

13 August 2014

Prof Ngaire Kerse
261 Morrin Rd St Johns
Auckland 1072

Dear Prof Kerse

Re: Ethics ref:	14/STH/101
Study title:	Transforming way of living and ageing

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.

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

- The Committee noted the PIS needs more white space between paragraphs/sections throughout. It seems the researchers have sacrificed readability for getting it on less pages.
- The Committee is not sure of the usefulness of having a cover page that seems to just repeat the 2nd page but in a larger font.
- Please change the HDEC referred to in PIS/CF

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.

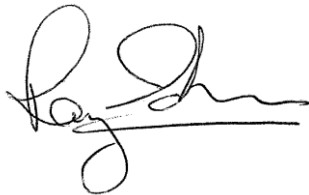
Your next progress report is due by 13 August 2015.

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,

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

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>
CV for CI: CV-Ngaire Kerse	1	29 July 2014
PIS/CF: PIS	1	29 July 2014
PIS/CF: Consent Form	1	29 July 2014
Survey/questionnaire: MPR	1	29 July 2014
Survey/questionnaire: Questionnaire 3-month follow-up	1	29 July 2014
Survey/questionnaire: Questionnaire 15-month follow-up	1	29 July 2014
Survey/questionnaire: Baseline questionnaire	1	29 July 2014
Survey/questionnaire: Medical Review	1	29 July 2014
Survey/questionnaire: Falls Calendar	1	29 July 2014
Survey/questionnaire: Reply card and FRAIL Scale	1	29 July 2014
Protocol: Protocol	1	29 July 2014
CVs for other Investigators: CV- Ruth Teh, Rob Doughty, Eruera Maxted, Anna Rolleston, Kathy Peri, Carol Wham, Martin Connolly, Richard Edlin	1	29 July 2014
Evidence of scientific review: HRC letter	1	29 May 2014
Covering Letter: Covering letter	1	29 July 2014
CVs for other Investigators: CV-Leigh Hale	1	29 July 2014
CVs for other Investigators: CV-Debra Waters	1	29 July 2014
CVs for other Investigators: CV-ClaireH	1	29 July 2014
Evidence of scientific review: HOD approval	1	30 July 2014
Application		

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
Ms Gwen Neave	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Dr Nicola Swain	Non-lay (observational studies)	01/07/2012	01/07/2015
Dr MARTIN THAN	Non-lay (intervention 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>