

Ethics reference: 2023 EXP 15077

2 November 2023

Associate Professor Kirsten Coppell

Otago Medical School, Dept of Medicine
PO Box 56
Dunedin
9054
New Zealand

Tēnā koe Associate Professor Coppell

APPROVAL OF APPLICATION

Study title: He Oranga mō te Whānau: Improving outcomes for people with hip and/or knee osteoarthritis and co-morbidities

I am pleased to advise that your application was **approved** by the Southern Health and Disability Ethics Committee (the Committee). This decision was made through the expedited 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 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 *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 02 November 2024.

Participant access to compensation

The Southern 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



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
Scientific Peer Review	Abbott Peer Review Summaries		
Surveys/questionnaires	BaselineSelfEfficacyForManagin		
Surveys/questionnaires	BaselineEQ5D_MOAPIPTrial		
Surveys/questionnaires	Baseline_MOAPIPTrial (1)		
Surveys/questionnaires	PROMIS_SF_v1.0_-_ED-Depression_8a_5-31-2019		
CV for Coordinating Investigator	Coppell_HRC_NZ_standard_CV_Nov 2021		
Protocol	MOA-PIP-Study-Protocol_2023-04-05		
PIS/CF	PIS-CF 2023-04-05		
Data and Tissue Management Plan	Data management plan_AD_31_3_23		
Evidence of Consultation	Inaugural 19 May 2022 hui notes_22 05 26_Update	01/02/2023	1
Response to PA Document	2023 EXP 15077_Ethics Committee Response Letter_Reply	09/10/2023	
Response to PA Document	2023 EXP 15077_PIS-CF 2023-09-25_Track Changes	09/10/2023	
Response to PA Document	2023 EXP 15077_PIS-CF 2023-09-25_Clean	09/10/2023	

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