

From: no_reply@regis.health.nsw.gov.au <no_reply@regis.health.nsw.gov.au>
Sent: Monday, October 11, 2021 3:15:04 PM
To: Laura Mackenzie (Hunter New England LHD) <Laura.Mackenzie@health.nsw.gov.au>
Subject: 2021/ETH00928: Application HREA - Approved

Date of Decision Notification: **11 Oct 2021**

Dear Dr Mackenzie

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

2021/ETH00928: The use of BIS monitoring in comparison to limb-isolation technique in ECT: A pilot study

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 **15 September 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:

- **Calvary Mater Newcastle Hospital**

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

- **HREA** (Version 3 dated 17 September 2021)
- **Response to Committee Form HNEHREC** (dated 10 October 2021)
- **Project description - The use of BIS in comparison to limb isolation technique to predict awareness in ECT: A pilot study** (Version 3 dated 7 October 2021)
- **Information for Participants** (Version 2 dated 7 October 2021)
- **Consent Form for the Research Project: The use of BIS in comparison to limb-isolation technique to predict awareness in ECT: A pilot study** (Version 2 dated 7 October 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 (**11 Oct 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).

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

Ph: 02 49855929

Email: Debbie.madden@health.nsw.gov.au

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