

Policy Number: 2.0201  
Date of Issue: 03/82  
Date of Review/Revision: 02/94, 06/94  
09/94, 04/96,  
06/97, 04/00;  
11/01, 11/03.  
05/08

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## **UHS Inpatient Pharmacy Research Policy and Procedure**

### **Policy:**

At University Health System, all inpatient studies are required by Hospital Policy to use the Research Pharmacy for storage, control and dispensing of Investigational Drugs or Study Drugs. However, this policy does not cover clinical Outpatient studies. Outpatient studies have the option to use or not use the UHS inpatient pharmacy for storage and dispensing of investigational drugs.

An Investigational Drug is defined as a drug in clinical stages of evaluation which has not been approved for general use by the Food and Drug Administration (FDA). Investigational Study Drug is defined as any FDA approved drug prescribed for human research, possibly outside of FDA approved labeling. The FDA requires the investigators/designee to establish a record of receipt, use and disposition of all investigational drugs.

Research drugs handled by the University Health System Inpatient Pharmacy include Phase I, II, III and IV clinical trials. The receipt, storage, inventory and return of research drug supplies are the responsibility of the research pharmacist or designee.

### **Procedures for Protocol Approval:**

Any physician wishing to perform investigational drug studies at University Health System facilities must receive approval from the Investigational Review Board (IRB) and the University Health System Investigational Research Department. (Extension 4815.) The research office may be contacted to obtain application forms required to conduct an investigational study or may be found on line at the University Health System web page.

### **Upon IRB approval:**

All investigation drug studies are submitted for approval to the Research Department for University Health System. The Research Department Coordinator contacts the respective areas for review of the protocol. Once approved by all contacted areas, the Research Department will assign a project number to complete the approval process. For studies requiring drug administration at University Hospital, the Inpatient Pharmacy must dispense drugs.

The pharmacy department will not start a study until the department has reviewed the protocol, has been serviced by the coordinator or sponsor and has received the investigational medication.

## **Investigational Medications**

### A. Drug Shipment Location

Initial order and shipment of drugs to the Research Pharmacy may be conducted one of two ways. The method employed for each study will be stipulated when the Research Pharmacy is contacted.

- 1) The principle investigator can instruct the study sponsor to ship the study medication directly to the Inpatient Research Pharmacy.
- 2) The principle investigator can have the study medication shipped to him/her in care of the Department of Pharmacy. The preferred method is described in point 1.

### B. Drug Shipment Arrival

- 1) Upon receipt of study medication the research pharmacist will check the order using the shipping invoice, noting lot numbers, expiration dating, discrepancies and breakage. Any discrepancies or damaged contents will be reported to the principal investigator and the sponsor.
- 2) Investigational drug accountability and disposition logs will have initial entries of drug shipment recorded. The log sheet will contain the following information: drug name, strength, unit size, protocol title and numbers, principal investigator, manufacture's lot number, stock balance, and investigational pharmacist's initials.
- 3) Research medications are stored under appropriate and secure conditions.
- 4) Required verification of drug receipt is returned to the sponsor.
- 5) The invoices for drug shipment are placed into the corresponding study notebook.

### C. Drug Storage

- 1) A permanent storage space, separate from other hospital medications will be designated for the investigational study medication.
- 2) Refrigerated items will be stored in a separate investigational refrigerator.
- 3) Temperature logs for both refrigerated and room temperature investigational study medication will be recorded daily.
- 4) Investigational and study drugs may be stored in other areas (satellites) as long as pharmacy policies and procedures for inventory control and dispensing are followed. Master drug accountability logs may be retained in the central research pharmacy with drug signed out to the satellite or maintained at the satellite with all documentation performed there.

#### D. Drug Inventory

- 1) A perpetual inventory will be maintained for every study to include the receipt, dispensing and return/destruction of study medication. The research pharmacist will monitor inventory on a monthly basis.
- 2) Final reconciliation of investigational drug accountability logs will be completed by the Research Pharmacist upon notification of a study closeout. A close out audit by the study monitor will be arranged. At that time, detailed drug disposition and dispensing records will be reconciled against shipping receipts and a physical inventory of all remaining study drug. Copies of dispensing records and inventory logs will be provided to the study monitor, as well as the principal investigator. Upon reconciliation, a "Return Drug Form" (provided by the study monitor) will be completed and signed by the study monitor and research pharmacist. A copy of the "Returned Drug Form" is sent with the prepaid (by the sponsor) returned shipment. A copy of all "Return Drug Forms", as well as all drug accountability records will be maintained in the "Closed Studies" section of the IDS files.

