

0800 4 ETHICS hdecs@moh.govt.nz

11 May 2015

Dr Timothy Short Adult Anaesthesia, Auckland City Hospital Private Bag 9204 Victoria St Auckland 1142

Dear Dr Short

Re:	Ethics ref:	12/NTA/16/AM04
	Study title:	The Influence of Anaesthetic Depth on Patient Outcome after Major Surgery

I am pleased to advise that this amendment has been <u>approved</u> by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

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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 and approved

Document	Version	Date
Protocol: sub-study protocol	1	09 January 2015
Survey/questionnaire: Cognitive Assessment Measurement tool	1	09 January 2015
Manuscript publication:3D-CAM: Derivation and Validation of a 3- Minute Diagnostic Interview for CAM-Defined Delirium	none	21 October 2014
Post Approval Form	04	10 February 2015
PIS/CF: In New Zealand the sub-study will only be conducted at the Auckland City Hospital due to resourcing of staff involved.	2.1 Auckland only	25 March 2015
Survey/questionnaire: MMSE questionnaire	1	28 November 2014
Covering letter	none	05 May 2015
Explanation relating to sub study PIS.pdf		05 May 2015
Response to Request for Further Information		05 May 2015

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 Brian Fergus	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Dr Karen Bartholomew	Non-lay (intervention studies)	01/07/2013	01/07/2016
Ms Susan Buckland	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Ms Shamim Chagani	Non-lay (health/disability service provision)	01/07/2012	01/07/2015
Dr Christine Crooks	Non-lay (intervention studies)	01/07/2013	01/07/2015
Mr Kerry Hiini	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Mr Mark Smith	Non-lay (intervention studies)	01/09/2014	01/09/2015
Ms Michele Stanton	Lay (the law)	01/07/2012	01/07/2015

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