

**CHILDREN'S HEALTH QUEENSLAND
HOSPITAL AND HEALTH SERVICE
HUMAN RESEARCH ETHICS COMMITTEE**

Professor Alan Isles AM (Chair) 3069 7002
Mrs Amanda Smith (Co-ordinator) 3069 7002



Level 7, Centre for Children's Health Research
Queensland Children's Hospital Precinct
62 Graham Street, South Brisbane QLD 4101
Telephone (07) 3069 7002

7th March 2024

Dr Miriam Cameron
Respiratory and Sleep Medicine
Children's Health Queensland
South Brisbane QLD 4101

Dear Dr Cameron,

HREC Reference number: HREC/23/QCHQ/105292

Project title: Prevention of aspiration lung disease in children – A novel treatment approach targeting respiratory muscle strength

Many thanks for your response to queries raised in relation to the above project. This has now been reviewed.

I am pleased to advise the proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2023) and the Committee is happy to give approval. 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 (2023), and all subsequent updates, the Australian Code for the Responsible Conduct of Research (2023) and the CPMP/ICH Note for Guidance on Good Clinical Practice.

This project has Ethics approval for the following sites:

- Queensland Children's Hospital/Centre for Children's Health Research

Please note the HREC does not issue pre-determined approval periods. Ethical approval is ongoing, subject to the submission of an annual report on the anniversary of approval.

The documents reviewed and approved include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Cover letter		15 January 2024
Application (105292)		14 January 2024
Protocol	2	12 February 2024
Participant Information Form for Parent/Guardian	2	12 February 2024
Participant Information Form for Parent/Guardian – Control Group	1	12 February 2024
Child Information Sheet	2	12 February 2024
Child Information Sheet – Control Group	1	12 February 2024
Participant Consent Form for Parent/Guardian	2	12 February 2024
Participant Consent Form for Parent/Guardian - Control Group	1	12 February 2024
Diary of RMST Exercises	1	15 January 2024
Cleaning and Disinfection Guidelines	1	15 January 2024
EMST 150 User's Guide	1	15 January 2024
Letter of Support – Associate Professor Sadasivam Suresh, Department of Respiratory and Sleep Medicine		6 March 2024
Response to queries		28 February 2024

Please note the following conditions of approval:

1. We require an annual progress report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of the project by the HREC. A comprehensive Final Report upon completion of the project. (In accordance with National Statement 5.5.3) All documentation must be completed and submitted via the ERM website:
<https://au.forms.ethicalreviewmanager.com/>
2. Please note if identifiable or potentially re-identifiable data for this research project is to be accessed without the written consent of the person to whom the data relates an application for disclosure of this data must be made under the *Public Health Act*. Further information regarding the *Public Health Act* is available via this link:
https://www.health.qld.gov.au/hiiro/html/regu/aces_conf_hth_info
3. Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure. All documentation must be completed and submitted via the ERM website:
<https://au.forms.ethicalreviewmanager.com/>
4. If the project does not proceed, the Committee must be informed as soon as possible. (In accordance with National Statement 5.5.6)
5. The Committee must be informed of any potential or realised problem with bioethical implications, if such occurs during the conduct of the research project.
6. Safety Reporting for clinical trials must follow the [2018 NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods](#) and the [Reporting of Serious Breaches of Good Clinical Practice \(GCP\) or the Protocol for Trials Involving Therapeutic Goods](#). All Safety Reporting must be submitted via the ERM web portal for researchers, by creating a sub-form under the relevant project and application form. Please see CHQ HREC Website for details of Safety Reporting [CHQ HREC Website](#)
8. The HREC, authorising institution and/or their delegate/s may conduct an audit of the project at any time.
9. Ethical approval to undertake this research project is given on the understanding that you have an intention to publish your findings in a refereed journal or similar peer-reviewed forum. If you do not have this intention, it is an absolute requirement that you notify the Ethics Committee formally. In this latter instance, approval for this research is not given at this time; and will require further negotiation. Your work must be in accordance with the following:
 - *National Statement on Ethical Conduct in Human Research:*
[National Statement on Ethical Conduct in Human Research 2023 | NHMRC](#)
 - *Queensland Health Management Research Policy:*
https://www.health.qld.gov.au/_data/assets/pdf_file/0020/164162/qh-pol-013.pdf
 - *Declaration of Helsinki:*
<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
 - *Guidelines under Section 95 of the Privacy Act 1995 and Guidelines approved under Section 95A of the Privacy Act 1995.* <https://nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988>
10. Researchers should note, if not QLD Health employees, a Blue Card may be required for contact with children.
11. The Researcher must send the '**Notification of Commencement of Research Protocol**' as soon as research begins. Status of the project will remain as 'Not Started' until this form is received. All documentation must be completed and submitted via the ERM website:
<https://au.forms.ethicalreviewmanager.com/>
12. In accordance with the National Statement (3.3.12), before beginning the clinical phase of the research, researchers should register clinical trials in a publicly accessible domain.

Should you have any queries about the HREC's consideration of your project please contact Mrs Amanda Smith (Co-ordinator) or Professor Alan Isles (Chairperson). The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from:

http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

You are reminded that this letter constitutes ethical approval only. This project cannot proceed until separate research governance authorisation has been obtained from the institution where the research will be conducted.

The HREC wishes you every success in your research.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Rebecca Doyle', with a long horizontal stroke extending to the right.

Rebecca Doyle
Deputy Chair, Children's Health Queensland
Hospital and Health Service
Human Research Ethics Committee

Cc: Ethics Committee Files

**Children's Health Queensland Hospital and Health Service Human
Research Ethics Committee (HREC)**

NOTIFICATION OF COMMENCEMENT OF RESEARCH PROTOCOL

HREC No: HREC/24/QCHQ/105292

PROTOCOL TITLE: Prevention of aspiration lung disease in children – A novel treatment approach
targeting respiratory muscle strength

PRINCIPAL INVESTIGATOR:

This is to advise that the above research protocol commenced on:

/ /

Signature:----- Date: -----/-----/-----

Please email to: CHQEthics@health.qld.gov.au