

	Standard Operating Procedures
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Procedure Category:	Study Preparation Activities
Procedure CLN-03-06:	Pharmacy Procedures

Procedure Overview

This procedure describes the responsibilities of the Investigational Drug Services for investigational material receipt, maintenance, dispensing and return to the sponsor. General guidelines are provided below. Specific policies are maintained within the department of pharmacy services.

Responsible Individuals

Investigators; IDS Pharmacists; Qualified MICHHR personnel (including, but not limited to, Study Coordinator and Research Assistant); Director, MICHHR

Procedure

The investigational material is received, maintained and dispensed by IDS pharmacy. Blinded studies may require measures to ensure that the investigational material is indistinguishable from control material, that differing doses of investigational material are indistinguishable, and that the investigator and/or coordinator are unaware of patient treatment group assignment. These measures, as well as procedures for emergency unblinding, should be outlined in the study protocol and supporting documentation.

The study pharmacist may or may not be identified on the FDA Form 1572 or the investigator's agreement, but should have provided their signature on the site signature log. The study pharmacist is provided with a study-specific pharmacist manual. The pharmacist should follow all procedures outlined in the pharmacist manual for the receipt, maintenance, dispensing and return of the investigational material.

Investigational Material Receipt and Storage - Pharmacist

- Upon receipt of the investigational material, immediately open, inspect and inventory the shipment. If a transit thermometer was utilized, note and record the temperature of the investigational material upon receipt.

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Approval Signature, Date:	

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- Upon confirmation of receipt, transfer the investigational material to the appropriate storage area (i.e., refrigerator or locked storage cabinets). Note any special storage requirements (e.g. Protect from exposure to light). In addition, if a refrigerator is to be utilized for investigational material storage, a temperature log should be maintained.
- Update the investigational material accountability log with new supply information.

Investigational Material Dispensing - Pharmacist

- Upon receipt of investigational material dispensing documentation from the primary investigator, prepare the investigational material according to the sponsor's specifications. All investigational material preparation, including IV or syringe preparation or repackaging should be documented on hospital source documents or forms provided by the sponsor.
- After dispensing the investigational material, record the date and, the amount dispensed in the investigational material accountability log.
- If empty investigational material containers are to be returned, retain these containers for accountability assessment by the study monitor and, if applicable, return to the sponsor. If partially used investigational material containers are returned, store these containers under appropriate conditions for accountability assessment by the study monitor and, if applicable, return to the sponsor.

Investigational Material Accountability - Pharmacist

- All investigational material accountability documentation should be made available to the study monitor upon request so that investigational material accountability assessment can be performed. This includes invoices, investigational material preparation source documentation and investigational material shipment information.
- The study monitor also inspects the investigational material storage facilities, the temperature log for the refrigerator (if used for study purposes), as well as any unused, partially used, and/or empty investigational material containers before return to the sponsor.

Note: See IDS web page for specific SOP related material.

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Documentation

Documentation for this procedure includes:

- All invoices and shipment information for the investigational material
- Investigational material preparation source documentation
- Investigational material dispensing documentation
- Investigational material accountability log
- Pharmacist manual
- Study protocol and supporting documentation
- IDS SOPs

Deviation Approval

The Director, MICHIR or designee, must approve deviation from this procedure. The Director, MICHIR or designee, must store documentation of the deviation approval.

Procedure Author

Manager, Research Support Core

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