Research Ethics and Governance – Handling and shipping of infectious substances for clinical trials Procedure

TARGET AUDIENCE and SETTING

Principal Investigator and all staff conducting research.

PURPOSE

A guide for Principal Investigators, Associate Investigators and Research Coordinators' responsibilities in procedures for the handling and shipping of infectious material.

DEFINITIONS

ICAO: International Civil Aviation Organisation

PRECAUTIONS/CONTRAINDICATIONS

All researchers at Monash Health must conduct research in the manner indicated in the Human Research Policy and the Research Governance Procedure.

STANDARD REQUIREMENTS

All investigators must abide by relevant legislation, the Australian code for the responsible conduct of research (NHMRC, 2018), the National Statement on Ethical Conduct in Human Research (NHMRC 2023), the Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016) and the International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016)

PROCEDURE

The Principal Investigator or delegate must:

- Ensure that clinical specimens are handled and packed in accordance with local, sponsor, and if being shipped by air, International Civil Aviation Organisation requirements. 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).
- Identify patient specimens for which there is minimal likelihood that pathogens are present, are not subject to the International Civil Aviation Organisation (ICAO) requirements, if the specimen is transported in Packaging for Exempt Patient specimens.
- Determine whether a patient specimen has a minimal likelihood that pathogens are present, and exercise an element of professional judgement, based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions.
- Appropriately package patient specimens (human or animal) that have a minimal likelihood of containing pathogens, in order to further minimize the risk of exposure.
  Guidance on regulations for the transport of infectious substances 2009-2010.
  https://www.who.int/csr/resources/publications/biosafety/WHO_HSE_EPR_2008_10.pdf?ua=1

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

- The investigator / delegate must ensure that documentation related to handling and shipping of infectious substances is maintained and filed to facilitate tracking and to satisfy Good Clinical Practice requirements.

KEY STANDARDS, GUIDELINES OR LEGISLATION

Australian code for the responsible conduct of research (NHMRC, 2018),

National Statement on Ethical Conduct in Human Research (NHMRC 2023)

Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016)

International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016)

International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, 2005-2006 and subsequent addendums.
https://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.aspx

ICAO Technical Instructions for packaging of exempt human or animal specimens.
Guidance on regulations for the transport of infectious substances 2009-2010.
https://www.who.int/csr/resources/publications/biosafety/WHO_HSE_EPR_2008_10.pdf?ua=1

KEYWORDS

International Civil Aviation Organisation, Infectious Substances, Dangerous Goods, Shipping, Transport.

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