Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

hdecs@moh.govt.nz

22 February 2019

Dr Nick Abbott
Department of Anaesthesia
Christchurch public hospital
2 riccarton ave
Christchurch 8011

Dear Dr Abbott

Re:	**Ethics ref:**	**18/NTA/196**
	Study title:	An evaluation of oxygen concentration within the airway in patients undergoing airway surgery using THRIVE (transnasal humidified rapid insufflatory ventilatory exchange).

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.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

1. The protocol states that the documents will be destroyed at the end of the study and electronic records will be held for 10 years. *All* study records should be stored for 10 years including documents and electronic information.

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

2. The study results will be published more widely than the University of Otago library, please remove the reference to it as it implies that there will be only a narrow publication of the study results.

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:

3. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

4. 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/.

5. 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:

6. Please revise the protocol so as to state that both the study documents and electronic records will be held for 10 years. Please submit this change with the first amendment or progress report.
7. 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, 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.

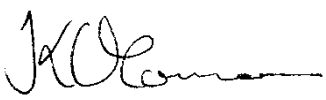
Your next progress report is due by 21 February 2020.

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,



Ms Kate O'Connor
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

Document	*Version*	*Date*
CV for CI	1	10 September 2018
Evidence of scientific review	1	26 July 2018
PIS/CF: clean version of updated consent form following review meeting	2	14 January 2019
PIS/CF: clean version of updated PIS following committee review meeting.	2 (PIS)	14 January 2019
Protocol	1	10 September 2018
Application		01 November 2018
Protocol	1	10 September 2018
Covering Letter: Cover letter responding to ethical issues following review meeting.	1	14 January 2019
Protocol: clean version updated protocol	2	14 January 2019
Protocol: tracked changes updated protocol	2	14 January 2019
PIS/CF: clean version updated consent form	2	14 January 2019
PIS/CF: tracked changes updated consent form	2	14 January 2019
PIS/CF: clean version updated participant info sheet	2	14 January 2019
PIS/CF: tracked changes version updated participant info sheet	2	14 January 2019
PIS/CF	2	19 February 2019
PIS/CF	3	19 February 2019
PIS/CF	3	19 February 2019
Protocol	1.2	19 February 2019

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

Name	*Category*	*Appointed*	*Term Expires*
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