

Effective Date:

--	--	--	--	--	--	--

SOP No: P9

PRE-STUDY PLANNING OF INVESTIGATIONAL PRODUCTS**CLINICAL TRIALS CENTRE DEVELOPMENT TEAM:**

James Thorburn
 Johan Karlberg
 Selene Tam
 Yolanda Yan

APPROVED BY:

 Investigator's Name

 Signature/Date
REVISIONS:

No.	Section No.	Page No.	Initials/Date

DATES OF NEXT REVISION OF THIS SOP:

Date	Signed	Date	Signed

SOP No: P9**PRE-STUDY PLANNING OF INVESTIGATIONAL PRODUCTS****I. Purpose**

To describe the pre-study procedures relating to the receipt, storage, dispensing and accountability of Investigational Product (IP) used in clinical trials.

II. Other Related Procedures

SOP T2: Blinding: Codes and Code Breaking

SOP T3: Investigational Products Accounting and Dispensing

III. Procedures

IPs are experimental by definition and include drugs, vaccines and devices. For this reason, all aspects of manufacture, distribution, storage, handling and dispensing and excess recovery are subject to ICH GCP guidelines. The Investigator is ultimately responsible for all study drug management. However, this responsibility may be delegated to a Pharmacist or Clinical Research Co-ordinator (CRC).

1. General

- a) The Investigator and the CRC are responsible for ensuring adequate communication exists between the Sponsor and the individual responsible for the management of the IP.
- b) Review fully the study protocol and discuss with the Sponsor the following issues relating to the IP:
 - Description of IP
 - Packaging of IP
 - Labelling plans of the IP
 - Space required to store the IP
- c) Establish with the Sponsor the procedure(s) that should be followed for requesting further supplies of the IP.
- d) Agree with the Sponsor the methods and/or forms to be used for documenting the movement of trial medication with all the involved parties.
- e) Discuss and agree with the Sponsor the documentation needed for the procedures for checking subject compliance with the IP, e.g. checking that the diary cards are consistent with returns and measuring plasma or urine levels of the drug.

- f) Agree on the documentation for the presentation format (e.g. blister packs, inhaler device or liquid) of the IP before the entry of the first patient into the study.

2. Delivery and Storage of IP

- a) Document the receipt of each delivery of the IP at the study site and/or pharmacy and notify the Sponsor in writing of the receipt in accordance with their requirements.
- b) Document the conditions of storage as requested by the Sponsor, e.g. the daily temperature of the refrigerator which stores the IP.
- c) Ensure that sufficient space will be made available to store the IP until arrangements have been made by the Sponsor that the unused drugs can be retrieved or destroyed.
- d) Establish the procedures to be followed for the return or destruction of the IP at the end of the study. If the IP is to be destroyed without being returned to the Sponsor, this action should be documented clearly before the beginning of the study.

3. Preparation for Dispensing

- a) Document in the Investigator's study file who has direct access to the IP during the study.
- b) If the IP is to be dispensed by the Investigator and not a pharmacist, identify a secure area with restricted access and conditions appropriate for the storage of the IP.

4. Supply of IP on a Named Subject Basis

- a) Discuss with the Sponsor whether a named patient supply of the IP will be available at the end of the study.
- b) Agree with the Sponsor the procedure(s) for requisitioning the IP for the named subjects/patients.
- c) Discuss with the Sponsor if the IP will continue to be available to subjects after the study ends, if the subjects benefited from the intervention and if so, will there be a cost and how will this be met?

5. Accountability

- a) Discuss and agree with the Monitor the procedures to be employed for ensuring proper and adequate accountability of the IP.