

Human Ethics Application Approval

ATTENTION: PROF Kelsey Hegarty

196 - General Practice
140 - Medicine, Dentistry and Health Sciences
The University of Melbourne

Research Application

Reference Number: 2022-22745-26160-3

Project Title: BETTER MAN: Evaluating resources for improving men's relationships with their partners

10 March 2022

Dear PROF Kelsey Hegarty,

Thank you for your recent response to queries raised and/or clarification sought by the STEM 2 HREC following their review of your project at their February 2022 meeting.

The Committee agreed to **approve** the application on the basis that it meets the requirements of the National Statement on Ethical Conduct in Human Research (2007, Updated 2018). Please see overleaf, *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. This approval will be formally ratified by the full Committee at their March 2022 meeting, but you may commence working on this study immediately.

Desk-based elements of your project and face-to-face research can commence now, as can data collection that can be conducted online or via telephone, subject to necessary approvals or amendments to ethics applications.

Please consult the COVID-19 website for research guidance, FAQ and updates. <https://staff.unimelb.edu.au/covid-19-response/research-activity>

If you have any queries on these matters, or require additional information, please contact me using the details below. Please quote the ethics ID number and the title of the Project in any future correspondence.

Yours sincerely,

Sue Cameron

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

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|------------------------------------|--|
| Project Title: | BETTER MAN: Evaluating resources for improving men's relationships with their partners |
| Reference Number: | 2022-22745-26160-3 |
| Approval Date: | 10/03/2022 |
| Expiry Date: | 10/03/2025 |
| Responsible Human Ethics Committee | STEMM 2 |
| Project Supervisor | PROF Kelsey Hegarty |
| Other Investigators | A/PROF Laura Tarzia, A/PROF Panagiota Chondros, MR Matt Addison, PROF Cathy Humphreys, DR Carolina Navarro Medel |

Documents table:

| Document Type | File Name | Date | Version |
|-----------------------------------|---|------------|---------|
| Consent form | Consent Form_Female and Male Partners_final | 29/11/2019 | 1 |
| Consent form | Consent Form_Male Participants_final | 29/11/2021 | 1 |
| Recruitment materials | Better Man online advertisement | 07/03/2022 | 2 |
| Recruitment materials | PLS_Male Participants_final_v3 | 07/03/2022 | 3 |
| Recruitment materials | PLS_Female and Male Partners_final_v3 | 07/03/2022 | 3 |
| Participant distress protocol | RISK MANAGEMENT STRATEGY_final_v3 | 07/03/2022 | 3 |
| Adverse event protocol | Adverse Event Protocol_final_v3 | 07/03/2022 | 3 |
| Interview questions and/or themes | Questions and Survey_men | 07/03/2022 | 1 |
| Interview questions and/or themes | Questions and Survey_partners | 07/03/2022 | 1 |
| Participant distress protocol | Distress Protocol_Male Participants_final_v2 | 07/03/2022 | 2 |
| Participant distress protocol | Distress Protocol_Female and Male Partners_final_v2 | 07/03/2022 | 2 |
| Other | Answers to the Ethics Committee | 07/03/2022 | 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.
6. **Auditing:** All projects are subject to audit by members of the Committee.