

AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE**ETHICAL APPROVAL FOR NEW STUDY**

Prof Rinaldo Bellomo
Intensive Care Unit
Austin Health

17 Sept 2015

Dear Prof Rinaldo Bellomo

AU RED HREC Reference Number: LNR/15/Austin/391

Austin Health Project Number: Audit 15/391

Project Title: Evaluation of Dexmedetomidine in ICU patients with severe sepsis: A retrospective cohort study

I am pleased to advise that the above project 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).

HREC Approval Date: 17 Sept 2015

Participating Sites:

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
Audit Application incorporating the Protocol	1	08 Sept 2015

Conditions of Ethics Approval:

- You are required to submit to 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.

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

Yours sincerely,

A handwritten signature in red ink, appearing to read 'Sianna', with a long, sweeping horizontal line extending to the right.

Dr Sianna Panagiotopoulos, PhD
Manager, Office for Research