

02 June 2021

Dr Andrew Cameron
7 Lawrence St
Herne Bay 1011

Dear Dr Cameron

Re:	Ethics ref:	21/NTB/10
	Study title:	Cerebral Oximetry when VEntilated oR Spontaneously breathing

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

Summary of resolved ethical issues

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

1. Issues addressed including updates to protocol and PISCF and provision of a data management plan. NB: for future reference it is helpful to upload a tracked changes version of updated documents to aid review.

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 B Health and Disability Ethics Committee is required.

Standard conditions:

2. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
3. 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/>.
4. 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.

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 1 June 2022.

Participant access to ACC

The Northern B 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 Kate O'Connor
Acting Chairperson
Northern B 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>	
CVs for other Investigators: CV for David Choi	1	03 December 2020	
CVs for other Investigators: CV for Nick Lightfoot	1	03 December 2020	
Covering Letter: Cover letter outlining changes made in response to initial Committee feedback	2	13 May 2021	
CV for CI	1	23 November 2020	
Evidence of scientific review: Review by Dr A Wong, an independent anaesthetic colleague with a substantial practice in shoulder anaesthesia	1	03 September 2020	
Letter of support from Maaori Health consultation	1	22 May 2020	
PIS/CF: Updated PIS/CF based on HDEC template and with contact details for Maori support contact.	2	15 May 2020	
Protocol: Detailed outline of intraoperative and preoperative patient management	4	23 November 2020	
Protocol: This protocol has been rewritten on Counties Manukau Health template and including an expanded section on statistical and power analysis	5	13 May 2021	
Application		03 December 2020	
Data Management Plan	1	13 May 2021	
Response to Request for Further Information			

Appendix B Statement of compliance and list of members

Statement of compliance

The Northern B 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 00008715) 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>	
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018	
Dr Nora Lynch	Non-lay (health/disability service provision)	19/03/2019	19/03/2026	
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	20/05/2017	20/05/2020	
Mrs Kate O'Connor	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018	
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2015	01/07/2018	
Mrs Leesa Russell	Non-lay (intervention studies), Non-lay (observational studies)	14/12/2015	14/12/2018	
Ms Susan Sherrard	Lay (consumer/community perspectives)	19/03/2019	19/03/2022	
Mrs Jane Wylie	Non-lay (intervention studies)	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>