

Research Integrity & Ethics Administration
Human Research Ethics Committee

Friday, 18 November 2016

Prof Lindy Clemson
Ageing Work and Health Unit; Faculty of Health Sciences
Email: lindy.clemson@sydney.edu.au

Dear Lindy

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

After consideration of your response to the comments raised your project has been approved.

Approval is granted for a period of four years from **18 November 2016 to 18 November 2020**

Project title: Evidence-based programs to improve the wellbeing of people with dementia and their carers: Implementing COPE in the Australian health context - phase 2

Project no.: 2016/834

First Annual Report due: 18 November 2017

Authorised Personnel: Clemson Lindy; Day Sally; Jeon Yun-Hee; Scanlan Justin; Kurrle Susan; Low Lee-Fay; Cations Monica; Comans Tracy; Crotty Maria; Laver Kate; Rahja Miia; Culph Jennifer;

Documents Approved:

Date Uploaded	Version number	Document Name
26/10/2016	Version 2	pre/post questionnaires carer v 2
26/10/2016	Version 2	pre/post questionnaires proxy consent v2
26/10/2016	Version 2	Pre/post questionnaires for person with dementia v 2
26/10/2016	Version 2	interview for proxy consent v2
26/10/2016	Version 2	interview for carer v 2
26/10/2016	Version 2	interview- person with dementia v2
21/09/2016	Version 1	Protocol
21/09/2016	Version 1	Health Professional Log
15/09/2016	Version 1	Interview Guide
15/09/2016	Version 2	Questionnaires
15/09/2016	Version 1	Project outline
15/09/2016	Version 1	Program outline
15/09/2016	Version 1	Easy read interview
15/09/2016	Version 1	Easy read

Condition/s of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.



- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
 - Serious or unexpected adverse events (which should be reported within 72 hours).
 - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.
- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.
- The Ethics Office may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

This letter constitutes ethical approval only.

Please contact the Ethics Office should you require further information or clarification.

Sincerely

Associate Professor Stephen Assinder
Chair
Human Research Ethics Committee

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007) and the NHMRC's Australian Code for the Responsible Conduct of Research (2007).