



Investigator Responsibilities for Handling, Inventory, and Disposing of Devices



The responsibilities for investigators conducting investigations on devices are analogous to those for investigators conducting studies on drugs. Generally, the investigator is responsible for ensuring that an investigation is conducted according to the signed written agreement, the investigational plan and applicable FDA regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for control of the devices under investigation.

- An investigator must conduct the investigation in accordance with the signed agreement with the sponsor, the investigational plan, any applicable FDA regulations, particularly those on investigational devices, and any conditions of approval imposed by an IRB or FDA.
- An investigator must permit an investigational device to be used only with subjects under the investigator's supervision. An investigator must not supply an investigational device to any person unauthorized under the regulations to receive it.
- Upon completion or termination of a clinical investigation or the investigator's part of the investigation, or at the sponsor's request, an investigator shall return to the sponsor any remaining supply of the device or dispose of the device in accordance with the sponsor's directions (21 CFR §812.110).

In addition, the regulations require participating investigators to discharge obligations with regard to documentation of device use. In particular, the FDA regulations list the following record keeping obligations:

Records.

- (a) Investigators records. Participating investigators must maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:
 - (1) All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.
 - (2) Records of receipt, use, or disposition of a device that relates to (see sample [FOR238](#)):
 - a. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
 - b. The names of all persons who received, used, or disposed of each device.
 - c. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.