

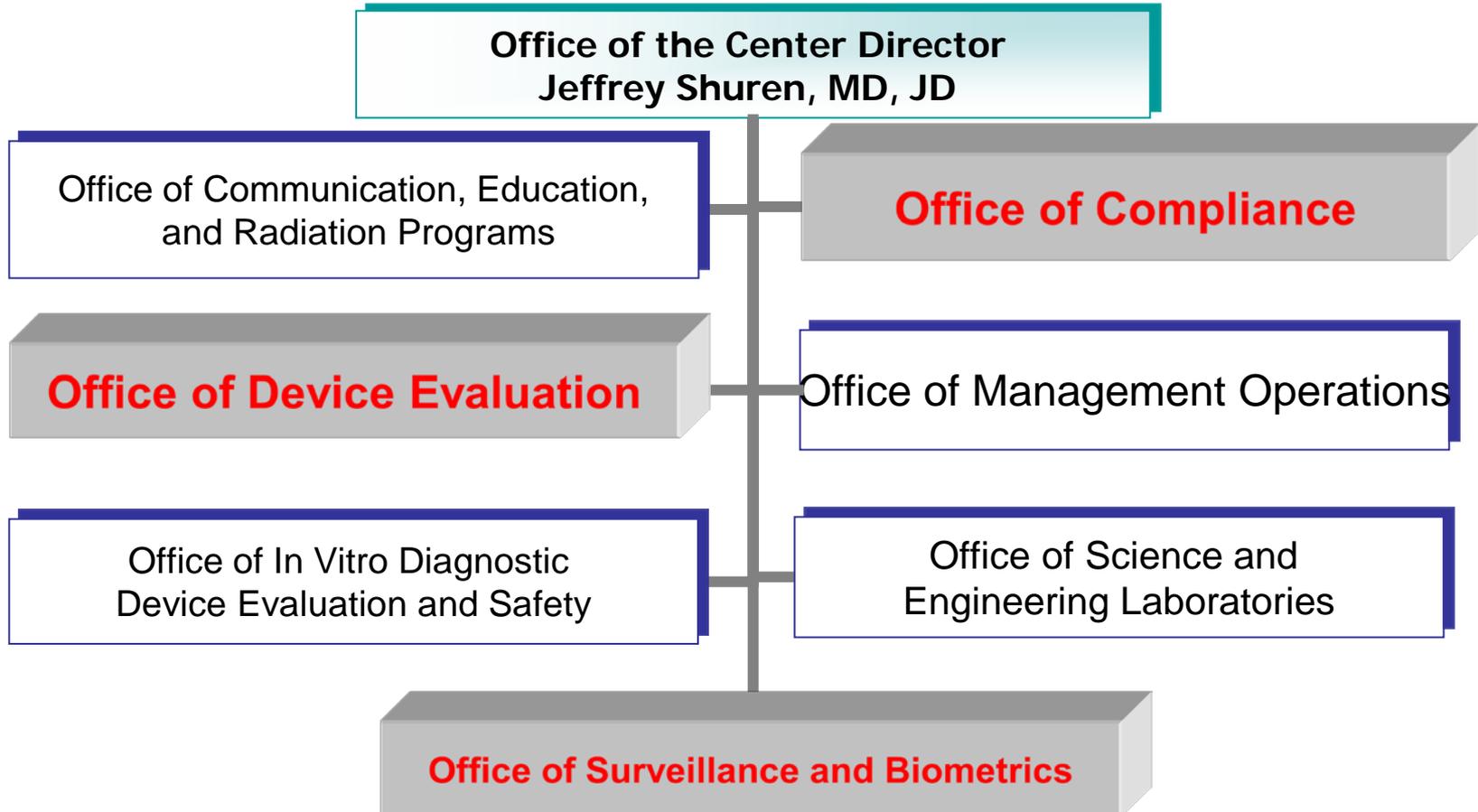


# **The End of Your Search for Information on FDA's IDE Regulations**

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# CDRH Organization



# IDE Primer Outline

- The purpose of an IDE submission
- What an IDE does/does not permit
- Significant Risk determination
- Stages of clinical development for IDEs
- PIDS Form
- Roles of IRBs





