THE UNIVERSITY OF SYDNEY

Research Integrity & Ethics Administration
HUMAN RESEARCH ETHICS COMMITTEE

Wednesday, 23 August 2023

Dr Eleonora Feletto
Daffodil Centre; Faculty of Medicine and Health
Email: eleonoraf@nswcc.org.au

Dear Eleonora,

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.

If your research project is a clinical trial and is being sponsored by the University or is to be conducted on a University of Sydney site, you must comply with additional University governance requirements prior to commencing your Clinical Trial.

Protocol Number:	**2023/496**
Protocol Title:	**MAIL, GP & SCALE trial: A general practice-led intervention to increase National Bowel Cancer Screening Program participation.**
Sites Approved:	
Authorised Persons:	**Feletto Eleonora; Treby Melissa; Austin Glenn; Walker Stephanie; David Michael; Lew Jie Bin; Cuff Jeff; Buchanan Tanya; Dessaix Anita; Durkin Sarah J.; Goodwin Belinda; Horn Christopher; Jenkins Mark A.; Nightingale Claire; Taylor Natalie; Broun Kate;**
Approval Period:	**23/08/2023 to 23/08/2027**
First Annual Report Due:	**23/08/2024**

Documents Approved:

Date Uploaded	Version Number	Document Name
10/07/2023	Version 1	Appendix 1B General Practitioner and Practice Staff recruitment templates
10/07/2023	Version 1	Appendix 2A General practice PIS
10/07/2023	Version 1	Appendix 4A Clinician and general practice staff IPSBQ questionnaire pre-trial
10/07/2023	Version 1	Appendix 4G Clinical Trial Co-ordinator Project Log
10/07/2023	Version 1	Appendix 4B Clinician and general practice staff IPSBQ questionnaire post-trial
10/07/2023	Version 1	Appendix 4C Implementation Outcomes survey mid-trial
10/07/2023	Version 1	Appendix 4D Implementation Outcomes survey post-trial
10/07/2023	Version 1	Appendix 4E General Practice Readiness for Change Questionnaire pre-trial
10/07/2023	Version 1	Appendix 4F General Practice Readiness for Change Questionnaire post-trial
14/07/2023	Version 1	External researcher declaration_Belinda Goodwin
14/07/2023	Version 1	External researcher declaration_Natalie Taylor
26/07/2023	Version 1	Paul Grogan - Manual Declaration
26/07/2023	Version 1	Emily He - Manual Declaration
11/08/2023	Version 1	Recruitment email_Appendix1C_V1_07August2023
11/08/2023	Version 2	Study Protocol_V2_08August2023_CLEAN
11/08/2023	Version 2	Participant Consent Form_Appendix 3B_V2_08August2023_Clean
11/08/2023	Version 2	Practice consent form_Appendix3A_V2_08August2023_CLEAN

11/08/2023	Version 2	PIS_Appendix2B_V2_08August2023_CLEAN
11/08/2023	Version 1	Intervention Design_Appendix6A_V1_08August2023
11/08/2023	Version 2	Practice recruitment_Appendix1A_V2_09August2023_CLEAN
16/08/2023	Version 1	External researcher declaration_Tanya Buchanan
16/08/2023	Version 1	External researcher declaration_Glenn Austin
16/08/2023	Version 1	External researcher declaration_Melissa Treby

Special Conditions of Approval for Clinical Trials

- **This letter constitutes ethical approval only.** This project cannot proceed at any site until the necessary research governance authorisation is obtained. If your study is sponsored by the University or is to be conducted on a University of Sydney site you may need to comply with additional University governance requirements prior to commencing. Please contact the Clinical Trials Governance Office at clinical-trials.research@sydney.edu.au
- Clinical Trials must be registered on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). For trials conducted in Australia or New Zealand registration should be on the Australian New Zealand Clinical Trial Registry before recruitment of the first subject (http://www.anzctr.org.au/).

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.

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

Sincerely,

Associate Professor Helen Mitchell
Chair
Human Research Ethics Committee (HREC 1)

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