

GUIDANCE: Drug accountability

Policy: Investigators must maintain that investigational drugs are used only in approved clinical trials and under the direction of appropriate members of the research team.

Key Terms

Clinical Investigation: Any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. An experiment is any use of a drug/product/agent except for the use of a marketed drug in the course of medical practice.

Dispense: to prepare, package, compound, or label, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order.

Administer: to directly apply a prescription drug to the body of a patient by any means, including injection, inhalation, or ingestion, by: (A) a person authorized by law to administer the drug, including a practitioner or an authorized agent under a practitioner's supervision; or (B) the patient at the direction of a practitioner.

Investigational new drug: New drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are synonymous.

Investigation: A clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a drug.

Sponsor-Investigator: Individual who initiates and conducts an investigation and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual.

General Responsibilities: It is the responsibility of the Principal Investigator (PI) at the site of a clinical trial to ensure accurate and complete accountability and proper storage of investigational drugs/products used in a clinical trial.

For studies conducted under an Investigational New Drug (IND) application, FDA regulations charge investigators with the following responsibilities:

1. Document the receipt, use and disposition of all investigational agents including dates, quantity and use by subjects.
 - a. Required documentation for receipt of product:
 - i. Protocol title/number
 - ii. Name of Investigator
 - iii. Product delivery information: date of deliver, quantity received, expiration date(s), lot number(s) or batch number(s)
 - iv. Shipping records
 - v. Inventory list of product at the site
 - vi. Temperature log of drugs storage
 - b. Required documentation for Dispensing/Return of product:

- i. Protocol title/number
 - ii. Name of investigator
 - iii. Dose(s) provided to each subject, in accordance with the protocol
 - iv. Date dispensed
 - v. Amount used by each patient since last dispensed (Date/time used by subject if administered at site)
 - vi. Quantity of medications returned to the pharmacy
 - vii. Amount and date of returned product to the sponsor.
2. 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 CRF 312.59.
3. Ensure investigational drugs are stored in a secure location as specified by the sponsor (Journal of Clinical Research Best Practices, vol.6, No. 10, October 2010).
4. Ensure the investigational drug is given only to those persons authorized under the protocol to receive it. The drug, agent or biologic may only be used in subjects under the investigator's personal supervision or under the supervision of physicians who are directly responsible to the investigator.

The investigator may designate this responsibility and all of the investigator's duties for investigational product accountability at the trial site(s) to an appropriate pharmacist or another designee who is under the supervision of the investigator/institution.

The PI and/or designee must make sure that the sponsor has the correct shipping address of the site to ship investigational products.

Accountability: Upon receiving investigational products from the study sponsor, the Investigator or designee will ensure that information on packaging slip matches exactly with what the site has received. The investigator or designee should also check the number of investigational products, lot numbers, batch numbers etc. It is good practice to update the device accountability log with relevant information immediately.

If there is a discrepancy, the sponsor or supplier of the product should be contacted as soon as possible. The research team should not attempt to re-label or tamper with the product label without prior approval from the study sponsor.

Copies of shipping inventory and packing slips should be maintained in the regulatory binder, along with an updated Drug Accountability log, The PI and/or designee should provide access to study monitors to assess investigational product accountability during monitoring visits.

Storage: Investigational product should be stored in a secure/locked environment with access provided only to key study personnel who have the appropriate authorization. Store all investigational products separately, by protocol. Store all investigational product according to the manufacturer's recommendations (either located in the protocol or package insert). Ensure that the investigational product is stored at required temperature and maintain area temperature log. If the investigational product is blinded, every effort should be made not to break the blind except in the case of an emergency or a protocol-defined situation.

Dispensing: It is the investigator's responsibility to ensure that the study drug is used only for study subjects under PI's personal supervision or under the supervision of a properly trained sub-Investigator. A Study Subject Investigational Product Dispensing Form should be used for each subject including visit number, date, lot number, and the amount dispensed, returned, and lost by each study subject.

Immediately record shipments received, drugs dispensed, and drugs returned on the Drug Accountability log. Open and inspect contents of shipment to verify condition upon receipt of drug shipment. Compare invoice or packing slip to contents by lot number, dosage, and quantity. Report any discrepancies to the sponsor immediately, if applicable.

Study Drug Accountability Log should be updated every time a drug or device is dispensed or returned.

During routine study monitoring visits and the study closeout visit, the Monitor will verify that investigational product documentation has been accurate and complete throughout the study.

Disposal: Document any investigational inventory that has to be wasted (i.e. mixing errors, broken or cored vials). Should the sponsor require that partially filled vials are saved; they are to be stored in a separate location from the investigational drug supply.

Upon completion or termination of the study or investigators part of the study or at the sponsor's request, an investigator must return to the sponsor any remaining supply of the investigational product obtained for the specific purpose for a research study. Contact Environmental Health and Safety at 713-500-8100 (www.uthouston.edu/safety) for disposal of non-sponsored investigational product.

Only with the written authorization of the sponsor (and in compliance with the Federal Regulations and institutional policies) the investigator can discard the drug at site or retain the drug.

Applicable Regulations and Guidelines

- Occupations Code Chapter 551, General provisions, Title 3, Health professions, Subtitle J. Pharmacy and Pharmacists
- 21 CFR 312

Applicable Institutional Policies and Procedures

- None

Attachments

If you find errors in this document, contact clinicaltrials@uth.tmc.edu

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