



Material Accountability

Purpose and Scope

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

Responsible Individuals

Accountability for materials is a shared responsibility of SIREN Award Hubs, Hubs, Spokes, other sites, the SIREN CCC and DCC, and the leadership of individual trials.

Definitions

Material – Any project-provided drug, device, or biologic material used in the course of an investigation.

Procedure

1. Site responsibilities for materials include:
 - a. Ensuring material supply on site is adequate and has not expired.
 - b. Ensuring proper documentation of investigational material receipt and examination by an individual designated to receive materials. When appropriate the receiving individual may need to be designated on the Delegation of Authority (DoA) log.
 - c. Ensuring material is stored appropriately in a secured area.
 - d. Ensuring material is properly dispensed.
 - i. material dispensing records are complete and accurate.
 - ii. material dispensed according to the protocol (e.g., sequential, stratified, dose appropriate).
 - e. Ensuring materials are properly accounted for and unused supplies are returned/destroyed at end of study:

- i. Unused materials are returned or destroyed as instructed.
- ii. Used material containers are either returned or properly disposed-of (as specified by the supplier of the material).
- iii. Follow any instructions for provision of records or returns at the end of study.

2. Coordinating Center responsibilities for materials

- a. Coordinating or delegating provision to sites of required materials.
- b. Monitoring of site materials and documentation at the time of on-site visits.
- c. When applicable and designated for a specific project and material, documentation and tracking of distribution and supply of materials in WebDCU.
- d. Maintenance of documentation related to coordinating center responsibilities for materials acquisition and distribution to sites.

3. Documentation

- a. Sites should retain all local material dispensing records, and records of material return or destruction.
- b. When applicable and designated for a specific project, the DCC retains material dispensing and tracking that is documented in WebDCU.
- c. All parties maintain records of any material accountability records required by the supplier if applicable.



Standard Operating Procedure Material Accountability

SIREN CCC PI Sign-off: _____

SIREN DCC PI Sign-off: _____

NIH Administrative PO Sign-off: _____