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1. Overview

Purpose

The purpose of this guidance document is to describe the process for receipt, storage, dispensing/administration, transport, and accountability of study drugs and devices, also considered investigational product (IP), at the study site from the time of receipt through final removal or authorized destruction, in accordance with all applicable regulations. Investigational products generally fall under the oversight of the FDA.

2. Definitions

Humanitarian Use Device (HUD) – a medical device intended to diagnose, treat, or mitigate a disease or condition that affects or is manifested in no more than 8,000 individuals in the United States per year, and does not serve a purpose of disease prevention.

Investigational Product (IP) – a therapeutic, preventative, diagnostic, or palliative product (e.g., a drug, biologic, diagnostic assay, device, vaccine) that is being tested or used as a reference in clinical research, either for the first time or for a new indication.

3. Receipt of Shipped Drugs and Devices

Upon receipt of study drugs and devices at the clinical site, delegated personnel must:

- Verify the contents of the shipment against the packing list and study protocol, ensuring that the correct drug/device, quantity, and (if applicable) dosage and formulation have been received. If shipping contents contain a shipping temperature range indicator, information from this device must be documented on the shipping record as being within limits or above/below limits and reported according to the protocol.
- Confirm that drugs/devices are within an appropriate expiration date.
- Ensure the integrity and condition of the products. Any discrepancies (e.g., damaged goods, damaged seals, or missing items) should be immediately reported to the sponsor and documented in the accountability log.
- Record the receipt of each study drug/device in the accountability log, including:
    - Name/description of the drug/device
    - Batch/lot number
    - Quantity received
    - Date of receipt
    - Expiration date
    - Any special handling or storage conditions required

4. Drug/Device Storage

4.1 Drug Storage

Study drugs must be stored in a secure area with restricted access limited to essential research personnel with the delegated responsibility of IP management, and under conditions appropriate for the product as specified in the protocol.

Drugs must be stored at the appropriate temperature, and the temperature of the drug storage area must be monitored and recorded at routine intervals as per protocol. The temperature record contains the acceptable temperature range for that storage area.

If the temperature is found to be outside the required range, the drug must be moved to an appropriately monitored environment until the temperature range can be restored. This movement and the temperature excursion must be documented. Additionally, the sponsor must be notified of any temperature excursions outside the required range. Follow the sponsor/manufacturer's guidelines for product use, quarantine, and/or destruction.

4.2 Device Storage

Devices must be stored in a secure area, locked cabinet or room, with restricted access limited to essential research personnel with the delegated responsibility of IP management, and under conditions appropriate for the product as specified in the protocol.

5. Training

5.1 Investigational Drug Training

The investigator must ensure that personnel delegated study-related activities, including investigational product administration are appropriately qualified and adequately informed about relevant aspects of the protocol, the investigational product(s) and their assigned study activities. Study-related training and product-specific training to personnel assisting in the study should correspond to what is necessary to fulfill the delegated activities.

5.2 Investigational Device Training

All personnel involved in the use, handling, or administration of an investigational device must receive appropriate training prior to participation in the study, in accordance with FDA regulations [21 CFR 812.43(c)(4) and 21 CFR 812.100].

Investigators are responsible for ensuring that all study staff are adequately trained on the proper use of the investigational device, including its intended use, potential risks, handling requirements, storage conditions, and procedures for reporting adverse events or malfunctions.

Documentation of this training must be maintained as part of the study records and must be available for review upon request by the sponsor, IRB, or regulatory authorities. No individual may use or administer the investigational device without documented evidence of having completed the required training.

For Humanitarian Use Devices (HUDs), the sponsor is responsible for ensuring that all investigators and applicable study personnel are adequately trained on the use of the device prior to initiation of clinical use.

Training must include, at a minimum:

- Proper use, storage, and handling of the device
- Potential risks and benefits
- Protocol-specific procedures and requirements

- Device accountability and documentation expectations
- The site must obtain and retain documentation of all sponsor-provided training. This documentation must be maintained in the study regulatory binder and made available for review by the IRB, FDA, or other regulatory authorities upon request.
    - No investigational or HUD device may be used by study personnel until all required training has been completed and documented.

