New Zealand
Association of Clinical Research

SOP Title	Decentralised Clinical Trials NZ Ethics and Governance				
SOP Number:	SOP-12	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose:

To describe the procedure for obtaining ethical and governance approval for new and existing decentralised clinical trials.

2. Scope

This SOP applies to the Co-ordinating Investigator (CI), the Principal Investigator (PI), Sub-Investigators (Sub-I), and to all members of the study team participating in a Teletrial at both PSs and SSs. This is additional to standard processes of ethics and governance.

3. Responsibilities

3.1 The CI is responsible for ensuring that ethical approval i.e., Health and Disability Ethics committee – (HDEC) approval and governance approval is obtained for the new and existing clinical trials they are responsible for, as per standard procedures.

3.2 The CI is responsible for collecting and reviewing the information necessary for HDEC submissions from all the PSs and SSs participating in the teletrial.

3.3 The CI is responsible for acting in the capacities required to conduct the study and communicate with HDEC and sites as per standard policy.

3.4 The CI may delegate the administrative process of ethical and governance submissions to be undertaken by a member of the Primary Site (PS), or Satellite Site (SS) team, or an external provider as appropriate and specified in the supervision plan.

4. Background

The International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) guidelines state that any trial regardless of its location should be conducted in an ethical manner after receiving relevant approvals. This means that all clinical trials taking place within the teletrials framework are conducted in compliance with the clinical trial protocol that has received prior ethical and governance approval by the New Zealand (NZ) HDEC and relevant regulatory procedures. The process for ethical approval by HDEC is available through their website. Further details on these guidelines are listed in Appendix 'Z'. In cases where HDEC approval is not applicable to a particular study involving human participants (for example, low-risk registry audit study), the study's lead investigator (CI) shall seek further ethical advice from their institutional review boards or research offices. The CI is the ICH-GCP and HDEC term for an investigator assigned the responsibility for the coordination of investigators at different centres participating in a multi-centre trial -this position is described as the PI by Medsafe. This SOP is in addition to these standard processes.

5. Quality Management

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

6. Supporting and Related Documents

SOP-11 Essential Document Management.
SOP-03 Clinical Trial Training
Teletrials NZ Glossary
Teletrials NZ Terms

7. Definitions

Refer to Teletrials NZ Glossary
Teletrials NZ Terms

8. Procedure:

8.1 HDEC submission considerations: the CI or delegate may begin preparation for the online submission to HDEC, in collaboration with the CI who still retains final responsibility.

8.1.1 All the relevant HDEC submissions, approvals, and correspondence should be retained in the investigator site file (ISF) as a part of the study's essential documentation in accordance with SOP-11– Essential Document Management.

8.2 Locality Authorisation

8.2.1 Once the approval (validation) letter from HDEC has been received, each site named on the HDEC application is informed by the delegate that they can apply for their locality review/approval

8.2.2 Each site (including the SS) follows its own processes for obtaining locality approval with support from the PS as detailed in the supervision plan.

8.3 Notification of Decision

8.3.1 A copy of the submission and HDEC acknowledgment should be kept in the ISF as a part of the study's essential documentation in accordance with SOP-11 Essential Document Management.

8.3.2 If the HDEC application is declined, the CI decides how to take the study forward.

8.3.3 If the study is approved, the delegate scans the letter so that the copies can be sent and filed in each approved site's ISF in accordance with SOP-11 (Essential Document Management). They then inform the Sponsor, CI, and other parties (as relevant).

8.6 Post-approval

8.6.1 Communication with the HDEC post-approval is via the specific study's listing in Ethics RM and should be according to standard processes.

- This correspondence is to be filed in each approved site's ISF in accordance with SOP-11 (Essential Document Management).

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-12, 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/

- Ethics Review Manager user manual (Ethics RM)
  https://ethics.health.govt.nz/assets/ERM-Manual-March2022-v1.0.pdf
- 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
- Health and Disability Ethics Committees Operational Procedures
  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
- The Human Tissue Act 2008
  https://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html
- The Privacy Act 2020
  https://www.legislation.govt.nz/act/public/2020/0031/latest/LMS23223.html
- The Health Information Code 2020
  https://www.privacy.org.nz/privacy-act-2020/codes-of-practice/hipc2020/

Appendix

Summary of HDEC Guidelines

1. Health and disability research needs ethical review by an HDEC only if it involves one or more of the following (exceptions do apply, see current Standard Operating Procedures for Health and Disabilities for more details <https://ethics.health.govt.nz/operating-procedures/>):
   - **1.1** Human participants recruited in their capacity as:
     a. consumers of health or disability support services, or
     b. relatives or caregivers of consumers of health or disability support services, or
     c. volunteers in clinical trials (including, for the avoidance of doubt, bioequivalence and bioavailability studies)
   - **1.2** The use, collection, or storage of human tissue (as defined by the Human Tissue Act 2008 <https://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html)>
   - **1.3** the use or disclosure of health information (as defined by Health Information Privacy Code (<https://www.privacy.org.nz/privacy-act-2020/codes-of-practice/hipc2020/>).

2. Health and disability research is research that aims to generate knowledge for the purpose of improving health and independence outcomes.
Comment: For the purposes of New Zealand HDEC SOPs, health and disability research does not include research that creates or uses a human gamete, human embryo, or hybrid embryo. Such 'human reproductive research' must be approved by the Ethics committee on Assisted Reproductive Technology (<https://ecart.health.govt.nz/>).

3. There are two main types of health and disability research: intervention studies and observational studies.
An Intervention study: is a study in which the investigator controls and studies the intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). The term 'intervention study' is often used interchangeably with the terms 'experimental study' and 'clinical trial'.
An Observational study: is all health and disability research that is not an intervention study.
Observational studies may involve looking at the health effects of interventions provided to human participants. However, researchers in such an observational study do not control these interventions, which would have been provided regardless of participation in the study.

3. The ethical standards that researchers must meet or exceed in conducting interventional and observational studies are contained in the Health and Disability Ethics Committees Operational Procedures (**<** https://ethics.health.govt.nz/operating-procedures/>).

5. Unless an exemption applies, most health and disability research requires HDEC review. Exemptions include studies on low-risk devices; minimal-risk observational studies; audits and related activities and student-led research. All studies that don't involve exemptions must be submitted to an HDEC for consideration prior to the initiation of a study. The HDEC will review the research Protocol, and other relevant project documentation such as the Patient Information Sheet and Consent Form to assess whether the dignity, rights, safety, and well-being of research subjects will be protected in the research study.

6. The application assessment process by HDECs is time-controlled. Once applications are validated, they are normally assigned for HDEC review within 3 days of their being submitted. The Co-ordinating Investigator is informed of this and given the date on which the 15-day (through the expedited review pathway) or 35-day review clock for the final decision begins.

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Internal Document Management

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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	