

ADDRESS FOR ALL CORRESPONDENCE

RESEARCH ETHICS AND GOVERNANCE OFFICE
ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050

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REFERENCE: **X20-0450 & 2020/ETH02634**
10.9/JAN21



Health
Sydney
Local Health District

21 January 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 Ingles,

Re: Protocol No X20-0450 & 2020/ETH02634 - “The NSW Inherited Cardiomyopathy Cohort Study”

The Executive of the Ethics Review Committee, at its meeting of 21 January 2021 considered your correspondence of 21 January 2021. In accordance with the decision made by the Ethics Review Committee at its meeting of 14 October 2020, ethical approval is granted.

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

This approval includes the following:

- HREA (Version 3, 15 January 2021)
- Protocol (Version 3, 24 December 2020) * see additional condition below
- Participant Information Sheet/Consent and Withdrawal Form (Version 3, 24 December 2020)
- Participant Information Statement (Cardiac MRI) (Version 1, 30 September 2020)
- Participant Consent Form (Cardiac MRI) (Version 1, 30 September 2020)
- NSW Hearts Master Flyer (Version 2, 24 December 2020)
- Society Advert (Version 1, 30 September 2020)
- Letter to Health Professionals (Version 1, 30 September 2020)
- Invitation Letter/Email (Version 1, 30 September 2020)
- Invitation letter from Clinical Team (Version 1, 24 December 2020)
- Clinical Outcomes Datasheet (Version 1, 16 November 2020)
- Fax Request Letter (Version 1, 30 September 2020)
- Master Code Sheet (Master Version 1, 24 December 2020)
- Support Group Advert (Version 3, 24 December 2020)

- Social Media Posts (Version 3, 24 December 2020)
- Baseline Clinical Survey (17 December 2020)
- Follow-up Clinical Survey (20 November 2020)
- Environmental Factors Survey (20 November 2020)
- Health Status Survey (20 November 2020)
- NSW Hearts Stop-Bang Questionnaire (Version 1, 17 December 2020)
- Charlson Comorbidity Index (Version 1, 18 December 2020)
- NSW Hearts Pre-Consent Phone Script (Version 1, 30 October 2020)
- Stop-Bang Phone Call Script (Version 1, 24 December 2020)
- NSW Hearts Baseline Phone Call Script (Version 2, 24 December 2020)
- Cardiac MRI Phone Script (Version 1, 30 September 2020)
- Phone Script for Clinical Outcomes Data Collection (Version 1, 16 November 2020)
- Apnoealink Air Participant Instruction Sheet (undated)
- Appendix A: Cardiac MRI Protocol (Version 1, 24 December 2020)
- Appendix B: Lab Processing Instructions (Version 1, 24 December 2020)
- AppendixC: NSW State Wide Biobank EDP (Version 1, 24 December 2020)
- ResMed Manufacturer's Declaration of Conformity(Apnoealink Air) (303418) (14 January 2020)
- ARTG summary Apnoealink Air (303418)

The following are noted with thanks:

- RPAH MRI Safety / Consent Form (undated)
- SVH MRI Safety / Consent Form (undated)

*(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:

On the basis of this ethics approval, authorisation may be sought to conduct this study within any NSW/QLD/VIC/SA/WA/ACT public health organisation and/or within any private organisation which has entered into an appropriate memorandum of understanding with the Sydney Local Health District, Sydney Local Health Network or the Sydney South West Area Health Service.

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

- Royal Prince Alfred Hospital
- St Vincent's Hospital
- Victor Chang Cardiac Research Institute
- Westmead Hospital
- Centenary Institute

- 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 **January 2022**. If recruitment is ongoing at the conclusion of the five year approval period, a full re-submission will be required. Ethics approval will continue during the re-approval process.
- 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.
- If you or any of your co-investigators are University of Sydney employees or have a conjoint appointment, you are responsible for informing the University's Risk Management Office of this approval, so that you can be appropriately indemnified.
- Where appropriate, the Committee recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purposes of conducting this study.

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.

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.

Yours sincerely,



Patricia Plenge
Executive Officer
Ethics Review Committee (RPAH Zone)
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