

Austin Hospital

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Date: 8 December 2014

To: Prof Rinaldo Bellomo

Intensive Care Unit, Austin Health

Project: A PILOT ASSESSMENT OF THE FEASBILITY OF A NOTIFICATION

SYSTEM FOR PATIENTS WITH HIGH-RISK LABORATORY

ABNORMALITIES IN ACUTE SURGICAL WARDS

Project No: LNR/14/Austin/407

Approval Period: 1 year

Approval of Audit Activity

Document	Version	Date
Audit Activity Application	1	05 August 2014
Protocol	2	26 November 2014

I wish to inform you that the audit application named above has been reviewed and approved by the Austin Health Office for Research on behalf of the Austin Health Human Research Ethics Committee.

An audit is defined as an activity instigated by an Austin Health Principal Investigator with the relevant expertise and experience, involving a research hypothesis which includes the analysis of data from previous collected patient information with an intention to publish or otherwise present the data beyond the staff of the hospital. Audits are generally retrospective reviews however prospective audits can be conducted in certain circumstances. An audit does not involve the collection of new raw data (other than information that would ordinarily be collected as part of patient management) from a patient either in person, through a survey/questionnaire.

Should your audit not commence twelve (12) months from the date of this letter this approval will lapse. A resubmission to the Office for Research would then be necessary before you could commence.

Should you plan for your audit to go beyond the ethics approval period, please request in writing an extension of ethics approval prior to it lapsing.

Please note a final report must be submitted for all audits once completed.

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.

Document name: Audit Activity approval Author: VM

Version Date: August 2014