

2019

HEALTH+MEDICAL RESEARCH

Handling and transporting biological specimens

Standard Operating Procedure



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The NSW Ministry of Health has developed these resources as a guide to support public health organisations in developing local governance around clinical trials. The resources should not be relied upon as a complete summary of obligations on public health organisations in relation to clinical trials and are not intended to circumvent clinical judgment or replace locally developed clinical trials policies. Public health organisations are encouraged to seek legal or other advice if there is any uncertainty around compliance with clinical trials requirements.

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1. Purpose

To describe the procedures followed by staff for the collection, handling, processing, and transport of clinical trial biological specimens outside a pathology service. To ensure that sites conducting clinical trials take appropriate account of the Guidelines for Good Clinical Practice based on sponsor requirements¹.

2. Scope

All clinical trials (except Teletrials)² conducted at NSW Public Health Organisations.

3. Applicable to

The principal investigator (PI) and all site staff involved in a clinical trial.

Pathology departments and other laboratories involved in trial-related activities.

4. Definitions

Refer to SOP-G-01: Glossary of terms.

5. Background

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 provide evidence 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 kit provided by sponsors should also be stored in an appropriate environment and reviewed periodically to ensure they remain in date.

6. Procedure

Principal Investigator (PI)

Ensure biological samples are collected, stored, packed and shipped in accordance with the protocol/laboratory manual. Ensure all relevant records

(e.g. temperature logs) are maintained to support evidence of appropriate storage (e.g. appropriate temperature if frozen - 20°C, -70°C or -80°C, the storage period did not exceed the maximum storage period prior to analysis).

Ensure study staff who handle or ship dangerous goods (e.g. biological samples, dry ice, liquid nitrogen, etc.) by air hold a current certificate in the IATA Approved, Civil Aviation Safety Authority (CASA) Certified Dangerous Goods Packaging Course.

- Where research personnel do NOT hold current certification, ensure arrangements for biological substances made with IATA certified NSW Pathology laboratory staff or a certified third-party laboratory.
- Ensure samples transported by air are packed and transported, in accordance with International Air Transport Association (IATA) and International Civil Aviation Organization (ICAO).
- 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.

PI or delegate

Collect and handle all biological samples in accordance with the protocol/laboratory manual, ensuring that the correct collection method is used and the handling process is followed (e.g. standing time, centrifuge time and speed) and the sample is clearly and accurately labelled. Utilise personal protective equipment (PPE) as appropriate.

Whilst samples are stored on site, track the location using a biological sample tracking log filed in the investigator site file.

Transport all biological samples in accordance with the protocol/laboratory manual. On receipt, check that all relevant documentation for sample transportation (e.g. waybill, shipping invoice and customs declaration if applicable) are available as described in the protocol/laboratory manual.

Check that samples are packaged according to the instructions outlined in the protocol/laboratory manual and provide the appropriate completed shipping documents to the courier booked for pick up (following an ID check).

¹ All trials must comply with the principles of GCP (Section 2 of ICH GCP (E6 R2) or Clause 4 of ISO 14155) however sponsors submitting data to regulatory authorities will normally require full compliance with ICH GCP (E6 R2) or ISO 14155 GCP Guidelines.

² NSW Health have published an annotated version of these SOPs for sites utilising a Teletrials model.

Ensure that all documentation (e.g. receipts, shipping records, order forms, pro formas, etc.) related to handling and transport of biological specimens are filed.

Ensure evidence of all requisite training (including recertification for CASA Certified Dangerous Goods Packaging Course according to CASA requirements) is documented in personal training records and that these records are made available to the sponsor, on request.

Lab staff

Laboratory staff are responsible for the coordination of equipment maintenance in accordance with NSW policy.

7. References

[ICH GCP \(E6 R2\): Good Clinical Practice Guidelines – Annotated by the TGA](#)

[Australian Code for the Transportation of Dangerous Goods by Road and Rail Edition 7.5](#) (March 2017)

[NSW Policy Directive PD2018_020: Transport of Pathology Specimens to Laboratories](#)

[IATA Dangerous Goods Regulations 59th Edition 2018](#)

[National Pathology Accreditation Advisory Council \(NPAAC\) Requirements for the packaging and transport of pathology specimens and associated materials \(Fourth Edition 2013\)](#)

[ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories](#)

8. Associated documents

Biological specimen tracking log template – available in the Standard Operating Procedures templates [zip file](#)