New Zealand
Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Essential Document Management				
SOP Number:	SOP-11	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose:

To describe the procedures relevant to the collection and maintenance of essential documents for clinical trials at the Primary Site (PS) and Satellite Site (SS).

2. Scope

This SOP applies to both the PS and SS participating in a Decentralised clinical trial.

3. Responsibilities

3.1 The Principal Investigator (PI) or delegate provides all essential documents and ensures they are collected prior to the clinical trial initiation and maintained in a timely manner throughout the study in an Investigator Site File (ISF).

3.2 Site staff at the SS are responsible for the collection and maintenance of the specific SS documents for the SS ISF and for the provision of these documents as required to the PS.

4. Background

International Conference on Harmonisation Good Clinical Practice (ICH-GCP) guidelines define essential documents as “documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.” (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996, sec.8.1). Collection and maintenance of essential documents demonstrate PI and site ICH-GCP and local regulatory compliance. Filing essential documents in an orderly and timely manner is important in the coordination and management of clinical trials. Essential documents are kept in a study-specific ISF with the responsibility for maintaining and updating the file clearly delegated on the Delegation Log. Specific sections of the ISF can be maintained electronically, with appropriate password protection.

5. Quality Management

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

6. Supporting and Related Documents

List of Essential Documents [https://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial]
SOP-03 Clinical Trial Training with Decentralised Clinical Trials.
SOP-04 Delegation of Duties with Decentralised Clinical Trials.
SOP-08 Hosting a Regulatory Inspection, Sponsor, or other Audit
SOP-09 Archiving with Decentralised Clinical Trials.

7. Definitions

Refer to: Decentralised Clinical Trials NZ Glossary,
Decentralised Clinical Trials NZ Terms for SOPs.

8. Procedure:

8.1 Creation and Collection and Inspection of Essential Documents

8.1.1 Essential documents are those listed in the ICH-GCP guidelines for the conduct of a clinical trial.

8.1.2 Essential documents will be created using the same ISF template at the PS and SS to maintain consistency.

8.1.3 Essential documents are filed in the electronic/paper ISF and may be organised by an index generated by the PS or by the Sponsor.

8.1.4 Any electronic ISF should display the local reference number, protocol short name, and PI name.

8.1.5 All essential documents may be subject to inspection or audit (as outlined in SOP-08: Hosting a Regulatory Inspection, Sponsor, or other Audit).

8.2 The Investigator Site File

8.2.2 All essential documents will be filed in the study specific ISF and participant folders in a timely manner as per local SOPs.

8.2.3 Essential documents are filed according to the ISF Table of Contents.

8.2.4 Electronic documents should be uploaded and managed within the electronic ISF and not duplicated in a paper ISF.

8.2.5 If any documents are filed separately from the ISF (i.e., source documents, etc.,) a file note should be created and placed in the appropriate section detailing where the documents are stored.

8.3 Curriculum Vitae.

8.3.1 All study team members are required to provide an abbreviated Curriculum vitae (CV) using a suitable template from either the PS or a TransCelerate-approved template.

8.3.2 The CV should detail clinical experience and relevant training and clinical trial experience as per local policy.

8.3.3 Each PS and SS will maintain a central copy of the CVs, which can be provided to Sponsors as required. For SS, the original will be maintained by the SS, and a copy provided to the PS.

8.4 ICH-GCP documentation

8.4.1 All study team members are required to complete a Transcelerate approved ICH-GCP training, with refresher training as required.

8.4.2 Copies of the certificates will be filed at the PS or SS with a copy for the PS for collection by the Sponsor as required.

8.5 Professional Licences

8.5.1 Up-to-date and current information about their registration status is available to Sponsors e.g., via the Medical Council of New Zealand and Nursing Council of New Zealand websites and will not be collected or maintained in the ISF by the study team.

