



How to Put Together an IDE Application

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What is an IDE?

- The purpose of an IDE submission
- Different types of IDEs
- What an IDE does/does not permit
- When should manufacturers or physicians seek an IDE
- New eCopy requirement
- Pre-IDE submissions
- Recent IDE tracking improvements
- Clinical study requirements for FDAAA

“Investigational Device Exemption”

- An IDE is a **regulatory submission** that permits clinical investigation of devices.
- This investigation is **exempt** from some regulatory requirements.
- The name “Investigational Device Exemption” stems from this description in 21 CFR 812.1:

“An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device.”

Law ⇒ Regulation

Code of Federal Regulations (21 CFR):

- Part 812 - IDE Regulation
- Part 50 - Protection for Human Subjects, Informed Consent (IC) Regulation
- Part 54 – Financial Disclosure of Investigators
- Part 56 - Institutional Review Boards (IRBs) Regulation

Section 520(g) of the FD&C Act

Purpose of an IDE

To encourage discovery and development of useful medical devices for human use, to the extent consistent with the protection of the public health and safety and with ethical standards, while maintaining optimum freedom for scientific investigators in their pursuit of that purpose

Purpose of an IDE

An approved Investigational Device Exemption (IDE) allows:

- an investigational device to be used in a clinical study in order to collect S&E data required to support a Premarket Approval (PMA) application, a Humanitarian Device Exemption (HDE), or a Premarket Notification [510(k)] submission to FDA.
- a device to be shipped lawfully for the purpose of conducting investigations

Provisions of the IDE Regulation

- All clinical investigations subject to the regulation must be approved before they can begin
- Assigns responsibilities to all participants in clinical investigation
- All subjects in the investigation must give informed consent

Definitions

Investigational Device

- Is still in the developmental stage
- Object of a clinical investigation is to determine safety and efficacy
- Is not considered to be in commercial distribution

Investigational Use

- Clinical evaluation of an already legally marketed device for a new intended use

Different Types of IDEs

Traditional IDE Study

- Feasibility Study (Early or Traditional)
- Pivotal Study

Expanded Access

- Emergency Use
- Compassionate Use
- Treatment Use
- Continued Access

Approved IDEs are **EXEMPT** from:

- Misbranding
- Registration
- Performance Standards
- 510(k)
- PMA
- HDE
- Good Manufacturing Practices (GMPs)
- Color Additive requirements
- Banned Devices
- Restricted Device requirements

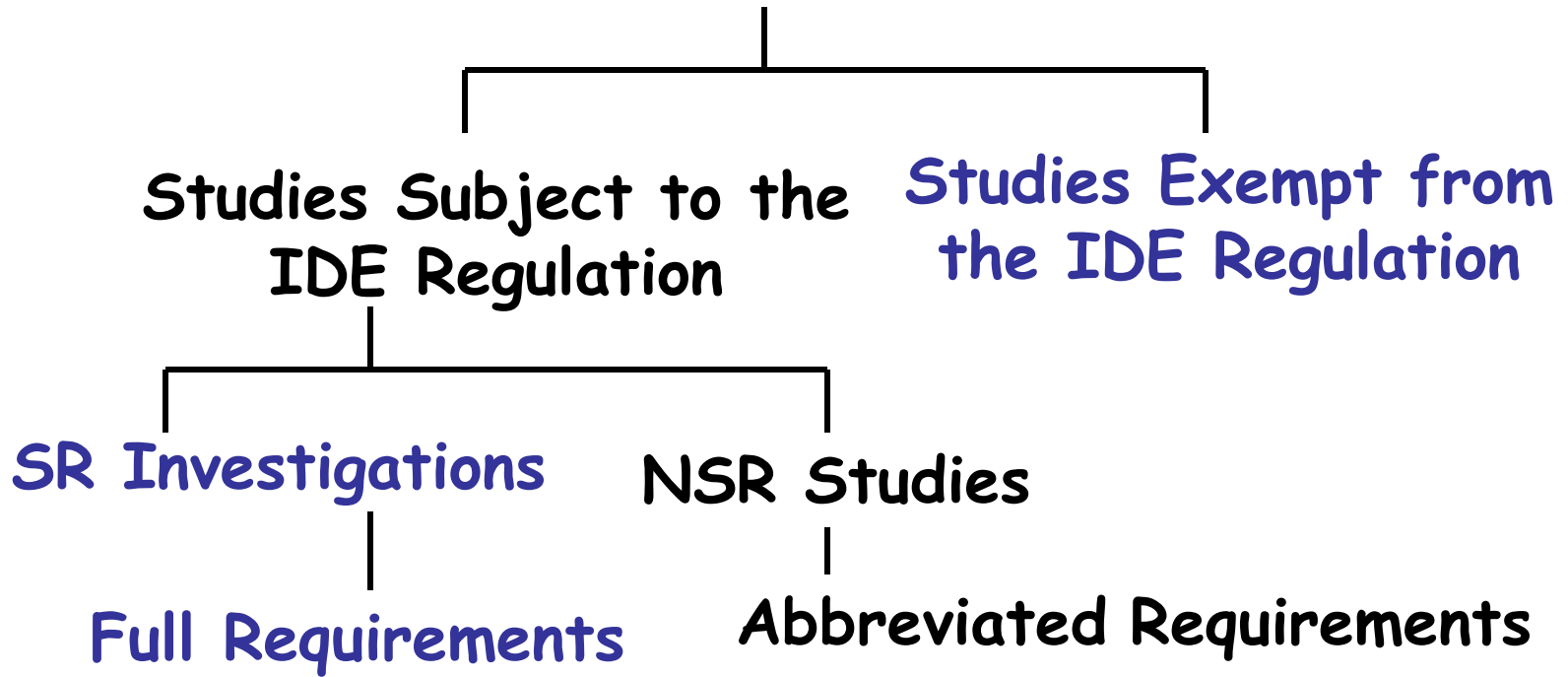
Approved IDEs are NOT EXEMPT from:

