HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Notification of Approval

To Chief Investigator or Project Supervisor:	**Professor John Attia**
Cc Co-investigators / Research Students:	**Doctor Alexis Hure** **Conjoint Associate Professor Jonathan Sturm** **Professor Catherine D'Este** **Dr Walter Abhayaratna** **Professor Andrew Tonkin** **Professor Henry Krum** **Professor Joseph Hung** **Conjoint Professor Chris Levi** **Dr David Durrheim** **Mr Mark McEvoy** **Professor Amanda Thrift** **Professor Phil Hansbro** **Associate Professor David Newby** **Mrs Roseanne Peel** **Professor Derek Chew** **Associate Professor Tom Briffa** **Dr Lynelle Moon** **Dr Phil Anderson**
Re Protocol:	**Does pneumococcal vaccination protect against cardiovascular disease? A randomised placebo-controlled double blind trial**
Date:	**17-Apr-2014**
Reference No:	**H-2014-0064**
Date of Initial Approval:	**16-Apr-2014**

Thank you for your **Response to Deferred** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under **L3 Full** review by the Committee. I am pleased to advise that the decision on your submission is **Approved** effective **16-Apr-2014**.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the *National Statement on Ethical Conduct in Human Research, 2007*, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. *If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.*

A formal *Certificate of Approval* is available upon request. Your approval number is **H-2014-0064**.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

*****Please note and action the following:**

Amendments to the Information Statements and Consent Forms.
The HREC is aware of the consent requirements for the Department of Human Services (DHS). The researchers will need to make amendments to the current Information Statements and Consent Forms to reflect these requirements. The consent to access data via DHS should be presented as a separate page/form in the consent process. The documents seeking participants' overall consent for the project should still be retained. The Information Statements will need to be amended to reflect these consent requirements. Please submit the revised documents via email to Ruth.Gibbins@newcastle.edu.au prior to commencing recruitment processes.

Conditions of Approval

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress*, *Reporting of Adverse Events*, and *Variations to the Approved Protocol* as detailed below.

PLEASE NOTE:
In the case where the HREC has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's HREC.

- ***Monitoring of Progress***

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

- ***Reporting of Adverse Events***

1. It is the responsibility of the person **first named on this Approval Advice** to report adverse events.
2. Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.
3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form (via RIMS at https://rims.newcastle.edu.au/login.asp) within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
4. Serious adverse events are defined as:
    - Causing death, life threatening or serious disability.
    - Causing or prolonging hospitalisation.
    - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
    - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
    - Any other event which might affect the continued ethical acceptability of the project.

5. Reports of adverse events must include:
    - Participant's study identification number;
    - date of birth;
    - date of entry into the study;
    - treatment arm (if applicable);
    - date of event;
    - details of event;
    - the investigator's opinion as to whether the event is related to the research procedures; and
    - action taken in response to the event.

6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

- ***Variations to approved protocol***

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research* (via RIMS at https://rims.newcastle.edu.au/login.asp). Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Professor Allyson Holbrook
Chair, Human Research Ethics Committee

For communications and enquiries:
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RIMS website - https://RIMS.newcastle.edu.au/login.asp

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref
NHMRC (National Health & Medical Research Council)/Project Grant(**)	Does pneumococcal vaccination protect against cardiovascular disease?	Attia John,	G1300127