

09 March 2018

Mrs Jessica Tupou
39 Rawhiti Steet
Lower Hutt 5019

Dear Mrs Tupou

Re: Ethics ref:	18/CEN/29
Study title:	Evaluation of an Inclusive Preschool-Based Approach to Early Intervention for Children with Autism Based on the Early Start Denver Model

I am pleased to advise that this application has been approved by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Summary of Study

1. The study is an evaluation of an inclusive preschool-based approach to early intervention for children with autism based on the Early Start Denver Model (EDSM).
2. The first study in this proposal involves an intervention delivered to children by an individual trained in EDSM.
3. The Second involves training teachers to use EDSM strategies with children in their classes.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

4. The Committee noted that Māori consultation had been completed for this study.
5. The Committee queried how participants would be identified. The Researcher explained that they have approached a kindergarten association of 19 pre-schools and each of these schools has around 1 student with a diagnosis of autism spectrum disorder.
6. The Committee asked how the results would be analysed and assessed. The Researcher explained that an independent observer will view videos and transcripts and check for agreement. The independent observer is another student with expertise in the EDSM.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

7. Explain what EDSM is and what the coordinating investigator and teachers will be doing. This includes a brief explanation of procedures and techniques.
8. Please amend the non-participating child information sheets to state that the CI/teachers may be working with a young child in your child's kindergarten. It is important that information about the participant's diagnosis is not disclosed.

9. Remove the statement about anticipating improvement in the child's behaviours as this leading.
10. Remove the statement about affecting their learning or ability to improve.
11. Explain to teachers in their information sheet that participation will qualify for CME points.

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 Central 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 amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies para 6.22*).

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 8 March 2019.

The Central 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 'Helen Walker', written in a cursive style.

Mrs Helen Walker
Chairperson
Central 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>
PIS/CF for persons interested in welfare of non-consenting participant: PIS/CF for parents of participating children - Study One	01	14 February 2018
PIS/CF for persons interested in welfare of non-consenting participant: PIS/CF for parents of participating children - Study Two	01	14 February 2018
PIS/CF: Teacher PIS/CF - Study Two	01	14 February 2018
PIS/CF: PIS/CF for non-participating teachers to be included in video data - Study 2	01	14 February 2018
PIS/CF: PIS/CF for non-participating teachers to be included in video data - Study 1	01	14 February 2018
Protocol: Research protocol	01	15 February 2018
Covering Letter: Covering letter	01	15 February 2018
CV for CI	01	09 February 2018
Evidence of scientific review: Peer review form, completed by Dr Vijaya Dharan from Massey University.	01	09 February 2018
Survey/questionnaire: Parent demographic survey	01	09 February 2018
Survey/questionnaire: Teacher demographic survey - Study 1	01	09 February 2018
Survey/questionnaire: Teacher demographic survey - Study 2	01	09 February 2018
PIS/CF for persons interested in welfare of non-consenting participant: PIS & CF for parents of non-participating children who may be included in video data (Study 1).	02	09 February 2018
PIS/CF for persons interested in welfare of non-consenting participant: PIS & CF for parents of non-participating children who may be included in video data (Study 2).	03	09 February 2018
Application		

Appendix B Statement of compliance and list of members

Statement of compliance

The Central 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 00008712) 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>	<i>Present on 27/02/2018?</i>	<i>Declaration of interest?</i>
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018	Yes	No
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	30/07/2015	30/07/2018	Yes	No
Dr Melissa Cragg	Non-lay (observational studies)	30/07/2015	30/07/2018	Yes	No
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018	Yes	No
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018	Yes	No
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020	Yes	No

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>