UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

5.14.1 Investigational Product Handling

Version	V2.5
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Effective date	01/04/2022
Review date	01/04/2024

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Introduction / Background

Good Clinical Practice (GCP) requires investigational product accountability at the trial site. It also requires that the Investigational Product(s) are used only in accordance with the approved study protocol.

Objective

This SOP describes the processes for investigator and study personnel when prescribing, receiving, transporting, and accounting of Investigational Products involved in clinical studies.

This SOP does not cover the following:

- Preparation of Investigational Products by the sponsor or Site Pharmacy
- Transport of Investigational Product between manufacturer and pharmacy
- Transfer of Investigational Product between sites and pharmacies.

These procedures are described within the pharmacy manuals supplied to Site Pharmacies for each study.

Scope

This SOP applies to all staff involved in clinical studies conducted by the IMPACCT Trials Coordination Centre (ITCC), including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST), irrespective of individual organisational employment, role, or position.

This SOP also encompasses new procedures related to Direct to Patient delivery of study investigational product using a Just In Time model operating from a third party pharmacy

Ownership and Responsibility

Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.

Responsibilities of the Principal Investigator and/or other designee(s) as documented in the Staff Signatures and Delegation Log (refer SOP 4.2.4 Delegation of Duties)

- To receive prescriptions, transport, deliver and return investigational products

Responsibilities of the Site Pharmacy including a third-party pharmacy

- To account for and destroy or return all product containers (including the unused product) on exit from the study

Procedure

1. Prescribing

All prescriptions for the use of Investigational Products for clinical studies are:

- Completed in accordance with standard hospital prescription procedures and the study protocol (*refer* Guidance 6).

2. Receipt of the Investigational Product

Prescribed investigational products can be received by:

- The participant and/or family member
- The study Principal Investigator or clinical study team member (as designated in the study staff signature sheet)
- A third-party pharmacy

The person receiving the Investigational Product signs the receipt of the Investigational Product as specified by the appropriate legislation (for e.g., where Schedule 4 or 8 drugs are being dispensed).

The Investigational Product being received is checked against the prescription. In the event of an unanticipated delay in transporting the Investigational Product (for e.g., if the Investigational Product has been collected from pharmacy for delivery to the participant, and the participant is not available to receive the Investigational Product as planned), the Investigational Product is returned to the pharmacy for storage, if possible.

In the event that returning the Investigational Product to pharmacy is not possible, the Investigational Product is stored within a storage safe, consistent with regulatory and legislative requirements. For example, Schedule 4 and Schedule 8 products are stored within a securely fixed and locked safe which meets the local State or Territory requirements. The short-term storage must also meet the specified storage requirements for the Investigational Product, such as refrigeration, protection from light etc.

Investigational Products must not be stored within unsecured premises at any time.

3. Transporting

The Investigational Product is contained within a zip lock pack (or other suitable packaging) for one participant only with the associated prescribing and checking documents. This pack is transported intact and within any other necessary packaging to further ensure safety and maintenance of temperature (if required) during transport. This may include storage within the car boot, within a bag or case, within a cooler or ice pack and temperature monitoring during transport as determined by the protocol and/or instruction from the pharmacist.

Security of the Investigational Product is paramount during transportation. Security measures include (but are not limited to):

- Planning ahead to ensure receipt and dispensing times coincide with as little delay as possible.
- When transporting the Investigational Product by car, the model of car optimises security. For example, a car boot that is fully enclosed and has a well-fitting door. A station wagon/hatch model car may not suit this requirement.
- Locking the transport vehicle at all times, with the key carried by the driver. The vehicle must not be left unattended with the engine running.
- The transport vehicle must not be left unattended for extended periods of time while carrying Schedule 4 or 8 drugs.
- Use of an appropriate courier service with the level of licence and security in line with the medication schedule

4. Delivery

The Investigational Product is delivered to the participant. This includes delivery by the study team members, or by any third-party pharmacy.

The following measures are to be considered when planning and executing delivery of an Investigational Product:

- Ensuring the participant is available to receive the Investigational Product.
- The product is explained by an appropriate person as delegated by the Principal Investigator as per the Study Signatures and Delegation Log (*refer* SOP 4.2.4 Delegation of Duties). This may include the use of a counselling script and any appropriate instruction sheets or cards.
- The Investigational Product container is checked for contents. Shortages or discrepancies are reported immediately to the pharmacy of origin. In the case of drugs of dependence, any unresolved discrepancies are reported to police within 24 hours in accordance with the local State or Territory regulatory and legislative requirements.
- Where required, the study team member delivering the Investigational Product signs the prescription copy to indicate delivery to the participant. When able, the participant signs the appropriate section to indicate receipt of the product.
- Participants are requested to retain all packages and containers when empty.
- Participants are advised not to share the product with any other person under any circumstances.

5. Return

All containers, packs and other packaging for the Investigational Product are retained by the participants and returned to the study team or direct to the third-party pharmacy via courier or postage on exit from study.

- The study team member collects all study documents, packages, containers, and records.
- All product containers, including any unused product, are collected, and returned to the Pharmacy for accounting and destruction.

- The return of the Investigational Product (used and unused packets) are recorded within the Data Collection Worksheets and the electronic Case Report Forms.
- The appropriate signatures are made on return to pharmacy if required (in the case of Schedule 4 and 8 drugs, for example)
- Any unused product is never passed on to others for further use.

Related SOPs

4.0 Investigator Roles and Responsibilities
4.2.4 Delegation of Duties

Related documents

Guidance 6: Prescription of Study Drug
Other: Any state or national regulations that cover the transport or storage if medicines that exceed the requirements described in this SOP.

References

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

Controlled Substances Act (SA) 1996.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 10/02/2020)

https://www.ich.org/page/efficacy-guidelines

History			
Version	Date	Author	Reason
1.1	23/08/2007	B Fazekas	New procedure
1.2	16/10/2007	B Fazekas	Update after David Currow review
1.3	9/06/2010	B Fazekas	Periodic review
1.4	7/01/2011	B Fazekas	Changes ratified by MAB
2.0	1/02/2011	B Fazekas	New version with all updates
2.1	19/05/2015	C Hope	Review of procedure
2.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
2.3	06/12/2018	L Brown	Update to include CST and ©
2.4	10/02/2020	J Lourdesamy	Periodic review
2.5	14/01/2022	B Fazekas	Periodic review Incorporate new direct to patient delivery and Just in Time dispensing model

Approval		
Version	Approval Name	Approval Signature
2.5	Meera Agar