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1. Purpose

This Standard Operating Procedure describes the procedures for Investigators to maintain and ensure accountability and proper storage of the investigational drugs and biologics.

2. Scope and Responsibility

It is the responsibility of the Principal Investigator (PI) to ensure accurate and complete accountability and proper storage of the investigational drugs and biologics used in a clinical trial. The PI is responsible for maintaining drug accountability records from the time of receipt to the time of final disposition.

3. Definitions

- 3.1 **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 the patient at the direction of a practitioner.
- 3.2 **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.
- 3.3 **Dispense:** to prepare, package, compound, or label, in the course of professional practice, a prescription drug for delivery to an ultimate user or the user’s agent under a practitioner’s lawful order.
- 3.4 **Investigation:** A clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a drug.
- 3.5 **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. In this policy, these are referred to as “investigational product”.
- 3.6 **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.

4. Policy

- 4.1 The Principal Investigator must ensure that investigational products are used only in approved clinical trials and under the direction of appropriate members of the research team.
- 4.2 Clinical trials may involve FDA approved drugs. These clinical trials may be conducted under an FDA Investigational New Drug (IND) application or may be FDA IND Exempt. Some of these trials may not involve an external sponsor. In these cases, the PI should develop plan for drug accountability based on this policy.

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5. Procedures

5.1 General Responsibilities:

- 5.1.1 It is the responsibility of the PI at the site of a clinical trial to ensure accurate and complete accountability and proper storage of investigational products used in a clinical trial.
- 5.1.2 The PI is responsible for documenting the receipt, use and disposition of all investigational agents including dates, quantity and use by subjects.
- 5.1.3 Ensure investigational product are stored in a secure location as specified by the sponsor.
- 5.1.4 Ensure the investigational drug is given only to those persons authorized under the protocol to receive it.
- 5.1.5 The PI 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.
- 5.1.6 The PI and/or designee must make sure that the sponsor has the correct shipping address of the site to ship investigational products.

5.2 Accountability:

- 5.2.1 Upon receiving investigational products from the study sponsor, the PI 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 drug accountability log with relevant information immediately.
- 5.2.2 Documentation for receipt of product should include:
 - a. Protocol title/number
 - b. Name of Investigator
 - c. Product delivery information: date of deliver, quantity received, expiration date(s), lot number(s) or batch number(s)
 - d. Shipping records
 - e. Inventory list of products at the site
 - f. Temperature log of drugs storage
- 5.2.3 If there is a discrepancy, the PI or designee should contact the sponsor or supplier of the product 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.
- 5.2.4 PI or designee should maintain copies of shipping inventory and packing slips in the regulatory binder, along with an updated Drug Accountability log.
- 5.2.5 The PI or designee should provide access to study monitors to assess investigational product accountability during monitoring visits.

5.3 Storage:

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- 5.3.1 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.
- 5.3.2 Investigational product should be stored 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.
- 5.3.3 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.

5.4 Dispensing:

- 5.4.1 The PI should to ensure that the investigational product is used only for research participants under PI's personal supervision or under the supervision of a properly trained sub- Investigator.
- 5.4.2 The PI or designee is is responsible for documentation for dispensing of investigational product (A Study Subject Investigational Product Dispensing Form may be used). Documentation should include:
 - a. Protocol title/number
 - b. Name of investigator
 - c. Dose(s) provided to each subject, in accordance with the protocol
 - d. Date dispensed
 - e. Amount used by each patient since last dispensed (Date/time used by subject if administered at site)
- 5.4.3 Study Drug Accountability Log should be updated every time the investigational product is dispensed or returned.
- 5.4.4 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.

5.5 Disposal:

- 5.5.1 PI or designee should document any 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 should to be stored in a separate location from the investigational product supply.
- 5.5.2 The investigator is responsible for documentation for dispensing of investigational product. Documentation should include:
 - a. Protocol title/number
 - b. Name of investigator
 - c. Amount returned by each patient
 - d. Quantity of medications returned to the pharmacy
 - e. Amount and date of returned product to the sponsor

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- 5.5.3 If the investigation is terminated, suspended, discontinued, or completed, the PI must return the unused supplies of the investigational product to the sponsor, or otherwise provide for disposition of the unused supplies.
- 5.5.4 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
- 5.5.5 Only with the written authorization of the sponsor (and in compliance with the Federal Regulations and institutional policies) the investigator may discard or retain the investigational product.

6. References

- 6.1 Occupations Code Chapter 551, General provisions, Title 3, Health professions, Subtitle J. Pharmacy and Pharmacists
- 6.2 21 CFR 312
- 6.3 www.uthouston.edu/safety

7. Appendices

- 7.1 Drug Accountability Log
- 7.2 MHH IDS Waiver Form

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

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