

Ethics reference: 2024 EXP 19723

15 May 2024

Dr Nejo Joseph

50 Ruahine street
Roslyn
Palmerston North
4442
New Zealand

Tēnā koe Dr Joseph

APPROVAL OF APPLICATION

Study title: An Aoteara-New Zealand multi-centre study of acute pancreatitis management and outcomes

I am pleased to advise that your application was **approved** by the Southern Health and Disability Ethics Committee (the Committee) with non-standard conditions. This decision was made through the expedited pathway.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

1. Dr Nejo is the Coordinating Investigator of the study; please amend the cover page of the Data Management Plan (DMP) to reflect this.
2. Please amend Section 4 of the DMP to state that consent will not be obtained due to a waiver of consent being granted by the approving HDEC. It is incorrect to state that this is a routine audit as data may be used for future related research.
3. Please delete references to a CRO from the DMP.
4. Identifiable data will be accessed by site staff to collect required study data, and identifiable data will be collected and held on site excel spreadsheets, as stated in Section 9.1 of the DMP. Please amend Sections 7.1 and 8.1 of the DMP accordingly.
5. Data is not collected anonymously; individuals will not have access to study results due to the study being conducted under a waiver of consent. Please amend Section 11 of the DMP accordingly.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

- Please update the data management plan to incorporate the feedback above.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDECs.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through the [Ethics Review Manager](#). Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see paragraphs 125 and 126 of the [Standard Operating Procedures for Health and Disability Ethics Committees \(SOPs\)](#).

After HDEC review

Please refer to the [SOPs](#) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 15 May 2025.

Further information and assistance

Please contact the HDECs Secretariat at hdec@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information, as well as our [General FAQ](#) and [Ethics RM user manual](#).

Nāku noa, nā



Mr Dominic Fitchett

Chair

Southern Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Evidence of Consultation	Locality Approval-merged		
CV for Coordinating Investigator	nejo CV		
Data Management Plan	data_management_plan		
Scientific Peer Review	PANORAMA_V_1.1.0_peer_review_SGB		
Protocol	PANORAMA_V_1.1.0_peer_reviewed		
Response to PA Document	Letter of Response re PANORAMA		
Response to PA Document	PANORAMA_protocol_V_1.1.0_final		
Response to PA Document	updated_data_management_plan		
Scientific Peer Review	STRATA project (PANORAMA)	08/03/2024	1.1.0

<http://www.ethics.health.govt.nz>