

Human Ethics Application Approval

06/04/2023

ATTENTION: PROF Lena Sanci

5850 - General Practice
5000 - Medicine, Dentistry and Health Sciences
The University of Melbourne

Reference Number: 2023-25885-38972-4

Project Title: Strengthening care for rural children: a stepped-wedge translational trial in rural Victoria and New South Wales

Dear PROF Sanci,

Thank you for your response to queries raised by the STEMM 2 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 \(2007, Updated 2018\)](#). 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.

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

Kind regards,

Erin Dyson

Research Ethics Officer

Human Ethics Team

Office of Research Ethics and Integrity | Research, Innovation & Commercialisation
Level 5, Alan Gilbert Building, 161 Barry Street, Carlton
The University of Melbourne, Victoria 3010, Australia
E: erin.dyson@unimelb.edu.au

Summary Details for the Approved Human Ethics Project:

Project Title: Strengthening care for rural children: a stepped-wedge translational trial in rural Victoria and New South Wales

Reference Number: 2023-25885-38972-4

Approval Date: 6/4/2023

Expiry Date: 6/4/2026

Responsible Human Ethics Committee: STEMM 2

Project Supervisor: PROF Lena Sanci

Other Investigators: DR Bianca Forrester, PROF Kim Dalziel, DR Ann-Maree Duncan, A/PROF Panagiota Chondros, A/PROF Adrian Bickerstaffe

External Investigators: A/Prof John Preddy, Dr Kylie Vuong, Prof Michael Brydon, Dr James Best, Dr David Tickell, Prof Faye McMillan, Dr Kathleen McCloskey, Dr Joanne Ging, Dr Mike Forrester, Dr Maya Eamus, Hon A/Prof Peter Hibbert, Dr Nan Hu, Dr Michael Hodgins, Ms Kris Pierce, Dr Hayley Smithers-Sheedy, Ms Sonia Khano, Prof Harriet Hiscock, Prof Raghu Lingam

Documents Table:

Document Type	File Name	Date	Version
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Document Type	File Name	Date	Version
Other	A. GRHANITE explained v1 290922	29/09/2022	1
Questionnaire(s) and/or survey instrument(s)	R. General_Practitioner_Control Survey_V1_14-12-22	14/12/2022	1.1
Questionnaire(s) and/or survey instrument(s)	S. General Practitioner Intervention Survey_V1_141222	14/12/2022	1.1
Questionnaire(s) and/or survey instrument(s)	X.SC4RC GP sustainability survey_v1.1_14-12-22	14/12/2022	1.1
Questionnaire(s) and/or survey instrument(s)	J. SC4RC_Family control survey_V1.1_14-12-22	14/12/2022	1.1
Questionnaire(s) and/or survey instrument(s)	K. SC4RC_Family intervention survey_V1.1_14-12-22	14/12/2022	1.1
Focus group questions and/or themes	U. Interview Guide_GP practice staff_V1_14-12-22	14/12/2022	1.1
Focus group questions and/or themes	V. Interview Guide_paediatricians_V1_14-12-22	14/12/2022	1.1
Focus group questions and/or themes	W. Interview Guide_ParentsChild_v1.1_14-12-22	14/12/2022	1.1
Other	G. Paediatrician co-consultation Proforma_v1.1_14-12-22	14/12/2022	1.1
Other	H. Paediatrician Multi-case Discussion Proforma_v1.1_14-12-22	14/12/2022	1.1
Other	Y. GP sustainability survey_REDCap email cover letter_V1.1_14-12-22	14/12/2022	1.1
Questionnaire(s) and/or survey instrument(s)	M. Family_Survey_non-face-to-face_V1.1_14-12-22	14/12/2022	1.1
Other	L Sanci_GCP	16/01/2023	1
Other	B Forrester-GCP	16/01/2023	1
Other	K Dalziel_GCP	16/01/2023	1
Other	20221117-Bickerstaffe-GCP	16/01/2023	1
Other	ICH_Good Clinical Practice_Certificate_15May2020_Chondros	16/01/2023	1
Other	SC4RC DMP_160123_amd_v02	18/01/2023	02
Other	Pre-submission review response	18/01/2023	1
Consent form	Q. Waiver_of_Consent_Cover_Letter_v2.13-03-23	13/03/2023	2
Consent form	P. Interview_PISCF_Families_Mature_Minors_v2.13-03-23	13/03/2023	2
Consent form	D. SC4RC_GP Consent_V2.13-03-23	13/03/2023	2
Consent form	O. Child Interview_PISCF_Child_Friendly_V2.13-03-23	13/03/2023	2
Recruitment materials	C. SC4RC_GP PLS_V2.13-03-23	13/03/2023	2
Recruitment materials	N. Parent-caregiver interview PLS Consent_V2.13-03-23	13/03/2023	2
Recruitment materials	F. Clinician Interview PICF_V2.13-03-23	13/03/2023	2
Recruitment materials	I. SC4RC_Family Survey PLS_V2.13-03-23	13/03/2023	2
Other	B. MOU with GP practices to Install GHRANITE_v2_13-03-23	13/03/2023	2
Other external approvals	Q. Waiver_of_Consent_Cover_Letter_v2.13-03-23	13/03/2023	2
Recruitment materials	E. SC4RC EOI_v1.2_15-03-23	15/03/2023	1.2
Recruitment materials	L. General_Practice_Waiting_Room_Posters_v2_15-03-23	15/03/2023	2

Document Type	File Name	Date	Version
Other	T. GP Survey REDCap email cover letter_reminder_V2.15-03-23	15/03/2023	2
Other	SC4RC Reviewer comments and responses_150323	15/03/2023	1
Full protocol (for medical research)	SC4RC_Study Protocol_V1.2_16-03-23	16/03/2023	1.2

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.