Health
Nepean Blue Mountains
Local Health District

NEPEAN BLUE MOUNTAINS LOCAL HEALTH DISTRICT HUMAN RESEARCH ETHICS COMMITTEE

CERTIFICATE OF APPROVAL – Low and Negligible Risk Study

5th March, 2018

Mrs Irene Kopp
Diabetes Service
Nepean Hospital

Dear Irene,

Study Reference: LNR/18/NEPEAN/36
Study Title: Reducing hospital length of stay and readmission rates in surgical inpatients with diabetes mellitus through improved glycaemic control using an automated glucose system

*Your request to undertake the above protocol as a **Low and Negligible Risk (LNR)** was considered by a subcommittee of members from both the Human Research Ethics Committee (HREC) and the Scientific Advisory Committee (SAC). We are satisfied that your protocol meets the criteria for an LNR research project and was exempt from full ethical review.*

*On receipt of your response dated 1st March, 2018 to the concerns of the Committee dated 21st February, 2018, we are satisfied that you protocol meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **5th March, 2018.***

It is the Principal Investigator's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principle Researcher is required to note the following conditions of approval:

- The coordinating investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- The coordinating investigator will immediately report any protocol deviation / violation, together with details of the procedure put in place to ensure the deviation / violation does not recur.
- Proposed amendments to the protocol or conduct of the research which may affect the ethical acceptability of the project, must be provided to the HREC to review in the specific format. Copies of all proposed changes must also be provided to the Research Governance Officer.
- The HREC must be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The Coordinating Chief Investigator must provide an Annual Report to the HREC and a Final Report at completion of the study, in the specified format. HREC approval is valid for 12 months from the date of final approval and continuation of the HREC approval is contingent upon submission of an annual report each year. Annual Reports for all studies should be submitted on the anniversary of the approval date of project. They will be processed and presented to the HREC at the next scheduled meeting. A copy of the Annual / Final Research Report Form can be obtained electronically from the Research Office on request.
- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the investigators.
- The Ethics Committee may conduct an audit at any time.

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ABN 31 910 677 424
PO Box 63, Penrith NSW 2751
Tel (02) 4734 2000
Website www.nbmlhd.health.nsw.gov.au

LNR/18/NEPEAN/36- Cont'd

The NBMLHD HREC has been accredited by the NSW Ministry of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*

Approved Documents

Documents reviewed and approved at the meeting were:

Document	Version	Date
LNR Submission code AU/	1/123437	
Protocol	2	01/03/2018
Data Collection Sheet	1	05/03/2018
LOS, RR & Comp Data Sheet	1	05/03/2018
Master Coding Sheet	1	05/03/2018

Approved Sites:

Approval is given for this research project to be conducted at the following sites and campuses:

- ***Nepean Hospital***

RESEARCH GOVERNANCE - Site-Specific Assessment (SSA):
SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence via the Chief Executive or their delegate – the Research Governance Officer.
The completed Site-Specific Assessment Form as well as a copy of this ethics approval letter and all approved documents must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

Yours Sincerely,

A/Professor Ian Seppelt
Chair, Human Research Ethics Committee
Nepean Blue Mountains LHD

Please quote project number and title in all correspondence