# Law $\Rightarrow$ 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

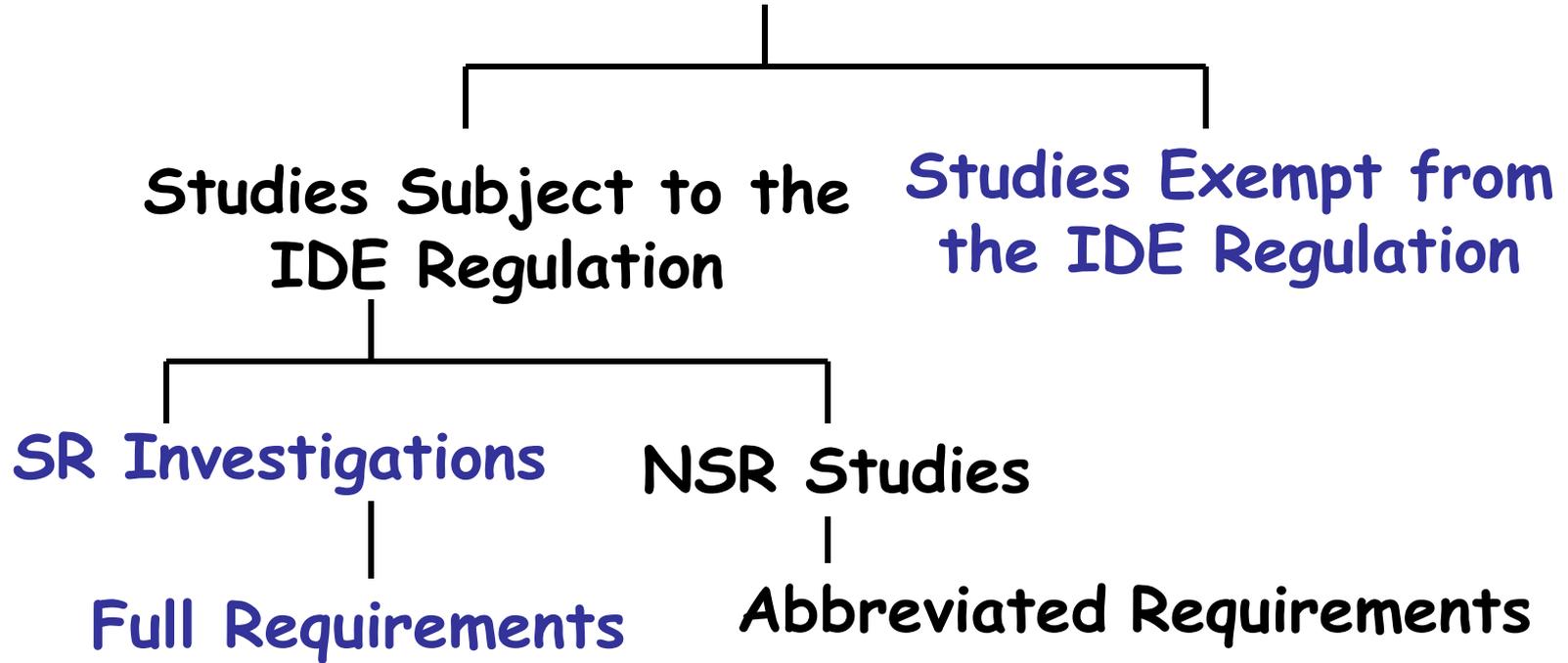
- All clinical investigations subject to the regulation must be **approved** before they can begin
- **Assigns responsibilities** to all participants in clinical investigation
- All subjects in the investigation must give **informed consent**



# 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** or **basic physiological research**

# 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

Example: **extended wear** contact lens

# Significant Risk IDEs

- Sponsor submits IDE application to FDA
- FDA **approves, conditionally approves 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

Example: **daily wear** contact lens

# Stages of Clinical Development for IDEs

For new medical devices, as well as for significant changes to marketed devices:

- **First-in-Man Studies**
- **Pilot Studies**
- **Pivotal Trials**
- **Randomized Controlled Trials**



# First-in-Man Studies

- Risk assessment
- Informed consent
- Study design
  - Staggered entry
  - Flexibility to allow procedural evolution
- Stopping criteria
  - Predefined
  - Independent safety oversight – need for ability to rapidly terminate enrollment in studies if safety issues arise followed by careful reassessment

# Pilot Studies

- Prior to conduct of larger studies
- Designed to provide information for future studies
  - Patient selection criteria
  - Dosing schedules
  - Surgical approach
  - Pre- and post-operative best practices

# Pivotal Trials

- Multicenter studies
- Design expertise needed
- Best design in the context of providing information to guide decision-making should be pursued

