GOVERNANCE AUTHORISATION

22 November 2023

Prof Harriet Hiscock
Health Services
Murdoch Children's Research Institute

Dear Prof Hiscock,

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

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

I am pleased to advise that the below amendment has received **governance authorisation** at the Melbourne Children's Campus (incorporating The Royal Children's Hospital, Murdoch Children's Research Institute and the University of Melbourne Department of Paediatrics).

HREC Approval Date: **19 August 2023**
HREC Amendment Approval Date: **22 November 2023**
Governance Amendment Authorisation Date: **22 November 2023***

Please note ongoing governance authorisation is subject to the submission of a progress report on **19 August annually.*

Authorised Documents
The following documents have been authorised for use at the Melbourne Children's Campus:

Document	Version	Date
Protocol	2.0	01 November 2023

Conditions of Governance Authorisation
As Principal Investigator, you are required to:

1. Comply with the Investigator's responsibilities as outlined in the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).*
2. If the study involves radiation submit a copy of this letter to the Radiation Safety Officer. Where the Medical Physicist's report advises that the proposed radiation doses may exceed the dose constraints, the researcher must notify DHHS Radiation Team via the *Notification of a research project where the dose constraints will be exceeded* form within 14 days of the research project receiving site authorisation at RCH. This form must also be supplied to the Radiation Safety Officer.
3. Notify the RGO of:
    - The actual start date of the project.
    - Any amendments to the project after these have been approved by the reviewing HREC.
    - Any adverse events involving patients at this site, in accordance with the NHMRC Position Statement: *Safety monitoring and reporting in clinical trials involving therapeutic goods November 2016*.
    - Any changes to the indemnity, insurance arrangements or Clinical Trial Research Agreement for this project. This includes changes to the project budget or other changes which may have financial or other resource implications at this site.

- Your inability to continue as Principal Investigator or any other change in research personnel involved in this project.
- Failure to commence the study within 12 months of the Reviewing HREC approval date or if a decision is taken to end the study at this site.
- Any other unforeseen events.
- Any other matters which may impact the conduct of the project at this site.

4. Ensure that HREC approval remains current for the entire duration of the project. Investigators undertaking projects without current Reviewing HREC approval risk their indemnity, funding and publication rights.
5. Submit an annual progress report every 12 months for the duration of the project. This report is due on the anniversary of HREC approval. Continued Governance Authorisation is contingent on receipt of an annual report by the RGO. In addition, a comprehensive final report should be submitted to the RGO upon completion of the project.

You must also abide by the following requirements:

1. Where applicable, ensure that the CTN has been electronically lodged to the TGA by the sponsor.
2. For clinical trials where the site is the Sponsor, you are required to contact MCTC to organise submission of the electronic Clinical Trial Notification (e-CTN) to the TGA. This must be completed before commencement of your project.
3. It is the Principal Investigator's responsibility to ensure that copies of the complete submitted e-CTN and TGA issued acknowledgement are included in the study Site File for the project at this site.
4. Ensure that the Clinical Trial Research Agreement (CTRA) and Indemnities (or other research agreements as applicable) are fully executed, i.e. signed by all parties; and an original version (or copy) placed in the study file.

The RGO may conduct an audit of the project at any time.

If you have any matters that arise regarding conduct of the research at this site, please ensure you contact the Research Governance Manager on 03 9345 5044.

I wish you and your colleagues every success in your research.

Yours sincerely,

Research Ethics and Governance
The Royal Children's Hospital Melbourne
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Web : www.rch.org.au