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Subject: **FDA Sponsor Requirements for Investigators Who are Serving as Sponsors of Investigational Drug or Biologic Studies**

SPONSOR REQUIREMENTS

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)