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

Contact for this correspondence:
Research and Development
Ethics & Governance Administration Assistant
Phone: (02) 9845 1253
Facsimile: (02) 9845 1317
Email: ethics.schn@health.nsw.gov.au

Corner Hawkesbury Road
and Hainsworth Street
Locked Bag 4001
Westmead NSW 2145
Sydney Australia
DX 8213 Parramatta
Tel +61 2 9845 0000
Fax +61 2 9845 3489
http://www.schn.health.nsw.gov.au/
ABN 53 188 579 090

2 June 2014

Dr Sandra Chuang
Respiratory Department
Sydney Children's Hospital, Randwick

Dear Dr Chuang,

HREC Reference: **HREC/14/SCHN/12**

Project title: ***A Pilot Study to Investigate the Feasibility, Tolerability and Safety of Using a Single Oesophageal Balloon Catheter with Multipair Electrodes to Assess Work of Breathing in Children during Sleep***

Reviewed for: ***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 (SCHN HREC) at its meeting held on 21 February 2014. The SCHN HREC is accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

This SCHN 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 following subsequent review of the further information provided, the SCHN HREC has granted ethical approval of this research project.

Your approval is valid from the date of this letter.

The documents reviewed and approved include:

Document	*Version*	*Date*
NEAF, Submission Code AU/1/83B6116		7 February 2014
Scientific Protocol	2	6 February 2014
Parent or Guardian Information Sheet	3	20 March 2014
Standard Consent Form	3	31 March 2014
Pain Management Practice Guidelines (CHW Policy)		
Kids Health Information (Website) Nasogastric Tube		
Test Report, TPU Pellet (Polyurethene) Polyester Type		7 September 2007

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Document	*Version*	*Date*
Response to SAC Correspondence		6 February 2014
Response to Biomedical Review		1 April 2014
Response to Expert Reviewer		23 April 2014

Please note the following conditions of approval:

1. The co-ordinating investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
   - Unforeseen events that might affect continued ethical acceptability of the project.

2. Proposed changes to the research protocol, conduct of the research, or length of HREC approval, will be provided to the HREC for review in the specified format.

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 and at completion of the study. The annual report form is available on the Hospital's intranet and internet or from the Secretary.

5. Your approval is valid for 5 years from the date of the final approval letter. If your project extends beyond five years then at the 5 year anniversary you are required to resubmit your protocol, according to the latest guidelines, seeking the renewal of your previous approval. 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

Ms Jillian Shute
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.**