Office of Research Ethics and Integrity

Human Ethics Application Approval

ATTENTION: PROF Jonathan Emery

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

Research Application

Reference Number: 2022-23168-25744-3
Project Title: IC3 - A Randomised Controlled Trial Identifying Cirrhosis and Liver Cancer in Primary Care Patients

Dear PROF Jonathan Emery,

Thank you for your response to queries raised by STEMM 1 at a meeting held on 08 February 2022.

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.

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,

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:	IC3 - A Randomised Controlled Trial Identifying Cirrhosis and Liver Cancer in Primary Care Patients
Reference Number:	2022-23168-25744-3
Approval Date:	25/02/2022
Expiry Date:	25/02/2025
Responsible Human Ethics Committee	STEMM 1
Project Supervisor	PROF Jonathan Emery
Other Investigators	PROF Alexander Thompson, A/PROF Panagiota Chondros, Miss Lucy Boyd, DR Kristi Milley, MRS Deborah de Guingand

External Investigators	Professor Christopher Reid, Professor Gary Jeffrey, Clinical Associate Professor Michael Wallace, Dr Andrew Kirke, Associate Professor Simone Strasser, Associate Professor Charlotte Hespe, Professor Clare Heal, Professor Darrell Crawford, Associate Professor Louisa Gordon, Professor Leon Adams

Documents table:

Document Type	File Name	Date	Version
Questionnaire(s) and/or survey instrument(s)	11. IC3_baseline	10/01/2022	1.0
Questionnaire(s) and/or survey instrument(s)	12. IC3_2MonthQuestionnaire	10/01/2022	1.0
Questionnaire(s) and/or survey instrument(s)	13. IC3_12MonthQuestionnaire	10/01/2022	1.0
Other	14. IC3_Attention Control	10/01/2022	1.0
Other	15. Intervention next steps	10/01/2022	1.0
Consent form	4. IC3 Participant Revocation of Consent Form	10/01/2022	1.0
Consent form	6. IC3_Services Australia Participant Consent Form Dec 21	10/01/2022	1.0
Consent form	7. IC3_Services Australia Participant Withdrawal of Consent Form Dec 21	10/01/2022	1.0
Consent form	9. IC3_consent GP	10/01/2022	1.0
Consent form	10. IC3 GP Revocation of Consent Form	10/01/2022	1.0
Consent form	4. IC3 Participant Revocation of Consent Form	10/01/2022	1.0
Consent form	7. IC3_Services Australia Participant Withdrawal of Consent Form Dec 21	10/01/2022	1.0
Consent form	3. IC3_consent patient_v1.1	16/02/2022	1.1
Consent form	6. IC3_Services Australia Participant Consent Form Dec 21_v1.1	16/02/2022	1.1
Consent form	9. IC3_consent GP_v1.1	16/02/2022	1.1
Consent form	10. IC3 GP Revocation of Consent Form_v1.1	16/02/2022	1.1
Recruitment materials	2. IC3_PLS_patient_v1.1	16/02/2022	1.1
Recruitment materials	5. IC3_Services Australia Participant Information Document_PID Dec 21 v1.1	16/02/2022	1.1
Recruitment materials	8. IC3_PLS_GP_v1.1	16/02/2022	1.1
Full protocol (for medical research)	1. IC3 Protocol_v1.8	16/02/2022	1.8
Other	16. IC3_Participant Invitation Letter_v1.1	16/02/2022	1.1
Other	17. TorchRecruit GP Agreement 20.12.2021 FINALv.2	16/02/2022	2
Other	IC3_Researchers response to committee 16022022	16/02/2022	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.