

02 December 2020

Professor Beverley Lawton
42 Kelburn Parade
Wellington 6140
(Amended)

Dear Professor Lawton,

Re: Ethics ref:	20/NTB/311
Study title:	He Tapu Te Whare Tangata- a model for empowering rural solutions

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.

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:

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 see further comments from the Committee - PIS- Qualitative, please add in reassurances regarding the safety of the audio recordings, storage, access and destruction PISs - Main - Please review for typographical errors, and provide reassurances regarding data, i.e. that it is kept safely by the research team in a de-identified, password secured computer. Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDEC.

- **1)** Please ensure data risks (privacy breach) are addressed in each PISCF. The HDEC PISCF template 'What will happen to my information?' section includes a paragraph under 'risks' that may be adapted for this purpose.
- **2)** Please make it clear in the PISCFs that de-identified data from this study could be used for future research as per the application form b.4.4; whether this could include research not directly related to the current study; whether it may be shared with other researchers (and state whether this may include overseas researchers).

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 128 and 129 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

After HDEC review

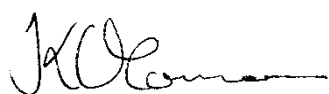
Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 02 December 2021.

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,



Mrs Kate O'Connor
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>
PIS/CF: Qualitative consent form draft	1	13 October 2020
Covering Letter: cover letter to explain aspects of submission	1	10 November 2020
PIS/CF: PICF for women on Pathway 2 in Wairoa	1	09 November 2020
Evidence of scientific review: researchers response to HRC scientific review	1	20 March 2020
Protocol: Protocol final draft	1	09 November 2020
PIS/CF: PICF for Pathway 1 women in Ngāti Porou Hauora (NPH)	1	09 October 2020
CV for CI: Bev Lawton's CV	1	09 October 2020
Evidence of scientific review	1	04 March 2020
Evidence of scientific review	1	04 March 2020
Evidence of scientific review	1	04 March 2020
Evidence of scientific review	1	04 March 2020
wording for a poster for the clinics in Pathway 2 - this version is for Tāiratwhiti site - the wording will be altered to be site specific	1	10 October 2020
wording for poster for Pathway 1 for clinics to display- this is Tairāwhiti site version	1	13 October 2020
Application		20 November 2020

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
Dr Nora Lynch	Non-lay (health/disability service provision)	19/03/2019	19/03/2026
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	20/05/2017	20/05/2020
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
Mrs Jane Wylie	Non-lay (intervention studies)	20/05/2017	20/05/2020

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>