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Specimen Collection and Management

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1.0 Introduction / Background

The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines requires that there is evidence that document the competence of facility to perform required test(s) and support reliability of results. This requires that the site have documented processes for quality controls and assessments.

Specimens must be appropriately handled, prepared, stored, packaged, labelled and transported to ensure the integrity and safety of specimens in accordance with:

- 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 – these regulations apply whether the containers are sent by air, road or sea. Infectious substances fall under either category A or B as described in these procedures
- Australian Civil Aviation Amendment Regulations 2003 (Part 92) – these regulations apply to staff packing infectious substances or dry ice.
- Specimens for Viral Haemorrhagic Fever (VHF), commonly known as Ebola Virus, must be collected, packaged and transported in accordance with the NSW Health NSW Contingency Plan for Viral Haemorrhagic Fevers Guideline GL2016_002 and in the associated guidance.

The NSW Health Policy PD2018_020 Transport of Pathology Specimens to Laboratories must be followed for transporting specimens to NSW Pathology.

Each department will assess the capabilities of the clinical trials teal to determine the process for collecting and processing the samples internally or externally with the support of external providers such as NSW Pathology.

2.0 Objective

To describe the procedure for the overall management for the handling, processing and shipping of infectious substances in clinical trials.

3.0 Scope

This SOP applies to all staff involved in clinical trials at South Western Sydney Local Health District (SWSLHD) and the Ingham Institute.

4.0 Ownership and Responsibility

The Principal Investigator (PI) or delegate is responsible for determining whether the collection and management of specimens is performed internally or externally. And overseeing that this process is in lines with the protocol and the above mentioned standards. This applies to Industry Sponsored, Collaborative Groups and Investigator initiated clinical trials.

5.0 Associate Documents

SOP_CTSU_02 Investigator Responsibilities

SOP_CTSU_04 Clinical Trial Start up

FM_026_Biological specimen Tracking Log

6.0 Procedure

All clinical trial staff collecting and managing specimens should ensure:

- Local work health and safety guidelines in accordance with NSW health policy and procedure are met for infection control, venepuncture and handling of blood products where applicable. Please refer to the local hospital policy or equivalent regulatory documentation for further information.
- Clinical trial specimens are handled, processed, stored and/or packed in accordance with site policy and the clinical trial protocol laboratory manual provided by the Sponsor.

If the biological samples are being shipped by air requirements outlined with the International Air transport Association (IATA) and International Civil Aviation Organization (ICAO) are mandatory. This includes documentation that all clinical trials staff and/or delegates who are involved in packaging and shipping of infectious waste/dangerous goods are appropriately qualified and trained.

In the situation where the clinical trial site is unable to perform the task of handling, processing, packaging and shipping specimens required by the clinical trial, the duties can be carried out by an accredited pathology company. A quote should be obtained during the start-up process to include these costs into the budget negotiations with the Sponsor as described in SOP_CTSU_04 Clinical Trial Start up.

6.1 Preparation of Samples

The biological sample(s) are collected, stored and/or processed as instructed in line with the approved protocol and laboratory manual which has been provided by the Sponsor.

If a central laboratory is being used the allocated lab kits provided by the Sponsor prior to the Site Initiation visit should be used. The Clinical Trials Coordinator (CTC) or delegate will record the patient initials, patient ID and the date and time when the sample was obtained on each of the samples. If an external vendor is being used the kit should be provided to be used.

In case of any damage to sample kits or if samples following collection are unusable, immediately inform the Sponsor/CRO and accurately document the findings, discussion and follow-up requirements.

6.2 Collection of Samples

For all duties related to the handling, processing and shipping of specimens, the PI must ensure that all delegated staff has current IATA dangerous goods training. This training is required every two years and training evidence kept in the Investigator Site File (ISF).

The PI, CTC or delegate should ensure that documentation related to handling, storage and shipping of infectious substances is maintained and filed to facilitate tracking and to satisfy protocol and ICH GCP requirements.

After collecting the sample in accordance with the study protocol and lab manual, the CTC or delegated person will record the details using the FM_026_Biological specimen Tracking Log. The log is maintained by the delegated person and kept in the ISF.

In cases where a participant reports an adverse event following collection of biological sample the following reporting requirements are required;

1. Document the even in the medical records and complete the adverse event log
2. Document in the IMS reporting system if required

6.3 Storage and monitoring of biological samples

Samples are required to be stored as per the protocol. All equipment used for processing and storage of samples require ongoing monitoring either by the individual trial department, NSW Health pathology department or the external vendor.

Ongoing monitoring involves the maintenance of centrifuge, fridge and freezer as per the manufacturer's guidelines. Clinical trial sites are also required to ensure temperature requirements are met for fridges and freezers used for storage of samples and keep a daily log of temperature recordings.

Additionally as per local policy the biomedical engineering department is require to electronically tag all hospital equipment on a yearly basis to ensure NSW Health safety guidelines are met.

6.4 Shipment of Samples

The frequency of shipment of samples will be dependent on the protocol and laboratory manual.

The courier service will be generally organised by the Sponsor prior to the Site Initiation visit and details provided. This will include the relevant documentation, instructions and packaging material to pack and schedule the specimen pickup. If there are no instructions please consult with the Sponsor to ensure this is provided.

Ensure the FM_026_Biological specimen Tracking Log is completed and stored in the Investigator site file.

7.0 References

NSW Health Policy PD2018_020 Transport of pathology specimens to laboratories

NSW Health Policy PD2017_011 Accreditation of pathology laboratories in NSW Health

https://www.pathology.health.nsw.gov.au/research-and-innovation/research-services

ICH GCP (E6 R2): Good Clinical Practice Guidelines - Annotated by TGA

National Statement on Ethical Conduct in Human Research (2018)National Statement on Ethical Conduct in Human Research (2018)

Australian Code for the Responsible Conduct of Research (2018)

8.0 Amendment History

Version	Date	Amended by	Details of Amendment

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