

29 February 2024

Prof Victoria Manning
Department of Turning Point
110 Church Street, Richmond, Vic 3121

Dear Prof Manning,

Study Title: A pilot randomised controlled trial of a novel approach bias modification smartphone application (Modif-i Tobacco) to reduce tobacco use and craving among tobacco smokers interested in attempting to quit

Principal Investigator: Victoria Manning

Associate Investigator/s: Joshua Garfield, Dan Lubman, Catherine Segan, Petra Staiger, Billie Bonevski, Hugh Piercy, Samuel Liu, Danielle Whelan & Bosco Rowland

Other personnel: Faisha Surjatin, Ellen McSheedy & Michelle Chen

Eastern Health Reference Number: E24-002-101584

Thank you for your correspondences on 21 & 27 February 2024 addressing the matters raised in the HREC's letter dated 19 February 2024 following the ethical review of the above project at its meeting held on 15 February 2024.

I am pleased to advise that the above study has received full ethical approval from the Eastern Health Human Research Ethics Committee (HREC). The study has received full governance authorisation also from the Office of the Chief Executive Officer or delegate at Eastern Health and may commence at the nominated site.

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2023) (**National Statement**). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (**NHRMC**) National Statement and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles (HPP's) described in the Health Records Act 2001 (Vic).

HREC Final Approval Date: 29 February 2024

Research Governance Authorisation: 29 February 2024

Ethical approval for this project applies at the following site/s: Turning Point

Approved Documents:

The following documents have been reviewed and **approved** by the HREC:

Document	Version	Dated
Human Research Ethics Application (HREA) - Review Reference: HREC/101584/EH-2024-414416(v2)	2	27Feb2024
Protocol	2	20Feb2024
Participant Information Sheet and Consent Form (PICF)	2	21Feb2024
Facebook Advertisements	1	19Jan2024
SMS TEXT_REDCap	1	17Jan2024
Survey Questionnaires_REDCap	2	21Feb2024
Modif-i app FAQ - ABM	1	17Jan2024
Modif-i app FAQ - control	1	17Jan2024
Victorian Specific Module (VSM) - Review Reference: VSM/101584/EH-2024-409523(v1)	1	23Jan2024

The following documents have been reviewed and **noted** by the HREC:

Document	Version	Dated
Modif-i app Privacy Policy	1	17Jan2024

The following documents have been reviewed and authorised / noted by the Office of Research and Ethics (Research Governance):

Document	Version	Dated
Site Specific Assessment (SSA) – Review Reference: SSA/101584/EH-2024-409524(v1)	1	23Jan2024

Approval is subject to:

1. The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement.
2. Immediate notification to the Office of Research & Ethics of any serious adverse events on participants.
3. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project.
4. Immediate notification to the Office of Research and Ethics of any breach of data, breach of participant's rights and participant complaints.
5. Notification of any changes to personnel on the study.
6. Notification and reasons for ceasing the project prior to its expected date of completion.
7. Submission to the HREC of any proposed modifications to the project or documents as approved by the HREC and noted above.
8. Submission of an annual report due in February each year for the preceding calendar year, for the duration of the study. Further guidance can be found <https://www.easternhealth.org.au/research-ethics/guidance>
9. Submission of a final report and papers published on completion of the project.
10. Projects may be subject to an audit or any other form of monitoring by the Eastern Health Office of Research & Ethics at any time.

Confidentiality, Privacy & Research:

Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable. No patients' names or UR numbers must be stored on these devices. Electronic storage devices must be password protected or encrypted. The conduct of research must be compliant with the conditions of ethics approval and Eastern Health policies.

Publications:

Publications are very important for disseminating research and demonstrating the research activity of investigators and their institutions. Publications provide evidence of the contribution that participants, researchers and funding sources make. It is therefore important that the role of Eastern Health including the investigator's Eastern Health affiliation (if appropriate) is provided in publications.

Composition of the HREC

We confirm at the meetings at which the above project was considered, the Committee fulfilled the requirements of the NHMRC National Statement in that it contained men and women encompassing different age groups and included people in the following categories:

HREC Members

Chairperson

Person/s bringing a broader community or consumer perspective

Lawyer

Person/s fulfilling a Pastoral Care Role

Person/s with knowledge of and current experience in the professional care or treatment of people

Person/s with Current Research Experience

Please quote the reference number **E24-002-101584** in all future correspondence.

Yours sincerely



Amy Tang

Research Ethics and Governance Officer

Eastern Health Office of Research and Ethics

On behalf of

1. Eastern Health Human Research Ethics Committee (Ethics Approval)
2. Executive Director of Eastern Health Institute (Site Research Governance Authorisation)