

Monash University Human Research Ethics Committee
Approval Certificate

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

Project ID: 39827
Application Type: HREC Review
Project Title: Modif-i Alcohol Community Trial: A clinical trial of a "brain-training" smartphone app to help reduce alcohol use in people with alcohol use disorder
Chief Investigator: Professor Victoria Manning
Approval Date: 13/11/2023
Expiry Date: 13/11/2028

Terms of approval - failure to comply with the terms below is in breach of your approval and the *Australian Code for the Responsible Conduct of Research*.

1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash letterhead and the Monash University complaints clause must include your project number.
6. Amendments to approved projects including changes to personnel must not commence without written approval from MUHREC.
7. Annual Report - continued approval of this project is dependent on the submission of an Annual Report.
8. Final Report - should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected completion date.
9. Monitoring - the project may be subject to an audit or any other form of monitoring by MUHREC at any time.
10. Retention and storage of data - The Chief Investigator is responsible for the storage and retention of the original data pertaining to the project for a minimum period of five years.

Kind Regards,

Professor Nip Thomson

Chair, MUHREC

CC: Miss Faisha Surjatin, Ms Ellen McSheedy, Miss Vivian Pham, Miss Danielle Whelan, Mr Hugh Piercy, Mr Samuel Liu, Dr Joshua Garfield, Dr Bosco Rowland, Professor Dan Lubman, Professor Antonio Verdejo-Garcia, Assoc Professor Sonja de New, Assoc Professor John Reynolds, Dr Nicola Huxley, A/Prof. Petra Staiger

List of approved documents:

Document Type	File Name	Date	Version
Supporting Documentation	Services Australia Participant Withdrawal of Consent Form - Modif-i 6.1.23	06/01/2023	1
Explanatory Statement	RMS2713 - Services Australia Participant Information Document - Modif-i 9.6.23	09/06/2023	1
Supporting Documentation	Modif-i alcohol Baseline text message text	05/10/2023	1
Supporting Documentation	Modif-i alcohol facebook advertisement 05.10.23	05/10/2023	1

Document Type	File Name	Date	Version
Questionnaires / Surveys	Modif-i Alcohol REDCap survey text - all time points	12/10/2023	1
Supporting Documentation	Modif-i app privacy policy	17/10/2023	1
Supporting Documentation	Modif-i FAQ - Active	18/10/2023	1
Supporting Documentation	Modif-i FAQ - Sham	18/10/2023	1
Supporting Documentation	Modif-i FAQ - Waitlist	18/10/2023	1
Explanatory Statement	Modif-i immediate-start information and consent form v2 1.11.23 tracked changes	01/11/2023	2
Explanatory Statement	Modif-i wait-list information and consent form v2 1.11.23 tracked changes	01/11/2023	2
Consent Form	Modif-i immediate-start information and consent form v2 1.11.23 tracked changes	01/11/2023	2
Consent Form	Modif-i wait-list information and consent form v2 1.11.23 tracked changes	01/11/2023	2
Consent Form	RMS2713 - Services Australia Participant Consent Form - v2 1.11.23 tracked changes	01/11/2023	2
Supporting Documentation	Modif-i protocol version 2 1.11.23 tracked changes	01/11/2023	2