



Queensland  
Government

**Metro North Health**  
Human Research Ethics Committee

**Metro North Health**

Enquiries to: [MetroNorthResearch-Ethics@health.qld.gov.au](mailto:MetroNorthResearch-Ethics@health.qld.gov.au)  
Telephone: 07 3646 5280  
File Ref: ERM: 84614 Approval

12 August 2022

Dr Usha Gurunathan  
Department of Anaesthesia  
The Prince Charles Hospital  
Chermside Qld 4032

Dear Dr Gurunathan,

**Re: HREC/2022/MNHB/84614: CARDIAC Surgery PReoperative INspiratory muscle Training**

Thank you for submitting the above research project for single ethical review. This project was considered by the Metro North Health Human Research Ethics Committee B (EC00168) at its meeting held on 28 July 2022.

I am pleased to advise that this research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)* and that the Metro North Health Human Research Ethics Committee B has granted final ethical approval of this research project.

Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

**This letter constitutes ethical approval only.** This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
2021 ANZCA pilot grant approval		16 February 2022
Curriculum Vitae of Alison Mahoney		29 May 2022
Appendix 1 – Melbourne Group Scale Version 2 (criteria for diagnosis of a PPC)	2	06 August 2022

<i>Document</i>	<i>Version</i>	<i>Date</i>
Appendix 2 – Shortness of Breath Scale 0-10	2	06 August 2022
Appendix 3 – IMT Acceptability Questionnaire	2	06 August 2022
Appendix 4 – EQ-5D-5L	2	06 August 2022
Appendix 5 – Clinical Frailty Scale	2	06 August 2022
Response to request for further information		10 August 2022
HREA	Aug ver 2	11 August 2022
Protocol	2	06 August 2022
Participant Information Sheet & Consent Form	2	11 August 2022

This information will be tabled for noting at the HREC meeting to be held on 25 August 2022.

Ongoing approval is for the duration of the project, conditional on:

1. In accordance with Section 5.5.6 (b) of the National Statement the Principal Investigator will report to the HREC annually (**Due by 30 April each year**) in the specified format and a final report is to be submitted on completion of the study.  
[www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp](http://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp)
  2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
    - a. Unforeseen events that might affect continued ethical acceptability of the project.
    - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
  3. Amendments to the research project are to be submitted to the HREC for review. Amendments should be reflected in a cover letter from the principal investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Further advice on submitting amendments is available from:  
[www.health.qld.gov.au/metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting](http://www.health.qld.gov.au/metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting)
  4. The Principal Investigator will notify the HREC if the project is discontinued at the participating site(s), with reasons provided.
  5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.
- **Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:**  
[www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp](http://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp)

[reporting/default.asp](#)

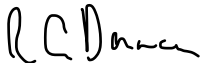
- The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from: [https://www.health.qld.gov.au/hiiro/html/regu/regu\\_home](https://www.health.qld.gov.au/hiiro/html/regu/regu_home)

The nominated participating sites for this project are:

No.	Site
1.	The Prince Charles Hospital

The Metro North Health Human Research Ethics Committee B wishes you every success in your research.

Yours sincerely,



Dr Russell Denman  
**Chairperson**  
**Metro North Health Human Research Ethics Committee B**

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2007)* and the CPMP/ICH Note for Guidance on Good Clinical Practice.