

29 May 2018

Dr Nina Scott
Te Puna Oranga, Hockin L1
Pembroke Street
Waikato District Health Board
Hamilton 3204

Dear Dr Scott

Re:	Ethics ref:	18/CEN/88
	Study title:	A Randomised Controlled Trial of an Opportunistic, Holistic and Family Centred Approach to Improve Outcomes for Hospitalised Children and their Families

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-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 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 registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or <https://clinicaltrials.gov/>.
3. Before the study commences at *each 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:

4. Data should be retained for 10 years.
5. Please remove the yes/no tick boxes from the consent form for all statements that aren't truly optional, that is a participant could select 'no' and still participate in the study, for example, whether the participant would like to receive a copy of the study results.

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

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. Please clearly identify in the amendment form 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 for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

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 29 May 2019.

Participant access to ACC

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,



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>
Participant checklist/coversheet	1	08 May 2018
CV for CI	1	01 October 2017
Evidence of scientific review: Independent scientific peer review using the HDEC form	1	30 April 2018
PIS/CF: Qualitative component PISCF	1	30 April 2018
Survey/questionnaire: Form A (ascertainment) for RCT component	1	19 April 2018
Survey/questionnaire: Form C (contact) for RCT component of the study	1	30 April 2018
Survey/questionnaire: Satisfaction with care questionnaire (SWCQ) for RCT component	1	30 April 2018
Pharmacy on Meade referral form for flu vaccinations	1	30 April 2018
Pharmacy on Meade referral form for throat swabs	1	30 April 2018
Qualitative study flyer	1	30 April 2018
Qualitative component whanau interview schedule	1	30 April 2018
Household safety questions	1	30 April 2018
PIS/CF: RCT PIS_CF	1	04 May 2018
GP referral letter	1	01 May 2018
Survey/questionnaire: Harti Hauora Tamariki Tool	1	04 May 2018
Protocol: Study Protocol	1	04 May 2018
Whanau Information and Activity Booklet	1	04 May 2018
Application	1	-

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>
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	30/07/2015	30/07/2018
Dr Melissa Cragg	Non-lay (observational studies)	30/07/2015	30/07/2018
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020

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>