Office of Research Ethics and Integrity

Human Ethics Application Approval

10/11/2022

ATTENTION: PROF Jonathan Emery

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

Reference Number: 2022-23168-34308-7
Project Title: IC3 - A Randomised Controlled Trial Identifying Cirrhosis and Liver Cancer in Primary Care Patients

Dear PROF Jonathan Emery,

Your application for amendment to your project has been considered by an Executive Committee. You have been given approval to proceed with the project in line with the amendments on the basis that it meets the requirements of the National Statement on Ethical Conduct in Human Research (2007, Updated 2018).

Any original conditions attached to your project remain applicable. 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,

MR Robert Reid

Research Ethics Officer

Human Ethics Team
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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:	2022-23168-34308-7
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, DR Kristi Milley, MRS Deborah de Guingand, Miss Tarryn Miles, Miss Katerina Piakis, MR Adrian Laughlin
External Investigators	Professor Leon Adams, Professor Christopher Reid, Professor Gary Jeffrey, Clinical Associate Professor Michael Wallace, Dr Andrew Kirke, Associate Professor Simone Strasser, Associate Professor Charlotte Hespe, Professor Darrell Crawford, Associate Professor Louisa Gordon, Associate Professor Riitta Partanens, Ms Sophie Frear, Ms Holly Napret, Professor Chamindie Punyadeera, Mr Lucas Trevisan Franca de Lima

Documents Table:

Document Type	File Name	Date	Version
Other external approvals	IC3_Trial Registered with UQ		
Other	Saliva Collection cheat sheet _CP		
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
Other external approvals	Decision notification letter	02/03/2022	NA
Other external approvals	Cross Inst approval Hespe Adams et al. 2022-071S	09/05/2022	NA
Recruitment materials	IC3_Participant_Invitation_Letter_v2.1_23052022[1]	23/05/2022	V2
Recruitment materials	IC3_Participant Invitation Letter_v2.1_23052022	30/05/2022	2.1
Questionnaire(s) and/or survey instrument(s)	IC3_BaselineQuestionnaire_Revised_30-5-2022[1]	30/05/2022	V2
Questionnaire(s) and/or survey instrument(s)	IC3_2MonthQuestionnaire_Revised_30-5-2022[1]	30/05/2022	V2
Questionnaire(s) and/or survey instrument(s)	IC3_12MonthQuestionnaire_Revised_30-5-2022[1]	30/05/2022	V2
Other	GP_Letter_V1_30052022_IC3_Incidental_findings_Final[1]	30/05/2022	V1
Full protocol (for medical research)	1._IC3_Protocol_v1.9_Amendment[1]	01/06/2022	V1.9
Consent form	Consent Form GPs-V2.2_3-6-2022	03/06/2022	V2.2
Consent form	Consent Form patient v2.1_3-6-2022	03/06/2022	V2.1
Consent form	Consent_Form_GPs-V2.2_3-6-2022[1]	03/06/2022	V2
Consent form	Consent_Form_patient_v2.1_3-6-2022[1]	03/06/2022	V2
Plain Language Statement (PLS)	ic3-GP-Vic-A5 v2.1_6-6-2022	06/06/2022	V2

Recruitment materials	IC3_Participant_Invitation_Letter_v2.2_30-06-2022	30/06/2022	V2
Recruitment materials	IC3_Participant_Invitation_Letter_v2.2_30-06-2022	30/06/2022	V2.2
Recruitment materials	IC3_Participant_Invitation_Letter_v2.2_30-06-2022	30/06/2022	V2.2
Recruitment materials	FibroScan Participant Information	18/07/2022	V1
Other	15. IC3_Intervention next steps_tracked_V2.0 18-07-2022	18/07/2022	V2
Consent form	4. IC3 Participant Revocation of Consent Form_Vic 18-07-2022	18/07/2022	V2
Consent form	10. IC3 GP Revocation of Consent Form_v2.0 18-07-2022	18/07/2022	V2
Full protocol (for medical research)	1. IC3 Protocol_v2.0_Amendment_2_18th July 2022	18/07/2022	V2
Other	2022.7.19 TorchRecruit GP Agreement (1)	19/07/2022	V2
Recruitment materials	ic3-dl-Patient-Vic_v2.0_20-07-2022_digital (2)	20/07/2022	V2
Plain Language Statement (PLS)	ic3-dl-Patient-Vic_v2.2_20-07-2022_digital	20/07/2022	V2.2
Questionnaire(s) and/or survey instrument(s)	IC3_Baselinesurvey_revised_25-07-2022	25/07/2022	V3
Questionnaire(s) and/or survey instrument(s)	IC3_1WeekSurvey_revised_25-07-2022	25/07/2022	V3
Questionnaire(s) and/or survey instrument(s)	IC3_12monthSurvey_revised_25-07-2022	25/07/2022	V3
Consent form	Consent Form patient v2.2_25-07-2022	25/07/2022	V2.2
Consent form	Consent Form patient v2.2_25-07-2022	25/07/2022	V2.2
Full protocol (for medical research)	1. IC3 Protocol_v2.1_28092022	28/09/2022	2.1
Questionnaire(s) and/or survey instrument(s)	IC3_Baselinesurvey_revised_28-9-2022	28/09/2022	4
Other	IC3 Distress Protocol IC3Trial V1.0 13102022	13/10/2022	V1
Plain Language Statement (PLS)	ic3-dl-Patient-Vic_v2.3.1_19-10-2022_digital highlighted	19/10/2022	V2.3.1
Plain Language Statement (PLS)	ic3-GP-Vic-A5 v2.2.1_19-10-2022 highlighted	19/10/2022	V2.2.1
Other	IC3_GP Letter V2 28102022_IC3_Incidental findings_Final	28/10/2022	V2
Other	THE_IC3_TRIAL__DMP_Updated October 2022	01/11/2022	V3
Questionnaire(s) and/or survey instrument(s)	IC3_Baselinesurvey_revised_1-11-2022	01/11/2022	V5
Consent form	Consent Form patient v2.3.1_4-11-2022 highlighted	04/11/2022	V2.3.1
Consent form	Consent Form GPs-V2.3.1_04-11-2022 highlighted (1)	04/11/2022	v2.3.1
Full protocol (for medical research)	1. IC3 Protocol_v2.2_04112022_Tracked	04/11/2022	V2.2
Questionnaire(s) and/or survey instrument(s)	IC3_1weeksurvey_revised_04-11-2022	04/11/2022	V4
Questionnaire(s) and/or survey instrument(s)	IC3_12Monthsurvey-revised_04-11-2022	04/11/2022	V4
Other	15. IC3_Intervention next steps_tracked_V2.1.1 04-11-2022	04/11/2022	V2.1.1
Other	2022.11.07 TorchRecruit IC3 Project Form	07/11/2022	V3

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.