SOP Number: 110
SOP Title: Management of Investigational Product

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Amendment History

Version	Date	Author/s	Amendment Details
1.0	1 June 2010	Katrina Brosnan	New
2.0	December 2017	Roberta Lusa &Bernadette Morris-Smith,	All sections, incorporating ICH GCP E6 (R2) and teletrials: QH TELETRIAL PILOT VERSION 1.0
3.0	June 2018	Roberta Lusa	All sections, refinement after CRC input: PUBLIC RELEASE VERSION 3.0
4.0	April 2019	Roberta Lusa	Amendments post Round 1 Health Service Directive Consultation

1 Purpose

To describe the procedures related to managing all aspects of Investigational Product, either medicinal product or device. Management includes but is not limited to the receipt, storage, accountability, preparation and administration, shipment and destruction of investigational product.

Note: *Relabeling of investigational product is not covered here as it will follow the procedures sent to the sites by the sponsor or follow the institution's pharmacy procedures for relabeling.*

2 Responsibility / Scope

This standard applies to all Queensland Health employees (including visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients and staff. All study personnel involved in the clinical study must operate within their scope of practice.

3 Glossary

For an explanation of acronyms and the definition of terms used in these SOPs, please refer to Chapter Two: Glossary of The Australian ICH GCP (Including Teletrials) SOP Compendium.

4 Procedure

4.1. Management of Investigational Product (Medicinal Product or Device)

Responsibility for Investigational Product (IP) management and accountability at the trial site rests with the Principal Investigator (PI). However, the PI may delegate responsibility for IP management to the site pharmacist or, where a pharmacist is not available or involved, to an appropriately qualified person (as per AUSTRALIAN ICH GCP (Including Teletrials) SOP 30).

In accordance with the Health (Drug and Poisons) Regulation 1996 (Qld), an endorsement is not required for a person to dispense, prescribe, and supply a restricted drug or controlled drug for an approved clinical trial.

The site pharmacist or the appropriately qualified person will undertake management of the Investigational Product at the Primary Site and / or the Satellite Site.

Where the delegation of this activity requires supervision (e.g. pharmacist or appropriately qualified person new to the role), the delegated activity is to be clearly documented on the supervision plan, the Delegation and Training Logs. (see AUSTRALIAN ICH GCP (Including Teletrials) SOP 30).

4.2 The investigator, pharmacist or appropriately qualified non-pharmacist, must:

- Ensure the Investigational Product is used only in accordance with the approved protocol.
- Maintain records of all aspects of the management of the investigational product. These records at a minimum should include: shipping documents; date of each transaction; quantities; batch/serial numbers; expiration dates/retest dates (if applicable); temperature logs showing the storage conditions of investigational product throughout the trial period; the set of unique code numbers assigned to the Investigational Product and to the trial participant; and record of destruction/return.
- Provide maintenance and calibration records for storage equipment (e.g. refrigerators, thermometers) in accordance with sponsor requirements.
- Ensure that the Investigational Product is received, stored respecting correct temperature control, prepared, administered, shipped and destroyed as specified by the sponsor in accordance with the Protocol, pharmacy manual and applicable regulatory requirement. Consideration must be given to security of the Investigational Product, with restricted access to approved personnel.
- Ensure any deviation to required temperature, storage conditions, potential defect / issue with IP is notified to sponsor in a timely manner and in accordance with study Protocol. Follow study site quarantine process as applicable.
- Explain the correct use of the investigational product to each participant and should check, at intervals appropriate for the trial, that each participant is following the instructions properly. Instruct participant where relevant to return empty and partially used medication containers at their next visit. Extra counseling by the investigator or delegate, for study participants regarding poor medication compliance may be required.
- Follow the trial's randomisation procedures, if any, and ensure, for blinded studies, the blind is broken only in accordance with the protocol. For a blinded study, the investigator must promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product.

- Where the investigational product is shipped to, and/or returned from, a satellite site, a written working instruction or procedure documenting the manner in which this process is to occur must be in place at the primary site pharmacy. The sponsor will require evidence of this document for the primary site to manage the satellite site stock. The document must address, at a minimum, aspects of IP shipment such as: the appropriate transfer method, respecting temperature control and monitoring thereof; clear identification of what is being shipped; that the IP is to be used according to the sponsor's guidelines; relevant documentation to accompany the shipment; acknowledgement of receipt by satellite site or primary site; delivery information of IP from or to the primary site; filing of relevant documentation at both sending and receiving sites.

5 Guidance Documents

1. Health (Drugs and Poisons) Regulation 1996 (Qld)
2. AUSTRALIAN ICH GCP (Including Teletrials) SOP 30: Site Staff Qualifications, Training Records and Capability.

6 Appendices

Appendix1 Example of Individual Participant Investigational Product (IP) Accountability Record