Standard Operating Procedure

Title: Handling, processing, storage and transport of biospecimens in human research

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Applicability: All externally sponsored human research with prospective collection of biospecimens

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

Document History

Revision	Modified by	Date of Release	Description of Change
1.0	CRDO – Fiona Williams	N/A	New Issue
2.0	Saranga Senanayake	19/05/2023	Update to information in line with current practice and current SOP format Update to information in line with National SOP: SOP 10 Handling and Shipping of Biological Substances (Cat B) and Dangerous Goods (published 2020) Update to applicability to include all prospective human participant research (not only trials) with collection of biospecimens. Update to scope includes biospecimens collected off site when processed in MCRI/RCH laboratory space. Update to procedure to include use of correct tubes and use of tubes/sample kits.

Contents

1. PURPOSE

To document the procedure for the handling and transport of biospecimens collected from human research participants and to ensure:

- integrity of the specimens
- safety of all staff involved in these activities; and
- compliance with the study protocol, associated procedures, ICH-GCP and local/national requirements.

2. BACKGROUND

This Standard Operating Procedure (SOP) has been developed to assist staff to comply with GCP and regulations that guide the safe handling of biospecimens including:

- The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines
- National Pathology Accreditation Advisory Council (NPAAC) Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fourth Edition 2013)
- International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) and Packing Instructions 602, 650 and 904
- Australian Civil Aviation Amendment Regulations 2003 (Part 92).

3. SCOPE

This SOP covers the general processes related to the safe handling, processing, storage and transport of research biospecimens category B (such as blood, urine, tissue, sputum, faeces). When references to biospecimens/biological samples/substances are made, category B is implied.

This SOP applies to research team members who are performing these procedures in Melbourne Children's Research Unit (MCRU) and/or other designated RCH or MCRI laboratory space.

This SOP also applies to biospecimens collected off site and delivered to research team members for the performance of study specific processing and shipping procedures.

This SOP does not apply to MCRI sponsored investigator initiated studies.

4. RESPONSIBILITY

Research team members delegated to process samples and trained to this SOP.

The PI will delegate responsibility only to trained and qualified research team members.

The PI remains responsible for any delegated activity.

All research team members must operate within their scope of practice.

5. PROCEDURE

5.1 Training and Delegation

Research team members must complete the following training to be delegated biospecimen processing and shipping activities. Training must be completed before conducting any of these activities.

1. Study Protocol and study specific Laboratory Manual, and in accordance with individual department training methods.

   Training should be documented on the study Training log and certificates of training must be filed. Delegation of staff should be documented on the Delegation log and signed on/off by the PI.

2. Biological Safety

   Online training via MCRI Nucleus account/Employee Health and Safety (EHS):

   - Biological Safety Induction
   - Online Safety Induction – Online Delivery
   - Online Safety Induction - Assessment

3. Use of the MCRU space, and any other space used for biospecimen handling activities.

   For MCRU, this is done by completing the MCRU Induction training with the MCRI Laboratory Manager.

   For all other RCH/MCRI Laboratory space, the research team should consult the relevant laboratory manager to establish the laboratory training requirements.

4. Preparing biospecimens for shipment by air by completing the IATA/CASA approved Certified Dangerous Goods Packaging Course.

   Staff must be re-certified every two years. For guidance on training courses (for MCRI staff only), please see MCTC172 Factsheet: IATA Compliant Shippers Training Course.

If trial staff do not hold current IATA/CASA certification and it is not practical for them to do so, arrangements for biospecimen/dry ice shipments must be made with certified staff (such as MCRI Shipping Services).

5.2 Documentation of Biospecimen Movement

To ensure that the integrity of biospecimens 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.

All documentation (e.g. receipts, shipping records, order forms, proformas) related to the collection, handling and transport/shipment of biospecimens must be maintained and filed in the respective Investigator Site File.

If requested by the Sponsor, maintain a biospecimen tracking log and file in the Investigator Site File.

5.3 Equipment and Supplies

Specimens must be processed according to Sponsor requirements including the study Protocol and study specific Laboratory Manual.

Research team members must ensure they use the correct tubes as per protocol/Laboratory Manual/trial-specific SOPs and that these are in date. Laboratory kits provided by Sponsors must be stored in an appropriate environment and reviewed periodically to ensure they are sufficient for the purpose of the study and they remain in date.

Research team members must ensure that the equipment used for processing and storage of biospecimens display evidence that they are appropriately maintained.

