

11 August 2021

Professor Ross Lawrenson
c/- Strategy & Funding, Hockin L3
Waikato Hospital,
Private Bag 3200
Hamilton 3240

Dear Professor Lawrenson,

Re:	Ethics ref:	21/NTB/148
	Study title:	The determinants of health for Māori mothers and adults with chronic diseases

I am pleased to advise that this application has been approved by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or <https://clinicaltrials.gov/>.
3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. 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 ensure the Data Plan has a section addressing the management of audio files.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms.

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 section 125 and 126 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 11 August 2022.

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* paragraphs 206 - 208 for further information.

Participant access to ACC

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 trialled. 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 (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Chairperson
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

<i>Document</i>	<i>Version</i>	<i>Date</i>	
CV for CI: Ross Lawrenson CV	1	04 May 2021	
CVs for other Investigators: CV Nina Scott	1	04 May 2021	
CVs for other Investigators: CV Polly Atatoa Carr	1	04 May 2021	
CVs for other Investigators: CV Nikki Barrett	1	04 May 2021	
CVs for other Investigators: CV Amy Jones	1	04 May 2021	
CVs for other Investigators: CV Jade Tamatea	1	04 May 2021	
CVs for other Investigators: CV Lynne Chepulis	1	04 May 2021	
CVs for other Investigators: CV Ryan Paul	1	04 May 2021	
Covering Letter: cover letter to HDEC	1	15 May 2021	
Survey/questionnaire: EXAMPLE of Hapu Mama Hauora Assessment. The final version used in the research is yet to be developed through the co-design process.	1	25 May 2021	
Email from WHO outlining that a UTN number is not available at present-missing for Qb.4.7	1	25 May 2021	
PIS/CF: PIS/CF for focus groups (Hapu mama and chronic disease)	1	02 June 2021	
Evidence of scientific review: peer review letter	1	03 June 2021	
PIS/CF: Patient information and consent form for pilot with Hapu mama and Chronic conditions	1	03 June 2021	
Protocol: Study protocol version 1	1	03 June 2021	
Application		04 June 2021	
PIS/CF: Patient information and consent form for focus groups UNTRACKED	2	30 July 2021	
PIS/CF: Patient information and consent form for focus groups TRACKED	2	30 July 2021	
PIS/CF: Patient information and consent form for hauora assessment UNTRACKED	2	30 July 2021	
PIS/CF: Patient information and consent form for hauora assessment TRACKED	2	30 July 2021	
Covering Letter: Cover letter for response to ethics provisional approval	2	30 July 2021	
HDEC Data Management Plan for the Collaboration study	1	30 July 2021	
Protocol: Study Protocol version 2 untracked	2	30 July 2021	
Protocol: Study Protocol version 2 tracked	2	30 July 2021	
Response to Request for Further Information			

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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>	
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018	
Mrs Kate O'Connor	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018	
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2015	01/07/2018	
Mrs Leesa Russell	Non-lay (intervention studies), Non-lay (observational studies)	14/12/2015	14/12/2018	
Ms Susan Sherrard	Lay (consumer/community perspectives)	19/03/2019	19/03/2022	

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>