the children's hospital at Westmead + SYDNEY CHILDREN'S HOSPITAL RANDWICK = The Sydney Children's Hospitals Network (Randwick and Westmead)

Research and Development
Contact for this correspondence:
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Dr Soundappan Sannappa Venkatraman
Department of Surgery
CHW

Dear Dr Venkatraman,

HREC reference number: **12SCHN156**
You must quote this number for all future correspondence

Project title: **Open vs. Ultrasound guided tunnelled central venous access in children - A randomised single blinded controlled trial.**

NSW Sites listed: **The Children's Hospital at Westmead**

Thank you for submitting the above project for single ethical and scientific review. This project was reconsidered by the Sydney Children's Hospitals Network Human Research Ethics Committee (HREC) at its meeting held on 3rd August 2012. This HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

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

I am pleased to advise that after receiving all outstanding items required for this project on 09/10/12, the HREC has granted ethical approval of this research project. **Your approval is valid from the date of this letter.**

This letter constitutes ethics approval ONLY. You may NOT commence at the public health sites specified in this letter until you receive site authorisation through a site approval letter from the research governance manager at each site. To receive site authorisation, you must submit a "Site Specific Application" or an "Access Request Form" to each site and await your site approval letter.

The documents reviewed and approved include:

Document	*Version*	*Date*
NEAF Application Submission code (AU/1/16CC013)	2.0	04/04/2012
Study Protocol	6	19/09/2012
Parent Information Sheet (encl.)	3	05/10/2012
Child Information Sheet (encl.)	3	28/11/2012
Consent Form	1	26/03/2012
Data collection form	3	26/08/2012

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 and Governance Administration Assistant on 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 HREC wishes you every success in your research.

Yours faithfully

Signature: _____ Date: 30 · 11 · 2012

Dr Peter Cooper
Chair,
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.**