 Mar 2019

IDE Templates, Education & Useful Links

Templates & Forms

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

Useful Links

- FDA Device Advice
- Amendments, Safety Reports & Annual Reports (FDA Guidance)
- Center for Devices & Radiological Health Documents
- Device Classification
- FAQs about IDEs
- IDE Policy
- IDE Required Elements
- Marketing Your Medical Device
- Sponsor's Responsibilities for Significant Risk Device Investigations
- FDA Guidance: Significant Risk and Nonsignificant Risk Medical Device Studies
- FDA Guidance: Frequently Asked Questions About Medical Devices

Last updated: 20 Mar 2019

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