- Adulteration
- Labeling
- Prohibition on: promotion and/or marketing, commercialization, prolonging the investigation, representing the device as safe and effective
- Import/Export

Studies Subject to the Regulation

- To support marketing application [PMA, HDE or 510(k)]
- Collection of safety and effectiveness information (e.g., for a new intended use of a legally marketed device)
- Sponsor-investigator studies of unapproved devices or new intended use of approved device (even if no marketing application planned)

All Device Investigations



Studies Exempt from Need for IDE

- Preamendments (pre-1976) devices
- 510(k)-cleared or PMA-approved devices, if used in accordance with approved labeling
- ***In vitro*** diagnostic devices (most of the time)
- Consumer preference testing
- Combinations of legally marketed devices
- Custom devices (NARROWLY defined)

“Practice of Medicine”

“Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship....”

From Section 906 of the FD&C Act

“Practice of Medicine”

- Physician should:
 - **Be well informed about the product**
 - **Use firm scientific rationale and sound medical evidence**
 - **Maintain records on use and effects**
- IDE not required; institution may require IRB review/approval and informed consent
- Other prohibitions still apply

“Basic Physiological Research”

- Investigating a physiological principle
 - No intent to develop the device for marketing
 - Only using the device to address the research question
- ⇒ No IDE needed; IRB approval and informed consent should be obtained

If NOT Exempt from Device Regulation, then...

- Need to assess whether proposed study of device is considered **SIGNIFICANT RISK (SR)**, or **NONSIGNIFICANT RISK (NSR)**
- IRBs can and do make this assessment most of the time
- FDA can assist IRBs and/or investigators by making risk determinations; this determination is final
- See IRB Information Sheet on SR/NSR:
<http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/UCM118082.pdf>

Significant Risk (SR) Study

Presents a **potential serious risk** to the health, safety, and welfare of a subject and is:

- an implant; or
- used in supporting or sustaining human life; or
- of substantial importance in diagnosing, curing, mitigating, or treating disease or preventing impairment of human health

Significant Risk (SR) Study Examples

- Evaluation of a marketed biliary stent for use in the peripheral vasculature
- Evaluation of unapproved radiofrequency ablation device for treatment of primary hepatic neoplasia
- Extended wear contact lenses

Significant Risk IDEs

- Sponsor submits IDE application to FDA
- FDA approves, approves with conditions or disapproves IDE within 30 calendar days
- Sponsor obtains IRB approval
- After both FDA and IRB approve the investigation, study can begin

Non-Significant Risk IDEs

- Sponsor presents protocol to IRB and a statement why investigation does not pose significant risk
- If IRB approves the investigation as NSR, it can begin
- Abbreviated IDE requirements (labeling, IRB, consent, monitoring, reporting, prohibition on promotion)
- **No** IDE submission to FDA needed

