

Vice Chancellor for Research

Investigational Drug/Device Accountability Policy

Introduction:

Good clinical research practice requires that investigators and research teams insure accurate accountability for any investigational drug or device used in a research trial at Washington University. This is true whether the study is funded through an industrial sponsored trial, a federal grant or contract, or an investigator-initiated trial using department funds. Our institutional responsibility requires that any investigational drug or device is used in the manner intended by the research project, is stored under appropriate controlled conditions, and is used only by (on) subjects who have consented to participate in the research project.

Typically industrial sponsors of a clinical trial will provide procedures for handling of investigational drugs/devices and forms for record-keeping. This guideline is meant to outline acceptable methods for accountability where there is no sponsor guidance.

Scope:

Any investigational drug or device being used in clinical research must be strictly accounted for. This includes keeping records of (1) receipt and inventory of investigational drugs/devices, (2) storage of investigational drugs/devices, (3) dispensing of investigational drugs/devices and (4) return or disposal of the investigational drugs/devices.

Procedures:

1. Receipt and Inventory of Investigational Drugs/Devices:

Upon receipt of investigational drugs/devices, inventory the shipment, insuring that information on all packing slips (inside and outside containers) matches exactly the contents of the containers including:

- Quantity
- Lot numbers
- Quantity per dispensing package

Insure that drugs/devices and supplies required for study conduct are within an appropriate expiration date. Record receipt (see Sample Form: Study/Device Shipment Receipt Log).

2. Storage of Investigational drugs/devices

Store investigational drugs/devices in a secure environment with access limited to essential research personnel. Insure that study article is stored at the appropriate temperature and maintain a daily storage area temperature log if refrigeration or freezing is required.

3. Dispensing of Investigational drugs/devices

Each time study article is dispensed by the Investigator or other member of the research team, the Study Drug Dispensing Log (See Sample Form) or the Study Device Dispensing Log (See Sample Form) will be completed. Documentation on these forms will include:

- Date of dispensing
- Subject's identifying number and/or initials
- Lot number(s)
- Amount dispensed
- Name or initials of individual dispensing
- Amount of study drug returned by subject
- Date/time study drug or device returned by subject
- Subject who returned drug or device identified by number and/or initials

See Sample Forms: Study Drug Dispensing Log and Study Device Dispensing Log

After use by the subject, accept and retain all returned, used study article containers/units/devices and store in a secure environment and according to the protocol. If article containers/units/devices are missing, document the reasons. If discrepancies between amounts used by subjects and amounts expected to be returned exist, document the reasons.

4. Return or disposal of Investigational Drugs/Devices

Ensure that study article is prepared for return to supplier or disposed of on-site according to the study protocol.

File copies of study drug packing slips, shipment receipts, accountability records, and disposal instructions appropriately. Note return or disposal on the Dispensing Log (either Study Drug Dispensing Log or Study Device Dispensing Log).