New Zealand Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Decentralised Clinical Trials Processes				
SOP Number:	SOP-01	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose:

To describe the variations to normal clinical trial procedures when undertaking a Decentralised Clinical Trial in New Zealand.

2. Scope

This SOP applies to the Co-ordinating Investigator (CI) Principal Investigator (PI), sub-investigators (Sub-I), and all members of the study team at the Primary site (PS) and Satellite site (SS) participating in Decentralised Clinical Trials.

3. Responsibilities

3.1 Sponsor, CI, and PI at the PS are responsible for the site selection process including SS. SS's will be selected on a per trial basis.

3.1.1 The PI may delegate some or all of the study related activities to a delegate according to their level of experience and document this in the delegation log.

3.1.2 Delegated activities to be performed by the SS are trial-specific and should be agreed upon and documented at the time of site selection.

3.2 The Sponsor

3.2.1 The Sponsor must have up-to-date insurance for the clinical trial to provide participants compensation if they are injured as a result of taking part in the study.

3.2.2 The Sponsor is responsible for the system for randomisation of the participant in the trial.

3.3 All PS and SS will need to obtain governance approval and other regulatory authorisations from their local Research Office before the commencement of the study at that site.

3.4 The PI

3.4.1 The PI must ensure all relevant communications from the sponsor are disseminated to the SS.

3.4.2 The PI/delegate must ensure the CI includes in the relevant section of the ethics application that the trial may be undertaken using telehealth with SS, and if applicable, the informed consent process and/or some or all of the study assessments will be undertaken using telehealth (face-to-face consultation or a combination of both).

3.4.3 The PI must ensure the CI includes all sites, both PS and SS, in the SCOTT application where applicable.

3.4.4 The PI must ensure there are adequate study-related resources at the SS to meet the requirements for the Decentralised Clinical Trial conduct.

3.4.5 The PI whilst on videoconference calls with the SS will make all trial-related decisions unless otherwise stated.

3.4.6 The PI must ensure all investigational site staff, at both PS and SS, or Independent Third Party, and External Service Providers are qualified by education, training, and experience according to their role, including Good Clinical Practice (GCP) training, to assume responsibilities to perform and delegate study-related duties and functions.

3.4.7 The PI will ensure all staff in the study sites at both the PS and SS have a current CV in the PS Research Office/Study Master File (SMF) for sighting by the Sponsor and/or regulatory authority.

3.4.8 The PI will ensure the Supervision Plan template is completed (outlined in section 8.4) with the agreement from the study team and sponsor before the commencement of the study.

3.4.9 The PI/delegate is responsible for ensuring the delegation log is completed before clinical trial initiation and maintained throughout the study at both sites.

3.4.10 The PI/delegate at the site is responsible for ensuring the participant randomisation process is correctly followed.

3.4.11 The PI/delegate is responsible for the notification of randomisation and the results of randomisation to the SS.

3.4.12 The PI/delegate at the PS will be responsible for uploading source data into the CRF or eCRF and this may include data from the SS.

3.5 The SS Sub-I/delegate

3.5.1 The SS Sub-I/delegate is responsible for managing all Source Documents and record keeping at the SS in line with SOP-11 (Essential Documentation Management) as outlined in section 8.9.

3.5.2 The SS Sub-I/delegate will ensure that all initial and follow-up safety reporting is completed within required timelines at all times.

3.5.3 The SS Sub-I/delegate will ensure trial related activities are carried out in keeping with GCP, the study and the supervision plan.

4. Background

A decentralised Clinical trial is the conduct of a clinical trial from a PS utilising one or more SS to enhance participant reach, recruitment, and management. Decentralised Clinical Trials provide an opportunity to increase access to clinical trials for participants living in regional, rural, and remote locations. The NZ Decentralised Clinical Trial Standard Operating Procedures (SOPs) have been adapted from the Clinical Oncology Society of Australia (COSA), the Australasian Tele-trial Model Standard SOPs, and the Victorian Comprehensive Cancer Centre (VCCC) SOPs.

