Washington University in St. Louis

Vice Chancellor for Research

Investigational Drug/Device Accountability Policy

Created 05/2001
Revised 02/2008; 08/09/2024

Introduction:

Good clinical research practice requires that investigators and research teams ensure accurate accountability for any investigational drug or device used in research at Washington University. This is true whether the study is an industry-sponsored clinical trial or an investigator-initiated study. 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 subjects who have consented to participate in the research project.

This policy is meant to outline acceptable methods for accountability with regard to the handling of investigational drugs/devices, and will apply, in particular, in the absence of any clinical trial sponsor-specified procedures or record-keeping requirements.

Scope:

There must be strict accountability for any investigational drug or device being used in clinical trial. This includes keeping records of (1) receipt and inventory of investigational drugs/devices, (2) storage of investigational drugs/devices as indicated in the protocol, Investigator's Brochure (IB), Instructions for Use (IFU), or the investigational product manual, (3) dispensing of investigational drugs/devices and (4) return or disposal of investigational drugs/devices.

Procedures:

1. Receipt and Inventory of Investigational Drugs/Devices:

Upon receipt of investigational drugs/devices, review content within the shipment for accuracy, ensuring that the information on all packing slips (inside and outside containers) matches exactly the contents of the containers including:

- Study device/drug name (if applicable, dose and formulation)
- Quantity
- Batch/serial numbers
- Expiration dates (if applicable)
- Quantity per dispensing package

Ensure that drugs/devices and supplies required for study conduct are within an appropriate expiration date. Record receipt of investigational product on the day the shipment is received (see Sample Form: Study Drug Accountability Log or Study Device Accountability Log).

2. Storage of Investigational drugs/devices

Store investigational drugs/devices in a secure environment with access limited to essential research personnel. Ensure the study drug/device is stored at the appropriate temperature and maintain an appropriate storage area temperature log. Storage areas should be routinely monitored for acceptable conditions and if the temperature is found to be out of range, ensure plans are in place to move the investigational drugs/device to an alternate area. Appropriate measures should be taken if temperature excursions are noted.

3. Dispensing of Investigational drugs/devices

Each time study drug/device is dispensed by the Investigator or a delegated member of the research team, the Study Drug Dispensing Log (See Sample Form) or the Study Device Dispensing Log (See Sample Form) must be completed. Documentation on these forms includes:

- Date of dispensing
- Subject's identifying number and/or initials
- Lot/kit number(s)
- Expiration date
- Amount dispensed
- Amount of study drug returned by subject
- Date study drug or device returned by subject

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

After use by the subject, collect, account for, document and retain all returned, used study article containers/units/devices and store in a secure environment and according to the protocol. All discrepancies between expected quantities and returned quantities should be explained, where applicable. Any lost or un-returned drug/device/container should be explained and documented.

4. Return or disposal of Investigational Drugs/Devices

Ensure that study article is prepared for return to supplier/sponsor or disposed of on-site according to the study protocol or sponsor instructions. Disposal of the drug/device should be documented on the appropriate accountability logs.

Investigators are responsible for maintaining adequate records pertinent to the investigation. Copies of study drug/device packing slips, shipment receipts, accountability records, disposal instructions, and accountability logs should be retained within the trial's essential regulatory file(s) as agreed upon with the sponsor or determined by the institution's policies.

References:

ICH Good Clinical Practice E6(R2)

Code of Federal Regulations Title 21

- 21 CFR Part 312
- 21 CFR Part 812