

Human Ethics Application Approval

ATTENTION: PROF Jane Hocking

145 - Melbourne School of Population and Global Health
140 - Medicine, Dentistry and Health Sciences
The University of Melbourne

Research Application

Reference Number: 2022-23435-29990-3

Project Title: Rebate for adolescent and young person's (14-24 years) health assessment in general practice: a cluster RCT

Dear PROF Jane Hocking,

Thank you for your response to queries raised by STEMM 1 at a meeting held on 31 May 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:	Rebate for adolescent and young person's (14-24 years) health assessment in general practice: a cluster RCT
Reference Number:	2022-23435-29990-3
Approval Date:	01/07/2022
Expiry Date:	01/07/2025
Responsible Human Ethics Committee:	STEMM 1
Project Supervisor:	PROF Jane Hocking
Other Investigators:	PROF Lena Sanci, DR Jemimah Ride, PROF Susan Sawyer, A/PROF Panagiota Chondros, PROF Meredith Temple-Smith, PROF George Patton, MS Megan Lim, PROF Jane Pirkis, DR Cathy Watson, MS Sara Newton, MS Amelia Wardley, PROF Dougie Boyle, A/PROF Grant Blashki, DR Caroline Johnson, PROF Kim Dalziel

Documents table:

Document Type	File Name	Date	Version
Consent form	Attachment 10_Practice consent for GRHANITE	28/04/2022	1
Recruitment materials	Attachment 11_Recruitment_Script_VICREN	28/04/2022	1
Other	Attachment 17_Data Management Plan	28/04/2022	1
Other	Attachment 1_GP template for YP health assessment	28/04/2022	1
Interview questions and/or themes	Attachment 7_Broad_Process Evaluation Schedule_ClinicStaff	28/04/2022	1
Consent form	Attachment 15_GP_Consent_Form	11/05/2022	2
Recruitment materials	Attachment 12_Practice_PLS	11/05/2022	2
Recruitment materials	Attachment 14_PLS_GPs	11/05/2022	2
Recruitment materials	Attachment 13_GP_Postcard	11/05/2022	2
Recruitment materials	Attachment 4_GP Baseline Survey_KAP	11/05/2022	2
Recruitment materials	Attachment 16_Practice Flyer	11/05/2022	2
Recruitment materials	Attachment_9_Clinic_GRHANITE_information	11/05/2022	2
Questionnaire(s) and/or survey instrument(s)	Attachment 6_GP_Post_induction_survey	11/05/2022	2
Questionnaire(s) and/or survey instrument(s)	Attachment 5_GP_24_month_survey	11/05/2022	2
Other	Attachment 2_GP Induction	11/05/2022	2
Other	Attachment 3_Resources for GPs Parents and Young People (1)	11/05/2022	2
Recruitment materials	UPDATED_Attachment 4_GP Baseline Survey_KAP	27/06/2022	3
Recruitment materials	UPDATED_Attachment 12_Practice_PLS	27/06/2022	3
Recruitment materials	Attachment_18_Practice_Survey	27/06/2022	1
Recruitment materials	UPDATED_Attachment 11_Recruitment_Script_VICREN	27/06/2022	3
Other	Researchers response to the Committee's comments	27/06/2022	1
Recruitment materials	Attachment 8_Audio Diaries_invitation script	28/06/2022	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.