5. Quality Management

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

6. Supporting and Related Documents

Association of Clinical Research (NZACRes) Clinical Trial Research Agreement
The CTRA sub-contract for studies conducted under a Decentralised Clinical Trial Model
Supervision Plan Template
SOP-02 Informed Consent
SOP-03 Clinical Trial Training with Decentralised Clinical Trial
SOP-04 Delegation of Duties
SOP-11 Essential Document Management
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 Contracts

8.1.1 **Investigator-Initiated Decentralised Clinical Trials and Co-operative Trials - the** most recent version of the New Zealand Association of Clinical Research (NZACRes) Clinical Trial Research Agreement (CTRA) for the Decentralised Clinical Trial should be utilised.

8.1.2 Sponsored Trials in New Zealand - the main legal contract between the Sponsor and the PI's Institution at the PS will remain the NZACRes Standardised Clinical Trial Research Agreement (CTRA).

8.1.3 The CTRA sub-contract for studies conducted under a Decentralised Clinical Trial Model should be utilised between the PS and SS.

8.1.4 Any proposed variations to the CTRA may be addressed and agreed to by both parties in Schedule 6.

8.2 Indemnity

8.2.1 Public hospitals and clinicians are covered for professional and medical indemnity within their standard insurance as applicable, subject to the terms and exclusions of the policy wording.

8.2.2 Accidents and injury as part of participating in a clinical trial are covered by ACC unless it is a clinical trial that is for the principal benefit of a commercial sponsor, in which the sponsor should compensate for injury at a minimum ACC equivalent.

8.2.3 Relevant information must be available in the CTRA, protocol, and approved patient information and informed consent forms.

8.2.4 A copy of the indemnity certificate, including all the updates, as well as a copy of insurance certificates, if applicable, must be stored as a part of the study essential documentation retained by the PS.

8.2.5 Private hospitals and non-employed clinicians will need to provide evidence of professional and medical indemnity from their providers.

8.2.6 Studies covered by ACC will fall under ACC requirements as per the standard process, regardless of where the event has occurred.

8.2.7 ACC does not cover all situations.

8.3 Documentation of Study Teams Qualifications

8.3.1 SS study staff are permitted to use a Transcelerate approved abbreviated CV template.

8.3.2 The CV should detail clinical experience and relevant training

8.3.3 CVs are required to be updated every three years unless a change in position has occurred, at which time a new CV must be provided if the staff member continues involvement with the trial.

8.3.4 The SS staff will retain the wet ink signed and dated original CVs and will provide the PS with a copy.

8.4 Supervision Plan

8.4.1 The Supervision Plan outlines processes for a PI in the supervision of any individual or party where there is delegation of study-related duties and functions conducted at any of the participating study sites.

8.4.2 The Supervision plan includes, but is not limited to, details on joint consultations using telehealth, collation, and monitoring of documents, frequency of joint Decentralised Clinical Trials meetings across a Decentralised Clinical Trials cluster i.e., the PS and SS(s), (with minutes of these meetings), and clarification of activities performed by the PI, Sub-I, other study staff and any independent third party i.e., external service providers.

8.4.3 The Supervision Plan will outline the trial-specific communications with the local Research Office (RO).

8.4.4 The Supervision Plan will outline all drug ordering, storage, administration, and destruction management with each individual SS as per the Sponsor's guidelines.

8.4.5 The Supervision Plan needs to document the method of randomisation when it occurs per each specific trial protocol.

8.4.6 The Supervision Plan will define the procedure for consent and reconsent at SS. This will outline the responsibility of the investigators at each site and a clear process specific to the trial.

8.4.7 The Supervision Plan will document any variations in the consent process.

8.4.8 The Supervision Plan documents how the confidentiality of participants will be maintained.

8.4.9 The Supervision Plan will outline the process of reporting the safety events and protocol deviations/violations occurring at the SS to the PI for each trial.

8.4.10 The Supervision Plan will outline the location of source documents in each SS for Sponsor Source data verification (SDV) where applicable.

8.4.11 The Supervision Plan for each SS will be stored in the SS Site File (SSSF) and at the PS Site File (PSSF). (Responsibilities for their provision are described in SOP-11 on Essential Document Management).

8.4.12 The Supervision Plan must be updated with any new processes or delegated responsibilities and agreed to by the team and sponsor before any changes take place. A signed copy of each update is stored in the Study Master File (SMF) with the PS.

8.5 Delegation Log - prior to performing any clinical trial-related tasks, training will be performed as outlined in SOP-03 (Clinical Trial Training with Decentralised Clinical Trials).

