

03 October 2016

Dr Peter Beaver
The University of Auckland
Auckland City Hospital Support Building Level 12
2 Park Road, Grafton
Private Bag 92019
Auckland 1142

Dear Dr Beaver

Re:	Ethics ref:	16/NTB/143
	Study title:	Evaluation of the MORSim programme: A multidisciplinary simulated team training initiative for all operating room staff in New Zealand.

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 a *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 2 October 2017.

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.

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>
CVs for other Investigators: CV Jennifer Weller	V1	01 August 2016
Survey/questionnaire: Culture Survey SCSS	V1	01 August 2016
Survey/questionnaire: Culture Survey SSC Pre Culture	V1	01 August 2016
Survey/questionnaire: PROMs survey	V1	01 August 2016
Survey/questionnaire: Qualitative Interview Guide	V1	01 August 2016
Survey/questionnaire: Observation BMRI	V1	01 August 2016
Survey/questionnaire: Observation WHOBARs	V1	01 August 2016
p.2.1.	V1	01 August 2016
Transcriber confidentiality	V1	01 August 2016
Word count reading score	V1	01 August 2016
PROMs information	V1	01 August 2016
Qualitative interview information	V1	01 August 2016
Qualitative interview consent	V1	01 August 2016
a.6.2.	V1	01 August 2016
PROMs consent	V1	01 August 2016
CV for CI: CV Peter Beaver	V1	01 August 2016
Survey/questionnaire: Evaluation of training	V1	01 August 2016
Survey/questionnaire: Evaluation of online resources	V1	01 August 2016
Survey/questionnaire: Evaluation of self	V1	01 August 2016
Survey/questionnaire: Survey and observation guide	V1	01 August 2016
Survey/questionnaire: Evaluation of practice	V1	01 August 2016
Protocol: MORSim Protocol 11.8.2016v1	V1	11 August 2016
Evidence of scientific review: Contract for the provision of MORSim training	19/02/2016	19 February 2016
Evidence of scientific review: Peer Review	Peer Review	01 August 2016
Application		
(None)	1	16 August 2016
Response to Request for Further Information: Evidence of Maori cultural consultation	1	22 August 2016
PROMs Consent	v2	23 September 2016
PROMs Information	v2	23 September 2016
Qualitative Interview Information	v2	23 September 2016
Email to staff	v1	23 September 2016
New Consent Plan	v1	23 September 2016

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
Mrs Phyllis Huitema	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2018
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
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

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>