Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2023 FULL 16735

19 December 2023

Senior Lecturer, Consultant Meghan Hill

Level 1, Building 507
2 Park Road, Grafton
Auckland
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New Zealand

Tēnā koe Senior Lecturer, Consultant Hill

APPROVAL OF APPLICATION

Study title: Mifepristone versus placebo to increase the rate of spontaneous labour in women with a prior caesarean: A double blind randomised controlled trial
(Mi-labour Trial)

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 19 December 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 hdecs@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

CGarvey

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	SR Mifepristone 14Nov2022	14/11/2022	1
Scientific Peer Review	SR Response Mifepristone 16Nov2022	16/11/2022	1
Protocol	MifeTrialProtocoHDEC	04/04/2023	1
Investigator's Brochure	mifegynetab	04/04/2023	1
PIS/CF	PISCF-post-input	15/06/2023	2
Data Management Plan	HDEC-data-only-management-MiLabour-Nov2022	18/07/2023	1
CV for Coordinating Investigator	M Hill_NZ MSI Standard CV Template - July2023	18/07/2023	1
Surveys/questionnaires	Mife Trial PostParticipationSurvey2	18/07/2023	2
Response to PA Document	MifeTrialProtocolFinalRGGandHDEC	07/11/2023	2
Response to PA Document	PISCF-post-inputHDECResponse	07/11/2023	2
Response to PA Document	HDECResponseLetterProvisionalApproval	10/11/2023	1

Review Document Type	Review Document File Name	Review Document Version Date

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