Austin Hospital

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AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE

ETHICAL APPROVAL FOR AMENDMENT

Prof Rinaldo Bellomo
Department of Intensive Care
Level 2 , Austin Tower
Austin Health

30 June 2017

Dear Prof Rinaldo Bellomo

AU RED HREC Reference Number: HREC/17/Austin/75

Austin Health Project Number: DT 17/75

Project Title: A pilot comparative evaluation of the haemodynamic and electrolyte effects of Frusemide and Acetazolamide in critically ill patients

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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: 2/03/2017

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol	4	19/06/2017
AH PICF	4	19/06/2017
AH Person Responsible ICF	4	19/06/2017

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

Digitally signed by Lisa Pedro
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Date: 2017.06.30 13:07:09 +10'00'

Lisa Pedro
HREC Manager - DrugTrials