



16 April 2018

Mrs Michelle Bolte  
Infection Prevent Service  
Tamworth Rural Referral Hospital

Dear Mrs Bolte,

**Re: Evaluation of a bundled care approach to preventing Surgical site infections post caesarean section (18/03/21/5.11)**

**HNEHREC Reference No: 18/03/21/5.11**  
**NSW HREC Reference No: LNR/18/HNE/80**  
**SSA Reference No: LNRSSA/18/HNE/114**

Thank you for submitting the above study for single ethical review. This project was considered to be eligible to be reviewed as Low and Negligible risk research, and so was reviewed at an Executive Meeting of the Hunter New England Human Research Ethics Committee on **11 April 2018**. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research* and, following acceptance of the requested clarifications and revised HREA by Dr Nicole Gerrand Manager, Research Ethics & Governance Office, under delegated authority from the Committee, grants ethical approval of the above project.

The *National Statement on Ethical Conduct in Human Research (2007)*, to which the Committee is obliged to adhere, include the requirement that the Committee monitors the research protocols it has approved. **Ethics Approval will be ongoing subject to the following conditions:**

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals, or, 2 months after the proposed closure date of the project if this date is less than 12 months. A proforma for the annual report will be sent. Your review date is **April 2019**.
- All variations or amendments to this protocol must be forwarded to, and approved by, the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.
- Adherence to the safety reporting requirements of the with the NHMRC Safety Monitoring and Reporting Guidance for Therapeutic Goods Trials (November 2016) available at

**Hunter New England Research Ethics & Governance Office**

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<http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx>

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

Document	Version	Date
HREA [Submission Code: AU/1/F28438]	-	
Maternity Obesity Risk Assessment	-	
FACT SHEET: Negative Pressure Dressings for LSCS Women	-	December 2017
STAFF FACT SHEET: Negative Dressing 2	-	
FACT SHEET: Tamworth Rural Referral Hospital Preventing Surgical Site Infections (SSI) in patients Undergoing Lower Segment Caesarean Section (LSCS) through an evidence-based bundled approach to care	-	
FACT SHEET: CIP bundle audit tool	-	January 2018
Comparison of Negative pressure dressings – (Smith and Nephew) PICCO dressings with the (KCI) Prevena dressings on high risk LUCS wounds.	-	
FACT SHEET- Documentation required for LSCS prevention of SSI Strategies in Maternity	-	December 2017
TRRH Pre-admission / antenatal clinic - Identifying high risk patients for negative pressure dressings. Staff Fact sheet	-	February 2018
TRRH Pre-admission clinical - Maternity patient information sheet	-	February 2018

Approval has been granted for this study to take place at the following sites:

- **Tamworth Rural Referral Hospital**

**You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.**

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **18/03/21/5.11** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter  
Chair  
Hunter New England Human Research Ethics Committee

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