

ADDRESS FOR ALL CORRESPONDENCE
RESEARCH ETHICS AND GOVERNANCE OFFICE
ROYAL PRINCE ALFRED HOSPITAL



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EMAIL: SLHD-RPAEthics@health.nsw.gov.au
REFERENCE: X22-0162 & 2022/ETH00929

25 July 2022

This letter constitutes ethical approval only. You must NOT commence this research project at ANY site until you have submitted a Site Specific Assessment Form to the Research Governance Officer and received separate authorisation from the Chief Executive or delegate of that site.

Dear Professor Yee,

Re: Protocol No: X22-0162 & 2022/ETH00929 - “The effect of positive airway pressure therapy on cardiac remodeling, cardiovascular risk and neurocognitive function in patients with overlap syndrome.”

The Executive of the Ethics Review Committee, at its meeting of 25 July 2022 considered your correspondence of 22 July 2022. In accordance with the decision made by the Ethics Review Committee at its meeting of 8 June 2022, ethical approval is granted.

I am pleased to advise that final ethical approval has been granted on the basis of the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research*.
- The Committee granted a waiver of the usual requirement for the consent of the individual for the use of their health information in a research project, in accordance with the *Health Records and Information Privacy Act 2002* (NSW) and the NSW Privacy Commissioner’s Statutory guidelines on research and the NHMRC Guidelines approved under Section 95A of the Privacy Act 1988.

This approval includes the following:

- HREA (Version 2, 14 June 2022)
- Protocol (Version 1.0, 16 May 2022) * see additional condition below
- Participant Information Sheet (Version 1.1, 25 June 2022)
- Participant Consent Form (Version 1.1, 25 June 2022)
- eConsent (Version 1, 7 July 2022)

- Epworth Sleepiness Scale
- Pittsburgh Sleep Quality Index
- Functional Outcomes of Sleep Questionnaire
- Standardised Mini-Mental State Examination (SMMSE)
- Montreal Cognitive Assessment (MOCA®)
- DASS Response Form
- SF36
- Master Code Sheet (Version 1.0, 8 March 2022)
- Data Collection Form (Version 1.1, 21 June 2022)
- SLHD Privacy compliance Form (Version 3, October 2020)
- Research Data Management Plan (21 July 2022)

Noted:

- MoCA Certification – Dr Benjamin Nguyen (11-7-2022)

* (If Applicable) In accordance with the National Statement, chapter 4.7; you must seek ethical approval from the HREC of the Aboriginal Health and Medical Research Council (AHMRC) if you intend to use ATSI status in any presentation or publication.

The Committee noted that authorisation will be sought to conduct the study at the following sites:

- Royal Prince Alfred Hospital
- Woolcock Institute of Medical Research
- This approval is valid for **five years**, and the Committee requires that you furnish it with annual reports on the study's progress beginning in **July 2023**. This will be through the submission of a milestone in REGIS.
- This human research ethics committee (HREC) has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review and is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.
- You must immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- You must notify the HREC of proposed changes to the research protocol or conduct of the research in the specified format.

- You must notify the HREC and other participating sites, giving reasons, if the project is discontinued at a site before the expected date of completion.

Should you have any queries about the Committee's consideration of your project, please contact me. The Committee's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Sydney Local Health District website.

If you are not using REGIS, a copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The Ethics Review Committee wishes you every success in your research.

Regards,

A handwritten signature in cursive script that reads "R G Carney".

Rosemary Carney
Executive Officer
Ethics Review Committee (RPAH Zone)