MonashHealth

Research Support Services
Monash Health
Level 2, I Block
Monash Medical Centre
246 Clayton Road
Clayton Victoria 3168

Tel (03) 9594 4611
Fax (03) 9594 6306
Email: research@monashhealth.org

7 July 2017

Dr Erin Mills
Paediatric Emergency Consultant
Monash Medical Centre
246 Clayton Road
Clayton VIC 3168

Dear Dr Mills,

Study title: Investigating the Management of paediatric procedural Pain Relief Obtained through Virtual Reality (IMPROVR)
NMA HREC Reference Number: HREC/17/MonH/15
NMA SSA Reference Number: SSA/17/MonH/21
Monash Health Ref: 17-0000-038A
Protocol: IMPROVR V1.2 dated 06 June 2017

Thank you for submitting a Site Specific Assessment Form for authorisation of the above project at Monash Health.

I am pleased to inform you that authorisation has been granted for this project to be conducted at the Monash Medical Centre Clayton campus of Monash Health.

The following conditions apply to this research project at your site. These conditions are additional to those imposed by the Human Research Ethics Committee that granted ethical approval.

The Principal Investigator is required to notify Research Support Services, Monash Health of the following:

1. Any change in protocol and the reason for that change together with an indication of ethical implications (if any).
2. Suspected Unexpected Serious Adverse Reactions (SUSARs) involving a Monash Health participant or a participant at site that Monash Health has provided HREC Review.
3. Serious Adverse Events (SAEs) that occur with a Monash Health participant or with a participant from a site that Monash Health has provided HREC review that are considered by the Investigator as being definitely related, probably related, possibly related and unknown.
4. Any unforeseen events that might affect continued ethical acceptability of the project.
5. Any expiry of the insurance coverage provided in respect of sponsored trials.
6. Discontinuation of the project before the expected date of completion, giving reasons.
7. Any change in personnel involved in the research project including any study member resigning from Monash Health &/or the study team.

MonashHealth

Research Support Services
Monash Health
Level 2, I Block
Monash Medical Centre
246 Clayton Road
Clayton Victoria 3168

Tel (03) 9594 4611
Fax (03) 9594 6306
Email: research@monashhealth.org

At the conclusion of the project or every twelve months if the project continues, the Principal Investigator is required to complete and forward an annual report to Research Support Services.

List of Approved Documents:

Document	*Version*	*Date*
Monash Health Participant Information Sheet and Consent Form based on Master Participant Information Sheet and Consent Form V1.2 dated 06 June 2017	1.2	06 June 2017
Monash Health ED Flyer	1.0	06 June 2017
Monash Health Pathology Flyer	1.0	06 June 2017

If you should have any queries about your project please contact Mr Michael Kios on 9594 4606 or via email michael.kios@monashhealth.org or Ms Deborah Dell on 9594 4605 or via email deborah.dell@monashhealth.org

Research Support Services wishes you and your colleagues every success in your research.

Yours sincerely

MICHAEL KIOS
Research Governance Manager

Attachments:
3 x CIRA (commercially sponsored)
3 x Standard Indemnity

Cc: Dr Evelyn Chan, Paediatrics

Please Note: It is requested that correspondence be forwarded electronically to research@monashhealth.org with the local Monash Health reference number inserted.

MonashHealth

Research Support Services
Monash Health
Level 2, I Block
Monash Medical Centre
246 Clayton Road
Clayton Victoria 3168

Tel (03) 9594 4611
Fax (03) 9594 6306
Email: research@monashhealth.org

Checklist: Post-ethics approval requirements that must be met before a research project can commence at a study site.

Requirements	Yes/No/NA
CTN Acknowledgement for Commercially Sponsored Studies The PI must forward a copy of the CTN Acknowledgement to Research Support Services	No
CTN Lodgement for Collaborative Group/Investigator Driven Studies The PI or nominated delegate is requested to make an appointment with the Monash Health Research Support Services contact for the study deborah.dell@monashhealth.org or michael.kios@monashhealth.org so that the lodgment may be completed by both the investigator and Research Support Services. The banking details for payment to the TGA will need to be brought along to this appointment, in order to finalise notification to the TGA. The fee for lodging a CTN is $335.	No
Clinical Trial Research Agreement The PI must forward an original fully executed copy of the CTRA to Research Support Services	No
Indemnity The PI must forward an original fully executed copy of the Indemnity to Research Support Services	No
Radiation If applicable, the RGO must contact the Medical Physicist so that the study may be notified to the Radiation Risk Section of the Department of Health and Human Services.	No
Other Commonwealth statutory requirements Ensure compliance with the following e.g. Office of the Gene Technology Regulator, NHMRC Licensing Committee, NHMRC Cellular Therapies Advisory Committee.	NA
Declaration of Interest /Gifts and Benefits It is recommended that the Monash Health Principal Investigator and research team are familiar with the "HR - Conflict of Interest (Operational)" policy and the "HR – Declaration of Gifts, Benefits & Hospitality" procedure available on PROMT. In the event that a member of the Monash Health research team for this project has an item to declare, a Declaration Form available on PROMPT should be completed and submitted to Human Resources.	Yes