Non-Significant Risk Study Examples

- Most functional MRI studies
- Study of non-invasive blood pressure measuring device
- Electroencephalography studies
- Studies of wound dressings
- Contact lens studies (daily wear only)

New eCopy Requirement

- In effect January 1, 2013
- Final guidance issued October 10, 2013
- Two paper copies and one eCopy should be submitted
- eCopy may consist of a compact disc (CD), digital video disc (DVD) or a flash drive
- Include statement that 'eCopy is exact duplicate of paper copies'
- Submission will remain on eCopy hold until resolved
- eCopy Program for Medical Device Submissions – Guidance for Industry and FDA Staff
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>
- **Questions?** Contact CDRH-eCopyinfo@fda.hhs.gov or 240-402-3717

Study Determination Inquiries

- If an IRB is uncertain whether a study is exempt, significant risk or nonsignificant risk, FDA will make a determination
- Submit an outline/draft protocol and details about the device(s) that are being investigated as a “Pre-IDE” submission.
- FDAs will issue a letter; the determination is binding on the study sponsor and IRBs.

The IDE Pre-Submission Program

Pre-IDE is appropriate:

- During testing or protocol development
- For NSR study protocols
- To determine whether a significant or non-significant risk device study
- For *in vitro* diagnostic device study protocols
- Study protocols to be conducted outside U.S. (OUS)
- Draft Guidance for Industry and FDA Staff Medical Devices: The Pre-Submission Program and Meetings with FDA Staff:
<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm310375.htm>

FDASIA Section 601 – Investigational Device Exemptions

- Specifically prohibits FDA from disapproving IDEs simply because the proposed study will not support a future marketing application
- Does not change the subject protection criteria necessary for approval of an IDE study
- IDE boilerplate letters have been revised
- FDA will continue communicating concerns related to use of study for future marketing submissions (“Study Design Considerations”)
 - Such concerns will not be the basis for a disapproval decision
 - Sponsor is encouraged, but is not required, to address these concerns
- Plan to re-issue draft guidance: *FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations*, issued November 10, 2011

Recent IDE Tracking Improvements

- System updated August 2013
- IDEs, EUAs and Pre-EUAs affected
- Submission hierarchy now mirrors that of PMAs and HDEs
- Permits better tracking of clinical trial development
- Now supplements, amendments and reports
- Please state submission reason, FDA letter to which responding (if appropriate), and related submission number in cover letter
- **If more than one submission reason, send them in separately**

Food and Drug Administration Amendments Act (FDAAA) TITLE VIII – CLINICAL TRIAL DATABASES

- Expanded ClinicalTrials.gov clinical trial registry to include devices, and added results database
- Implementation is primarily responsibility of NIH
- Information on how to register is available on the National Library of Medicine (NLM) Protocol Registration System (PRS) website (<http://prsinfo.clinicaltrials.gov/>)
- NIH Fact Sheet on Registration:
<http://prsinfo.clinicaltrials.gov/s801-fact-sheet.pdf>

Resources

- Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>

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

- Device Advice:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>

- CDRH Learn:

<http://www.fda.gov/Training/CDRHLearn/default.htm>

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Guidances, Information
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Information Sheet Guidances Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors

Background

Through FDA's new Information Sheet Guidance Initiative, these Information Sheets will be revised and updated as needed. The date of the most recent revision is listed next to the title. [Learn more about this initiative.](#)

Resources for You

- Federal Register Notice: Protection of Human Subjects
- A Self-evaluation Checklist for IRBs

General

- Frequently Asked Questions (1998)
- IRB Information Sheets--Research and Review (Updated 9/98) -- Cooperative Research (1998)
- Non-Local IRB Review (1998)
- IRB Information Sheets--Research and Review (Updated 9/98) (1998)
- Sponsor-Investigator-IRB Interrelationship

Medical Devices

Home > Medical Devices > Device Advice: Device Regulation and Guidance

Device Advice: Device Regulation and Guidance
Overview of Medical Device Regulation
How to Market Your Device
Postmarket Requirements (Medical Devices)
Compliance Activities (Medical Devices)
Medical Device Databases
Guidance Documents (Medical Devices)
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Reprocessing of Single-Use Devices
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Information for regulated industry on determining how to comply with the federal laws and regulations governing medical devices.

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Disclosure:

The presenters are FDA/CDRH staff and therefore, as employees, have claimed no interests, financial or otherwise, with medical device or radiation-emitting products that may be shown in any of the presentations.

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