8.1 RESPONSIBILITIES FOR BIOMEDICAL RESEARCH

Biomedical research involving the investigational use of test articles is subject to FDA regulations. A test article is any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act. FDA regulations also describe additional requirements for investigations involving the use of approved drugs, biologics, or devices in a manner that differs from the specifications under which the article was originally approved.

Clinical investigations involving test articles must comply with the FDA regulations outlined in 21 CFR 50 and reviewed in concordance with 21 CFR 56. A clinical investigation is an experiment that involves a test article and one or more human subjects. The terms research, clinical research, clinical trial, clinical study, study, and clinical investigation are deemed synonymous for the purposes of this chapter.

In addition, the FDA has issued numerous information sheets that provide further guidance on FDA requirements for conducting clinical trials and provide answers to frequently asked questions. The FDA information sheets can be accessed on the FDA website - Guidance Documents (Including Information Sheets) and Notices.

i. Investigators

An Investigator is an individual who conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals; the investigator is the responsible leader of the team.

Investigators have responsibilities that include:

- Conducting the study in accordance with Good Clinical Practice, the protocol as outlined and approved by the IRB, and all applicable FDA regulations; and follow Institutional responsibilities outlined in Section 5: Investigator Responsibilities of this Policies and Procedures Manual;
- Ensuring that the informed consent of each subject is obtained (and retained in study files);
- Personally conducting or supervising the investigation;
- Protecting the rights, safety, and welfare of subjects;
- Ensuring adequate medical care for the study subjects;
- Obtaining necessary approvals from the IRB;
- Maintaining and retaining drug disposition and subject case history records
- Providing written reports to the IRB as required (e.g. reports of unanticipated problems that place subjects or others and risk of harm);
- Ensuring changes are not implemented without prospective IRB/FDA approval (unless the change is required to prevent immediate harm);
- Furnishing Progress Reports and Safety Reports; and
- Ensuring all study personnel are informed of their obligations.

ii. Sponsors

Sponsor is a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation (i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual). A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

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 within the FDA application, including maintenance of the an effective applications 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.

The full responsibilities of Sponsors of clinical investigations involving test articles can be found at 21 CFR 312 (drugs/biologics) and 21 CFR 812 (devices).

iii. Sponsor-Investigators

Sponsor-Investigator is an individual who both initiates and conducts a clinical investigation, and under whose immediate direction the test article is administered or dispensed. Similarly, if the investigator initiates a study to test a commercially available drug for a new indication, the investigator is generally considered a Sponsor-Investigator.

Responsibilities of Sponsor-Investigators (in addition to the general responsibilities of investigators above) include:

- Filing and updating the test article paperwork with the FDA;
- Selecting participating sites and investigators;
- Ensuring proper manufacture, labeling and control of the test article and disposition of unused supply of investigational drug;
- Developing and implementing plans for monitoring study conduct;
- Reporting of adverse events and adverse device effects in accordance with FDA regulations;
- Keeping participating investigators, reviewing IRBs, and the FDA informed of new findings, reports of problems related to the research, new information affecting risks to subjects, and other relevant information related to the conduct of the ongoing research;
- Filing reports of study progress with the FDA at least annually and upon study closure; and
- Determining whether the study needs to be registered on the clinicaltrials.gov website.