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

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Amendment History

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Based on, and with permission of the Victorian Managed Insurance Authority – VMIA GCP SOPS
Reviewed by the QH Clinical Research Coordinators Network May 2010
1 Purpose

To outline the procedures authorising the handling and shipping of Biological substances, Category B and/or Dangerous Goods in clinical trials.

2 Responsibility / Scope

This standard applies to all Queensland Health employees (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients and staff.

It applies to all phases of clinical investigation requiring the handling and shipping of Biological Substances, Category B and/or Dangerous Goods.

3 Applicability

Principal Investigator, Associate investigator, Clinical Research Coordinators and other staff delegated trial-related activities by the Principal Investigator, who may have cause to handle or ship Category B specimens and/or Dangerous Goods in Clinical Trials, at any time during the conduct of a clinical trial.

4 Procedure

4.1 Handling and Shipping of Biological Substances, Category B and Dangerous Goods for Clinical Trials

The investigator(s) should:

- Ensure that specimens are handled and packed in accordance with local and sponsor requirements and, if being shipped by air, IATA requirements.

- Ensure all study staff who have cause to handle or ship specimens (Biological substances, Category B) or Dangerous Goods have undertaken, passed and hold a current certificate in the IATA Approved, CASA Certified Dangerous Goods Packaging Course, approved by Qld Health.

- Ensure that in situations where research personnel do NOT hold current certification to handle Category B specimens and Dangerous Goods, arrangements are made with suitably certified Pathology Queensland Laboratory staff or another certified staff member to handle these items.

- Be aware that in Queensland, to organise training for handling and shipping of Dangerous Goods and Category B specimens, staff should contact their local Pathology Queensland Laboratory. Training may also be available via the study sponsor. However, that training must comply with the standards required for operation in Queensland Health.

- Be mindful that the Civil Aviation 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.

- Be aware that re-certification is required every two years, and that 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 CASA (Civil Aviation Safety Authority).
4.2 Tracking of Handling and Shipping of Biological Substances, Category B and/or Dangerous Goods for Clinical Trials

The investigator/delegate should ensure that documentation related to handling and shipping of Category B specimens and/or dangerous goods is maintained and filed to facilitate tracking and to satisfy GCP requirements.

5 Glossary

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

Biological substances, Category B
An infectious substance which does not meet the criteria for inclusion in Category A. Most human or animal material (‘patient specimens’) 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 considered Biological substances, Category B.

Biological substances, Category A (not included in the scope of this document)
An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans.

Dangerous Goods
Articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in the IATA Regulations or which are classified according to the IATA Regulations.

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 Air Transport Association (IATA)
An international organisation that develops the commercial standards globally, for the air transport system. See definition from “Current Edition” in the manual.

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

Sub / Associate investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, clinical research coordinators. The P.I. will designate who will be nominated as Associate Investigators for that site.

6 References

3. CaSSS Pathology Queensland Hand book for “Course for Shippers of Biological Substances, Category B, and Dry Ice “.