New Zealand Association of Clinical Research

SOP Title:	Decentralised Clinical Trials NZ Management of Safety Information				
SOP Number:	SOP-06	Version:	1.0	Effective Date:	
Document Owner:		Document Location:		Revision Date:	

1. Purpose
To describe the procedure related to the management of safety information.

2. Scope
This SOP applies to all clinical trial Primary Site (PS) and Satellite Site (SS) staff conducting and participating in a Decentralised Clinical Trial in NZ

3. Responsibilities
3.1 Annual safety reporting will be submitted by the lead site for all participating PS and SS.

3.2 Dear Investigator Letters (DIL) the Principal Investigator (PI) will send these to all SS for information, and acknowledgment, and determines the necessary action for the participants

3.2.1 The lead site in NZ will submit any DIL to the Health and Disability Ethics Committee **(**HDEC**)** on behalf of all PS and SS in NZ, including any information on how participants are informed or updated study information.

4. Background

International Conference on Harmonisation Good Clinical Practice (ICH-GCP) guidelines defines the requirements to ensure that all clinical trial participants taking part in a clinical trial are safe and their rights protected. In the event that a safety concern is raised, then all local requirements for reporting to Medsafe, HDEC, and the local research governance organisations are to be notified as required.

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

6. Supporting and Related Documents
New Zealand Medsafe Guidelines
https://medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf
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 2-2017. MOH
https://medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf
Decentralised Clinical Trial NZ Glossary
Decentralised Clinical Trial NZ Terms

7. Definitions
Refer to: Decentralised Clinical Trial NZ Glossary
Decentralised Clinical Trial NZ Terms

8. Procedure
8.1. Safety Reporting

An annual safety report will be submitted to the Health and Disability Ethics Committee (HDEC) as part of the annual ethical renewal of the clinical trial in NZ. The report may be made up of the following information as per HDEC's current guidelines and SOPs

8.1.1 A safety report produced for International Regulators

8.1.2 A brief description and analysis of new and relevant findings that may have a significant impact on the safety of participants

8.1.3 A brief analysis of the safety profile of the new medicine and its implications for participants, taking into account all safety data as well as the results of any relevant non-clinical studies

8.1.4 A brief discussion of the implications of safety data to the risk-benefit ratio for the intervention study, and whether study documentation has been or will be updated

8.1.5 A description of any measures taken or proposed to minimise risks, where it has not already been submitted to HDEC as a substantial amendment.

8.1.6 Development Safety Update Reports (DSURs) and renewed certificates of insurance may also serve as an annual update of safety information.

8.2. Submission of Safety reports

8.2.1 Reports will be submitted to Medsafe in line with NZ regulations.

8.2.2 Section 30(7)(d)(ii) of the Act requires the sponsor to submit routine progress reports to Medsafe. Reports should be submitted online.

8.2.3 The first report should be sent to Medsafe not more than 6 months after the date of approval of the trial, whether or not recruitment of New Zealand trial participants has commenced.

8.2.4 Subsequent reports should be submitted at 6 monthly intervals throughout the duration of the trial in New Zealand.

8.2.5 Medsafe should be informed when the New Zealand trial, or the New Zealand arm of a multinational trial, is completed. There is no need to continue submitting 6 monthly progress reports once the New Zealand arm has been completed, even if the trial continues elsewhere.

8.3. Dear Investigator letters (DIL)

8.3.1 When a PI receives a DIL they will be dealt with within a timely manner

8.3.2 The PI determines if the clinical trial participants should be contacted immediately regarding the information provided

8.3.3 Either the PS or SS will contact participants, discuss the information and any potential impact on them, and document this discussion fully in the participant source records and who does this is documented in the supervision plan.

8.3.4 If immediate notification is not required, the participant will be informed of the information at their next visit either by PS or SS, and this will be documented in the participants' source records and who does this is documented in the supervision plan.

8.4. Individual Line Listings and Suspected Unexpected Serious Adverse Reactions

8.4.1 Individual Suspected Unexpected Serious Adverse Reactions (SUSARs) or 6 monthly line listings may be received by the PS management.

8.4.2 These line listings will be filed in the Investigator Site File at the PS either in paper if provided, or electronically if provided in that format.

8.4.3 No documentation will be required to be maintained at SS, unless specified otherwise in the supervision plan.

9. Corrective Actions

All Decentralised Clinical Trial sites must follow this SOP. If a site is not able to follow the Decentralised Clinical Trial SOP-06, this must be documented in Supervision Plan / individual site processes.

10. Training and Distribution

Training will be conducted at the Site Initiation Visit (SIV) by the study monitor on behalf of the sponsor or by the PI or delegate as appropriate to the delegated role. This can be performed either face to face or virtually and must be recorded on the training log.

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	