



Final Approval for Ethics Application

15 February 2018

Professor Jennene Greenhill
Flinders University of South Australia
Director of Flinders Rural Health
College of Medicine and Public Health
PO Box 852
Renmark
5341
South Australia

Dear Professor Greenhill,

OFR Number: 277.17
HREC reference number: AK03414
Project title: Harmony in the Bush
Chief Investigator: Professor Jennene Greenhill

Ethics Approval Period: 14th February 2018 – 14th February 2021

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided approval for this application which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

You are reminded that this letter constitutes **Ethics** approval only. **Ethics approval is one aspect of the research governance process.**

You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form, has been approved by the Chief Executive or delegate of each site.

The below documents have been reviewed and approved:

- Project Description v4 11/02/2018
- HREA v4 11/02/2018
- Introductory Letter v1 16.11.2017
- Response to the 277.17 HREA review v4 17/01/2018
- Response to the 277.17 HREA review v4 11/02/2018
- Participant Information Sheet/Consent Form Senior Staff or Manager v4 11/02/2018
- Participant Information Sheet/Consent Form Carer of Nurse v4 11/02/2018
- Participant Information Sheet/Consent Form Artist v4 11/02/2018
- Participant Information Sheet/Consent Form Family Member v4 11/02/2018
- Participant Information Sheet/Consent Form Legal Guardian v4 11/02/2018
- Resident with dementia participation informagraphic information sheet v4 17/01/2018
- Resident with dementia participation information sheet v4 17/01/2018
- Gantt chart 1 Overall intervention activities timelines v3 16/01/2018
- Gant chart 2 Three months intervention activities timelines v3 16/01/2018
- Photographic Release Form v3 16/01/2018
- Assessment Tools v1 14.10.2017
- Approved Activity Work Plan v1 14.10.2017
- Aged Care Facilities Support Letters v1 14.10.2017
- Elders' Approval from Yarrabah Community v1 17.11.2017
- Evidence of Consultation with Aboriginal and Torres Strait Islander Organisations v1 17.11.2017

- Questionnaires and guidelines for interviews and focus group discussions v1 14.10.2017
- Music in Dementia Assessment Scale v1 14.10.2017
- Article from Behavioral Sleep Medicine, 13:S4–S38, 2015 Ancoli-Israel et al 2015

Terms And Conditions Of Ethics Approval:

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5*.

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval only covers the science and ethics component of the application. A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research (2007)* & the *Australian Code for the Responsible Conduct of Research (2007)*.
4. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.

For any queries about this matter, please contact The Office for Research on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au

Yours sincerely



A/Professor Bernadette Richards
Chair, SAC HREC