Western Health

STANDARD OPERATING PROCEDURE

HANDLING AND SHIPPING OF INFECTIOUS SUBSTANCES FOR CLINICAL TRIALS

Standard Operating Procedure

Western Health

SOP reference	012
Version:	3.0 dated June 2019
Effective Date	June 2019
Review Date	June 2021
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	

Amendment History

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

1. AIM

To outline the correct procedures for the handling and shipping of infectious substances in clinical trials.

2. SCOPE

All research studies and phases of clinical investigation for medicinal products, medical devices and diagnostics that involve the handling and shipping of infectious substances.

3. APPLICABILITY

All research and other staff delegated research/trial-related activities by the Principal Investigator.

4. PROCEDURE

For investigator initiated trials where Western Health (WH) is also the sponsor, obligations owed to or emanating from sponsor should be interpreted to mean WH.

4.1. Handling and Shipping of Infectious Substances for Clinical Trials

The investigator(s) should:

STEP	ACTION
4.1.1	Ensure that clinical specimens are handled and packed in accordance with local, sponsor and, if being shipped by air International Civil Aviation Organization (ICAO) requirements (Appendix 1). This includes the confirmation that staff involved in packaging and shipping of infectious waste/dangerous goods are appropriately qualified and trained. (Dangerous Goods Handling training courses & certification may be required if this service is not provided by the courier company).
4.1.2	Identify patient specimens for which there is minimal likelihood that pathogens are present are not subject to the ICAO requirements if the specimen is transported in Packaging for Exempt Patient Specimens.
4.1.3	In determining whether a patient specimen has a minimal likelihood that pathogens are present, exercise an element of professional judgement. That judgement should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported as a patient specimen for which there is a minimal likelihood that pathogens are present include: a. blood or urine tests to monitor cholesterol levels, blood glucose levels or hormone levels b. tests required to monitor organ function such as heart, liver or kidney function for humans with non-infectious diseases c. therapeutic drug monitoring d. pregnancy tests e. biopsies to detect cancer, and f. antibody detection in humans or animals Patient specimens (human or animal) that have a minimal likelihood of containing

	pathogens must be packaged appropriately to further minimise the risk of exposure. While these specimens have a minimal likelihood of containing infectious pathogens in a form that would cause infection, appropriate packaging further minimises the risk of exposure (see Appendix 2).

4.2. Tracking of Handling and Shipping of Infectious Substances for Clinical Trials

The investigator/delegate should ensure that documentation related to handling and shipping of infectious substances is maintained and filed in the Trial Master File (TMF) to facilitate tracking and to satisfy Good Clinical Practice (GCP) requirements.

5. GLOSSARY

Associate Investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a study site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, residents, research fellows). Also referred to as “Sub-Investigator”.

Delegate

A person delegated specific but appropriate tasks in relation to the conduct of a clinical trial.

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.

Infectious substances

Those substances which are known to contain, or are reasonably expected to contain, pathogens.

International Civil Aviation Organization (ICAO)

A specialized agency of the United Nations which sets international standards and regulations necessary for the safety, efficiency and regularity of air transport.

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 clinical trial at a trial site ensuring that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Medical or clinical wastes

Those derived from the medical treatment of animals or humans or from bio-research.

Pathogens

Micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

Patient specimens

Those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Sponsor

An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Trial Master File (TMF)

A file that contains all the applicable essential documents that demonstrate that the study/trial has been conducted in accordance with regulatory requirements and ICH GCP, enabling both the conduct of a project and the quality of the data produced to be evaluated. The preparation and maintenance of the Study File resides with the Site Investigator and set up at the start of a trial and is archived at the end of the trial. This may also be called the "Study Site Master File" or "Investigator Site File".

6. REFERENCES

1. Based on VMIA GCP SOP No.012 Version:1.0 Dated 17 September 2007
2. Based on MACH GCP SOP No.012 Version 1.0
3. International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, 2005-2006.

7. APPENDICES

Appendix 1: ICAO technical instructions for packaging of exempt human or animal specimens.

Appendix 2: Example of packing and marking for exempt human specimens or exempt animal specimens

8. AUTHORS/CONTRIBUTORS

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9. PRIMARY PERSON/DEPARTMENT RESPONSBLE FOR DOCUMENT

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APPENDIX 1: ICAO TECHNICAL INSTRUCTIONS FOR PACKAGING OF EXEMPT HUMAN OR ANIMAL SPECIMENS

Patient specimens (human or animal) that have a minimal likelihood of containing pathogens must be packaged appropriately to further minimize the risk of exposure.

While these specimens have a minimal likelihood of containing infectious pathogens in a form that would cause infection, appropriate packaging further minimizes the risk of exposure.

ICAO Technical Instructions require exempt human or animal specimens to be packaged and marked according to the following:

i. a leak-proof primary receptacle(s);

ii. a leak-proof secondary packaging; and

iii. an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm;

For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;

When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

If such a packaging is used it must be marked "Exempt human specimen" or "Exempt animal specimen", as appropriate (see appendix 2 graphic of an Exempt Patient Specimen Packaging).

Note: if other dangerous goods are present with patient specimens the relevant provisions of the ICAO technical instructions apply to those goods (see referenced document).

APPENDIX 2: EXAMPLE OF PACKING AND MARKING FOR EXEMPT HUMAN SPECIMENS OR EXEMPT ANIMAL SPECIMENS