

From: [Debbie Madden \(Hunter New England LHD\)](#)
To: [Amanda Dawson](#)
Cc: [Kristy Atherton](#)
Subject: 2022/ETH02457 - 2ND RE-ISSUE: Application HREA - Approved
Date: Wednesday, 8 March 2023 6:58:52 AM

2ND RE-ISSUE 8 MARCH 2023 - RE-ISSUED 16 JANUARY 2022 (INCORRECT RE-ISSUE DATE) - Date of Decision Notification: 21 Dec 2022

Dear A/Professor Dawson

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

2022/ETH02457: Global Cohort Study: Hernias, Pathway and Planetary Outcomes for Inguinal Hernia Surgery (HIPPO)

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 14 December 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 site/s:

- Gosford Hospital

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

- HREA (Version 2 created 16 December 2022)
- Hunter New England Human Research Ethics Committee (HNEHREC) Response to Committee Form (dated 20 December 2022)
- HIPPO Protocol (Version 2.1 dated 17 December 2022)
- HIPPO – Data Summary Document (Version 1.0 dated 18 November 2022)

[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 (21 Dec 2022)

The Hunter New England Human Research Ethics Committee has approved a waiver of consent under section 2.3.10 of the National Statement of Ethical Conduct in Human Research, 2007 (updated 2018) for the above study protocol.

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 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.

Kind regards

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