GOVERNANCE AUTHORISATION

12 September 2017

Professor Andrew Davidson
Anaesthesia and Pain Management
The Royal Children's Hospital

Dear Professor Davidson,

Project Title: **Investigating the Management of paediatric procedural Pain Relief Obtained through Virtual Reality (IMPROVR)**

HREC Reference Number: **HREC/17/MonH/15**
SSA Reference Number: **SSA/17/RCHM/101**
RCH HREC Reference Number: **37077A**

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

Governance Authorisation Date: 12 September 2017*
Please note that governance authorisation is ongoing, subject to the submission of an annual report on the anniversary of approval.

Authorised Documents:
As per the documents listed on the HREC approval letter, the following documents have been authorised for use at the Melbourne Children's Campus:

Document	Version	Date
Protocol	1.2	06 June 2017
Parent/Guardian Information statement and consent form	1.2	28 August 2017
Parent guardian questionnaire	1.2	28 July 2017
Proceduralist questionnaire	1.1	28 July 2017
Observer questionnaire	1.1	28 July 2017
Child questionnaire	1.2	06 June 2017
Lay Summary (Clinicians)	1.1	28 August 2017
Lay Summary (Families)	1.1	28 August 2017
RCH Emergency Department flyer		
RCH Pathology flyer		

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. Submit a copy of this letter to the person responsible for radiation safety at this site. **This condition only applies if** the project involves exposure to ionising radiation that exceeds dose constraints, and the Medical Physicist's report has advised that the project needs to be added to the site's *Licence for Research Involving Human Volunteers* issued by the Department of Health Radiation Safety Section (for more information, visit http://www.health.vic.gov.au/radiation/). *Note: If the Medical Physicist's report has advised that the project needs to be added to the site's licence, the project cannot commence at site until you have confirmed that the project has been added to the site's licence.*
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: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*.
- 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. <u>This must be completed before commencement of your project.</u>
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

Emma Land
Research Ethics and Governance Officer
Research Ethics and Governance
The Royal Children's Hospital Melbourne
Phone : (03) 9345 5044
Email : rch.ethics@rch.org.au
Web : www.rch.org.au