



Royal Brisbane & Women's Hospital  
Human Research Ethics Committee

Metro North  
Hospital and Health Service

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File Ref: HREC/16/QRBW/428  
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Professor Fiona Coyer  
Centre for Clinical Nursing  
Nursing and Midwifery Research Unit  
Level 2, Building 34  
Royal Brisbane & Women's Hospital  
Herston Qld 4029

Dear Professor Coyer,

**Re: Ref N<sup>o</sup>: HREC/16/QRBW/428: Efficacy of nasogastric and endotracheal tube securement devices, preventative dressings and topical skin applications for reducing device-related pressure injuries in intensive care patients; a randomised controlled trial**

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 12 September 2016. 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 waiver of consent and breach of the Australian Privacy Principles, for the period before patients or Substitute Decision Makers may consent, were considered justified in accordance with National Statement 2.3.10 and are approved.*

*For information on submitting a Public Health Act (PHA) application for the release of confidential health information for research purposes, please visit the Health and Medical Research website at:*

*[http://www.health.qld.gov.au/ohmr/html/regu/aces\\_conf\\_hth\\_info.asp](http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp)*

The nominated participating sites for this project are:

- Royal Brisbane & Women's Hospital, Qld
- Redcliffe Hospital, Qld
- Royal Melbourne Hospital, Vic

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 RBWH HREC. Notification of withdrawn sites should also be provided to the RBWH HREC in a timely fashion.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>
Covering Letter		29 August 2016
Application: NEAF ( <i>Submission Code: AU/1/F968217</i> )	2.2 (2014)	29 August 2016
Master NGT Case Report Form	1	26 August 2016
Master Enrolled Patient Log	1	26 August 2016
Master ETT Case Report Form	1	26 August 2016
Master Enrolment Form	1	26 August 2016
Curriculum Vitae of Sarah Sage		
Curriculum Vitae of Nicola Clarice Barker-Gregory	July 2016	
Curriculum Vitae of Amanda Louise Vann		25 August 2016
Curriculum Vitae of Michelle M Spence		25 August 2016
Curriculum Vitae of Marie Gerdtz		30 June 2016
Curriculum Vitae of Nick Santamaria		
Response to Request for Further Information		09 October 2016
REMEDy Study Protocol	2	09 October 2016
Victorian-Specific Module	January 2015	26 August 2016
Master Participant Information Sheet	2	09 October 2016
Master Participant Information Sheet & Consent Form - Patient	2	09 October 2016
Master Participant Information Sheet & Consent Form - Person Responsible	2	09 October 2016
Master Withdrawal of Participation Form - Patient	2	09 October 2016
Response to Request for Further Information		10 October 2016
Withdrawal of Participation Form - Person Responsible	3	10 October 2016

Approval of this project from the RBWH HREC is valid from **14.10.2016** to **14.10.2019** subject to the following conditions being met:

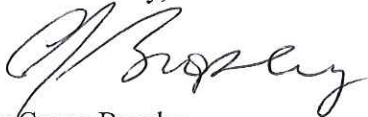
- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RBWH HREC of any event that requires a modification to the protocol or other project documents and submit 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 **14.10.2017** 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 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/s.
- 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,



Dr Conor Brophy  
**Chairperson RBWH** Human Research Ethics Committee  
Metro North Hospital and Health Service  
14.10.2016

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 multi-centre research proposals have been certified by the National Health and Medical Research Council.