# Randomized Controlled Trials

- More likely to inform and much less likely to mislead, has become gold standard for judging whether a new therapy does more good than harm
- Some questions on therapy do not require RCTs



# Pivotal IDE Descriptive Summary (PIDS) Form

The screenshot shows a web browser window displaying the FDA website. The page title is "Investigational Device Exemption (IDE) - Pivotal IDE Description Summary Form". The page content includes a navigation menu, a search bar, and a main heading "Investigational Device Exemption (IDE) - Pivotal IDE Description Summary Form". Below the heading, there is a paragraph explaining that an IDE allows an investigational device to be used in a clinical study to collect safety and effectiveness data. The page also includes a section for "Additional Information" with a link to the "Pivotal IDE Descriptive Summary Form (PDF - 572KB)".

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### Investigational Device Exemption (IDE) - Pivotal IDE Description Summary Form

An investigational device exemption (IDE) allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data to support a Premarket Approval (PMA) application or a Premarket Notification (510[k]) submission to FDA. Data included in a PMA or 510(k) are often generated from a substantive, or pivotal, clinical trial conducted to support the safety and effectiveness of a medical device.

The Pivotal IDE Descriptive Summary form is completed by FDA reviewers as part of the IDE review process for pivotal trials to provide an accessible summary of the major trial design elements. This Summary serves as a tool to move FDA closer to our goal of rigorously-designed pivotal studies that will be better able to answer essential questions of safety and effectiveness during the review of marketing applications. The information in this Summary also assists FDA reviewers in maintaining consistency, where appropriate, across clinical trials for devices similar in design and/or intended use.

Under the CDRH Transparency Initiative, FDA is making available for the first time a sample copy of this form so that investigators and others are aware of the key elements of clinical trial design that FDA evaluates in a pivotal IDE application.

#### Additional Information

- [Pivotal IDE Descriptive Summary Form \(PDF - 572KB\)](#)  
Persons using assistive technology may not be able to fully access information on this page. For assistance, please call 888-INFO-FDA.

[http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparenc  
y/ucm205697.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparenc/y/ucm205697.htm)

# Pivotal IDE Descriptive Summary (PIDS) Form

- Background
- Study Design
- Safety
- Effectiveness
- Statistics
- Future Concerns

The screenshot shows a web browser window displaying the Pivotal IDE Descriptive Summary form. The browser address bar shows the URL: [http://erom.fda.gov/eRoomReqFiles/CDRH/CDRHInvestmentonaDeviceExemptionIDEProgram/0\\_1f17b/PIDsv1.20.pdf](http://erom.fda.gov/eRoomReqFiles/CDRH/CDRHInvestmentonaDeviceExemptionIDEProgram/0_1f17b/PIDsv1.20.pdf). The form is titled "Pivotal IDE Descriptive Summary" and is part of the FDA's Center for Devices and Radiological Health. It is divided into three main sections: I. ADMINISTRATIVE, II. BACKGROUND, and III. STUDY DESIGN. Each section contains various input fields for user information, study details, and design parameters.

**I. ADMINISTRATIVE**

Subject IDE #:  Supplement #:

Lead Reviewer:  Division:  Branch:

Clinical Reviewer:  Decision:

Statistical Reviewer:  Premarket Submission:

**II. BACKGROUND**

Sponsor:  Study Title:

Device:  ProCode(s):

Device Description:

Indications for Use:

Keyword(s): Provide search terms for this and similar IDEs. (e.g. device type, medical condition, etc.)

**III. STUDY DESIGN**

Sample Size:  Anticipated Study Duration (months):

Number of Sites:  Duration of Patient Consent (months):

Number of Study Arms:  Length of Follow-up (months):

Type of Control:  OUS Data?  Yes  No

Control Arm:  Randomized?  Yes  No

# IRB Responsibilities

- Determine **jurisdiction**
  - FDA, NIH, “basic physiologic research”
- Determine the **risk**
  - Minimal risk (expedited IRB procedures)
  - NSR or SR (unless FDA has already decided)
- **Review** study
  - Approve, approve w/modifications, table pending additional information, disapprove

# IRB Responsibilities

- Review **informed consent**
  - For SR device trials, FDA has reviewed for compliance w/section 50.25
- Review **study changes & adverse events**; do continuing review
- **Submit reports** to sponsor & FDA

# 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>



## Questions/Comments

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