

**Subject:** 2021/ETH11508: Application HREA - Approved  
**Date:** Monday, 29 November 2021 at 12:10:07 pm Australian Eastern Daylight Time  
**From:** no\_reply@regis.health.nsw.gov.au  
**To:** peter.pockney@newcastle.edu.au  
**CC:** Lorane Gaborit, isabellaludbrook@gmail.com, vsiribaddana@gmail.com

Date of Decision Notification: **29 Nov 2021**

Dear Dr Pockney

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

**2021/ETH11508: Opioid PrEscRiptions and Usage After Surgery (OPERAS)**

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **Hunter New England Human Research Ethics Committee** at its meeting held on **20 October 2021**.

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 site/s:

- **Gosford Hospital**
- **Newcastle Private Hospital**

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

- **HREA** (Version 4 dated 18 November 2021)
- **Response to Committee form HNEHREC** (undated)
- **Hunter New England Human Research Ethics Committee (HNEHREC) Response to Committee Form** (undated)
- **OPERAS Study Protocol** (Version 2.0.5 dated 25 November 2021)
- **Opioid Prescriptions and Usage After Surgery Patient Information and Consent form** (Version 3.0 dated 25 November 2021)
- **Script for follow up interview** (Version 1.0 dated 15 October 2021)
- **Operas Study follow up script** (Version 2.0 dated 3 November 2021)

[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 approval is for a period of 5 years from the date of this e-mail (**29 Nov 2021**)

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 **Hunter New England Human Research Ethics Committee** is constituted in accordance with the National Statement on Human Conduct in Human Research, 2007 (NHMRC).

The processes used by the HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

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.

Kind regards

**Debbie Madden**

*Ethics Administration Officer*

*Research Office*

*Hunter New England Local Health District*

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