

Ethics reference: 2023 FULL 17956

22 November 2023

Associate Professor Kirsten Coppell

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Nelson
New Zealand

Tēnā koe Associate Professor Coppell

APPROVAL OF APPLICATION

Study title: Delivering optimal weight gain advice to pregnant women (DOT): a case study

I am pleased to advise that your application was **approved** by the Northern A Health and Disability Ethics Committee (the Committee). This decision was made through the FULL 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 A 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 22 November 2024.

Participant access to compensation

The Northern A 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 Catherine Garvey

Chair

Northern A 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
Scientific Peer Review	21-911_Coppell_Portfolio_Panel_reports	18/09/2023	1
Scientific Peer Review	21-911-Coppell_55_Applicant_Peer_Review_Report	18/09/2023	1
Scientific Peer Review	21-911-Coppell_78_Applicant_Peer_Review_Report	18/09/2023	1
Scientific Peer Review	21-911-Coppell_94_Applicant_Peer_Review_Report	18/09/2023	1
CV for Coordinating Investigator	HRC_NZ_standard_CV_KCoppell_Sep 2023	18/09/2023	1
PIS/CF	participant-information-sheet-consent-form-template-v5.0april2023_DOT Study_SubmittedEthicsAppl	18/09/2023	1
Data Management Plan	2023 09 29_DOT Study Data Management Plan_Ethics Application	29/09/2023	1
Protocol	2023 09 29_DOT Full Study_Protocol_Ethics Application	29/09/2023	1
Covering Letter	2023 09 29_DOT Full Study_Covering Letter_Ethics Application	29/09/2023	1
Response to PA Document	participant-information-sheet-consent-form-template-v5.0april2023_DOT Study_SubmittedEthicsAppl_V2_Track Changes	31/10/2023	2
Response to PA Document	participant-information-sheet-consent-form-template-v5.0april2023_DOT Study_SubmittedEthicsAppl_V2_Clean	31/10/2023	2
Response to PA Document	2023 10 31_DOT Study Data Management Plan_Track Changes	31/10/2023	2
Response to PA Document	2023 10 31_DOT Study Data Management Plan_Clean	31/10/2023	2
Response to PA Document	2023 10 31_DOT Full Study_Protocol_Ethics Application_Update_V2_Track Changes	31/10/2023	2
Response to PA Document	2023 10 31_DOT Full Study_Protocol_Ethics Application_Update_V2_Clean	31/10/2023	2
Response to PA Document	2023 11 14_DOT Full Study_Covering Letter_Ethics Application Response	14/11/2023	1

Review Document Type	Review Document File Name	Review Document Version Date
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Appendix B: Statement of compliance and list of members

Statement of compliance

The Northern A 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 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Ms Catherine Garvey (Lay (the law)), Dr Kate Parker (Non-lay (observational studies)), Dr Sotera Catapang (Non-lay (observational studies)), Mr Johnathan Darby (Lay (the law/ethical reasoning)), Dr Leonie Walker (Lay (ethical/moral reasoning)), Ms Jade Scott (Non-lay (observational/intervention studies)), Dr Andrea Forde (Non-lay (intervention studies)), Mr Derek Chang (Non-lay (intervention 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>