GV Health	**TITLE:**	**Clinical Trial Standard Operating Procedure 10: Handling and Shipping of Biological Substances (Cat B) and/or Dangerous Goods in Clinical Trials**	
Document Type:	Procedure	**Approved by:**	Research Management and Governance Committee
Directorate:	CMO + Medical Services	**Section:**	Research
Author/Prepared by:	Dr Ainsley Robinson	**Position:**	Clinical Trials Coordinator

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The definitive versions of all Goulburn Valley Health (GV Health) Clinical Trial Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the GV Health website or Prompt.

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Name:	Research Management and Governance (RM&G) Committee
Position:	Chair RM&G Committee
Date:	22 March 2024

Amendment History

Version	Effective Date	Review Date	Author(s)	Amendment Details
1.0	12 Nov 2020	16 June 2023	Dr Ainsley Robinson Research and Ethics	Reviewed and updated to v2.0

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1. 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 governs this activity in clinical trials.

2. SCOPE:

This Standard Operating Procedure (SOP) applies to all GV Health employees, visiting health professionals, contractors, any external researchers, consultants, and volunteers who propose to undertake, administrate, review and/or govern human research involving GV Health patients/participants, facilities and/or 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 biological samples/specimen/substances are written, category B is implied.

3. PROCEDURE:

3.1. Handling and Shipping of Biological Substances 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 GVH_CT-SOP-03 Site Staff Qualifications, Training records and Capability. It is still the Investigator's responsibility to ensure all procedures and regulations are adhered to.

3.1.1. 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.
- Ensure specimens are 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 is 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 GVH_CT-SOP-03 Site Staff Qualifications, Training records and Capability and copies of certificates are kept in the respective site file Study Master File (SMF)/ Satellite Site Study File (SSSF).

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- Ensure that documentation (e.g. receipts, shipping records, order forms, proformas etc.) related to handling and shipment of biological specimens is maintained and filed in the respective site file (SMF/SSSF).
- 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 of the chain of custody from their point of collection through processing, storage, transport, through to disposal, with evidence of appropriate storage and transit conditions.

Equipment used for processing and storage of samples (e.g. centrifuges, fridges and freezers) should be maintained by suitably qualified persons and periodically inspected, cleaned, and calibrated to the relevant ISO standard according to local policy and manufacturer's manuals. Sample kits provided by Sponsors should also 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.

3.2. 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 GVH_CT-SOP-03 Site Staff Qualifications, Training records and Capability.
- 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, 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 sponsor, regulatory authority, and CASA.

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ABBREVIATIONS AND TERMS:
Please refer to GVH_CT-SOP-Abbreviations and Terms.

KEY LEGISLATION, ACTS & STANDARDS:
National Safety and Quality Health Service (NSQHS) Standards:
- Standard 1 Clinical Governance

KEY ALIGNED DOCUMENTS:
GV Health Procedure:
- GVH_CT-SOP-03 Site Staff Qualifications, Training Records and Capability

REFERENCES:
National Clinical Trials Governance Framework and User Guide, Australian Commission on Safety and Quality in Health Care. (2022). Safetyandquality.gov.au. https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide

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