Austin Health

AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE

ETHICAL APPROVAL FOR AMENDMENT

Prof Rinaldo Bellomo
Austin Health

29 August 2016

Dear Prof Bellomo,

AU RED HREC Reference Number: HREC/14/Austin/219

Austin Health Project Number: HREC/14/Austin/219

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

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I am pleased to advise that the above project amendment has **received ethical approval** from the Austin Health Human Research Ethics Committee (HREC). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Research Involving Humans (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Original HREC Approval Date: 14 October 2014

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol	3	10 August 2016
Master PICF – Enrol	3	10 August 2016
Master PRICF – Enrol	3	10 August 2016
Master PICF – Continue Participation	3	10 August 2016
Master PRICF – Continue Participation	3	10 August 2016

Site Specific Assessment:

A copy of this letter must be forwarded to all Principal Investigators at every participating site and must be submitted to the relevant Research Governance Officer at each site.

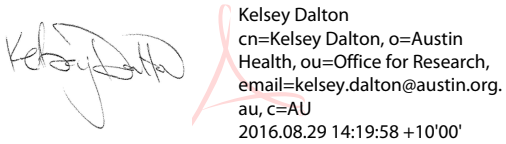
Conditions of Ethics Approval:

- You are required to submit to the HREC:
  - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
  - A comprehensive Final Report upon completion of the project.

- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).

The HREC may conduct an audit of the project at any time.

Yours sincerely,



Kelsey Dalton
Research Ethics Officer
Office for Research