



**Procedure Name:** Investigational Product Control and Accountability  
**Effective Date:** March 1, 2010  
**Revision:** 01  
**Initiating Department:** Office of Clinical Trials  
**Procedure Number:** CR-002, Rev 1  
**Application:** Principal Investigators, Coordinators and Staff  
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**OBJECTIVE:**

Describe the requirements for receiving, controlling and final disposition of investigational products.

Principal Investigators are responsible under the Code of Federal Regulations for receiving, controlling, and accounting for all investigational products, drugs or devices. Access to or use of investigational products is restricted to bona fide research subjects who have documented informed consent for participating in the clinical trial (reference CR-001 – Informed Consent and OPHS-IRB Manual Section 9 – Informed Consent Requirements).

**REFERENCES:**

<b>21 CFR 312.59</b>	Disposition of unused supply of investigational drug
<b>21 CFR 312.61</b>	Control of the Investigational Drugs
<b>21 CFR 812.110</b>	Investigational Device Exemptions—Responsibilities of Investigators: Specific responsibilities of investigators.
<b>ICH E-6, § 4.6</b>	Investigational Products
<b>ICH E-6, § 5.14.</b>	Supplying and Handling Investigational Product(s)
<b>OPHS-IRB Manual, Sections 15.1 and 15.2</b>	Investigational New Drug (IND) Exemption and Investigational Medical Devices

**SCOPE:**

This document describes the procedure for the receipt, control and eventual disposition of investigational products used in human clinical trials.

**RESPONSIBILITY:**

The Principal Investigator (PI) holds ultimate responsibility for the control of the investigational product. Certain responsibilities may be delegated to clinical staff, research pharmacists or other staff members; however accountability for compliance with regulatory requirements always rests with the PI.

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**PROCEDURE:**

Receipt and Storage of Investigational Products - The PI (or delegate) will:

- 1.0 Receive the investigational product from the trial sponsor. As applicable, record the following information in investigational product log:
  - 1.1 Record the date
  - 1.2 Reference the protocol ID or study name
  - 1.3 Record the source of the investigational product received. This may be the sponsor or it may be a third-party handling the investigational product. This step may be omitted if all investigational materials are shipped from the same source.
  - 1.4 Record the quantity of investigational product received. Record quantities received by lot number or serial number if applicable.
  - 1.5 Record any expiration date (by lot or serial number) as applicable.
  - 1.6 Record any control or code numbers that may apply to the investigational product.
- 2.0 The investigational product inventory is a permanent trial record and is subject to the requirements for recording and maintaining clinical trial documentation. This log/inventory forms the basis of the on-going investigational product inventory that will be in use throughout the trial.
- 3.0 Assure that the investigational product is stored in a securely locked space with access limited to only those personnel authorized to access the product.
- 4.0 Note the requirements for storage and handling of the investigational product as provided by the sponsor. Such requirements might include maintaining the product at controlled temperature and/or humidity, protecting the investigational product from light, etc. Assure that the investigational product is stored in compliance with any special requirements provided by the sponsor.

Dispensing the Investigational Product – The PI (or delegate) will:

- 5.0 Assure that only subjects under the investigator's personal supervision or the supervision of a sub/co investigator receive the investigational product. Do not supply the investigational product to anyone not authorized to receive it (i.e., anyone who has not been consented and randomized/enrolled.)
- 6.0 Dispense the investigational product as described in the current version of the protocol. Maintain records of the disposition/use of the investigational product including the date dispensed, quantity dispensed lot or batch number if applicable. As consistent with the protocol, assure that the subjects receiving the investigational product are instructed in its proper use.
- 7.0 Update the on-going inventory of the investigational product to reflect the product dispensed. Assure that the on-going inventory is detailed to the batch/lot number as applicable. For devices composed of multiple interchangeable parts, assure that these parts are individually inventoried and controlled.

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Reconciliation and Disposition of Investigational Products

- 8.0 Retrieve any unused investigational product (including empty containers as applicable).
- 9.0 Record the quantities of returned investigational product with the same level of detail regarding batch/serial numbers or components as was recorded when the materials were dispensed.
- 10.0 At the end of the study, inventory any investigational product that may remain on site and conduct a full reconciliation.
  - 10.1 Utilizing the initial quantities (by batch/lot/serial number), debit the quantities dispensed and any quantities remaining. If the quantity of material received minus the quantities used and remaining does not equal zero, document a note-to-file addressing the discrepancy. Review the note-to-file with the PI and where applicable with Quality Assurance.
  - 10.2 If warranted, create a corrective and preventative action plan to strengthen product accountability procedures.
- 11.0 Notify the sponsor of the results of the reconciliation and make arrangements for the return or destruction (as instructed by the sponsor) of any unused materials. Assure that investigational product returned or destroyed is accounted for in the inventory records.
  - 11.1 Typically, left-over investigational product is returned to the sponsor. In the event that the sponsor requires the product to be destroyed, request a procedure for product destruction from the sponsor and contact the Office of Clinical Trials management.

**REVISION HISTORY**

Rev	DCO	Description of Change	Approved by
1	08-010	Edited for clarity and style	Michael V.W. Bergamini (MVWB)