

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



**Health**  
Sydney  
Local Health District

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REFERENCE: X21-0376 & 2021/ETH11793

23 November 2021

**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 McCaughan,

**Re: Protocol No. X21-0376 & 2021/ETH11793 - Cardiac Dysfunction in Advanced Chronic Liver Disease: Assessment Pre- and Post-Liver Transplant Using Metabolomics and Cardiac Imaging”**

The Executive of the Ethics Review Committee, at its meeting of 23 November 2021 considered your correspondence of 23 November 2021. In accordance with the decision made by the Ethics Review Committee at its meeting of 10 November 2021, 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*.

This approval includes the following:

- HREA (Version 3, 17 November 2021)
- Protocol (Version 1.2, 18 November 2021) \* see additional condition below
- Participant Information Sheet (Version 1.2, 18 November 2021)
- Participant Consent Form (Version 1.2, 18 November 2021)
- eConsent Form (Version 1.0, 18 November 2021)
- Master Code Sheet (Version 1.1, 28 October 2021)
- Data Collection Form (Version 1.1, 28 October 2021)
- Research Data Management Plan (Version 1.1, 18 November 2021)

\* (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.

You are asked to note the following:

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

- Royal Prince Alfred Hospital
- 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 **November 2022**. 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,



Rosemary Carney  
**Executive Officer**  
**Ethics Review Committee (RPAH Zone)**