New Zealand
Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Document Management				
SOP Number:	SOP-10	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose

To describe the procedure for creation and implementation of Standard Operating Procedures (SOP) documents used for Decentralised Cancer Trials NZ, including version control and tracking amendments.

2. Scope

This SOP applies to any individual delegated the task of writing, reviewing, approving or distributing SOPs as part of Decentralised Clinical Trials NZ.

3. Responsibilities

3.1. SOP Author – responsible for initial writing of a SOP and ongoing review and amendment as necessary.

3.2. SOP Reviewer – responsible for providing review and comment on draft SOPs prior to finalisation and distribution.

3.3. SOP Approver – ensures that the SOP is appropriately documented and provides approval of final SOP ready for distribution.

4. Background

These National SOPs have been developed to assist organisations to standardise their procedures for key operations for conducting Decentralised Clinical Trials in NZ.

5. Quality Management

The writing of quality documents should be clear and concise, ensuring appropriate direction and uniformity in the delivery of clinical trials through the Decentralised Clinical Trials initiative in New Zealand.
Version control of documents ensures that all amendments are appropriately tracked and verifiable and that the correct version of the document is being used according to relevant ethical regulatory or local approvals.

6. Supporting and Related Documents

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

7. Definitions

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

8. Procedure

8.1. Identification of the need for an SOP

8.1.1. Any trial site member or clinical trial professional may identify the need for an SOP to be generated in order to assist with the smooth running and consistency of clinical trials in New Zealand being conducted under the Decentralised Clinical Trials model.

8.1.2. A notification of the need for an SOP should be sent in writing to the Decentralised Clinical Trials Project Manager and/or NZACRes (info@nzacres.org.nz), who will identify a suitable author and initiate the process of writing the SOP using the current SOP template.

8.2. Writing of the SOP

8.2.1. The identified author will take ownership for the SOP, including writing, review, amendment and finalisation of the SOP ready for authorisation and distribution. The Decentralised Clinical Trials Project Manager will negotiate timelines with the author for completion of SOP, which should be adhered to as much as possible.

8.2.2. The author will use the current SOP template for writing the new SOP, ensuring consistency across all SOPs. SOPs should be written clearly and concisely, avoiding repetition where possible, with all acronyms and abbreviations defined in the *Decentralised Clinical Trials NZ SOP XX Glossary and Terms.*

8.2.3. Once the initial draft of the SOP has been created, this will be sent to at least one Reviewer, who is identified by the Decentralised Clinical Trials National Committee as being an expert in the appropriate area. The Reviewer will return comments to the Author. The Author of the SOP will address the comments and issues raised by the reviewer prior to sending to the SOP Approver for approval.

8.2.4. Any unresolved comments between the Author and Reviewer(s) will be reviewed by the SOP Approver prior to providing approval for the final SOP.

8.3. Naming convention and document control

8.3.1. All SOPs will be named as follows:
Decentralised Clinical Trials NZ_SOP-Number _Name of SOP _Version Number _Date (DD-MM-YYYY).

8.3.2. The Decentralised Clinical Trials Project Manager will maintain a master list of all SOPs, documenting the SOP number, SOP name, current version and date of approval/distribution.

8.3.3. All SOPs will start at version 1.0 and be updated accordingly when changes are made to the SOP. Minor amendments not requiring full review, such as minor administrative changes, may be made without a formal review process and will be labelled as version 0.1 etc. Minor amendments may be completed by the Decentralised Cancer Trials Project Manager or Author but must be reviewed and approved by the SOP Approver before publishing.

8.3.4. When an SOP is updated, the Decentralised Cancer Trials Project Manager will update the master list with the updated information and ensure that the updated version is published on the Decentralised Clinical Trials SOP portal for public access.

8.3.5. All SOP templates will be available in PDF format once approved in order to ensure that changes are not made to the final document.

8.4. On-going Review of SOPs

8.4.1. Routine review of SOPs

- Routine review should occur at least every 2 years. The Decentralised Clinical Trials Project Manager is responsible for ensuring that each SOP is reviewed prior to the due date.
- The Decentralised Clinical Trials Project Manager will request review from a suitable Author who is appropriately experienced and is able to review the SOP in a timely manner.
- Any minor amendments identified within the 2-year period should now be incorporated into the SOP, along with further amendments as required.
- The Author will then follow section 9.2 through the review and approval process.
- The document history section of the SOP Document Management Form will be completed, identifying the version, changes made and the appropriate approval date.
- The Decentralised Clinical Trials Project Manager will issue the SOP with the next version number in the series, i.e., version 2.0.

- The Decentralised Clinical Trials Project Manager will ensure the master list is updated with the current version and approval date, noting amendments made for tracking purposes. The final approved updated SOP will be published in PDF format on the Decentralised Clinical Trials SOP portal for public access.

8.4.2. SOPs that do not require updating

In the case that an SOP does not require updating during routine review, the SOP will retain the same version number, with an updated approval date. This should be documented in the Document History section of the SOP Document Management page as "No updates required" and the appropriate approval/distribution date.

8.4.3. Making SOPs obsolete

If during the review of SOPs an SOP is deemed to not be applicable for conducting Decentralised Cancer Trials in NZ, the SOP Author can recommend that the SOP should be made obsolete. The SOP will then be marked on the master list as obsolete and removed from the Decentralised Cancer Trials SOP portal.

9. Corrective Actions

All Decentralised Clinical Trials sites must follow this SOP. If a site is not able to follow the Decentralised Clinical Trials SOP-10, 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 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	