This is an overview of the Food and Drug Administration (FDA) sponsor requirements contained in 21 CFR 312 for research with Investigational New Drugs (INDs). Other FDA regulations for sponsors include, but are not limited to, 21 CFR Parts 11, 54, 210, and 211. Please review the federal regulations before performing any sponsor’s duties. If you are the sponsor and the investigator for the drug, you must meet the requirements for the sponsor and the investigator. Additional information can be found on the FDA’s web site: http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr312_00.html

**Major Responsibilities of Sponsors with IND Studies**

- Submits an IND application form 1571 and other required documents to FDA. (21 CFR 312.23)
- Labels the investigational drug in accordance with FDA regulations. (21 CFR 312.6)
- Promotes and distributes the drug in accordance with FDA regulations. (21 CFR 312.7)

**21 CFR 312.53-55:**

- Selects qualified investigators based on training and experience.
- Ships investigational drugs only to investigator(s) participating in the investigation.
- Obtains FDA Form 1572 from the investigator(s).
- Obtains a written statement that the investigator(s) will conduct the study as outlined in the protocol.
- Obtains relevant financial information from the investigator(s). (21 CFR 312.54)
- Selects a qualified monitor to oversee the progress of the investigation.
- Complies with FDA regulations regarding emergency use. (21 CFR 312.54)
- Keeps investigator(s) informed on the safety and effectiveness of the drug. (21 CFR 312.55)
21 CFR 312.56:
- Monitors the progress of all IND investigations.
- Terminates investigator(s) participation when investigator(s) fails to follow protocol.
- Reviews and evaluates the evidence relating to the safety and effectiveness of the drug as it is obtained from each investigator(s).
- Discontinues the study if the investigational drug presents an unreasonable and significant risk to subjects.
- Notifies the FDA, IRB, and the investigator(s) if the study is discontinued.
- Sends safety reports to FDA. (21 CFR 312.32)

21 CFR 312.57:
- Maintains adequate records showing the receipt, shipment, or other disposition of the investigational drug.
- Maintains complete and accurate records of payments made to clinical investigator(s).
- Assures that investigator(s) return all unused investigational drugs. (21 CFR 312.59)

21 CFR 312.62:
- Requires investigator(s) to maintain adequate drug records.
- Requires investigator(s) to keep case histories on each individual administered the investigational drug or employed as a control in the investigation.
- Requires investigator(s) to meet local IRB requirements. (21 CFR 312.66)
- Collects reports (financial, progress, safety, and final report) from investigator(s). (21 CFR 312.64)
- Requires investigator(s) to store the investigational drug in a secure area. (21 CFR 312.69)