

## **Investigator Responsibilities for Drug Studies**

An investigator will provide a plan to control for the investigational drug proposed in the research study to the IRB (i.e. how it will be stored, controlled, and dispensed so that only qualified investigators and the participants may use the investigational drug.)

An investigator shall administer the drug only to participants under the investigator's personal supervision or under the supervision of a subinvestigator responsible to the investigator.

The investigator shall not supply the investigational drug to any person not authorized under this part to receive it.

An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by participants.

If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 21 CFR §312.59.

If the investigational drug is subject to the Controlled Substances Act, the investigator shall take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

Investigational drugs may be dispensed by the Investigator in an out-patient setting or designated prescriber (i.e., drug samples), and all related documentation must be completed as required by the study. The Sponsor may recommend that the investigational drug go through an investigational pharmacy, and this is encouraged by the IRB. Depending on safety issues, the IRB may determine that the drug will need to be given in a specific setting (e.g., GCRC setting).