

Ratification of External Human Research Ethics Approval

Project Number: 2023/HE000939

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

Version: 0.02

UQ Lead Investigator: Associate Professor Peter Lewis
School of Nursing, Midwifery and Social Work

Co-Investigator(s) Dr Ann Shirley Peacock
Mrs Renee MUIRHEAD

Funding Body (UQ ref#):

External HREC Name: Mater Misericordiae Ltd Human Research Ethics Committee

Approval End Date: 08 May 2026

Date of Ratification: Wednesday, 10 May 2023

As per Section 5.3 of the National Statement on Ethical Conduct in Human Research the University of Queensland has accepted the ethical review of the external review body.

Approved Documents: As listed on reviewing HREC approval and below if required

Document Type	File Name	Document Title	Application Version	Document Version	Last Modified
Application Attachment	0423_MM_NCCU_Parents Post Op Pain - A4 Flyer_F.pdf	0423_MM_NCCU_Parents Post Op Pain - A4 Flyer_F.pdf	0.1	1	10/05/2023 8:41:19 PM
Change Tracking	2023_HE000939 v0_01 - v0_02 Changes.pdf	2023/HE000939 v0_01 - v0_02 Changes	0.2	1	10/05/2023 8:41:24 PM
Application Attachment	Acute CardioRespiratory Events - Neonatal - Clinical Form-07 CFM.pdf	Acute CardioRespiratory Events - Neonatal - Clinical Form-07 CFM.pdf	0.2	1	10/05/2023 8:41:20 PM
Application Attachment	Ann Peacock_CV_2020 (3).docx	Ann Peacock_CV_2020 (3).docx	0.2	1	10/05/2023 8:41:19 PM

Research Ethics and Integrity

Application Attachment	CV_PeterLewis_0221.pdf	CV_PeterLewis_0221.pdf	0.2	1	10/05/2023 8:41:19 PM
Application Attachment	Daily participant data audit form.docx	Daily participant data audit form.docx	0.1	1	10/05/2023 8:41:18 PM
Application Attachment	Daily study checklist.docx	Daily study checklist.docx	0.1	1	10/05/2023 8:41:18 PM
Application Attachment	Fluid Quota Flow Record and Prescription - Neonatal - Clinical Form-07 CFM.pdf	Fluid Quota Flow Record and Prescription - Neonatal - Clinical Form-07 CFM.pdf	0.2	1	10/05/2023 8:41:21 PM
External Ethics Approval Certificate	HREC approval letter PAINS pilot.pdf	HREC approval Letter PAINS pilot	0.1	1	10/05/2023 8:41:17 PM
Application Attachment	Human Research Ethics Application(HREA)HRECMML94314 Version5.pdf	Human Research Ethics Application(HREA)HRECMML94314 Version5.pdf	0.2	1	10/05/2023 8:41:21 PM
Application Attachment	KathrynKynoch_CV (2).pdf	KathrynKynoch_CV (2).pdf	0.2	1	10/05/2023 8:41:19 PM
Application Attachment	MW0150 v3.00 Pain Assessment Tool (PAT) - Neonatal-07 CFM.pdf	MW0150 v3.00 Pain Assessment Tool (PAT) - Neonatal-07 CFM.pdf	0.2	1	10/05/2023 8:41:20 PM
Application Attachment	MW0151 v3.00 Observation Chart Neonatal-07 CFM.pdf	MW0151 v3.00 Observation Chart Neonatal-07 CFM.pdf	0.2	1	10/05/2023 8:41:20 PM
Application Attachment	Neonatal Long Stay Medication Chart - Clinical Form-07 CFM.pdf	Neonatal Long Stay Medication Chart - Clinical Form-07 CFM.pdf	0.2	1	10/05/2023 8:41:20 PM
Application Attachment	NNCA_Final model.pdf	NNCA Final model	0.1	1	10/05/2023 8:41:18 PM
Application	Output Form.pdf	Output Form	0.2	2	10/05/2023 8:41:17 PM

