New Zealand Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Clinical Trial Training				
SOP Number:	SOP-03	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose:

To describe the procedure for documenting training that has been undertaken by members of the study teams.

2. Scope

This SOP applies to the Principal Investigator (PI), Sub-Investigators (Sub-I), and all members of the study team participating in Decentralised Clinical Trials at all sites.

3. Responsibilities

3.1 **The PI** is responsible for the supervision of all study team members and retains overall responsibility for the conduct, delegation, and training on protocol and clinical trial-related requirements and for identifying ongoing training requirements on amendments to the protocol in a timely manner.

3.1.1 The PI must ensure that study team members are adequately delegated and supported to perform their duties.

3.1.2 The PI or delegate will provide all study team members with training materials (i.e., slides, a summary of changes, or tracked changes of amendments) via email or another source.

3.1.3 The PI is responsible for the oversight and interpretation of the results provided by the staff working within either the Primary Site (PS) or Satellite Site (SS) who as part of their routine practice complete a procedure (i.e., vital signs, ECG, venepuncture, imaging, etc) on a participant, and the actions required.

3.1.4 These staff (e.g., Clinicians, including Registrars and Fellows, Specialist Nurses, Nurses, Laboratory Staff, Ophthalmologists, Radiologists, Pathologists, Pharmacists, and Technicians, listed here, but not limited to) will not be considered part of the study team. As such, they are not required to undertake clinical trial education, training, and delegation.

3.2 **All study team members** are required to be qualified by education, training, and experience as per the International Conference on Harmonisation of Good Clinical Practice (ICH-GCP) and local regulatory requirements. All study team members are required to have current valid ICH-GCP training.

3.3 **Departmental Responsibilities.** Departments within the PS or SS may have clinical trial-related duties (i.e., IV IP administration or preparation) assigned to them by the PI.

3.3.1 A named person will assume responsibility for the conduct of such activity for that department and as such will be delegated this task on the delegation log.

3.3.2 The named person will be required to undertake appropriate protocol training relevant to the activity.

4. Background

N/A.

5. Quality Management

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

6. Supporting and Related Documents

SOP-04 Delegation of Duties
SOP-09 Handling and Shipping of Infectious Substances
SOP-07 Management of External Safety Information.
SOP-09 Handling and Shipping of Infectious Substances
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 Initial Protocol Training

8.1.1 Initial training will occur before performing any clinical trial-related tasks. This can be conducted at the Site Initiation Visit (SIV) by the study monitor on behalf of the sponsor or by the PI or delegate as appropriate to the delegated role.

8.1.2 PS and SS staff are to attend relevant SIV training where possible, which can be performed either face to face or virtually.

8.1.3 Staff not able to attend SIV will need to have initial protocol training (and other training material) separately recorded on a training log.

8.1.4 Initial training includes the protocol and all other associated documents or amendments, and training will be documented with respect to the current protocol version.

8.1.5 Training will be documented on the site training log of either the PS or Satellite SS as applicable and documented in the individual study supervision plan.

8.1.6 Once appropriately trained, duties will then be delegated by the PI as outlined in SOP-04: Delegation of Duties and documented on the delegation log.

8.1.7 Study team members are not required to document training in sponsor portals as long as all training is adequately documented on the site training log.

8.2 Protocol Amendment Training

8.2.1 It is the SS team's responsibility to ensure protocol amendment training is acted on in a timely manner and that confirmation of receipt and training is conducted before the implementation of the amendment, preferably before HDEC approval of the amendment where possible.

8.2.2 The SS will maintain a training record and send a copy of the training record to the PI or delegate for filing in the Investigator Site File (ISF). The original should be maintained at the SS in the SS ISF during the study.

8.2.3 Training on protocol amendments that result in updates to other documents (e.g., the participant information and consent form (PICF) will be documented by protocol version only on the site training logs.

8.3 Investigator Brochure (IB) Training

8.3.1 Updated versions of the IB are acknowledged by the PI and documented on the IB signature page (if provided by the Sponsor).

8.3.2 Training will be performed on protocol or PICF updates that occur as a result of changes to the IB and will be documented as per item 9.2.3.

8.4 Urgent Safety Data Training

8.4.1 The Sponsor is responsible for the dissemination of urgent safety data (including Dear Investigator letters requiring immediate action) to the PI and the PS team co-ordinating the clinical trial.

8.4.2 The PI will disseminate urgent safety data to the study team at both the PS and SS per SOP-07: Management of External Safety Information.

8.4.3 Training will be performed on protocol and/or other study documents that are updated because of the release of urgent safety information.

8.5 Other Training Requirements

8.5.1 Study team members are required to complete internal training on relevant, guidelines and policies as per the PS and SS local policies.

8.5.2 Internal training records will be made available on request.

8.5.3 Delegated study team members are required to complete training on the following supplementary trial requirements (as applicable) but not limited to the following:

- Study team members delegated to process samples per delegation log will complete laboratory sample processing training on the laboratory manual.
- Laboratory staff will also undertake training as outlined in SOP-09: Handling and Shipping of Infectious Materials.
- Study team members delegated to make entries/corrections on (e)Case Report Forms (CRF) and sign off (e)CRFs will complete (e)CRF training modules and provide relevant certification as required.

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-3, 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

- 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 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	