New Zealand
Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Delegation of Duties				
SOP Number:	SOP-04	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose:
To describe the procedure for delegating clinical trial related duties undertaken by members of the study teams.

2. Scope
This SOP applies to the Principal Investigator (PI), sub-investigators (Sub-I), and to 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.

3.1.1 Study team members must be adequately delegated and supported in order to perform their duties

3.1.2 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.

3.1.3 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 **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.

3.2.1 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.

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

4. Background
N/A

5. Quality Management
All study team members performing clinical trial-related tasks are required to be qualified to do so by education, training, and experience as per International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines and local regulatory requirements.

6. Supporting and Related Documents
SOP-03 Clinical Trial Training with Decentralised Clinical Trials
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 Delegation of Duties

8.1.1 Prior to performing any clinical trial related tasks, training will be performed as outlined in SOP-03: Clinical Trial Training with Decentralised Clinical Trials.

8.1.2 Once appropriately trained, duties will be delegated by the PI and documented on the delegation log for the trial as applicable.

8.1.3 All delegation of duties as part of a Decentralised Clinical Trial between a PS and SS will be further defined as part of the Supervision Plan for the trial.

8.1.4 The PI is responsible for ensuring the Delegation Log at all sites is maintained and current.

8.1.5 The Delegation Log will include:

- Full name, signature, and initials of study team member
- Delegated role(s)
- Start and end date of delegated role(s)
- Delegated tasks as per key
- PI signature confirming delegation

8.1.6 Where applicable each SS maintains its own site Delegation Log separate to the Primary Site (PS).

8.1.7 The original copy of the SS-specific delegation log will be maintained at the SS for the duration of the study and archived with the investigator site file at the completion of the study. A signed copy will be presented to the sponsor on request.

9. Corrective Actions

All Decentralised Clinical Trial sites must follow this SOP. If a site is not able to follow the Decentralised Clinical Trials SOP-04, 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 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	