Health and Disability Ethics Committees
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22 September 2014

Associate Professor Geoffrey Shaw
Department of Intensive Care
Christchurch Hospital
Private Bag 4710
Christchurch 8140

Dear Associate Professor Shaw

Re:	**Ethics ref:**	**14/STH/132**
	Study title:	Optimising positive end expiratory pressure in mechanical ventilation using pulmonary elastance: a randomised controlled trial

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

The main issues considered by the HDEC in giving approval were as follows.

- The study aims to assess how best to ventilate patients with injured lungs. Injured lungs are harder to inflate, but once they are inflated they need extra pressure.
- ICU specialists all over the world use a 'best guess' process for each individual patient requiring ventilation.
- This Study will measure the stiffness of the lungs in patients with ARDS and use computers to generate suggested ventilation pressures based on this information.
- The aim of this study is to optimise the ventilation of ICU patients.
- Patients are given sedation and muscle relaxant (standard practice). Over time upper and lower pressure limits are increased, and then decreased. This 'Recruitment Manoeuvre' is repeated twice – measuring for when the lung is the least stiff.
- The real time assessment in this study is novel.
- The committee queried how often it is measured. The Researchers explained it would be maximum of every 3 hours, but more likely to be every 6 hours. Mini-recruitment will occur every 6 hours 4-8 times a day. This continuous measurement is novel.
- The Committee noted that this was a formalised standard practice approach.
- The Committee noted that the clinicians were in control of the care at all times during the study.
- The Researchers explained the pilot study that has occurred prior to this application.
- The Committee discussed the proxy assent process, and delayed consent, and was satisfied with the processes in place.
- The Committee queried why pregnant women are excluded. The Researchers explained that it was an exclusion criterion in an earlier, related, study. The Researchers were agreeable that pregnant participants should be included, as they

are treated in clinical practice. The Committee agreed. The Researcher will discuss with the DMC and submit an amendment if approved.

- The Committee commended the quality of the PIS/CF and application.
- The Committee noted the interpret box could be removed. It would be preferable to have a sentence on the consent form reading 'I have read this in a language I understand'.

If a new application:

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 Southern 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 WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. 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.

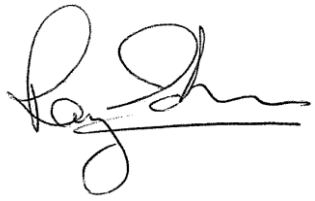
Your next progress report is due by 22 September 2015.

Participant access to ACC

The Southern 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,



Ms Raewyn Idoine
Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
CVs for other Investigators: Geoff Chase	1.0	25 July 2014
CVs for other Investigators: Chiew	1.0	25 July 2014
Evidence of scientific review: Related Research Publications	1.0	25 July 2014
Serious Event Reporting	1.0	25 July 2014
CV for CI: Geoff Shaw	1.0	28 July 2014
Investigator's Brochure: Information for Notice Board	2.0	04 September 2014
Covering Letter	1.0	04 September 2014
PIS/CF for persons interested in welfare of non-consenting participant: Statement by Family Whanau	2.0	04 September 2014
PIS/CF for persons interested in welfare of non-consenting participant: Information Sheet for Relative/Family/Whanau	2.0	04 September 2014
PIS/CF: Participant Information Sheet	2.0	04 September 2014
Protocol: Study protocol	11.0	04 September 2014
Application	1	04 September 2014
HRC Ref 1 – peer review	1	13 September 2014
HRC Ref 2 – peer review	1	13 September 2014
HRC Ref 3 – peer review	1	13 September 2014
Further peer review DMC	1	13 September 2014
Response to HRC review	1	13 September 2014
Response to DMC review	1	13 September 2014

Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern 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 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*	*Present on 16/09/2014?*	*Declaration of interest?*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Mrs Angelika Frank-Alexander	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Dr Sarah Gunningham	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No
Dr Nicola Swain	Non-lay (observational studies)	01/07/2012	01/07/2015	Yes	No
Dr Devonie Waaka	Non-lay (intervention studies)	01/07/2013	01/07/2016	Yes	No
Dr Mathew Zacharias	Non-lay (health/disability service provision)	01/07/2012	01/07/2015	Yes	No
Dr Fiona McCrimmon	lay (the law)	01/09/2014	01/09/2015	Yes	No
Associate Professor Mira Harrison-Woolrych	Non-lay (observational and intervention studies)	01/09/2014	01/09/2015	Yes	No

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