Application Attachment	PAIN Questionnaire-English.pdf	PAIN Questionnaire-English.pdf	0.2	1	10/05/2023 8:41:20 PM
Application Attachment	PAINS pilot cover letter 22nd Feb.docx	PAINS pilot cover letter 22nd Feb.docx	0.2	1	10/05/2023 8:41:21 PM
Application Attachment	PAINS pilot PICF 20thApril V2.docx	PAINS pilot PICF	0.1	1	10/05/2023 8:41:18 PM
Application Attachment	PAINS pilot protocol V2 1st April (002) clean.docx	PAINS pilot protocol	0.1	1	10/05/2023 8:41:17 PM
Application Attachment	parentspainbrochure V1.pdf	parentspainbrochure V1.pdf	0.1	1	10/05/2023 8:41:18 PM
Application Attachment	Participant Enrolment data form.docx	Participant Enrolment data form.docx	0.1	1	10/05/2023 8:41:18 PM
Application Attachment	Pita Birch CV 2020.doc	Pita Birch CV 2020.doc	0.2	1	10/05/2023 8:41:19 PM
Application Attachment	Renee Nicole Muirhead CV .docx	Renee Nicole Muirhead CV .docx	0.2	1	10/05/2023 8:41:19 PM
Application Attachment	Response to ChairpersonV2_20thApril (3).docx	Response to ChairpersonV2_20thApril (3).docx	0.2	1	10/05/2023 8:41:21 PM
Application Attachment	Response to HREC.docx	Response to HREC.docx	0.2	1	10/05/2023 8:41:21 PM
Application Attachment	Ventilation Flow Record - Neonatal - Mater Wide-07 CFM.pdf	Ventilation Flow Record - Neonatal - Mater Wide-07 CFM.pdf	0.2	1	10/05/2023 8:41:20 PM
Application Attachment	Withdrawal Assessment Tool (WAT-1) - Neonatal - Clinical Form-07 CFM.pdf	Withdrawal Assessment Tool (WAT-1) - Neonatal - Clinical Form-07 CFM.pdf	0.2	1	10/05/2023 8:41:19 PM

Delegated Officer
Research Ethics and Integrity
The University of Queensland

Additional Notes re UQ Ratification Approval

1. If a Public Health Act (PHA) application is applicable, researchers are reminded that they require a current ethics application to utilise data provided through a PHA application.
2. In accordance with Section 5.5.6 (b) of the National Statement, the Chief Investigator will report to via My Research as well as to the reviewing HREC the following:
 - a. annual and final reports
 - b. anything which might warrant review of ethical approval of the project, through My Research, for example unforeseen events that might affect continued ethical acceptability of the project
 - c. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
3. Any other incident attributable to the research affecting the welfare and/or health of participants or researchers while on UQ premises should be promptly reported through UQ Safe <https://staff.uq.edu.au/information-and-services/health-safety-wellbeing/health-safety-workplace/risk/assessments>, and to the reviewing HREC.
4. Amendments to any part of the approved protocol (including change of Investigator/s), documents, or questionnaires attached to the application must be submitted to the reviewing HREC for approval prior to submission for ratification.
5. All clinical trials need to be registered on a WHO approved clinical trials registry for example <http://www.anzctr.org.au>
6. The Chief Investigator must determine whether the study needs to be declared/notified to UQ Insurance Services as per Fact Sheet on [Insurance Services website](#) (refer flow chart at Appendix 1).¹
7. The Chief Investigator is responsible and accountable for full compliance of the protocol by all investigators including the collection, use, storage and disclosure of data as required by UQ policies and procedures.
8. Research Ethics and Integrity reserves the right to visit the research site and view materials at any time, and to conduct a full audit of the project.

Despite international and disciplinary norms, a wide range of studies involving humans can be considered a “Clinical Trial” for insurance purposes at UQ. E.g., in some cases, this can include epidemiological surveys, population level studies, blood sampling studies (e.g., seroprevalence), psychophysiological outcome studies, and parenting intervention evaluations.