



Human Ethics Approval

25/11/2024

ATTENTION: MR Christopher Armstrong

5210 - Biochemistry and Pharmacology
5000 - Medicine, Dentistry and Health Sciences
The University of Melbourne

Reference Number: 2024-30651-59984-4

Project Title: FARMS - FUNCAP 27, A Repeat Measure Study

Dear Christopher,

Thank you for your response to queries raised by the STEMM 1 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 2023](#). 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, and that other relevant approvals are obtained before work on this project begins.

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

Kind regards,

MR Robert Reid

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:	FARMS - FUNCAP 27, A Repeat Measure Study
Reference Number:	2024-30651-59984-4
Approval Date:	25/11/2024
Expiry Date:	25/11/2027
Responsible Human Ethics Committee	STEMM 1
Project Supervisor	MR Christopher Armstrong
Other Investigators	Dr David Fineberg, DR Elena Schneider-Futschik, DR Kristin Brown

Documents Table:

Document Type	File Name	Date	Version
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Document Type	File Name	Date	Version
Recruitment materials	Minimalist QR for advertisement	28/07/2024	1
Other	Minimalist QR for advertisement	28/07/2024	1
Recruitment materials	FARMS sample advertisement v2	16/09/2024	2
Recruitment materials	FARMS sample advertisement v2	18/09/2024	2
Other	FARMS DMP v2	18/09/2024	2
Recruitment materials	FARMS sample advertisement v2	18/09/2024	2
Other	FARMS sample advertisement v2	19/09/2024	2
Questionnaire(s) and/or survey instrument(s)	FUNCAP27InCrash_FARMS	19/09/2024	2
Questionnaire(s) and/or survey instrument(s)	FUNCAP27WhenWell_FARMS	19/09/2024	2
Questionnaire(s) and/or survey instrument(s)	ConsentWithdrawal_FARMS	19/09/2024	2
Consent form	FARMS PICF for redcap v3	19/09/2024	3
Questionnaire(s) and/or survey instrument(s)	PreScreeningSurvey_FARMS v3	06/11/2024	3
Full protocol (for medical research)	FARMS protocol 4	06/11/2024	4
Committee response	FARMS response to HREC v3	06/11/2024	3

Conditions of Approval:

Research projects are usually approved for 1 year (to the anniversary date of the approval). Projects may be renewed yearly upon receipt of a satisfactory annual report, for up to a total of three years. If a project is to continue beyond three years, an extension of one year is available, up to a total of 5 years (3+1+1). If a project extends beyond five years, a new application must be submitted. Please contact our office if you require assistance with this.

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.

- Limit of approval:** Approval is limited strictly to the research as submitted in your Project application.
- Variation to project:** Any subsequent variations to the Project must be notified formally to the Committee as an Amendment. These must be approved before they are implemented. If the Committee considers that the proposed changes are significant, you may be required to submit a new application.
- Incidents or adverse events:** Researchers must immediately submit to the Committee an incident report for any incident 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.
- Annual reports and monitoring:** All projects are subject to monitoring at least annually. An annual report must be submitted each year on the anniversary of project approval (progress report), and at the conclusion of the project (final report). If an annual report is not submitted, the conditions of approval for that year will not have been met.

FOR PROGRAM APPLICATIONS: Please ensure that you attach all Student Proposal Forms (to be completed before each student begins their research) to your annual report submission.

- Auditing:** All projects are subject to auditing at any time by the University.