New Zealand
Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Informed Consent				
SOP Number:	SOP-02	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose:

To describe the procedure for obtaining informed consent of participants for enrolment in a clinical trial.

2. Scope:

This SOP applies to all clinical trial investigators who obtain informed consent from clinical trial participants or their legally acceptable representative (LAR) and to all members of the study team participating in Decentralised Clinical Trials at all sites.

3. Responsibilities

3.1 **The Principal Investigator (PI)** is ultimately responsible for the clinical trial participant's care and the process of ensuring clinical trial participants or their legally acceptable representative have fully understood what they are consenting to.

3.1.1 The PI is responsible for the oversight of consent and the process of consent at all times for the PS and SS.

3.1.2 The PI is responsible for documenting within the study-specific supervision plan for each trial as follows:

- The consenting responsibilities for each SS.
- The original PICF will remain at the site where the participant engages in the trial unless otherwise documented in the Supervision Plan.
- Define a process for remote consent to be followed as accepted by the PI and PS, SS and Sponsor, if SS investigators are not delegated responsibility for obtaining consent.
- Any further requirements for consent (e.g., the availability of interpreters) as appropriate for the study and SS before consenting potential participants.
- The standard trial practice process for telephone re-consent as outlined in section 8.4 for the PS or SS.
- How the signed consent form will be filed.

3.1.3 The PI can delegate the duty of informed consent provided the criteria are met in section 8 on 'Delegating Informed Consent'.

3.2 **The Sub-Investigator** (Sub-I) at the PS or SS (whoever is gaining consent) prior to commencing the informed consent process, must discuss the eligibility criteria with the study team.

3.2.1 The Sub-I must ensure that relevant study team members at the PS have been notified of the potential clinical trial participant prior to commencing the informed consent process at a SS.

3.3 **All sites-** Each site will localise the Participant Informed Consent Form (PICF) for their site based on the HDEC-approved New Zealand (NZ) master PICF.

3.4 **The Primary Site** (PS) is responsible to provide the SS with an Alert card template if the SS does not have one.

3.5 **Each satellite site (SS)** should reference the PI at the PS and include contact details for the PS along with relevant study team members at the SS.

3.5.1 The header and logo for the PICF at the SS should be the local header and logo and not the PS header.

4. Background

Informed consent as part of a clinical trial is the process of providing information to a potential participant, including written and verbal information, discussing this information, allowing adequate time for answering any questions, and obtaining the potential participants' consent to participate in the clinical trial. The potential participant or legally acceptable representative must be informed of all relevant aspects to their decision to participate and give their informed consent voluntarily and freely prior to participating in any clinical trial procedures and know they can withdraw at any time.

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 Trial Training with Decentralised Clinical Trials
SOP-04 Delegation of Duties
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 Delegating Informed Consent

8.1.1 The Sub-I or other delegate is prepared to take on this additional responsibility and feels confident to take informed consent in line with professional and organisational guidelines.

8.1.2 The Sub-I or other delegate has a comprehensive understanding of the clinical trial and has been trained thoroughly on all protocol and trial requirements to suitably inform the potential participant.

8.1.3 The Sub-I or other delegate is appropriately qualified, with relevant experience and thorough protocol training (As outlined in SOP-04 Delegation of Duties).

8.1.4 Delegation of duties must be documented on the individual clinical trial delegation of duties log after the Sub-I/delegate has completed protocol training.

8.1.5 An effective line of communication is maintained between Sub-I and PI.

8.1.6 All study team members involved in the informed consent process including the PI, sub-investigators, or other study team members, must document the informed consent process in the clinical trial participant's medical record.

8.2 Obtaining informed consent

8.2.1 Once a participant has been identified as a potential clinical trial participant, those authorised to gain participant consent must provide a verbal explanation of the clinical trial to the potential participant or legally acceptable representative, along with provision of a written copy of the participant information and consent form (PICF) that has been HDEC approved for use at the site.

- It is acceptable for the PICF to be emailed or mailed to potential clinical trial participants. In some cases, the study will have been discussed with the potential participant prior to mailing but this is not required.
- If the PICF is emailed, it must be sent in PDF or an alternative format that will ensure that no changes to the form are made.

