Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

hdecs@moh.govt.nz

22 January 2019

Ms Katrina Bryant
7 Michie St
Belleknowes, Dunedin 9011

Dear Ms Bryant

Re:	**Ethics ref:**	**18/NTB/237**
	Study title:	Taurite Tū- Development of Falls Prevention exercise programme for Māori living in Te Rūnanga ō Ōtākou takiwa/region.

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:

4. Please ensure that the CI holds professional indemnity insurance throughout the duration of the study. Evidence of this may be uploaded at the time that the te reo versions of the Information Sheet are provided using the amendment pathway

5. Please ensure that if the researcher is to do interviews in participants homes a safety protocol is developed to ensure researcher safety.

6. Please remove tick boxes from consent clauses which are not optional for participation.

7. As this is an ACC-eligible intervention study please include the following statement in the PISC:

   *If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.*

   If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

8. Please ensure all health research data is kept for a minimum of ten years, in keeping with Health (Retention of Health Information) Regulations 1996, Regulation 5.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDEC.

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.

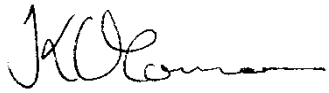
Your next progress report is due by 22 January 2020.

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,



Ms 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

Document	*Version*	*Date*
Evidence of scientific review: 3x HRC peer reviewer and 2 page rebuttal	1	18 May 2018
CV for CI: Ms Katrina Potiki Bryant CV	1	13 October 2018
CVs for other Investigators: CV for other investigators	1	13 October 2018
Evidence of scientific review: Report for development Grant	1	13 October 2018
Survey/questionnaire: Health Questionaire. Note that no information will be written on patient details. 4 number code will be used as an Identifier.	1	18 October 2018
Survey/questionnaire: laminated tool used for Hauora Maori Interviewing using WHAKĀRO PŌKARE VISUAL TOOL	1	18 October 2018
Survey/questionnaire: Guide for using WHAKĀRO PŌKARE VISUAL TOOL	1	18 October 2018
Protocol: Proposed Research Protocol for Taurite Tū- Development of Falls Prevention exercise programme for Māori along with description of research methodology	1	09 December 2018
Covering Letter: Covering letter	1	29 November 2018
PIS/CF: Information Sheet and Consent Form	1	10 December 2018
Investigator's Brochure: Draft of advertising material for Ngai Tahu Panui	1	10 December 2018
Application		11 December 2018

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

Name	*Category*	*Appointed*	*Term Expires*
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2018
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
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