

## ***Sponsor-Investigator Requirements***

A sponsor-investigator is the holder of the Investigational New Drug (IND) and assumes all sponsor responsibilities required by the Food and Drug Administration (FDA). In addition, the sponsor-investigator is also an investigator and is responsible for conducting the study according to the FDA regulations.

## ***Definitions***

*Investigational New Drug (IND)* is a new drug or biologic used in a clinical investigation.

*IND application* is a request for authorization to administer an investigational drug or biologic to humans or a marketed drug in an investigational drug or biologic to humans or a marketed drug in a new indication and/or patient population.

*Sponsor* is an individual, company, academic institution, or other organization that takes responsibility for and initiates a clinical investigation. The sponsor is not the “funding organization” by FDA definitions.

*Investigator* is an individual under whose immediate direction a drug is administered or dispensed.

*Sponsor-Investigator* is an individual who both initiates and conducts an investigation. The requirements and responsibilities under this role include both those applicable to the investigator and the sponsor.

## ***Responsibilities of IND Investigators***

Under FDA regulations and guidance, investigators (and investigator-sponsors) are responsible for the conduct of the study and for leading the team of individuals conducting the study. Their responsibilities include the following:

- Ensuring informed consent of each subject is obtained
- Ensuring the investigation is conducted according to the investigational plan
- Personally conducting or supervising the investigation
- Protecting the rights, safety, and welfare of participants
- Preparing and maintaining adequate, current, and complete case histories or records
- Retaining records for two years following the date the marketing application is approved or withdrawn
- Furnishing the required reports to the sponsor, including reports of adverse events and study completion
- Providing timely reports to the Institutional Review Board (IRB), including reports of changes in the research activity needed to avoid immediate hazards to participants, unanticipated problems involving risks to participants or others, including adverse events to the extent required by the IRB
- Ensuring that changes are not implemented without prospective IRB approval, unless required to eliminate immediate hazard to participants
- Complying with the requirements of the Controlled Substances Act

## Sponsor Investigator Responsibilities

- Complying with all FDA test article requirements
- Adequately maintaining control of test articles, including appropriate tracking documentation for test articles to the extent that such control and documentation are not centrally administered
- Supervising the use and disposition of the test article
- Disclosing relevant financial information
- Ensuring that all associates, colleagues, and employees assisting in the conduct of the investigation(s) are informed about their obligations in meeting the above commitments.

### ***FDA Responsibilities of Sponsor-Investigators Acting as the Sponsor***

The traditional **sponsor** (a pharmaceutical, biotech, or medical device company) takes responsibility for initiating the clinical investigation, and holding the IND or Investigational Device Exemption (IDE), but does not usually conduct the investigation. However, it is important to note that an individual or group of individuals or medical center can also be considered a **sponsor** for an investigation if they hold the IND or IDE. These studies are typically called investigator-initiated studies that use an investigational drug or device or use an approved drug or device for investigational purposes.

- Submit necessary amendments/supplements to FDA
- Select qualified investigators at other institutions for multi-site trials
- Ensure that FDA and all participating investigators are promptly informed of significant new adverse effects or risks
- Provide information to other investigators and study staff to ensure that the study is performed properly
- Maintain adequate records
- Maintain proper control of the study drug/device
- Ensure proper monitoring of the study
- Ensure the study is performed in accordance with the general investigational plan and protocol

### ***ClinicalTrials.gov Requirements (see Title 21 CFR 50.25 (c))***

When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act.

“A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

### ***IRB Requirements***

Prior to approving a protocol that involves a sponsor-investigator, the IRB must be satisfied that the sponsor-investigator is knowledgeable about his/her responsibilities and has adequate policies and procedures in place to comply with the FDA regulatory requirements.

## ***Regulations***

21 CFR §312

- Contains procedures and requirements governing the use of investigational new drugs
- Applies to all clinical investigations of products that are subject to section 505 of the FD&C Act

21 CFR §11 Electronic Records, Electronic Signatures

21 CFR §50 FDA (21 CFR) Protection of Human Subjects

21 CFR §54 Financial Disclosure by Clinical Investigators

21 CFR §56 Institutional Review Boards Institutional Review Boards

21 CFR §58 Good Laboratory Practices

21 CFR §211, §810 Good Manufacturing Practices

21 CFR §1271 Good Tissue Practices

## ***Investigational Application***

21 CFR §312 IND Drugs and Biologics Drugs and Biologics

21 CFR §812 IDE Devices 21 CFR §809

## ***IVD In Vitro Diagnostics Marketing Application***

21 CFR §601 BLA Biologics

21 CFR §314 NDA Drugs

21 CFR §814 PMA Devices

## ***Federally Funded***

45 CFR §46 (DHHS) Protection of Human Subjects