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Sponsor-investigator responsibilities IND

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SPONSOR-INVESTIGATOR RESPONSIBILITIES IND

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The Three R's

- Reporting to the FDA
- Record Retention
- Responsibilities-both as a sponsor and as an investigator

The Sponsor and The Investigator

- Sponsor means a person who takes responsibility for and initiates a clinical investigation.
- Investigator means an individual who actually conducts the research (drug administered under their immediate direction)
  - If there is a team, the Investigator is the responsible leader
  - Sub-investigator includes any other member of the team

Sponsor-Investigator

- An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed.
- The requirements described in 21 CFR Part 312 for sponsor and investigator both apply to this individual.

Reporting

- New protocols
- Changes in the protocol
- New investigator
- Information amendments
- IND safety/adverse event reports
- Annual reports
- Withdrawing the IND
- Discontinuation of investigation
- Financial diclosure

Record Keeping/Retention

- Drug accountability
- Financial interests
- Case Histories

Responsibilities: The Sponsor

- **General responsibilities:**
  - selecting qualified investigators and providing them with the information they need to conduct an investigation properly.
  - ensuring proper monitoring of the investigation.
  - ensuring that the investigation is conducted in accordance with the general investigational plan and protocols contained in the IND.
  - maintaining an effective IND with respect to the investigations.
  - ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug.

Responsibilities: The Sponsor

- **Responsible for the selection and monitoring of investigators**
  - selecting qualified investigators and monitors.
  - ensuring that the study drug is shipped only to participating investigators.
  - informing co-investigators of new observations with regard to the investigational drug and progress of the study.
  - reviewing on-going investigations, including assuring compliance of all investigators with the protocol, reviewing and evaluating safety and efficacy data of the investigational drug, and discontinuing studies that are deemed to pose an unreasonable and significant risk to subjects.

Responsibilities: The Sponsor

- Other responsibilities:
  - Record keeping and record retention
  - Inspection of sponsor records and reports
  - Disposition of unused supply of investigational drug

Responsibilities: The Investigator

- **General responsibilities of investigators**:
  - ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations.
  - protecting the rights, safety, and welfare of subjects under the investigator's care
  - ensuring the control of drugs under investigation.

Responsibilities: The Investigator

- Other responsibilities:
  - Control of the investigational drug
  - Investigator record keeping and retention
  - Investigator reports
  - Inspection of sponsor-investigator reports and records
  - Handling of controlled substance

Statement of the Investigator

Investigator Assurance: HRPO

- Additional references:
- FDA Form1572 – Statement of Investigator
- FDA Form 3454 – Certification: Financial Interests and Arrangements of Clinical Investigators
- FDA Form 3455 – Disclosure: Financial Interests and Arrangements of Clinical Investigators
- Clinical Research Forms Library
- HRPO Investigator Assurance of Commitment to Responsible Research