

Research Integrity & Ethics Administration

Human Research Ethics Committee

Thursday, 18 May 2023

Dr Julie Ayre

School of Public Health: Public Health; Faculty of Medicine and Health

Email: julie.ayre@sydney.edu.au

Dear Julie,

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 18/05/2023 to 18/05/2027

Project No.: 2023/276

Project Title: CheckMyText: A trial of online real-time health literacy text editing

software

Authorised Personnel: Ayre Julie; Bonner Carissa; Mac Olivia; McCaffery Kirsten; Muscat

Danielle; Mouwad Dana;

First Annual Report due: 18/05/2024

Documents Approved:

Date Uploaded	Version Number	Document Name
09/05/2023	v2	newsletter template (clean version) v2
09/05/2023	v1	focus group invitation email and phone scripts v1
09/05/2023	v2	PIS consumer clean v2
09/05/2023	v2	PIS health info developers (trial) clean v2
09/05/2023	v2	protocol v2 clean
09/05/2023	v2	Survey 1 and 2 (info developers) clean v2
09/05/2023	v2	survey consumers clean v2
09/05/2023	v1	PIS v1 focus groups
17/03/2023		training powerpoint slides
17/03/2023		flier for study participants
17/03/2023		social media flier
17/03/2023		participant log

Special Condition/s of Approval

The Committee approved the application/revised application in the absence of ethical objections and on the basis of satisfactory scientific merit. The special conditions of approval are as follows:

- Please ensure your study adheres to the University of Sydney's Research Data Management
 <u>Policy</u>, especially in regard to ZOOM recordings of focus group these can only be recorded
 on computers (not the Cloud) and only audio kept and moved to a University approved
 storage platform such as OneDrive and later RDS. Video needs to be deleted immediately.
- Please also bear in mind that transcription services will need to be approved to ensure that transcript data are only stored in Australia.

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.
- The Clinical Trials Support Office has been notified as outlined in the University's Clinical Trials Policy where a clinical trial is being undertaken.

This letter constitutes ethical approval only.

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

Sincerely,

Associate Professor Ingrid Gelissen

Interim Chair

Health Review Committee (Low Risk)

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) current National Statement on Ethical Conduct in Human Research (2018) and the NHMRC's current Australian Code for the Responsible Conduct of Research (2018).