

**Subject:** 2022/ETH02266: Application HREA - Approved  
**Date:** Friday, 18 November 2022 at 2:30:03 pm Australian Eastern Daylight Time  
**From:** no\_reply@regis.health.nsw.gov.au  
**To:** Emily Hibbert  
**CC:** Michael Hauser (Nepean Blue Mountains LHD)

Date of Decision Notification: **18 Nov 2022**

Dear Associate Professor Emily Hibbert,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

**2022/ETH02266:** Prospective audit comparing amount of nursing time taken and accuracy of blood glucose levels recorded in the electronic medical record for the standard AMSL glucose meter compared with the AMSL wi-fi connectivity Statstrip glucose meter.

This Application was reviewed as a **Low or negligible risk review pathway** and was initially considered by the **Nepean Blue Mountains Local Health District HREC** at its meeting held on 27/10/2022.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED**.

**This email constitutes ethical and scientific approval only.**

**This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.**

This project has been Approved to be conducted at the following sites:

- **Nepean Hospital**

The following documentation was reviewed and is included in this approval:

- Application, HREA
- Master data sheet V 1 dated 26.10.22
- Master participant sheet V 1 dated 26.10.22
- Participant Information Sheet, Nurse info sheet V 3 dated 16.11.22 clean
- Project Registration
- Study Protocol 2022 V 3 dated 18.11.22 clean
- Participant Information Sheet/s, Stage 1 patient info sheet V2 clean dated 09.11.22
- Participant Information Sheet/s, Stage 2 patient info sheet V1 dated 09.11.22

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.01

Date: 10 Nov 2022

The approval is for a period of 5 years from the date of this e-mail (**18 Nov 2022**)

The Coordinating Principal Investigator will:

- provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.
- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS

- will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.

Submission of annual progress/final reports (milestone), amendments and safety reports should be done through the forms provided in REGIS. Guidance on these processes can be found on the [REGIS website](#).

It is noted that the **Nepean Blue Mountains Local Health District HREC** is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2007 (NHMRC).

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this study with you throughout the project lifecycle.

Regards,

Penny Mahairas  
Executive Officer | **Research Office (Ethics)**  
Level 5, South Block, Nepean Hospital  
PO BOX 63, Penrith NSW 2751  
Tel 02 4734 3441 | Fax 02 4734 1967 | NBMLHD-Ethics@health.nsw.gov.au  
[www.health.nsw.gov.au](http://www.health.nsw.gov.au)