Austin Hospital

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Date: 17 June 2014

To: **Prof Rinaldo Bellomo**
Intensive Care Unit
Austin Health

Project: A Pilot, Randomised, Blinded, Feasibility, Safety and Biochemical and Physiological Efficacy Study of Terlipressin vs. Placebo in Cardiac Surgery Patients with the Post-operative High Cardiac Output and Hypotension Syndrome

HREC Ref No: HREC/14/Austin/217
SSA Ref No: SSA/14/Austin/218

Agenda Item No: 5.4 (May 2014 HREC)

Approval Period: 17 June 2014 to 17 June 2017

Document(s) reviewed	Version	Date
NEAF		03 June 2014
Protocol	2	03 June 2014
Austin Participant Information & Consent Form	2	03 June 2014
Austin Participant Information & Consent Form (Continue Participation)	2	03 June 2014
Austin Person Responsible Information & Consent Form	2	03 June 2014
Austin Person Responsible Information & Consent Form (Continue Participation)	2	03 June 2014
Victorian Specific Module		03 June 2014
LUCASSIN (Terlipressin 0.85 mg powder for injection) Product Information	120724	Not Dated
Site Specific Assessment Form		08 April 2014
Pharmacy Declaration		10 April 2014
Health Information Services Declaration		10 April 2014

Further to my letter dated **28 May 2014** concerning the above detailed project, I am writing to acknowledge that your response to the issues raised by the Human Research Ethics Committee at their meeting on **22 May 2014** is satisfactory. This project now has full ethical approval and site authorisation for a period of three years from the date of this letter.

Before the study can commence you must ensure that you have (if applicable):

- A signed Clinical Trial Agreement
- Signed Standard Indemnities
- A copy of the CTN acknowledgment from the TGA. Please note a copy of the acknowledgement is to be forwarded to the site Research Governance Officer (RGO).
- For trials involving radiation it is your responsibility to ensure the research is added to the site Management Licence issued by Department of Human Services – Radiation Safety Section prior to study commencement should it be required (check your Medical Physicist Report). The site RGO must be notified when the research has been added to the licence.
- It is a requirement that a progress report is submitted to the Committee annually, or more frequently as directed. Please note a final report must be submitted for all studies. Should you plan for your study to go beyond the 3-year ethics approval, please request in writing an extension

of ethics approval prior to its lapsing. If your study will not commence within 12 months, a request must be forwarded to the HREC justifying the delay beyond 12 months. Should such a request not be received, ethics approval will lapse and a resubmission to the HREC will then be necessary.

- After commencement of your study, should the trial be discontinued prematurely you must notify the HREC of this, citing the reason.
- Any changes to the original application will require a submission of a protocol amendment for consideration as this approval only relates to the original application as detailed above.
- Please notify the HREC of any changes to research personnel. All new investigators must be approved prior to performing any study related activities.
- It is now your responsibility to ensure that all people (i.e. all investigators, sponsor and other relevant departments in the hospital) associated with this particular study is made aware of what has been approved.

The Committee wishes to be informed as soon as practicable of any untoward effects experienced by any participant in the trial where those effects in degree or nature were not anticipated by the researchers. The HREC has adopted the NHMRC Australian Health Ethics Committee (AHEC) Position Statement 'Monitoring and reporting of safety for clinical trials involving therapeutic products' May 2009

Please ensure you frequently refer to the Research Ethics website http://www.austin.org.au/researchethics/ for all up to date information about research and ethical requirements.

DETAILS OF ETHICS COMMITTEE:
It is the policy of the Committee not to release personal details of its members. However I can confirm that at the meeting at which the above project was considered, the Committee fulfilled the requirements of the National Health and Medical Research Council in that it contained men and women encompassing different age groups and included people in the following categories:

Chairperson Ethicist Lawyer Lay Man Lay Woman Person fulfilling a Pastoral Care Role Person with Counselling Experience Person with Research Experience		**Additional members include:** • Chairs of all sub committees, or nominees • Other persons as considered appropriate for the type/s of research usually being considered

I confirm that the Principal Investigator or Co-Investigators were not involved in the approval of this project. I further confirm that all relevant documentation relating to this study is kept on the premises of Austin Health for more than three years.

Yours sincerely,

Dr Sianna Panagiotopoulos, PhD
Manager, Office for Research

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice annotated with TGA comments (July 2008) and the applicable laws and regulations; and the Health Privacy Principles in The Health Record Act 2001.* The process this HREC uses to review multi-centre research proposals has been certified by the NHMRC.