



Government of **Western Australia**  
Department of **Health**

**Child and Adolescent Health Service**



Dr Peter Richmond  
School of Paediatric and Child Health  
Princess Margaret Hospital School  
Level 4, Administration Building  
Roberts Road  
SUBIACO WA 6008

**RECEIVED**  
03 DEC 2009

Dear Dr Richmond

**REGISTRATION NUMBER: 1751/EP**

**TITLE: A phase 1 trial to evaluate the safety, tolerability and immunogenicity of 3 ascending dose levels of a 3-antigen staphylococcus aureus vaccine (SA3Ag) in healthy adults**

**MEETING DATE: 19 November 2009**

The Princess Margaret Hospital for Children Ethics Committee has recommended approval be given for you to undertake the abovenamed research study. This recommendation has been ratified by the Child and Adolescent Health Service.

The Ethics Committee does however wish to be informed immediately of:

- I. any untoward effects experienced by any participant in the trial where those effects in degree or nature were not anticipated by the researchers, and steps taken to deal with these,
- II. substantial changes in the research protocol together with an indication of ethical implications, and
- III. other unforeseen events.

The Ethics Committee has been charged with the responsibility of keeping the progress of all approved research under surveillance. A copy of the final result must be forwarded to the Committee upon completion of the research or if the research is not completed within twelve months you are asked to submit a progress report and annually thereafter. This information should include:

- a) The status of the project (completed/in progress/abandoned/not commenced). In the event that a project does not commence within 12 months of being approved by the Ethics Committee the study must be resubmitted to the Committee for approval.



- b) Compliance with conditions of ethical approval, including security of records and procedures for consent.
- c) Compliance with any special conditions stated by the Ethics Committee as a condition of approval.
- d) Results from the study to date, including outcome.

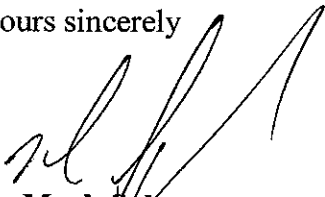
Please note that approval for studies is for **three years** and if the research is not completed within that period of time, a request for an extension of time should be submitted for consideration. In the event that a project does not commence within **12 months** of being approved by the Ethics Committee, the study must be resubmitted to the Committee for approval.

In accordance with the NHMRC National Statement on Ethical Conduct in Human Research Chapter 5.5.3, researchers have a significant responsibility in monitoring and must submit the following to the Ethics Committee:

- Annual Reports on the anniversary of the approval date of the study
- Adverse event reports as received
- Amendments and extensions to the study to be requested in adequate time

**Please quote the above registration number on all correspondence.**

Yours sincerely



**Dr Mark Salmon  
Executive Director  
Medical Services**

23 November 2009

- **The Ethics Committee is constituted, and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans**