

Investigational Device Storage and Control Guidelines and Considerations¹

Purpose: This document is intended to guide research teams on important considerations and best practices regarding receipt, storage, use, and disposition of investigational devices during a study to assure smooth study conduct, valid handling of the investigational devices, and compliance with applicable regulations and guidelines. These best practices also apply to all clinical research, whether or not the research falls under IDE regulations or other regulatory regimes.

Audience/User: Clinical Investigators, study coordinators, and others engaged in research involving investigational devices

Details: General considerations, applicable to all interventional clinical research studies, are presented in Section 1 of the document.

Additional detailed suggestions and guidance are provided in Section 2 of the document.

1. Considerations and Principles

1.1 Investigator responsibilities

For IDE studies, unless otherwise specified, the Principal Investigator is responsible for managing and documenting all of the following: ordering, receiving, and tracking inventory; storing, using, and returning investigational devices properly; and, where necessary, labeling of the investigational device prior to its use according to protocol guidelines and good manufacturing practices (GMPs), if applicable. If any of these responsibilities are delegated to another member of the study team, the Investigator is responsible for monitoring that individual's activities to ensure all requirements are being met. All personnel involved in the process must complete online CITI training as required by Children's Research Institute (CRI) policies and procedures.

1.2 Accountability definition and principles

Investigational device accountability is the process of documenting all aspects of the receipt, storage, use, and disposition of the investigational device so that a full accounting of each unit can be made.

- All investigational devices supplied for a protocol must be accounted for and tracked in a manual or electronic accountability log for the study. Accountability of the investigational device must be documented from the time of initial receipt through use on patients and final disposal of leftover investigational devices. The accountability log should indicate the date, amounts, serial/batch numbers, and conditions at receipt for all materials received from the supplier.
- Each time an investigational device is used, the occurrence should be thoroughly documented in the accountability log. The accountability log

should be unique to a study and should indicate the date, serial/batch number, and expiration date of each device. A copy of the device package (front description) should also be placed in the patient/research binder.

- At study completion, remaining investigational devices should be returned or destroyed as dictated by the protocol, specific Investigator instructions, or other documented instructions. The balance returned or sent for destruction should be recorded in the study's accountability log.
- Quality assurance reviews/inspections of the investigational device accountability documentation may be performed at intervals during a study by a clinical monitor. Similar document reviews may be conducted at any time by an auditor.

1.3 Initial planning and ordering of the investigational device

It is important to communicate early with the investigational device supplier to ensure that the product is delivered in time for planned study start. Sufficient quantities should be obtained to cover all possible study enrollment scenarios and should further allow for accidental loss of, damage to, or destruction of devices during the course of the study. If the product is not being donated, provisions should be made to ensure the budget can cover costs for this larger quantity of investigational devices.

2. Operational Guidelines

2.1 Investigational device ordering and receipt

Investigational devices may be ordered from the supplier, distributor, or manufacturer by the Principal Investigator, study coordinator, or other member of the study team, as designated by the Investigator.

Arrangements should be made between the investigational device supplier and the study site to determine the most appropriate time and place for study product delivery, particularly for products requiring special storage conditions. Additional considerations apply for shipments made from locations outside the United States.

Upon receipt of the investigational device, the Investigator or designee should ensure that the information on the packing slip matches the study product received. The shipping package receipt (or label located inside the box) should be retained and filed. At a minimum, the recipient should verify the following, where applicable:

- Product identification
- Amount of product received
- Serial/batch numbers
- Expiration dates

- Physical product is in good condition
- Maintenance of proper storage conditions

Evidence of breakage, compromised storage, or product tampering should be reported to the supplier immediately, and the investigational device should be quarantined and maintained under the correct storage conditions until further instructions are given.

Accountability: Enter the amount received, serial/batch numbers, expiration dates, date received, and condition of the investigational devices into the study's accountability log. Keep copies of shipping inventories and packing slips with the accountability records.

Note: Investigational devices must not be used on study participants until they are properly inventoried, the quality is verified, and proper authorization has been received that the enrollment process can begin.

2.2 Investigational device storage

Investigational devices should be stored in a limited-access location and according to instructions received from the supplier, distributor, or manufacturer. Proper storage conditions should address the temperature, light, moisture, ventilation, and sanitation needs of the investigational device. A log of key environmental conditions should be kept to document that required conditions were maintained during the entire storage timeframe.

Investigational devices that are to be shipped offsite for a protocol must be packaged in containers that maintain the proper storage conditions during transport. Maintenance of proper storage conditions during transport should be documented if possible. Chain of custody documentation should also be maintained for the transport, handling, and receipt of investigational devices.

If storage conditions have been compromised, or if there is any suspicion that the investigational device has not been stored properly:

- Quarantine the investigational device.
- Maintain the investigational device under the correct storage conditions until further notice.
- Contact the supplier, distributor, or manufacturer immediately, providing the protocol number, the protocol name, description of the type of violation, and the length of storage violation time.
- Document the occurrence and the action taken per supplier, distributor, or manufacturer input (e.g., return to the manufacturer, onsite destruction).

2.3 Investigational device requisition and use

The investigational device should be maintained under the control of the Principal Investigator or designee at all times until it is used for an enrolled trial participant. A mechanism must be established to ensure that the investigational device is used only upon the order of the Principal Investigator or a licensed clinician directly responsible to the Investigator.

The Principal Investigator should ensure that there is a current IRB-approved version of the protocol, product information package, and, when applicable, Investigator's Brochure on file for reference, and that the protocol is followed when using the investigational device. Additionally, the Principal Investigator should receive and have on file all protocol amendments, study-specific manuals of procedures (SOPs), and study-related correspondence, as applicable.

Accountability: The Investigator or designee should record in the study's accountability log the date of use, participant number, and serial/batch number of the investigational device being used.

The Investigator or designee should also document the serial/batch number of the investigational device and date/time of its use for an identified study participant in the case report form (CRF) for that participant.

2.4 Investigational device disposition

At the end of a study, the Principal Investigator or designee should ensure that leftover investigational devices are either destroyed with appropriate documentation thereof, the investigational device is donated as agreed to with the manufacturer (for marketed products only), or returned properly to the supplier, distributor, or manufacturer from where it came. Devices should be stored and shipped to the appropriate individual under conditions suitable to the product.

Accountability: The Investigator or designee should record in the study's accountability log the amount destroyed/donated/returned, serial/batch numbers, expiration dates, and condition of the devices.

¹Adapted from the National Center for Complementary and Alternative Medicine (NCCAM) Study Product Guidelines and Considerations