8.2.2 Potential clinical trial participants, or their legally acceptable representative, should be given adequate time to review all information provided and to discuss with whānau, friends, or any other person as applicable, prior to agreeing to participate in the clinical trial.

8.2.3 The potential participant must not be coerced to participate in the clinical trial. The potential participant or representative should be given adequate time to ask questions throughout the process, and their questions must be answered adequately before proceeding.

8.2.4 The person obtaining consent and the person acting as a witness (if a witness is required by the trial) must clearly understand the requirements of the witness and what they are witnessing prior to the informed consent process beginning.

8.2.5 Once the potential participant or representative has had time to read the PICF, had all questions answered, and is willing to sign consent, the investigator obtaining consent will request the participant to clearly print their full names, sign, and date the appropriate section(s) of the hard copy of the PICF.

8.2.6 The consenting investigator must personally clearly print their own full names on the PICF, sign it, and date it.

8.2.7 If an interpreter is required, the interpreter must sign and personally date the witness/interpreter section of the PICF.

8.2.8 If a witness is present, (as the witness required for the study) the witness must sign and personally date the PICF.

8.2.9 Once all parties have signed the PICF, a copy of the PICF must be provided to the clinical trial participant.

8.2.10 The original signed PICF will be filed as part of participant source documents or trial documents at the consenting site unless otherwise stated in the Supervision Plan.

8.2.11 Once consent has been obtained the consenting site must provide clinical trial participants with an Alert Card with the name of the trial the participant is involved in, and contact details for the study team including the SS and PS.

8.3 Informed consent documentation - the process of informed consent must be documented in the potential participant's medical file by the Investigator obtaining the consent.

8.3.1 The documentation should contain the following information:

- Participant name and NHI.
- Current HDEC approved Version number and date of PICF.
- Dated PICF and information are given to the potential participant.
- A statement by the investigator obtaining informed consent confirming that the clinical trial participant has had adequate time to read the PICF, discuss with relevant others, ask questions and that all questions have been adequately addressed and the participant was willing to sign consent.
- The date the PICF was signed by the potential participant and the consenting investigator.
- If an interpreter was used and the language used named.

8.3.2 If the consent process is only conducted at the SS, all documentation relating to the consent process will be documented and filed at the SS.

8.3.3 If consenting was conducted remotely from the PS, then documentation will be completed at both the PS and SS unless stated otherwise in the Supervision Plan.

8.4 Re-consent - the process of informed consent continues throughout the duration of the study and therefore when new information becomes available, the clinical trial participant must be informed and allowed to review for continued participation in the clinical trial.

8.4.1 When a new PICF is created with additional information, the participant or their LAR will be asked to re-consent to the study using the updated and HDEC approved version of the PICF.

8.4.2 Telephone re-consent may be conducted for studies that have undergone appropriate review and approval, which may include but not limited to ethics, local governance groups, and sponsor review.

8.4.3 The process of obtaining re-consent will follow the same process as the main consent in sections 8.2.and 8.3.

8.5 Consent of Non-English Speaking Clinical Trial Participants - non-English speaking individuals may be approached to participate in a clinical trial.

8.5.1 In these cases, a PICF will be provided in English and where possible in the potential participant's native language.

8.5.2 If it is not possible to provide a written copy in the potential participant's native language an English copy will be given and an independent interpreter from the relevant service available to the site will be provided to give a translation of any written documentation, and the conversation between the investigator and the potential participant.

8.5.3 Any interpreters required for informed consent will be encouraged to personally attend the site for at least the initial consent visits. Where this is not possible due to restrictions on face-to-face visits or other constraints, a telephone interpretation service would be acceptable. Documentation of the presence of an interpreter will be included as part of the consent process for the potential participant.

8.5.4 Professional interpreting services should be used for the consent process. The name of the interpreter and any relationship to the potential participant should be documented along with details of their attendance.

8.5.5 If the interpreter was present over the telephone or other method instead of in-person this should be clearly documented.

8.5.6 The interpreter will be asked to sign the PICF along with the participant and consenting investigator if they are present in person.

8.5.7 In the case that the interpreter does not attend in person, the consenting investigator will write the name of the interpreter in the relevant section on the PICF and that they attended by telephone or other method for the entire consenting process discussion.

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-02, 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	