

	<b>Standard Operating Procedures</b>
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Procedure Category:	Study Activities
Procedure CLN-04-02:	Investigational Material Accountability

**Procedure Overview**

This procedure describes the responsibilities of the sponsor and the investigator for investigational material accountability.

**Responsible Individuals**

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

**Procedure**

Study personnel must ensure that only qualified investigators participating in the study receive shipments of the investigational material. In addition, it is important that the study personnel confirm return of unused stock from former investigators, and exercise due diligence in preventing inappropriate use of an investigational material. Study personnel chosen to be responsible for drug accountability, dispensation and disposition must be listed on the Delegation of Authority Log.

All study drug accountability documentation should be made available to the study monitor upon request so that drug accountability can be performed. Drug accountability is performed by comparing invoices, drug preparation and dispensing source documentation, and drug shipment records against the investigation material accountability log. Failure to account for unused drug is a matter of concern to the FDA and if the study drug is a controlled substance, the Drug Enforcement Administration (DEA). Precautions must be taken to prevent illegal distribution and storage of investigational materials, particularly those that are controlled substances. In addition, the study personnel must ensure proper shipping, inventory control, storage and distribution for controlled substances.

- Reference specific IDS policies via <http://www.med.umich.edu/\pharmacy/policies/investigationaldrug...>

All study device accountability documentation should be made available to the study monitor upon request so that device accountability can be performed. Records of device shipments should include the name and address of consignee, type and quantity of device, date of shipment and a batch number or code mark. In addition, records of disposition of the investigational device should include the batch number or code mark for any investigational device, which is repaired, returned to the sponsor, or disposed of by the investigator or any other individual. The study

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Approval Signature, Date:	

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monitor evaluates device accountability by comparing these records against the device accountability log.

The FDA requires sponsors to assure the return of all investigational materials upon completion or discontinuation of the clinical study. The study sponsor may authorize alternative disposition of unused investigational material, as long as this disposition does not place humans at risk. Records of the disposition of all unused investigational material must be maintained by the sponsor.

### Documentation

Documentation for this procedure includes:

- All invoices and shipment records for the investigational material
- Investigational material preparation source documentation
- Investigational material/device dispensing documentation
- Investigational material/device accountability log
- Study protocol

### 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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