Austin Hospital

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Date: 15 October 2014

To: Prof Rinaldo Bellomo
Intensive Care Unit
Austin Health

Project: **A randomised, feasibility, safety and biological efficacy placebo-controlled trial of aspirin in ICU patients with the systemc inflammatory syndrome**

HREC Ref No: HREC/14/Austin/219

Agenda Item No: 5.5

Approval Period: **15 October 2014 to 15 October 2017**

Document(s) approved	Version	Date
Protocol	2	29 July 2014
Master Continue Participation PICF	2	29 July 2014
Master Enrol PICF	2	29 July 2014
Master Person Responsible Continue Participation ICF	2	29 July 2014
Master Enrol Continue Participation ICF	2	29 July 2014
NEAF Application AU/1/72F7113		29 July 2014
Victorian-Specific Module		16 April 2014

Further to my letter dated **28 May 2014** concerning the above detailed project, I am writing to acknowledge that your response to the issues raised by the Human Research Ethics Committee (HREC) at their meeting on **22 May 2014** is satisfactory.

This project now has full ethical approval for a period of three years from the date of this letter.

Approval is given for this research project to be conducted at the following sites and campuses:

- **Austin Health**
- **Western Health**
- **Barwon Health**

The Coordinating Principal Investigator (CPI) is responsible for notifying Principal Investigators (PI's). The CPI and PI's should forward a copy of this letter to their site's Research Governance Officer (RGO).

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval letter must be submitted to the RGO for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

Before the study can commence, the Lead site (Austin Health) and each participating site must have the following (if applicable):

- Signed Clinical Trial Agreement
- Signed Standard Indemnities
- A signed CTN form (copy of the CTN acknowledgment from the TGA is only applicable for the first site notifying the TGA).
- It is a requirement that a progress report is submitted to the Committee annually, or more frequently as directed. Please note a final report must be submitted for all studies. Should you plan for your study to go beyond the 3-year ethics approval, please request in writing an extension of ethics approval prior to its lapsing. If your study will not commence within 12 months, a request must be forwarded to the HREC justifying the delay beyond 12 months. Should such a request not be received, ethics approval will lapse and a resubmission to the HREC will then be necessary.
- After commencement of your study, should the trial be discontinued prematurely you must notify the HREC of this, citing the reason.
- Any changes to the original application will require a submission of a protocol amendment for consideration as this approval only relates to the original application as detailed above.
- It is now your responsibility to ensure that all people (i.e. all investigators, sponsor and other relevant departments in the hospital) associated with this particular study is made aware of what has been approved.
- In accordance with Sec 3.3.12 of the National Statement on Ethical Conduct in Human Research 2007 (Updated March 2014) – ensure the registration of clinical trials. The International Committee of Medical Journal Editors (ICMJE) has adopted a policy that the member journals will only consider publication of clinical trials if the trial has been registered in a World Health Organisation (WHO)-accredited clinical trial registry. Trials can be registered with:

    - The Australian New Zealand Clinical Trials Registry (ANZCTR): http://www.anzctr.org.au
    - The ClinicalTrials.gov registry of the US National Institutes of Health maintained by the National Library of Medicine: http://www.clinicaltrials.gov

The following points are Research Governance Requirements applicable to Austin Heath only (Participating sites must follow their Institutions RGO requirements):

- A copy of the CTN acknowledgment from the TGA. Please note a copy of the acknowledgement is to be forwarded to the site Research Governance Officer (RGO) as per your Governance Officer requirements.
- For trials involving radiation it is your responsibility to ensure the research is added to the site Management Licence issued by Department of Human Services – Radiation Safety Section prior to study commencement should it be required (check the Medical Physicist Report). The site RGO must be notified when the research has been added to the licence.
- Please notify the HREC of any changes to research personnel. All new investigators must be approved prior to performing any study related activities.

The Committee wishes to be informed as soon as practicable of any untoward effects experienced by any participant in the trial where those effects in degree or nature were not anticipated by the researchers. The HREC has adopted the NHMRC Australian Health Ethics Committee (AHEC) Position Statement 'Monitoring and reporting of safety for clinical trials involving therapeutic products' May 2009

Please ensure you frequently refer to the Research Ethics website http://www.austin.org.au/researchethics/ for all up to date information about research and ethical requirements.

DETAILS OF ETHICS COMMITTEE:
It is the policy of the Committee not to release personal details of its members. However I can confirm that at the meeting at which the above project was considered, the Committee fulfilled the requirements of the National Health and Medical Research Council in that it contained men and women encompassing different age groups and included people in the following categories:

Chairperson		**Additional members include:**

Lay Man Lay Woman Lawyer Person fulfilling a Pastoral Care Role Person with Counselling Experience Person with Current Research Experience		• Other persons as considered appropriate for the type/s of research usually being considered

I confirm that the principal investigator or co-Investigators were not involved in the approval of this project. I further confirm that all relevant documentation relating to this study is kept on the premises of Austin Health for more than three years.

Yours sincerely,

Dr Sianna Panagiotopoulos, PhD
Manager, Office for Research

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice annotated with TGA comments (July 2008) and the applicable laws and regulations; and the Health Privacy Principles in The Health Record Act 2001.* The process this HREC uses to review multi-centre research proposals has been certified by the NHMRC.