

16 October 2019

A/Prof Tony Walls  
University of Otago  
Christchurch school of medicine  
PO Box 4345  
Christchurch 8140

Dear Associate Professor Walls

Re:	<b>Ethics ref:</b>	<b>19/NTA/97</b>
	Study title:	Effect of probenecid on the pharmacokinetics of cefalexin in children

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 registry (such as the Australia New Zealand Clinical Trials Registry, [www.anzctr.org.au](http://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. Please remove the word, "Big" from "make a big difference to other children" from page 1 of the Children's Participant Information Sheet.

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](http://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](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

#### **Your next progress report is due by 15 October 2020**

#### 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,



Professor Manuka Henare  
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: A/Prof Tony Walls CV	1	01 March 2019
Evidence of scientific review: "All grant applications were subject to thorough review by our Medical and Scientific Advisory Committee as well as independent peer review. "	1	16 December 2018
PIS/CF: Child information sheet age 5-8 and assent form	1	21 March 2019
PIS/CF: Information sheet for child, 9-12y and assent form	1	22 March 2019
PIS/CF for persons interested in welfare of non-consenting participant: Information sheet for caregivers and consent form	1	21 March 2019
Protocol: Protocol: CHOC-Dip	1	22 March 2019
EMA: NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS	1	17 June 2019
Declined letter for previous application in respect of the same (or substantially similar) study: Invalid application letter	1	30 May 2019
Covering Letter: covering letter	1	19 June 2019
Application		02 July 2019
Covering Letter: Response to provisional approval, cover letter and response to questions raised by committee	2	28 August 2019
Protocol: Updated protocol with amendments "clean version"	2	30 August 2019
Protocol: Updated study protocol with amendments highlighted	2	30 August 2019
PIS/CF: Updated PIS with HDEC recommendations	2	30 August 2019
PIS/CF: Child age 5-12 information and assent form	2	30 August 2019
Response to Request for Further Information		

## 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>
A/Prof Manuka Henare	Lay (consumer/community perspectives)	19/03/2019	19/03/2022
Dr Karen Bartholomew	Non-lay (intervention studies)	18/07/2016	18/07/2022
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Ms Catherine Garvey	Lay (the law)	19/03/2019	19/03/2022
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>