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

8.5.2 The delegation log must be completed in line with SOP-04 (Delegation of Duties).

8.5.3 Any changes in delegation at PS or SS must be updated and sent to the PS for record maintenance as per SOP-04 (Delegation of Duties).

8.5.4 Any backup trial staff as required at SS(s) must also be recorded in the Delegation logs.

8.5.5 The Delegation Log will be stored at the SS until the trial is closed out and then sent to the PS for archiving. Variations to this will be outlined in the supervision plan.

8.6 Source Documents and Record Keeping at SS - the SS Sub-I/delegate must:

8.6.1 Maintain adequate Source Documents and trial records including all key observations on each of the site's trial participants. Store all trial-related documents in a SS Study File (SSSF).

8.6.2 Ensure, for both paper and electronic documents, all changes, corrections, and amendments are tracked, and version dates and numbers, are updated to reflect the changed data and to maintain the integrity of the data. An explanation of the changes is documented where appropriate.

8.6.3 Ensure that for telehealth consultations, the call is documented in the participant's medical record at each site by agreeing to the supervision plan on where the original and signed copies are stored. The written record will include a summary of the consultation; follow up instructions and that the visit was conducted via telehealth with the date and time recorded.

8.6.4 For paper records, be responsible for the collection and maintenance of the specific SS documents for the SSSF and for the provision of these documents as required to the PS.

8.6.5 Be responsible for the signed copies which need to be signed off as correct and complete e.g., legible, no pages missing.

8.6.6 Ensure where Electronic Medical Records (EMR) are in use, that access to the participant's trial related information is limited to authorised users only. Where access cannot be limited measures must be put in place e.g., PI delegates staff to ensure the participant's privacy and confidentiality are respected e.g., delegate prints the trial related information, sign as a signed copy, and place it in a paper record for access by the Sponsor, regulatory inspectors, and auditors, etc.

8.6.7 Ensure at the study conclusion, the SSSF is provided to the PS for closeout and archiving until approval is given for the destruction.

8.7 Completion of Case Report Forms (CRF)- data is entered into the eCRF according to the supervision plan for each SS.

8.7.1 Data may be completed by the SS staff if available or may be completed by the PS upon receipt of relevant source documents from the SS as agreed in the supervision plan.

8.7.2 If the PS completes data entry, the source documents from the SS should be provided in a timely manner in order to meet data entry timelines according to the CTRA.

8.7.3 Source data for all visits will be collated at the SS in the participant file.

8.8 Communications between the SS and PS - the SS will hold regular study teleconference meetings with the PS to provide trial updates, monitor protocol conduct, staff training, and resourcing as specified in the trial supervision plan where it will be documented.

8.8.1 The SS staff may also communicate with the PS via phone call and email as needed, and all communication should be clearly documented.

8.9 Informed Consent - the consent process will be as detailed in SOP-02 (Informed consent): Any variation to this process will be specified in the Supervision Plan.

8.9.1 Pre-Screening for eligibility will be undertaken at the SS.

8.9.2 The people involved in the consent process must be documented in the medical record at the SS.

8.9.3 Once the participant agrees to participate, the participant and the Sub-I/research delegate will sign the Informed Consent document together in person unless specified in the supervision plan.

8.9.4 The SS will send a signed copy of the PICF to the PS via email and file the original as a source document for records and send it to the PS when the study is completed.

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-01, this must be documented in Supervision Plan / individual site processes.

10. Training and Distribution

Local site training for Decentralised Clinical Trial SOPs is the responsibility of the local site and should follow Decentralised Clinical Trials SOP-03 Clinical Trial Training with 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: Decentralised Clinical Trial Project Manager.

Changes	Justification

12. External Related Documents/References

- The CTRA sub-contract for studies conducted under a Decentralised Clinical Trial Model https://www.health.qld.gov.au/__data/assets/pdf_file/0025/861118/CTRA-Teletrials-Subcontract-Template-2018_-V4-.pdf
- Association of Clinical Research (NZACRes) Clinical Trial Research Agreement National https://www.nzacres.org.nz/contract_templates/
- 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
- 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
- Australian ICH GCP (Including Teletrials) SOPs
  https://www.sahealth.sa.gov.au › wcm › resources pdf

New Zealand
Association of Clinical Research

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	