LSU HEALTH COORDINATOR COMPETENCIES

PROTOCOL COMPLIANCE

Investigational Device Exemption (IDE) Sponsor and Investigator Responsibilities

Objectives

- Define Investigational Device Exemption (IDE), Sponsor, and Investigator
- Discuss the responsibilities of a Sponsor with an IDE
- Discuss the responsibilities of an Investigator using an Investigational Device with an IDE

What is an Investigational Device & an Investigational Device Exemption?

- An **investigational device** is a device that has not been cleared for marketing by the FDA. It is used in clinical studies in order to collect safety and effectiveness data.

- An **Investigational Device Exemption (IDE)** application permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act (FD&C Act) that would apply to devices in commercial distribution.

IDE Application

The FDA has a website designed for individuals from pharmaceutical companies, government agencies, academic institutions, private organizations or other organizations interested in bringing a new device to market.

In the IDE application, researchers must include:

- Report of prior investigations
- Investigational plan
- A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and installation of the device
- Information about the investigators, sites, and IRBs
- Amount charged for device

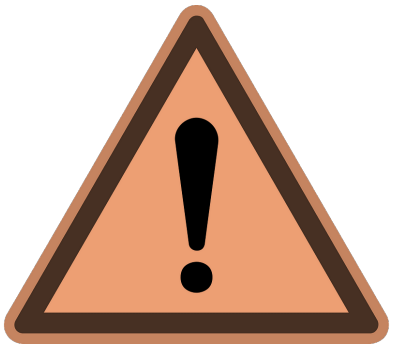
IDE Application Types

IDE	Abbreviated IDE	IDE Exempt
• Involves an Investigational Device; ***and***, • Used in clinical research investigation; ***and***, • Intended to design, cure, mitigate, treat, or prevent disease; ***and***, • Intended to affect the structure or function of the body; ***and***, • Device is deemed significant risk (SR)	• Involves an Investigational Device; ***and***, • Used in clinical research investigation; ***and***, • Intended to design, cure, mitigate, treat, or prevent disease; ***and***, • Intended to affect the structure or function of the body; ***and***, • Device is deemed non-significant risk (NSR)	• Involves a legally marketed device used in accordance with labeling; ***or***, • Diagnostic device that meets the requirements of §809.10(c); ***or***, • A device undergoing additional testing; ***or***, • A device intended solely for animal use

Classifications of Devices

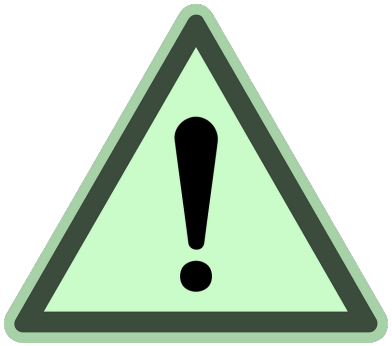
Significant Risk (SR):

- Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- For a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.



Non-Significant Risk (NSR):

- One that does not meet the definition of a significant risk device.



Other Important Terms

Sponsor: the person who takes responsibility for and initiates a clinical investigation.

Investigator: an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the device is administered or dispensed to a subject).

Sponsor-Investigator: assumes BOTH investigator and sponsor responsibilities.

Sponsor Responsibilities

General Responsibilities [21 CFR 812.40]

Sponsors are responsible for:

- Selecting qualified investigators;
- Providing them with the information they need to conduct an investigation properly;
- Ensuring proper monitoring of the investigation and IRB review and approval;
- Submitting an IDE application to the FDA for significant risk
- Ensuring that FDA and IRB are promptly informed of significant new information about the investigation.

Selecting Qualified Investigators

Selecting Investigators

The Sponsor shall select only Investigators qualified by training and experience as appropriate experts to study the investigational device.

Investigator Agreements must include:

- ✓ A Curriculum Vitae
- ✓ A statement of relevant experience
- ✓ A statement of the investigator's commitment to conduct the investigation in accordance with the Investigational Plan, the IDE and other federal regulations
- ✓ Financial disclosure information

Providing Investigators with Information Needed to Conduct an Investigation Properly

Provide each Investigator with:

- ✓ The currently-approved IRB Protocol
- ✓ Report of prior investigations of the Device
- ✓ Revised Investigator Brochure, reprints of published studies, reports or letters directed to Investigators, or other appropriate means.

Ensuring Proper Monitoring of the Investigation

Selecting Monitors

A Sponsor must appoint monitors who are qualified by training and experience to monitor the study, ensuring conduct in accordance with the IDE and applicable regulations

Monitoring Plan

- Securing compliance
- Evaluating and reporting unanticipated adverse device effects
- No resuming terminated studies

Obtaining IRB and Other Regulatory Body Approvals

A Sponsor cannot begin an investigation or any part of an investigation until an IRB and FDA have both approved the application or supplemental application.

Additional Responsibilities

- **Device Control**
  - Ship Investigational Devices only to qualified investigators
- **Sponsor Records**
  - Maintain accurate and complete records relating to the investigation
- **Sponsor Reports**
  - Provide reports in a timely manner to FDA, the IRB's, and/or the investigators.
- **Device Labeling**
  - Package device with a label including manufacturer information, quantity of contents, and investigational device statement

Investigator Responsibilities

IRB Initial and Ongoing Approval

- Assure an IRB is responsible for the initial and continuing review/approval of proposed study
- Make no changes to the study, except to eliminate immediate hazard, without IRB approval
- Promptly report all changes and unanticipated problems to the reviewing IRB

Informed Consent

- Obtain prospective informed consent of each subject
- Document collection of informed consent

Supervision of Device Use

- Use the investigational device only on research subjects who are under the Investigator's personal supervision
- Not supply the investigational device to any person who is not authorized to use or receive the device
- Ensure that the device is stored in a securely locked, substantially constructed cabinet or other enclosure; access to which is limited so as to prevent theft or diversion of the device into illegal channels of distribution.

Financial Disclosures

- The clinical investigator must disclose to the sponsor sufficient accurate financial information to allow the IDE applicant (or sponsor) to submit certification or disclosure of financial interests
- The investigator must update the information if any relevant changes occur during the course of the investigation and for one year following completion of the study.

Device Disposal

- Upon completion or termination of a clinical investigation or the investigator's part of the investigation or at the sponsor's request, an investigator must return to the sponsor any remaining supply of the device or dispose of the device as the sponsor directs
- The investigator should document the return or destruction of the device

Record Keeping

- All correspondence including required reports
- Records of receipt, use, or disposition of the investigational device
- Records of each subject's case history and exposure to the device
- All versions of the protocol and documentation of each deviation from the protocol
- Any other records required by a regulatory body

Investigator Reports

- **Investigator must provide the following reports as required:**
  - Unanticipated adverse device effects
  - Withdrawl of IRB approval
  - Progress reports
  - Deviations from the protocol
  - Failures to obtain informed consent
  - Final report

LSU Health Coordinator Competencies

- ✓ Onboarding
- ✓ Ethical Standards
- ✓ Protocol Compliance
- ❑ Informed Consent
- ❑ Patient Recruitment & Retention
- ❑ Management of Patients
- ❑ Documentation & Document Management
- ❑ Data Management & Information Technology
- ❑ Financial Stewardship
- ❑ Leadership & Professional Development