ETHICS APPROVAL

02 March 2021

Professor Harriet Hiscock
Health Services
Murdoch Children's Research Institute

Dear Professor Hiscock,

Project Title: **Strengthening Care for Children: A stepped-wedge translational trial to reduce hospital burden**

HREC Reference Number: **HREC/65955/RCHM-2020**
RCH HREC Reference Number: **65955**

I am pleased to advise that your proposed amendment has received ethical approval from The Royal Children's Hospital Human Research Ethics Committee (HREC). This HREC is organised and operates in line with the:

- National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
- Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988, and subsequent guidelines.

The HREC confirms that your amendment meets the requirements of the National Statement.

HREC Amendment Approval Date: **02 March 2021**
Please note the HREC are no longer issuing pre-determined approval periods. Ethical approval is now ongoing, subject to the submission of an annual report on the anniversary of approval.

Participating Sites
Ethical approval for this project applies at the following sites:

Site Name
• Melbourne Children's Campus (incorporating The Royal Children's Hospital, Murdoch Children's Research Institute and the University of Melbourne Department of Paediatrics).
• Sydney Children's Hospital Network

Approved Documents
The following documents have been reviewed and approved:

Document	Version	Date
Protocol	1.3	23 February 2021
Appendix O – General Practitioner Control & Intervention Surveys	2.0	11 February 2021

Site Specific Assessment
Site-specific governance authorisation must be obtained by each participating site before the study can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator at each site covered by this ethics approval to assist each site PI with obtaining governance approval to commence the project at that site.

Conditions of Ethics Approval

- You are required to submit to the HREC:
    - An Annual Progress Report, that covers all sites listed on approval, for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
    - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: Safety monitoring and reporting in clinical trials involving therapeutic goods November 2016.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves exposure of persons to ionising radiation, you must ensure that your research is carried out in accordance with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the 'Exposure of Humans to Ionizing Radiation for Research Purposes (2005)' (Radiation Protection series Publication No.8)
- The HREC, authorising institution and/or their delegate/s may conduct an audit of the project at any time.

Yours sincerely,

Elly Ganakas
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