DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION.

Version control will be managed through the Department of Research and Innovation.

The Department of Research and Innovation, in collaboration with the Cancer Centre Clinical Trials Unit, has developed a series of standard operating procedures (SOPs) designed to facilitate good clinical trials practice and compliance with applicable regulatory requirements for clinical trial research at Bendigo Health. These SOPs are based on those developed by the Parkville Cancer Clinical Trials Unit (PCCTU) who have kindly granted permission for adaptation and use at Bendigo Health.

SOP 8: Handling and Shipping of Biological Substances and/or Dangerous Goods for Clinical Trial Research

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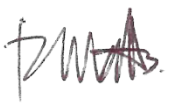
	Final revisions by:	Approved on behalf of the Interdisciplinary Research Steering Committee by Chair:
Name	Dr. Rani Watts	Dr. Angela Crombie
Position Title	Clinical Trials Research Manager	Director of Research and Innovation
Signature		
Date	20-Dec-2021	20-Dec-2021

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1. Introduction and Background

The handling and shipping of clinical trial participant samples is often required in order to assess eligibility, safety parameters, measure response to treatment and to assess pharmacokinetics, pharmacodynamics and pharmacogenomics.

Participant samples form a crucial part of clinical trial analysis and is the primary end point to most clinical trial protocols.

Correct handling and shipping procedures are vital in ensuring the integrity of the sample.

2. Objective

To describe the procedure for the handling and shipping of biological substances and/or dangerous goods for clinical trials.

3. Scope

This standard operating procedure (SOP) applies to all members of the study team involved in the handling and shipping of participant samples.

4. Ownership and Responsibility

The Principal Investigator (PI) is responsible for ensuring study team members are appropriately trained and delegated to handle and ship participant samples as outlined in *SOP 3: Clinical Trial Research Training* and *SOP 4: Clinical Trial Research Delegation of Duties* (see Related Documents).

The study team members delegated to handle and ship samples are required to complete International Air Transport Association (IATA) shipping and handling training or other appropriate course, renewed every three years.

5. Glossary of Terms

Please refer to Bendigo Health's *Clinical Trial Research Standard Operating Procedures Glossary of Terms* (see Related Documents) for a full supporting glossary.

6. Procedure

6.1 Handling Biological Substances and/or Dangerous Goods

The delegated study team member has oversight of clinical trial specific participant sample requirements and utilise sponsor templates (i.e. Clinical Trial Sample Log) where provided to ensure appropriate handling of all protocol-mandated samples at specified time points and document the storage and shipping of samples where appropriate to enable adequate tracking.

The study team are responsible for the coordination of equipment maintenance in conjunction with Spotless and Bendigo Health. Spotless are responsible for category 3 equipment and Bendigo Health are responsible for category 2 equipment.

Participant samples are handled in accordance with the clinical trial specific laboratory manual which is stored centrally for easy reference.

Personal Protective Equipment (PPE) is utilised while handling all participant samples as outlined in Bendigo Health's Standard & Transmission Based Precautions Protocol.

6.2 Shipping Biological Substances and/or Dangerous Goods

The study team member will:

- Complete checks of shipping materials, including waybill, shipping invoice and customs declaration if applicable, to ensure all required components are available and consistent with the laboratory manual requirements.
- Ensure samples are packaged according to the instructions outlined in the laboratory manual and local guidelines.
- Provide appropriate completed shipping documents with provision for ID check on collection and courier booked for pick up from the relevant location.

6.3 Tracking Biological Substances and/or Dangerous Goods

The study team member will ensure adequate documentation of handling and shipping is maintained and copies of the shipping documents retained for tracking purposes. This may include the completion of a Clinical Trial Sample Log provided by the sponsor.

7. Dissemination and Implementation

The Department of Research and Innovation at Bendigo Health is responsible for the dissemination and implementation of the Bendigo Health SOPs related to clinical research. Any content updates will be tabled at the Clinical Trials Sub-Group and the Interdisciplinary Steering Committee meetings. Content updates will be accompanied by relevant promotions and training.

Approved SOPs will be published on the Bendigo Health intranet and available through the SiteDocs portal. SOPs will be made available in hard copy format upon request to: clinicaltriasresearchsupport@bendigohealth.org.au.

Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

8. Monitoring Compliance and Effectiveness

SOP compliance will be monitored as part of the Bendigo Health SOP monitoring and audit process, initiated by the Clinical Trial Sub-group.

Any queries concerning the effectiveness of the SOP identified during the Bendigo Health monitoring and audit process or through use will be escalated to the Interdisciplinary Research Steering Committee to advise.

9. Review and Updating

This SOP will be reviewed every two years, or when changes to legislation or working practices impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

10. Reference(s)

SOP 3: Clinical Trial Research Training
SOP 4: Clinical Trial Research Delegation of Duties
Template: Site Signature and Delegation of Duties Log
Template: Study Team Training Log

11. Related Document(s)

SOP Glossary of Terms
Integrated addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)

12. Amendment History

Version	Date	Amended By	Details of Amendment
2	10-Nov-2021	Jasmine Gillingham Dr. Rani Watts	Revisions in line with amendments to those made by the Parkville Precinct Clinical Trial Unit Minor administrative amendments