CLINICAL TRIAL SOP 11: Handling and Shipping of Biological Substances

Purpose

To outline the procedures to follow when handling and shipping Biological Substances (Cat B) and/or Dangerous Goods in clinical trials to ensure the safety of all staff when carrying out this activity. To also outline the regulations that govern this activity in clinical trials.

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.

This SOP covers the handling and shipment of biological substances category B and dangerous goods (dry ice) only. When references to biological samples/specimen/substances are made, category B is implied.

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

11.1 Handling and Shipping of Biological Substance and Dry Ice in Clinical Trials

This activity may be delegated to another staff member or third-party service provider, provided they hold a current certificate to do so. This duty is delegated as per SOP 02 Site Staff Qualifications, Training and Capabilities. It is still the Investigator's responsibility to ensure all procedures and regulations are adhered to.

The Investigator must:

- Ensure all study staff, who have cause to handle or ship biological substances, hold a current certificate in the International Air Transport Association (IATA) Approved, Civil Aviation Safety Authority (CASA) Certified Dangerous Goods Packaging Course.
- Sample kits provided by Sponsors should be stored in an appropriate environment and reviewed periodically to ensure there are sufficient for the purpose of the study and they remain in date.
- Ensure specimens are collected and handled in accordance with local and Sponsor requirements as written in the Protocol and laboratory manual.
- Ensure specimens are packed and shipped in accordance with local and Sponsor requirements as written in the Protocol and laboratory manual and according to IATA requirements, including that a valid export permit is in place, if required.
- Ensure that in situations where research personnel do NOT hold current certification, arrangements for biological substance/dry ice shipment are made with IATA certified Pathology Laboratory staff or external third party.
- Ensure that the *National Pathology Accreditation Advisory Council (NPAAC): Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials* are followed by relevant certified staff.
- Ensure any training is recorded on the Training Log as per SOP 02 Site Staff Qualifications, Training and Capabilities and copies of certificates are kept in the SMF.
- Ensure that documentation (e.g. receipts, shipping records, order forms, proformas) related to handling and shipment of biological specimens is maintained and filed in the respective site file, either the SMF or participant Source File. Sites frequently take biological samples (e.g. tissue, blood, urine, and sputum) from trial participants that are then processed, stored, packed and transported to local or central laboratories. To ensure that the integrity of biological samples has been maintained, there should be evidence for the activities performed or overseen by site of the chain of custody, such as from their point of collection through processing, storage, transport, through to disposal, with evidence of appropriate storage and transit conditions. Third parties engaged by sponsors for such activities, including couriers, are to be managed by the sponsor or their representative.

11.2 Notes regarding Certification to handle and transport biological substances and Dry Ice

- The CASA Certified Dangerous Goods Packaging Course can be done by any media and must be recorded on the respective Training Log as per SOP 2 Site Staff Qualifications, Training and Capabilities.

- CASA Regulations have defined categories of personnel who should attend training and the subject matter in which they must be qualified. These regulations are mandatory and legally binding and consequently must be adhered to in full.
- Re-certification is required every two years. Certificates and any training records must be kept for a minimum period of 36 months from the most recent training completion date, and must be made available, upon request to the Sponsor, regulatory authority, and CASA.

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