

Austin Hospital

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AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE

ETHICAL APPROVAL

Prof Rinaldo Bellomo
Austin Health

11 November 2021 (Updated 12 November 2021)

Dear Prof Rinaldo Bellomo,

HREC Reference Number: HREC/77347/Austin-2021

Austin Health SITE REFERENCE Number: DT 77347/2021

Project Title: A multi-centre, cluster, cross-over, pilot study comparing efficacy of magnesium administration to shorten early atrial fibrillation in intensive care patients requiring vasoactive drug support.

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, updated 2018). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007, updated 2018), 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: 11/11/2021

Ethical approval for this project applies at the following sites:

Site
Ballarat Base Hospital
Austin Health

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
HREA (HREC/77347/Austin-2021-288043)	3	29 October 2021

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VSM	2	29 October 2021
Protocol	2.0	20 August 2021
Data Collection Fields	1	19 August 2021
Product Information – Magnesium Sulfate	3	12 August 2020

Governance Authorisation:

Governance Authorisation is required at each site participating in the study before the research project can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site-specific assessment application.

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 November 2016*.
- 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 affect the conduct of the project.

Request for a Waiver of the Requirement for Consent- The request for a waiver of the requirement of consent is approved.

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

Yours sincerely,

Bernadette Nguyen
Acting HREC Manager – Drug Trials
 Office for Research, Austin Health
 Level 8 HSB.

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E-mail: ethics@austin.org.au

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