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To: [gin.malhi@sydney.edu.au](mailto:gin.malhi@sydney.edu.au)  
Date: 7/31/2023 7:30:44 PM  
Subject: 2023/ETH01392: Application HREA - Approved

Date of Decision Notification: 01 Aug 2023

Dear Professor Gin Malhi,

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

2023/ETH01392: Positioning Esketamine Treatment (PoET) in the real-world management of depression

This Application was reviewed as a Greater than low risk review pathway and was initially considered by the Northern Sydney Local Health District Human Research Ethics Committee at its meeting held on 10 July 2023.

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:

- Royal North Shore Hospital

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

- Ethics Application (HREA) 2023/ETH01392
- Study Protocol Version 2, Dated 17 July 2023
- Participant Information Sheet and Consent Form Version 2, Dated 17 July 2023
- Notification of discharge from study Version 1, Dated 23 June 2023
- Referral Form Version 1, Dated 23 June 2023
- Risk Language Version 1, Dated 23 June 2023
- Study Wallet Card Template Version 1, Dated 23 June 2023
- Daily Log Version 1, Dated 23 June 2023
- Flyer for clinicians Version 1, Dated 23 June 2023
- Flyer for participants Version 1, Dated 23 June 2023
- Revocation of Consent Form Version 2, Dated 17 July 2023
- NSW Health guide to healthcare visitation, Dated 25 October 2023

[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: 18 Jul 2023

The approval is for a period of 5 years from the date of this e-mail (01 Aug 2023)

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.
- submit any necessary reports related to the safety of research participants in accordance with NHMRC Safety and Reporting Guidance. This will be through the Significant Safety Issue or Third Party Breach form in REGIS.
- Interventional trials must be registered on one of the clinical trial registries e.g. <https://www.anzctr.org.au> .

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 Northern Sydney Local Health District Human Research Ethics Committee is constituted in accordance with the National Statement on Ethical 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.

Regards,

Peter Caddy

Research Ethics and Governance Officer | NSLHD Research Office

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<https://www.nslhd.health.nsw.gov.au/Research/ResearchOffice/Pages/default.aspx>

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