

AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE**ETHICAL APPROVAL**

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

02 March 2017

Dear Prof Rinaldo Bellomo,

HREC Reference Number [AU RED HREC reference number]: HREC/17/Austin/75

Austin Health SITE REFERENCE Number: DT 17/75

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

I am pleased to advise that the above project has **received ethical approval** from the Austin Health Human Research Ethics Committee (HREC). The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (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).

HREC Approval Date: 2/03/2017

Ethical approval for this project applies at the following sites:

Site
Austin Health

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
NEAF (AU/1/692C25)		28/02/2017
VSM		24/02/2017
Protocol	2	18/12/2016
PICF – Participant (enrol and continue to participate)	1	21/02/2017
PICF Person Responsible	1	21/02/2017
Product Information: Diamox		
Product Information : frusemide i.v.		

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.

Please note: Template forms for reporting Amendments, Adverse events, Annual/Final reports, etc. can be accessed from: <https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials>.

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

Yours sincerely

Lisa Pedro
HREC Manager – Drug Trials