Queensland Government
Townsville Hospital and Health Service

Our Reference: HREC/2018/QTHS/44139_4

20th December 2018

A/Prof Sally Bennett
School of Health and Rehabilitation Sciences
University of Queensland

Sally.Bennett@uq.edu.au

Dear A/Prof Bennett,

HREC Reference number: HREC/2018/QTHS/44139

Project title: Implementing the Tailored Activity Program for people with dementia or memory loss and their informal carers living at home- i-TAP (Australia): Phase 2

Thank you for submitting a response to the Townsville Hospital and Health Service Human Research Ethics Committee (HREC) on 18/12/2018.

The Townsville Hospital and Health Service HREC is constituted according to the National Health and Medical Research Council's *'National Statement on Ethical Conduct in Human Research' (NHMRC, 2007, updated 2018).* The Townsville Hospital and Health Service HREC operates in accordance with the *' Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (NHMRC, 2018)*; and the *'National Statement on Ethical Conduct in Human Research' (NHMRC, 2007, updated 2018)*. Attached is the HREC composition with membership category and affiliation with the Hospital (Attachment I).

The Human Research Ethics Committee has granted approval of this research project. The research proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research 2007 (updated May 2015).*

Documents reviewed and approved:	Version	Date
Response letter		17.12.18
Protocol	3.0	17.12.18
Letter of invitation to Qld Health Managers	1.0	17.12.18
Letter to carer prior to phone call	1.0	17.12.18
Response letter		01.12.18
Participant Information Sheet / Consent (Carer)	2.0	09.11.18
Participant Information Sheet / Consent (Carer - interview)	2.0	09.11.18
Participant Information Sheet / Consent (PWD/Mem Loss)	2.0	09.11.18
Participant Information Sheet / Consent (PWD/Mem Loss - interview)	2.0	09.11.18
Participant Information Sheet / Consent (Person responsible/Carer)	2.0	09.11.18
Participant Information Sheet / Consent (Person responsible/Carer - interview)	2.0	09.11.18
Participant Information Sheet / Consent (Legal decision maker)	2.0	09.11.18
Participant Information Sheet / Consent (Legal decision maker - Interview)	2.0	09.11.18
Participant Information Sheet / Consent (OT)	2.0	09.11.18
Participant Information Sheet / Consent (OT - Interview)	2.0	09.11.18
Participant Information Sheet / Consent (Manager - Interview)	2.0	09.11.18
Participant Information Sheet / Consent (Manager)	2.0	09.11.18
Participant Information Sheet / Consent (GP - Interview)	2.0	09.11.18
Participant Information Sheet / Consent (Referrer - Interview)	2.0	09.11.18
Withdraw Participation (Carer)	2.0	09.11.18
Withdraw Participation (Carer - Qual)	2.0	09.11.18
Withdraw Participation (PWD/Mem Loss)	2.0	09.11.18

Withdraw Participation (PWD/Mem Loss - Qual)	2.0	09.11.18
Withdraw Participation (Person responsible/Carer)	2.0	09.11.18
Withdraw Participation (Person responsible/Carer - Qual)	2.0	09.11.18
Withdraw Participation (Legal decision maker)	2.0	09.11.18
Withdraw Participation (Legal decision maker - Qual)	2.0	09.11.18
Withdraw Participation (OT)	2.0	09.11.18
Withdraw Participation (OT - Qual)	2.0	09.11.18
Withdraw Participation (Manager - Qual)	2.0	09.11.18
Withdraw Participation (Manager)	2.0	09.11.18
Withdraw Participation (Refer/GP - Qual)	2.0	09.11.18
Interview Questions (Person with Dementia)	2.0	09.11.18
Interview Questions (Carers)	1.0	15.10.18
Interview Questions (OTs)	1.0	15.10.18
Interview Questions (Managers)	1.0	15.10.18
Interview Questions (Referrer)	1.0	15.10.18
Brochure (Referrer)	2.0	09.11.18
Brochure (Managers)	1.0	15.10.18
Brochure (Consumer)	2.0	09.11.18
Brochure (OT)	1.0	15.10.18
Social Media Message (OT)	1.0	09.11.18
Social Media Message (Consumer)	1.0	09.11.18
Reach Record	2.0	09.11.18
Recruitment Decision Form	2.0	09.11.18
Letter of invitation	2.0	09.11.18
Assessment Forms (OT)	1.0	15.10.18
Questionnaire PRE_TAP Carers	1.0	15.10.18
Questionnaire POST_TAP Carers	1.0	15.10.18
Questionnaire Pre-Implementation OT	1.0	15.10.18
Questionnaire Post Training OT	1.0	15.10.18
Questionnaire Post Implementation OT	1.0	15.10.18
Questionnaire 6 months Post Implementation OT	1.0	15.10.18
Questionnaire Pre-Implementation Manager	1.0	15.10.18
Questionnaire Post Implementation Manager	1.0	15.10.18
Questionnaire 6 months Post Implementation Manager	1.0	15.10.18
Documents noted:	**Version**	**Date**
Human Research Ethics Application Form *(Dec Ver 5)*		18.12.18
NHMRC Funding Assessment		
Curriculum Vitae – B.Gannon		
Curriculum Vitae – A.Khan		
Curriculum Vitae – S.Areaiiti		Feb 2018

