

HUMAN RESEARCH ETHICS COMMITTEE

8 November 2024

Associate Professor Genevieve Steiner-Lim
NICM Health Research Institute

Dear Genevieve,

Project Title: "Underlying Mechanisms of Non-Invasive Brain Stimulation on the Cognitive and Mood Symptoms of Menopause: A Randomised, Sham-Controlled, Double-Blinded Pilot Clinical Trial"

HREC Approval Number: H16200

Risk Rating: High

I am pleased to advise the above research project meets the requirements of the National Statement on Ethical Conduct in Human Research 2023.

Ethical approval for this project has been granted by the Western Sydney University Human Research Ethics Committee. This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research 2023.

Approval of this project is valid from 8 November 2024 until 8 November 2027.

This protocol covers the following researchers:

Genevieve Steiner-Lim, Najwa-Joelle Metri, Edwin Lim, Daniel Hochstrasser, Heather Francis, Carolyn Ee, Rocco Cavaleri

All researchers named on this application must ensure that conflicts of interest are recorded on the University's Conflict of Interest Register.

Approved Documents

A list of documents appears on page 2 of this letter.

Summary of Conditions of Approval

1. A progress report will be due annually on the anniversary of the approval date.
2. A final report will be due at the expiration of the approval period.
3. Any amendments to the project must be approved by the Human Research Ethics Committee prior to being implemented. Amendments must be requested using the HREC Amendment Request Form.
4. Any serious or unexpected adverse events involving participants must be reported to the Human Research Ethics Committee via the Human Ethics Officer as a matter of priority.
5. Any unforeseen events that might affect continued ethical acceptability of the project should also be reported to the Committee as a matter of priority.
6. Consent forms are to be retained within the archives of the School or Research Institute and made available to the Committee upon request.
7. The Chief Investigator or Principal Supervisor must notify the HREC if the project is discontinued before the expected completion date, with reasons provided.
8. Approval is only valid while you hold a position or are enrolled at Western Sydney University. You will need to transfer your project or seek fresh ethics approval from your new institution if you leave Western Sydney University.



9. The research must comply with the National Statement requirement 3.1.7 which states that any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform [ICTRP] on the World Health Organisation website) before the recruitment of the first participant.

10. Project specific conditions:

There are no specific conditions applicable.

This letter constitutes ethical approval only. The Chief Investigator is responsible for obtaining any additional approvals required to conduct the research.

Please quote the HREC reference number and title as indicated above in the subject line on all future correspondence related to this project. All correspondence should be sent to humanethics@westernsydney.edu.au as this email address is closely monitored.

The Western Sydney University HREC Terms of Reference, membership and standard forms are available from https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics

The Western Sydney University HREC wishes you every success in your research.

Yours sincerely

Dr Kristy Coxon
Presiding Member,
Western Sydney University Human Research Ethics Committee

H16200 8 November 2024

List of approved documents

NM03368_v1_02 - H16200 More Information Required 170924
NM03368_v1_02 - Attachment 1_Project Description_Revised 120924
NM03368_v1_02 - Output Form
NM03368_v1_02 - Attachment 2_Study Protocol_Revised 120924
NM03368_v1_02 - Attachment 3_Clinical Trial Form_Final 190724
NM03368_v1_02 - Gen Steiner Approval
NM03368_v1_02 - Attachment 6_Najwa-Joelle Metri CoC V2_Submitted 150724
NM03368_v1_02 - Attachment 7_CoC Approval GRS_Received 260724
NM03368_v1_02 - Attachment 13_PhD Recruitment Poster Updated 220824
NM03368_v1_02 - Attachment 14_Social Media Advertising 220824
NM03368_v1_02 - Attachment 5_Study PISCF_Revised 120924
NM03368_v1_02 - Attachment 10_Screening Questions_310724
NM03368_v1_02 - Attachment 11_B16151 - BRSC Approval - Aug 2024
NM03368_v1_02 - Attachment 8_Investigator GCPs_Final 290724
NM03368_v1_02 - Attachment 9_Investigator CVs_Final 290724
NM03368_v1_02 - Attachment 12_SOP Storage of Biospecimens 1527-TRTS-V1
NM03368_v1_02 - Attachment 4_Study RDMP_Revised 130924