

Department of Pharmacy Policy

SUBJECT: Receipt and Control of Investigational Drugs

PURPOSE: To assure that all investigational and study drugs used within the Hospital and received by the Investigational Drug Service (IDS) will be handled consistently with regard to procurement, storage, inventory control, and return or destruction.

GENERAL: The primary activity of the IDS is to ensure the appropriate procurement, storage, distribution, and inventory control of investigational and study drugs. The IDS performs these activities consistent with policies governing routine drug distribution from the Pharmacy Department. However, it is recognized that greater accountability and control is required for the handling of these medications as specified by Federal agencies, JCAHO, and study sponsors.

Investigational drug refers to any drug, which has not received FDA approval for use in humans. Study drug refers to any drug, which is FDA approved and is being used under protocol for human research, possibly outside of FDA approved labeling.

POLICY:

1. Initial order and shipment of drugs to IDS may be conducted one of two ways. The method employed for each study will be stipulated when IDS services are contracted.
 - a) The principal investigator will supply to the IDS all documents necessary for ordering initial and subsequent shipments of drugs. The principal investigator will instruct the sponsor to ship all drugs to him/her in care of the Investigational Drug Service, Department of Pharmacy University of Kentucky Medical Center. The IDS will set minimum inventory levels based on space requirements for physical storage, expected rate of stock turnover, and estimated patient accrual rates. IDS will reorder drug when minimum inventory levels are met. If problems develop in obtaining the drug, the investigator will be notified.
 - b) The principal investigator will order initial shipment of drugs and forward them to IDS. The IDS will contact the investigator when minimum inventory levels are met so that more drugs can be ordered from the sponsor. The investigator will then forward all subsequent shipments to IDS. The preferred method is described in (a).

2. Investigational or study drugs will be delivered to the Central Pharmacy. Drugs sent to other areas should be forwarded to Central Pharmacy for receipt and processing by IDS. All packing slips will be filed by the IDS unless otherwise agreed upon by the IDS and the investigator.
3. The Investigational Drug Technician (IDT) will accept investigational drugs during specified working hours Monday through Friday. The Investigational Drug Service Pharmacist will accept investigational drugs during specified working hours when the IDT is absent due to vacation, sick leave, etc.
4. Investigational drugs arriving during hours other than those covered by the IDT will be accepted by:
 - a) Investigational Drug Service Pharmacist,
 - b) a pharmacy supervisor,
 - c) Shift Manager Pharmacist

Investigational drugs accepted by a pharmacy supervisor or shift manager pharmacist will be placed in the designated Investigational Drug Area (refrigerated and non-refrigerated) for subsequent receipt by the IDT.

5. The IDT will log receipt of all investigational drugs. The packing slip and accompanying information should be included in the study file to include the name of the drug, date of acceptance, lot numbers, principal investigator and protocol number.
6. The IDT will locate packing slips to identify the drug, principal investigator, and associated protocol. If the IDT finds this information is incomplete, the IDT will contact the investigator or sponsor to clarify the status of the drug.
7. Properly identified drugs will have shipping records reconciled to the shipping contents. Any discrepancies will be reported to the principal investigator for clarification. A report of contents damaged during shipping will be given to the investigator and to the sponsor.
8. Investigational drug accountability and disposition logs will have initial entries of drug shipment recorded. The log sheet will be kept with the drug stock. The IDS will use National Institutes of Health Log Sheets for all drug studies unless the study sponsor specifically designates other forms. The log sheet will contain the following information: drug name, strength, unit size, protocol title and numbers, principal investigator, manufacturer's lot number, identification, date dispensed, units and doses dispensed, stock balance, and dispensing pharmacist's initials.
9. A permanent storage space, separate from other hospital medications, will be identified and labeled with drug name. Stock located in stationary shelving units and refrigerators is listed on an inventory location list. An appropriate minimum inventory (based on rate of patient enrollment and anticipated drug use) will be maintained in the Central Pharmacy.

10. Appropriate storage requirements (temperature, lighting, etc.) should be specified during IDS protocol review. However, if storage requirements are unknown, the Investigational Drug Service Pharmacist will examine package literature, phone investigator or study sponsor, to verify storage requirements.
11. The IDT will reconcile the Investigational Drug Logs to the physical inventory. The IDT will attempt to reconcile any differences with Department of Pharmacy staff. If the IDT cannot successfully resolve the discrepancy, the IDT will contact the Investigational Drug Service Pharmacist (IDP) to further investigate and document findings. The IDP will generate a report for the Director and the principal investigator describing the known details.
12. The IDT will check the inventory level of each investigational or study drug. Appropriate restocking and possible order placement will result from this assessment.
13. 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 as well as applicable state and federal law. The master log will be retained in IDS with drug signed out to the satellite. The satellite is responsible to maintain the individual sign out log detailing drug dispensed for each patient.
14. The IDS pharmacist will review all protocols involving the use of investigational and study drugs. After review of the protocol, the pharmacist will perform the following functions:
 - a) Contact the Principal Investigator concerning the cost involved with the IDS handling the study and clarify any potential areas of confusion.
 - b) The pharmacist will then prepare the following information sheets:
 - i) Investigational/Study Drug Information Forms
 - ii) Drug Monograph Form
 - iii) Randomization forms (if any)
 - iv) A sample Investigational Drug Manufacturing Card and Label
15. Copies of the material generated by the IDS pharmacist will be forwarded to all areas of Medical Center Pharmacy handling the drug(s) and designated satellites.
16. The IDS Pharmacist will provide information to all Pharmacy staff members involved with the handling and dispensing of the investigational study drug.
17. Final reconciliation of investigational drug accountability logs will be completed by the IDS upon notification of a study closeout by the protocol sponsor or principal investigator. A close out audit by the protocol study monitor will be arranged. At that time, detailed drug disposition and dispensing records will be reconciled with shipping receipts and a physical inventory of all remaining study drug. Copies of dispensing

records and inventory logs will be provided to the protocol sponsor, as well as the principal investigator. Upon reconciliation of all study drug records by the monitor, a "Return Drug Form" (provided by the protocol sponsor) will be filled out and signed by the study monitor and the IDS Pharmacist (or IDS technician). A copy of the "Return Drug Form" is sent with the prepaid (by the sponsor) return shipment of all remaining study drug. 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 protocol sponsor, both used and unused study drug may be destroyed on site. Study drug will be placed in a red sharps container and labeled for destruction. Personnel from environmental services will pick up these containers for incineration. This will only be done after reconciliation of all remaining inventory and verification of all drug disposition records by the protocol monitor. If provided by the sponsor, a "Drug Destruction Form" can be signed by the protocol monitor and the IDS Pharmacist (or IDS technician). A copy of this form will be maintained in the "Closed Studies" section of the IDS files.

For NCI sponsored studies (SWOG, NSABP, etc.) where a protocol monitor is not used, a "Return Drug List" form is filled out by the IDS Pharmacist (or IDS technician) and a copy is returned with any remaining inventory at close out of the study. Upon receipt of the drug at NCI, a received date and verification of the returned drug is stamped on a copy of the Returned Drug List and mailed back to the IDS. This form is maintained in the "Closed Studies" files.

18. If requested, the Investigational Drug Service will generate statistics describing service activities. The information collected can include indicators of: patient enrollment, dates of enrollment, units of drugs dispensed, and revenue generation.
19. The Investigational Drug Service will conduct periodic assessments for quality improvement. IDS will identify quality improvement indicators for study and review.

Approved: _____ Steve Sitzlar, RPh Manager Investigational Drug Service	Authorized: _____ John Armitstead, MS Director of Pharmacy
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