

17 October 2016

Dr Mickey Fan
Department of Surgery and Anaesthesia
PO BOX 7343
Wellington South
Wellington 6242

Dear Dr Fan

Re:	Ethics ref:	16/NTA/153
	Study title:	Renal bicarbonate handling and acute mountain sickness

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.

Please look over and correct the Participant Information Sheet of grammatical errors before the study commences.

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.

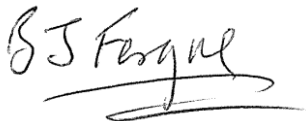
Your **next progress report** is due by **16 October 2017**.

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,

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>
Survey/questionnaire: Lake Louise AMS questionnaire	1	10 August 2016
Survey/questionnaire: Environmental Symptoms Questionnaire	1	10 August 2016
CV for CI: Mickey's CV	1	10 August 2016
PIS/CF: Amended PIS/CF	3	10 October 2016
Evidence of scientific review: Scientific review by Prof Bengt Kayser	1	06 September 2016
Protocol: study protocol	3	07 September 2016
Covering Letter: cover letter	2	10 October 2016
Survey/questionnaire: health history	1	06 September 2016
Investigator's Brochure: poster	1	07 September 2016
Evidence of scientific review: Peer review- Subudhi	1	07 September 2016
CVs for other Investigators: Mr O'Donnell's CV	1	07 September 2016
Application		
Declined letter for previous application in respect of the same (or substantially similar) study: amended PIS/CF as outlined	3	10 October 2016
Response to Request for Further Information		13 October 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
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Kate Parker	Non-lay (observational studies)	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>