LSU HEALTH COORDINATOR COMPETENCIES

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PROTOCOL COMPLIANCE

# Investigational New Drug (IND) Sponsor and Investigator Responsibilities

# Objectives

- Define Investigational New Drug (IND), Sponsor, and Investigator
- Discuss the responsibilities of a Sponsor with an IND
- Discuss the responsibilities of an Investigator using an IND

# What is an Investigational New Drug?

- An Investigational New Drug (IND) is a drug or biological that has not been approved for general use by the FDA. It is used in a clinical trial to investigate its safety and efficacy.
- The term also includes biological products that are used in vitro for diagnostic purposes.
- An IND application is a request for authorization from the FDA to administer an investigational drug or biological product to humans.

# IND 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 drug to market.

In the IND application, researchers must include:

- Animal study data and toxicity data
- Manufacturing information
- Clinical protocols (study plans) for studies to be conducted
- Data from any prior human research
- Information about the investigator

# Three Types of INDs

**Research IND**: study of an unapproved drug, an approved product for a new indication, or an approved product on a new patient population

**Emergency Use IND**: allows for use of an unapproved drug in an emergency situation that does not allow time for submission of an IND or when a patient does not meet inclusion criteria for an approved research IND

**Treatment IND**: submitted for experimental drugs that show promise in clinical testing for serious or immediately life-threatening conditions (*usually approved towards the end of a clinical trial*)

# 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 drug is administered or dispensed to a subject).

**Sponsor-Investigator:** assumes BOTH investigator and sponsor responsibilities.

# Sponsor Responsibilities

# General Responsibilities [21 CFR 312.50]

**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(s);
- Ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND;
- Maintaining an effective IND with respect to the investigations; and,
- Ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug.

# Selecting Qualified Investigators

**Selecting Investigators**

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

**Obtaining Information from the Investigator**

- ✓ A signed Investigator's Statement (i.e., FDA Form 1572)
- ✓ A Curriculum Vitae or other statement of the qualifications of the Investigator that includes the education, training, and experience
- ✓ Sufficient accurate financial information to allow the sponsor to submit complete and accurate certification or disclosure statements required under 21 CFR 54.

# Providing Investigators with Information Needed to Conduct an Investigation Properly

**Provide each Investigator with:**

- ✓ The Investigator's Brochure
- ✓ The currently-approved IRB Protocol
- ✓ Revised Investigator Brochure, reprints of published studies, reports or letters directed to Investigators, or other appropriate means.
- ✓ IND Safety Reports

# Ensuring Proper Monitoring of the Investigation

**Investigator Compliance**

A Sponsor who discovers that an Investigator is not complying with the obligations shall promptly either secure compliance or discontinue supplying the investigational drug to the Investigator and end the Investigator's participation in the clinical study.

**Proper Monitoring of the progress and conduct of the clinical investigation(s) at each of the involved study sites**

- Ensure the investigation is conducted in accordance with the IND application
- Comply with GCP guidelines for Sponsors

# Maintaining an Effective IND with Respect to the Investigations

**The Sponsor shall:**

- ✓ Review and evaluate evidence relating to the safety and effectiveness of the investigational drug as it is being obtained from the Investigator(s).
- ✓ Submit written IND Safety Reports to the FDA and participating Investigators.
- ✓ Submit Annual Reports to the FDA.

# Ensuring that FDA and Investigators are Promptly Informed of Significant New Adverse Effects or Risks

If it is determined that the investigational drug presents an unreasonable and significant risk to human subjects, the Sponsor shall

- ✓ Discontinue the clinical studies that present the risk as soon as possible (no later than 5 days)
- ✓ Notify the FDA
- ✓ Notify all involved institutional review boards (IRBs)
- ✓ Notify all Investigators who have, at any time, participated in clinical studies of the drug.

If a clinical study is discontinued, the Sponsor shall require that involved Investigators dispose of or return the investigational drug to the Sponsor.

# Additional Responsibilities

- **Record-keeping and record retention**
  - Investigational drug accountability (shipment, receipt, other disposition)
  - Retaining all records and reports for the life of the study plus 2 years after marketing application approval
- **Disposition of unused supplies of the investigational drug**
  - Ensure all unused supplies are returned or destroyed
- **Inspection of records and reports**
  - FDA Inspections
  - Other Regulatory Bodies

# Investigator Responsibilities

# General Responsibilities [21 CFR 312.60]

**Investigators are responsible for:**

- Ensuring that the clinical study is being conducted according to the terms of the signed Investigator's Statement (FDA Form 1572), the investigational plan, and the FDA regulations governing INDs
- Comply with Good Clinical Practice (GCP) guidelines for clinical safety
- Protecting the rights, safety, and welfare of research subjects
- Controlling access to, and use of, the drug/biologic under investigation

# Protecting the Rights, Safety, and Welfare of Research Subjects

**IRB Review**

- 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

**Consent of Human Subjects**

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

# Control of the Investigational Drug

**Investigators shall**

- Administer the investigational drug only to research subjects who are under the Investigator's personal supervision
- Not supply the investigational drug to any person who is not authorized to receive the drug
- Ensure that the drug 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 drug into illegal channels of distribution.

# Additional Responsibilities

- **Reporting**
  - Financial Interest Disclosure reports
  - Progress reports
  - Safety reports
  - Final reports
- **Record-keeping and record retention**
  - Record disposition of the investigational drug
  - Return all unused supplies
  - Prepare and maintain case histories
  - Retain all records and reports for the life of the study plus 2 years after marketing application approval
- **Inspection of Records and Reports**

# 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