

16 July 2015

Doctor John Woodfield
Department of Surgery
Dunedin Hospital
Great King Street
Dunedin Otago

Dear Doctor Woodfield

| | | |
|-----|--------------------|--|
| Re: | Ethics ref: | 15/STH/116 |
| | Study title: | High Intensity Interval Training to optimize fitness before major abdominal surgery. Can High Intensity Interval Training improve preoperative fitness and postoperative outcomes? |

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-Expedited 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 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 **15 July 2016**.

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,

A handwritten signature in black ink, appearing to read 'Raewyn Idoine', written over a horizontal line.

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

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|--------------------------|------------------|
| Protocol: Protocol for preoperative exercise study | First submitted protocol | 30 June 2015 |
| Evidence of scientific review: Letter from peer review co-ordinator | Peer review letter | 26 May 2015 |
| CV for CI: CV with publications | 2015 | 02 March 2015 |
| Survey/questionnaire: SF Quality of Life questionnaire | SF 36 | 27 April 2015 |
| Survey/questionnaire: Surgical Recovery Scale | SRS | 16 December 2014 |
| Patient information sheet | One | 30 June 2015 |
| CVs for other Investigators: Shortened CV or co investigators using University of Otago format. | One | 30 June 2015 |
| Consent Form | Two | 30 June 2015 |
| Covering Letter: Covering letter | One | 02 July 2015 |
| Application | - | 03 July 2015 |

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

| <i>Name</i> | <i>Category</i> | <i>Appointed</i> | <i>Term Expires</i> |
|----------------------------------|---|------------------|---------------------|
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 |
| Ascc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 01/09/2014 | 01/09/2015 |
| Dr Fiona McCrimmon | Lay (the law) | 01/09/2014 | 01/09/2015 |
| Dr Nicola Swain | Non-lay (observational studies) | 01/07/2012 | 01/07/2015 |
| Dr Devonie Waaka | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 |

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