New Zealand
Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Handling and Shipping of Biological Samples				
SOP Number:	SOP-07	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose
To describe the procedure for handling and shipping of biologic samples.

2. Scope
This SOP applies to all study team members involved in handling and shipping of biological samples as part of a Decentralised Clinical Trial in NZ.

3. Responsibilities
3.1 Satellite Site (SS): Each SS responsible for the collection and handling of samples will follow central sample requirements according to the clinical trial-specific lab manual and the International Airport Transport Association (IATA) regulations where applicable.

3.2 The Laboratory Staff: The Laboratory Staff at each site are responsible for the coordination of equipment maintenance.

4. Background
Handling and shipping of biological samples is often required within trials, particularly for central analysis of samples. Correct handling and shipping procedures are vital to ensure the integrity of the samples. This may include transportation of biological samples to the Primary Site (PS) from the SS or directly from the SS to the laboratory for central analysis depending on SS capabilities. These arrangements are detailed in the Supervision Plan.

5. Quality Management

6. Supporting and Related Documents
SOP-03 Clinical Trial Training with Decentralised Clinical Trials
Template from NZACRes for tracking biological samples
Decentralised Clinical Trials NZ Glossary
Decentralised Clinical Trials NZ Terms

7. Definitions
Refer to Decentralised Clinical Trials NZ Glossary
Decentralised Clinical Trials NZ Term

8. Procedure:
8.1 Handling Potential Infectious Substances
8.1.1 The Primary Site (PS) and SS site staff (e.g., laboratory staff, Registered Nurses, or other clinical staff) will utilise the template from NZACRes for tracking biological samples to ensure appropriate handling of all protocol-mandated samples at specific time points and document the storage and shipping of biological samples where appropriate to enable adequate tracking

8.2 Tracking Potentially Infectious Substances
8.2.1 The PS and SS study team and/or laboratory staff will ensure adequate documentation of handling and shipping is filed in the Investigator Site File (ISF) at the PS and SS and shared between sites as outlined in the supervision plan and

copies of the shipping documents are retained for tracking purposes. This includes the completion of relevant trial sample logs.

8.2.2 For samples shipped locally between sites, the courier booking reference number must be documented to ensure the shipment can be tracked.

8.2.3 The receiver must confirm receipt of samples to the sending study team/laboratory staff once received.

8.2.4 Documentation of the handling and shipping, courier booking reference numbers, and relevant trial sample logs will be filed in the Investigator Site File (ISF) at the PS and SS and shared between sites as outlined in the supervision plan.

9. Corrective Actions

All Decentralised Clinical Trial sites must follow this SOP. If a site is not able to follow the Decentralised Clinical Trial SOP-07, this must be documented in the Supervision Plan / individual site processes.

10. Training and Distribution

Local site training for Decentralised Clinical Trial SOPs is the responsibility of the local site and should follow Decentralised Clinical Trial SOP-03 Clinical Trial Training with Decentralised Clinical Trials or the local site training SOP.

11. Document Control & Change History

This SOP will be reviewed at least every 2 years.
If you have any queries regarding the information in this document, please forward details to the Decentralised Clinical Trial Project Manager.

Changes	Justification

12. External Related Documents/References

- National Ethics Advisory Committee. 2019. National Ethical Standards for Health and Disability Research and Quality Improvement. Wellington https://neac.health.govt.nz/publications-and-resources/neac-publications/national-ethical-standards-for-health-and-disability-research-and-quality-improvement/
- Ministry of Health Guidelines on the Regulation of Therapeutic Products in New Zealand Part 11, Edition 2.0 2018 https://medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf
- Clinical trials-regulatory approval and good clinical practice requirements. Edition 2. 2017. MOH https://ethics.health.govt.nz/operating-procedures/
- Official Information Act 1982 https://www.legislation.govt.nz/act/public/1982/0156/latest/DLM64785.html
- New Zealand Medsafe Guidelines https://medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf
- VCCC-TT-SOP-01a v1.0: Teletrials Overarching Processes Developed by VCCC and PCCTU (based on COSA Australasian Tele-trials model) October 2018 https://vcccalliance.org.au › assets › Teletrials
- COSA Australasian Teletrial Model https://www.cosa.org.au/media/332607/introduction-to-the-cosa-australasian-tele-trial-model.pdf

- National Standard Operating Procedures for Clinical Trials, in Australia. 2020. https://www.health.gov.au/resources/collections/the-national-teletrials-compendium

Internal Document Management

***Not for publication with the SOP

This page should be completed and retained with the master copy of the document, but should not be published for shared, public-facing documentation.
Formatting: All documents should be in Arial, with the main body being size 11.
****DOCUMENT IDENTIFICATION: Every Document must contain a footer in the format shown on this document in order for documents to be uniquely identifiable. All stand-alone Procedure/work instruction documents must contain a footer in this format****
SOP should not include a reference to a person's name but should be limited to the use of position titles/roles only.

1. Document Management

SOP Title:					
SOP Number:		**Version:**		**Effective Date:**	
Document Owner:		**Review Cycle:**		**Supersedes SOP:**	(if no document superseded, state 'New SOP')
Reviewed By:	(Name, position, organisation)			**Document Location:**	(Link to cloud based location)

2. Document History

Changes	Justification
New Document	