CLINICAL TRIAL SOP 12: Management of Investigational Product

Purpose

To describe the procedures related to managing all aspects of Investigational Product (IP), either medicinal product or device. Management includes but is not limited to the receipt, storage, accountability, preparation and administration, shipment and destruction of IP.
Note: Relabelling of IP is not covered here as it will follow the procedures sent to the sites by the Sponsor or follow Cabrini pharmacy procedures for relabelling.

Scope

This SOP applies to all Investigators (Principal and Sub-Investigator), Study Coordinators, visiting medical officers (VMO), and other Research staff and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

Cabrini Health policies and regulatory requirements

This SOP should be read in conjunction with policies and other documents provided by the Cabrini Research Governance Office (CRGO) relevant to the conduct of clinical research at Cabrini Health including but not limited to:

- Aboriginal and Torres Strait Islander Health – asking for Aboriginal and Torres Strait Islander identity
- Monitoring of Research Policy
- Research Integrity and Misconduct Policy
- Safety Monitoring and Reporting in Research Policy
- Cabrini Research Data Management, Access and Sharing Policy
- Data Classification and Labelling Standard
- Cabrini Authorship and Publications for Research Policy
- Research Participants Complaints and Compliments Procedures Policy
- Cabrini Research Governance Handbook

Researchers at Cabrini must foster quality research and abide by the following directives:

- The National Clinical Trials Governance Framework (NCTGF)
- National Statement on Ethical Conduct in Human Research (2023)
- Catholic Health Australia Code of Ethical Standards
- Act in accordance with Cabrini Research policies in order to protect the rights, safety and welfare of research participants
- Support patient and family carer involvement in their own research participation through abidance with the Australian open disclosure policy, and Charter of healthcare rights.
- Agree to comply with all reasonable directions and policies by Cabrini Research for Cabrini to meet or exceed the requirements of the NCTGF. To the extent that the NCTGF

applies to the position, compliance with the specified roles and functions of the workforce, as set out by the NCTGF.

Procedure

12.1 Management of Investigational Product (Medicinal Product or Device)

Responsibility for IP management and accountability at the trial site rests with the 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 SOP 2 Site Staff Qualifications, Training Records and Capability).

The site pharmacist or the appropriately qualified person will undertake management of the IP.

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 Delegation and Training Logs (see SOP 2 Site Staff Qualifications, Training Records and Capability).

The task of prescribing IP should only be delegated, as appropriate and within a health practitioner's scope of practice, to medical practitioners, dentists or nurse practitioners. The task of administering IP should only be delegated to medical or clinical staff and within their scope of practice (e.g. registered nurses).

The Investigator, Pharmacist or appropriately qualified non-pharmacist must:

- Ensure the IP is used only in accordance with the approved Protocol.
- Confirm IP certification and all relevant trial approvals/notifications are in place before releasing IP for dispensing to participants (i.e. ethics and Cabrini Research Governance Office (CRGO) approval, CTN/CTA, drug committee approvals and product compliance with guidance documents and legislation).
- Maintain records of all aspects of the management of the IP. 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 IP throughout the trial period; the set of unique code numbers assigned to the IP 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 requirements.
- Ensure that the IP 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 IP, with restricted access to approved personnel.
    - IP should be transported, stored and supplied according to jurisdictional and Cabrini policies.
    - The majority of IP will be received, stored and managed within a pharmacy. However, exceptionally, it may be necessary for IMP to be stored in a ward or facility (e.g. for trials where IP is administered in the emergency setting or outside of pharmacy opening hours). Arrangements for IP storage outside of the pharmacy should only occur following consultation with the Cabrini pharmacy service. Where Cabrini policy allows delivery

directly to storage areas outside pharmacy, these should be assessed by staff (e.g. pharmacy) to ensure storage conditions are adequate, temperature monitoring is in place and accountability (including an area for returns) meets Protocol/pharmacy manual requirements.

- Where IP is logged out of pharmacy and transferred to a department/facility/area (or other location) for administration to the patient/participant (e.g. IV infusion in a ward or administration of a vaccination at a participant's home), appropriate chain of custody records should be maintained. Where IP (compounded or reconstituted in pharmacy or for immediate use by nursing or other qualified staff) has limited stability/short half-life, records should be able to demonstrate that it was transported and administered within the specified timeframe.
- IP should not be destroyed without prior written authorisation by the Sponsor. IP that is unused, expired or returned by patients/participants should be stored in an appropriately controlled area, until ready for return to the Sponsor (usually at intervals) or disposal at site. Returned IP should be stored separately to unused IP. Where IP is to be returned to the Sponsor, all patient/participant-identifiers must be removed beforehand.

- Ensure any deviation to required temperature, storage conditions, potential defect/issue with IP is notified to the Sponsor in a timely manner and in accordance with the study Protocol. Follow study site quarantine process as applicable.
- Explain the correct use of the IP to each participant and check, at intervals appropriate for the trial, that each participant is following the instructions properly. Instruct participants where relevant to return empty and partially used medication containers at their next visit. Extra counselling by the Investigator or delegate, for study participants regarding poor medication compliance, may be required.
- Ensure all staff follow the trial's randomisation procedures, if any.
- 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 IP.
- Where the IP is shipped to, and/or returned from, a non-Malvern Cabrini Site, a written working instruction or procedure documenting the manner in which this process is to occur must be in place at the Cabrini pharmacy. 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 the Primary Site; delivery information of IP from or to the Primary Site; filing of relevant documentation at both sending and receiving sites.
- File all relevant trial related documentation in the ISF as per SOP 3 The Investigator Site File.

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Document Approval

NAME	POSITION	SIGNATURE	DATE
Professor Gary Richardson	Group Director, Cabrini Research		18 September 2024

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