The research project has ethical approval for the following sites:

Central West Hospital and Health Service
Central Queensland Hospital and Health Service
Gold Coast Hospital and Health Service
Mackay Hospital and Health Service
Metro North Hospital and Health Service
North West Hospital and Health Service
Wide Bay Hospital and Health Service
Darling Downs Hospital and Health Service
Cairns Hinterland Hospital and Health Service

Please note the following key dates for this study:

HREC approval expiry: 19/12/2023
Annual report due: 19/12/2019

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the CEO or Delegate of that site has been obtained.

If conducting this study in a Health Service, a copy of this approval must be submitted to the Health Service Research Governance Officer/Delegated Personnel with a completed Site Specific Assessment (SSA) Form and supporting study documents for authorisation from the CEO or Delegate to conduct this research at the

approved sites. Refer to the local THHS website for further information on Site Specific Assessment: https://www.health.qld.gov.au/townsville/tresa/index

Please note the following conditions of approval:

1. The Principal Investigator or study sponsor will report anything to the Committee which might warrant review of ethical approval of the project, including:
   a) Within 72 hours of becoming aware of the event:
      i. All significant safety issues and urgent safety measures taken as a response to the significant safety issue.
   b) Within 15 calendar days of a sponsor's decision:
      i. Notification of temporary halt of a study for safety reasons,
      ii. Early termination of a study for safety reasons.
   c) Within 15 calendar days of becoming aware of the event or report:
      i. Any unforeseen events that might affect the ethical acceptability of the project,
      ii. Any protocol violations and deviations from the study protocol that implicate participant consent, participant safety or data integrity,
      iii. If the project is discontinued at a site before the expected date of completion,
      iv. Where applicable, all industry safety monitoring and or Data and Safety Monitoring Board (DSMB) reports.

   Do not submit individual line listings or individual adverse event reports to the HREC.

2. The Principal Investigator will provide an **annual progress report** and a final report at the completion of the study in the specified format to the HREC. The final report should include a copy of the results and/or publication, if not available at the time of reporting these must be provided in a timely manner. For clinical trials the annual report must include a safety report including a clear summary of the evolving safety profile of the trial.

3. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing ethical acceptability of the project must be submitted first to the HREC for review, then to the relevant Research Governance Offices (RGO).

Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project are to be submitted to the relevant RGOs only.

Further advice on submitting amendments is available from https://www.health.qld.gov.au/townsville/tresa/index/human-research-ethics-committee-hrec/amendments

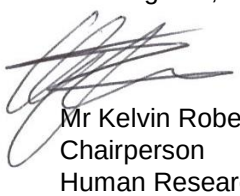
4. The HREC may undertake active monitoring of this research at any time. This may include random inspections of research sites, data, or consent documentation; and or interviews with research participants or other forms of feedback from them.

Should you require any additional information, please contact the HREC Coordinator on (07) 4433 1440 or TSV-Ethics-Committee@health.qld.gov.au. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from https://www.health.qld.gov.au/townsville/tresa/index/human-research-ethics-committee-hrec.

Once site specific authorisation to conduct the research has been granted, please complete the Commencement Form (Attachment II) and return to the HREC Coordinator.

The HREC wishes you every success in your research.

Kind regards,



Mr Kelvin Robertson
Chairperson
Human Research Ethics Committee
Townsville Hospital and Health Service