



Queensland
Government

Metro North
Hospital and Health Service

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

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File Ref: HREC/17/QRBW/162
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Professor Jeanine Young
School of Nursing, Midwifery and Paramedicine
University of the Sunshine Coast
Locked Bag 4
Maroochydore DC Qld 4558

Dear Professor Young,

Re: Ref N^o: HREC/17/QRBW/162: Enabling Safe and Close Care In Postnatal Environments: A Pilot

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) at its meeting held on 10 April 2017. The research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*.

I am pleased to advise that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

The nominated participating site for this project is:

- Sunshine Coast University Hospital

This letter constitutes ethical approval only. This project cannot proceed until separate research governance authorisation has been obtained from the CEO or Delegate of the Sunshine Coast University Hospital under whose auspices the research will be conducted.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		24 March 2017
Application: NEAF (<i>Submission Code: AU/1/E5CC214</i>)	2.2 (2014)	24 March 2017

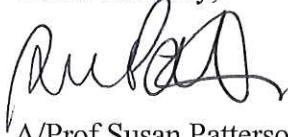
<i>Document</i>	<i>Version</i>	<i>Date</i>
Wishlist Research Grant Scheme 2016 Approval Letter		06 September 2016
Amendment Letter to Wishlist, Sunshine Coast Health Foundation		15 February 2017
Wishlist Research Committee Amendment Email Approval		02 March 2017
KidSafe Letter of Support		22 March 2017
Consumer Product Safety Unit, Queensland Office of Fair Trading Letter of Support		23 March 2017
Master Staff Questionnaire	1.0	13 January 2017
Master Data Collection Form	1.0	18 February 2017
Master Observational Assessment - Infant Sleep Position and Environment	1.0	14 March 2017
Master MaBim Quick Guide	1.0	09 March 2017
Master First Days Pepi-Pod Quick Guide	1.0	09 March 2017
Master Standard Neonatal Cot Quick Guide	1.0	09 March 2017
MaBim Neonatal Cot for Co-Sleeping Product Brochure		
Clinical Trial Participant Label		
Informed Consent Process Label		
Poster	1.0	22 March 2017
First Days Pepi-Pod Brochure	June 2015	
Curriculum Vitae of Jeanine Young		
Curriculum Vitae of Dr Lauren Kearney		
Curriculum Vitae of Stephanie Frances Cowan	March 2017	
Curriculum Vitae of Cheryl Rutherford		
Curriculum Vitae of Joanne Hoey	2017	
Curriculum Vitae of Kendall George		
Response to Request for Further Information		10 May 2017
The ESCCaPE Trial Protocol	1.1	05 May 2017
Master Staff Questionnaire Participant Information Sheet	1.1	03 May 2017
Master Participant Information Sheet & Consent Form - Safe Sleep Device	1.1	03 May 2017
Master Participant Information Sheet & Consent Form - Infant Sleep Observation & Chart Audit	1.1	03 May 2017
Master 4 Month Questionnaire	1.1	05 May 2017
Master 6-8 Week Questionnaire	1.1	05 May 2017
Master In Hospital Questionnaire	1.1	05 May 2017

Approval of this project from the RBWH HREC is valid from **17.05.2017** to **17.05.2020** subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RBWH HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp>.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the RBWH HREC policy and procedures. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>.
- In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to the RBWH HREC annually in the specified format, the first report being due on **17.05.2018** and a final report is to be submitted on completion of the study. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>.
- The Coordinating Principal Investigator will notify the RBWH HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RBWH HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp>.
- The Coordinating Principal Investigator will notify the RBWH HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site Specific Assessment (SSA) and any other requirements must be submitted by the Coordinating Principal Investigator to the Research Governance Office at the Sunshine Coast University Hospital 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 RBWH HREC's consideration of your project please contact the HREC Coordinator on 07 3646 5490. The RBWH HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/membership/default.asp>.

The RBWH HREC wishes you every success in your research.

Yours sincerely,



A/Prof Susan Patterson

A/Chairperson RBWH Human Research Ethics Committee

Metro North Hospital and Health Service

17.05.2017

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)*. The processes used by this HREC to review research proposals have been certified by the National Health and Medical Research Council.