

Health and Disability Ethics Committees

Ministry of Health 133 Molesworth Street PO Box 5013 Wellington 6011

0800 4 ETHICS hdecs@health.govt.nz

23 September 2019

Dr Douglas Campbell
Dept Anaesthesia
Level 8, Building 1, Auckland City Hospital
Park Road
Grafton
Auckland 1023

Dear Dr Campbell

Re:	Ethics ref:	19/NTB/163
	Study title:	A multi-centre, patient and assessor-blinded, parallel group, randomised controlled trial (RCT) comparing a 'standard' and 'augmented' systolic blood pressure strategy during general anaesthesia for endovascular clot retrieval in acute ischaemic stroke

This letter is to confirm receipt of this application for HDEC review, which was submitted on 18 September 2019.

Arrangements for HDEC review

Your application has been assigned for HDEC review by the HDEC-Full Review pathway.

HDEC: Northern B Health and Disability Ethics Committee

Time: 4:00-4:25pm

Meeting date: 01 October 2019

Meeting venue: Ministry of Health, Level 3, Rangitoto Room, Unisys Building, 650 Great

South Road, Penrose, Auckland

Teleconferencing: Dial **0800 633 866 (New Zealand callers)** then the conference code pin

625054.

If you are calling from Australia, please dial 1800 633 281 then the

conference code pin.

If you are calling from any other countries, please email the HDEC secretariat at hdecs@moh.govt.nz for a calling code specific to your

country.

We encourage you to attend this meeting in person or by teleconference, or to have a coinvestigator attend in your place. Your attendance may facilitate the HDEC review process by allowing some issues to be discussed and resolved at the meeting itself, rather than in correspondence after it.

This meeting will be audio-recorded for minute taking purposes. Once the meeting minutes are finalised, the audio recording will be deleted. If you do not wish the meeting to be recorded please advise the secretariat.

Please contact us as soon as possible to confirm whether you or a co-investigator can attend.

(Refer to Appendix C for public parking options around the Ministry of Health-Auckland site).

Timeline for giving a final opinion

The 35-day clock for giving a final opinion on this application starts on 19 September 2019. This clock may stop once only, where the HDEC requires further information from you in order to make a final decision. You would then have up to 90 days to provide this further information, at which point the review clock would be re-activated.

No amendments to be made before HDEC approval

No amendments can be made to your application before it is approved, except where requested by the HDEC as a condition of approval. If you think you may need to amend your application during this time, we advise you to withdraw and re-submit it at a later date.

Please don't hesitate to contact the HDEC secretariat for further information.

Yours sincerely,

Courtney Parnell Administrator

Health and Disability Ethics Committees

hdecs@moh.govt.nz

Encl: appendix A: documents submitted

appendix B: statement of compliance and list of members

appendix C: map

Appendix A Documents submitted

Document	Version	Date
Evidence of scientific review: HRC response	none	31 May 2019
Evidence of scientific review: A + Trust Grant reviewer commentary	none	30 November 2018
Protocol: Main Study protocol vs.1 5th August 2019	1	05 August 2019
CV for CI: NZ MSI Standard CV - Doug Campbell	none	30 September 2018
Survey/questionnaire: Modified Rankin Scale - Masterstroke CRF	none	19 September 2019
PIS/CF for persons interested in welfare of non-consenting participant: Independent Physician agreement of Best interest	1	05 August 2019
PIS/CF for persons interested in welfare of non-consenting participant: Family and Friends information discussion	1	05 August 2019
PIS/CF: Provision for follow-up	1	05 August 2019
Application		18 September 2019

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

Name	Category	Appointed	Term Expires
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018
Dr Nora Lynch	Non-lay (health/disability service provision)	19/03/2015	19/03/2022
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

http://www.ethics.health.govt.nz

Appendix C

