THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

Sponsor Investigator Responsibilities

Sponsor-Investigator Requirements
A sponsor-investigator is the holder of the IND and assumes all sponsor responsibilities required by the FDA of the sponsor. 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 part include bot those applicable to the investigator and the sponsor.

Responsibilities of IND Investigators
Under FDA regulations and guidance, investigators (and investigator-sponsor) 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- Retaining records for two years following the date the marketing application is approved or withdrawn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 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
- Complying with all FDA test article requirements

Sponsor Investigator Responsibilities

- 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 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 ~~g~~ 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.

Sponsor Investigator Responsibilities

Regulations

21 CFR §312

- Contains procedures and requirements governing the use of investigational new drugs
- Applies to all clinical investigations of products that are 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