

31 July 2018

Professor Alan Merry
School of Medicine
Faculty of Medical and Health Sciences
University of Auckland
Private Bag 92019
Auckland 1142

Dear Professor Merry

Re:	Ethics ref:	18/NTB/61
	Study title:	The effect of implementing a bundle for anaesthetists to reduce postoperative infections: a stepped wedge cluster randomised multi-site trial: the Anaesthetists Be Clean (ABC) Study

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.

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:

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.

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 30 July 2019.

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,

A handwritten signature in black ink, appearing to read 'K O'Connor', with a long horizontal flourish extending to the right.

Mrs Kate O'Connor
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>
Appendix 1 - study personnel	1.0	21 March 2018
Appendix 2 - lay summary	1.0	21 March 2018
Appendix 3 - Administrative details	1.0	21 March 2018
Appendix 4 - protocol amendments	1.0	21 March 2018
Appendix 5 - draft questions for feedback on the bundle	1.0	21 March 2018
Appendix 6 - Register of agreement to support ABC	1.0	21 March 2018
Appendix 7 - ABC BARS	1.0	21 March 2018
CV for CI: CV for Alan Merry	July 2017	21 March 2018
CVs for other Investigators: CV for Simon Mitchell	2017	21 March 2018
CV for CI: CV for Derryn Gargiulo	July 2017	21 March 2018
Protocol: Study protocol	1.0	21 March 2018
Evidence of scientific review: Head of Department Approval and evidence of review	22Mar18	22 March 2018
Protocol: Updated version of the protocol with tracked changes	1.1	05 July 2018
Evidence of statistical review	4July2018	04 July 2018
Covering Letter: Letter from PI to Chairperson Northern B HDEC	4July2018	04 July 2018
Letter from ADHB General Counsel	23May2018	23 May 2018
PIS/CF: Participant information and consent form	1.0	11 June 2018

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>
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2018
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
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>