

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: 2.01

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Funding Body (UQ ref#):

Approving Committee: University of Queensland Human Research Ethics Committee A

Approval End Date: 28 Feb 2026

Date of Approval: Monday, 20 May, 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 Title	Application Version	Document Version	Last Modified

Application Attachment	01_Home Care Phase 2 Protocol_v5_tracked.docx	01_Home Care Phase 2 Protocol v5 tracked	2.1	3	15/05/2024 1:50:55 AM
Project Protocol	01_Home Care Phase 2 Protocol_v5_clean.docx	01_Home Care Phase 2 Protocol_v5_clean.docx	2.1	3	15/05/2024 1:50:55 AM
Change Tracking	2023_HE002236 v1_01 - v2_01 Changes.pdf	2023/HE002236 v1_01 - v2_01 Changes	2.1	1	15/05/2024 1:50:58 AM
Application Attachment	App_D_Participant Info Sheet_P2_v3_clean.docx	Appendix D Participant Info Sheet P2 V3 clean	2.1	3	15/05/2024 1:50:55 AM
Application Attachment	App_D_Participant Info Sheet_P2_v3_tracked.docx	Appendix D Participant Info Sheet P2 V3 tracked	2.1	3	15/05/2024 1:50:55 AM
Application Attachment	App_E_consent forms_P2_V3_clean.docx	Appendix E Consent Forms P2 V3 clean	2.1	3	15/05/2024 1:50:55 AM
Application Attachment	App_E_consent forms_P2_V3_tracked.docx	Appendix E Consent Forms P2 V3 tracked	2.1	3	15/05/2024 1:50:55 AM
Application	Output Form.pdf	Output Form	2.1	4	15/05/2024 1:50:54 AM

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.