Research team members must know how to access the maintenance/calibration records and provide access to Monitors/Auditors/Inspectors upon request.

5.4 Handling and Storage of Biospecimens

Specimens must be handled and stored in accordance with Sponsor requirements including the study Protocol and study specific Laboratory Manual.

Please refer to SOP MCTC164 Temperature Controlled Storage for further information about responsibilities for monitoring temperature-controlled storage.

5.5 Transport of Biospecimens

The courier service for shipment of biospecimens will be organised by the Sponsor and details will be provided to the study team. This will include but is not limited to shipping instructions, documentation, and packaging material.

Where there is a delay in biospecimen collection by the allocated courier service, the Sponsor should be notified.

6. CORRECTIVE ACTIONS

The Principal Investigator is responsible for ensuring that any deviation from this SOP that results in a potential risk to the integrity of biospecimens or safety of staff is investigated as per MCTC061 SOP Continuous improvement: A corrective and preventive action (CAPA) plan.

7. GLOSSARY

Biospecimen

Any biological material obtained from a person including tissue, blood, urine and sputum; it also includes any derivative of these, such as cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person.

Category A Substance

A Category A substance is an infectious substance such that, when exposure to it occurs, is capable of causing permanent disability, a life-threatening or fatal disease in otherwise healthy humans or animals.

Category B Substance

A Category B substance is an infectious substance that does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373**,** and their proper shipping name is 'Biological Substances, Category B'.

Human or animal material including but not limited to excreta, secreta, blood and its components, tissue and tissue fluids, and body parts, being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention, are assigned to UN 3373. These are classified under IATA Hazard Class 6.2 and IATA Packing Instruction 650.

Category C Substance

A Category C substance (also known as Exempt) is a patient Specimen for which there is minimal likelihood that pathogens are present. It is exempt from air transport and can be for land transport. It is not subject to the IATA Dangerous Goods Regulations if the Specimen is transported in triple packaging that prevents leakage and is marked with the words 'Exempt human Specimens' or 'Exempt animal Specimens', as appropriate.

Clinical Research Coordinator

A research worker who works at a clinical research site under the immediate direction of a Principal Investigator, whose research activities are conducted under Good Clinical Practice guidelines. May also be called a study coordinator or clinical trial coordinator (for clinical trials).

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".

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.

Melbourne Children's Campus

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. M

Principal Investigator (PI)

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.

Research Team

Refers to the extended group of people involved in a research study. This includes the investigator team and any additional members of staff who are involved in the set-up or conduct of the study e.g. research nurse coordinator, study/clinical research/trial coordinator.

Sponsor

An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. For investigator-initiated trials, MCRI or RCH will act as the Sponsor but delegate many sponsor responsibilities to the Coordinating Principal Investigator. In this case the CPI has the role of both Sponsor and Investigator and hence the MCTC has adopted the term Sponsor-Investigator to reflect the dual role of the CPI in investigator-initiated trials.

Standard Operating Procedure (SOP)

Detailed, written instructions to achieve uniformity of the performance of a specific function.

8. REFERENCES

Civil aviation amendment regulations 2003 (part 92)
Available from: https://www.casa.gov.au/search-centre/rules/part-92-casr-consignment-and-carriage-dangerous-goods-air

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.
Available from:
https://www.health.qld.gov.au/__data/assets/pdf_file/0020/151067/gcp_sop12.pdf

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

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

National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia Based On The International Council For Harmonisation Guideline For Good Clinical Practice ICH E6 (R2), SOP 10 Handling and Shipping of Biological Substances (Cat B) and Dangerous Goods
Available from: https://www.health.gov.au/sites/default/files/documents/2021/03/national-standard-operating-procedures-for-clinical-trials-national-standard-operating-procedures-for-clinical-trials-including-teletrials-in-australia.pdf

9. COLLABORATORS

This Guidance document was reviewed by:

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10. RELATED DOCUMENTS

Handling biologicals in laboratories-SWP

MCRI Laboratory Practice Policy -https://intranet.mcri.edu.au/rso/environment-health-and-safety/laboratory-practice-plant-and-equipment

MCTC172_Factsheet_CAAA Shippers Training Course Booking Process

MCTC164 SOP | Temperature Controlled Storage

MCTC025 Guidance | Signature and Delegation Logs

MCTC017 Template | Study Staff Training Logs

MCTC054.01 Template | Sample Tracking and Processing Log

Safe Operation and Cleaning of Class II Biological Safety Cabinets

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

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