If requested by the sponsor, both used and unused study drug may be destroyed on site. If provided by the sponsor "Drug Destruction Forms" will be completed and signed by the monitor and the Research Pharmacist. A copy of this form will be maintained in the "Closed Studies" section of the pharmacy research files. Refer to Pharmacy Drug Return/Destruction Policy # 1.1101

#### E. Dispensing

- 1) Study medication will be dispensed upon a pharmacist receipt of an authorized physician order.
- 2) An authorized physician is defined as an individual designated in the IRB submission as principle or co investigator or their agent.
- 3) The order must contain the following information in order for a drug to be dispensed: patient's full name and hospital number; protocol name and/or number; drug name, dose, route of administration, and scheduled of drug administration; name of authorized physician and signature.
- 4) The drug will be prepared and dispensed in accordance with the protocol, as well as established pharmacy manufacturing guidelines.
- 5) Study drug will be labeled according to the protocol or contain standard identifying information if not specified. All study drugs will be labeled with an auxiliary sticker stating "For Investigational Use Only"
- 6) The "Investigation Drug Information Form" will be available to all nurses, physicians, and pharmacist through the hospital system. (Sunrise). Additional drug information can be obtained from the research pharmacy upon request.

## F. Drug Return

### 1) Inpatient Medications Returned

These are medications that had been dispensed by UHS Pharmacy Research Department for a specific patient and study and are being returned to UHS Pharmacy Research Department by the nurse, study coordinator or pharmacy staff, because the dose was not given.

These medications are counted by the pharmacy research staff and recorded in the appropriate pharmacy study binder's dispensing record. A note will be entered in the dispensing record by the Research Pharmacist explaining why the dose was not given. These medications will be kept in UHS Pharmacy Research Department until the Sponsor instructs the pharmacy to either destroy or return the medication.

### 2) Outpatient Medications Returned:

These are medications that had been dispensed by UHS Pharmacy Research Department for a specific patient and study and are being returned by the patient to the study coordinator to determine compliance as instructed by the protocol.

These medications are counted by the coordinator and then brought to UHS Pharmacy Research Department, where they are recounted by the pharmacy research staff. The information is then recorded in the appropriate pharmacy study binder's dispensing record. These medications will be kept in the UHS pharmacy research department until the Sponsor instructs the pharmacy to destroy or return the medication.

### 3) Medications Returned to the Sponsor

Intact or used containers of research drug are returned to the study sponsor if specifically requested by the study sponsor. This may occur at the termination of the study, upon expiration of a lot number or at any time if specifically requested by the study sponsor.

The lot number, quantity, protocol number, date for any drugs returned will be recorded in the pharmacy study binder's drug inventory control records. Copies of all the paper work documenting the return including Fed Ex or UPS will be kept in UHS pharmacy records.

#### G. Drug Destruction

- 1) If specifically requested by the study sponsor, intact and/or used containers of research drugs may be destroyed as per the pharmacy standard drug destruction operating procedures.
- 2) The lot number, quantity, protocol number, date for any drug destruction will be recorded in the Pharmacy Study binder's drug inventory control records.
- 3) (See policy #1.1101)

#### H. Charges for Investigational Drug Services

- 1) Study Initiation Fee- A one time charge at study initiation will be applied to all studies.
- 2) Randomization—per subject charge
- 3) Preparation and dispensing- varies depending on the type of medication (IV, oral, chemotherapy etc.) number of doses and duration of treatment
- 4) Drug/supply costs- the costs of any FDA approved drugs or supplies purchased by the pharmacy for the study
- 5) Inventory and record keeping- includes quality assurance, perpetual inventory monitor visits, storage, and destruction of the product

Billing will occur on a monthly basis. Completed charge forms are forwarded by the pharmacy research department to the hospital billing system.

#### I. Storage and Dispensing of Investigational Drugs Not Directly Handled by the Research Pharmacy

Information will be provided to all outpatient studies detailing Inpatient Research Procedures for storage and handling investigational medications. All Outpatient studies are expected to be maintained at the same level as all inpatient studies. These studies can be audited by the research pharmacy to insure compliance.

#### J. Patient brought into the hospital on investigational drugs:

The physician is responsible for coordinating continued use of the medication by contacting investigator and getting information on the drug. The drug must be taken to pharmacy and logged in. It would be dispensed by pharmacy after the pharmacist has received all clinical information pertinent to the drug. The pharmacist would work with the physician to assure that nursing staff receive information for basic competency about the medication. A signed

consent form must be in the patient chart before the medication can be administered.

K. Procedures for auditing the studies:

- 1) University Hospital Inpatient Pharmacy will work with the Medical and Dental Research Committee to monitor outpatient research studies as deemed necessary.
- 2) When audits are performed the principal investigator will be notified in advance of the audit.
- 3) A pharmacy audit form will be used to aid in verifying adherence to standard regulatory investigational drug storage and accountability procedures. The audit form will document:
  - a. Proper drug storage conditions, including limited –access areas and proper temperature conditions.
  - b. Accurate and complete drug inventory records, including the recording of dates, lot numbers, date the drug is received, the date drug is dispensed to a subject or returned to the sponsor.
- 4) At the end of each audit, a memorandum will be prepared and sent to the principal investigator describing the outcome of the audit and suggestions for improvement, if necessary.
- 5) If the suggestions are not adopted, the Medical and Dental Research Committee will notify the principal investigator that the audit findings may be reported to the Institutional Review Board (IRB).