

06 April 2018

Professor Jeff Sigafoos
School of Education, Victoria University of Wellington
Kelburn Campus, PO Box 600
Kelburn Parade, Murphy Bldg., Level 8
Kelburn 6140

Dear Professor Sigafoos

Re: Ethics ref:	17/NTA/260
Study title:	Teaching Adults with Developmental Disability to Use an iPad for Communication

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-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 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.

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 **05 April 2019**.

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,

A handwritten signature in black ink, appearing to read 'B J Fergus', with a horizontal line underneath.

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>
CV for CI: Sigafoos CV	Version 1	27 November 2017
Evidence of scientific review: Evidence of Peer Review	1	27 November 2017
Protocol: Revised Protocol for the proposed study on Teaching Adults with Developmental Disability to Use an iPad for Communication	2	07 March 2018
Covering Letter: Revised Cover Letter from Jeff Sigafoos	2	07 March 2018
Revised Parent Information Sheet and Consent Form	2	07 March 2018
Parent Consent Form	1	27 November 2017
Revised Staff Information Sheet and Consent Form	2	07 March 2018
Staff Consent Form	1	27 November 2017
Survey/questionnaire: Sample pages from the Vineland Adaptive Behavior Scales	1	27 November 2017
PIS/CF for persons interested in welfare of non-consenting participant: Parent Information Sheet	1	27 November 2017
PIS/CF: Parent Consent Form	1	27 November 2017
Application	NA	29 November 2017
Evidence of scientific review	1	30 November 2017
Evidence of scientific review	1	30 November 2017
Response to Request for Further Information	NA	07 March 2018

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
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Catherine Jackson	Non-lay (health/disability service provision)	11/11/2016	11/11/2019
Ms Toni Millar	Lay (consumer/community perspectives)	11/11/2016	11/11/2019
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

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>