

Ethics reference: 2023 FULL 16757

11 September 2023

Dr Ewan Kennedy

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Dunedin North
Dunedin
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New Zealand

Tēnā koe Dr Kennedy

APPROVAL OF APPLICATION

Study title: Improving health services for people with musculoskeletal chest pain - a randomised controlled feasibility trial

I am pleased to advise that your application was **approved** by the Northern B Health and Disability Ethics Committee (the Committee). This decision was made through the full review pathway.

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 Northern B 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 *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au or <https://clinicaltrials.gov/>).
- 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.

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 11 September 2024.

Participant access to compensation

The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialed. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation.

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



Ms Kate O'Connor

Chair

Northern B Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix B: statement of compliance and list of members

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Non-Review Document	Declince_Letter_HDEC Mar 2023		
Evidence of Consultation	Maori Consultation_Recommendation_23314_20220612		
Surveys/questionnaires	Sample_UK-English-EQ-5D-5L-Paper-Self- Complete-v1.2-ID-24700		
Data Management Plan	MSK Chest pain data mamangement plan_HDEC template_Jan 2023		
Data Management Plan	UoO_Data management plannin tool_MSK chest pain feasibility trial-txt file		
CV for Coordinating Investigator	EKennedy Otago format CV 2023 (002)	10/05/2023	
Scientific Peer Review	hdec-peer-review-MSK chest pain study CC	10/05/2023	
Advertisement	MSK chest pain study invitation_Dunedin_clean	12/05/2023	
PIS/CF	Participant Information Sheet_May 2023	12/05/2023	
Surveys/questionnaires	Brief illness perceptions questionnaire_tool	15/05/2023	
Protocol	MSK chest pain_Feasibility protocol_May 2023	15/05/2023	
Response to PA Document	HDEC cover letter July 2023	13/07/2023	
Response to PA Document	MSK chest pain study invitation_Dunedin_June2023_highlighted	13/07/2023	
Response to PA Document	MSK chest pain study invitation_Dunedin_June2023	13/07/2023	
Response to PA Document	Participant Information Sheet_June 2023_highlighted	13/07/2023	
Response to PA Document	Participant Information Sheet_June 2023	13/07/2023	
Response to PA Document	MSK chest pain_Feasibility protocol_June 2023_highlighted	13/07/2023	
Response to PA Document	MSK chest pain_Feasibility protocol_June 2023	13/07/2023	

Appendix B: Statement of compliance and list of members

Statement of compliance

The Northern B Health and Disability Ethics Committee

- is constituted in accordance with its Terms of Reference
- operates in accordance with the [Standard Operating Procedures for Health and Disability Ethics Committees](#), and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Ms Kate O'Connor (Lay (ethical/moral reasoning)), Mr Barry Taylor (Non-lay (observational/intervention studies)), Ms Joan Pettit (Non-lay (intervention studies)), Mr Ewe Leong Lim (Lay (consumer/community perspectives)), Ms Maakere Marr (Lay (consumer/community perspectives)), Ms Amy Henry (Non-lay (observational studies)).

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference).

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

