

12 April 2016

MR RICKY BELL  
School of Physiotherapy  
University of Otago  
PO Box 56  
Dunedin 9054

Dear MR BELL

Re:	<b>Ethics ref:</b>	<b>16/NTB/28</b>
	Study title:	Huarahi Hauora – a pathway forwards to wellness for Māori.

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 (such as the Australia New Zealand Clinical Trials Registry, [www.anzctr.org.au](http://www.anzctr.org.au)). However <https://clinicaltrials.gov/> is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.
3. Before the study commences at a *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.

#### After HDEC review

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

**Your next progress report is due by 11 April 2017.**

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,

A handwritten signature in black ink, appearing to read 'K O'Connor', written in a cursive style.

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>
Survey/questionnaire: Study completion/exit questionnaire	word	05 February 2016
Survey/questionnaire: Exercise participant participation log	word	05 February 2016
Protocol: Protocol - summary	word	05 February 2016
Evidence of scientific review: Research Funding and Peer Review (part a)	word	05 February 2016
Investigator's Brochure: Advertising Brochure Example	word	05 February 2016
PIS/CF: Information sheet for participants - revised	word	30 March 2016
PIS/CF: Consent form for participants - revised	word	30 March 2016
Māori consultation and support	word	05 February 2016
University of Otago Ethics approval - prior research that informed this proposed study	pdf	05 February 2016
Protocol: Protocol - FULL - revised	word	30 March 2016
Evidence of scientific review: Peer Review (Part B)	word	05 February 2016
CV for CI: CV of on-site researcher	pdf	05 February 2016
CVs for other Investigators: CV's of off-site researchers	word	08 February 2016
Investigator's Brochure: Revised advertising example - is the same content with better graphics.	PDF	30 March 2016
PIS/CF: Revised consent form	word	30 March 2016
Doctors consults participant data	pdf	30 March 2016
Information sheet for Doctors	pdf	30 March 2016
Exercise participant participation log	word	30 March 2016
Covering Letter: Response letter to HDEC - new	pdf	30 March 2016
Memorandum of Understanding (MOU) Huarahi Hauora - participant 4 Doctors visits.	pdf	07 April 2016

## 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>
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
Mrs Phyllis Huitema	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2018
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
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

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>