

23 May 2016

Mr Robin Martin Matthews
197 Rowesdale Drive
Ohauti
Tauranga 3112

Dear Mr Matthews

Re:	Ethics ref:	16/NTA/53
	Study title:	Acoustic, respiratory, cognitive and wellbeing comparisons of two groups of people with Parkinson's disease receiving voice and choral singing group therapy or music appreciation activity

I am pleased to advise that this application has been approved by the Northern A 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 A 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:

- Please ensure the Consent Form has yes/no boxes against only the truly optional statements.
- In your Consent Form please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state.

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.

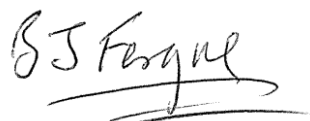
Your **next progress report** is due by **22 May 2017**.

Participant access to ACC

The Northern A 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,



Dr Brian Fergus
Chairperson
Northern A 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: VHI-10	001	20 April 2016
Survey/questionnaire: PDQ-8	001	20 April 2016
Survey/questionnaire: MDS-UPDRS	001	20 April 2016
Survey/questionnaire: DASS-21	001	20 April 2016
Survey/questionnaire: ACE-III Administration NZ	001	20 April 2016
PIS/CF: PIC/CF	001	20 April 2016
CV for CI: CI CV	001	20 April 2016
CVs for other Investigators: CV for other Investigator	001	20 April 2016
Evidence of scientific review: Scientific review	001	20 April 2016
Protocol: Study Protocol	003	20 April 2016
Covering Letter: BOPDHB clinical School research approval application form.	001	20 April 2016
Covering Letter: Maori Health	001	17 June 2015
Covering Letter: Parkinsonism Tauranga support letter	001	19 August 2015
Survey/questionnaire: Questionnaire	001	20 April 2016
Covering Letter: Covering letter	001	20 April 2016
Application		
PIS/CF: amended PIS	005	11 May 2016
Protocol: amended protocol	004	04 May 2016
PIS/CF: Participant's partner PIS	001	11 May 2016
HDEC response 001Responses to further requested information	001	11 May 2016
PIS/CF: Participant Information Sheet v.6_Highlighted	6.0	13 May 2016
Protocol: Study Protocol v.6.Tracked	6.0	13 May 2016

Appendix B Statement of compliance and list of members

Statement of compliance

The Northern A 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 00008714) 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>
Dr Brian Fergus	Lay (consumer/community perspectives)	11/11/2015	11/11/2018
Ms Rosemary Abbott	Lay (the law)	15/03/2016	15/03/2019
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Charis Brown	Non-lay (intervention studies)	11/11/2015	11/11/2018
Ms Susan Buckland	Lay (consumer/community perspectives)	11/11/2015	11/11/2016
Ms Shamim Chagani	Non-lay (health/disability service provision)	11/11/2015	11/11/2016
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Kate Parker	Lay (consumer/community perspectives)	11/11/2015	11/11/2018

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>