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Date: 19 April 2013

Dr Nicholas Wood
National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases
The Children's Hospital at Westmead

Dear Dr Wood,

HREC reference number: 12 SCHN223
You must quote this number for all future correspondence

Project title: **Optimising pertussis vaccination in infants: a new approach**

NSW Sites listed: **Sydney Children's Hospitals Network (Westmead Campus)**

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 (HREC) at its meeting held on 7 December 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 considering your responses and revised Information Sheet, Consent Form, and Study Poster submitted dated 14 February 2013, the 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
NEAF Application Submission code AU/1/8AFD07	1	02/07/2012
Protocol DTPa180612	4	6 February 2013
Parent information sheet	3	14 February 2013
Consent form	3	14 February 2013
Study Poster CHW version	2	14 February 2013
Study Brochure / Recruitment Flyer	4	2 July 2012
Diary Cards	1	22 June 2012



Further, at the HREC Executive meeting of 18 April 2013, the proposed Amendment requested by you in your correspondence of 14 February 2013, namely to also distribute study brochures to mothers on the postnatal wards of public hospitals, was also **approved**.

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 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: Peter Cooper

Date: 22.4.2013

Dr Peter Cooper **Chair,**
Sydney Children's Hospitals Network Human Research Ethics Committee