The Sydney children's Hospitals Network
care, advocacy, research, education

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7 October 2015

Professor Johanna Westbrook
Centre for Health Systems and Safety Research
Macquarie University

Dear Professor Westbrook,

HREC Reference: **HREC/15/SCHN/370**

Project title: ***Evaluating the safety and cost-effectiveness of eMMS in paediatric settings***

Sites: **The Children's Hospital at Westmead**
The Sydney Children's Hospital, Randwick

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Sydney Children's Hospitals Network Human Research Ethics Committee's Executive Committee ("the Committee") at its meeting held on 30 September 2015.

The HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review, and by the National Health and Medical Research Council as a certified committee in the review of multi-centre clinical research projects.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and *CPMP/ICH Note for Guidance on Good Clinical Practice.*

I am pleased to advise that the Committee has granted ethical approval of this research project. Your approval is valid for five (5) years, effective the date of this latter.

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
NEAF, Submission Code: AU/1/411128		31 August 2015
Statistician's Report		31 August 2015
Protocol • Appendix A: Serious error protocol • Appendix B: Medication administration error classification • Appendix C: Prescribing error types and classification • Appendix D: Parent/Carer Questionnaire • Appendix E: Nurse Participant Information Sheet, Consent Form and Demographic Form • Appendix F: Costs of eMMS implementation Participant Information Sheets and Consent Forms	V1	28 August 2015

Please note the following conditions of approval:

1. The Coordinating Investigator will immediately report anything which may warrant review of ethical approval of the project in accordance with the SCHN adverse event reporting policy.

2. All proposed changes to the research protocol, including the conduct of the research, changes to site or personnel, or an extension to HREC approval, are to be provided to the HREC or its delegate for review before those changes can take effect.

3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

4. The co-ordinating investigator will provide an annual report to the HREC on the anniversary of this approval letter, and a final report on completion of the study.

5. Your approval is valid for five (5) years from the date of the final approval letter. If your project extends beyond that five year period and you are still actively recruiting you will be required to resubmit your application incorporating any amendments within six (6) months of that approval expiry date. If your project is in follow up on, or analysis, please submit and application for amendment to extend the approval period. Ethics approval can be extended for a period of twelve (12) months at a time.

6. In the event of a project **not having commenced** within 12 months of its approval, the approval will lapse and reapplication to the HREC will be required.

Should you have any queries about the HREC's consideration of your project please contact the Ethics Administration Assistant on (02) 9845 1253.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The SCHN HREC wishes you every success in your research.

Yours faithfully

J Bunting

Ms Jillian Bunting
Executive Officer
Sydney Children's Hospitals Network Human Research Ethics Committee

NB: All clinical trials must now be registered on a publicly accessible registry such as the Australian New Zealand Clinical Trials Registry. For further information please go to www.anzctr.org.au. **Please provide this office with a copy of your registration number for our records if you have not already done so.**