

## Investigational Material Accountability

### Procedure Overview

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

### Responsible Individuals

Qualified NETT and Hub Complex personnel (including, but not limited to, Site Manager and Project Monitor; Contracted Clinical Research Associates; NETT Director of Site Operations and/or designee).

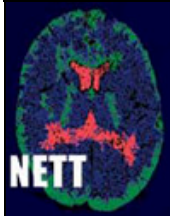
### Definitions

1. Investigational Material – Any drug device or biologic material used in the course of an investigation.

### Procedure

1. The following activities are performed during a site visit to assess the handling of investigational material supplies.
  - a. Ensure investigational material supply is adequate, and verify product expiration date (e.g. the amount available is not confounded by expiration of the investigational material).
  - b. Ensure investigational material is received, examined, and signed for by a designated investigational site individual (see Delegation of Authority log)
  - c. Ensure investigational material is stored appropriately in a secured area.
  - d. Ensure investigational material is properly dispensed.
    - i Investigational material dispensing records are complete.
    - ii Investigational material dispensing records are accurate (compare to drug accountability logs).
    - iii Investigational material was dispensed according to the protocol (e.g., sequential, stratified, dose appropriate).
  - e. Ensure investigational material supply is properly accounted for and unused supplies are returned/destroyed at end of study:
    - i All unused investigational material is returned/destroyed.
    - ii All used investigational material containers are either returned or properly disposed-of (as specified by the supplier of the investigational material).

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- iii Dependent upon the requirements of the supplier of the investigational material, 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).
- 2. Documentation
  - a. Copies of the investigational material dispensing records are retained at the site.
  - b. All appropriate documentation is uploaded to the NETT WebDCU™, or kept in the NETT Clinical Coordinating Center project files.
  - c. Signed investigational material accountability record (provided by sponsor, if applicable).
  - d. Documentation of return or destruction of investigational material (provided by sponsor, if applicable).
- 3. Approval for Process Exemption
  - a. The Director of Site Operations or designee must approve exemption from the processes outlined in sections two and three of this policy. The Director of Site Operations or designee must maintain documentation of the exemption approval.

### Procedure Author

NETT Network Operations Committee, NETT CCC

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