

MEDICAL COLLEGE OF OHIO

Subject: RECEIPT AND CONTROL OF INVESTIGATIONAL
DRUGS

Policy No.: 02-006

The primary purpose of the Investigational Drug Service (IDS) is to ensure the appropriate procurement, storage, distribution, and inventory control of all investigational and study drugs used at the Medical College of Ohio that are associated with IRB approved protocol. The IDS performs these activities consistent with the 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. A charge mechanism for Investigational Drug Services will apply to extramurally funded drug studies to offset costs. Please contact the Pharmacy Director for details.

Investigational drug refers to any drug that has not received FDA approval for use in humans or any Study Drug (FDA approved or investigational) which is provided by a sponsor specifically for a research study and for which the clinical study agreement from the sponsor requires MCO pharmacy involvement in the receipt, storage and distribution or accountability for the drug. Study drug refers to any drug that is FDA approved and is being used under protocol for human research, possibly outside of FDA approved labeling.

Only investigational and study drugs that have IRB approved protocol can be used within the Medical College of Ohio and the Investigational Drug Service (IDS) will handle these study drugs consistently with regard to procurement, storage, dispensing, inventory control, and return or destruction.

PROCEDURE

1. Initial order and shipment of drugs to IDS must be conducted as follows:
 - 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 Medical College of Ohio. 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 a problem develops in obtaining the drug, the investigator will be notified.
2. Investigational or study drugs will be delivered to the MCO Hospital Pharmacy. All packing slips will be kept by the IDS unless otherwise agreed to by the IDS and the investigator.
3. The Investigational Drug Service Pharmacist (IDSP) will accept investigational drugs during specified working hours Monday Through Friday.
4. Investigational drugs arriving during hours other than those covered by the IDSP will be accepted by:
 - a. Investigational Drug Service Pharmacist on call, or
 - b. Charge Pharmacist, or
 - c. Department Manager

Investigational drugs accepted by a charge pharmacist or Department Manager will be placed in the designated Investigational Drug Area (refrigerated and non-refrigerated) for subsequent receipt by the Investigational Drug Service Pharmacist or designee.

5. The IDSP 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 IDSP will locate packing slips to identify the drug, principal investigator, and associated protocol. If the IDSP finds this information to be incomplete, the IDSP 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 by the IDS. 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 by the IDS. 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 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 maintained in the Central Pharmacy will be based on rate of patient enrollment and anticipated drug use.
10. Appropriate storage requirements (temperature, lighting, etc.) should be specified during IDS protocol review. If storage requirements are unknown, the IDSP will examine package literature and phone investigator or study sponsor to verify storage requirements.
11. The IDSP will reconcile the Investigational Drug Logs to the physical inventory. The IDSP will reconcile any differences with Department of Pharmacy staff. The IDSP will generate a report for the Pharmacy Director and the principal investigator describing the known details.
12. The IDSP 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 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 area. The PI or designee is responsible for the creation and maintenance of the individual sign out log for this "other area" detailing drug dispensing for each patient.
14. The IDSP will review all protocols involving the use of investigational and study drugs. After review of the protocol, the pharmacist will;
 - a. Contact the principal investigator concerning the cost involved with the IDS handling the study and clarify any potential areas of confusion.
 - b. 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 the 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. This reconciliation will take place upon notification by the protocol sponsor or principal investigator of a study closeout. 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 protocol study monitor and the IDS Pharmacist. 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 opened and unused study drugs 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 **after** reconciliation of all remaining inventory and verification of all drug disposition records by the protocol monitor. If provided by the sponsor, the protocol monitor and the IDSP can complete a "Drug Destruction Form." A copy of this form will be maintained in the "Closed Studies" section of the IDS files.

For National Cancer Institute (NCI) sponsored studies where a protocol monitor is not used, a "Return Drug List" form is filled out by the IDS Pharmacist and a copy is returned with any remaining inventory at the 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. The Investigational Drug Service may generate statistics describing service activities. The information collected may 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.

Source: Research and Grants Administration

Effective Date: 11/19/04

Revision/Review Date: