



## Standard Operating Procedures

### 5.14.1 Investigational Product Handling and Storage ©2007

History			
Version	Date	Author	Reason
1.1	23 <sup>rd</sup> August 2007	B Fazekas	New procedure
1.2	16 <sup>th</sup> October 2007	B Fazekas	Update after David Currow review

Approval				
Version	Author	Signature	Approval Name	Approval Signature
1.2	B Fazekas	<i>B. Fazekas</i>	David Currow (CI)	<i>David Currow</i>

Scheduled review

Date: August 2009

Responsible person: Project Officer

## **Purpose**

This SOP is to describe the processes for investigator and study personnel when prescribing, receiving, transporting and accounting of investigational products involved in clinical trials.

This SOP does not cover the preparation of investigational products by the sponsor or site pharmacy. This SOP also does not cover transport of investigational product between manufacturer and pharmacy, or transfer of Investigational Product between sites and pharmacies.

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## **Other related SOP's**

4.0 Investigator roles and responsibilities

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## **Attachments**

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## **References**

Controlled Substances Act (SA) 1996.  
Code of Practice for the storage and transport of drugs of dependence, Department of Human Services, 31 July 2000 (South Australia).

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## Definitions

### Delivery

Where the investigational product is delivered to the patient after dispensing by the pharmacy. For example, this is where the study nurse is delivered by the nurse for them to either self administer, or for administration via an infusion or other route.

### Dispensing.

Where the Investigational Product is provided to the study participant by the pharmacist who prepared the drug. In most cases this will be a secondary process, as the drug may well be dispensed to the study nurse for delivery to the patient.

### Investigational Product (IP)

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

### Site Investigator.

A person responsible for the conduct of the clinical trial at a trial site. If conducted by a team of investigators, the site investigator who is the responsible leader of the team may be called the principle site investigator.

### Prescribing.

The written prescription (where applicable) detailing the investigational product for a specific participant.

### Receipt.

Where the prescribed Investigational Product has been handed over to another person. In most cases this will be to the study nurse for transport and dispensing to the participant.

### Return.

Where all used **and unused** Investigational Product and the associated records are returned to the pharmacy of origin after each participant has ceased their participation in the study.

### Storage.

This is where IP is stored on a temporary basis due to a delay (either planned or unplanned) in the transport from the receipt to dispensing.

### Sub Investigator.

An individual member of the clinical trial team designated and supervised by the investigator to perform critical trial related procedures and/or make important trial related decisions.

### Transporting.

Where specific IP is moved from one location from another. This might be from the pharmacy to the patient in their own home.

## Procedure

### 1. Prescribing

All prescriptions for the use of investigational products for clinical trials must be:

- Completed by a person authorised to do so
  - The principle site investigator
  - Sub investigators
  - Those medically authorised to prescribe the specific product under investigation
- Completed on a hospital prescription form
- Detail full description of the
  - Patient details
  - Study protocol number
  - Drug
  - Dose
  - Frequency
  - Routeas specified within the study protocol and/or study implementation procedures
- In accordance with standard hospital prescription orders.

### 2. Receipt

Prescriptions for investigational products can be received by

- The participant and/or family member
- Study nurse
- Other personnel as described on the study staff signature sheet

That person must sign receipt of the investigational product as specified by the appropriate legislation (for example where Schedule 4 or 8 drugs are being dispensed).

The product being received must be checked against the prescription.

If there is unanticipated delay in transporting the Investigational Product for any reason (for example: if the Investigational Product has been collected from pharmacy for delivery to the participant, and the participant is for some reason not available to receive the Investigational Product as planned);

- Return the Investigational Product to the pharmacy for storage if possible
- If not possible to return for storage
  - Secure within a storage safe appropriate for the Investigational Product (in the case of schedule 4 or 8 drugs this will be within a securely fixed and locked safe which meets the State or Territory requirements for such drugs)
  - Do not 'hide' the Investigational Product within unsecure premises until delivery can be undertaken.

### 3. Transporting

The investigational product will be provided within a zip lock pack containing the product for one participant only and the associated prescribing and checking documents. This pack

should be transported intact and within any other necessary packaging to further ensure safety during transport. This may include storage within the car boot, within a bag or case, within a cooler or ice pack as determined by the protocol and/or instruction from the pharmacist.

Transportation must be undertaken with a view to maximising security.

- Arrange receipt and dispensing times to coincide with as little delay as possible.
- In the case of Schedule 4 or 8 drugs they must be contained within a fully enclosed metal compartment with a well fitting door, in order to protect the drug as much as possible. This might be within locked boot.
  - A station wagon/hatch model car will not suit this requirement
- The transport vehicle must be kept locked at all times, with the key carried by the driver. Do not leave the car unattended with the engine running.
- The transport vehicle must not be left for extended periods of time while carrying Schedule 4 or 8 drugs.

#### 4. Delivery

The investigational product should be delivered to the person participating in the study.

- Ensure the person to receive the Investigational Product will be available to receive the delivery.
- The product should be explained by an appropriate person as delegated by the investigator per the Study Signature Sheet.
- Check the Investigational Product container contents. Shortages or discrepancies are to be reported immediately to the pharmacy of origin. In the case of Drugs of Dependence, any unresolved discrepancies must be reported to police within 24 hours according to the State or Territory legal or procedural requirements.
- Where required, the person delivering the Investigational Product should sign the prescription copy to indicate delivery to the participant, or the participant should sign the appropriate section to indicate receipt of the product.
- In all studies advise participants to keep all packages and containers even if empty. They will all be collected on completion of participation in order to monitor compliance.
- Inform participants to not share the product with any other person under any circumstances.

#### 5. Return

All bottles, packs and other packaging of the investigational product must be kept by the participant and collected on study completion.

The study nurse, or other delegated person, should collect all study documents, packages, containers and records.

All product containers, including the unused product, must be collected and returned to the site pharmacy for accounting and destruction.

The return of the Investigational Product (used and unused packets) must be recorded within the Case Report Form.

The appropriate signature must be made on return to pharmacy if required (in the case of Schedule 4 and 8 drugs for example)

The unused product must not be passed on to others for further use.