Health and Disability Ethics Committees
Ministry of Health
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31 August 2017

Dr Dalice Audrey Sim
Dean's Department
University of Otago
PO Box 7343
Wellington South
Wellington 6023

Dear Dr Sim

Re:	**Ethics ref:**	**17/NTA/133**
	Study title:	Reading for Pleasure: The benefits of a dementia-friendly book club.

I am pleased to advise that this application has been *approved* by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Full 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 Northern A 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 clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

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.

Non-standard conditions:

4. For the Carer Participant Information Sheet, please consider whether the Yes/No column is required for this consent form. Leave the Yes/No boxes for the truly optional statements only that is, if answered with a No, participants can still take part in the study.

Non-standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to or reviewed by HDEC before commencing your study.

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the Standard Operating Procedures at http://ethics.health.govt.nz/home.

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 **30 August 2018.**

Participant access to ACC

The Northern A 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,

Dr Brian Fergus
Chairperson
Northern A 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*
Declined letter for previous application in respect of the same (or substantially similar) study: Letter declining previous application and list of resolved and outstanding ethical issues.	1	29 June 2017
CV for CI: Dr Dalice Sim CV	1	05 July 2017
CVs for other Investigators: Dr Gillian Claridge Bio	1	05 July 2017
CVs for other Investigators: Dr Sally Rimkeit CV	1	05 July 2017
Survey/questionnaire: Revision Form 8 Resident-QoL-AD Quality of Life for Study Participant	1	21 August 2017
Survey/questionnaire: Revision Form 10 Thriving Questionnaire 32 items (Self report)	1	21 August 2017
Survey/questionnaire: Revision Form 12 Faces Test Theory of Mind sample	1	21 August 2017
Survey/questionnaire: Revision Form 13 Addenbrooke's ACE-III	1	21 August 2017
Survey/questionnaire: Revision Form 14 Geriatric Depression Scale GDS	1	21 August 2017
Survey/questionnaire: Revision Form 15 The Neuropsychiatric Inventory–Questionnaire	1	21 August 2017
Investigator's Brochure: Revision Form 7 Recruitment Poster 21 August	1	21 August 2017
CVs for other Investigators: Astika Kappagoda CV	1	05 July 2017
Protocol: Revision Form 2 Pilot Study Protocol for HDEC application 21 August	2	21 August 2017
Evidence of scientific review: Peer Review by Prof William Levack	1	05 July 2017
CVs for other Investigators: Dr Gillian Claridge CV	1	05 July 2017
PIS/CF for persons interested in welfare of non-consenting participant: Omit and strikeout of Personal Representative Information Sheet and Consent Form	1	21 August 2017
PIS/CF: Revision Form 5 Information and consent form for carer participation 21 August	1	21 August 2017
PIS/CF: Revision Form 4 Information and Assent for PWD 21 August	1	21 August 2017
PIS/CF: Revision Form 3 Information and Consent for PWD 21 August	1	21 August 2017
Covering Letter: Revision Form 1 Cover letter for revisions 21 August 2017	2	21 August 2017
Evidence of scientific review: Peer Review Dr Gounder	1	06 July 2017
Application		
Revision Form 6 Family Information Sheet and Carer Views on their relative's participation 21 August	1	21 August 2017
Survey/questionnaire: Revision Form 9 Resident-QoL-AD-proxy Quality of Life for Carer Participant	1	21 August 2017
Survey/questionnaire: Revision Form 11 TOPAS-proxy version (32-item)	1	21 August 2017
Survey/questionnaire: Revision Form 16 NPI-Q summary	1	21 August 2017
Response to Request for Further Information		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern A 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 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Dr Brian Fergus	Lay (consumer/community perspectives)	11/11/2015	11/11/2018
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Catherine Jackson	Non-lay (health/disability service provision)	11/11/2016	11/11/2019
Ms Toni Millar	Lay (consumer/community perspectives)	11/11/2016	11/11/2019
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

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