POLICY NAME: Receipt and Control of Investigational Medications
POLICY NUMBER: PH 04-304
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PURPOSE:

The purpose of this policy is to assure that all investigational drugs used at the University of Chicago Medical Center (UCMC) and received by the Investigational Drug Service (IDS) Pharmacy are handled consistently with regard to procurement, storage, inventory control, and returns or destruction.

DEFINITIONS:

1. **Investigational Drug** – A drug, not FDA approved, which is being tested in a clinical trial for safety and efficacy. Investigational drugs also include FDA approved drugs that are being tested for a different formulation, strength, route of administration or packaging than is approved. An FDA approved drug may also considered an investigational drug if it is being tested for an indication which is not approved or to gain further information about an approved use. An investigational drug may also be referred to as “study medication” or “study drug.”

2. **Persons Responsible:**
   a. **Principle Investigator (PI)** – Primary researcher responsible and accountable for the distribution of the investigational drug involved in the approved clinical study. The PI may delegate responsibility for the investigational drug to another qualified researcher involved in the study, but may not delegate accountability.
   b. **Investigational Drug Service (IDS) Staff** – IDS Staff is responsible for ensuring receipt, handling, storage, labeling and distribution of investigational agents in accordance with current regulatory requirements maintained by the FDA, the Joint Commission, and International Conference Harmonization (ICH) Good Clinical Practice (GCP) Guidelines.

3. **Sponsor** – Company that provides the medication and writes the research protocol.

POLICY:

Investigational drugs are procured, stored, inventoried, dispensed and used through the UCMC IDS Pharmacy are to be in full compliance with regulations and requirements of the study protocol, FDA, The Joint Commission, Illinois Board of Pharmacy, and other applicable organizations (e.g., Environmental Protection Agency, Illinois Environmental Protection Agency).
PROCEDURES:

1. For each study, the method employed for the initial order and shipment of drugs to IDS will be stipulated when IDS services are contacted.
   a. If the IDS provides oversight of the ordering and shipping of investigational drugs:
      i. The PI, or designee, will supply to IDS all documents necessary for ordering initial and subsequent shipments of drugs.
      ii. The PI, or designee, will instruct the sponsor to ship all drugs in care of IDS, Department of Pharmacy at the University of Chicago Medical Center.
      iii. The IDS will set minimum inventory levels based on space requirements for physical storage, expected rate of stock turnover, and estimated patient accrual rates.
      iv. The IDS will reorder drug when minimum inventory levels are met. The investigator will be notified if drug procurement problems occur.
   b. If the PI provides oversight of the ordering and shipping of investigational drugs:
      i. The PI will order the initial shipment of drugs and forward them to IDS.
      ii. The IDS will contact the investigator when minimum inventory levels are met so that more drugs can be ordered from the sponsor.
      iii. The investigator will then forward all subsequent shipments to IDS.

2. Investigational drugs will be delivered to the Pharmacy. The IDS will retain the original or a copy of all shipping receipts.
   a. The IDS staff will accept investigational study drugs during the hours of 8:00 am through 4:30 pm Monday through Friday.
   b. After hours, investigational drugs will be delivered to the central pharmacy and received by non-IDS pharmacy staff. The investigational drugs shall then be placed in the designated area in the IDS pharmacy, based on its storage requirements, for subsequent processing by IDS staff.

3. IDS staff will log receipt of all investigational study drugs.
   a. Upon receipt of the study drug, the shipment shall be inventoried and verified that the receipt date, lot number, drug type, batch number, and quantity on the packing slips is the same as what was actually received.
   b. The shipping receipt, packing slips, and accompanying relevant documents shall be stored with the pharmacy records according to federal and state regulations and A08-03 Record Maintenance and Retention.
   c. Shipment receipt shall be confirmed with the sponsor/supplier by IDS staff, if requested.
   d. If discrepancies in the shipment are noted, IDS staff shall promptly contact the investigator or the sponsor/supplier of the drug.

4. Drug accountability documentation shall be completed on arrival of supplies, every time a drug is dispensed, and when a drug is returned to the sponsor or destroyed.
5. The expiration date of the drug shall be noted, and the drug shall be returned, disposed of, or destroyed in accordance with the approved protocol when the drug expires. An ongoing audit of drug expiration will be performed as the medication is received and as the medication is dispensed.

6. The temperature of the storage area shall be recorded daily According to PH 02-121 Temperature Monitoring and Excursion Management. Access to the storage area will be limited to IDS staff and pharmacists.

7. Unused, intact drug materials remaining at the end of a study are inventoried and returned to the sponsor or discarded by IDS staff in accordance to PH 04-308 Destruction of Investigational Medications.

8. Used or partially used medication or associated supplies will be discarded in accordance to PH 04-308 Destruction of Investigational Medications.

9. A copy of all accountability documents will be maintained in the regulatory files and in accordance to A08-03 Record Maintenance and Retention.

**INTERPRETATION, IMPLEMENTATION, AND REVISION:**
The Investigational Drug Service, in consultation with the Pharmacy Policy and Procedure Committee, is responsible for the interpretation, implementation, and revision of this policy.

**CROSS-REFERENCES:**
1. PH 02-121 Temperature Monitoring and Excursion Management
2. PH 04-308 Destruction of Investigational Medications
3. A08-03 Record Maintenance and Retention

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