New Zealand Association of Clinical Research

SOP Title:	Decentralised Clinical Trials Hosting a Regulatory Inspection, Sponsor, or other Audit				
SOP Number:	SOP-08	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose

To describe the procedure and activities for facilitating a regulatory inspection, either by the sponsor or an initiated audit by the Health and Disability Ethics Committee (HDEC).

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. They are responsible for the preparation, conduct, and follow-up of inspections/audits.

3. Responsibilities

3.1 The Sponsor or Research Governance Group or Regulatory Authority- will notify an impending inspection/audit to the Primary Site (PS) or the Satellite Site (SS).

3.2 The PI/delegate, will immediately notify all the relevant parties (including Sponsor, PS, vendors, or institutional research review board).

3.2.1 PI/delegate to review and finalise the agenda for the audit prior to its start and circulate it among the applicable team members.

3.2.2 The PI ensures all staff are aware that, upon request, direct secure access to all trial-related records is given to the auditor, or Research Governance Group (RGG) or Localities or regulatory authorities, to enable source data verification, Sponsor audits, or regulatory inspection.

3.2.3 The PI (with the SS team) on receipt of the audit report (to the SS leadership team, SS Manager, and PI) will collectively develop an appropriate action plan addressing the findings as required.

3.2.4 The PI ensures that any findings identified through audit or inspection are actively managed to ensure that appropriate Corrective and Preventative Actions (CAPA) have been implemented and findings reported to the health service organisation and HDEC.

3.3 The SS Sub-I or SS Manager coordinating the clinical trial in conjunction with the PI is responsible for reviewing all documentation (investigator site files and participant folders) to ensure they are complete.

3.3.1 The SS Sub-I or SS manager will provide the key contact for inspection/audit.

3.3.2 The SS Sub-I will nominate a SS study team member to act as the inspection/audit representative.

3.4 The Nominated SS study team member - will be responsible for coordinating audit preparations and the needs of the auditor e.g., provision of space, internet connection, point of contact, etc., once the date is known.

4. Background

External audits and regulatory inspections may be scheduled periodically at sites.

An **audit** is a systematic and independent examination of trial activities to review protocol compliance and adherence to the International Conference on Harmonisation Good Clinical Practice (ICH-GCP), during or after the completion of a study.

An **inspection** is similar to an audit in that it is an official review of trial-related activities but is conducted by a regulatory authority that has rights conferred by regulation.

Regularity Authorities may include Public Health Localities (usually be DHBs), academic institutions (such as universities), private companies (such as clinical trial units), private hospitals or clinical practices, and other health and disability research centres.

Regulatory inspections normally require more extensive planning and input from the organisation than routinely conducted trial audits. Inspections often involve an opening meeting and are conducted according to a pre-prepared plan, which may be revised based on initial findings. Inspections normally include interviews with the trial team, supporting department staff and research office, document review, and facility tours.

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 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 Site Notification - on the notification of an impending inspection/audit pre-Inspection/audit activities will be followed.

8.2 Pre-Inspection/Audit Activities

8.2.1 The set-up required for the auditor is identified.

8.2.2 Documents are filed in an organised way that will facilitate the conduct of the trial audit, or inspection. Contents should enable the adequate reconstruction of trial conduct at the site along with any key trial decisions.

8.2.3 Direct access is stipulated in the clinical trial research agreements (CTRA) and outlined to the participant via the Patient Information and Consent form (PICF).

8.3 Inspection/Audit Conduct

8.3.1 The study team will maintain a professional relationship with the specific regulatory authority, sponsor or any other regulatory bodies conducting the inspection/audit.

8.3.2 The PI and appointed representative (including the SS Sub-I /SS Manager) will be present during the opening and closing of the inspection/audit to briefly introduce and conclude the process and to be available to discuss any questions or findings with the inspector/auditor.

8.3.3 The inspector/auditor must be accompanied at all times while on the study site.

8.3.4 Meeting minutes will be taken by the site representative to document any comments or observations made by the inspector/auditor.

8.3.5 The meeting minutes will be reviewed by the study team so as to assist with inspection/audit responses.

8.3.6 Original documentation and records may be provided during the inspection/audit process on request.

8.3.7 No documentation of any kind may be retained by the inspector/auditor.

8.3.8 The Investigator Site File (ISF) (see Essential Document Management SOP-11) will be provided to the inspector/auditor, and upon request, all SOPs will be provided.

8.4 Inspection/Audit Closeout Activities

8.4.1 The closeout meeting with the inspector/auditor will be attended by the PI or delegate and appropriate representatives from the SS study team.

8.4.2 The closeout meeting is an opportunity to clarify and discuss any findings raised during the inspection/audit with the inspector/auditor(s).

8.4.3 The PS and SS study team will meet to discuss and evaluate the inspection/audit meeting minutes and outcomes.

8.4.4 On receipt of the audit report to the PS leadership team,the PI will collectively with the PS and SS develop an appropriate action plan addressing the findings as required.

8.4.5 Any relevant documentation should be retained as a part of the (ISF)

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-08, 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 Guideline on the Regulation of Therapeutic Products in New Zealand Part 11 Clinical trials-regulatory approval and good clinical practice requirements - Edition 2 2018. https://medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf
- 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	