Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011
hdecs@health.govt.nz

Ethics reference: 2023 FULL 13189

15 June 2023

Associate Professor Michelle Wise

The University of Auckland
Level 1, Building 507, 22-30 Park Avenue Grafton
Auckland
1023
New Zealand

Tēnā koe Associate Professor Wise

APPROVAL OF APPLICATION

Study title: Follow up of early medical abortion: a multicentre randomised controlled trial

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

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried whether Māori would be specifically targeted for recruitment. The Researcher stated there would not be a specific focus and everyone would be randomised as they came to clinic. The Researcher noted existing data shows Māori tend to prefer a surgical option over an EMA. The Committee noted wāhine Māori are frequently lost to follow up and suggested the study could investigate why there was a preference for the surgical option. The Researcher stated they were involved with a separate study of anonymous surveys that may be able to provide data on this question. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.1).*

Summary of outstanding ethical issues

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

1. The Committee queried whether Pasifika would be specifically targeted for recruitment. The Researcher stated there would not be a specific focus and again anyone eligible to participate would be recruited into the study. The Committee noted the answer to C10 in the application indicated the researchers did not expect cultural issues for Pacific women and requested the researchers reconsider this. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 4.3).*
2. The Committee requested the researcher obtain authorisation from the University of Auckland's research office in the EthicsRM system. (*HDEC Standard Operating Procedure*, para 175).

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. The Committee advised that as EMA itself is not under study the associated risks can be removed from the information sheet as these will be explained as part of standard of care.
2. The Committee requested a proof-read of te reo Māori words used in the sheets, specifically to check for correct macron use.
3. The Committee noted the consent form does not mention accessing medical records, but this is described in the protocol. Please include a clause in the consent form so participants consent to this.
4. The Committee requested more detail about how urine tests will be delivered to participants who consented via telehealth (e.g. sent via courier or collected from a pharmacy) in the information sheet.
5. Please include a comment regarding discretion e.g. if participants do not want members of their whānau/family to be informed or involved it is their choice and any study communications will be sent discreetly.
6. Please insert headers and appropriate logos into the PIS.

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.

Non-standard conditions:

- Please address all outstanding ethical issues raised by the Committee
- Please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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 June 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 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

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
CV for Coordinating Investigator	2022 HRC CV		
Evidence of Consultation	Letter of suport Misty IUE	04/04/2022	1
Scientific Peer Review	2022_Health_Delivery_Research_Project_Grant_-_Full_Application_Form_v3	18/07/2022	1
Surveys/questionnaires	EMA_surveys_combined	21/05/2023	3
Advertisement	Poster EMA_v3	23/05/2023	3
PIS/CF	PIS CF_v4_patient	23/05/2023	4
PIS/CF	PIS practitioner v3	24/05/2023	3
Other	pamphlets_combined	24/05/2023	1
Protocol	protocol_v5	24/05/2023	5
Data Management Plan	Data Management Plan v2	24/05/2023	2

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

Mr Barry Taylor, Ms Alice McCarthy, Ms. Kate O'Connor, Ms Maakere Marr, Mr Ewe Leong Lim, Ms Joan Pettit, Dr Amber Parry Strong, Ms Amy Henry .

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