Title: Standard Operating Procedure (SOP) for the collection, handling and transport of biological samples in human research

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Author: Fiona Williams, Clinical Research and Development Office (CRDO)

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The author is signing to confirm the technical content of this document

Institution name: Melbourne Children's

Reviewed and Approved by:  **Date:** 5 December 2018

Andrew Davidson – Medical Director, Melbourne Children's Trial Centre (MCTC)

These signatures confirm the reviewers agree with the technical content of the document and that this document is approved for implementation at the RCH Campus.

This document is effective from the date of the last approval signature and will be reviewed in two years.

Document History

Revision	Modified by	Change No.	Description of Change
1.0	CRDO – Fiona Williams	N/A	New Issue

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1. PURPOSE

To document the procedure for the collection, handling and transport of biological samples in human research. This procedure should be read in conjunction with the MCRI policy "Transport of Biological Materials", available on the MCRI intranet.

2. RESPONSIBILITY, SCOPE AND APPLICABILITY

This standard operating procedure (SOP) applies to Melbourne Children's campus employees who undertake any of the following roles in human research:

- Principal Investigator (PI) at Melbourne Children's
- Members of research team who have been delegated responsibility for the collection, handling and/or transport of biological samples in clinical trials/research.

3. PROCEDURE

3.1. Documentation of Sample Movement

It is important to track the movement of biological samples, including tissue, blood, urine and sputum, from the point of collection from the donor, during processing, storage, distribution and/or use, and disposal.

The time and date of collection should be recorded on the Case Report Form; the time the samples are received in the laboratory and the time of testing should be recorded by the laboratory.

All samples that are to be stored prior to shipment to an off-site laboratory or another site must be stored under appropriate conditions and a log of the stored samples should be maintained (e.g. a freezer or refrigeration log). These logs are considered essential study documents and they (or certified copies) must be archived with the rest of the study documents following study completion.

When samples are shipped off-site, a copy of the courier form should be retained.

3.2. Collection and handling of samples

Samples must be handled in accordance with the requirements specified in the study protocol.

- Select the appropriate container to collect and store the sample
- Accurately label the sample
- Ensure that the immediate sample handling (methods and time requirements) complies with the study protocol and/or study Laboratory Manual. For example:
    - "Immediately place on ice"
    - And/or centrifuge [paying attention to the requirements such as the type of centrifuge, speed and duration])".

3.3. Storage of samples

All samples must be stored in accordance with the requirements set out in the study protocol and/or study Laboratory Manual. Consider aspects such as:

- Storage temperature (freezer requirement eg, -20°C, -70°C or -80°C)
- The maximum storage period allowed prior to analysis

3.4. Transport of samples

According to Australian legislation (Civil Aviation Act 1988), transporting of dangerous goods such as biological and infectious products, dry ice and liquid nitrogen by air must be packed by certified staff. Failure to do so could result in the air carrier refusing to accept the package or financial penalties or a jail term.

MCRI has a number of trained support staff to assist staff members with shipping. These staff members have completed the Safe Transport of Infectious Substances by Air (International Air Transport Association; IATA) course. Contact the MCRI Shipping Service staff for assistance.

Where transport of samples is delegated, it remains the Investigator's responsibility to ensure all procedures and regulations are adhered to.

The investigator must:

- Ensure that ethical approval and participant consent is in place prior to transporting biological to a third party.
- Ensure specimens are handled in accordance with local and Sponsor requirements as written in the protocol and laboratory manual (if applicable).
- Ensure specimens are packed and shipped in accordance with local and Sponsor requirements as written in the protocol and laboratory manual (if applicable) and according IATA and Civil Aviation Safety Authority (CASA) requirements, including:
    - Ensure that all study staff, who handle or ship biological substances (i.e. who enclose the goods in packaging, or mark or label the consignment, or prepare a shipper's declaration) are certified hold a current certificate gained through completion of an IATA/CASA approved Certified Dangerous Goods Packaging Course (see section 3.5). Where research personnel do NOT hold current certification, arrangements for biological substance / dry

ice shipment must be made with certified staff (as noted above, contact MCRI Shipping Services).

- Ensure that a valid export permit is in place (where required). Contact MCRI Shipping Services for assistance, if required.
- 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 Investigator File.

3.5. Notes regarding Certification to handle and transport biological substances and dry ice

- 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.
- All study staff, who handle or ship biological substances (i.e. who enclose the goods in packaging, or mark or label the consignment, or prepare a shipper's declaration) hold a current certificate gained through completion of a Civil Aviation Safety Authority (CASA)- approved Certified Dangerous Goods Packaging Course – see
  - https://www.casa.gov.au/standard-page/dangerous-goods-courses
  - https://www.casa.gov.au/standard-page/organisations-offering-shippers-courses-infectious-substances-diagnostic-specimens-and-dry-ice).
- 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 good clinical practice requirements and that copies of certificates are kept in the respective Site Investigator File.
- 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.

3.6. Disposal of samples

- Human research waste must be disposed of according to the "MCRI Laboratory Waste Disposal Chart", available on the MCRI intranet.

4. GLOSSARY

Essential documents
Essential documents are "Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced".

Case Report Form (CRF)
A paper or electronic data collection document used in human research. It is a tool used to collect data on each study participant. The CRF consists of CRF pages.

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

International Conference on Harmonisation (ICH)
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Investigator
An individual responsible for the conduct of a study, ensuring that the study complies with GCP guidelines.

- If a study is conducted by a team of individuals at a study site, the investigator is the responsible leader of the team and may be called the Principal Investigator (PI). In this instance they may delegate tasks to other team members.
- If a study is conducted at more than one study site, the Principal Investigator taking overall responsibility for the study and for the coordination across all sites is known as the Coordinating Principal Investigator (CPI); the Principal Investigator at each site will retain responsibility for the conduct of the study at their site.

Note that for investigator-initiated research, the PI or CPI leading the research takes on responsibilities of the Sponsor and the term "Sponsor-Investigator" should be adopted to highlight the combined sponsor and investigator role.

Melbourne Children's
This term is used to encompass all staff from The Royal Children's Hospital, Murdoch Children's Research Institute and Department of Paediatrics University of Melbourne

Standard Operating Procedure (SOP)
Detailed, written instructions to achieve uniformity of the performance of a specific function.

5. REFERENCES

- Transport of Biological Materials, MCRI policy available on the MCRI intranet.

- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) - annotated with TGA comments https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

- Handling and Shipping of Biological Substances, Category B and/or Dangerous Good for Clinical Trials Standard Operating Procedure Office of Health and Medical Research Queensland Health https://www.health.qld.gov.au/__data/assets/pdf_file/0020/151067/gcp_sop12.pdf

- National Pathology Accreditation Advisory Council (NPAAC) Requirements for the packaging and transport of pathology specimens and associated materials (Fourth Edition 2013 and all updates) https://www.health.gov.au/internet/main/publishing.nsf/content/health-npaac-publication.htm

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