

Procedure Category:	Clinical Management
Procedure CLM-01-08:	Investigational Material Accountability

**Procedure Overview**

To define the standard procedures for accounting for investigational material supplies at the investigative site.

**Responsible Individuals**

Qualified MICHHR personnel (including, but not limited to, Project Manager and Clinical Study Monitor); Contracted Clinical Research Associates; Director, MICHHR

**Procedure**

The following activities are performed during a site visit to assess the handling of investigational material supplies:

- Ensure investigational material supply is adequate.
- Ensure investigational material is stored appropriately in a secured area.
- Ensure investigational material is properly dispensed:
  - ◊ Investigational material dispensing records are complete;
  - ◊ Investigational material dispensing records are accurate (compare to CRFs);
  - ◊ Investigational material was dispensed according to the protocol (e.g., sequential, stratified).
- Ensure investigational material supply is properly accounted for and unused supplies are returned at end of study:
  - ◊ All unused investigational material is returned;
  - ◊ All used investigational material containers are either returned or properly disposed-of (as specified by the client);
  - ◊ Obtain signature on the investigational material accountability record prior to distribution;
  - ◊ Investigational material dispensing records are shipped with returned investigational material at end of study along with the investigational material return form (if applicable; copy to be retained at site);
  - ◊ Copies of the investigational material dispensing records are retained at the site;
  - ◊ All appropriate documentation is received by the client.

**Documentation**

The following serve as documentation for this procedure:

Version Number: 004	Implementation Date: February 11, 2000
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Approval Signature, Date:	

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- Signed investigational material accountability record (provided by sponsor).
- Documentation of return or destruction of investigational material (provided by sponsor).

**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.

**Relevant Definitions**

CRA - Clinical Research Associate

**Procedure Author**

Administrative Core, Michigan Institute for Clinical and Health Research

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