SOP Number: 100
SOP Title: Handling and Shipping of Biological Substances (Cat B) and/or Dangerous Goods in Clinical Trials

SOP number:	**100**
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Approved by:	A/Director, Health Innovation, Investment and Research Office of the Director- General

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 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.

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, 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 Glossary

For an explanation of acronyms and the definition of terms used in these SOPs, please refer to Chapter Two: Glossary, located at the front of the Australian ICH GCP (including Teletrials) Standard Operating Procedures (SOP) Compendium.

4 Procedure

4.1 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 Australian ICH GCP (including Teletrials) SOP 3. 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 IATA Approved, Civil Aviation Safety Authority (CASA) Certified Dangerous Goods Packaging Course, approved by Queensland Health (QH).

- 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 International Air Transport Association (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 Queensland 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 AUSTRALIAN ICH GCP (including Teletrials) SOP 30 and copies of certificates are kept in the respective site file (SMF/ SSSF)
- 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/ satellite site SF).

4.2 Notes regarding Certification to handle and transport biological substances and dry ice

- In Queensland, to organise training for handling and shipping of biological substances and dry ice, staff should contact their local Pathology Queensland Laboratory. The Civil Aviation Safety Authority (CASA) Certified Dangerous Goods Packaging Course can be done by any media and must be recorded on the respective training log as per Australian ICH GCP (Including Teletrials) SOP 30.
- 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.

5 Guidance Document

1. Australian Code for the Transportation of Dangerous Goods by Road and Rail Edition 7.5 (March 2017)

2. IATA Dangerous Goods Regulations 59th Edition 2018.
3. CaSS Pathology Queensland Dangerous Goods Manual: Manual for Shipper of Infectious Substances, GMOs GMMOs and Dry Ice (Updated with 2018 IATA 59th Edition. Small changes to Table 2.3.A and Road ADG Code 7 updated to 7.5. Mandatory from March 2018)
4. National Pathology Accreditation Advisory Council (NPAAC) Requirements for the packaging and transport of pathology specimens and associated materials (Fourth Edition 2013)
5. Australian ICH GCP (including Teletrials) SOP 30