

23 August 2016

Miss Elizabeth Binns
A-11, Private Bag 92006
Auckland 1142

Dear Miss Binns

Re:	Ethics ref:	16/NTB/121
	Study title:	Brain and body stimulation (CogEx) for older people with mild to moderate dementia: feasibility study

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-Full 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). 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.

Non-standard conditions (if applicable):

- Please add page numbers, date, and version number to all participant facing documents and the clinician enrolment form.
- Please add a section for the enrolling clinician's signature and date to the clinician enrolment form.
- Please include information in all relevant participant information sheets about travel costs being covered for community dwelling participants.

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

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment 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 at <http://ethics.health.govt.nz/home>.

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 23 August 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,



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>
CV for CI	1	08 June 2016
Protocol	5	08 June 2016
Survey/questionnaire: Baseline information	1	08 June 2016
Survey/questionnaire: Pain and Fatigue	1	08 June 2016
Survey/questionnaire: guiding questions for participants	1	08 June 2016
Survey/questionnaire: Staff guiding questions	1	08 June 2016
Adverse events form	1	08 June 2016
Withdrawal form	1	08 June 2016
Brief-BESTest	1	08 June 2016
SPPB	1	08 June 2016
MoCA	1	08 June 2016
GDS	1	08 June 2016
QOL-AD	1	08 June 2016
Covering Letter: Covering letter responding to HDEC provisional approval	1	02 August 2016
Evidence of scientific review: HDEC external reviewer	1	23 June 2016
Application	1	-
Response to Request for Further Information	1	-
Response to Request for Further Information	1	-
PIS/CF	4	-
PIS/CF	4	-
PIS/CF	5	-
PIS/CF for persons interested in welfare of non-consenting participant	5	-
PIS/CF	1	-
PIS/CF for persons interested in welfare of non-consenting participant	1	-
Response to Request for Further Information	1	-
PIS/CF: Consent form for person with dementia	2	02 August 2016
Clinician enrollment form v1	1	02 August 2016
Response to Request for Further Information	1	-
PIS/CF for persons interested in welfare of non-consenting participant	1	-
PIS/CF for persons interested in welfare of non-consenting participant	1	-
PIS/CF for persons interested in welfare of non-consenting participant	1	-
PIS/CF	1	-
PIS/CF	1	-

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>