Human Research Ethics Approval

Project Number: 2023/HE002236

Project Title: Implementation and evaluation of a home hearing and vision care program to improve quality of life for frail older Australians

Version: 1.01

Chief Investigator: Professor Piers Douglas Dawes

Audiology

Co-Investigator(s)

Professor Chyrisse Heine
Dr Carly Jade Meyer
Professor Hamid Sohrabi
Associate Professor Iracema Leroi
Professor Judy Lowthian
Dr John Newall
Professor Lisa Keay
Dr Melinda Toomey
Dr Marianne Coleman
Professor Nancy Ann Pachana
Dr Sabrina Lenzen
Dr Sheela Kumaran
Dr Smriti Raichand
Associate Professor Yuanyuan Gu

Funding Body (UQ ref#):

Approving Committee: University of Queensland Human Research Ethics Committee A

Approval End Date: 28 Feb 2026

Date of Approval: Wednesday, 20 March, 2024

University of Queensland Human Research Ethics Committee A confirms that this project meets the requirements of the National Statement on Ethical Conduct in Human Research (2023). The University's human research ethics committees are organised and operate in accordance with the National Statement on Ethical Conduct in Human Research (2023).

Approved Documents

Document Type	File Name	Document Tile	Application Version	Document Version	Last Modified
Application Attachment	01_Home Care Phase 2 Protocol_v4_tracked.docx	01_Home Care Phase 2 Protocol v4 tracked	0.2	2	18/03/2024 7:45:07 PM
Project Protocol	01_Home Care Phase 2 Protocol_v4_clean.docx	01_Home Care Phase 2 Protocol_v4_clean.docx	0.2	2	18/03/2024 7:45:07 PM

Application Attachment	App_A_Example Advert_P2.docx	App A Example Advert	1.1	1	18/03/2024 7:45:09 PM
Application Attachment	App_B_Contact information_P2.docx	App B Contact Information	1.1	1	18/03/2024 7:45:09 PM
Application Attachment	App_C_Screening questions_P2.docx	App C Screening questions	1.1	1	18/03/2024 7:45:09 PM
Application Attachment	App_D_Participant Info Sheet_P2_v2_clean.docx	App D Participant Info Sheet P2 v2 clean	0.2	2	18/03/2024 7:45:08 PM
Application Attachment	App_D_Participant Info Sheet_P2_v2_tracked.docx	App D Participant Info Sheet P2 v2 tracked	0.2	2	18/03/2024 7:45:08 PM
Application Attachment	App_E_consent forms_P2_V2_clean.docx	App E Consent Form P2 V2 clean	0.2	2	18/03/2024 7:45:08 PM
Application Attachment	App_E_consent forms_P2_V2_tracked.docx	App E Consent Form P2 V2 tracked	0.2	2	18/03/2024 7:45:08 PM
Application Attachment	App_F_Dementia Friendly PIS_P2_v2_clean.docx	App F Dementia Friendly PIS P2 v2 clean	0.2	2	18/03/2024 7:45:09 PM
Application Attachment	App_F_Dementia Friendly PIS_P2_v2_tracked.docx	App F Dementia Friendly PIS P2 v2 tracked	0.2	2	18/03/2024 7:45:08 PM
Application Attachment	App_G_assessing_capacity_P2.docx	App G Assessing Capacity	1.1	1	18/03/2024 7:45:09 PM
Application Attachment	App_H_Sociodemographic questionnaire_P2.docx	App H Sociodemographic questionnaire	1.1	1	18/03/2024 7:45:09 PM
Application Attachment	App_I_Outcome Measure_collated.docx	App I Outcome measures collated	1.1	1	18/03/2024 7:45:10 PM

Application Attachment	App_J_Logbooks.docx	App J Logbooks	1.1	1	18/03/2024 7:45:10 PM
Application Attachment	App_K_Topic Guide SCN_v2.docx	App K Topic Guide	1.1	1	18/03/2024 7:45:10 PM
Application	Output Form.pdf	Output Form	1.1	3	18/03/2024 7:45:07 PM
Application Attachment	00_Response Letter_Phase2_resubmission.docx	Response Letter Phase 2 Resubmission	0.2	2	18/03/2024 7:45:07 PM

Ethics committee

University of Queensland Human Research Ethics Committee A
EC00456
The University of Queensland

Additional Notes to HREC Approval

1. The University of Queensland HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2023)*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

2. If a Public Health Act (PHA) application is applicable, please visit the Health and Medical Research Unit website at:
   http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp
   Researchers are reminded that they require a current ethics application to utilise data provided through a PHA application.

3. In accordance with Section 5.5.6 (b) of the National Statement, the Chief Investigator will report to the HREC annually for the duration of the project. A final report is to be submitted on completion of the study.

4. The Chief Investigator will immediately report anything that might warrant review of ethical approval of the project, in the specified format, including:
   - Unforeseen events that might affect continued ethical acceptability of the project.
   - Serious Adverse Events that materially impact on the continued ethical acceptability of the project.

   Any other incident attributable to the research affecting the welfare and/or health of participants or researchers should be promptly reported through UQSafe and the relevant reviewing HREC.

5. Amendments to any part of the approved protocol (including change of Investigator/s), documents, or questionnaires attached to the clearance must be submitted to the HREC and approval granted before the changes are implemented.

6. All clinical trials need to be registered on a World Health Organization (WHO) approved clinical trials registry (for example http://www.anzctr.org.au).

7. The Chief Investigator must determine whether the study needs to be declared/notified to UQ Insurance Services as per Fact Sheet on Insurance Services website (refer flow chart at Appendix 1).[1]

8. The Chief Investigator is responsible and accountable for full compliance of the protocol by all investigators including the collection, use, storage and disclosure of data as required by UQ policies and procedures.

9. The HREC reserves the right to visit the research site and view materials at any time, and to conduct a full audit of the project.

[1] Despite international and disciplinary norms, a wide range of studies involving humans can be considered a "Clinical Trial" for insurance purposes at UQ. E.g., in some cases, this can include epidemiological surveys, population level studies, blood sampling studies (e.g., seroprevalence), psychophysiological outcome studies, and parenting intervention evaluations.

Additional Notes to LNR Panel Approval

1. Research reviewed and approved by LNR Panel meets National Statement Requirements as per s5.1.18 – s5.1.21

2. In accordance with Section 5.5.6 (b) of the National Statement, the Chief Investigator will report to the LNR Panel annually for the duration of the project. A final report is to be submitted on completion of the study.

3. The Chief Investigator will immediately report anything which might warrant review of ethical approval of the project, in the specified format, including:
   - Unforeseen events that might affect continued ethical acceptability of the project.
   - Serious Adverse Events that materially impact on the continued ethical acceptability of the project.

   Any other incident attributable to the research affecting the welfare and/or health of participants or researchers should be promptly reported through UQSafe and the relevant LNR Panel.

4. Amendments to any part of the approved project description (including change of Investigator/s), documents, or questionnaires attached to the application must be submitted to the HREC and approval granted before the changes are implemented.

5. The Chief Investigator is responsible and accountable for full compliance of the protocol by all investigators including the collection, use, storage and disclosure of data as required by UQ policies and procedures.

6. The LNR Panel reserves the right to visit the research site and view materials at any time, and to conduct a full audit of the project.