8.6 Statement of Investigator (1572 Form)

8.6.1 The Sponsor is required to provide the PI with a complete and accurate form to sign.

8.6.2 If required, the PI can be responsible to sign off the 1572 form or equivalent.

8.6.3 For Decentralised Clinical Trials, the SS and any local external service providers will be listed on the Form FDA 1572-Statement of Investigator or equivalent.

8.6.4 Any external labs utilised by clinical trial participants for routine blood draws will not be considered as part of the services engaged for the clinical trial. [This is not required as outlined in Frequently Asked Questions – Statement of Investigator (Form FDA 1572) (U.S. Department of Health and Human Services et al, 2010, sec,29].

8.6.5 The original wet ink 1572 will be available at the PS for collection by the Sponsor.

8.6.6 Only the PS is required to hold the 1572 in the ISF.

8.7 Financial Disclosure Form (FDF)

8.7.1 FDFs will be collected per requirement from the clinical trial sponsor.

8.7.2 The wet ink original will be located at the SS with a copy provided to the PS.

8.8 Delegation Log

8.8.1 As outlined in SOP-04 Delegation of Duties with Decentralised Clinical Trials.

8.8.2 Any differences in these procedures will be outlined in the supervision plan.

8.9 Training Records

8.9.1 As outlined in SOP-03: Clinical Trial Training with Decentralised Clinical Trials.

8.9.2 Any differences in these procedures will be outlined in the Supervision Plan / individual site processes

8.10 Participant Logs

8.10.1 A pre-screening/screening log will be used for clinical trials at each site.

8.10.2 For all clinical trials, the following two logs will be maintained:

- Participation identification log (ID log): a confidential list of names of all clinical trial participants and their allocated clinical trial identification numbers.
- Enrolment log: chronological enrolment list of clinical trial participants by clinical trial identification number.

8.10.3 The SS will maintain the two logs specified above and provide the PS with updated copies of the log each time a participant is enrolled.

8.10.4 To ensure confidentiality, participant logs will not be provided to the Sponsor but may be viewed during monitoring visits.

8.10.5 The Sponsor may require a screening log of potential participants to be kept. If this is requested, individual logs will be maintained at PS and SS and a copy will not be provided to the PS unless specified in the supervision plan.

8.11 Source documents

8.11.1 It is the Sponsors responsibility to ensure that the source documents are adequate for monitoring the trial and to attend the SS as required to view these if needed.

8.11.2 All source documents will be retained at the relevant site i.e., the PS or SS.

8.11.3 The PS will be responsible for ensuring that the SS collects the data required per protocol in the source documents.

8.11.4 Source worksheets may be provided by the PS to the SS, or they may create their own as documented in the supervision plan.

8.11.5 Documentation of source documents and the location of these will be included in the Supervision Plan for each individual trial and SS.

8.11.6 If the PS is responsible for entering data according to the Supervision Plan, then the Supervision Plan will detail how these source documents (either original or certified copies) are provided to the PS for data entry.

8.12 Clinical Trial Correspondence

8.12.1 All electronic correspondence will be maintained electronically at the PS or SS or both and archived upon completion of the trial.

8.12.2 If correspondence includes the PS, the PS will be responsible for ensuring this communication is filed appropriately.

8.12.3 If correspondence is only with the SS, the SS will be responsible for ensuring this communication is filed in the SS ISF.

8.12.4 The SS informs the PI of any relevant correspondence e.g., with respect to approvals, and safety.

8.13 Archiving of ISF

8.13.1 The ISF will be archived at the conclusion of the trial as per SOP- 09: Archiving with Decentralised Clinical Trials.

8.13.2 For Decentralised Clinical Trials, the SS ISF (paper and electronic) will be archived with the PS ISF folders, with archiving details provided to all sites for future reference.

9. Corrective Actions

All Decentralised Clinical Trials must follow this process. If a site is not able to follow the Decentralised Clinical Trials SOP-11, (Essential Document Management) this must be documented in the supervision plan.

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 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 Teletrials 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	