



**Metro North**  
Hospital and Health Service

**Royal Brisbane & Women's Hospital**  
**Human Research Ethics Committee**

Enquiries to: Ann-Maree Gordon  
Coordinator  
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File Ref: HREC/17/QRBW/21  
Email: [RBWH-Ethics@health.qld.gov.au](mailto:RBWH-Ethics@health.qld.gov.au)

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/17/QRBW/21: Efficacy of Incontinence-Associated Dermatitis Interventions for Critically Ill Patients in Intensive Care: the Distinct Pilot Randomised Control 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 13 February 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:

- Royal Brisbane & Women's 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 Royal Brisbane & Women's Hospital under whose auspices the research will be conducted.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		20 January 2017
Application: NEAF ( <i>Submission Code: AU/1/D16B29</i> )	2.2 (2014)	25 January 2017
3M™ Cavilon Advanced High Endurance Skin Protectant Investigator's Brochure	4	14 July 2015
Certificate of Insurance (BusinessGuard Liability) for the period 01.03.2016 to 01.03.2017		12 February 2016
Certificate of Currency (Clinical Trials) for the period 01.11.2016 to 01.11.2017		18 January 2017
Response to Request for Further Information		06 March 2017
Protocol	2	02 March 2017
Participant Information Sheet & Consent Form - Patient	2	03 March 2017
Participant Information Sheet & Consent Form - Person Responsible	2	03 March 2017
Form for Withdrawal of Participation - Patient	2	02 March 2017
Form for Withdrawal of Participation - Person Responsible	2	02 March 2017

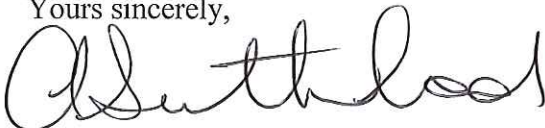
Approval of this project from the RBWH HREC is valid from **10.03.2017** to **10.03.2020** subject to the following conditions being met:

- 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 **10.03.2018** 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 Royal Brisbane & Women's 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,



Dr Allison Sutherland

**A/Chairperson RBWH** Human Research Ethics Committee

Metro North Hospital and Health Service

10.03.2017

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.