

Human Ethics Application Approval

09/01/2023

ATTENTION: DR Jennifer McIntosh

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

**Reference
Number:**

2023-25313-35822-3

Project Title:

SMARTERscreen: A randomised controlled trial of patient SMS messaging in general practice to increase participation in the National Bowel Cancer Screening Program

Dear DR McIntosh,

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

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Summary Details for the Approved Human Ethics Project:

Project Title: SMARTERscreen: A randomised controlled trial of patient SMS messaging in general practice to increase participation in the National Bowel Cancer Screening Program
Reference Number: 2023-25313-35822-3
Approval Date: 09/01/2023
Expiry Date: 09/01/2026
Responsible Human Ethics Committee: STEMM 2
Project Supervisor: DR Jennifer McIntosh
Other Investigators: PROF Jon Emery, A/PROF Panagiota Chondros, PROF Carlene Wilson, MS Anna Wood, PROF Shanton Chang, PROF Jane S Hocking, PROF Mark Jenkins, DR Judith Trevena
External Investigators: Dr Belinda Goodwin, Professor Finley Macrae, Dr Tina Campbell, Ms Sally Doncovio, Ms Kate Broun, Dr Joyce Jiang, Mr Glenn Austin, Mr Ian Dixon, Mrs Makala Castelli, Mr Nicholas Lee, Mrs Tamara Jolley, Mr Lyle Innes

Documents Table:

Document Type	File Name	Date	Version
Participant distress protocol	SMARTERscreen_confidentiality_privacy form	18/10/2022	1.0

Recruitment materials	Poster_waiting_room_V1.0 (2)	18/10/2022	1.0
Recruitment materials	SMARTERscreen PLS 14_11_22 (1)	14/11/2022	1.1
Consent form	SMARTERscreen_General practice consent form V1.1	14/11/2022	1.1
Recruitment materials	Data capture timepoint_NCSR protocol (2)	03/01/2023	1.0
Recruitment materials	Clinical Trial Letter Agmt_SMARTERscreen V1.0-1	04/01/2023	1.0
Other	Ethics reponse_HREC 25313	05/01/2023	1.0

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.
6. **Auditing:** All projects are subject to audit by members of the Committee.