

Health and Disability Ethics Committees
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10 Brandon Street
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Wellington

0800 4 ETHICS hdecs@moh.govt.nz

19 December 2014

Prof Ngaire Kerse 261 Morrin Rd St Johns Auckland 1072

Dear Prof Kerse

Re: Ethics ref: 14/STH/101/AM01

Study title: Transforming way of living and ageing

I am pleased to advise that this amendment has been <u>approved</u> 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.

- Minor changes to PIS/CF.
- Confirmation that study data is de-identified.

Non-standard conditions:

- 1. Please confirm that all documents will be deidentified or use a study number before being stored and potentially used in other future studies.
- 2. Please make following changes to PISCF.
- 3. The Committee noted that the font size is 12 which is ok but linespacing and general layout makes it look very dense and hard to read. Would suggest they go to 5 pages and open it up a bit
- 4. Currently says it was approved by the multiregional ethics committee but gives a Southern HDEC approval number.
- 5. It says that it is 4 pages log including consent. However, it is 4 pages not including the consent which wasn't included in the amendment.

Non-Standard conditions must be completed before commencing your study. Nonstandard conditions do not need to be submitted to HDEC before commencing your study.

Please submit your Non-standard conditions please emailn-standard conditions to HDECS@moh.govt.nz. Do not submit Non-standard conditions as a Post Approval form.

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 and approved

Document	Version	Date
PIS/CF: PIS	ISPA v2 03 Dec 2014	03 December 2014
Survey/questionnaire: Questionnaire-Baseline	Qnaire: Baseline v4 29 Sept 14 (CHAMPS)	29 September 2014
Survey/questionnaire: Questionnaire-3 month follow-up	Qnaire: 3- mth_CHAMP v3 05 Nov 14 (CHAMPS)	05 November 2014
Survey/questionnaire: Questionnaire-15 months follow-up	Qnaire: 15- mth v2 04 Dec 14 (CHAMPS)	04 December 2014
Post Approval Form	1	-

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
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
Assc 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