

01 May 2014

Miss Katrina Aitken
10 Fernbrook Place
Mairehau
Christchurch 8013

Dear Miss Aitken

Re: Ethics ref:	14/STH/46
Study title:	What are the effects of an electronic memory book on the quality and quantity of conversations in adults with mild to moderate dementia?

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.

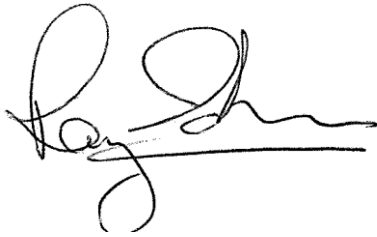
After HDEC review

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 **01 May 2015**.

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Protocol: Protocol for memory book study	one	29 October 2013
CV for CI: CV for CI Katrina Aitken	one	29 October 2013
Survey/questionnaire: Questionnaire for family member participants to complete at completion of the study.	one	29 October 2013
PIS/CF: Information provided to participants with dementia and family member participants and consent forms.	one	05 February 2014
Investigator's Brochure: Recruitment notice placed with Alzheimer's Canterbury for their newsletter.	one	05 February 2014
Confidentiality agreement form for transcribers	one	05 February 2014
Evidence of scientific review: Reviewed by Susan Gee, Lead researcher for Psychiatry of Old Age Academic Unit, CDHB	one	09 April 2014
Application		16 April 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

<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	01/07/2014
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	01/07/2014
Dr MARTIN THAN	Non-lay (intervention studies)	01/07/2012	01/07/2014
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>