Austin Hospital

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Date: 18 November 2014

To: Prof Rinaldo Bellomo
ICU
Austin Health

Project: **An Audit of a Change in the Blood Glucose Targets Protocol for Diabetic Patients Admitted to the Intensive Care Unit**

LNRR Ref No: LNR/14/Austin/487

Agenda Item No: 5.5

Approval Period: 18 November 2014 to 18 November 2017

Re: Low & Negligible Risk Research (LNRR) Application APPROVED		
Document(s) reviewed	**Version**	**Date**
Protocol	2	04 July 2014
LNR SSA (submission code: AU/14/D08A117)		08 September 2014
LNR VIC (submission code: AU/13/E08A113)		08 September 2014
Budget	1	11 July 2014

Further to my letter dated 14 October 2014 concerning the above detailed project, I am writing to acknowledge that your response to the issues raised by the Austin Health Clinical Research Review Committee (CRRC) at their meeting on 7 October 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 on the provision that the following conditions are met.

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.

1. Conditions

The Austin Health HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

The Principal Investigator will provide a progress report to the Office for Research annually, or more frequently as directed. Please note a final report must be submitted for all studies.

These are to be submitted electronically to: ethics@austin.org.au using templates provided at: http://health.vic.gov.au/clinicaltrials/application-instructions.htm.

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 Office for Research justifying the delay beyond 12 months. Should such a request not be received, ethics approval will lapse and a resubmission of the application will then be necessary.

2. Adverse Events

The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including any unforeseen events that might affect continued ethical acceptability of the project. Serious Adverse Events must be notified to the Committee **within 24 hours of the event** by the Principal Investigator. In addition the Principal Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Participant Information Sheet and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

3. Amendments

If there is an event requiring amendments to be submitted you should follow the instructions found on the following website: http://www.austin.org.au/researchethics/

Should you have any queries about the Austin Health CRRC consideration of your project please contact the Office for Research. The Austin Health CRRC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Office for Research.

Yours sincerely,

Dr Sianna Panagiotopoulos, PhD
Manager, Office for Research

This CRRC 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 (Updated March 2014) NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the applicable laws and regulations; and the Health Privacy Principles in The Health Record Act 2001.