

Investigational Device Exemption (IDE) Overview

Marian Serge, RN

Division of Bioresearch Monitoring

Office of Compliance

Center for Devices and Radiological Health

FDA

Provisions of the IDE Regulation - 21 CFR 812

- Submission process of an IDE application to FDA for significant risk device studies
- Process for obtaining IDE for non-significant risk device studies
- Assigns responsibilities to sponsor and clinical investigator for the conduct of a clinical investigation
 - Investigator agreement
 - Reporting and records
 - IRB review and informed consent

Topics

- Medical device definition
- Significant risk (SR) device
- Nonsignificant risk (NSR) device
- IDE not required
- IDE required

Sponsors, clinical investigators, IRBs must know three basic things

- 1. Does the study involve a device?**
- 2. Is the device SR or NSR?**
- 3. Does it need an IDE?**

Question 1: What is a medical device?

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent . . .or component, part, or accessory. . . intended for dx of disease or condition or cure, mitigation, tx, or prevention of disease or affects the structure or function of the body.....and does not achieve primary purpose through chemical action. . . or being metabolized

Question 2: Is the device SR or NSR?

Significant Risk Device Definition at 812

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

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

Significant Risk Device IDEs

- Sponsor submits IDE application to FDA
- FDA approves or disapproves or
- FDA Conditionally approves means there are no safety concerns and the study can begin while deficiencies are being addressed
- After FDA approval and IRB approval study can begin

Non-significant risk device

- Any device that is not significant risk

Examples:

- carries removal solution
- contact lens, daily wear
- gastroenterology and urology endoscopes and/or accessories
- externally worn monitors for insulin reactions

Non-significant risk device IDEs

- Sponsor presents the IRB with
 - protocol & a brief explanation why the device is not a significant risk device
- If IRB determines the investigation is NSR and approves it
 - it is considered to have approved application for IDE
- No formal IDE submission to FDA

Quick summary SR and NSR device studies

- Significant risk device study
 - Requires FDA and IRB approval
- Non-significant risk device study
 - Requires IRB approval
- Need help deciding?
 - CDRH has procedures: see handout.
- Want to see FDA's decision letter?
 - Ask the sponsor.

**Does the device study
require an IDE?**

Is an Investigational Device Exemption (IDE) Needed?

- “No”

- Practice of medicine
- Basic physiological research
- Exempt studies [21 CFR 812.2(c)]

- “Yes”

- Studies that support research or marketing applications
- Results of an investigation to FDA
- Studies of new indications

Practice of Medicine (no IDE)

- Physician should
 - Be well informed about the product
 - Use firm scientific rationale and sound medical evidence
 - Maintain records on use and effects
- Not research but check Institutional policy: it may require IRB review and Informed Consent

Basic Physiological Research (no IDE)

- Investigating a physiological principle
 - No intent to develop the device for marketing
 - Only using the device to address the research question – not safety and effectiveness
- ⇒ IRB review and informed consent

Exempt Studies (exempt from 21 CFR 812) (no IDE)

- Description of exempt devices
[21 CFR 812.2(c)]
 - Approved devices used in accordance with labeling
 - Most in vitro diagnostic devices (IVDs)
 - Consumer preference testing, testing of a modification, testing of a combination of approved devices
 - FDA post approval studies
- ⇒ Compliance with Parts 50 (IC) and 56 (IRB) needed for an FDA-regulated study

Studies that support research or marketing (IDE needed)

- **Significant risk device research**
 - Submission of an Investigational Device Exemption (IDE) application to FDA
 - Follow all of 21 CFR 812
- **Non-significant risk device research**
 - IRB approval; after which the study is considered to have an IDE
 - Follow only 21 CFR 812.2(b)

Results of an investigation to FDA (IDE needed)

- Investigators should use caution when developing an investigation of a device
 - Ensure IDE is obtained if results will be submitted to FDA

Studies of new indications (IDE needed)

- New intended use of an approved device
 - Different age population
 - New disease or condition
 - Different body placement
 - Changing from ‘treatment’ to ‘prevention’ for the same disease
- Also, new materials or design used in approved devices

Where's the Line?

NO IDE

- Practice of Medicine
- Basic physiological research
- Exempt studies:
Studying a cleared/approved device w/in label

IDE

- Studies of investigational devices (support research & marketing applications)
- Studies of new indication

Summary

- Medical device definition
- Significant risk (SR) device
- Nonsignificant risk (NSR) device
- IDE not required
- IDE required

Contact Information and Websites

- **IDE/HDE Staff**

- Sheila.Brown@fda.hhs.gov
- Stephen Rhodes, Director

- **Websites:**

- www.fda.gov/oc/ohrt/irbs/offlabel.html
- www.fda.gov/oc/ohrt/irbs/devices.html#risk
- www.fda.gov/cdrh/ode/blue-ide-d01-1.html
- www.fda.gov/cdrh/ode/idepolicy.html
- www.fda.gov/cdrh/ode/hdeinfo.html