





## Investigational Product Storage and Accountability 301-01

### 1. Purpose

The purpose of this operating procedure is to define the procedure for management of the investigational product inventory.

### 2. Responsibilities

**Qualified Investigator (QI):** Is responsible for following the protocol and provided procedures concerning the Investigational Product.

**Methods Centre (MC):** The MC, under the guidance of the Sponsor, is responsible for ensuring government legislation and ICH Guidelines regarding the handling, storage and supply of the investigational product are followed.

### 3. Procedures

3.1 The MC, under the direction of the Sponsor, is responsible for supplying the research sites with the investigational product.

3.2 The MC may delegate the investigational product inventory management to an external party (e.g. manufacturer of the product).

3.3 The MC should not supply a research site with investigational product until all required regulatory documentation, including research ethics board approval, has been received (see SOP 208).

3.4 The MC should ensure that the research site is provided with written procedures concerning:

- 3.4.1 Investigational product storage conditions
- 3.4.2 Investigational product shipping and handling instructions
- 3.4.3 Investigational product dispensing
- 3.4.4 Investigational product destruction or return

3.5 The MC should ensure that the research site maintains, and when requested, provides written documentation concerning:

- 3.5.1 Handling and receipt of investigational product
- 3.5.2 Investigational product storage conditions, including temperature logs
- 3.5.3 Investigational product delivery, inventory and return
- 3.5.4 Investigational product use records, including accountability and inventory logs, training of staff involved with these processes (e.g. site Pharmacy staff).
- 3.5.5 Investigational product destruction or return

3.6 The MC should ensure timely delivery and adequate investigational product supplies at the research sites.

3.7 The MC should maintain documentation concerning investigational product shipment, receipt, disposition, return and destruction.

3.8 The MC should maintain a tracking system for the investigational product to ensure easy retrieval of recalled product (e.g. defect recall, trial completion, expired product) and unused product.



Investigational Product Storage and Accountability  
301-01

3.9 The MC should maintain documentation concerning investigational product stability, specification conformance and batch sample analysis.

**4. References**

4.1 ICH GCP Section 5.13: Manufacturing, Packaging, Labeling, and Coding of Investigational Products

4.2 ICH GCP Section 5.14: Supplying and Handling Investigational Products

4.3 Food and Drug Regulations, Division 5: Drugs for Clinical Trials Involving Human Subjects section C.05.012, 3(e).