New Zealand
Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Archiving				
SOP Number:	SOP-09	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose

To describe the procedure for archiving essential documents for clinical trials for Primary Site (PS) and Satellite Site (SS).

2. Scope

This SOP applies to all clinical trials utilising Decentralised Clinical Trials in NZ.

3. Responsibilities

3.1 **The Sponsor** for the clinical trial informs the Principal Investigator (PI) of the PS when a clinical trial may be archived and provides the appropriate documents for completion.

3.1.1 The Sponsor will authorise the PI in writing when essential documents may be destroyed.

3.2 **The PI** ensures that all essential documents are archived appropriately ensuring that they are stored as securely as possible from any fire, water damage, pest infestation, or another disaster.

3.2.1 The PI may delegate responsibility for the preparation of all essential documents for archiving, including SS essential documents, to a clinical trial team member.

3.2.2 The PI informs the SS when all essential documents need to be archived.

3.2.3 The PI informs the Sponsor of all archiving arrangements or any changes to these arrangements.

3.2.4 The PI will ensure that all essential documents are received from the SS in preparation for archiving.

3.2.5 The PI is responsible once approval from the Sponsor has been received, to inform the SS that the essential documents will be destroyed and the date of completion of this task.

3.2.6 **T**he PI is responsible for ensuring that permission from the Sponsor has been obtained prior to destroying any records.

3.3 **The SS** is responsible for sending all documents to the PS for archiving once instructed.

3.3.1 All SS must be aware of the local requirement and the timeframes indicated in order to retrieve archived documents.

4. Background

According to The Guideline on the Regulations of Therapeutic Products in New Zealand. Part 11: Regulatory approval and good clinical practice requirements, all essential documents relating to clinical trial conduct must be archived at the completion of the clinical trial. The archiving process must ensure that the clinical trial can be reconstructed, demonstrating compliance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and applicable local regulatory requirements.

5. Quality Management

All study personnel involved in the clinical study must operate within their scope of practice.

6. Supporting and Related Documents

SOP-03 Clinical Trial Training in Decentralised Clinical Trials
Decentralised Clinical Trials NZ Glossary
Decentralised Clinical Trials NZ Terms

7. Definitions

Refer to Decentralised Clinical Trials NZ Glossary
Decentralised Clinical Trials NZ Terms

8. Procedure:

8.1 Interventional Clinical Trial Archiving

8.1.1 Essential documents are required to be retained for a minimum of 15 years as referenced in the site's Clinical Trial Research Agreement (CTRA). Archiving at sites will follow local procedures.

8.2 Non-interventional Clinical Trial Archiving

8.2.1 For non-interventional clinical trials, the relevant documentation must be archived for a minimum of 10 years after the conclusion of the clinical trial (National Ethical Standards for Health and Disability Research - NEAC guidelines), unless the funding body stipulates otherwise.

8.2.2 Records may be retained for longer where they are required by regulatory requirements or other research requirements.

8.2.3 Extensions of archive retention periods will be agreed upon between the PS and SS and the trial sponsor.

8.2.4 A clinical trial participants' medical documents are archived in accordance with local legislation and will be archived separately from the clinical trial essential documents.

8.3 Archival Preparation

8.3.1 All administrative aids used to maintain essential documents for the duration of the clinical trial must be removed in preparation for archiving e.g., plastic wallets, prior to being placed in the archiving box.

8.3.2 The original delegation log from the PS and SS will be archived alongside all essential documents.

8.3.3 Archiving should not typically take place until all documents are ready, including the final study report and final notification and acknowledgment of receipt from HDEC and Medsafe as applicable.

8.3.4 Once all PS and SS boxes are prepared, these can be sent to the archiving facility by the PS as per local procedures.

8.3.5 The PS has the ability to retrieve documents from the central archiving location as needed for both the PS and SS.

8.3.6 In case of digital handling of the essential documentation, all the documents should be downloaded onto an encrypted USB used for an individual study, and this USB must be clearly labelled and retained alongside any paper documents relevant to the study in a secure archival location.

8.3.7 The retention period for electronic data will be the same as for hard copies.

8.4 Retrieval and Return of Archived Essential Documents

8.4.1 The responsibility for retrieving archived boxes remains with the PS.

8.4.2 All essential documents for the clinical trial will be made available during normal working hours for inspection/audit by any appropriate sponsor/regulatory authority.

8.5 Disaster Recovery

8.5.1 In circumstances where archived documents are potentially involved in an event, (e.g., fire/flood/earthquake) the PS will recall all documents and

reconcile those that are complete and those that may have been damaged or lost and will produce a file note documenting any loss to be provided to the relevant Sponsor and regulatory authority as required.

9. Corrective Actions

All Decentralised Cancer Trials sites must follow this SOP. If a site is not able to follow the Decentralised Clinical Trials SOP-09, this must be documented in Supervision Plan **/** individual site processes.

10. Training and Distribution

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

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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	