6. Drug/Device Dispensing and Administration

6.1 Drug/Device Dispensing

Dispensing of study drugs and devices must be completed according to protocol by delegated personnel. Delegated personnel prepare the drug or device for dispensing and document applicable details. The individual who removes the drug or device from the storage area must fill and sign the appropriate drug or device accountability log documenting dispensation of the drug or device.

Study drugs and devices must be labeled as per protocol and may include:

- Participant study number
- Participant initials
- Study name/Protocol number
- Name of investigator
- Expiration date
- Directions for use
- Include the statement "for investigational use only"
    - Investigational drugs or biologics falling under the FDA purview must be labeled with the statement "*Caution: New Drug--Limited by Federal (or United States) law to investigational use*" per 21 CFR 312.6.
    - Investigational devices falling under the FDA purview must be labeled with the statement "*CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use*" per 21 CFR 812.5.

6.2 Expiration of Investigational Product

In accordance with FDA regulations (21 CFR 312.6 and 312.62), the use of expired investigational drug is strictly prohibited. All investigational products must be monitored routinely for expiration status, and any expired product must be promptly identified, clearly labeled as expired, and segregated from active inventory to prevent accidental use. Expired product must be managed in accordance with sponsor instructions, including return or documented destruction, with full accountability records maintained. In the event of a drug shortage or potential lack of available product, expired investigational drug must not be used as a substitute. The sponsor or manufacturer must be contacted immediately to determine appropriate next steps before any further use of the investigational product is considered.

6.3 Directed administration by participant

Study coordinator or delegated personnel dispenses the study drug/device to the participant and instructs the participant how and when to use the product and how to record dosing. Dispensation must be recorded in the drug or device accountability log.

Participants are provided with an adequate supply of the product until the next study visit.

For study drugs, a pill count is completed at designated study visits or as per protocol to assess participant compliance. Any discrepancies must be recorded on the drug accountability log and source records, and all unused product should be collected and stored per protocol upon return.

6.4 In-office administration by personnel

Investigational products are administered to the participant by delegated personnel as outlined in the study protocol.

Personnel must record the time and date of use as well as signature, in the participant's study record, and complete the drug/device accountability log.

7. Transport of Drugs and Devices

When IP needs to be transported to an alternate location, considerations should be made for proper transport and storage, e.g., using a cooler with ice packs for product requiring refrigeration, if applicable. Follow sponsor requirements for IP storage and transport. Document the transport and storage appropriately by documenting the date, time, participant ID number, temperature (if required), and alternate storage location.

8. Return and Destruction of Drugs/Devices

Ensure all study drug or device accountability records are maintained and available for inspection or close-out.

If the sponsor requests the return of study drugs or devices, the study monitor, delegated site personnel, or pharmacist must package and return the items. A return receipt for the drug or device is then requested from the sponsor.

Study drugs or devices that are not returned to the sponsor must be destroyed according to protocol, regulations, and sponsor and institutional requirements and documented accordingly.

9. Documentation and Record Retention

Documentation must be retained throughout the trial and after closure for the duration required by applicable regulatory standards and institutional requirements.

10. Responsibilities

10.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, and monitoring. For inquiries regarding these procedures, please contact the

Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

10.2 Principal Investigator Responsibilities

The PI retains overall responsibility for the study and delegating study tasks as appropriate. The PI is accountable for appropriate management of study drugs and devices and their receipt, storage, and dispensation and administration. The PI is responsible for ensuring that study personnel are properly trained on drug and device accountability procedures and all delegated tasks, as applicable and in accordance with the sponsor, protocol, applicable regulations and institutional requirements. In addition, the PI is responsible for the requirements as described in ORI-002 Procedures for Principal Investigator Eligibility and Responsibilities and HRP-070 Investigator Responsibilities.

11. Resources

- ICH E6 R2 Guidance for Industry Good Clinical Practice
- ICH E6 R3 Guidance for Industry Good Clinical Practice
- 21 CFR 312.6 Labeling of an Investigational New Drug
- 21 CFR 812.5 Labeling of Investigational Devices
- ORI-622 Drug Accountability Log
- ORI-622 Device Accountability Log

12. Revision and Workgroup Members

12.1 Revision

Version 001/Effective Date 04/29/2026: Original Document – Investigational Drug and Device Accountability

12.2 Workgroup & Advisory Members

The Office for Research and Innovation appreciate the following individuals who served as Workgroup and Advisory Members:

Workgroup & Advisory Members	
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