



Mater Misericordiae Ltd  
Raymond Terrace,  
South Brisbane Qld 4101

P 07 3163 8111  
ACN 096 708 922

8 May 2023

Mrs Renee Muirhead

Raymond Terrace  
South Brisbane  
Brisbane QLD 4101

Dear Mrs Muirhead

**Project Id:** 94314

**Project Title:** PAINS pilot study: testing of a neonatal nurse led model of analgesia to manage pain in the surgical neonate.

**Full Project Title:**

**Reference Number:** HREC/MML/94314 (V5)

Thank you for submitting the above research project for single ethical review. This project was considered by the Mater Misericordiae Ltd Human Research Ethics Committee (MML HREC) at its meeting held on 14 March 2023 and I further reviewed on 6 April 2023 and 26 April 2023.

I am pleased to advise you that the above research project meets the requirements of the [National Statement on Ethical Conduct in Human Research \(2007\) updated 2018](#) and ethical approval for this research project has been granted by the Mater Misericordiae Ltd Human Research Ethics Committee.

The nominated participating site/s for this project is/are:

- Mater Misericordiae Ltd

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 MML HREC. Notification of withdrawn sites should also be provided to the MML HREC in a timely fashion.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. At Mater Misericordiae Ltd please contact the Research Governance Office on 07 3163 3769.**

The approved documents include:

Submission Document Name	Version	Date
Human Research Ethics Application (HREA) HREC/MML/94314	5	08-May-2023
PAINS pilot protocol	2	01-Apr-2023
PAINS pilot PICF	2	20-Apr-2023
PAIN Questionnaire-English Copyrighted (Noted)	-	-
Managing post operative pain in the NCCU	2	20-Mar-2023
CV KathrynKynoch (Noted)	-	02-Feb-2023
CV PeterLewis (Noted)	-	02-Feb-2023

Submission Document Name	Version	Date
CV Pita Birch (Noted)	-	02-Feb-2023
CV Ann Peacock (Noted)	-	02-Feb-2023
CV Renee Muirhead (Noted)	-	22-Feb-2023
Daily study checklist	1	02-Feb-2023
Daily participant data audit form	1	02-Feb-2023
Participant Enrolment data form	1	02-Feb-2023
parents pain brochure	1	02-Feb-2023
Withdrawal Assessment Tool (WAT-1) - Neonatal - Clinical Form-07 CFM (Noted)	1	02-Feb-2023
MW0150 v3.00 Pain Assessment Tool (PAT) - Neonatal-07 CFM (Noted)	1	02-Feb-2023
Neonatal Long Stay Medication Chart - Clinical Form-07 CFM (Noted)	1	02-Feb-2023
Fluid Quota Flow Record and Prescription - Neonatal - Clinical Form-07 CFM (Noted)	1	02-Feb-2023
Ventilation Flow Record - Neonatal - Mater Wide-07 CFM (Noted)	1	02-Feb-2023
Acute CardioRespiratory Events - Neonatal - Clinical Form-07 CFM (Noted)	1	02-Feb-2023
MW0151 v3.00 Observation Chart Neonatal-07 CFM (Noted)	1	02-Feb-2023
NNCA Final model (Noted)	1	22-Feb-2023
PAINS pilot cover letter 22nd Feb (Noted)	-	22-Feb-2023
Response to HREC (Noted)	-	01-Apr-2023
Response to ChairpersonV2_20thApril (Noted)	-	20-Apr-2023

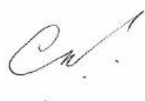
Approval of this project by the MML HREC is valid from 8 May 2023 to 8 May 2026, subject to the following conditions being met:

- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Principal Investigator will notify the MML HREC of any modification that is to be made to the protocol or other project documents and will submit any required amendments.
- The Principal Investigator will submit any necessary reports related to the safety of research participants.
- In accordance with *Section 5.5.5 (a)* of the National Statement, the Principal Investigator will report to the MML HREC annually, the first report to be submitted by 8 May 2024 and a final report submitted on completion of the study with presentation or publication of the main findings.
- The Principal Investigator will notify the MML HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Principal Investigator will notify the MML HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- A copy of this approval letter together with completed Site Specific Assessment (SSA) and any other required documents must be submitted by all site Principal Investigators to the Research Governance Office at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site.

Should you have any queries about the MML HREC's consideration of your project, please contact the HREC Liaison Officer on (07) 3163 1585. The MML HREC Terms of Reference, membership and standard forms are available from our [website](#).

The MML HREC wishes you every success in your research.

Yours sincerely



Professor Ross Pinkerton MD; FRCPCH

**Chairperson**

Mater Misericordiae Ltd Human Research Ethics Committee

***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), updated 2015. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.***

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