

Human Ethics Application Approval

10/05/2023

ATTENTION: PROF Jane Pirkis

5050 - Melbourne School of Population and Global Health
5000 - Medicine, Dentistry and Health Sciences
The University of Melbourne

Reference Number: 2023-26011-40150-3

Project Title: A randomised controlled trial evaluating the effectiveness of the Engaging Men in Crisis Support training program for Crisis Supporters at Lifeline Australia

Dear PROF Pirkis,

Thank you for your response to queries raised by the STEMM 2 ethics committee.

The committee agreed to approve your application on the basis that it meets the requirements of the [National Statement on Ethical Conduct in Human Research \(2007, Updated 2018\)](#). Please see below **Summary Details for the Approved Human Ethics Project** and **Conditions of Approval**. It is your responsibility to ensure that all people associated with the project are made aware of what has been approved.

Please contact us via the Correspondence tab if you have any questions or if you require further assistance.

Kind regards,

Erin Dyson

Research Ethics Officer

Human Ethics Team

Office of Research Ethics and Integrity | Research, Innovation & Commercialisation
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Summary Details for the Approved Human Ethics Project:

Project Title: A randomised controlled trial evaluating the effectiveness of the Engaging Men in Crisis Support training program for Crisis Supporters at Lifeline Australia

Reference Number: 2023-26011-40150-3

Approval Date: 10/05/2023

Expiry Date: 10/05/2026

Responsible Human Ethics Committee: STEMM 2

Project Supervisor: PROF Jane Pirkis

Other Investigators: A/PROF Simon Rice, PROF Andrew MacKinnon, DR Zac Seidler, Miss Katherine Trail, MR Kieran O'Gorman, MS Justine Fletcher

External Investigators: Dr Anna Brooks, Mr Satish Shrestha, Professor Cathy Mihalopoulos, Dr Long Le, Professor John Oliffe, Dr Tara Hunt

Documents Table:

Document Type	File Name	Date	Version
Other external approvals	2022 101 UoM Services agreement	04/04/2022	1

Document Type	File Name	Date	Version
Other external approvals	FINAL Lifeline Data Access Agreement_for execution_AJM_KOG	20/03/2023	1
Other	Engaging Men in Crisis Support trial - victorian-specific-module-doc	28/03/2023	1
Recruitment materials	4. Engaging Men in Crisis Support trial - Participant Communications	31/03/2023	1
Consent form	2. Engaging Men in Crisis Support trial - PDCF	31/03/2023	1
Questionnaire(s) and/or survey instrument(s)	3. Engaging Men in Crisis Support trial - appendix all items	31/03/2023	1
Recruitment materials	4. Engaging Men in Crisis Support trial - Participant Communications	31/03/2023	1
Full protocol (for medical research)	1. Lifeline PSBM RCT- protocol	04/04/2023	1

Conditions of Approval:

Research projects are normally approved to the anniversary date of the approval. Projects may be renewed yearly for up to a total of three years upon receipt of a satisfactory annual report. If a project is to continue beyond three years, two optional extensions of one year each (3+1+1) will need to be applied for. Anything beyond 5 years will need a new application to be submitted.

Please note that the following conditions apply to your approval. Failure to abide by these conditions may result in suspension or discontinuation of approval and/or disciplinary action.

1. **Limit of Approval:** Approval is limited strictly to the research as submitted in your Project application.
2. **Variation to Project:** Any subsequent variations to the Project must be notified formally to the Committee for consideration and approval before they are implemented. If the Committee considers that the proposed changes are significant, you may be required to submit a new application.
3. **Incidents or adverse events:** Researchers must report immediately to the Committee anything that could affect the ethical acceptability of the project, including adverse effects on participants or unforeseen events. Failure to do so may result in suspension or cancellation of approval.
4. **Monitoring:** All projects are subject to monitoring at any time by the Committee.
5. **Annual Report:** An annual report must be submitted each year on the anniversary of project approval, and at the conclusion of the project. Ethics approval will lapse if an annual report is not submitted.
FOR PROGRAM APPLICATIONS: Please ensure that you attach all Student Proposal Forms (which should have been completed before each student began their research) to your annual report submission.
6. **Auditing:** All projects are subject to audit by members of the Committee.